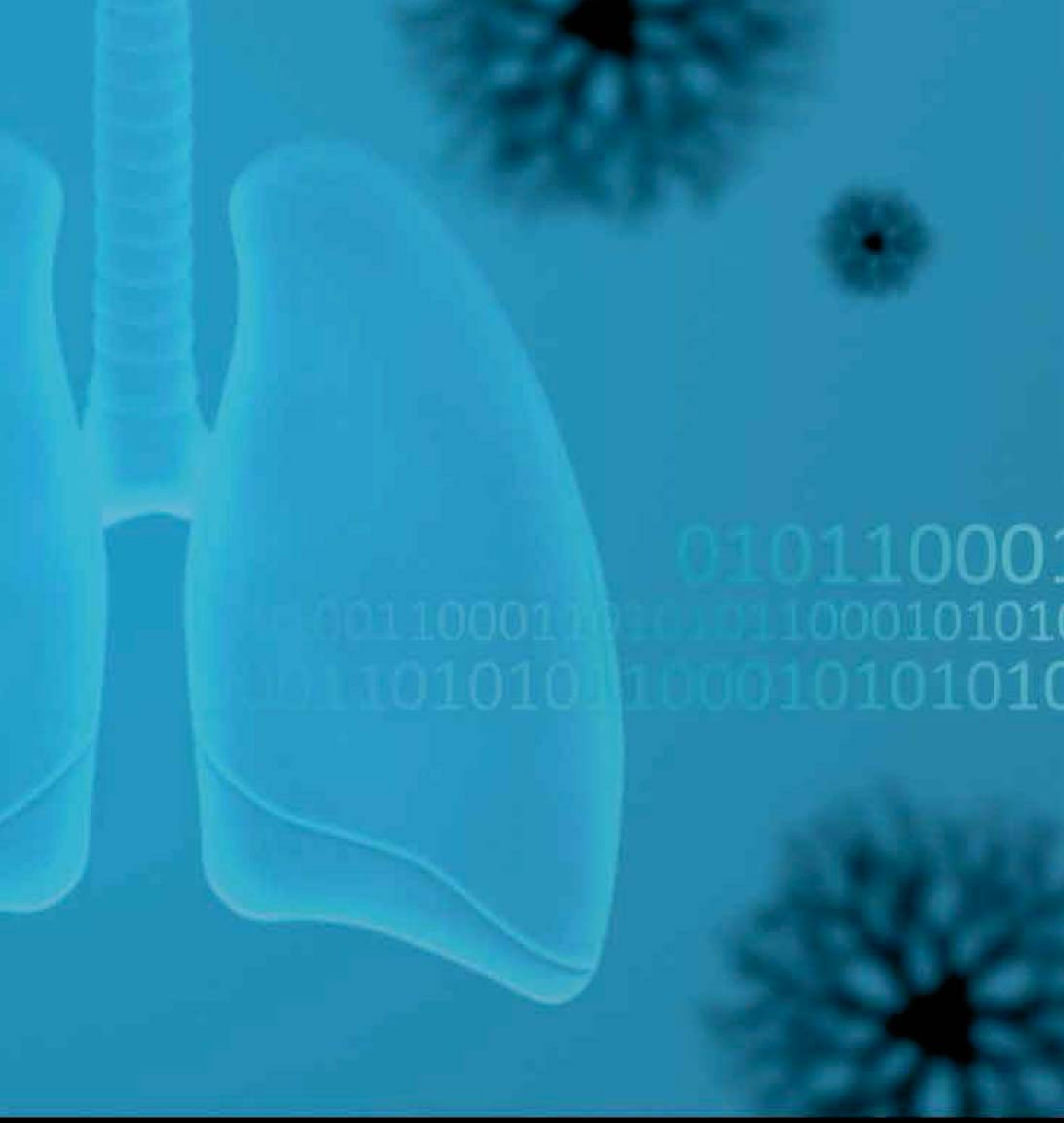
Impact of Information and Communication Technologies on Remote Testing

Forced Spirometry as a Use Case

Felip Burgos Rincón



Impact of Information and Communication Technologies on Remote Testing

Doctoral Thesis

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Impact of Information and Communication Technologies on Remote Testing

Forced Spirometry as a Use Case

Report of the Doctoral Thesis presented by
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Prof. Josep Roca Torrent

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La inteligencia consiste no sólo en el conocimiento, sino también en la destreza de aplicar los conocimientos en la práctica.

Aristóteles, (384 ac-322 ac)

Medicine has built on a long history of innovation, from the stethoscope and roentgenogram to magnetic resonance imaging and robotics. Doctors have embraced each new technology to advance patient care. But nothing has changed clinical practice more fundamentally than one recent innovation: the Internet.

Pamela Hatzband and Jerome Groopman
NEJM 2010;363:1063-66

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Dedicatoria

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Dedicated to my beloved parents, to my brother, my darling daughter and specially to my “girlfriend”.

“El placer del conocimiento sería escaso si para alcanzarlo no hubiera que vencer tantos pudores”

Friedrich Nietzsche, **Más allá del bien y del mal**

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Nunca dejaré de aprender de todos vosotros y siempre estaréis en mi corazón.

Muchas gracias!

Personal motivation

Motivación personal

Finalizada mi primera formación como profesional sanitario en 1973, tras mi paso por la Escuela de Ayudantes Técnicos Sanitarios de la Facultad de Medicina, Universidad de Barcelona (hoy llamado 'Campus Clínic'), hice una rotación en el Hospital Clínic durante un período de 3 años, en calidad de estudiante, en la Medica B (Cátedra del Profesor Soriano). Después, ya como enfermero contratado en los Laboratorios de Bioquímica y Hematología, presenté formando parte de este último equipo humano, el que fue mi primer resumen en unas Jornadas *"Evaluación del Coulter modelo "S" Vallespí MT, Burgos F, Manat C, Vives Corrons JL. III Jornadas Técnicas de Izasa. 1974"*, participando activamente en la primera automatización del Laboratorio con la incorporación de los equipos Technicon® y Coulter-S®, que nos permitieron la primera aproximación a la automatización de los análisis clínicos como fue el hemograma.

Laboratorio de Función Pulmonar

En 1974 el Prof. Robert Rodriguez Roisin me propuso participar en el proyecto de Laboratorio de Función Pulmonar (LFP) que quería llevar a cabo en la Medica C, bajo la dirección del Prof. C. Rozman. Tenía entonces 20 años y un océano de conocimientos por descubrir. Probablemente me sedujo el empuje y el entusiasmo del RoRo en aquel ya lejano 1975, años aquellos en los que se estaban produciendo grandes cambios en nuestro país acelerados con la muerte del dictador. Inicié en esa época marcada por la esperaza y la ilusión mi andadura en lo que fue el embrión de lo que más tarde acabaría siendo el LFP del Clínic. Fue entonces cuando aprendí mi primera lección sobre espirometría forzada (EF) con un Vitalograph de fuelle, que permitía calcular a mano la Capacidad Vital Forzada (FVC), el volumen espiratorio máximo en el primer segundo, los flujos mesoespiratorios, el VEMS. Entonces todavía no hablábamos del FEV_1,. De inmediato me sumergí en la medición de los gases respiratorios en sangre arterial (la gasometría arterial), en la medición de los volúmenes pulmonares por dilución y la capacidad de transferencia de CO y, De esta época son mis dos primeras presentaciones en el XI Congreso de la SEPAR celebrado en Oviedo en 1978 (¡¡sólo hace 35 años!!) que llevaban por título "Curvas de flujo volumen: ¿Osciloscopio versus registro gráfico?" Burgos F, Añaños F, Gistau C, Rodriguez Roisin R, Picado C, Agustí Vidal A.; y "Funcionalismo *pulmonar en trabajadores intensamente expuestos al amianto: estudio comparativo". Picado C, Rodriguez Roisin R, Burgos F, Añaños F, Estopá R, Marin A, Agustí Vidal A*. En ese mismo año vio la luz mi primera publicación en una revista internacional "Lung function in workers heavily exposed to asbestos and

cotton. Comparative studies. Rodriguez Roisin R, Picado C, Añaños F, Burgos F, Agustí Vidal A. Bull Europ Physiop Resp 1978;14:55-57". Y ya en 1980, llegará mi primer artículo como primer autor *"Curvas de flujo volumen (MEFV). Registro gráfico versus osciloscópico. Burgos F, Rodriguez Roisin R, Añaños F, Gistau C, Agustí Vidal A, Rotger MM, Navajas D. Arch Bronconeumol 1980;16:111-116".*

Informatización en el Laboratorio

La década del los 80 fue el de la informatización del LFP. Se adquirió en 1978 un equipo Hewlett Packard HP9825-A, que permitió entre otras actividades el generar los valores de referencia de la función pulmonar de la población mediterránea: fue la tesis doctoral del que ahora es mi director de tesis, el Prof. Josep Roca (1982). Mi dedicación a este proyecto me permitió profundizar intensamente en la metodología científica, en la epidemiología, en la estadística y en la informática. Un dato para la memoria histórica, el PC de IBM apareció en el mercado americano en 1981.

Estandarización de la Función Pulmonar

Mi estancia en 1996 en Harbor-UCLA Medical Center en Los Angeles, CA (USA), bajo la tutela del Dr. R. Casaburi me abrirá las puertas al conocimiento de uno de los grandes Laboratorios de Función Pulmonar mundiales, y en especial de las pruebas de ejercicio cardio-respiratorio, así como a profundizar en el concepto de estandarización. Fue sin duda una experiencia inolvidable. Quisiera destacar también mi participación en la task force ATS-ERS sobre la estandarización de la función pulmonar en el 2003-2005 que me permitió adentrarme en la cuestión de la normatización de la función pulmonar.

Infrautilización de la espirometría forzada

Uno de los aspectos que más me "sublevó" durante mucho tiempo, a pesar de que la EF tenía un gran recorrido histórico desde que en 1846 el cirujano John Hutchinson describiera la capacidad vital, fue la evidente infrautilización de EF. Era y sigue siendo un enorme reto para la medicina el diagnóstico precoz de enfermedades respiratorias como la EPOC. El Dr. Tomas Petty, a quien tuve el honor de conocer en mi estancia en Harbor-UCLA Medical Center en 1996, decía: "The vital capacity and the FEV1 must emerge as important as BP, cholesterol tests, and other

indicators of incipient disease states to alert physicians and the patients that they serve to the importance of early treatment for COPD and related disorders". Pero a menudo la realidad es muy tozuda a la hora cambiar, y seguimos con una evidente infrautilización de la espirometría forzada, lo que se traduce en una altísima tasa de infradiagnóstico. Un mal que la medicina moderna no se puede permitir cuando hay medios para resolverlo.

Telemedicina y soporte al diagnóstico

La espirometría forzada es la técnica fundamental para la evaluación de la función respiratoria. A pesar de que su metodología está muy bien establecida es bien conocido que su calidad, en numerosas ocasiones, deja mucho que desear. Como ya he comentado mi relación con la tecnología viene de muy lejos. Conseguí mi primera conexión a la red de Medicina en marzo de 1997, el FTP; mi primer email se conectaba utilizando el "elm" "Mailbox", la utilización de programas de comunicación como el Eudora© o el Pegasus©, precursores del actual Outlook y lenguajes como el HPLC, Basic, etc. El nacimiento de World Wide Web se me hicieron inmediatamente familiares y siempre me interesó estar "a la última" en este campo.

Gracias a una beca de la Unión Europea "Chronic" "An Information Capture and Processing Environment for Chronic Patients in the Information Society", que en 1999 nos abrió las puertas a la investigación en nuevos modelos asistenciales y a la utilización de la telemedicina en nuestro ámbito, entramos en contacto con grupos que empezaban a trabajar en modelos de telemedicina. En ese mismo año, el FIS me concedió una beca de investigación en el que por primera vez pilotamos un modelo de soporte al diagnóstico usando TIC's (FIS de 99 "Control de calidad y aplicabilidad de la espirometría forzada en diferentes niveles asistenciales"). Fruto de esa experiencia fue la extensión a todo el territorio nacional en un proyecto coordinado en el que participaron varios Hospitales y 18 centros de atención primaria de varias comunidades autónomas, y que fue financiado por el FIS en 2004 como proyecto colaborativo "La espirometría forzada en atención primaria: impacto de un programa de tele-trabajo en la calidad de los resultados y en las interacciones entre niveles asistenciales". Aquí se halla el núcleo central de mi investigación que ahora toma cuerpo en la presente tesis doctoral.

Finalmente la oportunidad de cursar el Master Oficial de Medicina Respiratoria de la Universidad de Barcelona – Pompeu Fabra, me ha permitido el obtener el grado de Master (MSc), abriéndome las puertas a mi mayor sueño como profesional, obtener el grado académico de doctor. Todos estos antecedentes han modulado a lo largo de los años mi carrera profesional y, gracias al apoyo constante de mi director de tesis, Josep Roca y de mi mentor Robert Rodriguez Roisin, me han dado el empujón necesario para presentar esta tesis doctoral.

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Glossary

ATS	American Thoracic Society
AHR	Airway Hyper-Responsiveness
CDA	Clinical Document Architecture
CDS	Clinical Decision Support
CDSS	Clinical Decision Support Systems
CPh	Community Pharmacy
CRO	Contract Research Organization
EAI	Enterprise Application Integration
COPD	Chronic Obstructive Pulmonary Disease
ERS	European Respiratory Society
ESDL	European Spirometry Driving License
EHR	Electronic Health Records
EPR	Electronic Personal Records
FEV_1	Forced expiratory volume in the first second
FIRS	Forum International Respiratory Societies
FS	Forced Spirometry
FV	Flow-Volume curves
FVC	Forced Vital capacity
GOLD	Global Initiative for chronic Obstructive Lung Disease
GP	General Practitioner
HERMES	Harmonized Education in Respiratory Medicine for European Specialists
HIE	Health Information Exchange
HIS	Hospital Information Systems
HI-Sharing	Health Information Sharing
HL7	Health Level Seven
HTA	Health Technology Assessment
ICCC	Innovative Care for Chronic Conditions initiative
ICS	Integrated Care Services
IES	Institut d'Estudis de la Salut - Institute of Health Studies
ICT	Information and Communications Technology
NCDs	Non-Communicable Diseases
NEXES	Supporting Healthier and Independent Living for Chronic Patients and Elderly
NIOSH	National Institute for Occupational Safety and Health
PDMAR	Pla Director de Malalties Respiratòries - Master plan of respiratory diseases
PC	Primary care center
PCc	Primary care center (control)
PCi	Primary care center (intervention)
SNOMED CT	Systematized Nomenclature of Medicine—Clinical Terms
USPSTF	U.S. Preventive Services Task Force
VT	Volume-time curves
WHO	World Health Organization
XML	Extensible Markup Language

Introduction

Functional testing in the new healthcare scenario

Population ageing and changes in lifestyle are central factors in explaining the increasing prevalence of chronic disorders, a trend that it is expected to continue over the coming decades, challenging the sustainability of health care systems worldwide. Non-communicable diseases (NCDs) represent close to 70% of the total burden on health care systems in Europe, and impact significantly on both morbidity and mortality(1-3).

There is evidence indicating that the current fragmented care system generates avoidable inefficiencies at system level(4), perpetuates a reductionist approach to chronic disorders, precluding management of co-morbidities(5) and does not facilitate future predictive and personalized medicine.

Thus, there is an urgent need to introduce substantial changes in the way we approach the delivery of care for chronic patients, as well as its articulation with social support services. This need led the World Health Organization (WHO), in 2002, to launch the Innovative Care for Chronic Conditions initiative (ICCC-WHO)(1;6) formulating basic principles and strategies to enhance the management of chronic patients.

This PhD thesis has been generated within the NEXES project (2008-13)(7) conceived to develop the practicalities of the Innovative Care for Chronic Conditions (ICCC) initiative (1;6) acknowledging that Integrated Care Services (ICS) supported by Information and Communication Technologies (ICS-ICT)(8) constitute pivotal building blocks for the Chronic Care model proposed by the World Health Organization.

In NEXES(7), well-articulated innovative ICS-ICTs were proposed as the most efficient way of adopting the Chronic Care model by transferring complexity from specialized care to the community (9-13).

The NEXES project assessed the deployment of four different modalities of ICS-ICT(14;15), namely: *i)* Wellness and Rehabilitation; *ii)* Enhanced Care for frail patients; *iii)* Home Hospitalization and Early Discharge; and, *iv)* Remote Support to primary care for diagnosis and therapy, covering a wide spectrum of care coordination with a strong focus on prevention and modulation of the disease progress.

This PhD thesis specifically focuses on the fourth ICS-ICT of this list. That is, it explores the feasibility of all the aspects involved in the transfer of testing procedures for diagnostic and follow-up purposes, usually managed by specialists, to primary care professionals and to the patient's home. It must be emphasized that this transfer of complexity requires several major guarantees, namely: *i)* high-quality testing by non-specialized professionals; *ii)* strategies to

support the continuous training of professionals; *iii)* interpretative support; *iv)* interoperability among healthcare providers; *v)* collaborative tools for professionals working at different healthcare tiers and between patients and professionals; and, *vi)* availability of proper user interfaces to compare patient testing carried out by different providers over time.

Although NEXES had a patient-oriented approach focusing mainly on chronic respiratory conditions, cardiovascular disorders and diabetes mellitus type II, this PhD thesis only addresses chronic respiratory disorders. This focus has been chosen mainly due to the applicant's background, but also because respiratory diseases are a fundamental part of the NCDs group prioritized by WHO since 2001. The scientific respiratory community worldwide is strongly committed to the shift toward the new health scenario for the management of chronic conditions. The Forum of International Respiratory Societies (FIRS), which involves major international respiratory societies in all continents, recently prepared a document including the most relevant research on lung health together with a description of the impact of current respiratory health policies, with the aim of guiding world leaders in their debates during the 2014 United Nations meeting that will be devoted to chronic lung diseases(16).

NEXES was designed to assess the impact of five factors that have been classically identified as barriers to the extensive deployment of ICS-ICT, namely: *i)* poor evidence of clinical benefits; *ii)* technological issues; *iii)* service reimbursement; *iv)* regulatory and ethical aspects; and, *v)* organizational factors. The service-focused approach adopted in the project has important implications on future deployment strategies aimed at ensuring sustainability of the proposed ICS-ICT.

As mentioned above, the transfer of complexity from hospital-based specialized care to the community necessarily involves the development of collaborative tools for aiding interaction among the relevant actors across healthcare tiers, together with accessibility of validated test data throughout the health system. These two basic requirements shall be supported by an interoperable ICT platform constructed with the appropriate architecture.

We understand that the deployment of functional testing for chronic respiratory patients in a coordinated care scenario must promote developments in three major areas, namely:

- Case-finding programs.
- Assistance for high-quality diagnosis in primary care.
- Follow-up of patients across healthcare tiers.

Why Forced Spirometry as a use case?

Forced Spirometry (FS) is the principal testing procedure for the diagnosis and severity assessment of COPD patients, as stated by GOLD(17). It is of note that COPD generates a major burden on health systems being a representative entity among the highly prevalent NCDs, the impact of which is expected to increase to become the third leading cause of death by 2020(18;19) due to the continuous increase in smoking rates in developing countries and the ageing of the population. Consequently, forced spirometry testing constitutes an outstanding use case for the exploration of the potential of novel ICT-supported approaches for functional testing in patients with chronic conditions. The transfer of the complexity of diagnostic procedures to primary care professionals will change the current paradigm for clinical diagnosis, currently too restricted to hospital-based medical specialists.

This PhD thesis assesses, in a systematic manner, the relevant aspects of the transfer of high-quality forced spirometry to non-specialized professionals working at a community level. We view FS as a first line test in the clinical assessment of patients with respiratory symptoms. Because of its high applicability and information content, FS plays a pivotal role in the diagnosis and follow-up of chronic obstructive respiratory diseases. It is of note that relevant clinical guidelines indicate the need for widespread use of FS in primary care for the early detection and appropriate management of asthma and COPD.

It is hypothesized that that the rapid increase in the impact of COPD on healthcare can be prevented with actions at two different levels:

- Firstly, and most importantly, reduction of the disease's main causal risk factor - cigarette smoking - as well as inhalation of other known irritants.
- Secondly, as mentioned above, focus on the early diagnosis of COPD patients, which generally entails screening using FS in adults (> 40 years old) at risk (tobacco smokers), and/or with symptoms. This policy should facilitate appropriate patient stratification and preventive management aimed at modulating COPD disease progress in the early stages.

Both primary care physicians and respiratory specialists agree on the extensive use of high quality FS since it clearly has a positive impact on public health(20-26). However, although standard FS testing shows high applicability, at present it is difficult to perform as part of conventional day-to-day healthcare practice in primary care because the procedure requires skilled personnel. There is a great deal of controversy(27-29) regarding the quality of the tests performed in primary care by non-expert professionals leading to suboptimal deployment of FS in community care. Consequently, effective and sustainable training of non-specialized allied health professionals ensuring high quality FS testing in primary care is a crucial component for generating reliable results that should be accessible across healthcare tiers to prevent unnecessary test duplications.

Enhanced FS can have a major impact on health management

As a diagnostic test, spirometry is a reliable, simple, non-invasive, safe and inexpensive procedure for the detection of airflow obstruction. This method is recognized by international clinical guidelines as the essential test for making a diagnosis of COPD(22). Consequently, potential benefits of the transferability of FS from specialized diagnostic units to community care are acknowledged by both health professionals and managers. However, key organizational and technological aspects that would make possible such transferability while ensuring accessibility of the tests across the health system are not yet in place. Moreover, it is of note that by solving the challenges involved in the transfer of FS from specialized to community care, we are paving the way for reshaping several other diagnostic and follow-up testing procedures within an integrated care scenario. It is assumed that the changes proposed in this PhD thesis could have a major clinical impact on the following areas of respiratory medicine.

Underdiagnosis: this is a major problem in all chronic respiratory diseases and particularly in COPD(26). Only one third of patients with COPD are informed about their disease(30) and 21% of patients hospitalized for COPD exacerbation state that their respiratory problem is not regularly monitored by a physician(31). Furthermore, a high percentage of patients with a diagnosis of COPD do not have spirometric confirmation of the diagnosis. Walters et al (32) report that in Australia 31% of patients diagnosed with COPD lack spirometry and that 56% of supposedly COPD patients showed normal spirometric results. All epidemiological studies indicate that COPD has a very high rate of occult disease. Moreover, the different studies acknowledge limited progress during the last decade in effectively reducing the problem of COPD underdiagnosis (33-35).

We believe that screening for early diagnosis of COPD is needed to define coherent strategies aimed at efficient early disease management allowing the modulation of disease progress. Recently, different health strategies adopted on a national level in Europe (36;37) are recognizing the importance of appropriate policies to avoid COPD underdiagnosis. Among the different potential initiatives, it is well demonstrated that ensuring effective access to high-quality spirometry at community level should be the first priority (26;38), since it can be reasonably hypothesized that wider implementation of high-quality forced spirometry should reduce the COPD burden.

In summary, the use of Information and Communication Technologies (ICT) for the remote support of case-finding programs has enormous potential for paving the way in the development of novel and efficient approaches in the enhanced early diagnosis of COPD, as well as for generating efficiencies in respiratory diagnosis and follow-up in the community by remotely supported non-specialized professionals.

Airway Hyper-Responsiveness (AHR): AHR is an intrinsic feature of asthma and it is seen in some COPD patients in whom this phenomenon has clinical implications (GOLD) (17). Differences in the underlying mechanisms of airway inflammation in the two conditions, asthma and COPD, are beyond the scope of this thesis. Different types of bronchial challenges are used in specialized care to document and perform a quantitative assessment of AHR(39). FS testing is a key element in most bronchial challenge testing (40), but this should probably be limited to specialized units. It is of note, however, that increased spontaneous variability of FEV_1 over time constitutes a hallmark of AHR that can be assessed with FS only, without the need for bronchial challenges. Moreover, assessment of the spontaneous variability of FEV_1 complements the information provided by the standard post-bronchodilator response carried out as part of the FS testing. Limitations of the post-bronchodilator response in terms of sensitivity are well identified (41;42). In this regard, we would like to stress the importance of high-quality FS in patient follow-up in primary care as a tool for assessing AHR in respiratory patients. Increased variability of high-quality testing is a valuable tool in the diagnosis of AHR that requires the type of setting put forward in this PhD thesis to be able to contribute effectively to enhanced diagnosis and management of chronic respiratory conditions.

Enhanced diagnosis and patient follow-up: A review of COPD management has recently recommended that FEV_1 after administration of a bronchodilator should be measured repeatedly over the course of the disease to define the rate of decline in lung function(43), in order to help focus both therapeutic decisions and assessment of prognosis. This implies that spirometry should be used on a routine basis, to identify patients with a rapid decline in FEV_1 and to improve quality of care. These considerations have been well proven in the management of asthma(44) and can be reasonably extended to most respiratory conditions. Consequently, it can be concluded that high-quality FS testing accessible across the health systems is a valuable way of enhancing the management of chronic respiratory patients.

Factors limiting the transfer of FS to primary care

We have identified the following three major factors limiting the deployment of FS in primary care. All of them must be simultaneously tackled to ensure the successful adoption of enhanced FS: i) poor availability and suboptimal use of FS; ii) support for high-quality FS; and iii) accessibility of testing across healthcare tiers that are analyzed below.

Poor availability and use of FS. Insufficient use of FS, even in hospitals, has been identified as one of the most important factors of underdiagnosis of COPD(45;46). Compared with heart failure patients, COPD patients are less likely to have confirmatory testing, even in those cases in which the two conditions, heart failure and COPD, coexist(46;47). Consequently, awareness of the relevance of the test and the accessibility of FS carried out by trained primary care professionals through standardized coaching courses are the two main challenges to be faced. Moreover, knowledge about existing lung function testing resources both at hospital and primary care levels is currently incomplete. To resolve those issues, the Master Plan for Respiratory

Diseases in Catalonia (PDMAR)(36) undertook the initiative of identifying and characterizing existing lung function testing units and their territorial distribution. The results of this analysis represented a pivotal element in the design of strategies ensuring successful transferability of diagnostic tools from specialized care to the community.

Long-term sustainability of professional coaching. High-quality FS in primary care depends highly on adherence to international recommendations (48;49). 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 where non-expert professionals are likely to perform the tests.

In 2008, a survey carried out by the European Respiratory Society (ERS) confirmed that no formal training on spirometry testing was taking place in most EU countries(50). It is widely accepted that training is a pivotal element in achieving high-quality FS performed by non-expert professionals. Moreover, recent data (51) indicate that conventional training techniques are useful but they do not ensure sustained high-quality testing. Consequently, it can be concluded that there is a lack of appropriate training programs directed at non-specialized professionals aimed at generating sustainable high-quality FS testing.

Accessibility of testing across the healthcare system. The concept of the Electronic Health Record (EHR) has been evolving dramatically in recent years. The EHR are currently defined as a systematic collection of patient health information using a digital support, which should facilitate information-sharing across different healthcare levels. The EHR can be set up within a provider's Health Information System (HIS) delivering formal care. Chronic patients often have more than one EHR since they are frequently seen by several providers of formal healthcare. Moreover, EHRs handled by the patient themselves or by the patients' relatives are an emergent tool in Western countries where the Electronic Personal Record (EPR) or Personal Health Folder (PHF) is being increasingly and successfully used for patient empowerment in health self-management. This has had a beneficial impact not only in terms of enhancing the patient's adherence to therapy and preventive strategies, but also as a way of enhancing interoperability among healthcare providers and between formal and informal care. Unfortunately, this is not the current situation. Interoperability issues at a health system level are a major limitation in the extensive deployment of ICT-supported healthcare services. Moreover, FS testing is poorly implemented in the EHR, which clearly explains why interoperability has not been perceived as an issue for FS so far. We believe, however, that accessibility of FS testing across the system is a priority target.

The FS equipment is a medical device that measures either volume or flow signals during the maneuver, generating different parameters that are most often stored in a proprietary format, thus limiting interoperability at a health system level. To overcome such limitations many

testing procedures have adopted communication standards such as HL7 (Health Level Seven) and CDA (Clinical Document Architecture, Release 2) to ensure interoperability throughout the healthcare system.

A standardized CDA for FS contains patient data, information on the testing request and context, outcome variables and flow-volume and volume-time curves, as well as the original signal captured by the equipment during the testing procedure. Consequently, this standard creates a normalized dataset organized in such a way as to facilitate integration of FS testing into any health information system (HIS), and pave the way for accessibility of FS by health professionals working with different providers and/or on different healthcare tiers.

The first step required in the design of adequate strategies for paving the way for change is to acknowledge those major factors limiting the transfer of lung function testing from specialized to primary care, as described below.

Need for novel strategies generating high-quality assurance of FS

Despite the international recommendations on the quality of FS (ATS/ERS)(49) for both equipment and tests, it is common to find that adherence to these standards is lower than expected, even in specialized environments. The lack of appropriate strategies to enforce the use of those recommendations has been pointed out as a main barrier to high-quality FS. The statement is fully endorsed by the results of the Platino study (52;53), which used a centralized quality control assessment of FS. Moreover, as mentioned above, the problem is most relevant when tests are performed by non-expert professionals, notably in primary care centers.

Recently, Walters JA et al. (54) showed that the percentage of high-quality FS tests carried out by trained nurses was approximately 76%, whereas that percentage dropped to 44% in non-trained professionals. These results confirm the existing evidence (52;55) indicating that external quality assurance needs to be implemented in primary care testing to enhance quality of testing and to ensure long-term sustainability of high-quality testing over time. Moreover, 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 external expert decreased the acceptance rate to 64%. All in all, most authors(56;57) are skeptical about the potential of primary care to generate high-quality testing on its own, and they agree on the need for transferring well-established quality assurance programs from lung function laboratories to the primary care setting to ensure quality of the tests(58). In this regard, different reports (52;53;59) indicate the potential of telemedicine to enhance both quality of testing and diagnosis of FS carried out by non-expert professionals, but because of technological and/or logistic limitations precluding scalability, none of these studies show potential for generalization across the healthcare system.

Transitional steps for extensive use of high-quality FS at community level

The strategies for a successful transfer of the complexities involved in shifting patient testing from specialized care to the community with the aim of enhancing healthcare efficiencies require a combination of changes covering several dimensions, namely: re-design of clinical processes toward Integrated Care Services (ICS); organizational and cultural aspects involving all actors; regulatory issues; novel reimbursement modalities; and, last but not least, appropriate use of Information and Communication Technologies (ICT) as supporting tools. Consequently, the transition toward ICS-ICT shall be considered an intervention in a complex system(60-62), requiring a building blocks approach to ensure the modularity and flexibility of the transformational process. It is our understanding that this approach is valid even in the rather simple use case of forced spirometry (FS). To this end, we selected the main building blocks to be systematically addressed in this PhD thesis in order to shape a successful strategy aiming for scalability at a regional level with potential for transferability at a European level. We identified seven main conceptual building blocks that have been taken into account in the process, as briefly described below.

- Block 1 - To explore the feasibility and efficacy of web-based tools for enhancing high-quality forced spirometry in primary care aimed at expanding the reliable use of the testing procedure for the management of chronic respiratory patients at a community level.

- Block 2 - To characterize different aspects involving an efficient use of forced spirometry testing in an ICS-ICT scenario, namely: quality control, continuous professional enhancement, assistance in interpretation, etc.

- Block 3 - To identify the needs across healthcare sectors in the Catalan regions to ensure equity of high-quality testing at a regional level.

- Block 4 - To explore novel coaching strategies.

- Block 5 -To ensure interoperability of testing across the health system.

- Block 6 - To identify elements facilitating extensive deployment, e.g. automatic assessment of quality testing.

- Block 7 - To explore the boundaries for extending the testing approach and the potential role of informal care to support efficient case-finding strategies**.**

As a way to illustrate the integration of these building blocks into the clinical processes considered in this PhD thesis, we have generated two specific use cases described in the following

story board, from formal (Primary Care) and informal care (Pharmacy Office) scenarios, respectively. Mario and John's stories illustrate the potentialities of all seven of the building blocks described. Our hypothesis is that putting all the items into operation will significantly enhance management of the COPD patient. Moreover, it will pave the way for future developments in the testing of chronic patients in a Coordinated Care scenario.

Story Board I: Primary Care diagnosis and follow-up

Virtually any adult patient attending a primary care visit because of respiratory symptoms such as cough, shortness of breath, wheezing, phlegm, etc., with no suspicion of acute infection as a causal factor, will be a candidate for forced spirometric testing as a basic approach to assess lung function. Usually, FS testing including baseline spirometric curves and post-bronchodilator testing will be carried out by a non-specialized nurse.

Let's imagine the case of Mario, a 50-year-old man with long history of cigarette smoking (60 packs/year) seeking medical advice because of a history of chronic cough and shortness of breath with no previous history of hospital admissions for severe exacerbations. He is an obvious candidate for forced spirometry testing and a chest X-ray.

In a standard care scenario, we may face quality problems with the testing mentioned above because of the lack of a coaching program ensuring high-quality testing (Blocks 2-4). Additional problems are lack of transferability of the testing to other healthcare tiers because of non-existing interoperability among health professionals (Block 5) and, also, because of poor confidence in the quality of testing (Block 6). Moreover, such poor confidence in the quality of the testing does not stimulate the generation of strategies facilitating clinical judgments made on the basis of follow-up testing stored in the data systems of the same or different providers.

In this PhD thesis, we hypothesize that high-quality testing would be significantly reinforced if the primary care nurse could upload FS testing onto an ICT platform automatically assessing quality and providing feedback to non-specialized professionals (Blocks 1 and 7). Moreover, through the ICT platform, nurses can receive coaching for continuous professional development irrespective of their geographical location. The remote support could be designed for use by other health professionals and even for patients' self-empowerment.

Once the nurse transfers the pre- and post-bronchodilator testing to the general practitioner, he/she makes the diagnosis. In the case that we are analyzing, Mario's FS testing shows a moderate obstructive defect (post-bronchodilator FEV_1 55% reference value) with only moderate but significant changes in the bronchodilator response to salbutamol. Mario will get the diagnosis of COPD, GOLD II stage, with bronchial hyper-responsiveness. The GP will generate both preventive and therapeutic pharmacological and non-pharmacological recommendations following COPD guidelines.

The lack of a history of frequent severe exacerbations provides positive prognosis to the case, but Mario shows AHR and low body mass index (BMI) which justify his stratification as a patient with increased risk in terms of natural history of the disease. He will be managed by the general practitioner under the supervision of the specialist to assess the systemic effects of the disease and advice will be given regarding specific actions. Moreover, his AHR will require additional periodical FS testing to assess both variability and rate of decline of FEV_1. In these patients, the need for high-quality FS testing remotely accessible by different healthcare professionals and by the patient himself is particularly important in the design of an efficient strategy for successfully modulating disease progress. As mentioned above, it is well accepted that high-quality, accessible testing across the health system is an asset in enhancing the management of chronic respiratory patients. In the case of Mario, FS should be used routinely, as part of the overall strategy to modulate the natural history of the disease, reduce lung function variability and minimize FEV_1 decline.

Mario may require further visits to the respiratory specialist. In this case, it will be relevant that high-quality testing carried out in primary care is available for the specialist to properly assess follow-up data and to prevent unnecessary duplications of testing between different healthcare tiers and/or providers.

Story Board II: Pharmacy Office

We have previously illustrated the problem of underdiagnosis of COPD and its potential negative consequences in two main areas: *i)* increase of the COPD burden on the health system due to preventable hospital admissions; and, *ii)* delayed adoption of early prevention strategies that may have positive effects on modulation of the COPD progress. Consequently, the need for case-finding programs is accepted to such an extent that several publications(63;64) have recently explored different program designs. In this PhD thesis, we hypothesize that an integrated care approach with the support of an ICT platform, but based on informal care (Community Pharmacy, CPh), could provide the basis for an efficient COPD case-finding program without generating an additional burden for the healthcare system (Block 7).

The setting could be as simple as this: John, a 52-year-old man, active smoker, goes to the CPh to get arterial hypertension medication. In the CPh, he sees a banner displaying a short advertisement extracted from GOLD guidelines: *"Do you cough?; b) Do you bring up phlegm or mucus?; c) Do you get short of breath?; d) Are you over 40 years of age?; and e) Are you current smoker or an ex-smoker?"*.

John remembers his wife's frequent complaints about his chronic cough and decides that it is time to assess his respiratory condition. The CPh officer will administer the GOLD questionnaire and since it is positive, John will be invited to perform pre-bronchodilator FS testing only.

After successful quality testing certified by the ICT platform, the CPh officer indicates that John's FEV_1/FVC ratio is below 0.7. Consequently, an appointment to the GP is immediately generated to formally confirm the COPD diagnosis, to complete FS testing and to get appropriate therapeutic advice following GOLD guidelines. The FS administered by the CPh officer will be transferred to John's EHR in primary care along with information on the questionnaire and quality of testing.

The need for an open ICT platform

NEXES developed an open ICT platform, Linkcare®, to support the deployment of the four ICS-ICTs assessed in the project. Linkcare® has been conceived as a multi-tier health information-sharing platform to provide organizational interoperability and knowledge-sharing among stakeholders involved in coordinated care. In addition, it supports ICS-specific knowledge management and allows the integration of clinical decision support tools into the workflow of the ICS-ICT.

The Linkcare® platform functions as an Enterprise Application Integration[1] (EAI) framework to support the NEXES integrated care model. In an EAI perspective, the Linkcare® platform is composed of a set of technologies and services to provide the requested functionalities [i.e. definition and management of integrated care programs (both by professionals and patients), integration of information between the Linkcare® platform and external Hospital Information Systems (HIS), call-center capabilities and remote monitoring] for the execution of integrated care programs. A detailed description of the architecture and functionalities used in NEXES and further developments to support scalability at regional and international levels was reported by Cano et al (65). The technology of Linkcare® has been developed by a spin-off company, Linkcare Health Services (Linkcare HS), of the Hospital Clínic, Barcelona.

Linkcare® provides a common basic set of technologies and services grouped by functional modules to support Integrated Care Services. It is in a way, similar to the architecture of a Microkernel-based Computer Operating System (66;67). The Linkcare® core module provides a small set of simple abstractions to support the data model behind integrated care programs and use applications called Interoperability Middlewares to provide enhanced functionalities, as depicted in Figure 1.

[1] Enterprise Application Integration (EAI) is defined as the use of software and computer systems architectural principles to integrate a set of enterprise computer applications.

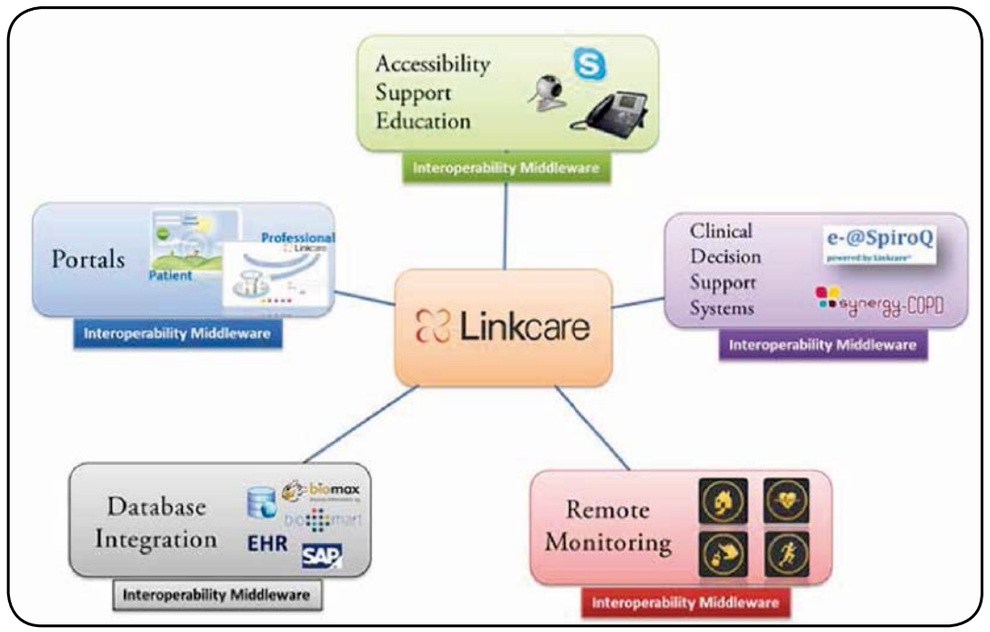

Figure 1: *Architecture of the Linkcare® Health Information Sharing Platform. The core module (central node) includes the functionalities responsible for the management of the integrated care programs. Interoperability with the five different extended functionalities (surrounding nodes) is ensured through the multi-tier architecture of the core module and a Simple Object Access Protocol (SOAP) web services communication bus. Those nodes cover different functionalities: i) Accessibility to the support center ; ii) User-profiled portals; iii) Interoperability with Electronic Health Records (EHR) from different providers and research databases; iv) Remote monitoring using wireless mobile technology; and, v) Clinical Decision Support (CDS).*

In this architecture, the core services of the Linkcare® platform are available as web services and support the general structure of the service model, depicted in Figure 2. At a high functional level, Linkcare® web services can potentially offer database integration and knowledge management, professional and access patient portals, accessibility, support and education capabilities, remote monitoring functionalities and services to facilitate the deployment of Clinical Decision Support Systems (CDSS). Furthermore, core services can be easily extended so that the system is ready to incorporate future resources of ICS-ICT. Overall, the Linkcare® platform is able to mediate between external applications that use web services to communicate between the Linkcare® core module, which acts as a common facade exposing only the relevant information and interfaces of the underlying applications to the end-user.

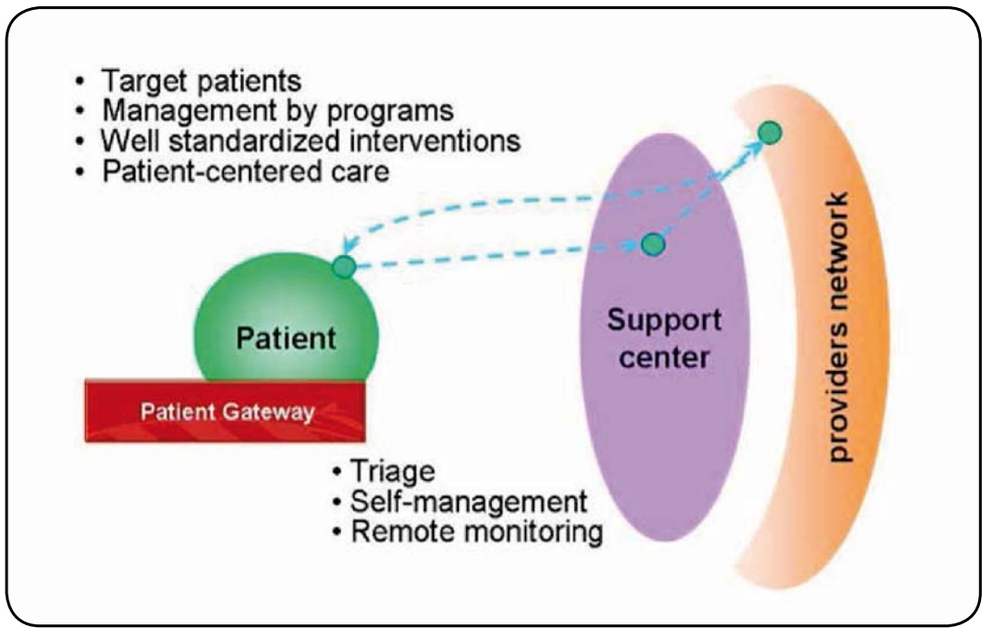

Figure 2: *The figure depicts the conceptual integrated care model assessed in the four ICS of NEXES. The Support Centre is one of the main access points and it plays a central role for three specific functions: i) patient triage, ii) promoting patient self-management, and, iii) management of remote monitoring. The tele-operator in the Support Centre receives different types of requests (health issues, administrative problems and social support requests) from target patients that are resolved or the most efficient resource from the network of providers is promptly activated (i.e. the call is transferred to a nurse, a home visit or day hospital visit is triggered, etc). The system is operational only for target patients with chronic conditions that are managed by programs (ICS) following well-standardized interventions, providing patient-centered care. Novel accessibility tools like the patient portal, also called the personal health folder, are generating positive outcomes.*

During 2012, the architecture of the ICT platform has evolved further to support scalability of ICS at regional level. Recent developments have focused on enhanced data security and privacy, plus, most importantly, achievement multicenter functionalities. The current platform covers three major areas. Firstly, it supports patient-centered care through ICS-ICT, as described above. Secondly, Linkcare® supports information-sharing across several working teams and continues to develop functionalities aimed at supporting knowledge-sharing. Finally, it is already providing interoperability at a health system level, among several proprietary health information systems, covering the requirements for accessibility of lung function testing described in this introductory section of the PhD thesis.

Summary of the introductory section

The emerging healthcare model facing the challenge imposed by NCD epidemics relies heavily on the deployment and adoption of innovative Integrated Care Services supported by Information and Communication Technologies (ICS-ICT).

Re-design of diagnostic and follow-up testing is an important component of the ongoing transfer of complexity from specialized care to the community. We are specifically addressing the re-design of forced spirometry as a use case of this scenario.

The introductory section identifies the specific components of the change as seven building blocks that will be covered by this PhD thesis. It is assumed that a high degree of transferability will be achieved and, consequently, the outcomes of the thesis will mark out the basic elements for novel interactions between hospital and primary care in terms of testing procedures.

Hypothesis

The transfer of functional testing from specialized to primary care within a coordinated care scenario will improve the efficiency of care delivery and will generate cross-fertilization between levels of care. It includes rather heterogeneous groups of services:

- Transfer of technology to enhance the potential for diagnosis, monitoring and treatment under the remote off-line supervision of the corresponding specialist.
- Programs ensuring sustainability of high-quality testing by non-specialized professionals, as well as interpretative support.
- Remote support for screening or case-finding programs.

The general hypothesis is that extensive deployment of different, well-articulated ICS-ICTs covering the entire spectrum of severity of chronic patients generates efficiencies at a system level. This PhD thesis focuses on functional testing and specifically addresses forced spirometry as a use case.

General objectives

This PhD thesis aims to identify the key factors that seem to modulate success of the transfer of forced spirometry (FS) testing to primary care and to other non-specialized professionals and to explore the deployment of services with potential for scalability.

We aim at achieving two main outcomes from this PhD thesis. Firstly, to generate a program for the transfer of FS to primary care and to other non-specialized professionals with potential for regional scalability. Secondly, to identify those dimensions of the program that can be generalized to other functional testing and therapeutic procedures.

Specific objectives

Objective 1 – Transferability of FS to Primary Care and Pharmacy Offices

Rationale

The first objective is to assess the deployment of the transfer of FS in two scenarios, each with different purposes. The first manuscript analyzes the sustainability of a service to ensure high-quality forced spirometry in primary care. The two other manuscripts under Objective 1 examine the potential of transferability to pharmacy offices, to generate a COPD case-finding program.

Manuscript 1

F.Burgos, C.Disdier, E.Lopez de Santamaria, B.Galdiz, N.Roger, ML.Rivera, R.Hervas, E.Durán, J. Garcia-Aymerich, J. Roca on behalf of e-Spir@p group.

Telemedicine enhances Quality of Forced Spirometry in Primary Care.

Eur Respir J 2012; 39: 1313–1318.

Manuscript 2

D.Castillo, R.Guayta, J.Giner, **F.Burgos**, C.Capdevila, JB. Soriano, M. Barau, P. Casan on behalf of the FARMAEPOC group.

Early detection of COPD in customers of urban community pharmacies: a pilot-study.

Respir Med 2009 Jun;103(6):839-45.

Manuscript 3

D. Castillo, **F. Burgos,** R. Guayta, J. Giner, J.B. Soriano, P. Lozano, X. Flor, M. Estrada, M. Mayos, M. Barau , and P. Casan on behalf of the FARMAEPOC group.

Spirometry in community-pharmacies: a novel strategy to reduce COPD underdiagnosis.

BMJ (submitted).

Objective 2 – Assessment of requirements for scalability at regional level

Rationale

Within objective 2, we performed two clusters of studies. The first two (manuscripts 4 and 5) analyze the status and needs of FS testing in Catalonia. The second cluster includes two studies (manuscripts 6 and 7) with specific proposals for training programs for deployment in Catalonia and at a European level. All these studies were performed directly under the auspices of the Catalan Master Plan of Respiratory Diseases.

Manuscript 4

Núria Roger, **Felip Burgos**, Jordi Giner, Alba Rosas, Ricard Tresserras, Joan Escarrabill y el grupo de trabajo de función pulmonar del Plan Director de las Enfermedades del Aparato Respiratorio (PDMAR).

Survey about the use of Lung Function Testing in Public Hospitals in Catalonia in 2009.

Archivos Bronconeumología 2013 Feb 13. doi:pii: S0300-2896(13)00003-3. 10.1016/j.arbres.2012.12.006. [Epub ahead of print].

Manuscript 5

MªAntonia Llauger, Alba Rosas, **Felip Burgos**, Elena Torrente, Ricard Tresserras, Joan Escarrabill y el grupo de trabajo de función pulmonar del Plan Director de las Enfermedades del Aparato Respiratorio (PDMAR).

Estudio de la función pulmonar básica en los centros de atención primaria de Cataluña.

Atención Primaria 2013 (submitted).

Manuscript 6

Escarrabill J, Roger N, **Burgos F**, Giner J, Molins A, Tresserras R en nombre del Grupo de Función Pulmonar y del equipo directivo del PDMAR.

Design of a basic training program to get quality spirometry.

Educación Médica 2012; 15 (2): 103-107.

Manuscript 7

B.G. Cooper, I. Steenbruggen, S. Mitchell, T. Séverin, E. Oostveen, ***F. Burgos***, H. Matthys, H. Normand, J. Kivastik, J. Leuppi, M. Flezar, M. Agnew,O. Pedersen, S. Sorichter, V. Brusasco, W. Tomalak, P. Palange.

HERMES Spirometry: the European Spirometry Driving Licence.

Breathe 2011; 7: 258-264.

Objective 3 – Technological contributions

Rationale

In this PhD thesis, two areas were identified in which specific technological contributions were needed to ensure the success of the deployment. Firstly, the design and production of a FS-CDA for structured data transfer supporting interoperability across healthcare tiers (manuscript 8) and, secondly, the development of an automatic tool (algorithm) for remote FS quality control (manuscript 9).

Manuscript 8

Tomàs Sala, Carles Rubies, Carlos Gallego, Pilar Muñoz, **Felip Burgos**, Joan Escarrabill.

Technical Requirements of Spirometers in the Strategy for Guaranteeing the Access to Quality Spirometry.

Arch Bronconeumol. 2011;47(9):466–469.

Manuscript 9

Felip Burgos, Umberto Melia, Montse Vallverdú, Filip Velickovski, Pere Caminal, and Josep Roca.

Clinical Decision Support System to Enhance Quality Control of Forced Spirometry.

Eur Respir J (to be submitted after patent registration).

Results

First study

Telemedicine enhances Quality of Forced Spirometry in Primary Care.

F.Burgos, C.Disdier, E.Lopez de Santamaria, B.Galdiz, N.Roger, ML.Rivera, R.Hervas, E.Durán, J. Garcia-Aymerich, J.Roca on behalf of e-Spir@p group.

Published in European Respiratory Journal.

Eur Respir J 2012; 39: 1313–1318.

Eur Respir J 2012; 39: 1313–1318
DOI: 10.1183/09031936.00168010

Telemedicine enhances quality of forced spirometry in primary care

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ABSTRACT: **Forced spirometry is pivotal for diagnosis and management of respiratory diseases, but its use in primary care is suboptimal. The aim of the present study was to assess a web-based application aiming at fostering high-quality spirometry in primary care.**

This was a randomised controlled trial with 12 intervention primary care units (PCi) and six control units (PCc) studied over 12 months. All 34 naïve nurses (PCi and PCc) received identical training. The PCi units had access to educational material and remote expert support. Quality of spirometry and usability of the web application were assessed.

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). During the study, PCi showed higher percentage (71.5%) of high-quality tests than PCc (59.5%) ($p<0.0001$). PCi had 73% more chance of high-quality performance than PCc. The web application was better for assessing quality of testing than the automatic feedback provided by the spirometer. Healthcare professionals' satisfaction and usability were high.

The web-based remote support for 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.

KEYWORDS: **Forced spirometry, information technology, primary care, quality control, telemedicine**

Forced spirometry (FS) is viewed as a first-line test for clinical assessment of patients with respiratory symptoms. Because of 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 for 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 nonexpert professionals, resulting in suboptimal deployment of FS. Consequently, effective training of healthcare professionals ensuring high quality of FS in primary care is crucial to generate reliable results preventing unnecessary test duplications across the healthcare 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 nonexpert professionals are likely to perform the tests. Previous experiences in remote support of FS [11–14] seem to indicate both feasibility and positive outcomes, but none of them shows scalability or potential for generalisation.

The current randomised controlled study carried out in five areas of Spain throughout a 1-yr follow-up period examines efficacy, acceptability and usefulness of a web-based application [15] providing remote assistance to nonexpert 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 organised for the study purposes as independent nodes located in: Extremadura (south-western region of Spain), Basque Country (north of Spain) and three nodes in Catalonia (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 (GPs) participating in the study [16].

Each node (fig. 1) had a reference centre (lung function laboratory) from a tertiary hospital with a specialised lung function professional playing the role of coordinator of the primary care units of the node. They were responsible for blindly scoring (from A (best score) to F (worse score)) (table 1) all spirometric tests performed in the area for both intervention and control groups [17].

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

The 18 primary care centres included in the trial were randomly allocated, within each node, either to one of 12 intervention primary care centres (PCi) or six control primary care centres (PCc). Up to 34 nurses, five coordinators, three telecommunication engineers and ~150 GPs participated in the study.

The research was approved by the Ethical Committee of the Hospital Clínic i Provincial de Barcelona (Barcelona, Spain) and the corresponding ethical committee of each participating node. Patient consent was not required for the present study.

The study protocol included a 2-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 (Centers for Disease Control, Atlanta, GA, 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 performed several FS manoeuvres and had participated in discussions on standardisation of FS [10].

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

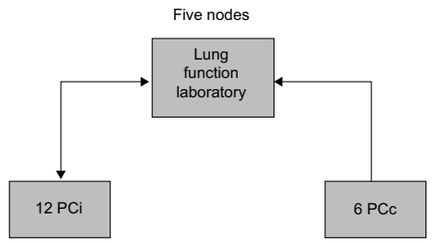

FIGURE 1. Structure of each node. The 12 intervention primary care units (PCi) had a bidirectional communication with the lung function laboratory playing a role as a support centre, whereas the six control primary care units (PCc) only transferred information to the support centre without any feedback. The five nodes were Bilbao (two PCi and two PCc), Cáceres (two PCi and one PCc), Vic (three PCi and one PCc), Badalona (two PCi and one PCc) and Barcelona (three PCi and one PCc).

The application provided a forum facilitating communication among healthcare professionals (GPs 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 individualised 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 generated, on a weekly basis, a report addressed to each PCi nurse including information on several aspects of quality control of the tests analysed, namely: repeatability of the manoeuvres, characteristics of the curves, and checks for starting (back-extrapolation) and ending (expiratory time) of those manoeuvres 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 coordinators' tasks performed by F. Burgos, assessing for homogeneity of the coordinators grading criteria.

In contrast, the healthcare professionals included in the control group did not have access to the web application. The 2-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 to the ATS/ERS recommendations [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 (EasyOne; ndd Medical Technologies, Barcelona, Spain) was used. The FS equipment had the original software without any modification except for the potential to export the data from all tests in XML (Extensible Markup Language) format. Briefly, each node used the same type of spirometer independently of being an intervention or control centre. In all cases, the nurses were instructed to use the automatic quality messages generated by the equipment. Although the two systems had a build-in capacity to generate automatic messages, only those of the EasyOne spirometer were explicitly for the users. Consequently, the comparison between remote reviewer and automatic feedback was only reported for those nodes using EasyOne spirometer.

The application tested in the current study is one of the modules of the information and communication technology platform used to support management of chronic patients [15, 19]. Such a platform provided traceability of all the actions taken during the follow-up period. A VeriSign™ Trust Node (Symantec™, Sunnyvale, CA, USA) security system was used to ensure confidentiality of encrypted data shared through the Internet. After the end of the follow-up, we assessed acceptability of the web-based quality control programme by the GPs involved in the study. Usability of the web application was

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TABLE 1 Quality scores for spirometric manoeuvres according to American Thoracic Society (ATS)/European Respiratory Society (ERS) standardisation [9, 10, 17]

Score	Description
A	3 acceptable manoeuvres, and best 2 matched with differences in FVC and/or FEV_1 <150 mL
B	3 acceptable manoeuvres, and best 2 matched with differences in FVC and/or FEV_1 <200 mL
C	2 acceptable manoeuvres, and best 2 matched with differences in FVC and/or FEV_1 <250 mL
D	1 acceptable manoeuvre
F	0 acceptable manoeuvres

A and B were considered high-quality spirometry; C was considered to represent high variability among manoeuvres. FVC: forced vital capacity; FEV_1: forced expiratory volume in 1 s.

also assessed (Software Usability Measurement Inventory (SUMI); University College Cork, Cork, Ireland) [20] by the nurses that performed the tests.

Data analysis

Characteristics of the sample are presented as n (%) for categorical variables or mean±SD for continuous variables (since all of them followed normal distributions). Comparisons of sociodemographic and lung function variables between the intervention and control group were made using Chi-squared or ANOVA tests, as appropriate. Effects of the intervention in the quality of the spirometry were tested by comparing the percentage of quality grade A and B spirometries between PCi and PCc, both at each month and during the whole study period, using the Chi-squared test. Additionally, multivariate logistic regression analyses were built with quality of spirometry 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 4,581 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 to a primary care clinic and FS was performed following the criteria of the GP.

TABLE 2 Main characteristics of the two study groups

	All	Intervention	Control	p-value
Subjects n	4581	3383	1198	
Males %	55.7	55.2	56.8	0.335
Age yrs	53.6±18.9	54.5±18.0	51.1±21.0	**<0.001**
Height cm	163.2±10.5	163.5±10.0	162.2±11.7	**0.030**
FEV_1 % pred	78.5±22.8	78.5±22.9	78.3±22.4	0.784
FVC % pred	83.5±19.6	83.8±19.6	82.5±19.3	**0.037**
FEV_1/FVC %	71.6±13.1	71.2±13.3	72.6±12.6	**0.001**

Data are presented as mean±SD, unless otherwise stated. FEV_1: forced expiratory volume in 1 s; % pred: % predicted; FVC: forced vital capacity. Bold indicates statistically significant p-values.

We observed that subjects in the intervention group were slightly older and moderately taller than those in the control group. Mean forced expiratory volume in 1 s % predicted was moderately abnormal with no differences between groups. In contrast, forced vital capacity 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 FS in primary care are displayed in table 3. It was answered by 146 (99%) GPs from the 18 primary care centres participating in the study.

Effects of the intervention

After the first quarter, monthly percentages of high-quality FS manoeuvres were significantly and consistently higher in the intervention than in the control group (fig. 2). The intervention group presented an average of 71.5% high-quality spirometries throughout the whole study period, with no differences between months 1 and 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%-points at month 1 up to 16%-points at month 12 (p<0.05). No differences between groups were seen in score C (table 1). However, while the proportion 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 sex), such that tests

TABLE 3 Status of forced spirometry (FS) among participating general practitioners (GPs) at baseline

	GPs %
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

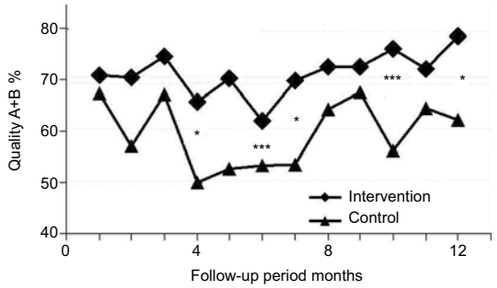

FIGURE 2. Percentage of high-quality tests, *i.e.* scores A and B (three acceptable manoeuvres and best of two with differences in forced vital capacity (FVC) and/or forced expiratory volume in 1 s (FEV_1) <150 mL, and three acceptable manoeuvres and best of two with differences in FVC and/or FEV_1 <200 mL, respectively), in the intervention and control groups throughout the study period. *: p<0.05; ***: p<0.001.

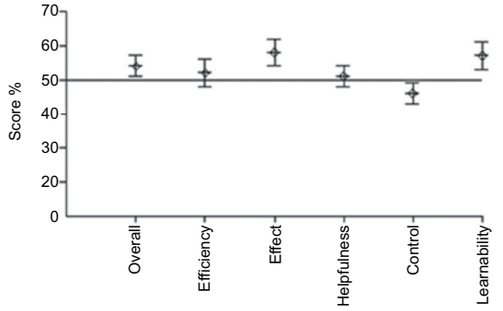

FIGURE 3. Median scores of the different dimensions of the Software Usability Measurement Inventory questionnaire [20] to assess usability of the web application (see text for further explanation). Whiskers represent 95% confidence intervals.

in the intervention group had a 73% higher chance of high-quality performance than those of the control group. We noticed that PCi professionals performed a higher number of spirometric manoeuvres than those of the PCc group. Up to 3% of intervention subjects made eight manoeuvres whereas the maximum amount of manoeuvres in the control group was six.

Automatic assessment of quality

In the subset of primary care centres 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 manoeuvres 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%-points. The equivalent figures using the same equipment but with the remote professional assessment were 71.5% (intervention group) and 59.5% (control group) (p<0.0001) with a similar mean difference of 12%-points between intervention and control. Accordingly, underestimation of acceptable spirometric manoeuvres generated by automatic quality assessment as compared with assessment carried out by expert professionals showed an average of -16%-points.

Acceptability of the web application

The results of the survey carried out among the GPs (n=126, 86% response rate) 1 month after the end of the study indicated an acceptable level of overall 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 GPs indicating problems of implementation of the intervention. Overall, the GPs reported 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 by administering the SUMI [20] questionnaire to the 34 nurses that carried out the tests with an 87% response rate. Figure 3 presents the results obtained for the five dimensions assessed in the questionnaire (efficiency, effect, helpfulness, control and learnability) as well as the score of overall satisfaction. Notice that except for the control, all the scores were >50, representing an acceptable degree of usability. As expected, the control (fig. 3) was uniformly <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: 1) accessibility to educational material for continuous professional development; 2) remote support for quality assurance of tests performed by nonexperts; and 3) remote assistance for lung function interpretation. We acknowledge that previous reports [11–14] have indicated the potential of telemedicine to enhance quality of both testing and diagnosis of FS carried out by nonexpert healthcare professionals, but none of the studies show potential for generalisation across the healthcare system due to technological and/or logistical factors precluding their scalability.

Our research clearly indicates a sustained beneficial impact of the intervention increasing high-quality tests (scores A and B) by ~20% (fig. 2) and decreasing the percentage of very low-quality spirometries (score F) during 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 nonexpert 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 fulfil unmet needs in primary care?

The baseline survey carried out with the participating GPs indicated that the professionals acknowledged the need for

support on training and interpretation of the tests in order to achieve the full potential of FS when used in primary care. Moreover, international clinical guidelines endorse extensive use of high-quality FS in primary care. Unfortunately, despite enhanced awareness of the problem over the last few years, COPD is still associated with marked underdiagnosis, without a significant decrease during the last decade (from 78% to 73% between 1997 and 2007) [21]. Still too often, a diagnosis of COPD is made after an episode of severe exacerbation or during the first hospital admission.

Our data confirm that accessibility of appropriate support facilitating quality assurance of the tests performed at the primary care level or in the patient's home is needed. It is classically accepted that ~10% of patients' data may need to be disregarded in lung function laboratories because of technical inadequacies. This percentage can be as high as 40% in epidemiological surveys without a proper quality assurance strategy [4]. We must acknowledge, however, that these figures 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 when performed by nonexperts. Recent data on a centralised quality control programme carried out as part of the PLATINO (Proyecto Latinoamericano de Investigación en Obstrucción Pulmonar) study [23] fully endorse the statement. In the primary care setting, WALTERS *et al.* [24] recently showed that the percentage of high-quality FS tests with trained nurses was ~76% whereas that percentage dropped to 44% in untrained professionals. Different authors [6, 25–27] have elaborated on the need to transfer well-established quality assurance programmes 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 performed in primary care, it was found that general practitioners identified ~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 a modality of assessment generated a marked underestimation (-16%-points) of acceptable spirometric manoeuvres as compared with assessment by experienced professionals.

To our knowledge, the current study constitutes the first attempt to successfully implement a web-based standard training programme reinforced by telecollaboration tools allowing remote assistance of primary care professionals by specialists. In this regard, the intervention was conceived to provide long-term sustainability of the training programme through continuous empowerment of primary care professionals. The results generated by the current research endorse this vision and they suggest that the current approach meets 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 the end of the test. We acknowledge that implementation of an automatic algorithm should be considered as a useful decision support tool for the node coordinator. As indicated above, the study is not addressing the impact of remote assistance on diagnosis with 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 severity.

Conclusions

The current study shows that telecollaboration between primary care professionals and lung function specialists has a positive impact on quality assurance of FS performed by nonexperts. We would like to emphasise that the intervention assessed in the current study seems to show high potential for generalisation across the healthcare system, such that future studies aiming to examine adoption of the proposed strategy should be encouraged.

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STATEMENT OF INTEREST

Statements of interest for F. Burgos, C. Disdier and J. Roca, and for the study itself can be found at www.erj.ersjournals.com/site/misc/statements.xhtml

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REFERENCES

1 Bateman ED, Hurd SS, Barnes PJ, *et al*. Global strategy for asthma management and prevention: GINA executive summary. *Eur Respir J* 2008; 31: 143–178.
2 Celli BR. The importance of spirometry in COPD and asthma: effect on approach to management. *Chest* 2000; 117: Suppl. 2, 15S–19S.
3 Rabe KF, Hurd S, Anzueto A, *et al*. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. *Am J Respir Crit Care Med* 2007; 176: 532–555.
4 Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. *Lancet* 2009; 374: 721–732.
5 Derom E, van Weel C, Liistro G, *et al*. Primary care spirometry. *Eur Respir J* 2008; 31: 197–203.
6 Eaton T, Withy S, Garrett JE, *et al*. Spirometry in primary care practice: the importance of quality assurance and the impact of spirometry workshops. *Chest* 1999; 116: 416–423.
7 Schermer T, Eaton T, Pauwels R, *et al*. Spirometry in primary care: is it good enough to face demands like World COPD Day? *Eur Respir J* 2003; 22: 725–727.
8 Schermer TR, Jacobs JE, Chavannes NH, *et al*. Validity of spirometric testing in a general practice population of patients with chronic obstructive pulmonary disease (COPD). *Thorax* 2003; 58: 861–866.
9 Miller MR, Crapo R, Hankinson J, *et al*. General considerations for lung function testing. *Eur Respir J* 2005; 26: 153–161.
10 Miller MR, Hankinson J, Brusasco V, *et al*. Standardisation of spirometry. *Eur Respir J* 2005; 26: 319–338.
11 Bonavia M, Averame G, Canonica W, *et al*. Feasibility and validation of telespirometry in general practice: The Italian "Alliance" study. *Respir Med* 2009; 103: 1732–1737.
12 Bellia V, Pistelli R, Catalano F, *et al*. Quality control of spirometry in the elderly. The SA.R.A. study. SAlute Respiration nell'Anziano = Respiratory Health in the Elderly. *Am J Respir Crit Care Med* 2000; 161: 1094–1100.
13 Centers for Disease Control and Prevention. Spirometry Longitudinal Data Analysis (SPIROLA) Software. www.cdc.gov/niosh/topics/spirometry/spirola.html Date last accessed: March 23, 2012. Date last updated: September 27, 2011.
14 Masa JF, Gonzalez MT, Pereira R, *et al*. Validity of spirometry performed online. *Eur Respir J* 2011; 37: 911–918.
15 Roca J, Vallespin B, Burgos F. Telemetric developments in respiratory monitoring. *ERS Buyers' Guide* 2009; 67–73.
16 Naberan K, de la Rosa C, Lamban M, *et al*. Utilizacion de la espirometria en el diagnostico y tratamiento de la EPOC en atencion primaria. [Use of spirometry in the diagnosis and treatment of chronic obstructive pulmonary disease in primary care.] *Arch Bronconeumol* 2006; 42: 638–644.
17 Ferguson GT, Enright PL, Buist AS, *et al*. Office spirometry for lung health assessment in adults: a consensus statement from the National Lung Health Education Program. *Chest* 2000; 117: 1146–1161.
18 Centers for Disease Control and Prevention. NIOSH Spirometry Training Guide. www.cdc.gov/niosh/docs/2004-154c/ Date last accessed: March 23, 2012. Date last updated: December 2003.
19 Roca J, Alonso A, Hernandez C. Integrated care for COPD patients: time for extensive deployment. *Breathe* 2008; 5: 26–35.
20 Wong GK, Rengger R. The Validity of Questionnaires designed to Measure User-Satisfaction of Computer Systems. National Physical Laboratory report DITC 169/90. Teddington, National Physical Laboratory, 1990.
21 Soriano JB, Ancochea J, Miravitlles M, *et al*. Recent trends in COPD prevalence in Spain: a repeated cross-sectional survey 1997–2007. *Eur Respir J* 2010; 36: 758–765.
22 Menezes AM, Perez-Padilla R, Jardim JR, *et al*. Chronic obstructive pulmonary disease in five Latin American cities (the PLATINO study): a prevalence study. *Lancet* 2005; 366: 1875–1881.
23 Perez-Padilla R, Vazquez-Garcia JC, Marquez MN, *et al*. Spirometry quality-control strategies in a multinational study of the prevalence of chronic obstructive pulmonary disease. *Respir Care* 2008; 53: 1019–1026.
24 Walters JA, Hansen EC, Johns DP, *et al*. A mixed methods study to compare models of spirometry delivery in primary care for patients at risk of COPD. *Thorax* 2008; 63: 408–414.
25 Levy ML, Quanjer PH, Booker R, *et al*. Diagnostic spirometry in primary care: proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations. *Prim Care Respir J* 2009; 18: 130–147.
26 Lopez de Santa ME, Gutierrez L, Legorburu C, *et al*. Calidad de la espirometria en las consultas neumologicas de un area jerarquizada. [Spirometry: quality in the respiratory medicine clinics of a public health care area.] *Arch Bronconeumol* 2002; 38: 204–208.
27 MacIntyre NR. The American Association for Respiratory Care and the National Lung Health Education Program: assuring quality in spirometry. *Respir Care* 2004; 49: 587–588.
28 Hankinson JL. Office spirometry: does poor quality render it impractical? *Chest* 1999; 116: 276–277.
29 White P, Wong W, Fleming T, *et al*. Primary care spirometry: test quality and the feasibility and usefulness of specialist reporting. *Br J Gen Pract* 2007; 57: 701–705.
30 Borg BM, Hartley MF, Fisher MT, *et al*. Spirometry training does not guarantee valid results. *Respir Care* 2010; 55: 689–694.

Second study

Early detection of COPD in customers of urban community pharmacies: A pilot study.

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COPD case finding by spirometry in high-risk customers of urban community pharmacies: A pilot study

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KEYWORDS
COPD;
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Summary
Background: COPD case finding is currently recommended at primary and tertiary care levels only.
Aim: To evaluate the feasibility of a community pharmacy program for COPD case finding in high-risk customers by means of spirometry.
Methods: Pilot cross-sectional descriptive study in 13 urban community pharmacies in Barcelona, Spain, from April to May 2007. Customers >40 years old with respiratory symptoms and/or a history of smoking were invited to participate in the study during pharmacists' routine work shifts. High-risk customers were identified by means of a 5-item COPD screening questionnaire based on criteria of the Global Initiative for Chronic Obstructive Lung Disease, and were invited to perform spirometry accordingly. Those with an FEV_1/FVC ratio less than 0.70 were referred to the hospital for a repeat spirometry.
Results: Of the 161 pharmacy customers studied, 100 (62%) scored 3 or more items in the COPD screening questionnaire, and after spirometry, 21 (24%) had an FEV_1/FVC ratio < 0.7. When these subjects with airflow limitation were offered referral to a hospital respiratory function laboratory for further assessments, 11 (52%) attended the appointment. Over 70% of spirometries were rated as being of acceptable quality. No significant differences were observed in lung function parameters between the pharmacy and hospital measurements.

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Conclusions: COPD case finding by spirometry in high-risk customers of urban community pharmacies is feasible. Similarly to primary care practitioners, pharmacists have access to high-risk, middle-aged subjects who have never been tested for COPD. Pharmacists can help with early detection of COPD if they are correctly trained.

Introduction

Early diagnosis of COPD is important because smokers with demonstrated airway obstruction are more likely to quit smoking.[1] Recently, the U.S. Preventive Services Task Force (USPSTF) recommended against screening the general population for chronic obstructive pulmonary disease (COPD) using spirometry (grade D recommendation).[2] However, the same document recognised that individuals presenting respiratory symptoms (chronic cough, increased sputum production, wheezing, or dyspnea) should be tested. This position is consistent with the recommendations of other relevant groups: the American Thoracic Society (ATS) and the European Respiratory Society (ERS) advise performing spirometry on all persons with smoking exposure, a family history of chronic respiratory illness, or respiratory symptoms,[3] and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) recommends that clinicians consider a diagnosis of COPD 'in any patient who has dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease' and that the 'diagnosis should be confirmed by spirometry'.[4]

At present, detection of COPD is limited to case finding at the primary or tertiary care levels, a strategy that has proven largely inadequate. One large population-based survey showed that a high percentage (63%) of subjects with airflow limitation had never received a diagnosis of obstructive lung disease.[5] In Spain, underdiagnosis has been estimated to be around 80%.[6]

Pharmaceutical care, which has been useful in the management of ambulatory patients with chronic diseases such as asthma,[7] might offer a new approach to COPD case finding. Community pharmacists trained to perform spirometry have been successful in improving access to lung function measurement in rural communities,[8] and we hypothesized that they might also be able to help in an urban general population. For such an approach to work, the pharmacist would need to be able to select high-risk individuals in whom spirometry should be performed. The aim of this pilot study was to assess the feasibility of a program of case finding of COPD by spirometry in community pharmacies.

Methods

Pharmacist selection and training

To recruit pharmacist participants, we contacted community pharmacies in a smoking prevention group formed through the professional association for this sector (Official College of Pharmacists, COFB) in Barcelona, Spain. The study had been approved by the ethics committee of Hospital Clinic i Provincial, Barcelona. Thirteen of the 19 members of the smoking prevention group accepted, agreeing that a staff pharmacist would attend a four-day spirometry training course in February and March 2007. Training was based on the guidelines of the National Institute for Occupational Safety and Health (NIOSH),[9] the ERS/ATS,[10] and the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR).[11] The volunteer pharmacists recruited subjects from among customers arriving during their regular work shifts of about 8 h per day and they conducted interviews and tests between attending customers. The daily routine of the pharmacy was not modified so that our results would not overestimate the number of new cases of COPD that can be found by this route in real conditions.

Spirometer and assessment procedures

The portable spirometer (Easy-One Spirometer, ndd Medical Technologies, Zürich, Switzerland) was chosen because it is easy to handle and has been used in other population screening studies.[12] Calibration was checked at the beginning of the study and did not have to be re-checked daily. The device has built-in software that ranks spirometry quality (grades A–F) in accordance with standard European classifications.[10] An A or B rating indicated acceptable quality, because both levels supposed three good manoeuvres with at least two readings of forced vital capacity (FVC) and forced expiratory volume in 1 s (FEV_1) differing by <150–200 ml. In addition, an expert in lung function (F.B.) reviewed and rated all spirometry curves according to the same criteria.

Lung function measurements included FEV_1, FVC and the FEV_1/FVC ratio. FEV_1 and FVC were expressed in liters and as the percentage of reference values for the Spanish population.[13] According to the Spanish COPD guidelines,[14] and as recently proposed elsewhere for mass screening programs,[15] we used pre-bronchodilator lung function to classify airflow limitation, defined by an FEV_1/FVC ratio < 0.70.

Subject selection and evaluation

During April and May 2007, customers who entered the participating community pharmacies and who seemed to be in the targeted age range (>40 years) were approached with opening questions about respiratory symptoms or smoking. If a candidate expressed interest in the topic, the pharmacist explained the objectives of the research and the voluntary nature of participation. Participants signed a consent form if interested, and the pharmacist then asked about previous diagnoses of lung disease or use of inhaled medication and sociodemographic data as stipulated by

a written questionnaire. Individuals aged <40 years or who had a history of lung disease or use of inhalers were excluded at this time. To assess the risk of COPD, we used the GOLD screening questionnaire, as recommended in the 2006 guidelines.[4] This questionnaire consisted of questions on five items referring to more breathlessness than people of the same age, chronic cough, chronic sputum, age >40 years, and smoking. Subjects with ≥ 3 affirmative answers were offered spirometry. Those in whom the FEV_1/FVC ratio was <0.70 were referred to a lung function unit in a university hospital (Hospital de la Santa Creu i Sant Pau or Hospital Clinic I Provincial, both in Barcelona). Within 24–48 h spirometry was repeated by an expert nurse using the same brand of spirometer. Refusal to continue participating in the study was recorded with the specified reason. Smokers were also encouraged to quit smoking through a cessation program, as giving this advice was part of the normal routine for these volunteer community pharmacists.

Statistical methods

Descriptive data of participants and subgroups are presented as mean and standard deviation unless otherwise stated. We compared participants with a low and high COPD risk, and spirometry data in the normal and abnormal groups, using *t*-tests for normally distributed parametric data and the Kolmogorov–Smirnov test for non-parametric data (quality spirometry, gender, tobacco exposure and GOLD screening score). Using the Wilcoxon rank sum test we compared each subject's expiratory flow rates measured at the pharmacy and the hospital. A Bland–Altman graph was also created to show individual differences between pharmacy and hospital FEV_1 values. Statistical significance was set at $P \leq 0.05$ for comparisons between groups. All analyses were performed using the Statistical Package for Social Sciences (SPSS) for Windows, version 15.0 (SPPS Inc., Chicago, Illinois, USA).

Results

A total of 254 customers approached by the pharmacists expressed interest in the study; 188 (74%) agreed to participate by signing the consent form after the nature of the study was explained. Reasons given by the 66 subjects who declined to participate included no time to wait ($n = 28$, 42%), no interest ($n = 12$, 18%), already diagnosed with a respiratory condition ($n = 14$, 21%) and others ($n = 12$, 18%). Twenty-seven of these 188 initial participants were excluded by the pharmacists when criteria were reviewed; reasons for exclusion at this time were age <40 years or previous lung disease (Fig. 1).

The 161 remaining volunteers agreed to fill in the GOLD screening questionnaire for COPD. The average age of these participants was 55 ± 11 years, 94 (58%) were women, and 124 (77%) were smokers or ex-smokers. The mean GOLD screening score was 3.0 ± 1.2. Sixty-one of the 161 respondents (38%) had a score <3 and 100 (62%) a score of ≥ 3, indicating they were at high risk for COPD (Table 1). The age and proportion of women in the two groups were similar. More high-risk customers were smokers or ex-smokers, and they also had a higher mean GOLD screening score than those at low risk. Those in the high-risk group were offered spirometry; only three refused and one was excluded because she was ill with a respiratory infection at that time. Customers who attended spirometry had at least one symptom. Chronic cough was the most common (66%) but each symptom was present in about half the subjects (chronic sputum 54%, breathlessness 63%). Low-risk subjects were more frequently asymptomatic (chronic cough 6%, chronic sputum 5%, breathlessness 3%).

Thus, 96 high-risk subjects performed spirometry in the pharmacy. Sixty-five (68%) had an $FEV_1/FVC\%$ ratio ≥ 0.70 and 21 (22%) had an $FEV_1/FVC\%$ ratio <0.70, indicating airflow limitation. The distribution of airflow limitation by age is shown in Fig. 2. Ten were unable to perform the manoeuvres correctly. Personal characteristics and spirometry results for those who performed a correct spirometry are shown in Table 2. According to our pre-bronchodilator data, airflow limitation was mild in 13 (62%) of the subjects in whom it was detected, moderate in 7 (33%) and severe in 1 (5%).

Out of the 86 patients who underwent spirometry, airflow limitation (FEV_1/FVC ratio <0.70) was detected in 21 (24%), and they were invited for referral to a hospital pulmonary function laboratory for further assessment. Only 11 (52%) subjects both accepted referral and actually went to the laboratory. In all cases, the airway obstruction was confirmed. Moreover, the lung function values recorded in the community pharmacy and in the hospital pulmonary function laboratory were similar in both settings (FEV_1, $P = 0.5$; FVC, $P = 0.89$; and FEV_1/FVC ratio, $P = 0.14$) (Fig. 3). Of note, among those referred to the hospital, two presented a pre-bronchodilator $FEV_1 < 60\%$.

Finally, spirometric curves in the pharmacy were of acceptable quality overall, with 70% rated as A or B quality by the spirometer software and 73% were considered of acceptable quality by the lung function expert. The quality rating tended to be even better in subjects with airflow limitation, 76% of whom were considered to have A or B quality curves, but the difference was not significant ($P = 0.71$).

Discussion

Individuals at high risk for COPD can be detected by spirometry screening undertaken by adequately trained pharmacists in urban community pharmacies. Our data show that pharmacists were able to identify customers with respiratory symptoms and/or smokers in a population in which the majority were middle-aged subjects who had never been tested for COPD. Furthermore, the pharmacists were able to supervise high quality spirometry manoeuvres in 70% of subjects, finding one case of airflow limitation for every five individuals tested, a rate that was similar to that reported for the UK primary care setting.[16]

Spirometry in the primary care setting has been shown to be useful in screening for COPD and it continues to be promoted as the means for diminishing the population underdiagnosis of this disease.[17] Additionally, the usefulness of reporting individual lung age to smokers has been elegantly confirmed recently.[19] However, lack of technical or human resources in primary care is a limiting

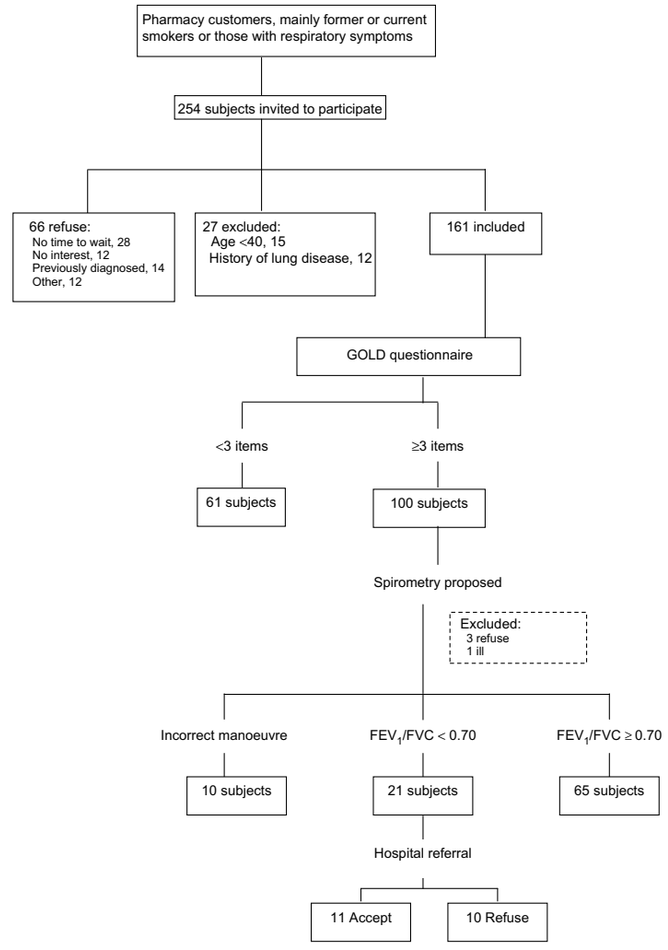

Figure 1 Flow chart showing subject processing from pharmacy to hospital referral.

factor,[18] compounded by primary care physicians' low rate of request for spirometry.[20] Therefore, underdiagnosis in the primary care setting continues to be inordinately common.[21] In this pilot study, our finding that the community pharmacy can provide a complementary setting for COPD case finding in the general population offers hope of improving the health care system's screening potential.

Table 1 Characteristics of the participating pharmacy customers.

	All customers ($n = 161$)	Low risk ($n = 61$)	High risk ($n = 100$)
Age, mean $\pm$ SD	55 ± 11	56 ± 11	55 ± 11
Women, *n* (%)	94 (58)	38 (62)	56 (56)
Smoking history, *n* (%)	124 (77)	36 (59)	88 (88)[a]
GOLD score, mean $\pm$ SD	3.0 ± 1.2	1.7 ± 0.4	3.8 ± 0.8[a]

[a] Significant differences were found between low-risk and high-risk groups for smoking history (smokers or ex-smokers) ($P = 0.01$) and GOLD score ($P = 0.01$). GOLD = Global Initiative for Chronic Obstructive Lung Disease.

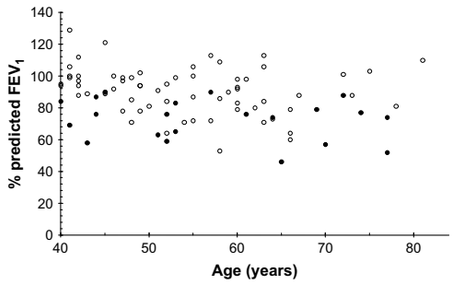

Figure 2 Distribution of percent predicted FEV_1 by age for all participants (subjects with airflow limitation are represented by filled circles).

Widespread use of spirometry in screening for COPD has been questioned.[2] The current recommendations are to study subjects at high risk.[2–4] All subjects offered spirometry in our study were in fact symptomatic as detected by the questionnaire, suggesting that inappropriate resource consumption can be kept under control by applying a GOLD-criteria-based screening questionnaire. Our use of the GOLD screening questionnaire to assess the risk of COPD followed recommendations in the 2006 guidelines,[4] although recently validated questionnaires with the same goal are available elsewhere.[22]

Our study also shows that pharmacists can obtain valid spirometries if they are well-trained and highly motivated. Seventy percent of the spirometry curves were judged to be of A- or B-level quality after review by an expert in lung function testing; that success rate was higher than the reported 63% in a previous pharmacy study.[8] Only 10% of the subjects who were invited to perform spirometry in the community were unable to produce correct manoeuvres under the pharmacists' supervision, a situation quite similar to that reported for the primary care level.[23] The quality of spirometry was also reflected in the lack of differences in results in pharmacy and hospital measurements for the same subjects.

An interesting finding was the predominance of women among the pharmacy customers. Given that the prevalence of COPD in Spain has been found to be 14.3% in men and 3.9% in women in a population-based study,[6] we expected males to predominate among the tested subjects. However, women accounted for 58% of the subjects and 57% of the positive spirometries. The pharmacy seems to be a particularly good setting, therefore, to find cases in women, among whom the prevalence of COPD seems to be rising.[24]

A limitation of this study was the absence of a bronchodilator test. Although most guidelines recommend the use of post-bronchodilator spirometry to diagnose and stage COPD, other authors call for simplicity, especially for large-scale screening.[15,25,26] We ruled out the use of post-bronchodilator tests in pharmacies because of evident concerns about practicality, safety, and efficiency. Should this approach be implemented, we continue to consider that bronchodilator tests should be performed in the hospital laboratory after referral. Another limitation and the main logistical problem of this study is related to referral of subjects with possible COPD from the community pharmacy to the hospital. In our study, nearly half of those with spirometry results indicating airflow limitation declined a hospital appointment. No time or lack of interest were the reasons most often stated. We suspect that declining referral may reflect either a lack of interest in quitting smoking or milder disease. The general population has little knowledge about COPD,[27] in comparison with other conditions such as cardiovascular disease, and they, therefore, do not consider respiratory disease to be a serious personal threat.

To conclude, in this pilot study, we have shown that COPD case finding by spirometry in urban community pharmacies is feasible. Pharmacists have access to high-risk, middle-aged subjects who have never been tested for COPD, and if the pharmacists are correctly trained, they can detect airflow limitation by spirometry with results that are similar to those previously reported at primary care level. Pharmacists are health service professionals who are not presently involved in screening for COPD but whose

Table 2 Characteristics and respiratory function data for subjects who performed spirometry correctly and were classified by FEV_1/FVC ratio as having normal (ratio ≥ 0.70) or reduced airflow.

	All spirometries ($n = 86$)	Normal spirometry ($n = 65$)	Airflow limitation ($n = 21$)
Women, *n* (%)	49 (57)	37 (57)	12 (57)
Age (y)	55 ± 11	54 ± 10	57 ± 12
Smoking history, *n* (%)	74 (86)	56 (86)	18 (86)
GOLD score	3.8 ± 0.8	3.8 ± 0.8	3.7 ± 0.8
BMI	27.1 ± 5.1	27.8 ± 4.7	25 ± 5.7[a]
FEV_1 (l)	2.5 ± 0.7	2.7 ± 0.6	2.1 ± 0.7[a]
FEV_1 (% ref. val.)	86 ± 0.2	91 ± 0.1	72 ± 0.1[a]
FVC (l)	3.4 ± 0.9	3.4 ± 0.9	3.24 ± 1.0
FVC (% ref. val.)	89 (0.2)	90 (0.2)	85 (0.1)
FEV_1/FVC ratio	0.76 (0.1)	0.79 (0.1)	0.64 (0.1)[a]

Data are expressed as mean ± SD unless otherwise noted.
[a] Significant differences in BMI ($P = 0.03$), FEV_1 ($P = 0.01$), FEV_1% ($P = 0.01$) and FEV_1/FVC ratio ($P = 0.01$) were found between the normal and abnormal spirometry groups.
FEV_1 = forced expiratory volume in 1 s; FVC = forced vital capacity; and GOLD = Global Initiative for Chronic Obstructive Lung Disease.

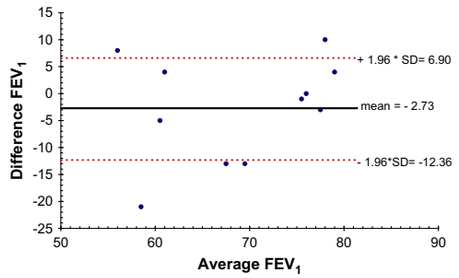

Figure 3 Bland–Altman graph for comparison of the pharmacy- versus hospital-obtained percent predicted FEV_1.

participation may represent a useful complementary strategy for early case finding.

Conflict of interest statement

Dr. Diego Castillo: Research grant: Boehringer–Ingelheim. Dr. Rafael Guayta, Jordi Giner, Felip Burgos, Carme Capdevila, Dr. J.B. Soriano, Merce Barau and Dr. Pere Casan: none of these authors have a conflict of interest to declare in relation to this work.

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References

1. Bednarek M, Gorecka D, Wielgomas J, Czajkowska-Malinowska M, Regula J, Mieszko-Filipczyk G, et al. Smokers with airway obstruction are more likely to quit smoking. *Thorax* 2006;**61**:869–73.
2. U.S. Preventive Services Task Force. Screening for chronic obstructive pulmonary disease using spirometry: U.S. preventive services task force recommendation statement. *Ann Intern Med* 2008;**148**:529–34.
3. Celli BR, MacNee W. ATS/ERS Task Force. Standards for the diagnosis and a treatment of patients with COPD: a summary of the ATS/ERS position paper. *Eur Respir J* 2004; **23**:932–46.
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2006. Global strategy for diagnosis, management, and prevention of COPD. Available at: <www.goldcopd.com/Guidelineitem.asp?l152&l251&intId5989> [accessed: April 2007] Date last updated: November 2006.
5. Mannino DM, Gagnon RC, Petty TL, Lydick E. Obstructive lung disease and low lung function in adults in the United States: data from the National Health and Nutrition Examination Survey, 1988–1994. *Arch Intern Med* 2000;**160**:1683–9.
6. Sobradillo Peña V, Miravitlles M, Gabriel R, Jimenez-Ruiz CA, Villansante C, Masa JF, et al. Geographic variations in prevalence and underdiagnosis of COPD: results of the IBERPOC multicentre epidemiological study. *Chest* 2000;**118**:981–9.
7. Armour C, Bosnic-Anticevich S, Brillant M, Burton D, Emmerton L, Krass I, et al. Pharmacy asthma care program (PACP) improves outcomes for patients in the community. *Thorax* 2007;**62**:496–502.
8. Burton MA, Burton DL, Simpson MD, Gissing PM, Bowman SL. Respiratory function testing: the impact of respiratory scientists on the training and support of primary health care providers. *Respirology* 2004;**9**:260–4.
9. National Institute of Occupational Safety and Health, Division of Respiratory Disease Studies. *NIOSH spirometry training guide*. Bethesda, MD: NIOSH; 1997.
10. Miller MR, Hankinson J, Brusasco F, Burgos F, Casaburi R, Coates R, et al. Standardisation of spirometry. In: Brusasco V, Crapo R, Viegi G, editors. *ATS/ERS Task Force: Standardisation of Lung Function Testing*. *Eur Respir J* 2005;**26**:319–38.
11. Sanchis J, Casan P, Castillo J, González N, Palenciano L, Roca J. Normativa para la práctica de la espirometría forzada. *Arch Bronconeumol* 1989;**25**:132–42.
12. Menezes AM, Pérez-Padilla R, Jardim JR, Muino A, López MV, PLATINO Team, et al. Chronic obstructive pulmonary disease in five Latin American cities (the PLATINO study): a prevalence study. *Lancet* 2005;**366**:1875–81.
13. Roca J, Burgos F, Sunyer J, Saez M, Chinn S, Antó JM, et al. Reference values for forced spirometry. *Eur Resp J* 1998;**11**:1354–62.
14. Barberà JA, Peces-Barba G, Agustí García-Navarro A, Izquierdo JL, Monsó E, Montemayor T, et al. Clinical guidelines for the diagnosis and treatment of chronic obstructive pulmonary disease. *Arch Bronconeumol* 2001;**37**:297–316.
15. Mannino DM. Defining chronic obstructive pulmonary disease… and the elephant in the room. *Eur Respir J* 2007;**30**:189–90.
16. Van Schayck CP, Loozen JM, Wagena E, Akkermans RP, Wesseling GJ. Detecting patients at a high risk of developing chronic obstructive pulmonary disease in general practice: cross-sectional case finding study. *BMJ* 2002;**324**:1370.
17. Enright PL, Studnicka M, Zielinski J. Spirometry to detect and manage chronic obstructive pulmonary disease and asthma in the primary care setting. In: Wouters EF, Gosselink R, Stam H, editors. *Lung Function Testing*. *Eur Respir Mon* 2005;**31**:1–14.
18. Parkes G, Greenhalgh T, Griffin M, Dent R. Effect on smoking quit rate of telling patients their lung age: the Step2quit randomised controlled trial. *BMJ* 2008;**336**:598–600.
19. Hueto J, Cebollero P, Pascal I, Cascante JA, Eguia VM, Teruel F, et al. Spirometry in primary care in Navarre, Spain. *Arch Bronconeumol* 2006;**42**:326–31.
20. Miravitlles M, De la Roza C, Naberan K, Lanban M, Gobartt E, Martin A, et al. Attitudes toward the diagnosis of chronic obstructive pulmonary disease in primary care. *Arch Bronconeumol* 2006;**42**:3–8.
21. Bednarek M, Maciejewski J, Wozniak M, Kuca P, Zielinski J. Prevalence, severity and underdiagnosis of COPD in the primary care setting. *Thorax* 2008;**63**:402–7.

22. Kotz D, Nelemans P, van Schayck CP, Wesseling GJ. External validation of a COPD diagnostic questionnaire. *Eur Respir J* 2008;**31**:298—303.
23. Rea HH, Eaton T, Withy S, Garrett JE, Mercer J, Whitlock RM. The impact of spirometry workshops. Spirometry in primary care practice: the importance of quality assurance. *Chest* 1999;**116**:416—23.
24. Soriano JB, Maier WC, Egger P, Visick G, Thakrar B, Synes J, et al. Recent trends in physician diagnosed COPD in women and men in UK. *Thorax* 2000;**55**:789—94.
25. Celli BR, Halbert RJ, Isonaka S, Schau B. Population impact of different definitions of airway obstruction. *Eur Respir J* 2003; **22**:268—73.
26. Enright P. Provide GPs with spirometry, not spirometers. *Thorax* 2008;**63**:387—8.
27. Miratvilles M, De la Roza C, Morera J, Montemayor T, Gobartt E, Álvarez-Sala JL. Chronic respiratory symptoms, spirometry and knowledge of COPD among general population. *Respir Med* 2006;**100**:1973—80.

Third study

Spirometry in community-pharmacies: a novel strategy to reduce COPD underdiagnosis.

D. Castillo, F. Burgos, R. Guayta, J. Giner, J.B. Soriano, P. Lozano, X. Flor, M. Estrada, M. Mayos, M. Barau and P. Casan on behalf of the FARMAEPOC group.

BMJ (submitted).

SPIROMETRY CASE FINDING IN COMMUNITY-PHARMACIES: A NOVEL STRATEGY TO REDUCE COPD UNDERDIAGNOSIS

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ABSTRACT

Objective: To assess the effectiveness of a COPD case finding program in community pharmacies.

Methods: Prospective, cross-sectional, descriptive, uncontrolled, remotely supported study **(**NCT01576068) in 100 community pharmacies (CP) in Barcelona, Spain. Pharmacists were trained in a four-day workshop on spirometry and COPD, and each was provided with a spirometer during 12 weeks. The program included questionnaires and forced spirometry measurements, whose quality was controlled and monitored by web-assistance.

Results: Overall 2,295 (73.5%) of 3,121 CP customers invited, accepted to participate in the program, and 1.456 (63.4%) were identified as "high risk" for COPD using the GOLD questionnaire. Only 33 could not conduct spirometry, and a pre-bronchodilator airflow limitation (FEV_1/FVC ratio <0.7) was confirmed in 282 (19.8%); 244 of them were referred to their primary care (PC) physician for further diagnostic and therapeutic work-up, but only 39 of them (16%) fed-back this information to the pharmacist. Finally, it is of note that clinically acceptable quality spirometries (grade A or B) were obtained in 69.4% of the cases.

Conclusions: This study shows that adequately trained and supported community pharmacists can effectively identify individuals at high risk of having COPD and can thus contribute to ameliorate underdiagnosis in this disease.

Abstract word count: 198 words.

KEY WORDS: COPD, case finding, quality forced spirometry, community pharmacies.

"What this paper adds" box

Section 1: What is already known on this subject

COPD underdiagnosis is one of the major problems in management of the disease. Current case-finding strategies have shown to be insufficient.

Section 2: What this study adds

Adequately trained and supported community pharmacists can effectively identify individuals at high risk of suffering COPD. Then, CP could be added to COPD case-finding programs.

INTRODUCTION

It is now estimated there are at least 328 million people with chronic obstructive pulmonary disease (COPD) in the World, yet 80% or more of them are not diagnosed and, hence, not treated.[1-2] Several position papers have recently emphasized the importance of strategies to reducing under-diagnosis in COPD.[3-4] In a previous small pilot study, we showed that COPD case finding in community-pharmacies (CP) is feasible.[5] Now, in the current study: *(1)* we extend this pilot observation to a much large number of CP (n=100); *(2)* we use Information and Communication Technologies (ICT) to provide remote spirometric quality control to CP, as recently shown in primary care(PC);[6] and, *(3)* we explore the real-life effectiveness of this COPD case finding program by focusing in particular on the inter-relationship between the formal (PC) and informal (CP) components of the health-care system.

METHODS

Design of the study, Participants and Ethics

This was a prospective, cross-sectional, descriptive, multicenter (CP), uncontrolled, remotely supported study (NCT01576068). The Official College of Pharmacists of Barcelona (*Col·legi Oficial de Farmacèutics de Barcelona-COFB*) offered to all its members the possibility to participate, and 100 CP located in the province of Barcelona (both rural and urban settings) volunteered, most of whom had previously participated in other CP health-care programs. CP were divided in 5 groups (20 pharmacists each) that participated in the study in five sequential "Study Rounds", from September 2010 to February 2012 (approximately 12 weeks each round). The study protocol was approved by the Ethics Committee of Hospital del Mar (Barcelona, Spain), and all

participants signed a consent form. Also, all smokers were encouraged to quit smoking by the attending pharmacist.

In brief (**Figure 1**), during regular working hours, CP customers within the targeted age range (>40 years) were asked by the attending pharmacists about respiratory symptoms and smoking. If the customer expressed an interest in the topic, the pharmacist explained the volunteer nature, objectives, goals and risks of the study. If interested, customers signed a consent form and answered a standardized questionnaire that included socio-demographic data as well as questions about previous respiratory diseases and use of respiratory medications. Individuals younger than 40 years or with a previous history of lung disease or use of respiratory medication were excluded from the study at this time (**Figure 1**). Remaining participants were asked to answer a 5-item questionnaire (older than 40 years of age?, current or previous smoking exposure?, more breathlessness than peers of the same age? and presence of chronic cough or expectoration?) to identify subjects at high-risk of suffering COPD (those with 3 or more "yes" answers), as proposed by the Global Initiative for Chronic Obstructive Disease (GOLD).[7] High risk subjects were then offered a standardized forced spirometry (see below), and those with evidence of airflow limitation (as defined by an FEV_1/FVC ratio lower than 0.70), were recommended to contact their PC physician for further clinical evaluation and eventual treatment (**Figure 1**). Finally, the PC physician was asked to return to the CP a questionnaire with the specific diagnostic and/or therapeutic actions taken in that particular individual within the next 3 months. In all cases, the specific reason(s) for refusal to participate in the study at any stage (**Figure 1**) were recorded.

Education and training of pharmacists

Every pharmacist participating in the study attended a four-day (16 hours) hands-on training course on forced spirometry (FS) according to international guidelines and officially accredited by the Catalonian Government using the spirometer later employed in the study (Easy-One®, ndd Medical Technologies and Sonmedica, Zurich, Swizerland).[8-10] Pharmacists were also instructed in the management of the web-database used during the study to collect all data (Linkcare®).[6]

Spirometry

Like in our pilot study,[5] spirometry was conducted by using an Easy-One® spirometer, because it has been shown to be adequate for population studies, it does not require regular calibration, and it fulfils all ERS/ATS technical recommendations.[11-13] As recommended by guidelines, each CP allocated an adequate space for spirometry testing. The spirometer was connected to a personal PC with internet access so spirometric results were uploaded automatically into a specific web database (Linkcare®).[6]

As have been recommended for COPD case-finding strategies, and in order to make a simple and feasible initial measure in CP, only pre-bronchodilatador spirometry was done.[14] Reference values used correspond to the Spanish population.[15] Spirometry quality was classified into grade A to F following international recommendations (**Table 1**).[8-9,16] An expert in spirometry (FB) reviewed and rated manually all measurements loaded into the system and reported back weekly to each CP on the quality of their tests, including their repeatability, characteristics and onset (back extrapolation) and end (expiratory time) maneuvers. Pharmacists were then able to ask

specific queries and feedback to the expert. The Linkcare® ICT platform provided traceability of all actions and dialogs that occurred during the study.[6]

Statistical analysis

Data were quality controlled centrally and a homogeneous template to translate all coding was applied. Variables were double-checked by each pharmacist and the principal investigator, and values that were considered as potential errors or outliers were individually discussed and confirmed, or removed. Comprehensive tabulations with ranges, mean and standard deviation of all quantitative variables, and percentages of all qualitative variables, were available for each CP. Results are presented as mean (±standard deviation) or n (and percentage) as needed. The Student T-test and Chi^2 test were used to compare differences between groups as appropriate. A $p<0.05$ was considered statistically significant.

RESULTS

The flow of participation in the study is presented in **Figure 1**. Of 3,121 CP customers invited to participate in the program, 2,295 (73.5%) accepted. There was no non-response bias, as the age and gender distribution of participants in all five rounds were not significantly different from those not participating (**Table 2**). Of the 2,295 participants, 1,456 (63.4%) were identified as "high risk" for COPD using the GOLD screener questionnaire. Demographic and clinical characteristics of participants at low or high risk groups for COPD are presented in **Table 3**, where it can be seen that age was similar in both groups (55.4±10.4 years versus 54.2±10.2 years in the low vs. high risk group, respectively, p n.s.), but participants at high risk were most often male

($p<0.05$), and with higher smoking exposure and, experiencing more respiratory symptoms, all these being items within the screener questionnaire (**Table 3**).

The majority (69.4 %) of spirometries performed were grade A and B, and they were considered of acceptable clinical quality by the expert (FB). This percentage remained stable in the five sequential study rounds (**Figure 2**, panel A). As a sensitivity analysis following previous reports, should we had considered grade C also as clinically acceptable, this figure would have risen to 75.1 %.[17] Only 8.9% were ranked as quality grade F, the worst possible.

Table 4 shows the clinical characteristics and spirometric results of participating subjects at high risk for COPD. Of 1,423 individuals completing quality-controlled pre-BD spirometry, 282 (19.8%) had airflow limitation with an $FEV_1/FVC\%$ ratio <0.70 compatible with COPD. This was remarkably reproducible in all temporal study rounds (Chi^2 p for trend n.s.) (**Figure 2, panel B**). Patients with airflow limitation were significantly older, mostly males and (by definition) had worse lung function than those with normal spirometry but interestingly, cumulative smoking exposure and body-mass index (BMI) were similar in both groups (**Table 4**). Figure 3 presents the distribution of FEV_1 (% predicted) by age in participants with and without airflow limitation.

All subjects with pre-BD airflow limitation but those 38 (13.5%) with poor quality spirometry were referred to their PC physician for further evaluations (244). Only 39 (15%) of them provided feed-back to the CP and returned the filled up questionnaire requested. In eleven of them (28%) COPD was confirmed by the PC physician, and in 6 (15%) inhaled treatment was started.

DISCUSSION

This study: *(1)* extends our previous pilot experience (7) to a larger population of community pharmacies (n=100) and confirms that a COPD case finding program in high-risk customers is feasible using a simple questionnaire and forced spirometry; *(2)* confirms that the use of a TIC platform to control the quality of spirometries is both feasible and effective, not only in PC as previously reported by our group, but also in CP;[6] and, *(3)* shows that this strategy can effectively identify undiagnosed COPD patients.

Underdiagnosis, hence undertreatment, is one of the main unmet medical needs in COPD. Decreased quality of life and daily life activities have been reported in undiagnosed COPD subjects.[18-19] Unfortunately, epidemiological studies in Spain showed that from 1997 to 2007 COPD underdiagnosis was reduced by only 5 percentage points, from 78% to 73%.[20] Therefore, reducing COPD underdiagnosis is a public-health priority. The spirometry case finding program assessed here was able to identify one in five (20%) of high risk individuals with airflow limitation. Because we limited our case-finding to find new diagnoses, as we excluded 245 participants who reported prior lung disease or current use of inhalers, the GOLD screener could have given a much higher yield, higher than one in three (i.e.: (282+245)/1423=37.0%). This figure is remarkably similar to that published in primary care,[21-22] indicating that this type of case finding strategies are likely to work similarly in PC and CP. Further, the proportion of individuals with airflow limitation in our study was independent of the study round (Figure 2, panel B), supporting the internal validity of this observation. Admittedly, the clinical diagnosis of COPD requires the combination of exposure to risk

factors, symptoms, non-fully reversible airflow limitation and the exclusion of other obstructive airway diseases such as asthma and bronchiectasis, among others.[23] Given that only a minority of individuals returned the information requested to their PC physician (Figure 1), we cannot provide a final figure for a confirmed diagnosis of COPD. Yet, this limitation illustrates the need to improve the coordination between formal (PC) and informal (CP) stake-holders in our health-care system, but does not detract from the validity of the case finding strategy in CP investigated here.

High quality forced spirometry is essential for the diagnosis and management of COPD.[2,23-26] We found that most spirometries were of clinically acceptable quality grade. Our study clearly indicates that well-trained and supervised (using web-based tools) pharmacists can obtain high quality spirometries in CP, similarly to what we showed recently in a primary care setting using similar tools.[6] In fact, these observations add to the emerging concept of "Healthy Living Pharmacy" (HLP) that explores the potential of CP to promote healthy living.[27] CP can play an important role in a number of health-promoting programs, including smoking cessation, cardiovascular diseases or screening for HIV.[28-29] Within respiratory diseases, previous studies have shown that CP can help in the management of asthma,[30] but to our knowledge, their role in COPD case finding had not been addressed before (other than in our previous pilot study).[5]

Our study has some limitations. Firstly, because of logistic issues, we did not measure post-bronchodilator spirometry despite that this is recommended for COPD diagnosis.[2,23] Yet, pre-bronchodilator spirometry has been widely used in epidemiological studies and, in any case, the goal of the COPD case-finding program was not establish the diagnosis of COPD (a competence of PC physicians) but to refer to them for further

work up undiagnosed individuals whom are most likely to suffer this disease.[14-31] Second, our strategy involved the use of well-trained pharmacists, TIC support, two questionnaires and quality-controlled forced spirometry. It can be argued it is too cumbersome for many CP, so simpler screening strategies, perhaps using questionnaires and peak-expiratory flow measurements, deserve investigation.[32-33]

In summary, this study shows that adequately trained and supported community pharmacists can effectively identify individuals at high risk of suffering COPD.

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Competing interest statement

None of these authors have a conflict of interest to declare in relation to this work.

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Author Contributions

D. Castillo: contributed to the study design; collection, analysis and interpretation of data; critical review of the manuscript; and has seen and approved the final version.

F Burgos: contributed to the study design; collection, analysis and interpretation of data; review all the spirometric data; critical review of the manuscript; and has seen and approved the final version

R Guayta: contributed to the study design; collection, analysis and interpretation of data; critical review of the manuscript; and has seen and approved the final version

J Giner: contributed to the study design; collection, analysis and interpretation of data; critical review of the manuscript; and has seen and approved the final version

J.B. Soriano: contributed to the study design; collection, analysis and interpretation of data; critical review of the manuscript; and has seen and approved the final version

P. Lozano: contributed to the study design; collection ;data managing; critical review of the manuscript; and has seen and approved the final version

X. Flor: contributed to the study design; collection, analysis and interpretation of data; critical review of the manuscript; and has seen and approved the final version

M. Estrada: contributed to the study design; collection, analysis and interpretation of data; critical review of the manuscript; and has seen and approved the final version

M. Barau: contributed to the study design; collection, analysis and interpretation of data; critical review of the manuscript; and has seen and approved the final version

P. Casan: contributed to the study design; analysis and interpretation of data; critical review of the manuscript; and has seen and approved the final version.

REFERENCES

1. Vos T, Flaxman AD, Naghavi M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012;380:2163-2196.
2. Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet.2009;374:721-732.
3. http://www.msc.es/organizacion/sns/planCalidadSNS/docs/EstrategiaEPOCSNS.pdf
4. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_116716>
5. Castillo D, Guayta R, Giner J, Burgos F, Capdevila C, Soriano JB, et al. COPD case finding by spirometry in high-risk customers of urban community pharmacies: a pilot study. Respir Med.2009;103:839-845.
6. Burgos F, Disdier C, de Santamaria EL, Galdiz B, Roger N, Rivera ML, et al. Telemedicine enhances quality of forced spirometry in primary care. Eur Respir J;39:1313-1318.
7. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2006. Global strategy for diagnosis, management, and prevention of COPD. Available at: www.goldcopd.com/Guidelineitem.asp?l152&l251&intId5989 [accessed: April 2007] Date last updated: November 2006.
8. National Institute of Occupational Safety and Health, Division of Respiratory Disease Studies. NIOSH Spirometry Training Guide. Bethesda, MD: NIOSH; 1997.
9. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, et al. Standardisation of spirometry. Eur Respir J.2005;26:319-338.
10. Escarrabill J RN, Burgos F, Giner J, Molins A, Tresserras R en nombre del Grupo de Función Pulmonar y del equipo directivo del PDMAR. Diseño de un programa de formación básico para conseguir espirometrías de calidad. Educ Med.2012;15:103-107.
11. Menezes AM, Perez-Padilla R, Jardim JR, Muino A, Lopez MV, Valdivia G, et al. Chronic obstructive pulmonary disease in five Latin American cities (the PLATINO study): a prevalence study. Lancet.2005;366:1875-1881.
12. Walters JA, Wood-Baker R, Walls J, Johns DP. Stability of the EasyOne ultrasonic spirometer for use in general practice. Respirology.2006;11:306-310.

13. Skloot GS, Edwards NT, Enright PL. Four-year calibration stability of the EasyOne portable spirometer. Respir Care.2010;55:873-877.

14. NHLBI Workshop;A case-finding strategy for moderate-to-severe COPD in the United States: executive summary. Available at: http://www.nhlbi.nih.gov/meetings/workshops/case-finding-exesum.htm[Date last updated: 2009. Date last accessed: 2011]

15. Roca J, Burgos F, Sunyer J, Saez M, Chinn S, Anto JM, et al. References values for forced spirometry. Group of the European Community Respiratory Health Survey. Eur Respir J.1998;11:1354-1362.

16. Ferguson GT, Enright PL, Buist AS, Higgins MW. Office spirometry for lung health assessment in adults: A consensus statement from the National Lung Health Education Program. Chest.2000;117:1146-1161.

17. Enright P, Vollmer WM, Lamprecht B, Jensen R, Jithoo A, Tan W, et al. Quality of spirometry tests perfomed by 9893 adults in 14 countries: the BOLD Study. Respir Med.2011;105:1507-1515.

18. Coultas DB, Mapel D, Gagnon R, Lydick E. The health impact of undiagnosed airflow obstruction in a national sample of United States adults. Am J Respir Crit Care Med.2001;164:372-377.

19. Miravitlles M, Soriano JB, Garcia-Rio F, Munoz L, Duran-Tauleria E, Sanchez G, et al. Prevalence of COPD in Spain: impact of undiagnosed COPD on quality of life and daily life activities. Thorax.2009;64:863-868.

20. Soriano JB, Ancochea J, Miravitlles M, Garcia-Rio F, Duran-Tauleria E, Munoz L, et al. Recent trends in COPD prevalence in Spain: a repeated cross-sectional survey 1997-2007. Eur Respir J.2010;36:758-765.

21. Hill K, Goldstein RS, Guyatt GH, Blouin M, Tan WC, Davis LL, et al. Prevalence and underdiagnosis of chronic obstructive pulmonary disease among patients at risk in primary care. CMAJ;182:673-678.

22. Van Schayck CP, Loozen JM, Wagena E, Akkermans RP, Wesseling GJ. Detecting patients at a high risk of developing chronic obstructive pulmonary disease in general practice: cross sectional case finding study. BMJ.2002;324:1370.

23. J. Vestbo, S. S. Hurd, A. G. Agusti, P. W. Jones, C. Vogelmeier, A. Anzueto, et al. Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease, GOLD Executive Summary. Am.J Respir Crit Care Med.2013; 187:347-365.

24. Schermer TR, Crockett AJ, Poels PJ, van Dijke JJ, Akkermans RP, Vlek HF, et al. Quality of routine spirometry tests in Dutch general practices. Br J Gen Pract.2009;59:376-82.

25. Derom E, van Weel C, Liistro G, Buffels J, Schermer T, Lammers E, et al. Primary care spirometry. Eur Respir J.2008;31:197-203.

26. Walters JA, Hansen EC, Johns DP, Blizzard EL, Walters EH, Wood-Baker R. A mixed methods study to compare models of spirometry delivery in primary care for patients at risk of COPD. Thorax.2008;63:408-414.

27. Departament of health. Pharmacy in England: building on strengths, delivering the future. 2008. Available at http://www.official-documents.gov.uk/document/cm73/7341/7341.asp. Accessed 8 Dec 2011

28. Brown D, Portlock J, Rutter P. Review of services provided by pharmacies that promote healthy living. Int J Clin Pharm.2012;34:399-409.

29. Gorostiza I, Elizondo Lopez de Landache I, Braceras Izagirre L. HIV/AIDS screening program in community pharmacies in the Basque Country (Spain). Gac Sanit.2013;27:164-166.

30. Armour C, Bosnic-Anticevich S, Brillant M, Burton D, Emmerton L, Krass I, et al. Pharmacy Asthma Care Program (PACP) improves outcomes for patients in the community. Thorax.2007;62:496-502.

31. Bakke PS, Ronmark E, Eagan T, Pistelli F, Annesi-Maesano I, Maly M, et al. Recommendations for epidemiological studies on COPD. Eur Respir J.2011;38:1261-1277.

32. Nelson SB, LaVange LM, Nie Y, Walsh JW, Enright PL, Martinez FJ, et al. Questionnaires and pocket spirometers provide an alternative approach for COPD screening in the general population. Chest.2012;142:358-366.

33. Jithoo A, Enright PL, Burney P, Buist AS, Bateman ED, Tan WC, et al. Case-finding options for COPD: results from the Burden of Obstructive Lung Disease study. Eur Respir J.2013;41:548-555.

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FIGURE LEGENDS

Figure 1. STROBE flowchart of participation in the study

Figure 2. Panel A. Proportion of A and B grade spirometries by study rounds. Footnote: There were no statistically significant differences between them. **Panel B**. Proportion of high-risk subjects for COPD with airflow limitation ($FEV_1/FVC < 0.70$) by study rounds. There were no statistically significant differences between them

Figure 3. Relationship between age and FEV_1 (% predicted) in participants with (blue circles) and without (green circles) airflow limitation.

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Table 1. Quality scores of spirometry maneuvers according to ATS/ERS standardization.[9,16] A and B scores are considered high quality measurements.

Quality score	Description
A	3 acceptable maneuvers, and best 2 matched with differences in FVC and / or FEV_1 <0.15 L
B	3 acceptable maneuvers, and best 2 matched with differences in FVC and / or FEV_1 <0.20 L
C	2 acceptable maneuvers, and best 2 matched with differences in FVC and / or FEV_1 <0.25 ml
D	1 acceptable maneuver
F	None acceptable maneuvers

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Table 2. Demographic characteristics of all invited individuals(see Figure 1) and also by the sequential study rounds (see Methods). Asterisk indicates p<0.05 between groups.

	Participants (n=2,295)	Refused to participate (n=826)
Age (years), mean±SD	55.0±11	55.3±11
Women, %	46.4	45.8
Study Round, %		
One	18.1	16.1
Two	21.17	12.2*
Three	16.7	12.0
Four	23.6	46.5*
Five	19.9	13.2

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Table 3. Demographic and clinical characteristics of participants at low and high risk of COPD. Asterisk indicate p<0.05 between the two groups.

	Low risk (n=228)	High risk (n=1,456)
Age, mean± SD	55.4±10.4	54.2±10.2
Women, n (%)	53.7%	45.1%*
Smoking history, (%)		
Never	14.1	0.7*
Current	38.3	64.0*
Former	47.6	35.3*
GOLD Risk Score, mean±SD	1.7±0.7	3.6±0.7*
With Chronic Cough, (%)	1.3	49.2*
With. Chronic sputum production, (%)	3.1	48.5*
More breathlessness than people of the same age, (%)	3.1	64.6*
Age over 40 years old, (%)	100	100
Current or former smoker, (%)	85.9	99.3*

Table 4. Clinical characteristics and respiratory function for subjects who performed spirometry correctly and were classified by FEV_1/FVC ratio as normal or with airflow limitation (FEV_1/FVC <0.70).

	Normal spirometry (n= 1,141)	Airflow Limitation (n= 282)
Age, mean±SD	52.8±9.6	59.7±10.7*
Women, n (%)	47.5	35.5*
Smoking history, (%)		
Never	0.5	0.7
Current	63.5	65.7
Former	36.0	33.6
GOLD screener score, mean±SD	3.5±0.7	3.7±0.7*
BMI in kg/m^2, mean± SD	26.9±6.0	26.5±4.4
FEV_1 in L. , mean±SD	2.9±0.69	2.21±0.75*
% predicted FEV_1, mean±SD	1.02±0.2	0.82±0.2*
FVC in L. , mean±SD	3.7±0.87	3.5±1.06*
% predicted FVC, mean±SD	1.01±0.2	0.99±0.2*
FEV_1/FVC, mean±SD	0.78±0.05	0.63±0.07*

BMI: Body Mass Index; FEV_1: Forced expiratory volume in the 1^{st} second; FVC: forced vital capacity.

Fourth study

Survey About the Use of Lung Function Testing in Public Hospitals in Catalonia in 2009.

Núria Roger, Felip Burgos, Jordi Giner, Alba Rosas, Ricard Tresserras, Joan Escarrabill y el grupo de trabajo de función pulmonar del Plan Director de las Enfermedades del Aparato Respiratorio (PDMAR).

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Original

Encuesta de utilización de la función pulmonar en los hospitales públicos de Cataluña en 2009

Nuria Roger[a,*], Felip Burgos[b], Jordi Giner[c], Alba Rosas[d], Ricard Tresserras[e], Joan Escarrabill[f] y el grupo de trabajo de Función Pulmonar del Plan Director de las Enfermedades del Aparato Respiratorio (PDMAR)

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INFORMACIÓN DEL ARTÍCULO

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Espirometría forzada
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RESUMEN

Introducción: El infradiagnóstico es uno de los problemas de mayor impacto en las enfermedades respiratorias y requiere intervenciones específicas. Una de ellas es tener acceso a una espirometría de calidad. Este es uno de los objetivos del Plan Director de Enfermedades Respiratorias del Departament de Salut de la Generalitat de Catalunya.
Objetivo: Conocer la utilización de la espirometría hospitalaria en Cataluña, y conocer los posibles déficits y las opciones de mejora.
Método: Estudio transversal mediante una encuesta a los 65 hospitales públicos de Cataluña durante el año 2009. Se realizó un análisis descriptivo para cada región sanitaria.
Resultados: Se observó una falta de homogeneidad en la utilización de la espirometría a nivel territorial (de 0,98 a 1,50 espirometrías por 100 habitantes). Se identificaron 2 factores que están asociados a una mayor tasa de espirometrías: la existencia de un servicio de neumología en el centro y disponer de una ubicación estable para realizar espirometrías. Como áreas de mejora se identificaron el control de calidad de la prueba, la inclusión en los sistemas hospitalarios de información y los programas de formación continuada.
Conclusiones: Los resultados de este estudio han permitido identificar las áreas de mejora para un programa a desarrollar.

Survey About the Use of Lung Function Testing in Public Hospitals in Catalonia in 2009

Keywords:
Spirometry
Quality control
Underdiagnosis
Standards

ABSTRACT

Background: Underdiagnosis is one of the problems with the greatest impact on respiratory disease management and requires specific interventions. Access to quality spirometry is especially important and is an objective of the Master Plan for Respiratory Diseases of the Department of Health of the *Generalitat de Catalunya*.
Objective: To determine the current use of spirometry at public hospitals in Catalonia, possible deficiencies and options for improvement.
Methods: A cross-sectional survey of 65 public hospitals in Catalonia in 2009. Descriptive analyses were developed for each public health-care region.

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◊ Ver anexo 1.

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Results: A lack of uniformity was observed in the use of spirometry at the regional level (between 0,98 and 1.50 spirometries per 100 inhabitants). We identified two factors associated with a higher rate of spirometry: i) the existence of a Respiratory Medicine Department at the hospital, and ii) the existence of a set location to carry out spirometries. Several areas for improvement also were identified: quality control of the test itself, the inclusion of spirometry in electronic health-care records and continuing education programs.
Conclusions: The results of this study have identified areas for improvement in spirometry programs.

Introducción

Las enfermedades respiratorias son la tercera causa de muerte en los países desarrollados[1]. El impacto sobre el sistema sanitario es muy elevado. En nuestro medio las enfermedades respiratorias causan el 10% de los ingresos hospitalarios, y el 20% de dichos ingresos está relacionado con la enfermedad pulmonar obstructiva crónica (EPOC)[2]. La prevalencia de la EPOC en personas de más de 40 años se sitúa alrededor del 10%[3,4]. La agudización de la EPOC es un problema de salud relevante, por el riesgo elevado para el paciente en lo que concierne a la supervivencia, y las exacerbaciones frecuentes aumentan la mortalidad[5]. La mortalidad durante el ingreso es del 6,7% y la mortalidad al año tras la agudización es del 33%[6], aunque en nuestro medio Almagro et al.[7] reportan una mortalidad del 22%, con un elevado porcentaje de reingresos: el 38% de los pacientes reingresan al año, y la media del tiempo desde el alta al reingreso es de 5 meses[8].

El infradiagnóstico es uno de los problemas más graves en el manejo de las enfermedades respiratorias, especialmente de la EPOC[9], que se mantiene persistente a lo largo de los años. Únicamente un tercio de los pacientes con EPOC reconocen que padecen esta enfermedad[10], y el 21% de los pacientes que ingresan por exacerbación de la EPOC afirman que ningún médico les atiende regularmente por el problema respiratorio[11]. Además del infradiagnóstico, es preciso considerar el porcentaje de «mal diagnóstico»[12,13]. Pellicer Císcar et al.[14] observan que, incluso en el medio hospitalario, la falta de espirometría es el factor más importante para explicar el mal diagnóstico de la EPOC. En comparación con los pacientes con insuficiencia cardiaca crónica, los pacientes con EPOC es menos probable que tengan una prueba confirmatoria realizada, incluso si ambas condiciones coexisten[15,16].

La reducción del infradiagnóstico y el diagnóstico apropiado requieren intervenciones específicas, pero sobre todo garantizar el acceso a una espirometría de calidad[17,18].

Uno de los retos más importantes de todos los sistemas sanitarios consiste en identificar las estrategias más adecuadas para establecer prioridades y trasladar las decisiones a la primera línea asistencial[19,20]. El Departament de Salut de la Generalitat de Catalunya se sirve de los Planes Directores[21] para acercar los planteamientos estratégicos a los operativos con el fin de mejorar la atención al paciente. Uno de los objetivos del Plan Director de Enfermedades Respiratorias (PDMAR) del Departament de Salut es el de garantizar al clínico el acceso a una espirometría de calidad independientemente del ámbito asistencial en el que trabaje. En este contexto, el presente estudio pretende conocer la utilización de la espirometría en el ámbito hospitalario de prestación pública de Cataluña, y hacer patentes los posibles déficits, opciones de mejora y posibles desequilibrios territoriales en el estudio de función pulmonar, y especialmente en la espirometría.

Material y método

El estudio se ha realizado en el marco de la red de hospitales públicos de Cataluña. El sistema sanitario público de Cataluña es un sistema nacional de salud por el que se garantiza la cobertura a toda la población, se financia a través de impuestos y el paciente no debe realizar pago alguno en el momento de la atención. La financiación de los servicios se realiza a través del Servicio Catalán de la Salud (CatSalut), que compra servicios a diversos proveedores. La encuesta se ha distribuido en la red de hospitales (XHUP) con los que el CatSalut tiene contratada la prestación de servicios. Estos proveedores, independientemente de la titularidad pública o privada, constituyen la red de hospitales de utilización pública que representa el porcentaje mayoritario del total de la red sanitaria de Cataluña.

Encuesta

Se realizó un estudio transversal mediante una encuesta que se distribuyó a los 65 hospitales de la red pública catalana durante el primer trimestre de 2009 (anexo 1). La distribución de las encuestas se realizó a través de las gerencias de los hospitales, que designaron un referente de neumología para conseguir las respuestas y la información complementaria si fuera necesario. Los resultados se recogieron entre los meses de abril y junio de 2009. Se hicieron un máximo de 3 intentos para conseguir los datos, efectuando un recordatorio telefónico a partir del segundo intento.

Datos

La encuesta recogía información sobre actividad del hospital, pruebas funcionales respiratorias que se realizaban en cada hospital, tanto básicas (espirometría forzada) como complejas (volúmenes pulmonares, capacidad de transferencia de CO, gasometría arterial), número de espirometrías realizadas en el año anterior, información sobre los espirómetros, solicitante de las espirometrías y el lugar de realización de estas, control de calidad que se realizaba, su incorporación a las bases de datos de los hospitales, información sobre los profesionales que realizaban e interpretaban las espirometrías, formación que recibían, etc. (anexo 1).

Respecto al lugar donde se realizan las espirometrías, a efectos del presente estudio, se definió el «laboratorio de función pulmonar» como un espacio identificado como tal en el que de una manera estable trabaja como mínimo un profesional de enfermería para realizar espirometrías, la medición de la capacidad de transferencia de CO (DLCO) y/o los volúmenes pulmonares.

Indicadores

Los indicadores calculados fueron: el número de espirometrías por cada 100 camas de hospital, por cada 100 altas, por cada 100 consultas externas, por cada 100 urgencias y por cada 100 habitantes. Todos ellos se calcularon por un año. Se obtuvieron los resultados globales y por región sanitaria.

Análisis estadístico

De forma inicial se realizó un análisis descriptivo de los ítems del cuestionario por el total de Cataluña, por cada una de las regiones sanitarias y por los sectores sanitarios de la región sanitaria de

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Barcelona. Se calcularon el número de casos y las frecuencias de las variables categóricas y los estadísticos de tendencia central y dispersión de las variables continuas. Para describir la magnitud de la diferencia entre regiones se ha empleado la razón de variación (RV). Este estadístico es el cociente entre el valor más alto y el más bajo de las tasas para el conjunto de regiones estudiadas. Su valor indica cuánto más varía la región con la tasa más alta respecto a la región con la tasa más baja.

El número de espirometrías realizadas en cada centro se distribuye siguiendo una ley de Poisson. Para explorar la asociación entre el número de espirometrías realizadas en cada centro y los distintos factores encuestados se construyó un modelo de regresión de Poisson multinivel, incluyendo el número de altas en el centro como variable *offset*. Los factores estudiados fueron la existencia de un servicio de neumología en el centro, que los pacientes ingresados fueran atendidos por un neumólogo, el número de pruebas de función pulmonar, disponer de una ubicación estable para realizar espirometrías, efectuar control de calidad de las pruebas, disponer de un sistema de información, que los profesionales reciban formación reglada y haber realizado formación en el último año. Se consideró significativa una asociación con un valor de p inferior a 0,05. Para el tratamiento de los datos se ha utilizado el programa SPSS v18, y para el análisis estadístico el programa STATA v11.

Resultados

Respuestas

Los 65 hospitales de la red pública catalana respondieron a la encuesta, y se identificó que 8 de ellos, por ser de características monográficas, no realizaban espirometrías. Los resultados que se presentan a continuación se expresan sobre los 57 hospitales que realizaban espirometrías. La encuesta se pilotó en 3 centros hospitalarios de Barcelona y Vic (autores del diseño) a fin de valorar la factibilidad de los ítems a responder. Las respuestas a la encuesta fueron encargadas a los responsables médicos de cada uno de los laboratorios de función pulmonar, que a su vez designaron al profesional que contestó la encuesta; no tenemos datos de la categoría profesional y/o responsabilidad.

Presencia del neumólogo

En el 34,5% (n = 19) de los hospitales existía servicio de Neumología, en el 34,5% (n = 19) existía sección de Neumología, en el 25,5% (n = 14) existía la figura del neumólogo consultor y en el 5,5% (n = 3) de los hospitales no existía ninguno de los 3 recursos anteriores. Los pacientes respiratorios ingresados eran atendidos en el 24,1% (n = 13) de los casos mayoritariamente por neumólogos, en el 35,2% (n = 19) por internistas y en el 40,7% (n = 22) restante de manera compartida entre neumólogos e internistas.

Tipos de pruebas

En la tabla 1 se muestra el tipo de exploraciones funcionales respiratorias que se realizaban en los 57 hospitales estudiados. Todos los centros realizaban espirometrías. En el 85,9% (n = 49) de los centros se realizaban al menos 3 de estas pruebas. En todas las regiones sanitarias se realizaban pruebas en pacientes pediátricos, aunque únicamente las realizaban el 67% de los hospitales, es decir, 39 de ellos. Los hospitales realizaban espirometría en diversas ubicaciones del hospital o fuera del hospital que no son mutuamente excluyentes: en el 47% (n = 27) de los hospitales tienen una ubicación física estable; en estos, el 37% (n = 21) tienen un laboratorio de función pulmonar según la definición efectuada previamente. Así mismo, la espirometría también se realiza en otros entornos hospitalarios: en el 37% (n = 21) en consultas externas, en el 26% (n = 15) en el hospital de día, en el 10% (n = 17) en la sala de hospitalización convencional, en el 7% (n = 4) en la casa del paciente, en el 14% (n = 8) en la sala de hospitalización de neumología y en el 10% (n = 17) en la sala de hospitalización de medicina general.

Control de calidad

En todos los hospitales se calibraba el espirómetro haciéndolo preferentemente el personal de enfermería o personal técnico: 81% (n = 43) enfermería, 30% (n = 16) técnico, 17% (n = 9) médico, aunque en algunos casos la calibración se realizaba indistintamente por los diferentes profesionales. La interpretación de las pruebas dependía de la organización de cada centro. En el 11% (n = 6) de los casos cada médico interpretaba las pruebas solicitadas por él mismo. En el 87% (46%) de los hospitales los neumólogos interpretan pruebas y en el 19% (n = 10) también los internistas. En el 9% (n = 5) de los centros la interpretación la realizan los médicos de familia, y en solo un hospital el personal de enfermería.

El 71% (n = 40) de los hospitales respondieron que efectuaban control de calidad de las pruebas. Dado que la pregunta permitía una respuesta abierta, los centros respondieron de forma variada, y las respuestas más frecuentes fueron la utilización de voluntarios o profesionales sanos, la supervisión directa de las pruebas, o la información procedente del propio equipo de espirometría y/o el análisis visual de las curvas flujo-volumen.

En el 35% (n = 20) la información aportada por la espirometría estaba en el sistema de información del hospital, incorporándose de forma manual en 9 de ellos y automáticamente en 11. En el 24,5% (n = 13) de los hospitales el contenido exacto del informe de la espirometría pasaba a la base de datos del hospital o a la historia clínica. En el 20,8% (n = 11) de los casos se incorporaban los datos de la espirometría en formato no desagregado, que no permite el tratamiento individualizado de los datos (formato pdf), en el 7,5% (n = 4) de los hospitales solo los datos en un formato desagregado, y la espirometría en su totalidad en un formato desagregado en el 3,8% (n = 2) de los hospitales.

Formación de los profesionales

Se observó que únicamente un hospital seleccionaba profesionales con formación previa, mientras que en la mayoría de ellos (86,8%, n = 46) se seleccionaban los profesionales y posteriormente recibían formación. En el 43,9% (n = 25) de los hospitales los profesionales que realizaban espirometrías recibían formación interna no reglada, en el 26,3% (n = 15) recibían formación interna reglada. A la pregunta de qué tipo de formación continuada realizaban, el 25% (n = 14) únicamente realizaban formación en el momento de la selección de los profesionales, el 14% (n = 8) realizaban formación periódica anual, mientras que el 59,6% (n = 34) realizaban formación de manera espontánea. A la pregunta de cuánto tiempo hacía desde que un profesional implicado en la realización de espirometrías había realizado un curso, en el 14,8% (n = 8) de hospitales la respuesta fue menos de 3 meses, en el 5,6% (n = 3) entre 3 y 6 meses, en el 20,4% (n = 11) fue menos de un año, en el 24,1% (n = 13) entre uno y 2 años, y en el 35,2% (n = 19), más de 2 años.

Solicitud de exploraciones

La encuesta mostró que los profesionales que solicitaban la espirometría eran en el 57% (n = 30) el neumólogo de hospital, en el 18% (n = 9) médicos especialistas en medicina interna, otros médicos del hospital en el 11% (n = 6) de los casos, neumólogos de fuera del hospital en el 3% (n = 2) de los casos, médicos de atención primaria en el 4% (n = 2), y médicos de otros hospitales en el 2% (n = 1).

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Tabla 1
Número y porcentaje de hospitales con pruebas de función respiratoria en cada región sanitaria. Cataluña, 2009

Región sanitaria	Vol + Difusión		Broncoprov.		P6M		Gases		Esfuerzo	
	n	%	n	%	n	%	n	%	n	%
Alt Pirineu i Aran	0	0%	1	25%	0	0%	4	100%	0	0%
Barcelona	18	62%	19	66%	23	79%	29	100%	10	34%
Catalunya Central	3	75%	3	75%	4	100%	4	100%	2	50%
Girona	1	13%	5	63%	7	88%	7	88%	4	50%
Lleida	2	100%	2	100%	1	50%	2	100%	2	100%
Camp de Tarragona	2	33%	3	50%	2	33%	6	100%	3	50%
Terres de l'Ebre	1	25%	1	25%	1	25%	4	100%	2	50%
Total	27	47%	34	60%	38	67%	56	98%	23	40%

Broncoprov.: pruebas de broncoprovocación; P6M: prueba de los 6 min de marcha; Vol + Difusión: volumen + difusión.

Distribución del número de exploraciones

La tasa de espirometrías por 100 altas hospitalarias/año fue de 14,97, con una RV de 1,82, indicando un 82% más de utilización entre la región con la tasa mayor respecto a la región con la tasa menor. La tasa de espirometrías por 100 habitantes/año fue de 1,32, con una RV de 1,53; en la figura 1 se puede observar la gran variabilidad en la región sanitaria de Barcelona. Dicha región se analizó por sectores sanitarios, debido a que aglomera el 67,8% de la población total de Cataluña (figs. 1 y 2 y tabla 2).

En la tabla 3 se presenta el análisis para explorar la asociación entre el número de espirometrías realizadas en cada centro y los distintos factores encuestados mediante un modelo de regresión de Poisson multinivel. De los distintos factores estudiados presentaron una asociación estadísticamente significativa la existencia de un servicio de neumología en el centro y disponer de una ubicación estable para realizar espirometrías, La presencia de estos factores en un centro incrementa el 59 y el 56%, respectivamente, las tasas de espirometrías. Así mismo conseguían explicar (el 8%) parte de la variancia existente entre centros, aunque esta seguía siendo considerable. En este sentido, el estadístico de la mediana de la razón de tasas de espirometrías (*median incidence rate ratio*, MIRR) se interpreta de forma que el incremento medio de la tasa de espirometrías entre 2 centros cualesquiera es del 98% en el modelo vacío y del 88%

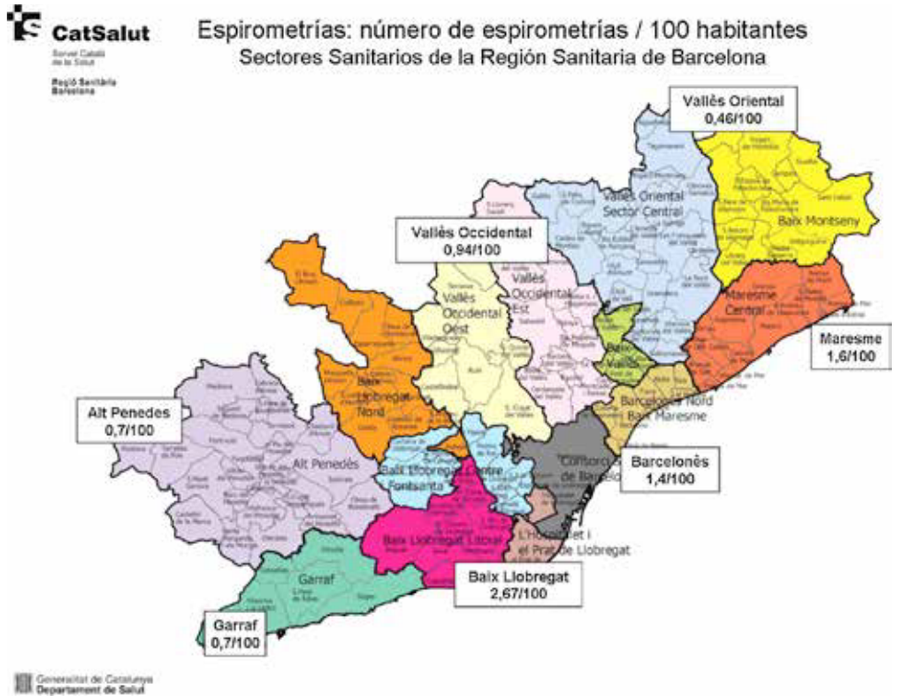

Figura 1. Tasas de espirometrías por 100 habitantes en la región sanitaria de Barcelona.

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Tabla 2
Tasa de espirometrías por regiones sanitarias de Cataluña. Cataluña, 2009

Región sanitaria	Tasa espirometrías/100 habitantes/año	Tasa espirometrías/100 altas/año	Tasa espirometrías/100 consultas externas declaradas[a]/año
Alt Pirineu i Aran	1,50	12,99	2,90
Barcelona	1,37	16,33	5,20
Catalunya Central	1,18	13,31	3,11
Girona	1,50	14,82	4,08
Lleida	1,01	13,78	5,65
Camp de Tarragona	0,98	8,97	1,87
Terres de l'Ebre	1,14	11,15	2,24
Total	1,32	14,97	4,31

Fuentes: Encuesta de Espirometrías PDMAR, 2009, y Registro Central de Asegurados del CatSalut, 2009.
[a] Datos declarados por los centros participantes en la encuesta.

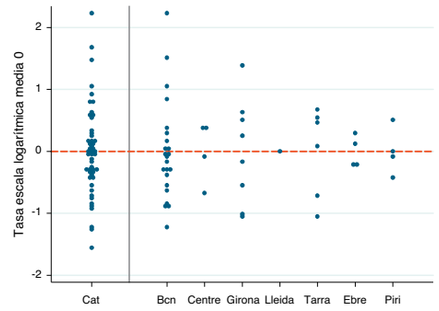

Figura 2. Tasas de espirometrías por centro (Cataluña, 2009). Se representan las tasas de espirometrías por centro para toda Cataluña y por región sanitaria en escala logarítmica y centradas en la media para mejorar su comparabilidad. Cada punto representa un centro hospitalario.
Bcn: región sanitaria Barcelona; Cat: total Cataluña; Centre: región sanitaria Centro; Ebre: región sanitaria Terres de l'Ebre; Girona: región sanitaria Girona; Lleida: región sanitaria Lleida; Piri: región sanitaria Alt Pirineu; Tarra: región sanitaria Tarragona.

en el modelo final. Esto sugiere una elevada variabilidad entre las tasas por centro, como reflejan la figura 1 y la tabla 2. En esta figura los puntos representan las tasas de espirometría de cada centro logaritmizadas y centradas en el 0 para una mejor comparabilidad.

Tabla 3
Modelo Poisson multinivel entre el número de espirometrías y distintos factores encuestados

	Estimador (error estándar)	
	Modelo vacío	Modelo final
Servicio de neumología	–	1,59 (0,33)
Ubicación física estable	–	1,56 (0,30)
Variancia hospital	0,72 (0,07)	0,66 (0,07)
Log likelihood	–409.986	–405.985
MIRR	1,98	1,88

El modelo de regresión de Poisson se emplea en estudios con variables de recuento en una unidad de tiempo o espacio, en este caso el número de espirometrías realizadas en un año. Los coeficientes del modelo se interpretan en términos de razones de tasa de incidencia. Tomando como ejemplo la variable «servicio de neumología», la presencia de este en un centro incrementa en un 59% la tasa de incidencia de espirometrías.
Se presenta primero el modelo vacío para mostrar la reducción, tanto en términos de verosimilitud (log-likelihood) como de varianza entre centros, que representa la inclusión de las variables «Servicio de neumología» y «Ubicación física estable».
El estadístico MIRR (del inglés *median incidence rate ratio*) representa la mediana de la distribución de la diferencia de tasas de espirometrías entre 2 centros cualesquiera.

Discusión

Los resultados de la encuesta de espirometrías de hospitales muestran una falta de homogeneidad entre los hospitales y regiones sanitarias de Cataluña respecto a la utilización de la espirometría, lo que puede ser un factor que contribuya al infradiagnóstico[9,22] de las enfermedades respiratorias[23].

Esta heterogeneidad en algunos estudios ha sido atribuida a factores como la accesibilidad a la prueba[15], o la falta de solicitud de la prueba por parte del médico. En nuestro estudio la variabilidad no puede ser atribuida a la accesibilidad, ya que todas las regiones sanitarias y todos los hospitales disponen de la infraestructura necesaria para la realización de espirometrías. La variabilidad puede explicarse por la existencia o no de un servicio de Neumología y por una ubicación física estable para la realización de la espirometría. Estos factores están asociados a un mayor número de espirometrías. El servicio de Neumología implica un reconocimiento explícito de la distribución de tareas en el centro. Por lo tanto, a la luz de los datos de la encuesta, podemos sostener que lo importante no es la estructura en sí misma (es decir, la existencia del Servicio) sino el reconocimiento explícito de la importancia de las pruebas funcionales respiratorias. Algunos estudios atribuyen a las características de la propia enfermedad la infrautilización de la espirometría respecto a otras pruebas como la ecocardiografía[15,16,24]. No hemos encontrado un indicador que nos permita conocer el rango adecuado de espirometrías por volumen de altas o por camas hospitalarias o por 100 habitantes, pero sí consideramos que obtener estos resultados en el momento inicial del diseño de un plan director nos puede proporcionar nuestro propio indicador para evaluar futuros resultados, teniendo en cuenta no obstante que siempre nos encontraremos ante un indicador de proceso y no de resultado.

Es probable que diversos factores puedan explicar la diferente utilización de la espirometría en los hospitales, desde factores centrados en los propios profesionales, a factores organizativos. La adhesión a la utilización de las guías de práctica clínica entre los profesionales[25] o la formación básica de los que atienden a los pacientes respiratorios de los hospitales puede hacer variar la utilización de la espirometría. Así, tal y como se muestra en nuestro estudio, en los hospitales en los que existía un servicio de Neumología y que disponían de una ubicación física estable para la realización de espirometrías, se realizaba un número mayor de espirometrías. Este resultado confirma el importante trabajo a realizar en todos los ámbitos y dispositivos sanitarios por parte de los neumólogos para potenciar el uso de la espirometría por otros especialistas y por los médicos de atención primaria.

La espirometría es una prueba con una elevada dependencia del profesional sanitario que la realiza. Se constata la importancia de la formación de este profesional en el momento de realizar la espirometría[26–28] y, por tanto, una necesidad organizativa de profesionales formados en el momento de acceder a dichos lugares de trabajo. Se evidencia además la necesidad de programas de formación continuada estandarizados y homogéneos aceptados por

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todas las organizaciones para lograr un elevado nivel de calidad en la espirometría. Destaca en nuestra encuesta la escasa rigurosidad en el apartado de formación continuada en espirometría, ya que en el momento de la selección de los profesionales para la realización de espirometrías, en la mayoría de los hospitales no se tiene en cuenta la formación previa y la formación que se realiza es una formación no reglada ni realizada de manera regular.

Al analizar el control de calidad efectuado sobre las espirometrías, destaca la diversidad de respuestas ante una pregunta abierta como era la realización de control de calidad. Estrategias de telemedicina probablemente podrían contribuir a mejorar este control de calidad y a conseguir un incremento de las espirometrías de calidad[29]. Así mismo se ha detectado otra área de mejora, como es el acceso a los datos de la espirometría desde los sistemas de información hospitalarios. A nuestro entender es crucial que, en el progresivo desarrollo de la historia clínica informatizada, la espirometría no debe quedar postergada.

La evaluación del resto de exploraciones funcionales respiratorias nos muestra que todas las regiones sanitarias tienen acceso a la realización de pruebas funcionales respiratorias complejas, excepto la Vall d'Aran, una región sanitaria de alta montaña pero que tiene sus flujos de conexión bien establecidos con la región sanitaria más cercana. Destaca no obstante que la prueba de los 6 min de marcha no está ampliamente difundida en todos los hospitales, como sería de esperar por su sencillez de utilización[30] y por su importancia en la valoración integral de los pacientes con EPOC[31].

Limitaciones del estudio

La metodología utilizada en el presente estudio ha sido una encuesta. Aunque no existían alternativas metodológicas para la realización del estudio, se deben tener en cuenta las limitaciones de esta fuente de información. El presente estudio no ha evaluado la red de atención primaria, pero recientemente hemos iniciado una encuesta a todos los centros de salud de la red pública de Cataluña. Dado que no existían otras encuestas territoriales ni nacionales ni internaciones, no podemos comparar nuestros datos con la bibliografía existente. No existe en la literatura ningún indicador sobre el número de espirometrías por habitante; por lo tanto, uno de los objetivos que se planteaban inicialmente sobre la valoración de la variabilidad de los resultados y su comparación con la literatura no ha podido ser estimado. Es por este motivo que no se valora la relevancia estadística y clínica de las tasas de espirometría por habitante y año.

Otras limitaciones de nuestro estudio pueden ser el sesgo de información derivado de quien ha respondido la encuesta y que las tasas estimadas no han podido ser estandarizadas en relación a la edad y el sexo de los pacientes. Parte de la variabilidad encontrada podría ser explicada por una distinta estructura de poblacional de cada área sanitaria, como también por un nivel de gravedad o comorbilidad distinto.

Conclusiones

El análisis de la utilización de las espirometrías en el ámbito hospitalario nos ha permitido: a) detectar como factores relacionados con la mayor realización de espirometrías la existencia de un servicio de neumología y de una ubicación estable para la realización de las mismas; b) elaborar un programa formativo homogéneo, descentralizado y «autorreplicable» para todas las regiones sanitarias de Cataluña que permita mantener la realización de espirometrías de calidad dentro de unas organizaciones en constante cambio[32]; c) objetivar la necesidad de la incorporación de la espirometría a las bases de datos de los hospitales (historia clínica electrónica) estandarizando la transferencia de datos, lo que facilitará la interoperabilidad, y d) establecer modelos de control de calidad de la espirometría utilizando las TIC[29]. Así mismo, nos ha permitido elaborar un indicador de la utilización de la espirometría forzada en una población (0,98 a 1,53 espirometrías por 100 habitantes), que según nuestro conocimiento no existe en la bibliografía revisada[33]. Todos estos cambios deben impactar tanto en los propios profesionales como en las estructuras organizativas de los hospitales, y en todos los casos garantizar el acceso a una espirometría de calidad para todos los clínicos, independientemente del nivel sanitario en el que trabajen.

Conflicto de intereses

No existen conflictos de intereses ni fuentes de financiación.

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Anexo 1. Grupo de Función Pulmonar

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Bibliografía

1. Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJ. Global and regional burden of disease and risk factors, 2001: systematic analysis of population health data. Lancet. 2006;367:1747–57.
2. Activitat assistencial de la xarxa sanitaria de Catalunya. Any 2009. Registre del Conjunt Bàsic Mínim de Dades (CMBD) CatSalut. Departament de Salut. Generalitat de Catalunya.
3. Halbert RJ, Natoli JL, Gano A, Badamgarav E, Buist AS, Mannino DM. Global burden of COPD: systematic review and meta-analysis. Eur Respir J. 2006;28:523–32.
4. Miravitlles M, Soriano JB, García-Río F, Muñoz L, Duran-Tauleria E, Sanchez G, et al. Prevalence of COPD in Spain: impact of undiagnosed COPD on quality of life and daily life activities. Thorax. 2009;64:863–8.
5. Soler-Cataluna JJ, Martinez-Garcia MA, Roman SP, Salcedo E, Navarro M, Ochando R. Severe acute exacerbations and mortality in patients with chronic obstructive pulmonary disease. Thorax. 2005;60:925–31.
6. Hoogendoorn M, Hoogenveen RT, Rutten-van Mölken MP, Vestbo J, Feenstra TL. Case fatality of COPD exacerbations: a meta-analysis and statistical modelling approach. Eur Respir J. 2011;37:508–15.
7. Almagro P, Calbo E, Ochoa de Echagüen A, Barreiro B, Quintana S, Heredia JL, et al. Mortality after hospitalization for COPD. Chest. 2002;121:1441–8.

Cómo citar este artículo: Roger N, et al. Encuesta de utilización de la función pulmonar en los hospitales públicos de Cataluña en 2009. Arch Bronconeumol. 2013. http://dx.doi.org/10.1016/j.arbres.2012.12.006

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8. Bahadori K, FitzGerald JM, Levy RD, Fera T, Swiston J. Risk factors and outcomes associated with chronic obstructive pulmonary disease exacerbations requiring hospitalization. Can Respir J. 2009;16:e43–9.
9. Soriano JB, Ancochea J, Miravitlles M, García-Río F, Duran-Tauleria E, Muñoz L, et al. Recent trends in COPD prevalence in Spain: a repeated cross-sectional survey 1997-2007. Eur Respir J. 2010;36:758–65.
10. Hill K, Goldstein RS, Guyatt GH, Blouin M, Tan WC, Davis LL, et al. Prevalence and underdiagnosis of chronic obstructive pulmonary disease among patients at risk in primary care. CMAJ. 2010;182:673–8.
11. Garcia-Aymerich J, Escarrabill J, Marrades RM, Monsó E, Barreiro E, Antó JM, EFRAM Investigators. Differences in COPD care among doctors who control the disease: general practitioner vs. pneumologist. Respir Med. 2006;100:332–9.
12. Menezes AM, Perez-Padilla R, Jardim JR, Muiño A, Lopez MV, Valdivia G, et al., PLATINO Team. Chronic obstructive pulmonary disease in five Latin American cities (the PLATINO study): a prevalence study. Lancet. 2005;366:1875–81.
13. Menezes A. Multi-center survey of COPD in five major Latin American cities. The Platino Survey. 2002 [consultado 2 Feb 2011]. Disponible en: www.platino-alat.org
14. Pellicer Císcar C, Soler Cataluña JJ, Andreu Rodríguez AL, Bueso Fabra J, en representación del Grupo EPOC de Sociedad Valenciana de Neumología. Calidad del diagnóstico de enfermedad pulmonar obstructiva crónica en el ámbito hospitalario. Arch Bronconeumol. 2010;46:64–9.
15. Damarla M, Celli BR, Mullerova HX, Pinto-Plata VM. Discrepancy in the use of confirmatory tests in patients hospitalized with the diagnosis of chronic obstructive pulmonary disease or congestive heart failure. Respir Care. 2006;51:1120–4.
16. Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet. 2009;374:721–32.
17. Torrubia Fernandez MJ, Comin Orce A, Moreno Venris M, Carrizo Sierra J, Marin Trigo JM. Uso de la espirometría versus ecocardiografía en pacientes hospitalizados por EPOC o insuficiencia cardíaca. An Med Interna (Madrid). 2008;25:222–5.
18. Schirnhofer L, Lamprecht B, Firlei N, Kaiser B, Buist AS, Halbert RJ, et al. Using targeted spirometry to reduce non-diagnosed chronic obstructive pulmonary disease. Respiration. 2011;81:476–82.
19. Lavis JN, Permanand G, Oxman AD, Lewin S, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP) 13: Preparing and using policy briefs to support evidence-informed policymaking. Health Res Policy Syst. 2009;7 Suppl 1:S13.
20. Lavis JN, Boyko JA, Oxman AD, Lewin S, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP) 14: Organising and using policy dialogues to support evidence-informed policymaking. Health Res Policy Syst. 2009;7 Suppl 1:S14.
21. Tresserras R. Planificación según prioridades de salud. Criterios de planificación relacionados con los Planes Directores. Med Clin (Barc). 2008;131 Supl 4:42–6.
22. Soriano JB, Miravitlles M, Borderías L, Duran-Tauleria E, García Río F, Martínez J, et al. Diferencias geográficas en la prevalencia de EPOC en España: relación con hábito tabáquico, tasas de mortalidad y otros determinantes. Arch Bronconeumol. 2010;46:522–30.
23. Ulrik CS, Løkke A, Dahl R, Dollerup J, Hansen G, Cording PH, et al., TOP study group. Early detection of COPD in general practice. Int J Chron Obstruct Pulmon Dis. 2011;6:123–7.
24. Han MK, Kim MG, Mardon R, Renner P, Sullivan S, Diette GB, et al. Spirometry utilization for COPD. Chest. 2007;132:403–9.
25. Lee TA, Bartle B, Weiss KB. Spirometry use in clinical practice following diagnosis of COPD. Chest. 2006;129:1509–15.
26. Center for Disease Control and Prevention. Workplace safety and health topics. Spirometry Spirometry training. 2004 [consultado 1 Mar 2011]. Disponible en: www.cdc.gov/niosh/topics/spirometry/training
27. Miller MR, Crapo R, Hankinson J, Brusasco V, Burgos F, Casaburi R, et al., ATS/ERS Task Force. General considerations for lung function testing. Eur Respir J. 2005;26:153–61.
28. Pérez-Padilla R, Vázquez-García JC, Márquez MN, Menezes AM, PLATINO Group. Spirometry quality-control strategies in a multinational study of the prevalence of chronic obstructive pulmonary disease. Respir Care. 2008;53:1019–26.
29. Burgos F, Disdier C, Lopez de Santamaria E, Galdiz B, Roger N, Rivera ML, et al., on behalf of e-Spir@p Group. Telemedicine enhances quality of forced spirometry in primary care. Eur Respir J. 2012;39:1313–8.
30. Burgos F, Casan P. Manual SEPAR de procedimientos n.° 4. Procedimientos de evaluación de la función pulmonar II. Barcelona: Permanyer; 2004.
31. Celli BR, Cote CG, Marin JM, Casanova C, Montes de Oca M, Mendez RA, et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. N Engl J Med. 2004;350:1005–12.
32. Escarrabill J, Roger N, Burgos F, Giner J, Molins A, Tresserras R, en nombre del Grupo de Función Pulmonar y del equipo directivo del PDMAR. Diseño de un programa de formación básico para conseguir espirometrías de calidad. Educ Med. 2012;15:103–7.
33. Mohanka M, McCarthy K, Xu M, Stoller JK. A survey of practices of pulmonary function interpretation in laboratories in Northeast Ohio. Chest. 2012;141:1040–6.

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Fifth study

Estudio de la función pulmonar básica en los centros de atención primaria de Cataluña.

Mª Antonia Llauger, Alba Rosas, **Felip Burgos**, Elena Torrente, Ricard Tresserras, Joan Escarrabill y el grupo de trabajo de función pulmonar del Plan Director de las Enfermedades del Aparato Respiratorio (PDMAR).

Atención Primaria 2013 (under review).

Abstract

Rationale: Forced spirometry (FS) is key in the diagnosis of respiratory diseases, but several studies suggest unavailability of equipment, deficits in training and insufficient quality control as causes of suboptimal results of FS in primary care. The aim of the study was to examine the accessibility and use of FS in public primary care facilities in Catalonia.

Aim: Cross-sectional study using a survey of 366 Primary Care Areas (ABS) during the third quarter of 2010, with information on spirometers, training, interpretation and quality control, and the priority that the quality of spirometry had for the team.

Indicators: FS/100 inhabitants/year, FS/month/ABS; FS/month/10,000 inhabitants.

Results: Response rate to the survey was 75%. 97.5% of the ABS had spirometer and made an average of 2.01 spirometries/100 inhabitants (34.68 spirometry/ABS/month). 83% of the primary care centers have trained professionals. Formal training is performed in more than 50% of the centers, but information was not obtained on quality control and 70% of the centers performed some sort of calibration.

The interpretation of the tests is made by the family physician in 87.3% of cases. In 68% of cases no quality control is carried out. 66% of the data is entered into the health medical record manually. 50% of the survey responders recognized the need for prioritization strategies for improving the quality of FS.

Conclusions: Despite the accessibility of FS, efforts should be prioritized in the integration of FS into electronic health records, improving standardized professional training, and promoting systematic quality control.

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Title: Estudio de la función pulmonar básica en los centros de atención primaria de Cataluña.

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Keywords: Palabras clave: espirometría forzada, control de calidad, formación, interpretación.

Key words: spirometry, quality control, training, interpretation.

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Abstract: La espirometría forzada (EF) es clave en el diagnóstico de las enfermedades respiratorias, pero diversos estudios sugieren falta de disponibilidad de espirómetros,déficits en la formación e insuficiente control de calidad.

El presente estudio pretende conocer la accesibilidad y la utilización de la EF en los dispositivos públicos de atención primaria en Cataluña. Estudio transversal mediante una encuesta a 366 áreas básicas de salud (ABS) durante el tercer trimestre de 2010, con información relativa a los espirómetros; la formación;la interpretación y el control de calidad; y el grado de prioridad que la calidad de la espirometría tenía para el equipo.

Indicadores: media de EF/100 habitantes/año; índice de EF/mes/ABS; índice de EF/mes/10000 habitantes.

Porcentaje de respuesta: 75%. El 97,5% de las ABS disponen de espirómetro y realizan una media de 2,01 espirometrías/ 100 habitantes (34,68 espirometrías/ABS/mes). El 83% disponen de profesionales formados. >50% de los centros realizan formación reglada, pero no se dispone de información sobre la calidad de la misma. En el 70% se

realiza algún tipo de calibración. Interpretación: el médico de familia en el 87,3%de los casos. En el 68% de los casos no se realiza ningún tipo de control de calidad de la exploración. 2/3 introducen manualmente los datos en la historia clínica informatiza. >50% se atribuye una prioridad alta a las estrategias de mejora de la calidad EF.

A pesar de la accesibilidad a la EF deben realizarse esfuerzos para estandarizar la formación, incrementar el número de exploraciones y promover el control de calidad sistemático.

Abstract

Forced spirometry (EF) is key in the diagnosis of respiratory disease, but several studies suggest unavailability of spirometers, deficits in training and insufficient quality control.

The study wants to examine the accessibility and use of EF in public primary care facilities in Catalonia.

Cross-sectional study using a survey to 366 health areas (ABS) during the third quarter of 2010, with information on spirometers, training, interpretation and quality control, and the priority that the quality of spirometry had for the team.

Indicators: EF/100 inhabitants/year, EF/month/ABS; EF/month/10000 inhabitants.

Response rate: 75%. 97.5% of the ABS had spirometer and made an average of 2.01 spirometries/100 inhabitants (34.68 spirometry/ABS/month). 83% have trained

professionals. > 50% centers perform formal training but no information is available on the quality. 70% performed some sort of calibration. Interpretation: the family

physician in 87.3% of cases. In 68% of cases not performed any quality control of exploration. 2/3 typed data manually into the computerized medical record. > 50%

recognized a high priority strategies for improving the quality. Despite the accessibility of EF efforts should be made to standardize training, increasing the number of scans and promote systematic quality control.

Suggested Reviewers:

Opposed Reviewers:

Estudio de la función pulmonar básica en los centros de atención primaria de Cataluña.

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***Manuscrito (sin información de autores)**

Resumen

La espirometría forzada (EF) es clave en el diagnóstico de las enfermedades respiratorias, pero diversos estudios sugieren falta de disponibilidad de espirómetros, déficits en la formación e insuficiente control de calidad.

El presente estudio pretende conocer la accesibilidad y la utilización de la EF en los dispositivos públicos de atención primaria en Cataluña.

Estudio transversal mediante una encuesta a 366 áreas básicas de salud (ABS) durante el tercer trimestre de 2010, con información relativa a los espirómetros; la formación; la interpretación y el control de calidad; y el grado de prioridad que la calidad de la espirometría tenía para el equipo.

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A pesar de la accesibilidad a la EF deben realizarse esfuerzos para estandarizar la formación, incrementar el número de exploraciones y promover el control de calidad sistemático.

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Despite the accessibility of EF efforts should be made to standardize training, increasing the number of scans and promote systematic quality control.

Key words: spirometry, quality control, training, interpretation.

Introducción

Las enfermedades respiratorias son la tercera causa de muerte en Cataluña[1], tras el cáncer y las enfermedades cardiovasculares, tal como ocurre en la mayoría de los países desarrollados[2]. Cerca del 30% de la población de 15 años o más se declara fumadora [3] y el tabaquismo sigue siendo un problema de salud importante y el mayor factor de riesgo de aparición y exacerbación de enfermedades respiratorias. En el caso de la enfermedad pulmonar obstructiva crónica (EPOC), a diferencia de las enfermedades cardiovasculares, no se ha constatado un descenso de la mortalidad. La prevalencia de la EPOC en la población de 40 a 80 años en nuestro medio se sitúa en un 10,2%[4 5].

El infradiagnóstico es otro problema relevante en relación a las enfermedades respiratorias. Únicamente un tercio de los pacientes con EPOC reconocen que la padecen y el 21% de los que ingresan por una agudización afirman que ningún médico les atiende regularmente por el problema respiratorio[7]. Además, en un elevado porcentaje de pacientes el diagnóstico de EPOC no se confirma mediante espirometría. Estudios recientes revelan que en el ámbito de la Atención Primaria (AP) se confirma el diagnóstico de EPOC con espirometría sólo en la mitad de los pacientes[8]. Walters et al[9] señalan que en Australia el 31% de los pacientes diagnosticados de EPOC carecen de espirometría forzada (EF) y que el 56% de los pacientes diagnosticados de EPOC tienen una espirometría normal.

La reducción del infradiagnóstico y el diagnóstico apropiado requiere intervenciones específicas, pero sobre todo garantizar el acceso a una espirometría de calidad[10 11]. En trabajos preliminares en nuestro medio ya se ha destacado la importancia de la formación y disponibilidad de espirómetros en el ámbito de AP[12]. Esta disponibilidad de EF mejora el diagnóstico y tratamiento de la EPOC[13]. La introducción de espirómetros pequeños permite realizar la espirometría en cualquier lugar[14]. No queda claro cuál es la mejor manera de organizar la logística para realizar EF en AP, pero no debería separarse la estrategia de mejoría en la realización de la prueba con de la de mejoría de su interpretación[15].

Uno reto importantes de todos los sistemas sanitarios consiste en identificar las estrategias más adecuadas para establecer prioridades y trasladar las decisiones a la asistencia [16]. El Departament de Salut de la Generalitat de Catalunya se sirve de los Planes Directores[17], como el Plan Director de Enfermedades Respiratorias (PDMAR), para acercar los planteamientos estratégicos a los operativos para mejorar la atención al paciente. Uno objetivo del PDMAR es garantizar al clínico el acceso a una espirometría de calidad independientemente del ámbito asistencial.

El presente estudio pretende conocer la accesibilidad y la utilización de la EF en los

dispositivos de AP del ámbito de la prestación pública de Catalunya, identificando los posibles déficits y opciones de mejora y los posibles desequilibrios territoriales.

Material y métodos

Estudio transversal mediante una encuesta, elaborada ad-hoc, que se distribuyó a las 366 áreas básicas de salud (ABS) de Cataluña durante el tercer trimestre de 2010. La distribución de las encuestas se realizó a través de las gerencias territoriales de AP, que enviaban la encuesta a los directores de los EAP y éstos mandaban las respuestas al PDMAR o a las gerencias; el PDMAR hacía el seguimiento de las respuestas. Tras el envío inicial se realizó un recordatorio a los 2 meses a aquellas ABS que no habían contestado.

El cuestionario recogía información sobre los equipos de espirometría, los profesionales y su formación en EF, la interpretación y el control de calidad; y el grado de prioridad que la calidad de la espirometría tenía para cada EAP.

Los resultados se recogieron entre julio y agosto de 2010. Se obtuvieron los resultados globales para cada ABS y para cada región sanitaria y, para esta última, se calculó la tasa de EF por 100 habitantes. Para estudiar el grado de variabilidad en la actividad relacionada con la espirometría de cada EAP, se midió la proporción mensual de espirometrías realizadas en cada equipo. Para cuantificar esta proporción de acuerdo al volumen de población de referencia para cada uno de ellos se calculó la tasa de actividad mensual en relación a los habitantes asignados.

Se estudió la distribución univariante de cada una de las variables y se realizaron análisis territoriales de aquellas más relevantes.

El análisis estadístico se realizó con el paquete estadístico SPSS versión 18.0 (SPSS, Inc, Chicago, IL), y se procedió a la elaboración del análisis descriptivo de los ítems del cuestionario para Cataluña, para cada región sanitaria y para los sectores sanitarios de la región de Barcelona, mediante un análisis de frecuencias de las variables cualitativas y calculando los estadísticos de tendencia central y dispersión de las variables cuantitativas. Los resultados de las variables categóricas se presentan como porcentaje y las de las variables cuantitativas como media y desviación estándar. Para el análisis territorial se calculó la media de espirometrías por cada 100 habitantes y añ, el índice de espirometría por mes y ABS y también por mes y habitante por ABS, todo ello para la descripción de su distribución territorial. Para explorar la posible relación entre el grado de prioridad del EAP en la mejora del proceso de las espirometrías y la actividad realizada (N de espirometrías mensuales) en las diferentes regiones sanitarias, se estudió la correlación de ambas variables ponderadas de acuerdo con el número de espirómetros existentes en cada región. Se realizó el test de chi-cuadrado para valorar la correlación entre el grado de prioridad y otras variables de la encuesta potencialmente relacionadas con el mismo, como la formación reglada del personal, la existencia de protocolo de mantenimiento del espirómetro, el registro de la espirometría en las historias clínicas informatizadas y el control de calidad.

Resultados

Respuestas

De las 366 ABS a las que se envió la encuesta, respondieron un 75% (275 ABS). En la tabla 1 se muestra una relación del índice de respuesta de cada territorio en función de las ABS existentes. Para el análisis de las respuestas, se excluyeron los resultados de los consultorios locales, por su bajo peso sobre el volumen total de centros estudiados y por su diferente estructura. Los resultados se expresan sobre las 275 ABS que contestaron la encuesta.

Dotación de las ABS

Un 97,5% de los EAP que respondieron a la encuesta declara tener espirómetro en su CAP. Un 67,8% declara tener un espirómetro, mientras que un 21,7% declara tener dos. Sólo un 4,7% de los centros dispone de 3 espirómetros. A pesar de la existencia de variedad de marcas y modelos, en un 99,6% de casos el modelo es un Datospir 120 (Sibelmed, Barcelona, España).

Actividad

En relación al número de EF mensuales, los datos son variables y se precisa ajustar al número de habitantes asignados o bien a la población con cobertura sanitaria pública en cada territorio. Lo mismo ocurre en cuanto a la variable sobre el número de citas semanales para hacer espirometrías. Con el objetivo de poder comparar el volumen de actividad, se ha calculado un indicador que mide el promedio de espirometrías realizadas anualmente en cada centro por cada 100 habitantes asignados. Durante 2009 se realizaron en la AP de Cataluña un promedio de 2,01 espirometrías por cada 100 habitantes (Tabla 2).

Población pediátrica

Durante el año 2009 se realizaron en Cataluña espirometrías a niños entre 10 y 15 años en un 68,2% de los centros. En el 47,3% de los casos estas pruebas se practicaron en niños menores de 10 años.

Profesionales técnicos

En 213 centros (83%) refieren tener entre una y cuatro enfermeras de referencia capacitadas para hacer espirometrías. En 7 (2,7%) centros no hay ninguna y en 37 (14,4%) hay más de cuatro. En la mayoría de EAP (62,9%) las mismas enfermeras hacen las espirometrías a los menores de 15 años. En cuanto a la ejecución de las pruebas en ausencia de los profesionales habituales, en más de la mitad de los EAP (51,7%) se desprograma la actividad, mientras que en un 41,8% las realiza otro profesional.

Formación

Un 77% de los EAP declara que sus profesionales que realizan la EF han recibido formación reglada, es decir, algún curso o taller específico sobre EF. El 60% de los EAP declara que la formación es no reglada (sesiones clínicas, prácticas EF), mientras que el 23% declara ambos tipos de formación. Aproximadamente la mitad (50,5%) de la formación reglada se realiza en el propio centro, mientras que la no reglada es predominantemente externa (69%). Cerca de un 42% de los EAP declaran realizar sesiones no regladas internas llevadas a cabo entre los mismos profesionales

del centro. El 52% de los EAP declara que la formación continuada para la realización de EF es de tipo esporádica, es decir a elección de cada profesional, mientras que sólo se declara formación periódica (una vez al año) en uno de cada cuatro centros.

Mantenimiento y calibración

Un 70% de los EAP afirman que se efectúa la calibración de los equipos, diariamente o cada vez que se usa el utillaje. En un 21,6% de los casos se realiza de forma periódica, pero no diaria. Destaca que en 17 centros no se realiza ningún tipo de calibración o bien se hace de forma incorrecta. Sólo un 52,7% de los centros afirman tener un protocolo de mantenimiento, cuyo personal responsable suele ser la enfermera responsable de la técnica.

Interpretación

En el 87,3% de los EAP la interpretación de la espirometría la hace el médico de familia de cada paciente. En 9 equipos (3,4%) interpreta la espirometría un médico referente del equipo, y en 14 (5,2%) los neumólogos de referencia. Por otro lado, la formación en interpretación de las espirometrías es escasa dado que casi una cuarta parte de los equipos declara no tener ningún tipo de formación específica al respecto, mientras que en un 43,3% de los casos responde haber recibido alguna sesión formativa.

Control de calidad

Prácticamente tres cuartas partes de los equipos (68,4%) no realizan ningún tipo de control de calidad.

Grabación de los datos

Dos terceras partes de los equipos, introducen manualmente los resultados de la espirometría en la historia clínica del paciente. En un 14,7% de los casos se incorporan de forma automática desde el programa del espirómetro , en formato de base de datos y en un 16,5% se efectúa como PDF o texto libre.

Prioridad

En respuesta al grado de prioridad asignado a la mejora en la elaboración de espirometrías , en una escala de gradación de 1 a 5, la moda y la media es de 3 y 2,40 respectivamente. En el 53,3% la prioridad para la mejora en la elaboración de espirometrías se sitúa en 4 ó 5. Las respuestas a la variable que preguntó sobre la prioridad en la mejora de la realización de las espirometrías se recodificaron en tres categorías agrupando el valor 1 para definir poca o baja prioridad, los valores 2 ó 3 para definir un grado de prioridad regular, y los valores 4 ó 5 para definir mucha o elevada prioridad.

En el 33,9% de los casos la prioridad es regular, mientras que en el 12,8% de los equipos la prioridad se categoriza como baja. En el análisis bivariado se observa una asociación entre la valoración del grado de prioridad de la realización de las espirometrías con la formación del personal ($x^2=6,50$; $p= 0.038$). La misma relación se observa con la existencia de un protocolo de mantenimiento para los espirómetros ($x^2=13,2$; $p= 0.001$). Sin embargo, dicha asociación no se observa si se analiza la correlación del grado de prioridad para la realización de espirometrías con el control de calidad ni con el registro de la espirometría en la historia clínica. La distribución territorial del grado de prioridad y la del número de espirometrías realizadas mensualmente por equipo y habitantes, ponderada por el número de centros de cada región sanitaria muestra una fuerte correlación con un coeficiente de 0,86 ($p<0,05$).

Discusión

El acceso a una espirometría de calidad es una necesidad inexcusable para la atención a los pacientes con enfermedades respiratorias en la AP[18]. Diversos estudios han puesto de manifiesto los problemas relacionados con la espirometría en AP en nuestro medio. Hueto et al[19] constata la disponibilidad de espirómetros aunque el 22% de los centros no los utilizan. Pellicer et al[20] observan que, incluso en el medio hospitalario, la falta de espirometría es el factor más importante para explicar el mal diagnóstico de la EPOC.

En comparación con los pacientes con insuficiencia cardiaca crónica, los pacientes con EPOC tienen menor probabilidad de disponer una prueba confirmatoria, incluso si ambas condiciones coexisten[21]. Estos hechos ponen de manifiesto la necesidad de garantizar a los clínicos el acceso a una espirometría de calidad, independientemente del ámbito asistencial en el que trabajen[22].

En el presente estudio analizamos la utilización de la espirometría en los equipos de AP, haciendo hincapié en la disponibilidad, la frecuencia de realización, la formación de los profesionales, el control de calidad, y la interoperabilidad.

Disponibilidad

Un cambio significativo muy positivo respecto a años anteriores es constatar el hecho que prácticamente todos los centros de AP disponen de un espirómetro. Esto es imprescindible para el diagnóstico de las enfermedades respiratorias[23], y puede ser un refuerzo en la estrategia de deshabituación tabáquica[24]. Hay dudas razonables sobre los beneficios de la espirometría como herramienta de cribado poblacional[25 26]. Sin embargo, estas evidencias no se contradicen con la necesidad que tiene el clínico de utilizar la espirometría para diagnosticar a los pacientes que acuden a la consulta y presentan factores de riesgo (principalmente tabaquismo) y/o síntomas sugestivos de enfermedades respiratorias (*case finding*)[27].

Utilización

La utilización contrasta con la disponibilidad. A pesar de disponer de espirómetros, la mayoría de centros de AP realizan menos de dos espirometrías diarias. No se conoce la cifra de espirometrías en base poblacional, pero atendiendo al infradiagnóstico de la EPOC es razonable pensar que esta cifra es muy baja. En el presente estudio se constata que en el ámbito de la AP se hacen 2 espirometrías por 100 habitantes, pero con un rango entre 1,39 y 2,71. En el área metropolitana de Barcelona en la zona sur se hacen casi el doble de espirometrías que en la zona norte. Es difícil encontrar razones que justifiquen estas variaciones. La realización de un bajo número de espirometrías o su realización de forma muy esporádica, dificulta mantener las habilidades que garanticen la calidad de la exploración.

Formación

Aunque hay profesionales formados, en su ausencia se suspende la programación en lugar de sustituir al profesional por otro formado en más de la mitad de los casos, lo que podría dificultar el acceso a la exploración. Este hecho es especialmente importante ante el problema del infradiagnóstico. No conocemos con precisión el tipo de formación reglada que reciben los profesionales. En cualquier caso, únicamente un pequeño porcentaje de profesionales recibe la formación reglada propuesta por el PDMAR[28]. La formación continuada es esporádica. Esta situación no es muy distinta a la observada en la encuesta sobre la utilización de la función pulmonar en los hospitales públicos de Cataluña, en la que se aprecia que en el 44% de los hospitales los profesionales reciben formación interna no reglada[29].

Eaton et al han puesto de manifiesto la importancia de la formación reglada[30]. Esta formación debería realizarse a nivel territorial y estar incentivada por los sistemas de financiación que compran los servicios sanitarios. El escaso número de pruebas que realiza cada profesional y las lagunas formativas permiten suponer que el mantenimiento de las habilidades técnicas para realizar espirometrías es, como mínimo, difícil de asegurar.

Interpretación

La mayor parte de las espirometrías realizadas en AP las interpreta el médico de familia, pero únicamente una cuarta parte de los profesionales reconoce haber recibido formación específica en interpretación. Para interpretar correctamente las espirometrías[31], es preciso disponer de tiempo y enfrentarse al número suficiente para mantener las habilidades[32]. La formación y el e-learning[33] pueden jugar un papel pero no sustituyen una formación rigurosa.

Control de calidad

La EF de calidad es un objetivo asumible, tal como se ha demostrado en estudios en los que han participado diferentes observadores[34]. Por lo tanto, es posible aspirar a obtener una espirometría de calidad en todos los ámbitos asistenciales, incluso en medios no sanitarios, como el domicilio del propio paciente[35] y oficinas de farmacia[36]. Sin embargo, casi tres cuartas partes de los puntos de realización de la espirometría no se someten a controles de calidad periódicos.

Interoperabilidad

El hecho de que, en el momento de la encuesta, dos terceras partes de los equipos introducían manualmente los datos de la espirometría en la historia clínica dificultaba la valoración de la calidad de la exploración. Además, la introducción manual es una fuente potencial de errores en la transcripción de los datos.

Para conseguir la normalización de un conjunto completo de datos relacionados con la espirometría la Oficina de Estándares e Interoperabilidad de TicSalut (Departamento de Salud) y el Plan para la Digitalización de la Imagen Médica del Departamento de Salud de la Generalitat, han creado un estándar basado en la versión 3 de HL7 (*Health Level Seven*), CDA R2 (*Clinical Document Architecture, Release 2*). El CDA[37] define la estructura de un documento clínico y utiliza un estándar para el intercambio de información estructurada entre aplicaciones (XML) y es independiente de la plataforma tecnológica utilizada. La disponibilidad del CDA de espirometría permite el intercambio de información de manera estándar, posibilita la interoperabilidad entre diferentes proveedores de salud y ámbitos asistenciales, explotación de datos sobre el informe de espirometría estandarizado resultante (muy importantes para la investigación) y facilita la implantación de procesos sistemáticos de control calidad[38 39]. Además, la disponibilidad de un estándar posibilita incorporar directamente los resultados de la espirometría a la historia clínica electrónica.

La necesidad de reducir el infradiagnóstico de las enfermedades respiratorias crónicas y en especial el asma y la EPOC, la mejora del tratamiento y su seguimiento adecuado, hace que la obtención de espirometrías de calidad sea un objetivo estratégico. Para ello, conocer los datos que provee esta encuesta es fundamental para el PDMAR y complementa la información obtenida en la encuesta realizada recientemente en el ámbito hospitalario proveyendo de un mapa más preciso sobre la utilización de la EF en el territorio. Los resultados de este estudio han permitido identificar áreas de mejora que permitirán desarrollar programas orientados a solventar carencias del sistema sanitario.

El grado de prioridad otorgado por cada EAP a la mejora del proceso de las espirometrías puede significar un buen indicador del interés en este proceso y de la posibilidad de mejora. El hecho que más de la mitad de EAP manifiesten una prioridad alta, y sólo un pequeño porcentaje una baja, puede reflejar una oportunidad para la actuación formativa, organizativa y contractual.

En definitiva, los datos de esta encuesta ponen de manifiesto que el acceso al espirómetro es casi universal pero que se debería aumentar el número de espirometrías que se realiza. No hay datos que confirmen las características de la formación que reciben los profesionales y parece necesario mejorar la formación en la interpretación de las espirometrías así como instaurar estrategias de formación de técnicos en todos los EAP. El control de calidad es francamente mejorable y no podrá conseguirse sin la plena interoperabilidad entre los datos que ofrecen los espirómetros y los sistemas de información relacionados con la historia clínica electrónica.

La prioridad con la que se aborda la espirometría es un buen parámetro para conseguir incrementar el número de exploraciones de calidad. En definitiva, mejorar la realización de la espirometría sirve para mejorar la atención a los pacientes con enfermedades respiratorias crónicas[40].

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Tabla 1. Índice de respuesta a la encuesta según el territorio. Cataluña, 2010.

Región sanitaria (RS)	ABS existentes	N respuesta en cada RS (%)
Alt Pirineu i Aran	8	8 (100)
Barcelona	**213**	**157 (74)**
Catalunya Central	37	24 (65)
Girona	42	37 (88)
Lleida	22	21(95)
Camp de Tarragona	33	20 (61)
Terres de l'Ebre	11	8 (73)
Total	**366**	**275 (75)**

Región sanitaria de Barcelona	ABS existentes	N respuesta en cada sector (%)
Barcelona: Garraf i Alt Penedès	9	8 (89)
Barcelona: Baix Llobregat (Metropolitana Sud)	51	41 (80)
Barcelona: Barcelonès Nord- Maresme	38	29 (76)
Barcelona: Vallès	48	41 (85)
Barcelona ciutat	67	38 (57)

Nota: Los datos provienen de la declaración de los diversos proveedore[1].

[1] El Departament de Salut considera que un proveedor sanitario es una empresa pública o privada (con o sin ánimo de lucro) que presta servicios asistenciales de forma concertada (a través de un contrato con el CatSalut).

Tabla 2. Número absoluto, media, desviación estándar de las espirometrías anuales realizadas en la atención primaria y promedio por mes y equipo y población de referencia del equipo. Cataluña, 2009.

REGIÓN SANITARIA	TOTAL ESPIROMETRÍAS AÑO	MEDIA ESPIROMETRÍAS POR CADA 100 HAB	DESVIACIÓN ESTÁNDAR (DE)	ESPIROMETRÍAS POR MES Y ABS (%)	ESPIROMETRÍAS POR MES Y HABITANTES ABS (10.000 hab)
ALT PIRINEU I ARAN	1.456	2,08	2,52	15,17	17,34
BARCELONA	73.216	1,97	2,11	38,86	16,39
Garraf i Alt Penedès	*3.276*	*1,44*	*1,43*	*34,13*	*11,98*
Baix Llobregat	*21.944*	*2,46*	*1,44*	*44,60*	*20,54*
Barcelonès Nord i Maresme	*12.792*	*2,18*	*1,17*	*36,76*	*18,16*
Vallès Oriental i Occidental	*15.028*	*1,39*	*0,71*	*30,54*	*11,55*
Barcelona ciutat	*20.176*	*2,16*	*2,08*	*44,25*	*18,01*
CATALUNYA CENTRAL	6.552	1,82	0,54	22,75	15,20
GIRONA	13.000	1,89	1,13	29,28	15,71
LLEIDA	7.124	2,22	4,05	28,27	18,53
CAMP DE TARRAGONA	9.308	2,35	1,99	38,78	19,56
TERRES DE L'EBRE	3.796	2,71	5,55	39,54	22,59
TOTAL CATALUNYA	**114.452**	**2,01**	**2,60**	**34,68**	**16,74**

Nota: Los datos provienen de la declaración de los proveedores que respondieron la encuesta.

Tabla 3. Prioridad para la realización de las espirometrías, según región Cataluña, 2009.

REGIÓN SANITARIA	PRIORIDAD (%)			N ESPIROMETRÍAS (100/habitantes)
	POCA	REGULAR	MUCHA	
ALT PIRINEU I ARAN	14,3	28,6	57,1	2,08
BARCELONA	13,1	32,4	54,5	1,97
Garraf i Alt Penedès	0	62,5	37,5	*1,44*
Baix Llobregat	7,5	27,5	65,0	*2,46*
Barcelonès Nord i Maresme	50,0	23,1	26,9	*2,18*
Valles Oriental i Occ.	2,8	30,6	66,7	*1,39*
Barcelona ciutat	5,7	40,0	54,3	*2,16*
CATALUNYA CENTRAL	25,0	41,7	33,3	1,82
GIRONA	11,8	35,3	52,9	1,89
LLEIDA	0	40,0	60,0	2,22
CAMP DE TARRAGONA	5,3	31,6	63,2	2,35
TERRES DE L'EBRE	25,0	25,0	50,0	2,71
TOTAL CATALUNYA	12,8	33,9	53,3	**2,01**

Nota: Los datos provienen de la declaración de los proveedores que respondieron a la encuesta.

Referencias

1 Departament de Salut. Anàlisi de la mortalitat a Catalunya, any 2009. Disponible en http://www20.gencat.cat/portal/site/salut/menuitem.f33aa5d2647ce0dbe23ffed3b0c0e1a0/?vgnextoid=26529ef5f40cf210VgnVCM2000009b0c1e0aRCRD&vgnextchannel=26529ef5f40cf210VgnVCM2000009b0c1e0aRCRD&vgnextfmt=default.

2 Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJ. Global and regional burden of disease and risk factors, 2001: systematic analysis of population health data. Lancet. 2006 May 27;367:1747-57.

3 Departament de Salut. Enquesta de salut de Catalunya 2006. Disponible en http://www.gencat.cat/salut/depsalut/pdf/r15.pdf

4 Halbert RJ, Natoli JL, Gano A, Badamgarav E, Buist AS, Mannino DM. Global burden of COPD: systematic review and meta-analysis. Eur Respir J. 2006;28:523-32.

5 Miravitlles M, Soriano JB, García-Río F, Muñoz L, Duran-Tauleria E, Sanchez G, Sobradillo V, Ancochea J. Prevalence of COPD in Spain: impact of undiagnosed COPD on quality of life and daily life activities. Thorax. 2009;64:863-8.

6 Hill K, Goldstein RS, Guyatt GH, Blouin M, Tan WC, Davis LL, Heels-Ansdell DM, Erak M, Bragaglia PJ, Tamari IE, Hodder R, Stanbrook MB. Prevalence and underdiagnosis of chronic obstructive pulmonary disease among patients at risk in primary care. CMAJ. 2010;182:673-8.

7 Garcia-Aymerich J, Escarrabill J, Marrades RM, Monsó E, Barreiro E, Antó JM; EFRAM Investigators. Differences in COPD care among doctors who control the disease: general practitioner vs. pneumologist. Respir Med. 2006;100:332-9.

8 Monteagudo M, Rodriguez-Blanco T, Parcet J, Peñalver N, Rubio C, Ferrer M, Miravitlles M. Variabilidad en la realización de la espirometría y sus consecuencias en el tratamiento de la EPOC en Atención Primaria. Arch Bronconeumol. 2011;47:226-33.

9 Walters JA, Walters EH, Nelson M, Robinson A, Scott J, Turner P, Wood-Baker R. Factors associated with misdiagnosis of COPD in primary care. Prim Care Respir J. 2011;20:396-402.

10 Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet. 2009;374:721-32.

11 Schirnhofer L, Lamprecht B, Firlei N, Kaiser B, Buist AS, Halbert RJ, Allison MJ, Studnicka M. Using Targeted Spirometry to Reduce Non-Diagnosed Chronic Obstructive Pulmonary Disease. Respiration. 2010 Aug 19. [Epub ahead of print]

12 Naberan K, De la Roza C, Lamban M, Gobartt E, Martín A, Miravitlles M. Utilización de la espirometría en el diagnóstico y tratamiento de la EPOC en atención primaria. Arch Bronconeumol. 2006;42:638-44.

13 Walker PP, Mitchell P, Diamantea F, Warburton CJ, Davies L. Effect of primary-care spirometry on the diagnosis and management of COPD. Eur Respir J. 2006;28:945-52.

14 Derom E, van Weel C, Liistro G, Buffels J, Schermer T, Lammers E, Wouters E, Decramer M. Primary care spirometry. Eur Respir J. 2008;31:197-203.

15 Walters JA, Hansen EC, Johns DP, Blizzard EL, Walters EH, Wood-Baker R. A mixed methods study to compare models of spirometry delivery in primary care for patients at risk of COPD. Thorax. 2008;63:408-14.

16 Lavis JN, Permanand G, Oxman AD, Lewin S, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP) 13: Preparing and using policy briefs to support evidence-informed policymaking. Health Res Policy Syst. 2009;7 Suppl 1:S13.

17 Tresserras R. Planificación según prioridades de salud. Criterios de planificación relacionados con los Planes Directores. Med Clin (Barc). 2008;131(Supl 4):42-6.

18 Molina París J. Espirometría en atención primaria. Una necesidad inexcusable. Aten Primaria 2004;34:333-5.

19 Hueto J, Cebollero P, Pascal I, Cascante JA, Eguía VM, Teruel F, Carpintero M. La espirometría en atención primaria en Navarra. Arch Bronconeumol. 2006;42:326-31.

20 Pellicer Císcar C, Soler Cataluña JJ, Andreu Rodríguez AL, Bueso Fabra J; en representación del Grupo EPOC de Sociedad Valenciana de Neumología. Calidad del diagnóstico de enfermedad pulmonar obstructiva crónica en el ámbito hospitalario..Arch Bronconeumol. 2010;46:64-9.

21 Damarla M, Celli BR, Mullerova HX, Pinto-Plata VM. Discrepancy in the use of confirmatory tests in patients hospitalized with the diagnosis of chronic obstructive pulmonary disease or congestive heart failure. Respir Care. 2006;51:1120-4.

22 Burgos F. La espirometría forzada de calidad en Atención Primaria, impacto en el tratamiento de la EPOC. Arch Bronconeumol. 2011;47:224-5.

23 Derom E, van Weel C, Liistro G, Buffels J, Schermer T, Lammers E, Wouters E, Decramer M. Primary care spirometry. Eur Respir J. 2008;31:197-203.

24 Clotet J, Gómez-Arbonés X, Ciria C, Albalad JM. La espirometría es un buen método para la detección y el seguimiento de la EPOC en fumadores de alto riesgo en atención primaria. Arch Bronconeumol. 2004;40:155-9.

25 Lin K, Watkins B, Johnson T, Rodriguez JA, Barton MB; U.S. Preventive Services Task Force. Screening for chronic obstructive pulmonary disease using spirometry: summary of the evidence for the U.S. Preventive Services Task Force. Ann Intem Med. 2008;148:535-43.

26 U.S. Preventive Services Task Force. Screening for chronic obstructive pulmonary disease using spirometry: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2008;148:529-34.

27 Jordan RE, Lam KB, Cheng KK, Miller MR, Marsh JL, Ayres JG, Fitzmaurice D, Adab P. Case finding for chronic obstructive pulmonary disease: a model for optimising a targeted approach. Thorax. 2010;65:492-8.

28 Escarrabill J, Roger N, Burgos F, Giner J, Molins A, Tresserras R, en nombre del Grupo de Función Pulmonar y del equipo directivo del PDMAR. Diseño de un programa de formación básico para conseguir espirometrías de calidad. Educ Med 2012;15:1575-1813.

29 Roger N, Burgos F, Giner J, Rosas A, Tresserras R, Escarrabill J. Encuesta de utilización de la función pulmonar en los hospitales públicos de Cataluña en 2009. Arch Bronconeumol 2013 (en prensa).

30 Eaton T, Withy S, Garrett JE, Mercer J, Whitlock RM, Rea HH. Spirometry in primary care practice: the importance of quality assurance and the impact of spirometry workshops. Chest. 1999;116:416-23.

31 D'Urzo AD, Tamari I, Bouchard J, Jhirad R, Jugovic P. Limitations of a spirometry interpretation algorithm. Can Fam Physician. 2011;57:1153-6.

32 Miravitlles M, de la Roza C, Naberan K, Lamban M, Gobartt E, Martin A. Use of spirometry and patterns of prescribing in COPD in primary care. Respir Med. 2007;101:1753-60.

33 Schermer TR, Akkermans RP, Crockett AJ, van Montfort M, Grootens-Stekelenburg J, Stout JW, Pieters W. Effect of e-learning and repeated performance feedback on spirometry test quality in family practice: a cluster trial. Ann Fam Med. 2011;9:330-6.

34 Pérez-Padilla R, Vázquez-García JC, Márquez MN, Menezes AM; PLATINO Group. Spirometry quality-control strategies in a multinational study of the prevalence of chronic obstructive pulmonary disease. Respir Care. 2008;53:1019-26.

35 Burgos F. ¿Son compatibles la calidad y el uso extensivo de la espirometría? Arch Bronconeumol. 2006;42:311-3.

36 Castillo D, Guayta R, Giner J, Burgos F, Capdevila C, Soriano JB, Barau M, Casan P; FARMAEPOC group. COPD case finding by spirometry in high-risk customers of urban community pharmacies: a pilot study. Respir Med. 2009;103:839-45.

37 Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo Shvo A. HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-9.

38 Salas T, Rubies C, Gallego C, Muñoz P, Burgos F, Escarrabill J. Requerimientos técnicos de los espirómetros para garantizar el acceso a una espirometria de calidad. Arch Bronconeumol. 2011;47:466-9.

39 Burgos F, Disdier C, Lopez de Santamaria E, Galdiz B, Roger N, Rivera ML, Hervas R, Durán E, Garcia-Aymerich J, Roca J and the Spir@p group. Telemedicine enhances Quality of Forced Spirometry in Primary Care. Eur Respir J 2012; 39: 1313–1318.

40 Dales RE, Vandemheen KL, Clinch J, Aaron SD. Spirometry in the primary care setting:influence on clinical diagnosis and management of airflow obstruction. Chest. 2005;128:2443-7.

Puntos clave

Lo conocido del tema

- Las enfermedades respiratorias crónicas representan un problema da salud muy importante pero existe un infradiagnóstico considerable.
- La espirometría es la exploración fundamental en el diagnóstico de estas enfermedades, y es conocida su utilización escasa, muy especialmente en el ámbito de la atención primaria.
- Un análisis detallado sobre la accesibilidad y utilización de esta exploración en los centros de atención primaria de todo un territorio, es necesario para poder diseñar estrategias de mejora en la atención a estos pacientes.

Qué aporta este estudio

- La accesibilidad a la espirometría en los centros de atención pri maria es elevada, lo que supone un punto fuerte en las posibilidades de mejorar el diagnóstico y seguimiento de los pacientes respiratorios crónicos.
- Algunas áreas de mejora son el aumento del número de exploraciones, la estandarización de la formación de los profesionales, la interoperabilidad entre los datos de los espirómetros y los sistemas de información de las historias clínicas electrónicas, y el control de calidad sistemático.
- Los equipos de atención primaria manifiestan en general una prioridad alta a la mejora del proceso de las espirometrías, lo que supone una oportunidad para incidir en los puntos débiles detectados y mejorar los resultados en salud.

Sixth study

Design of a basic training program to get quality spirometry.

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Abstract

Introduction Forced spirometry (FS) is a simple and noninvasive test to assess lung function. Obtaining high quality FS requires training, appropriate technical conditions (calibration, maintenance and availability of equipment), and patient cooperation. Several studies have found professional training deficits related to a high turnover in the same place, the lack of systematic training when new professionals performing spirometry are incorporated and the lack of periodic evaluation of responsibilities.

Materials and methods The Master Plan for Respiratory Diseases (PDMAR) has designed a minimum mixed practical/theoretical training program (16 hours) based on the training program of the National Institute for Occupational Safety and Health and the European Respiratory Society initiatives (HERMES). In 2010, 13 courses have been offered to 307 professionals.

Results During the year 2010, we organized a total of 13 training courses with a standardized program. Eleven courses were general, one was focused on pediatrics and another was a "Train the Trainer Program" course. In total, 307 professionals participated: nurses (68%), physicians (2%), pharmacists (21%), pediatric nurses (8%) and other (1%). The mean score at the beginning of the course was of 5 ± 2; 37% of the students had an initial score lower than 5 points. At the end of the training course the evaluation was repeated, resulting in a score of 8 ± 2 points, with only 15% of the students obtaining less than 5 points. The differences observed between baseline and post-assessment of FS knowledge were statistically significant ($p < 0.001$).

Conclusions Training must be organized on a decentralized and territorial basis in order to ensure access for all professionals performing spirometry. Moreover, a quality FS will only be achieved when all key components are integrated (training, technical aspects and interpretation) which requires interoperability between different levels of care.

ORIGINAL

Diseño de un programa de formación básico para conseguir espirometrías de calidad

Joan Escarrabill, Núria Roger, Felip Burgos, Jordi Giner, Ainhoa Molins, Ricard Tresserras,
en nombre del Grupo de Función Pulmonar y del equipo directivo del PDMAR

Introducción. La espirometría forzada es una manera sencilla y no invasiva de valorar la función pulmonar. La obtención de una espirometría de calidad requiere formación, condiciones técnicas adecuadas (calibración, mantenimiento y ubicación del aparato) y colaboración del paciente. Diversos trabajos han constatado déficits formativos de los profesionales, relacionados en parte con la elevada rotación en un mismo puesto, la falta de sistemática en la incorporación de nuevos profesionales que realizan espirometrías y la ausencia de planes de evaluación periódica de competencias.

Materiales y métodos. En el marco del Plan Director de Enfermedades del Aparato Respiratorio (PDMAR) se ha diseñado un programa formativo mínimo teórico-práctico de 16 horas de duración, basado en el programa de formación del National Institute for Occupational Safety and Health y de las iniciativas que surgen en el marco de la European Respiratory Society. Durante el año 2010 se realizaron 13 cursos en los que participaron 307 profesionales.

Resultados. Las diferencias observadas entre la evaluación de conocimientos previos y la evaluación final fue estadísticamente significativa ($p < 0{,}001$).

Conclusiones. La formación debe organizarse de modo descentralizado y con base territorial con el fin de garantizar el acceso de todos los profesionales que deben realizar espirometrías. La espirometría de calidad únicamente podrá conseguirse si se integran todos los elementos clave (formación, aspectos técnicos e interpretación), por lo que es imprescindible la interoperabilidad entre los diferentes ámbitos asistenciales.

Palabras clave. Espirometría. Espirometría de calidad. Formación.

Design of a basic training program to get quality spirometry

Introduction. The spirometry is a simple and noninvasive test to assess lung function. Obtaining a spirometry of quality requires training, appropriate technical conditions (calibration, maintenance and location of the device), and patient cooperation. Several studies have found professional training deficits related to a high turnover in the same place, the lack of systematic training when new professionals performing spirometry are incorporated and the lack of competences' periodic evaluation.

Materials and methods. The Master Plan for respiratory diseases (PDMAR) has designed a minimum practical/theoretical training program (16 hours) based on the training program of the National Institute for Occupational Safety and Health and the European Respiratory Society initiatives. In 2010, 13 courses have been offered to 307 professionals.

Results. The differences observed between the initial assessment and post evaluation knowledge was statistically significant ($p < 0.001$).

Conclusions. Training must be organized in a decentralized and territorial basis in order to ensure access for all professionals performing spirometry. Moreover, a spirometry of quality will only be achieved when all key components are integrated (training, technical aspects and interpretation) which requires interoperability between different levels of care.

Key words. Lung function test. Spirometry of quality. Training.

Introducción

El impacto de las enfermedades respiratorias en nuestro medio resulta muy elevado tanto desde el punto de vista de la mortalidad (tercera causa de muerte) [1] como en lo que se refiere al consumo de recursos (en nuestro medio causan el 10% de los ingresos hospitalarios y comportan el gasto de alrededor del 8,5% del presupuesto total del Servei Català de la Salut) [2]. La enfermedad pulmonar obstructiva crónica (EPOC) afecta al 10% de personas de más de 40 años [3,4] y constituye la afectación respiratoria no neoplásica con mayor carga asistencial.

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Las enfermedades respiratorias pueden diagnosticarse mediante una prueba no invasiva y de bajo coste: la espirometría forzada. Existe un amplio consenso sobre la estandarización de la prueba [5,6], pero como su realización requiere la colaboración del paciente, los resultados obtenidos son muy variables. Para conseguir una prueba de calidad se requiere disponer de aparatos fiables y calibrados, un ambiente apropiado, profesionales entrenados y pacientes adecuadamente informados y dispuestos a colaborar. Naberan et al [7] muestran que la falta de entrenamiento de los profesionales es un factor muy importante en el número y calidad de las espirometrías realizadas en atención primaria. Hueto et al [8] observan que en Navarra, a pesar de que la mayor parte de los centros de atención primaria tienen espirómetro, el 22% no lo utilizan. Este hecho no quiere significar que la espirometría en la atención primaria no sea posible [9,10]. Uno de los problemas más frecuentes, además de los déficits formativos, es el alto grado de rotación en los puestos de trabajo de los profesionales de enfermería entrenados.

El infradiagnóstico constituye uno de los problemas más graves en el manejo de las enfermedades respiratorias, especialmente de la EPOC [11], que junto al 'mal diagnóstico' [12,13] se observa incluso en el medio hospitalario [14]. La reducción del infradiagnóstico y el diagnóstico apropiado requieren intervenciones específicas, pero sobre todo garantizar el acceso a una espirometría de calidad [15-17].

El Departament de Salut de la Generalitat de Catalunya se sirve de los planes directores [18] para acercar los planteamientos estratégicos a los operativos con el fin de mejorar la atención al paciente. En este contexto, uno de los objetivos prioritarios del Plan Director de Enfermedades del Aparato Respiratorio (PDMAR) es garantizar al clínico el acceso a una espirometría de calidad independientemente del ámbito asistencial en el que trabaje [19]. Dado que se ha constatado el déficit formativo de muchos profesionales, parece razonable plantearse el diseño de un programa formativo general, entendiéndolo como una estrategia para conseguir la espirometría de calidad.

Materiales y métodos

La propuesta formativa se ha diseñado a partir del programa de formación del National Institute for Occupational Safety and Health (NIOSH) [20] y de las iniciativas que surgen en el marco de la European Respiratory Society [21]. La formación básica debe comprender aspectos teóricos y prácticos en un formato de cursos de 2-4 días, en función de la distribución de las clases. A través de un grupo de trabajo multidisciplinar se ha consensuado un programa teórico-práctico de 16 horas que se recomienda desarrollar a lo largo de dos días consecutivos. Los contenidos del programa se resumen en la tabla.

Los organizadores de los cursos recibieron, junto al programa, el desarrollo de los contenidos en versión PowerPoint, para que pudieran adaptarlos a sus necesidades.

Resultados

Durante el año 2010 se acreditaron 13 cursos de formación que siguieron el programa formativo diseñado en el marco del PDMAR. Once cursos fueron 'generales' (según el programa descrito en la tabla), uno se centró en pediatría y otro fue un curso de 'formación de formadores'. En total participaron 307 profesionales: enfermeras (68%), médicos (2%), farmacéuticos (21%), enfermeras pediátricas (8%) y otros (1%).

Valoración de conocimientos

Los asistentes a los cursos realizaron una evaluación inicial de conocimientos mediante 10 preguntas sobre aspectos básicos de la realización de la espirometría, que debían responder antes de iniciar el curso.

La media de puntos obtenida fue de 5 ± 2; el 37% de los alumnos alcanzó una puntuación inferior a 5 puntos.

Al final del curso se realizó una nueva evaluación con el mismo cuestionario, al cual se añadieron cinco preguntas más. El resultado obtenido (sobre 10 puntos) fue de 8 ± 2 puntos y únicamente el 15% de los alumnos obtuvo una puntuación inferior a 5 puntos. Las diferencias observadas entre la puntuación inicial y la final fueron estadísticamente significativas ($p < 0{,}001$).

Valoración de los alumnos

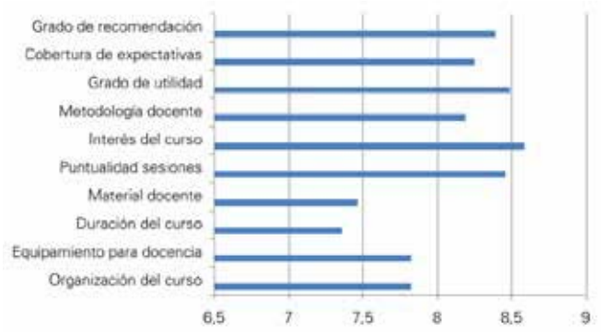
La valoración cualitativa de los cursos se resume en la figura.

Las puntuaciones más bajas en los aspectos organizativos y de calidad del material se relacionan con las valoraciones de los primeros cursos, en los que todavía se utilizaban materiales provisionales. A partir del cuarto curso, en el que ya se dispuso del material definitivo, las valoraciones medias fueron superiores a 8,7.

Tabla. Contenidos del programa.

		Contenido	Duración
Módulo 1	Anatomía y fisiología pulmonar relacionada con la espirometría	Sistema respiratorio: aspectos básicos de anatomía y fisiología Mecanismos de la respiración: la bomba respiratoria, aspectos básicos de la mecánica respiratoria	1,5 h
Módulo 2	Historia de la espirometría. La espirometría en neumología	Breve reseña histórica de la espirometría. La espirometría en las normativas de las enfermedades respiratorias (asma y EPOC)	0,5 h
Módulo 3	Aspectos básicos de la espirometría	Definición de espirometría Tipos de espirómetro Cómo hacen las medidas Representación de la espirometría Volumen/tiempo Flujo/volumen Alteraciones funcionales pulmonares (obstrucción y no obstrucción) en la espirometría Control y calibración de los espirómetros	1,0 h
Módulo 4	Técnica de la espirometría I	Indicaciones y limitaciones de la espirometría Valores de referencia Formas de medición de los parámetros observados respecto a la referencia Preparación del sujeto para realizar la espirometría Instrucciones Realización de la prueba Criterios de aceptabilidad y reproducibilidad de las maniobras Número de maniobras a realizar	1,0 h
Módulo 5	Técnica de la espirometría II	¿Qué hay que mirar de cada maniobra? Gráfica Números Inicio de la maniobra, extrapolación retrógrada Transcurso de la maniobra Final de la maniobra Maniobra inspiratoria Utilización de los rangos de referencia (LMN, LLN)	1,0 h
Módulo 6	Control de calidad	Componentes de un programa de control de calidad Verificaciones de la calibración y otras medidas de control de calidad de los equipos Contaminación de los equipos y control de las infecciones	1,0 h
Módulo 7	Práctica en la espirometría	Práctica conjunta con todos los asistentes. Realización de espirometrías en formato de *rol-play* con diferentes circunstancias Práctica en grupos pequeños. Práctica donde se hacen espirometrías a todos los participantes	5,0 h
Módulo 8	Valoración de la calidad de la espirometría. Sesión práctica para trabajar	Clasificación de la espirometría Errores más frecuentes: del sujeto y del técnico Valoración de les maniobras	1,0 h
Módulo 9	Espirometría en niños		0,5 h
Módulo 10	Otras aplicaciones de la espirometría	Valoración de les maniobres inspiromètricas Diferencia entre los resultados de la espirometría y de las medidas del flujo máximo (PFR) Prueba broncodilatadora Realización Valoración Pruebas de provocación bronquial Otras aplicaciones	1,0 h
Módulo 11	Interpretación de la espirometría	Sesión práctica en la que se valoran conjuntamente los aspectos gráficos y numéricos de las maniobras espirométricas	2,0 h
Módulo 12	Valoración final		0,5 h

Figura. Valoración cualitativa de los cursos.



Discusión

La propuesta formativa es factible. En ningún caso el curso propuesto se debió anular por problemas técnicos, aunque en algunos casos desde el PDMAR se colaboró facilitando el contacto con el profesorado experto.

Este tipo de formación plantea tres problemas importantes:

– Si los cursos se ofrecen de una manera espontánea es poco probable que se produzca una cobertura homogénea del territorio.
– Se requiere la implicación de los proveedores de servicios sanitarios para garantizar que las personas preparadas serán las que se destinarán a los lugares de trabajo en los que se realizan las espirometrías (lo cual no quiere decir que hagan espirometrías de una manera exclusiva).
– La formación básica no garantiza el mantenimiento de las habilidades, especialmente en los casos en los que los profesionales realizan pocas pruebas (o las realizan de una manera intermitente) [22].

En este sentido, desde el PDMAR se trabaja para que el Servei Català de la Salut incluya en el contrato de servicios la formación en espirometría, promoviendo la realización de cursos en los territorios donde todavía no se ha realizado esta formación.

La formación de profesionales que han de realizar espirometrías debería considerar estas características:

– Reglada.
– Descentralizada.
– Con un gran componente práctico.
– Con cobertura territorial.
– Debe contemplar la recertificación (o revalidación de competencias) [23].
– Formación continuada para mantener la calidad y programas de autocontrol de lo que cada uno sabe (programa que de una manera anónima permita contrastar los conocimientos personales).

Estos objetivos no se conseguirán con programas de formación puntuales y centralizados. Es necesario promover la formación de formadores en cada territorio para que puedan asumir esta perspectiva más amplia de la formación, que va más allá de la realización de cursos.

Steenbruggen et al [24] señalan que la formación es un elemento crucial para mejorar la práctica de la espirometría, pero en ningún caso es el objetivo final. Borg et al [22] presentan datos acerca de que la formación de 14 horas no es suficiente para garantizar espirometrías de calidad a los cinco meses de la formación y ponen énfasis en la necesidad de efectuar una revisión activa de las espirometrías para el mantenimiento de las competencias. No tendría demasiado sentido separar la formación de la calidad. Formamos profesionales para que sean capaces de obtener espirometrías de calidad. Ese es el objetivo: el acceso fácil por parte del clínico a espirometrías de calidad. Por lo tanto, los proveedores de servicios deberían promover sistemas de financiación que garantizaran la cobertura de las necesidades (es decir, incrementar el número de espirometrías) con garantías de calidad (pagar por pruebas bien hechas).

Los elementos para conseguir una espirometría de calidad son:

– Disponer de aparatos fiables y calibrados.
– Programas formativos adecuados para los profesionales que deben realizar espirometrías y que incluyan: formación básica, formación avanzada, formación específica para la edad pediátrica (incluida en el módulo general y, además, mediante un módulo específico pediátrico), formación de formadores y programas de revalidación de competencias.
– Los programas formativos deben incluirse en la compra de servicios a los proveedores.
– La interoperabilidad entre los distintos ámbitos asistenciales es imprescindible para permitir el control de calidad.
– Formación para la correcta interpretación de resultados [25].

– Formulación de objetivos individuales que incentiven a los profesionales a la realización de espirometrías de calidad: porcentaje de pacientes con EPOC y otras enfermedades respiratorias como el asma, en los que se ha practicado espirometría en un periodo dado.
– Definición de los criterios mínimos que deben reunir los centros sanitarios para realizar correctamente las espirometrías: identificación de los responsables de la calibración y el mantenimiento, condiciones mínimas del lugar donde se realizan las espirometrías y capacitación de los profesionales que deben realizar espirometrías.

Un tema abierto al debate se centra en la organización del control de calidad. En los estudios multicéntricos está claro que la mejor opción es un control de calidad centralizado [26], pero se requieren más estudios para poder aplicar este criterio a la práctica cotidiana.

En un futuro inmediato, para conseguir estos objetivos deberán utilizarse tecnologías de la información y de la comunicación que permitan la formación *online* y proporcionen soporte a la toma de decisiones, tanto organizativas y técnicas (calibración o control de calidad, por ejemplo) como asistenciales (indicación e interpretación).

Bibliografía

1. Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJ. Global and regional burden of disease and risk factors, 2001: systematic analysis of population health data. Lancet 2006; 367: 1747-57.
2. Gibert R, Brosa M. Avaluació de la participació del plans directors en la despesa sanitària del CatSalut. Estudis d'Economia de la Salut. Barcelona: Generalitat de Catalunya, Departament de Salut; 2006.
3. Halbert RJ, Natoli JL, Gano A, Badamgarav E, Buist AS, Mannino DM. Global burden of COPD: systematic review and meta-analysis. Eur Respir J 2006; 28: 523-32.
4. Miravitlles M, Soriano JB, García-Río F, Muñoz L, Durán-Taulería E, Sánchez G, et al. Prevalence of COPD in Spain: impact of undiagnosed COPD on quality of life and daily life activities. Thorax 2009; 64: 863-8.
5. Ferguson GT, Enright PL, Buist AS, Higgins MW. Office spirometry for lung health assessment in adults: a consensus statement from the National Lung Health Education Program. Chest 2000; 117: 1146-61.
6. Levy ML, Quanjer PH, Booker R, Cooper BG, Holmes S, Small I; General Practice Airways Group. Diagnostic spirometry in primary care: proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations –a General Practice Airways Group (GPIAG) document, in association with the Association for Respiratory Technology & Physiology (ARTP) and Education for Health. Prim Care Respir J 2009; 18: 130-47.
7. Naberan K, De la Roza C, Lamban M, Gobartt E, Martín A, Miravitlles M. Utilización de la espirometría en el diagnóstico y tratamiento de la EPOC en atención primaria. Arch Bronconeumol 2006; 42: 638-44.
8. Hueto J, Cebollero P, Pascal I, Cascante JA, Eguía VM, Teruel F, et al. Spirometry in primary care in Navarre, Spain. Arch Bronconeumol 2006; 42: 326-31.
9. Poels PJ, Schermer TR. Good wine needs no bush: quality spirometry in a primary care setting is possible. Arch Bronconeumol 2007; 43: 473.
10. Yawn BP, Enright PL, Lemanske RF Jr, Israel E, Pace W, Wollan P, et al. Spirometry can be done in family physicians' offices and alters clinical decision in management of asthma and COPD. Chest 2007; 132: 1162-8.
11. Soriano JB, Ancochea J, Miravitlles M, García-Río F, Durán-Taulería E, Muñoz L, et al. Recent trends in COPD prevalence in Spain: a repeated cross-sectional survey 1997-2007. Eur Respir J 2010; 36: 758-65.
12. Menezes AM, Pérez-Padilla R, Jardim JR, Muiño A, López MV, Valdivia G, et al; PLATINO Team. Chronic obstructive pulmonary disease in five Latin American cities (the PLATINO study): a prevalence study. Lancet 2005; 366: 1875-8.
13. Proyecto Latinoamericano de Investigación en Obstrucción Pulmonar (PLATINO). URL: http://www.platino-alat.org. [02.02.2011].
14. Pellicer-Císcar C, Soler-Cataluña JJ, Andreu-Rodríguez AL, Bueso-Fabra J; en representación del Grupo EPOC de la Sociedad Valenciana de Neumología. Calidad del diagnóstico de enfermedad pulmonar obstructiva crónica en el ámbito hospitalario. Arch Bronconeumol 2010; 46: 64-9.
15. Clotet J, Gómez-Arbonés X, Ciria C, Albalad JM. Spirometry is a good method for detecting and monitoring chronic obstructive pulmonary disease in high-risk smokers in primary health care. Arch Bronconeumol 2004; 40: 155-9.
16. Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet 2009; 374: 721-32.
17. Schirnhofer L, Lamprecht B, Firlei N, Kaiser B, Buist AS, Halbert RJ, et al. Using targeted spirometry to reduce non-diagnosed chronic obstructive pulmonary disease. Respiration 2011; 81: 476-82.
18. Tresserras R. Planificación según prioridades de salud. Criterios de planificación relacionados con los planes directores. Med Clin (Barc) 2008; 131 (Supl 4): 42-6.
19. Levy ML, Quanjer PH, Booker R, Cooper BG, Holmes S, Small I. Diagnostic spirometry in primary care: proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations –a General Practice Airways Group (GPIAG). Prim Care Respir J 2009; 18: 130-47.
20. Centers for Disease Control and Prevention. Spirometry Training Program. URL: http://www.cdc.gov/niosh/topics/spirometry/training.html. [01.03.2011].
21. Miller MR, Crapo R, Hankinson J, Brusasco V, Burgos F, Casaburi R, et al; ATS/ERS Task Force. General considerations for lung function testing. Eur Respir J 2005; 26: 153-61.
22. Borg BM, Hartley MF, Fisher MT, Thompson BR. Spirometry training does not guarantee valid results. Respir Care 2010; 55: 689-94.
23. Derom E, Van Weel C, Liistro G, Buffels J, Schermer T, Lammers E, et al. Primary care spirometry. Eur Respir J 2008; 31: 197-203.
24. Steenbruggen I, Mitchell S, Severin T, Palange P, Cooper BG; on behalf of the Spirometry HERMES Task Force. Harmonising spirometry education with HERMES: training a new generation of qualified spirometry practitioners across Europe. Eur Respir J 2011; 37: 479-81.
25. Pellegrino R, Viegi G, Brusasco V, Crapo RO, Burgos F, Casaburi R, et al. Interpretative strategies for lung function tests. Eur Respir J 2005; 26: 948-68.
26. Pérez-Padilla R, Vázquez-García JC, Márquez MN, Menezes AM; PLATINO Group. Spirometry quality-control strategies in a multinational study of the prevalence of chronic obstructive pulmonary disease. Respir Care 2008; 53: 1019-26.

Seventh study

HERMES Spirometry: the European Spirometry Driving Licence.

B.G. Cooper, I. Steenbruggen, S. Mitchell, T. Séverin, E. Oostveen, *F. Burgos*, H. Matthys, H. Normand, J. Kivastik, J. Leuppi, M. Flezar, M. Agnew,O. Pedersen, S. Sorichter, V. Brusasco, W. Tomalak, P. Palange.

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HERMES Spirometry: the European Spirometry Driving Licence

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Introduction

Spirometry testing is the most widely practiced, most common and adaptable of all lung function tests and spirometers are used as a key instrument in the diagnosis of patients with respiratory disease [1]. As a leading cause of death worldwide responsible for some 9.4 million deaths [2], and further increases predicted by 2020, the management of lung disease becomes even more dependent on spirometry testing. Yet evidence of widespread under-diagnosis [3] and, as a consequence, reduced quality of life and premature death [4] present cause for concern.

The grim reality evident in the presented studies highlights a real lack of training [5], under-utilisation of spirometers [6] and diagnosis based on inaccurate results [7]. It is reported that chronic obstructive pulmonary disease (COPD), the most prevalent of the lung diseases, is under-diagnosed in 75% of cases [3]. The outcome of delayed diagnosis deters effective management and treatment, which ultimately aims to relieve symptoms, prevent disease progression, improve health status and prevent premature death [4]. While educational modalities were introduced at a national level to train spirometry practice in some European countries, a survey carried out by the European Respiratory Society (ERS) in 2008 confirms that no formal training in, assessment of, or qualification in spirometry takes place in many other countries. Using the HERMES project framework (Harmonised Education of Respiratory Medicine in European Specialties), a new Spirometry initiative aspires to train and qualify healthcare professionals best able to deliver high-quality spirometry. The potential benefits of standardised educational documents and training in the practice of spirometry are real and significant, strengthening patient care and improving quality of life for respiratory disease patients.

HERMES

Begun in 2005, the value of the HERMES initiative is that it provides consensus-based standards and indicators to improve quality and practice of education and healthcare, and establishes a guide for teachers and students of sub-speciality respiratory medicine. To date, the Adult HERMES and Paediatric HERMES projects have produced internationally recognised educational documents and activities. If we consider the nature of these projects, it is clear that both the Adult and Paediatric projects appeal to a specific target audience, specialising in precise fields of respiratory medicine. The very essence of the Spirometry HERMES project is, in fact, different. For this purpose, a new proposed structure of four key development areas shall be implemented to ensure all facets of the educational cycle are covered (fig. 1)

1. Complete Training Programmes
2. Guidelines for certification of ERS Spirometry Training Programmes
3. Development of educational materials including training manuals, supporting online modules, videos and a knowledge test for part I
4. Assessment guidelines, production of assessments and assessment criteria to test Spirometry Theory and Spirometry Practice

HERMES syllabus link: module D.1

DOI: 10.1183/20734735.026310

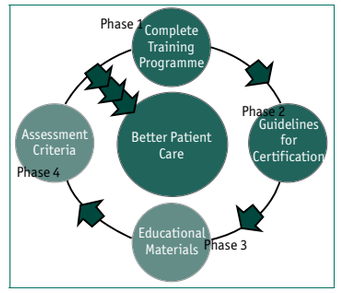

Figure 1
The four key areas of HERMES lead to better patient care.

This process of establishing ERS educational standards in spirometry are international in their development and actively overseen by an expert Task Force representing 13 countries across Europe (fig. 2). The very essence of the HERMES initiative is to offer structured support for educational reform to take place. Evolution of the HERMES ideology presupposes that each project phase recommends uniform educational criteria to be adopted and considered as best practice in training. Considering the statistical data confirming the gravity of lung disease worldwide, the mission of the HERMES spirometry project is to follow this intricate path to train and qualify health professionals to perform high-quality spirometry tests as well as increasing the number of accurate and repeatable spirometric measurements to be used in the diagnosis of patients with respiratory symptoms. The purpose of this publication is to present the outcome of the first two phases of the HERMES Spirometry Driving Licence project.

Figure 2

Historical background

Standardisation of spirometry [8], access to spirometers [4] and use of accurate and repeatable spirometry measurements [3] are requirements central to the diagnosis, management and treatment of lung diseases. The scale of the role spirometry plays in identifying patients at risk of disease or of perioperative pulmonary complications such as COPD, lung cancer, heart attack, stroke and asthma [9] dictates that the tools required to practice spirometry be given precedence within the medical arena. The available statistics echo the true reality that spirometers are underutilised due to absence of teaching practices [6], and there is an extensive call for educational reform in the training of spirometry within this medical domain [1, 3–7, 10].

If the aforementioned requirements to practice quality spirometry are considered, to some extent the ERS/American Thoracic Society 2005 Guidelines in Spirometry Practice and, in recent years, development of the spirometer, guaranteeing widespread distribution, offer some relief to spirometry practitioners. Yet, based on analysis of 14 countries within Europe, only four reported the opportunity to attend a spirometry training course approved by a professional body (fig. 3).

With the intention of producing a driving licence in spirometry for health professionals to reach competency level, the Task Force presents the first of the educational documents; Part I *Spirometry Knowledge and Skills,* Part II *Knowledge and Competence in Spirometry Measurement* (leading to the European Spirometry Driving Licence Level II) and *Guidelines for the Certification of ERS Spirometry Training Programmes.*

Methodology

The HERMES European Spirometry Driving Licence (ESDL) project was officially launched at the ERS Annual Congress in Berlin 2008 with the aim of harmonising training in spirometry throughout Europe to establish and raise

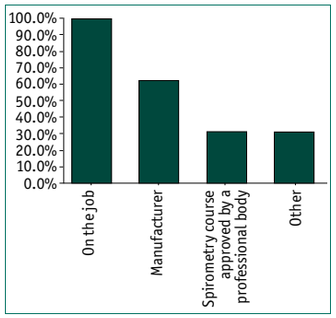

Figure 3

European standards in the skills required to qualify and practice as an expert in this field. Rationale for the project was justified following results of the ERS benchmark analysis carried out in 2008. As well as confirming a clear disconnect in spirometry training practices, insight into expectations of structure, duration, delivery and assessment that a spirometry training programme should possess were offered. Laying the foundations to move forward, the first step the Task Force would take was to produce a training programme outline utilising the well established consensus process, the Delphi technique [11].

Phase 1 – Development of the Training Programme Outline

Within the framework of the Delphi methodology, and following the steps taken by the HERMES giants, Adult and Paediatric, the Task Force began the process of designing knowledge items which should be included in a training programme for spirometry. A further panel of experts from 10 European countries was also identified as key contributors to project development. In line with the Delphi technique, the Task Force prepared a first survey round and received responses from 673 experts. The aim of this survey was to gather a larger representation from spirometry practitioners of both qualitative and quantitative data on the perceived skills required for training to endorse a qualification in spirometry practice.

At the ERS Annual Congress in 2009 in Vienna, results of the first survey round were presented during a plenary session including all Task Force and national respondents. High consensus levels for each of the items assume that the target of the survey was reached. With the inclusion of some new items and modification of existing items based on comments within the survey, a second Delphi round of 230 experts confirmed the final training programme outline which was approved by the Task Force in May 2010.

As the training programme items were now in place, a new process of developing rationale for training including the course aim, target audience, pre-requisites for training and teaching format would need to be developed. A skeleton structure utilising a number of references [12, 13], was presented to the Task Force in May 2010 and so began the final steps in the development of the European Spirometry Driving Licence Training Programme (fig. 4).

Phase 2 – Development guidelines for certification of ERS Spirometry Training Programmes document

A further output from this landmark May 2010 Task Force meeting was the generation of a number of operational issues relating to the Spirometry Training Programme. Questions surrounding venue specifications, trainer qualifications and minimum numbers of spirometry tests to be performed, only served to highlight imminent complexities that would need to be addressed.

Between May and the upcoming September 2010 Task Force meeting, the need to stipulate a

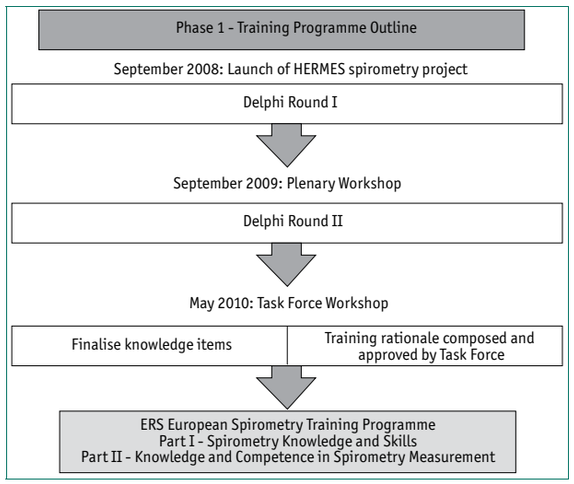

Figure 4
The first phase in the European Spirometry Driving Licence Training Programme.

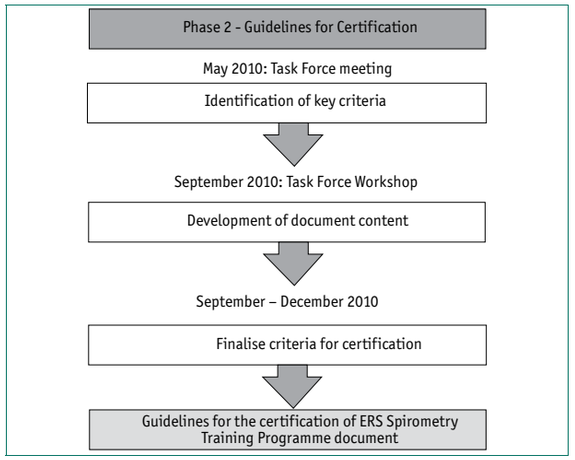

Figure 5
The second phase in the European Spirometry Driving Licence Training Programme.

robust structure including measurable elements and criteria to ensure best practices in training and dissemination of the ESDL became obvious.

Guided by the *Criteria for Accreditation of ERS European Training Centres in Adult Respiratory Medicine* document generated from the Adult HERMES Task Force [14], the framework provided fundamental standards for training programmes to follow. By September 2010, six sections were presented and approved and the *Guidelines for the certification of ERS Spirometry Training Programmes* document was established (fig. 5).

Results

If we consider the objective of the first two project phases to produce a training programme outline and the rationale and guidelines to launch a complete spirometry training programme, the presented documents symbolise the first challenge to lead this initiative toward its end goal, each constituting the minimum recommended criteria that training programmes should consist of for the training of spirometry at a European level.

Phase 1 – Development of the Training Programme Outline

Drafted by the Task Force during the first of their meetings, 47 knowledge items and skills were presented and included in the first Delphi round. Slight modifications and the addition of new items were made following the first Delphi. Following a second survey round, the training programme was agreed by the Task Force in May 2010, consisting of eight modules and 63 items including prerequisites for training. To ensure all components of an educational training programme were covered, and supported by the ERS education department, further development of the rationale for training was completed by the Task Force during the May meeting.

In order to train practically competent health professionals, it was necessary that the training programme be divided into two distinct training parts:

1. *Part I Spirometry Knowledge and Skills* covering important spirometry theory and demonstrate best practices in spirometry technique
2. *Part II Knowledge and Competence in Spirometry Measurement* will ensure participants perfect technique, consider pitfalls and errors in spirometric measurements and award a qualification to merit participants as practically competent to perform high quality spirometry tests

In order to prepare for Part II, the Task Force recognised the need to allow time for practical experience and first hand exposure between training programmes and so have stipulated in the guidelines that all participants must complete the *ERS Spirometry Workbook* before attending Part II.

Published documents on the complete Training Programme of both *Part I Spirometry Knowledge and Skills* and *Part II Knowledge and Competence in Spirometry Measurement* are the result of the first project phase.

Phase 2 – Development guidelines for accreditation of ERS Spirometry Training Programmes document

The objective of this phase was to generate a structured, simple and flexible model to allow dissemination of training across all health professional settings who practice and teach spirometry across Europe. Utilising specifications within the training programme outline, each of the six sections within the document lists the minimum measurable elements for training programmes to follow to qualify certification

and award ERS European Spirometry Driving Licence. In September 2010, the document sections were approved and a comprehensive document outlining *Guidelines for the certification of ERS Spirometry Training Programmes* was completed.

Discussion

The variety of HERMES initiatives are evolving based on an increasing demand for improved and systematic practices of education in specialist areas of respiratory medicine. Evidence of a current gap in training needs for medical practitioners merely offer conviction to the HERMES Task Forces and remind them of the need to supply this demand. The HERMES spirometry initiative is also the product of this inherent path, emerging from an evident disparity in training criteria in the training of spirometry. Yet producing, implementing and maintaining robust educational activities and documents in specialist medicine are not without challenges.

Challenges

Application and quality assurance

Ensuring all healthcare institutions demonstrate the ability to apply predetermined standards set out within the HERMES documents is embedded in complexity. The overarching goal of this project milestone, phase 2, was to produce a solid foundation of structured guidelines for certification of spirometry training programmes to follow. As the Task Force progresses through the project continuum, a new emphasis moves from documenting minimum criteria to application. In fact, the final section of the Guidelines for certification of ERS Spirometry Training Programmes was established to produce those procedures required for the certification process. For the first time, consideration of the approval body, the application process, the certification process and costs is realised, project success demands a vigorous, adaptable and inexpensive model.

To certify is to apply standards as a basis of quality assurance. Traditionally, accreditation or certification of educational programmes within the medical arena has been based on the well-established practice of site visitation [15]. However, site visitation is a resource-dependant process, the costs beared by the training centre and, as a consequence, too often excluding those unable to afford external and voluntary certification. The next stages will address this process of certification and it is the intention of the Task Force to publish *Section 7 Approval Process and Distribution of ESDL Certificates* at a later date which will employ new and diverse methods of quality assurance including preparation of standardised educational materials to be used during training, online training modules, and use of generic assessment methods all contributing as a means of quality control.

Dissemination of the European Spirometry Training Programme

Applying minimum standards not only offers guidance for trainers of spirometry to follow but also present an incentive to improve, or for some countries introduce, structured training and consequently dissemination of a European spirometry qualification. To accomplish success at this project step and indeed looking to future developments for the project, the initiative necessitates distribution to a wide audience of health professionals across a number of medical settings. Consequently, achievement demands educational documents which are simple, robust and adaptable. It is intended that the documents provide a guideline for training programmes of spirometry to follow and to allow flexibility across international, cultural and regional boundaries, which will allow delivery at local level. Support for ESDL trainers will be provided through standardised educational materials as well as a "Train-the-Trainer" course, which will be held each year at the ERS Annual Congress. Moreover, this HERMES project finds itself confronted with the fresh challenge of translation. A new wave of HERMES now looks towards distributing educational documents and activities to national delegates and respondents for translation. Reaching the intended audience requires coherence within ERS and across national societies.

Conclusion

Spirometry practitioners have the opportunity to take ownership to improve and measure their knowledge and practice of spirometry, emphasising commitment to education and value of attaining a European qualification. For the first time, harmonisation of training in spirometry offers an objective process for evaluation within Europe. With a training programme outline and

guidelines for certification of ERS training programmes now in place, the Task Force looks to putting theory into practice with a real focus on application. To facilitate a training model, the next project steps intend to design and utilise educational materials, online modules and assessment criteria aligned to concrete standards set out by the Task Force, further strengthening the value of the spirometry HERMES project.

The significance and impact of spirometry as a measure of global health and a predictor of morbidity and mortality resonate throughout the literature [16], and presuppose that spirometry testing receive priority within the medical arena. Yet evidence of a substantial lack of training and inconsistencies in standards across many European countries, there is most certainly scope to improve spirometry practice and reinforce quality patient care. At the core of this impending challenge, the Spirometry HERMES initiative attempts to produce consensus-based documents and guidelines fundamental to the delivery of best practices in spirometry training. It is hoped that project potential will be realised, establishing coherence across national societies, ERS members and all practitioners of spirometry. Building on the shoulders of the previous HERMES projects, with confidence the Spirometry HERMES Task Force takes the first step towards attaining their final mission: delivery of the best possible training to certify spirometry practitioners and improving quality health care for respiratory disease patients.

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References

1. Ferguson GT, Enright PL, Buist AS, *et al.* Office spirometry for lung health assessment in adults: a consensus statement from the National Lung Health Education Program. *Chest* 2000; 117: 1146–1161.
2. Loddenkemper R, Gibson GJ, Sibille Y. The Burden of Lung Disease, *In* European Lung White Book: The First Comprehensive Survey on Respiratory Health in Europe. Sheffield, European Respiratory Society/European Lung Foundation, 2003; pp. 2–13.
3. Derom E, Van Weel C, Liistro G, *et al.* Primary Care Spirometry. *Eur Respir J* 2008; 31: 197–203.
4. Rabe KF, Hurd S, Anzueto A, *et al.* Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease GOLD Executive Summary. *Am J Respir Crit Care* Med 2007; 176: 532–555.
5. Yawn BP, Enright PL, Lemanske RF Jr, *et al.* Spirometry can be done in family physicians' offices and alters clinical decision in management of Asthma and COPD. *Chest* 2007; 132: 1162–1168.
6. Bellia V, Pistelli R, Catalano F, *et al.* Quality control of spirometry in the elderly: The S.A.R.A. study: Salute Respiration nell'Anziano - Respiratory Health in the Elderly. *Am J Respir Crit Care Med* 2000; 161: 1094–1100.
7. Cleland J, Mackenzie M, Small I, *et al.* Management of COPD in Primary Care in North-East Scotland. *Scott Med J* 2006; 51: 10–14.
8. Miller MR, Hankinson J, Brusasco V, *et al.* Standardisation of spirometry. *Eur Respir J* 2005; 26: 319–338.
9. Petty TL. John Hutchinson's mysterious machine revisited. *Chest* 2002; 121: 219S–223S.
10. Townsend M, Hankinson J, Lindesmith L. Is my lung function really that good? Flow type spirometer problems that elevates test results. *Chest* 2004; 125: 1902–1909.
11. Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *J Adv Nurs* 2000; 32: 1008–1015.
12. Instructional Methods and the Clinical Learning Setting: An educational guide for the implementation of the Paediatric HERMES curriculum. JO Busari, et al. in press. 2010 *This document is a work in progress and should not be referenced unless and until it is approved and published. Until such time as this Editor's Note is removed, the inclusion of the above document is for informational purposes only.*
13. Talbot M. Monkey see, monkey do: a critique of the competency model in graduate medical education. *Medical Education* 2004; 38: 587–592.
14. R. Loddenkemper, T. Séverin, S. Mitchell, *et al.* Adult HERMES: criteria for accreditation of ERS European training centres in adult respiratory medicine. *Breathe* 2010; 7: 170–188.
15. Zach MS, *et al.* Paediatric respiratory training in Europe: syllabus and centres. *Eur Respir J* 2002; 20: 1587–1593.
16. Ferguson GT, Enright PL, Buist AS, *et al.* Office spirometry for lung health assessment in adults: a consensus statement from the national lung health education program. *Chest* 2000; 117: 1146–1161.

Eighth study

Technical Requirements of Spirometers in the Strategy for Guaranteeing the Access to Quality Spirometry.

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Special Article

Technical Requirements of Spirometers in the Strategy for Guaranteeing the Access to Quality Spirometry☆

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ABSTRACT

Access to quality spirometry is an essential objective in order to be able to minimize the underdiagnosis of respiratory diseases, especially that are most frequent, such as COPD and asthma. This objective can be reached in the short term, but it requires the simultaneous integration of different strategies: training of the health-care professionals who perform spirometry, definition of standards for the transmission of the information, technical requirements for acquiring apparatuses and the correct interpretation of the results.

This present study shows the use of standards for the electronic exchange of clinical information. In order to normalize the treatment of the data related with spirometry and to enable the exchange of information, we have used the standard CDA R2 (Clinical Document Architecture, Release 2) of HL7 (Health Level Seven), version 3. HL7 is a product by HL7 International, a non-profit organization that deals in the production of standards in the health-care setting in order to facilitate interoperability.

Furthermore, defining these standards is essential for ensuring that they are adopted by spirometer manufacturers. By means of this process, the base is set for facilitating access to spirometry at the health-care level, while at the same time it is a fundamental technical element for designing quality control programs of the explorations.

Requerimientos técnicos de los espirómetros en la estrategia para garantizar el acceso a una espirometría de calidad

Palabras clave:
Espirometría
Calidad
Interoperatibilidad
Pruebas de función pulmonar
Estándares

RESUMEN

El acceso a una espirometría de calidad es un objetivo imprescindible para poder minimizar el infradiagnóstico de las enfermedades respiratorias, especialmente en las más frecuentes como la EPOC y el asma. Este objetivo es alcanzable a corto plazo, pero requiere la integración simultánea de estrategias diversas: formación de los profesionales que deben realizar la espirometría, definición de estándares para la transmisión de la información, requerimientos técnicos en las adquisiciones de aparatos y la correcta interpretación de los resultados.

El presente trabajo muestra la utilización de estándares para el intercambio electrónico de información clínica. Para normalizar el tratamiento de los datos relacionados con la espirometría y permitir el intercambio de información se ha utilizado el estándar CDA R2 (Clinical Document Architecture, Release 2) de HL7 (Health Level Seven) versión 3. HL7 es un producto de HL7 international, una organización no lucrativa que se dedica a la producción de estándares en el ámbito de la salud para facilitar la interoperabilidad.

La definición de este estándar, además, es imprescindible para asegurar la adopción del mismo por parte de los fabricantes de espirómetros. Mediante este proceso se ponen las bases para facilitar el acceso a la espirometría desde todos los ámbitos asistenciales y, a su vez, es un elemento técnico fundamental para diseñar los programas de control de calidad de las exploraciones.

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Introduction

More than 150 years ago, John Hutchinson became interested in the value of the volume of air that humans could exchange with the environment.[1,2] Since then, spirometry (the systematic and standardized measurement of this capacity to mobilize air) has become a key piece in the detection, diagnosis, prognosis and the follow-up of respiratory diseases. Spirometry does not provide the etiologic diagnosis, but it enables us to observe the physiopathological basis of the process and in this manner to approximate the diagnosis by means of signs which are easy to detect: flow and volume.[3]

Although spirometry is a non-invasive test that is relatively easy to carry out, several studies give evidence of difficulties to access the test and the problems related with the quality of the data collected. In part, the problems related with spirometry are due to the fact that it is a test that requires complete patient cooperation. The expiration maneuver requires intensity, time and coordination in order to obtain measurable values with clinical significance. In order to achieve this, it is crucial for the professionals performing the test to be properly trained. But, moreover, it has been repeatedly observed that the availability of a spirometer does not guarantee its routine use.[4] In addition to its underuse, Monteagudo et al.[5] observed the incorrect register of spirometric data and their limited impact on treatment changes over the course of patient follow-up.

Despite everything, quality spirometry is a reachable objective, as has been demonstrated in epidemiological studies with different participating observers.[6] Therefore, it is possible to aspire to quality spirometry in all health-care settings and even in non-health-care settings, such as in the homes of patients themselves[7] and in pharmacies.[8]

One of the challenges of all health-care systems is the implementation of strategies that promote the change of clinical practices in accordance with the evidence available. The Health Department Directives (*Planes Directores del Departamento de Salud*)[9] intend to make decisions on strategic planning with technicians in order to improve the service provided. Thus, the Master Plan for Respiratory Diseases (*Plan Director de las Enfermedades Respiratorias*–PDMAR) was created in 2010, after a prior study of nearly two years, in order to improve the care of patients with respiratory diseases.

Since its inception, the PDMAR considered it as priority to guarantee the access to quality spirometry in all health-care settings. Quality spirometry is an essential tool for dealing with the problem of the underdiagnosis of respiratory diseases, especially chronic obstructive pulmonary disease (COPD).[10] A favorable element was the confirmation of the availability of spirometers in practically all primary care centers, but the problems described in the literature were likewise confirmed: little regulated training, rotation of the professionals, underuse of the spirometer and limited systematic quality control, both of the apparatuses as well as of the explorations carried out.

Based on the recommendations of experts, a specific workgroup, contributions of scientific societies and the evidence in the literature, these initial proposals for quality spirometry have been defined:

- From the outset, attempts made at promoting quality spirometry should be a group effort based on the participation of all the professionals involved, both from the specialized setting as well as from primary care.
- The training of the health-care professionals that perform spirometries is crucial and should be accompanied by management policies for the workplace that avoid excessive rotation.

Table 1
Key Elements for Achieving Quality Spirometry.

Elements	Actions
1. Precise and reliable local information	Surveys have been done about carrying out spirometries in hospitals and in primary care
2. Design a training program	Training program of a minimum of 16 h of theoretical and practical training, with a specific additional training for testing in pediatrics
3. Design of a training program for trainers	There, the objective is to have training offered in different regions and, in order to decentralize it, and it is necessary to train trainers.
4. Standardization of the values obtained by the spirometers	Creation of the CDA for spirometry and the guidelines for its implementation
5. Interoperability among different health-care settings	Design of projects for solution validation, with the collaboration among health-care centers, PDMAR, *Oficina d'Estàndards* and *Pla de digitalització de la imatge mèdica*
6. Design of a systematic control mechanism for spirometry	Standardization and interoperability are essential to guarantee quality control
7. Definition of the practical rules of organization and implementation of spirometry in the different health-care settings	These rules should include aspects of placement, conditions of the installation and use as well as the systemic control of the apparatuses
8. Training program for spirometry interpretation	Design of an on-line training program

- Quality control for spirometry implicates the standardization of the values obtained and the systematic analysis of the explorations. Both elements require communication technologies and guaranteed interoperability among the different apparatuses and the information systems of all the health-care settings.

Table 1 summarizes the actions that PDMAR promotes with the aim of providing quality spirometry.

Standarization

Promoted by the Office for Standards and Interoperability of the Catalonian Department of Health (*Oficina de Estándares e Interoperabilidad de TicSalut, Departamento de Salud*) and by the Plan for the Digitalization of Medical Images (*Plan para la Digitalización de la Imagen Médica del Departamento de Salud de la Generalitat de Cataluña*), standards have been created in order to achieve the normalization of a complete group of data related with spirometry. These standards have been based on version 3 of HL7, CDA R2. The CDA R2 (Clinical Document Architecture, Release 2) standard by HL7 (Health Level Seven) (version 3) is a product of HL7 International, a non-profitable organization that is dedicated to the production of standards in health care in order to facilitate interoperability. CDA[11] defines the structure of a clinical document and uses XML to label the different categories of information. XML is the standard for the structured information exchange between applications, regardless of the technological platform used. A CDA can be viewed from any computer using a web navigator. The CDA for spirometry includes the data of the patient, the information of the context of the test, the resulting clinical parameters, the flow-volume and volume-time charts as well as the original signal captured by the spirometer. Likewise, it includes data about the origin of the request obtained from the electronic medical files of the hospital or the health-care center. The clinical information is coded using SNOMED CT (Systematized Nomenclature of Medicine—Clinical Terms), which allows it to be processed

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automatically and incorporated into the patient medical files in a structured manner.

Interoperability

The Office for Standards and the Plan for Digitalization of the Department of Health have elaborated the guidelines for the implementation of the spirometry CDA in collaboration with the Master Plan for Respiratory Diseases (PDMAR).

The availability of the CDA for spirometry allows for information to be exchanged in a standard manner, making the interoperability between different health-care providers and settings possible, executing exploitation services with the data from the resulting standardized spirometry report (very important for research processes) and facilitating the implementation of systematic control processes that guarantee the objective of obtaining quality spirometry.

The suitability of this standard as a mechanism for the exchange of information will be evaluated in various projects with the participation of different service providers and professionals of different health-care settings.

Spirometer Requirements

The inclusion of this CDA as a technical requirement for acquiring spirometers is essential for ensuring that it is adopted by the manufacturers and for its mid-term generalized use. The Office for Standards has likewise established a procedure for homologation, through which the manufacturers can certify that their equipment conforms to this standard proposed.

The Plan for the Digitalization of Medical Images has proposed to the Catalonian Health Administration (*Servicio Catalán de la Salut–CatSalut*) the requirements that the spirometers should meet to guarantee interoperability. Table 2 describes the requirements as they appear in the public tender for the acquisition of spirometries. These requirements, which meet a general consensus, are essential to achieve the objectives set by the PDMAR for access to quality spirometry.

In short, the final objective of quality spirometry requires the integration of several strategies: training, definition of standards for the transmission of the data, technical requirements for the acquisition of spirometers, interpretation of results, etc. Each one of these strategies is fundamental, but their isolated impact is minimal if they are not properly integrated. All these should be done in response to a key health-care challenge: early diagnosis of respiratory diseases, particularly the most prevalent such as COPD and asthma. The dissemination of quality spirometry is a goal that is within our grasp in the near future. The previously explained technical requirements will allow us to make forced spirometry a reliable procedure, giving access the numerical as well as charted data, and quality spirometry will become compatible with its extensive use in all health-care settings.

Quality spirometry is a reachable objective.[12] The technological elements related with standardization and interoperability are the foundation on which quality spirometry is based. In the first place, without standardization and interoperability, it is very difficult to exchange data among providers with different computing platforms. Furthermore, by means of these technical elements, it is possible to propose performing spirometry outside the health-care system setting, for instance in patients' homes. But the most important challenge is quality control. All these technological advances should enable routine quality control of the procedures that are performed and, consequently, allow room for improvement. In any given territory, the final objective should be to guarantee the access of all the clinicians to quality spirometry, regardless of the type of health-care center. It is not a fantasy, as it is already possible with chest radiography or electrocardiography, for example. Technology and an integral, multidisciplinary approach is essential for reaching this goal.

Table 2
Requirements of CatSalut for Spirometries and Calibration Syringes (2011).

Definition
Spirometer with microprocessor and printer for lung function and bronchodilation tests, with memory for storing tests

Basic characteristics
- *Provides spirometry testing in both adults and children*
- *Has graphic incentives*
- *Provides volume-time or flow-time charts of a complete breathing cycle, both forced as well as slow*
- *Provides real-time viewing of the flow/volume and/or volume/time curves on a screen during forced spirometry*
- *Provides the following parameters:*
  - VC
  - FVC
  - FEV_1
  - PEF
  - $FEF_{25\%–75\%}$
  - $FEF_{75\%\ 50\%\ 1\ 25\%}$
- *Memorizes the results from a minimum of 6 tests (6 baseline tests and 6 post-bronchodilation tests)*
- *Provides the possibility for add-ons, such as SaO_2 modules, etc.*
- *Has exterior finishes that are chip-resistant, hard and color-fast*
- *Incorporates antibacterial filters*
- *Adapted for electric power supply and/or rechargeable batteries*
- *Includes printer for curves and parameters*
- *Exports data in a structured format; all information necessary should be provided in order to integrate these data with the health-care facility's information systems*

Other characteristics to consider
- *Interoperable with e-CAP systems (electronic clinical history)*
- *Integrated with the HIS of the centers by means of HL7 messaging in order to receive the activity program*
- *Exports data in the standard format of the Department of Health (CDA R2 for spirometry)*
- *Has Encapsulated CDA Storage, SOP Class 1.2.840.10008.5.1.4.1.1.104.2*
- *Provides the necessary software, server or client licensing to meet the interoperability requirements as well as the installation and configuration of the software included. In cases when a central server is necessary, it will not be included in the proposal*
- *Saves the different tests of a patient in order to choose the best*
- *Low-cost disposable parts and maintenance*
- *Low risk for contamination; maximum simplicity for sterilization and disinfection of the respiratory circuit; possibility for a disposable transducer*
- *Ports for RS-232 and/or USB, ethernet and data exportation to PC and printer*

Accessories
Basic
- Case for the equipment
- 3-L calibration syringe

Regulations
Mandatory
- Meets current legislation and other applicable regulations

References

1. Hutchinson J. On the capacity of the lungs, and on the respiratory functions, with a view of establishing a precise and easy method of detecting disease by the spirometer. Med-Chir Trans (Lond). 1846;29:137–61.
2. Petty TL. John Hutchinson's mysterious machine revisited. Chest. 2002;121 Suppl. 5:219S–23S.
3. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, et al., ATS/ERS TaskForce. Standardisation of spirometry. Eur Respir J. 2005;26:319–38.
4. Hueto J, Cebollero P, Pascal I, Cascante JA, Eguía VM, Teruel F, et al. La espirometría en atención primaria en Navarra. Arch Bronconeumol. 2006;42:325–30.
5. Monteagudo M, Rodriguez-Blanco T, Parcet J, Peñalver N, Rubio C, Ferrer M, et al. Variabilidad en la realización de la espirometría y sus consecuencias en el tratamiento de la EPOC en Atención Primaria. Arch Bronconeumol. 2011;47:466–9.
6. Pérez-Padilla R, Vázquez-García JC, Márquez MN, Menezes AM, PLATINO Group. Spirometry quality-control strategies in a multinational study of the prevalence of chronic obstructive pulmonary disease. Respir Care. 2008;53:1019–26.
7. Burgos F. ¿Son compatibles la calidad y el uso extensivo de la espirometría? Arch Bronconeumol. 2006;42:311–3.
8. Castillo D, Guayta R, Giner J, Burgos F, Capdevila C, Soriano JB, et al., FARMAE-POC Group. COPD case finding by spirometry in high-risk customers of urban community pharmacies: a pilot study. Respir Med. 2009;103:839–45.
9. Tresserras R. Planificación según prioridades de salud. Med Clin (Barc). 2008;131(Supl 4):42–6.
10. Soriano JB, Ancochea J, Miravitlles M, García-Río F, Duran-Tauleria E, Muñoz L, et al. Recent trends in COPD prevalence in Spain: a repeated cross-sectional survey 1997–2007. Eur Respir J. 2010;36:758–65.
11. Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, et al. HL7 Clinical document architecture release 2. J Am Med Inform Assoc. 2006;13:30–9.
12. Burgos F. La espirometría forzada de calidad en Atención Primaria, impacto en el tratamiento de la EPOC. Arch Bronconeumol. 2011;47:224–5.

Ninth study

Clinical Decision Support System to Enhance Quality Control of Forced Spirometry.

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Eur Respir J (to be submitted after patent registration).

Clinical Decision Support System to Enhance Quality Control of Forced Spirometry

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Key words: Forced Spirometry, Information Communication Technologies, Primary Care, Quality Control, Telemedicine.

Word count - body text, 1.687 and abstract, 200

Abstract

200 words

Background. We recently demonstrated that quality of forced spirometry (FS) in primary care can markedly improve with remote off-line support from specialized professionals *(Burgos et al Eur Respir J 2012; 39: 1313-1318)*. It is hypothesized that implementation of automatic on-line assessment of quality of FS may significantly enhance the potential for extensive deployment of a high quality FS program.

Aims. To elaborate and validate a Clinical Decision Support System (CDSS) for automatic on-line quality assessment of FS.

Method. The CDSS was done through a three-step process including: *i)* identification of optimal sampling frequency; *ii)* iterations to build-up an initial version using the 24 standard FS curves recommended by the American Thoracic Society; and, *iii)* iterations to refine the CDSS using 270 curves from 90 patients. In each of these steps the results were checked against one expert. Finally, 778 FS curves from 291 patients were analyzed for validation purposes.

Results. The CDSS generated appropriate on-line classification and certification in 88% of FS testing with 96% sensitivity and 95% specificity.

Conclusions. Consequently, only 12% of FS testing required off-line remote classification by an expert indicating a potential positive role of the CDSS in the deployment of a high quality FS program.

Introduction

High Quality Forced Spirometry (FS) testing across healthcare levels is pivotal for proper management of patients with prevalent chronic respiratory disorders, namely asthma and COPD(1).

We have recently reported effectiveness of a web-based application for remote off-line expert support to enhance quality of FS in primary care. High quality testing improved in a sustainable manner with the remote support(2). A relevant difference was observed between the intervention group, 71.5% high-quality FS, and the control group, 59.5% high- quality FS, throughout the 12-month follow-up period ($p<0.001$). Similar figures have been reported in pharmacy offices, as part of a COPD case finding program (3).

Extensive deployment of the web-based remote support from specialists to primary care is progressing in the Basque Country (Spain), wherein the program is planned to cover the whole population of the region, 2,2 million inhabitants, by 2014(4;5). Automatic assessment of quality of FS testing should enhance the efficiency of the program. Unfortunately, current applications for on-line assessment of quality of FS misclassify the tests, as compared with examinations done by expert professionals (2).

We hypothesize that elaboration and validation of a Clinical Decision Support System (CDSS) for on-line automatic assessment and certification of quality of FS in primary care may represent a pivotal step toward adoption of the high quality FS program in large regions. The current study is part of the refinement of the ongoing deployment of the high quality FS program in Catalonia (6), an European region of 7,5 million inhabitants.

Method

Building-up the CDSS

As displayed in **Figure 1**, the initial step in the process for elaboration of the CDSS was the identification of the optimal sampling frequency to achieve highest sensitivity and specificity in the analysis of the spirometric curves. The process was done using the 24 standard flow-volume (F/V) and volume-time (V/T) curves from the pulmonary waveform generator recommended by the European Respiratory Society/American Thoracic Society(7). To this end, a systematic examination of a large range of sampling frequencies, from 6.25 to 100 Hz, was done during the first iterative process indicated in the figure.

The construction of an initial version of the CDSS was carried out using the 24 standard FS curves (8;9) following an iterative process, as displayed in **Figure 1**. In each step, the results generated by the CDSS were compared with the criteria of one expert in the field of lung function testing (FB) and the iterative process was maintained until sensitivity and specificity of the results generated by the CDSS showed 100% agreement with the expert.

The CDSS combines the different aspects assessed on the FS curve in one score with three different categories: *i)* Grade 0, rejected due to unacceptable morphology of the FS curve; *ii)* Grade 1, acceptable for further classification according to **Table 1**; or, *iii)* Grade 2, undefined characteristics of the FS. The two first categories, Grades 0 and 1 allow proper on-line automatic classification of FS testing as well as the generation of a certified FS curve to be potentially shared across healthcare tiers; whereas Grade 2 requires off-line expert assessment.

The CDSS systematically assessed 27 different characteristics of each FS curve according to **Table 2**. Each of these 27 features had a well

defined specific algorithm for calculations with initial parameters that were refined through successive iterations until the final version of the CDSS was obtained (**Figure 1**). As indicated above, the performance of each of the successive versions of the CDSS was compared with the results provided by the expert. A refined version of the CDSS (**Figure 1**) was achieved using 270 curves from 90 patients from(2).

CDSS validation

The refined version of the CDSS was compared with a database of 778 curves from 291 patients from one of the Primary Care centers in Barcelona. The FS testing was done using a spirometer (Sibel 120, SIBELMED, Barcelona Spain). Again, the score generated by the CDSS was compared with the one obtained from the same expert evaluator.

The use of the two databases of FS curves from patients for refinement and validation purposes, respectively, was approved by the Ethical Committee of the Hospital Clínic i Provincial de Barcelona.

Data analysis

The ATS database (8) contains volume (V) values of each curve, from which flow (F) values were obtained by discrete differentiation.

$$F[i] = \frac{V[i] - V[i-1]}{\Delta t} \quad (1)$$

The two patient's databases contain flow (F) values, from which volume (V) values were obtained by discrete integration.

$$V[i] = \sum_{n=0}^{i} F[i-n] * \Delta t \quad (2)$$

wherein i= 1,…,N, being N the length of the sequence. The sample period is Δt = 0.01 s, so the sample frequency is 100 Hz.

Sensitivity and specificity of the CDSS were calculated for all curves classified as classes 0 or 1.

$$\text{Sensitivity} = \frac{TP}{TP+FN}$$

$$\text{Specificity} = \frac{TN}{TN+FP}$$

wherein TP (true positive) corresponds to curves classified as class 0 by both CDSS and the evaluator; TN (true negative) corresponds to curves classified as class 1 by the CDSS and the by the evaluator; FP (false positive) indicates curves classified as class 0 by the CDSS, but classified in class 1 by the evaluator; and, FN (false negative) corresponds to curves classified as class 1 by the CDSS, but as class 0 by the evaluator.

Results

The sampling frequency that provided the highest sensitivity and specificity for the analysis carried out with the 24 standard FS curves recommended by the ATS was 100 Hz (**Figure 1**) (see Table 1, in the on-line supplement). This result was confirmed in the 270 curves from 90 subjects (2).

Both sensitivity and specificity of the CDSS were initially calculated with the 24 standard FS curves recommended by the ATS(7) using only class 0 and class 1 curves. The results were as follows: class 0, n=15; class 1, n= 6; class 2, n= 3 with 100% sensitivity and 100% specificity. Up to five complete versions of the CDSS were generated in the two iterative processes indicated in **Figure 1**, until a final version of the CDSS was ready for validation.

The validation study using 778 curves from 291 patients showed the following distribution of FS curves: 419 maneuvers (54%) were appropriately classified as bad curves (Class 0); 266 maneuvers (34%) were appropriately classified as good curves (Class 1); and, only 93 maneuvers (12%) needed an off-line review by a Lung Function expert to assess quality of the test (Class 2). Sensitivity and specificity calculations for Class 0 and Class 1 curves were 96.1 and 94.9%, respectively.

DISCUSSION

The current research has generated and validated a CDSS showing ability to classify a reasonable percentage of FS curves, 88%, as either acceptable (class 1) or bad manoeuvres (class 0). Only 12% of the curves were classified as undefined (class 2) and were candidate for off-line remote validation by an expert. Moreover, we observed that both sensitivity and specificity of the CDSS were very high. Consequently, the results seem to indicate that a vast majority of FS testing carried out by non-specialized professionals in primary care can be reliably assessed on-line and, consequently, the high quality FS program partly based on remote automatic evaluation of the testing could be considered ready for regional scalability. Obviously, further steps toward extensive deployment of the program must planned with caution. A proper monitoring of the potential for generalization of the current results and the need for further refinements of the current CDSS should be taken into account.

In the new scenario, as indicated by the BPMN (Bussiness Process Management Notation) diagram, displayed in Figure 1 of the on-line supplement, acceptable manoeuvres (class 1) will be automatically addressed to the algorithm indicated in **Table 1** that classifies and certifies FS testing prior to its recording into the local (Electronic Health Record, HER) and regional repositories. In contrast, those manoeuvres classified as bad curves (class 0) will generate an on-line specific error message to the professional indicating the need to perform additional testing until quality acceptance is reached. As indicated, we estimate that approximately 12% of the curves will not be properly classified (class 2) and they will need an off-line remote supervision by an expert professional. In this case, the FS testing of a given patients will need to be re-scheduled.

Previous reports have indicated the potential of telemedicine to enhance both quality and diagnostic potential of FS testing carried

out by non-expert professionals(10-12), but the quality control in those studies was based on off-line analyses by expert professionals carried out in a time-consuming manner (13-15). Likewise, the need for an external, likely centralized, quality control program (12;14-17) is well established. The results of the current study refine previous achievements (2) and open the way to explore extensive and efficient adoption of this type of high quality FS programs.

We acknowledge that high quality FS programs combine several different dimensions, namely: *i)* professional coaching (18;19), *ii)* remote support (2); *iii)* interoperability of testing across healthcare levels (20); *iv)* standards for procurement of equipment(7;21); and, *v)* support to interpretation of testing (22;23). The current study provides pivotal results to efficiently address issues associated to remote support of FS testing. But, a proper integration of all the above elements needs to be considered in the process of shaping a successful high quality FS program for scalability at regional level.

Limitations of the study

We acknowledge two principal limitations of the study. Firstly, we included only one expert observed (FB). The CDSS should be re-assessed in the future with the inclusion of at least 3 different experts. Moreover, the current study evaluates the CDSS in an isolated manner. But, further assessment of the whole clinical process as defined in the BPMN (see Figure 1 in the on-line supplement) should be done before specific plans for scalability are undertaken.

Conclusions

To our knowledge, the current study constitutes the first successful attempt to validate an automatic CDSS for large scale on-line assessment of quality of FS testing. The incorporation of the CDSS into the web-based application for remote assistance to primary care professionals (2) may facilitate sustainable high quality FS.

The results indicate a high potential of the CDSS for discrimination between good and poor quality results of FS testing, but they require further independent validation before specific plans for implementation are materialized.

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REFERENCES

(1) Celli BR. The importance of spirometry in COPD and asthma: effect on approach to management. Chest 2000 February;117(2 Suppl):15S-9S.

(2) Burgos F, Disdier C, de Santamaria EL, Galdiz B, Roger N, Rivera ML et al. Telemedicine enhances quality of forced spirometry in primary care. Eur Respir J 2012 June;39(6):1313-8.

(3) Castillo D, Burgos F, Giner J, Estrada M, Soriano JB, Flor X et al. *Cribado de EPOC: nuevas herramientas y circuitos sanitarios. Resultados preliminares del Farmaepoc II. (FARMAEPOC)* . Arch Bronconeumologia 2011;(4):91.

(4) Eustat -. Population and Housing Census in Euskadi. http://www.eustat.es/estadisticas/tema_159/opt_0/ti_Poblacion/temas.html#axzz2WOLQZD8X. 2011.
Ref Type: Generic

(5) Marina Malanda N., Galdiz Iturri J.B., Lopez de Santa María Miró E. Estudio multicéntrico para el análisis de la efectividad de la telemedicina en programas de aseguramiento de la calidad de las espirometrías. Plan de Calidad para el Sistema Nacional de Salud del Ministerio de Sanidad y Política Social. Agencia de Evaluación de Tecnologías Sanitarias del País Vasco; 2012. Informes de Evaluación de Tecnologías Sanitarias: OSTEBA Nº 2009/03. 2012.
Ref Type: Generic

(6) Tresserras R. [Planning driven by health priorities. Master planning criteria]. Med Clin (Barc) 2008 December;131 Suppl 4:42-6.

(7) Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A et al. Standardisation of spirometry. Eur Respir J 2005 August;26(2):319-38.

(8) ATS statement--Snowbird workshop on standardization of spirometry. Am Rev Respir Dis 1979 May;119(5):831-8.

(9) Gardner RM, Hankinson JL. Standardization of spirometry--1987 ATS update (American Thoracic Society). J Occup Med 1988 March;30(3):272-3.

(10) Masa JF, Gonzalez MT, Pereira R, Mota M, Riesco JA, Corral J et al. Validity of spirometry performed online. Eur Respir J 2011 April;37(4):911-8.

(11) Bellia V, Pistelli R, Catalano F, Antonelli-Inc, Grassi V, Melillo G et al. Quality control of spirometry in the elderly. The SA.R.A. study. SAlute Respiration nell'Anziano = Respiratory Health in the Elderly. Am J Respir Crit Care Med 2000 April;161(4 Pt 1):1094-100.

(12) Spirometry Monitoring Technology - SPIROLA. NIOSH - Spirometry in Occupational Medicine.U.S.Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.www.cdc.gov/niosh/spirometry/spirola.htlm .
Ref Type: Generic

(13) Montes de OM, Talamo C, Perez-Padilla R, Jardim JR, Muino A, Lopez MV et al. Chronic obstructive pulmonary disease and body mass index in five Latin America cities: the PLATINO study. Respir Med 2008 May;102(5):642-50.

(14) Perez-Padilla R, Vazquez-Garcia JC, Marquez MN, Menezes AM. Spirometry quality-control strategies in a multinational study of the prevalence of chronic obstructive pulmonary disease. Respir Care 2008 August;53(8):1019-26.

(15) Janssens W, Liu Y, Liu D, Kesten S, Tashkin DP, Celli BR et al. Quality and reproducibility of spirometry in COPD patients in a randomized trial (UPLIFT). Respir Med 2013 May 25.

(16) Enright PL. How to make sure your spirometry tests are of good quality. Respir Care 2003 August;48(8):773-6.

(17) Enright PL, Skloot GS, Cox-Ganser JM, Udasin IG, Herbert R. Quality of spirometry performed by 13,599 participants in the World Trade Center Worker and Volunteer Medical Screening Program. Respir Care 2010 March;55(3):303-9.

(18) Steenbruggen I, Mitchell S, Severin T, Palange P, Cooper BG. Harmonising spirometry education with HERMES: training a new generation of qualified spirometry practitioners across Europe. Eur Respir J 2011 March;37(3):479-81.

(19) Escarrabill J, Roger N, Burgos N, Giner J, Molins A, Tresserras R et al. Diseño de un programa de formación básico para conseguir espirometrías de calidad. Educ Med 2012;15(2):103-7.

(20) Salas T, Rubies C, Gallego C, Munoz P, Burgos F, Escarrabill J. Technical Requirements of Spirometers in the Strategy for Guaranteeing the Access to Quality Spirometry. Arch Bronconeumol 2011 August 5.

(21) Miller MR, Crapo R, Hankinson J, Brusasco V, Burgos F, Casaburi R et al. General considerations for lung function testing. Eur Respir J 2005 July;26(1):153-61.

(22) Pellegrino R, Viegi G, Brusasco V, Crapo RO, Burgos F, Casaburi R et al. Interpretative strategies for lung function tests. Eur Respir J 2005 November;26(5):948-68.

(23) Pellegrino R, Brusasco V, Viegi G, Crapo RO, Burgos F, Casaburi R et al. Definition of COPD: based on evidence or opinion? Eur Respir J 2008 March;31(3):681-2.

TABLES AND FIGURES

Table 1. Quality scores for spirometric manoeuvres according to ATS/ERS standardization (7)

A	3 acceptable manoeuvres, and best 2 matched with differences in FVC and / or FEV_1 <150 ml
B	3 acceptable manoeuvres, and best 2 matched with differences in FVC and / or FEV_1 <200ml
C	2 acceptable manoeuvres, and best 2 matched with differences in FVC and / or FEV_1 <250 ml
D	1 acceptable manoeuvre
F	None acceptable manoeuvres

High quality spirometries, A and B scores, correspond to, (A, 3 acceptable manoeuvres with differences in FVC and/or FEV_1 <150 ml, and (B, 3 acceptable manoeuvres with differences in FVC and/or FEV_1 <200 ml); C to high variability among manoeuvres; D only one acceptable maneuver; and, F none acceptable maneuver

Table 2 – List of features of the forced spirometry curve explored by the CDSS

BEV trad,	Back extrapolation >0.15 L or < 5% of FVC
EOTV trad	End of test criteria, volume < 0.025 L in time ≥1 s
Tex	Time of end FVC (Tex>6 s)
EOTV new (5 criteria)	a) EOTV < 0.025 L or Tex>6 s; b) If Tex>6 s EOTV<0.025 L in time 0.5 s; c) If Tex>6 s, EOTV < 0.1 L; d) EOTV(Tex) = EOTV * 6/Tex; e) EOTV < 0.025 * Tex/6 L
EOTV trad AND EOTV new	EOTV trad and all EOTV new (a;b;c;d;e)
EOTV trad OR EOTV new	EOTV trad and some of EOTV new (a;b;c;d;e)
Tex AND EOTV new	Tex and all EOTV new (a;b;c;d;e)
Tex OR EOTV new	Tex and some EOTV new (a;b;c;d;e)
Peak_Valley_Single,	High local maximum (peak) and minimum (valley) in FV curve
Peak_Valley_Combined	High local maximum (peak) and minimum (valley) in FV curve close to FEV_1
VT_end,	Irregularity or oscillation at the end of VT curve
FV_slope_single,	Variation of FV slope or high FV slope.
FV_slope_combined,	Variation of FV slope and high FV slope.
FVSlope_Test_Combo,	Irregularity and variation of FV slope or high FV slope
FVSlope_Test_Combo_Area Under Rect,	Irregularity or variation of FV slope and high FV slope
FVSlope_Test_Combo4,	Irregularity and variation of FV slope and high FV slope
Diff_single,	Irregular concavity - convexity before the PEF value in FV curve
iff_combined,	Irregular slope and irregular concavity-convexity before the PEF value in FV curve
PEF TimeUp	Time of archive PEF < 130 milliseconds
PEF TimeDown,	Time of archive PEF > 0.25 milliseconds
PEF Cut,	PEF is not a peak in FV curve (is plane). Volume (F=PEF) > 15 % FVC
PEF Cut2 FEV_1,	PEF is not a peak in FV curve (is plane). Volume (F=PEF) > 17.5 % FEV_1
PEF Peak_Test_Combo,	Volume (F=PEF) > 15 % FVC and/or Volume (F=PEF) > 17.5 % FEV1
PEF Peak_Test_Combo2,	Volume (F=PEF) > 15 % FVC and Volume (F=PEF) > 17.5 % FEV_1
PEF DoublePeak,	PEF bimodal in FV curve
PEF Double_Peak_Combo,	PEF bimodal and PEF is not a peak (is plane) in FV curve
PEF Slow,	Volume of archive PEF < 20% FVC

BEV (back extrapolation); EOTV (end of test criteria, volume); Tex (Time to end FVC); VT (volume/time curve); FV (flow/volume curve); PEF (peak expiratory flow); FVC (forced vital capacity) ; FEV_1 (forced expiratory volume in the first second)

Figure 1. Flow of the process followed to elaborate and validate the CDSS

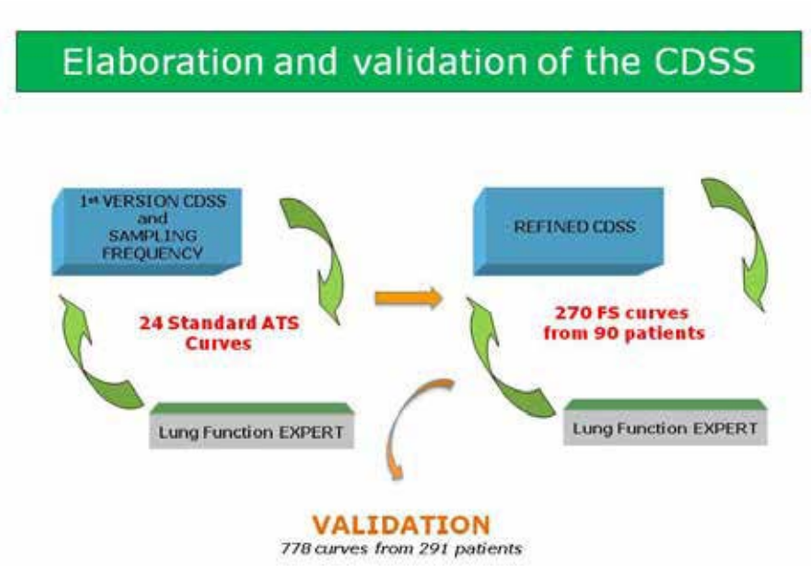
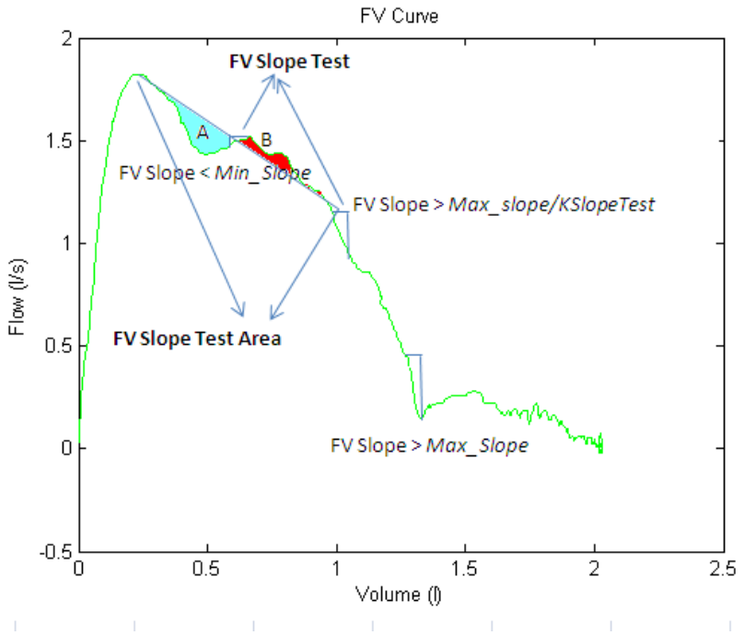


Figure 2. Analysis of the slope of a flow-volume forced spirometry curve



Discussion

The summary of the main findings and outcomes of the PhD thesis, grouped by each of the three main objectives, are described below:

Objective 1 – Transferability of FS to Primary Care and Pharmacy Offices

The first study clearly showed the potential of the web-based application to generate sustainable high-quality transfer of FS to inexperienced non-specialized primary care professionals from five different regions of Spain. The study showed that remote collaboration between primary care professionals and lung function specialists has a sustainable positive impact on quality assurance of FS performed by non-experts. A relevant difference was observed between the intervention group (71.5% high-quality FS) and the control group (59.5% high- quality FS) throughout the 12-month follow-up period ($p<0.001$). The study generated the seminal data that triggered the scalability program aimed at transferring FS to primary care professionals. Consolidation of such transferability, explored in other studies of this PhD thesis and in ongoing research, may pave the way for ICT-supported re-engineering of the management of patients with chronic respiratory diseases within a coordinated care scenario.

The second and third manuscripts tackled an innovative question, that is:

Can pharmacy offices be main actors in a COPD case-finding program run in close coordination with primary care physicians?

The results of these two studies confirm positive results for this type of service. Moreover, beyond the COPD case-finding objective, the two studies seem to identify a high potential of pharmacy offices as health agents in the borderline area between formal and informal care. It should be acknowledged that the two studies fail to demonstrate effectiveness of the entire value chain of the service, including coordination with primary care physicians. The latter is being currently partly approached, beyond this PhD thesis, through the validation of a Clinical Decision Support System in the Synergy-COPD EU project(68) and in the Catalan Master Plan for Respiratory Diseases (PDMAR).

Objective 2 – Assessment of requirements for scalability at a regional level in Catalonia

Manuscripts 4 and 5 analyze the current status of Lung Function Testing in Catalonia both at hospital level and at primary care level. They were carried out within the frame of PDMAR. The findings support the need for:

I) Expanding the role of FS beyond specialized care; and,

II) Achieving homogeneous distribution of lung function testing across the territory with accessibility of testing results across healthcare tiers.

Overall, the two analyses confirmed the need for the transferability program addressed in the PhD thesis.

Also within Objective 2, a second set of studies acknowledges the high relevance of the coaching programs addressed to non-specialized professionals as one of the main components of the strategies for deployment of ICT-supported functional testing in coordinated care. Manuscript 6 generates proposals in this area within the framework of PDMAR in Catalonia; whereas manuscript 7 describes the European situation, through the Hermes program for continuous professional development endorsed by the European Respiratory Society.

Objective 3 – Technological contributions to scalability

Two main outcomes must be highlighted within Objective 3:

Firstly, the connectivity of the measurement equipment had to be ensured through the elaboration of a properly standardized transfer of the relevant FS data using HL7 v3 and CDA R2 standards.

The initiative was promoted by the Office for Standards and Interoperability of the Catalonian Department of Health within the Plan for the Digitalization of Medical Images (69), as reported in manuscript 8. Some manufacturers have already implemented the design (70) that has become a requirement for public procurement in Catalonia. Furthermore, the Spanish Respiratory Society (SEPAR) has recently included the CDA in its official recommendations for forced spirometry standards (71). Although this outcome represents a key step for interoperability of FS at health system level, we acknowledge that it is just one of the steps required to ensure accessibility of FS across healthcare tiers. Interoperability strategies are further discussed below.

A second main outcome within Objective 3 was the validation of an algorithm for automatic assessment and certification of FS. The research included the design and validation of the new algorithm through the following steps: *i)* assess the optimal sampling frequency; *ii)* identify a novel quality criteria to be used in the algorithm, up to 27 characteristics of the FS curves were taken in to account to elaborate the new algorithm; *iii)* elaboration of a first version of the algorithm using the 24 standard Flow-Volume and Volume-Time curves recommended by the ATS (72;73); *iv)* elaboration of a refined version of the algorithm using 270 FS curves from 90 patients from (74) through an iterative process wherein results were compared with an expert professionals; and, *v)* validation of the algorithm using a database of 778 FS curves from 291 patients provided by one primary care center. Main study results were:

- The highest sensitivity and specificity in the analysis of FS curves was identified at a 100 Hz sampling. It is of note that most current equipment meets the requirement.
- Sensitivity and specificity of the algorithm for automatic quality assessment of FS was 96.1 and 94.9% respectively.
- Only 12% of FS maneuvers could not be properly classified by the algorithm and required off-line remote assessment by an expert.

The successful completion of the study (manuscript 9) constitutes a pivotal step toward scalability of the transfer of FS to primary care and pharmacy offices at regional level. Within the frame of the Synergy-COPD EU project, the algorithm has been integrated into the ICT-platform supporting coordinated care. One of the aims of this EU project is validation of the entire clinical process. Furthermore, scalability of the service is planned, as part of the PDMAR mainstream goals.

Do the outcomes of this thesis represent an added value to existing solutions?

All the documents on recommendations for FS standardization issued by international respiratory associations (49), primary care societies (58), as well as the contributions of numerous individual authors, emphasize the need for high quality FS. It is of note, however, that such a goal is only satisfactorily achieved in specific scenarios (75-79) such as clinical trials and controlled research studies, where tight centralized quality control of testing is in place. The logistics of the quality control is often done by a Contract Research Organization (CRO) that provides ICT-support to the trial sponsor on a proprietary system.

The challenge addressed in this PhD thesis is defined by the fact that the deployment must be carried out in a real clinical scenario in its transition from standard care to a coordinated care environment with ICT-support in which a substantial transfer of complexity from hospital-based specialized care to primary care is envisaged. This rather gigantic operation required at least three levels of complexity to be addressed:

- Identification of factors determining high-quality FS and design of a deployable service.
- Design of the ICT-support providing interoperability at a systems level and based on an open, modular ICT platform allowing scalability at a regional level.
- Definition of strategies for real step-by-step deployment of the innovative service in healthcare sectors with potential for scalability at regional and international levels.

Consequently, the outcomes generated should provide entirely new solutions in a novel scenario. The collection of studies of this PhD thesis should be envisaged as a coordinated effort to generate innovative solutions for functional testing in ICT-supported coordinated care for chronic patients.

Main elements of the service: training and web-based application

Different authors (27;58;80) have elaborated on the need for transferring well- established quality assurance programs from lung function laboratories to the primary care setting to ensure the quality of the tests. There is evidence (55;56;79) suggesting that external quality assurance in primary care needs to be implemented. In an extensive review of FS performed 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 63% (55).

We acknowledge that traditional training constitutes a pivotal element in obtaining high-quality FS, but conventional training does not ensure the sustainability of high-quality testing. Novel training modalities are being explored. Recently, the European Respiratory Society has initiated a certified e-learning training program for professionals (81). The impact of this program on high-quality FS should be evaluated over the coming years, but it does not seem to fulfill the coaching requirements of non-specialized health professionals.

The three studies under Objective 1 (manuscripts 1 to 3) demonstrate efficacy and potential for deployment of the high-quality FS program in the two scenarios assessed in this PhD thesis: primary care and pharmacy offices. Moreover, the design of the algorithm for automatic evaluation of FS quality and its results in terms of sensitivity and specificity (manuscript 9) set the basis for the design of a realistic strategy aimed at the deployment of a high-quality FS service in these two scenarios.

The studies under Objective 2 confirm the need of such a high-quality FS program in Catalonia (manuscripts 4 and 5), but they also identified that there is a clear need for an efficient interplay between the web-based application assessed in this PhD thesis and proper coaching programs for non-specialized healthcare professionals working in different healthcare tiers. Among the lessons learnt during the development of the program is the need to combine classical training approaches together with coaching programs embedded into the web-based application. The current platform generates customized reports on the evolution of professional's quality, as well as global trends at a health sector level indicating changes over time.

The introduction of enhanced coaching programs into the ICT-platform, embedded into novel CDSS that could include feedback models might improve sustainability of training. Potential functionalities to be considered in the updated web-based application for high quality FS are: *i)* information on the testing at request, *ii)* individualized description of FS errors based on the analysis carried out using the algorithm for automatic assessment of quality of the testing; *iii)* corrective actions to be performed; *iv)* interactive educational material; and *v)* self-assessment tools.

ICT-support

The ICT-platform supporting coordinated care for chronic patients briefly described in the introduction and presented in detail by Cano et al(65): *i)* provides organizational interoperability among actors across healthcare levels; *ii)* includes clinical decision support systems; and, *iii)* facilitates patient-centered management taking into account within the healthcare plan the patient's co-morbid conditions. Moreover, the open, modular nature of the ICT-platform (Linkcare®) together with its multicenter functionalities makes it a platform which offers adequate support for interoperability of the FS across the health system, despite the proprietary nature of most of the providers' health information systems. The ICT-platform can provide support for organizational interoperability by itself or as an additional layer on top of a Health Information Exchange (HIE) platform, communicating providers from a given healthcare sector.

The two technological outcomes of this PhD thesis: *i)* the algorithm for automatic assessment of FS; and *ii)* the elaboration of a CDA (Clinical Document Architecture) are pivotal for covering the two critical aspects necessary for achieving full scalability of the service.

The CDA R2 (CDA, Release 2) standard by HL7 v3 (Health Level Seven, version 3) is a product of HL7 International, a not-for-profit organization dedicated to the production of interoperability standards in health care (82). The CDA defines the structure of a clinical document and uses XML to label the different categories of information. XML is the standard for the structured information exchange between applications, regardless of the technological platform used, so that the CDA can be viewed from any computer using a web navigator.

The CDA for FS includes patient data, information about the context of the test, the resulting clinical parameters, the flow-volume and volume-time charts as well as the original signal captured by the spirometer. Likewise, it includes data about the origin of the request obtained from the providers' electronic medical files. The clinical information is coded using SNOMED CT (Systematized Nomenclature of Medicine—Clinical Terms), which allows it to be processed automatically and incorporated into the patients' medical files in a structured manner. The final CDA also includes certification of the quality control performed either through the algorithm for automatic quality control or manually by an expert professional. As described in the Introductory Section, interoperability between the Linkcare® core module and external equipment and/or applications is implemented via web services.

Deployment of the service

A complete description of the characteristics of the high quality FS service in primary care is provided by Figures 3 and 4 through Business Process Model Notation (BPMN) (83). The figures

display a scheme wherein all elements of the service in primary care (Fig 3) and in pharmacy offices (Fig 4) are identified and described in the figure legends.

We acknowledge that this PhD thesis has assessed efficacy and basic elements of the high quality FS service, but it has not validated the entire service process which is being partly implemented, as mentioned above, within the Synergy-COPD project and will be completed as part of the deployment of the PDMAR in Catalonia.

The predicted beneficial clinical impact of the high-quality FS service has already been described in the Introductory Section of this PhD thesis. Improvement should be expected in different areas, namely: *i)* enhancement of diagnosis and follow-up of patients with chronic respiratory disorders; *ii)* generation of novel reliable ways to assess bronchial hyper-responsiveness; *iii)* setting up of COPD case-finding programs and early disease prevention strategies; and, *iv)* decreasing duplicated testing due to the accessibility of reliable test results across the health systems.

Adoption of this type of service is strongly linked to policy decisions on early disease prevention strategies and, also, to the consolidation of novel models of reimbursement and incentives for chronic care. As extensively analyzed in NEXES(7), demonstration of efficiencies of the services and changes toward bundled payment models with shared risk among actors involved in the value chain are key elements for the extensive adoption of novel services into a coordinated care scenario.

Current deployment in the Basque Country

The high-quality FS service in the Basque Country was deployed in 2011 as part of the disease-oriented programs for chronic patients aimed at early disease intervention and efficient management of high-risk patients(84).

The service incorporates the web-based application assessed in manuscript 1 in combination with traditional training programs. Since 2011, it has been steadily deployed in the whole region, being currently used in 100 primary care units. By the end of 2012, the first year follow-up was successfully completed. The analysis of efficiencies comparing the remote support service against traditional ways to control quality of FS clearly indicated cost containment. The result triggered further deployment of the service at regional level up to its completion by 2014.

The results of the Basque Country indicate that the approach has a high degree of transferability. The excellent level of acceptance among users (non-specialized professionals) seems to be due not only to the quality assurance but also because the service highly reinforces the quality and potential of FS for diagnosis.

Scalability of high-quality FS services in Catalonia

Scalability in Catalonia has evolved along with the development of this PhD thesis, as part of the PDMAR. It has been also modulated by the evolution of the Linkcare® platform. Comparison of the Catalan program with the deployment in the Basque country shows the following three major differences:

- Interoperability issues have slowed down the process of deployment. These were mainly due to logistic aspects rather than to technological limitations. As compared to the Basque Country, the Catalan health system has a high degree of heterogeneity in terms of providers' health information systems.

- As mentioned above, the developments in Linkcare® aimed at a full consolidation of its multicenter functionalities have also modulated the process of deployment.

- The ambition of the Catalan program that is planning the deployment of two fully articulated services for primary care (Figure 3) and for pharmacy offices (Figure 4), respectively. Those services must be properly coordinated and validated.

As mentioned above, all the additional developments, beyond the outcomes of this PhD thesis, are planned to be accomplished within 2013, as part of the Synergy-COPD project(68) and the PDMAR deployment plan (36).

The high quality FS service in Catalonia should cover three main aspects:

- Provide remote certification of quality for FS testing done in Catalonia. A high proportion (estimated 88%) of the testing certification should be carried out automatically.

- Provide tools for sustainable coaching combining traditional approaches and novel CDSS designed for training purposes. Moreover, the web-based application should provide remote support to the interpretation of the tests by specialists.

- Accessibility of all certified FS testing across levels of care within and among healthcare sectors of the region. In this regard, the shared EHR in Catalonia (HC^3) should be the central repository for functional testing and additionally, ICS-ICT platforms should facilitate interoperability among providers and between citizens and providers.

We believe that this PhD thesis provides the basis for such developments that will obviously require the build-up of additional applications and refinement of the existing ones. Moreover, protocols for validation of the system should be designed and be in place before full scalability can be implemented.

Figure 3 Primary Care Scenario

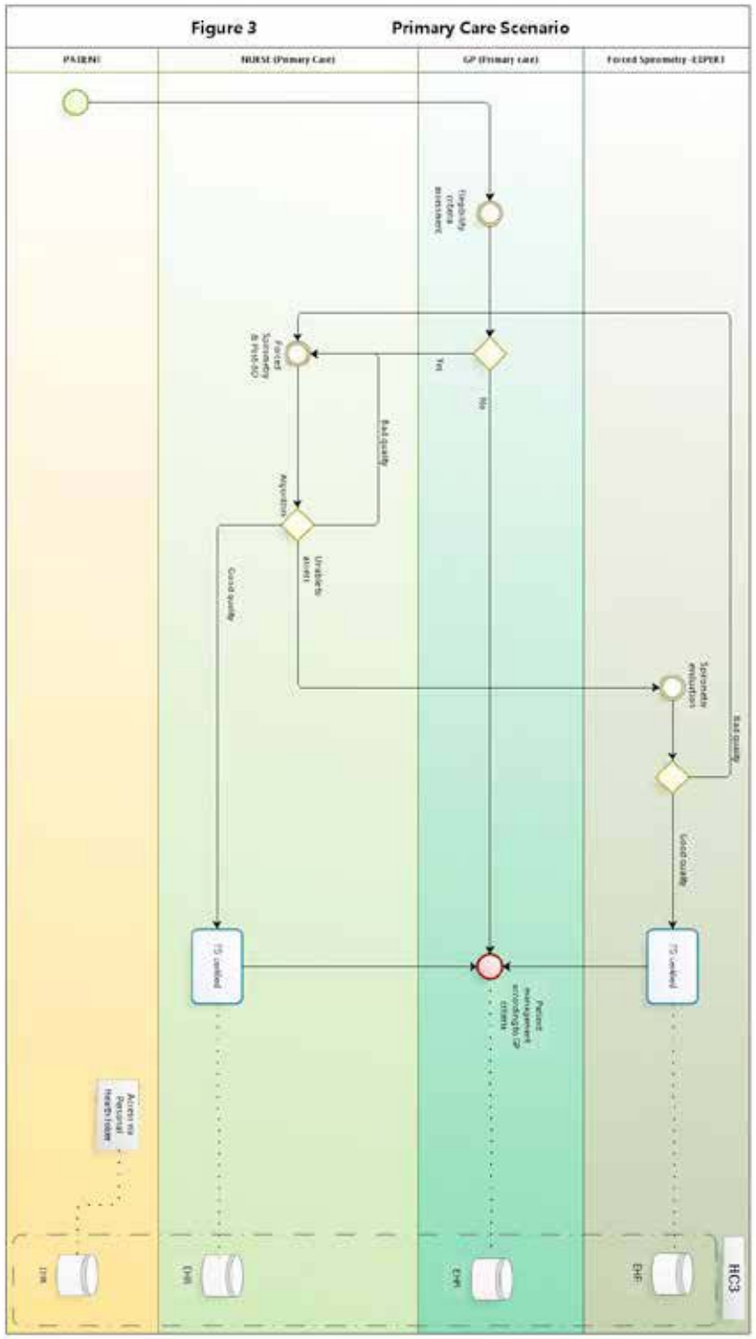


Figure 4 Pharmacy Office Scenario

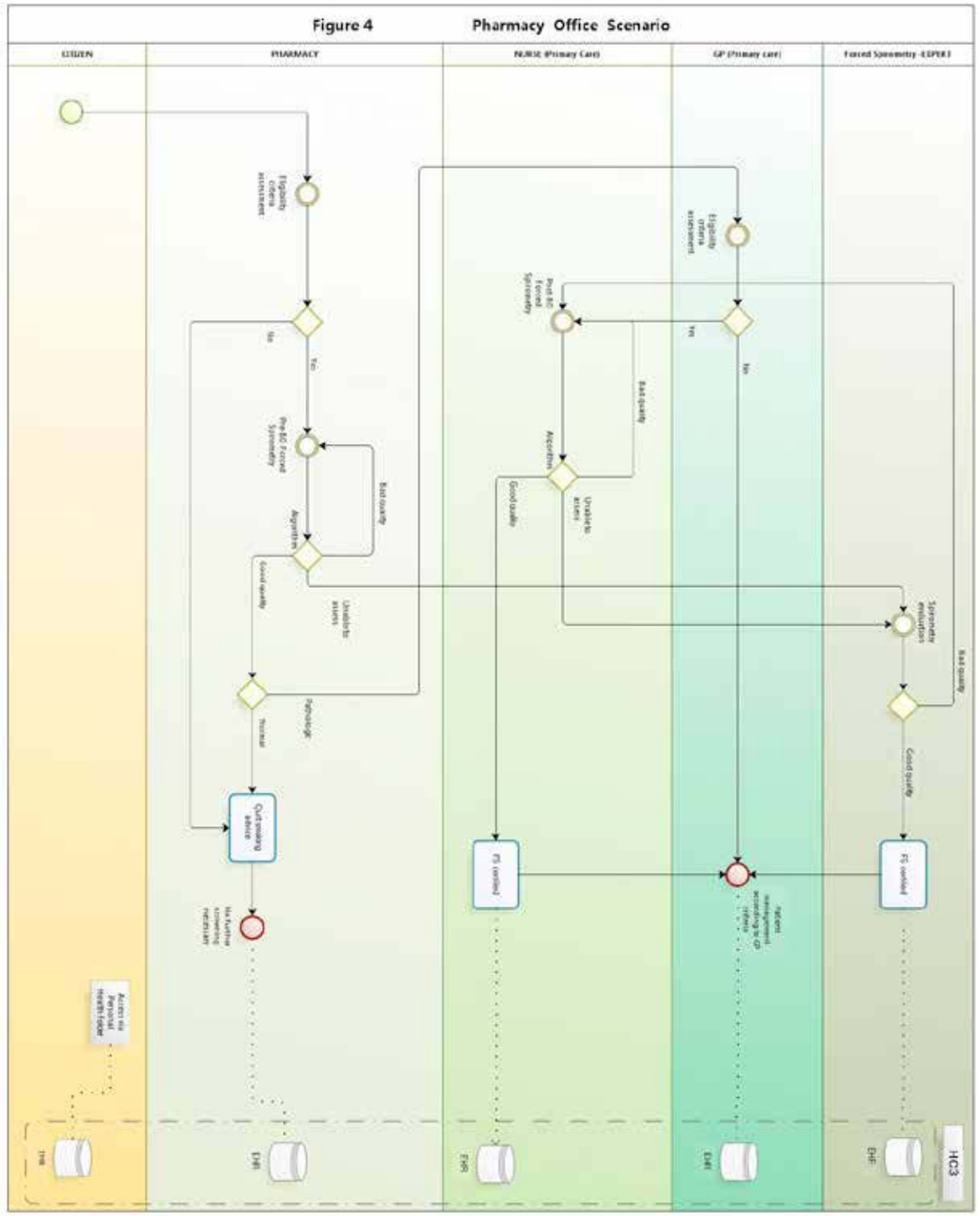


Figure 3 – Forced Spirometry (FS) transfer to Primary Care. The figure depicts the clinical process of a patient with respiratory symptoms attending a primary care visit. The flow is as follows: the general practitioner (GP) decides that the patient is a candidate for FS testing and both baseline and post-bronchodilator studies will be done by a non-specialized nurse. At the end of the testing, the results will be automatically assessed using the algorithm that will generate FS certification for quality. The three possible outcomes are: *i)* the FS testing qualifies as high quality. It will be used by the GP for his/her decision-making process and the certified FS will be sent to the patient's EHR and to the regional repository (shared EHR or HC^3, Historia Clinica Compartida de Catalunya); *ii)* the FS testing does not fulfill quality criteria. Then automatic feedback with specific information on the problem is forwarded to the nurse while the patient is still on site. Consequently, the nurse will have the opportunity to solve the problem and generate a high-quality FS test; and, *iii)* approximately 12% of the FS testing will be classified as undefined by the automatic algorithm and forwarded to the specialist for advice. The specialist will provide remote off-line recommendations directly to both the GP/nurse and the patient will be attended by the GP who will take the final decision on how to proceed. In two of these scenarios, the first and the third, the certified FS will be forwarded to the regional EHR (or HC^3).

Figure 4. Role of Pharmacy Offices (Community Pharmacy, CPh) in a COPD case finding program. The figure depicts the process of a citizen/customer attending a CPh where he/she sees a banner inviting participation in a respiratory health status assessment program. If the citizen decides to apply, then the CPh officer will administer the GOLD questionnaire to assess health status. If risk factors are identified, the citizen will be invited to perform a pre-bronchodilator Forced Spirometry (FS) testing carried out by the CPh officer.

Regarding the quality of the FS testing, there are three possible outcomes: i) the FS testing is qualified as high quality and it will be certified as such by the automatic algorithm and forwarded to the regionally shared EHR (or HC^3, Historia Clinica Compartida de Catalunya); *ii)* the FS testing does not fulfill quality criteria. Then, automatic feedback with specific info on the problem is forwarded to the CPh while the patient is still on site. Consequently, the CPh will have the opportunity to solve the problem and generate a high-quality FS test; and, *iii)* approximately 12% of the FS testing will be classified as undefined by the automatic algorithm and forwarded to the specialist for advice.

The specialist will provide remote off-line recommendations directly to the CPh officer and the certified FS testing will be forwarded simultaneously to the regionally shared EHR. The citizen's flow in the case of high-quality FS testing can be as follows: *i)* Normal FS testing: the CPh officer will generate a report on paper giving tests results and advice about stopping smoking; *ii)* Abnormal FS results: the CPh officer will generate a report on paper advising the subject to contact his/her general practitioner, who will have access to the certified FS testing through the HC^3; and *iii)* Undefined results (12% of the testing): the subject will be informed of the specialist's advice by the CPh officer.

The way forward: generalization of the ICT-supported service

Besides the consolidation of the scalability program in Catalonia, the results of this PhD thesis open a new exciting avenue consisting of the generalization of the transfer of other functional testing and therapeutic tools from hospital-based specialized care to primary care with the remote support of specialists.

Ongoing pilot studies in the area of sleep apnea and management of pulmonary hypertension are showing promising results that seem to confirm the potential for generalization of the approach. There is no doubt that any significant progress in this direction will require a proper analysis of the efficiencies generated by the new services, proposal for innovative reimbursement modalities, followed by profound reorganizations of the existing hospital units providing these services. The process will generate completely new modalities of interactions with primary care and with patient at home, as well as novel roles for professionals.

Conclusions

1. The potential for transferability of Forced Spirometry testing to Primary Care was demonstrated by the effectiveness of the web-based collaborative tool that showed sustainable enhancement of high-quality testing performed by non-specialized professionals (manuscript 1).

2. The feasibility of having pharmacy offices play a complementary role to primary care in early diagnosis of chronic respiratory disorders has been proven. Moreover, the potential of pharmacy offices in a future COPD case-finding program has been identified and will be developed beyond this PhD thesis (manuscripts 2 & 3).

3. The lung function testing map in Catalonia was drawn up and requirements for the deployment of high-quality FS within a coordinated care scenario were identified (manuscripts 4 & 5).

4. Conventional and novel coaching strategies to be further developed and integrated into the ICT-supported platform were analyzed (manuscripts 6 & 7).

5. Technological contributions to facilitate adoption of a high quality FS service supported by ICT were developed and validated, namely: Clinical Document Architecture and an algorithm for automatic assessment of FS quality (manuscripts 8 & 9).

Summary in Catalan

Impacte de les Tecnologies de la Informació i la Comunicació en les Proves de Diagnòstic
L'Espirometria Forçada com a prova de concepte

Introducció

El desplegament de nous models de salut basats en la coordinació entre nivells assistencials constitueixen una prioritat a nivell europeu davant la necessitat de gestionar les disfuncions generades per l'elevat impacte sanitari i social de les malalties cròniques.

La transferència de la complexitat des de l'atenció sanitària especialitzada, en general de base hospitalària, a professionals d'Atenció Primària constitueix un dels elements centrals del canvi en el model de salut.

Això implica el redisseny de processos clínics i la preparació del personal sanitari per al nou entorn.

L'ús eficient del potencial que ofereixen les Tecnologies de la Informació i la Comunicació (TIC), com a element facilitador de la col·laboració entre nivells assistencials i d'una major accessibilitat del pacient, té un rol important en el desplegament i l'articulació dels Serveis d'Atenció Integrada (SAI) que configuren el nou model de salut. En aquest context, la transferència de les intervencions diagnòstiques especialitzades a l'atenció primària constitueix un àrea molt rellevant en el procés de canvi.

L'hipòtesi central de la present tesi doctoral és que la transferència de determinades proves diagnòstiques a l'atenció primària genera eficiències a nivell del sistema de salut. Els diferents estudis realitzats en la tesi es centren en l'espirometria forçada (EF), seleccionada, per les seves característiques, com una prova de concepte. Els objectius generals són explorar aquells factors que s'han identificat com a claus en la modulació del procés de la transferència de l'EF, així com definir estratègies per a la seva escalabilitat regional. La tesi s'estructura en base a 3 objectius específics:

Objectiu 1 - Anàlisi de la transferència de la EF a Atenció Primària i a oficines de farmàcia.

En el primer estudi *"Telemedicine enhances Quality of Forced Spirometry in Primary Care" es va* demostrar l'eficàcia en el temps (12 m) d'un servei centralitzat pel control de qualitat de l'EF efectuada per professionals no especialitzats de tres regions espanyoles. Es va demostrar que la col·laboració remota entre professionals de primària i especialistes de funció pulmonar tenen un efecte positiu sostingut sobre la qualitat de l'EF realitzada per personal no expert. Es va observar una diferència significativa entre el grup d'intervenció (71.5% EF d'alta qualitat) i el grup control (59.5% EF d'alta qualitat) durant els 12 mesos de l'estudi ($p<0.001$).

La investigació va generar informació valuosa per planejar de forma adient l'escalabilitat del programa a nivell regional. Els resultats d'aquest estudi, junt amb altres apartats de la tesi i d'altres investigacions en curs, facilitaran el redisseny del rol de les proves diagnòstiques en la gestió dels pacients crònics en un entorn d'atenció integrada.

Els estudis 2 *(Early detection of COPD in customers of urban community pharmacies: a pilot-study)* i 3 *(Spirometry in community-pharmacies: a novel strategy to reduce COPD underdiagnosis)* de la tesi responen de forma afirmativa a la següent pregunta:

Poden les oficines de farmàcia tenir un rol rellevant en un programa de detecció de casos de MPOC?

Els resultats són clarament indicatius del potencial de les oficines de farmàcia com a agent sanitari en estreta col·laboració amb Atenció Primària. Cal senyalar que amdos estudis solament aporten informació sobre factibilitat. L'anàlisi d'eficiència es planeja com a una activitat més enllà d'aquesta tesi doctoral, en el marc del projecte EU Synergy-COPD i del Pla Director de Malalties de l'Aparell Respiratori (PDMAR) del Departament de Salut de la Generalitat de Catalunya.

Objectiu 2 – Avaluació de requeriments per a l'escalabilitat regional a nivell de Catalunya

En els estudis 4 *(Encuesta de utilización de la función pulmonar en los hospitales públicos de Cataluña en 2009)* y 5 ***(****Estudio de la función pulmonar básica en los centros de atención primaria de Cataluña. Atención Primaria)* s'analitzà la situació i necessitats futures de les proves de funció pulmonar a Catalunya a nivell hospitalari i extra-hospitalari en el marc del PDMAR.

Els resultats obtinguts confirmen la necessitat de desplegar l'EF a l'Atenció Primària i d'incrementar l'homogeneïtat territorial en el que respecta a l'accés a les proves de funció pulmonar per a pacients i professionals. Es confirma la necessitat del programa de transferència de l'EF plantejat en la tesi doctoral.

En un segon grup d'estudis en el Objectiu 2 de la tesi, efectuats en el marc del PDMAR, s'analitzaren les necessitats i estratègies pel que fa a l'entrenament dels professionals no especialitzats tant en l'àmbit català, estudi 6 *(Disseny d'un programa de formació basic para aconseguir espirometries de qualitat)*, com a nivell europeu, estudi 7 *(HERMES Spirometry: the European Spirometry Driving Licence)*.

Objectiu 3 – Contribucions tecnològiques a l'escalabilitat

L'estudi 8 *(Requerimientos técnicos de los espirómetros en la estrategia para garantizar el acceso a una espirometría de calidad) va* aportar un element essencial per assegurar l'interoperabilitat de les dades de l'EF al assegurar l'estandardització de la transferència d'informació utilitzant el protocol HL7 v3 i CDA (Clinical Document Architecture) amb estàndard R2. Efectuat amb el suport de l'Oficina d'Estàndards i Interoperabilitat del Departament de Salut de la Generalitat de Catalunya dins el Pla de Digitalització de la Imatge Mèdica. L'estàndard de transferència de l'EF ha estat ja adoptat per alguns fabricants d'equips de medició i és un requeriment per als concursos públics a nivell regional.

A més, a l'estudi 9 *(Clinical Decision Support System to Enhance Quality Control of Forced Spirometry)* es va generar i validar un algoritme per el control automàtic de la qualitat de l'EF. Els resultats de la validació amb 778 corbes espiromètriques varen indicar que la sensibilitat i especificitat de l'algoritme era del 96.1 i 94.9%, respectivament. La validació de l'algoritme aportà un segon element tecnològic necessari per a l'escalabilitat del programa de transferència de l'EF a Atenció Primària i a les oficines de farmàcia. L'algoritme ha estat integrat a la plataforma TIC de gestió de malalts crònics. La validació del procés clínic s'efectuarà dins del projecte EU Synergy-COPD i el pla d'escalabilitat a Catalunya es materialitzarà a curt termini en el marc del PDMAR.

Conclusions

1. Es demostra el potencial de transferibilitat de l'EF a Atenció Primària amb el suport d'una aplicació web de treball col·laboratiu que va facilitar un augment significatiu i sostenible de la qualitat de les proves efectuades per personal no especialitzat (manuscrit 1).

2. Es verificà la factibilitat del rol de les oficines de farmàcia per a la detecció de casos de MPOC en un programa coordinat amb Atenció Primària. Les oficines de Farmàcia podrien tenir un rol complementari a l'Atenció Primària en el diagnòstic de MPOC oculta. El desenvolupament i validació del programa es completarà una vegada finalitzada la present tesi doctoral (manuscrits 2 i 3).

3. L'elaboració del mapa de proves de funció pulmonar a Catalunya va permetre la identificació dels requeriments per a l'escalabilitat regional del programa de transferència de l'EF en el marc d'un model de atenció integrada (manuscrits 4 i 5).

4. Es va verificar el rol essencial de les estratègies d'entrenament dels professionals no especialitzats com a component essencial d'un programa de transferència d'EF de qualitat a l' Atenció Primària (manuscrits 6 i 7).

5. Es van efectuar dos contribucions tecnològiques rellevants per assegurar la interoperabilitat de l'EF a nivell del sistema de salut: l'elaboració del CDA (manuscrit 8) i el desenvolupament i validació d'un algoritme per l'avaluació automàtica de la qualitat de l'EF (manuscrit 9).

Summary in Spanish

Impacto de las Tecnologías de la Información y la Comunicación en las Pruebas de Diagnóstico
La Espirometría Forzada como prueba de concepto

Introducción

El despliegue de nuevos modelos de salud basados en la coordinación entre niveles asistenciales constituye una prioridad a nivel Europeo ante la necesidad de gestionar las disfunciones generadas por elevado impacto sanitario y social de las enfermedades crónicas.

La transferencia de complejidad desde la atención sanitaria especializada, en general de base hospitalaria, a profesionales de Atención Primaria, constituye uno de los elementos centrales del cambio en el modelo de salud. Ello implica el rediseño de procesos clínicos y la preparación del personal sanitario para el nuevo entorno.

El uso eficiente del potencial que ofrecen las Tecnologías de la Información y la Comunicación (TIC), como elemento facilitador de la colaboración entre niveles asistenciales y de una mayor accesibilidad del paciente, tiene un papel importante en el despliegue y articulación de los Servicios de Atención Integrada (SAI) que configuran el nuevo modelo de salud. En este contexto, la transferencia de las intervenciones diagnósticas especializadas a la atención primaria constituye un área muy relevante en el proceso de cambio.

La hipótesis central de la presente tesis doctoral es que la transferencia de determinadas pruebas diagnosticas a la atención primaria genera eficiencias a nivel del sistema de salud. Los diferentes estudios realizados en la tesis se centran en la espirometría forzada (EF), seleccionada, por sus características, como una prueba de concepto.

Los objetivos generales son explorar aquellos factores que se han identificado como claves en la modulación del proceso de la transferencia de la EF, así como definir estrategias para su escalabilidad regional. La tesis se estructura en base a 3 objetivos específicos:

Objetivo 1 - Análisis de la transferencia de la EF a Atención Primaria y a oficinas de farmacia.

En el primer estudio *"Telemedicine enhances Quality of Forced Spirometry in Primary Care"* se demostró la eficacia en el tiempo (12 m) de un servicio centralizado para control de calidad de la EF efectuada por profesionales no especializados de tres regiones españolas. Se demostró que la colaboración remota entre profesionales de primaria y especialistas de función pulmonar tiene un efecto positivo sostenido sobre la calidad de la EF realizada por personal no experto. Se observó una diferencia significativa entre el grupo intervención (71.5% EF de alta calidad) y el grupo control (59.5% EF de alta calidad) durante los 12 meses del estudio ($p<0.001$). La investigación generó información valiosa para planear de forma adecuada la escalabilidad del

programa a nivel regional. Los resultados de este estudio, junto con otros apartados de la tesis y otras investigaciones en curso, facilitarán el rediseño del papel de las pruebas diagnosticas en la gestión de los pacientes crónicos en un entorno de atención integrada.

Los estudios 2 *(Early detection of COPD in customers of urban community pharmacies: a pilot-study)* y 3 *(Spirometry in community-pharmacies: a novel strategy to reduce COPD underdiagnosis)* de la tesis responden de forma afirmativa a la siguiente pregunta:

Pueden las oficinas de farmacia tener un papel relevante en un programa de detección de casos de EPOC?

Los resultados son claramente indicativos del potencial de las oficinas de farmacia como agente sanitario en estrecha colaboración con Atención Primaria. Cabe señalar que ambos estudios solo aportan información sobre factibilidad. El análisis de eficiencia se planea como una actividad más allá de esta tesis doctoral, en el marco del proyecto EU Synergy-COPD y del Plan Director de Enfermedades de Aparato Respiratorio (PDMAR) del Departamento de Salud de la Generalitat de Catalunya.

Objetivo 2 – Evaluación de requerimientos para la escalabilidad regional a nivel de Catalunya

En los estudios 4 *(Encuesta de utilización de la función pulmonar en los hospitales públicos de Cataluña en 2009)* y 5 (*Estudio de la función pulmonar básica en los centros de atención primaria de Cataluña. Atención Primaria)* se analizó la situación y necesidades futuras de las pruebas de función pulmonar en Catalunya a nivel hospitalario y extra-hospitalario en el marco del PDMAR. Los resultados obtenidos confirman la necesidad de desplegar la EF en Atención Primaria y de incrementar la homogeneidad territorial en lo que respecta al acceso a las pruebas de función pulmonar para pacientes y profesionales. Se confirma la necesidad del programa de transferencia de la EF planteado en la tesis doctoral.

En un segundo grupo de estudios en el Objetivo 2 de la tesis, efectuados en el marco del PDMAR, se analizaron las necesidades y estrategias en lo que respecta al entrenamiento de profesionales no especializados tanto en el ámbito catalán, estudio 6 *(Diseño de un programa de formación básico para conseguir espirometrías de calidad)*, como a nivel Europeo, estudio 7 *(HERMES Spirometry: the European Spirometry Driving Licence).*

Objetivo 3 – Contribuciones tecnológicas a la escalabilidad

El estudio 8 *(Requerimientos técnicos de los espirómetros en la estrategia para garantizar el acceso a una espirometría de calidad)* aportó un elemento esencial para asegurar la interoperabilidad de los datos de EF al asegurar la estandarización de la transferencia de información utilizando el protocolo HL7 v3 y CDA (Clinical Document Architecture) con estándar R2. Efectuado con el soporte de la Oficina de Estándares e Interoperabilidad del Departament de Salut de la Generalitat de Catalunya dentro del Plan de Digitalización de la Imagen Médica. El estándar de transferencia de la EF ha sido ya adoptado por algunos fabricantes de equipos de medición y es un requerimiento para los concursos públicos a nivel regional.

Además, en el estudio 9 *(Clinical Decision Support System to Enhance Quality Control of Forced Spirometry)* se generó y validó un algoritmo para el control automático de la calidad de la EF. Los resultados de la validación con 778 curvas espirométricas indicaron que la sensibilidad y especificidad del algoritmo era del 96.1 y 94.9%, respectivamente. La validación del algoritmo aportó un segundo elemento tecnológico necesario para la escalabilidad del programa de transferencia de la EF a Atención Primaria y a oficinas de farmacia. El algoritmo ha sido integrado a la plataforma TIC de gestión de pacientes crónicos. La validación del proceso clínico se efectuará dentro del proyecto EU Synergy-COPD y el plan de escalabilidad en Catalunya se materializará a corto plazo en el marco del PDMAR.

Conclusiones

1. Se demostró el potencial de transferibilidad de la EF a Atención Primaria con el soporte de una aplicación web de trabajo colaborativo que facilitó un aumento significativo y sostenible de la calidad de las pruebas efectuadas por personal no especializado (manuscrito 1).

2. Se verificó la factibilidad del rol de las oficinas de farmacia para la detección de casos de EPOC en un programa coordinado con Atención Primaria. Las oficinas de Farmacia podrían tener un rol complementario a la Atención Primaria en el diagnostico de EPOC oculta. El desarrollo y validación del programa se completará una vez finalizada la presente tesis doctoral (manuscritos 2 y 3).

3. La elaboración del mapa de pruebas de función pulmonar en Catalunya permitió la identificación de los requerimientos para la escalabilidad regional del programa de transferencia de la EF en el marco de un modelo de atención integrada (manuscritos 4 y 5).

4. Se verificó el papel esencial de las estrategias de entrenamiento de profesionales no especializados como componente esencial de un programa de transferencia de EF de calidad a Atención Primaria (manuscritos 6 y 7).

5. Se efectuaron dos contribuciones tecnológicas relevantes para asegurar la interoperabilidad de la EF a nivel del sistema de salud: la elaboración del CDA (manuscrito 8) y el desarrollo y validación de un algoritmo para la evaluación automática de la calidad de la EF (manuscrito 9).

Annex

F. Burgos.

Quality of Forced Spirometry in Primary Care, Impact on the COPD Treatment.

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Editorial

Quality of Forced Spirometry in Primary Care, Impact on the COPD Treatment

La espirometría forzada de calidad en Atención Primaria, impacto en el tratamiento de la EPOC

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Spirometry is an essential test in the diagnosis, monitoring and management of respiratory diseases. Likewise, the reduction of forced vital capacity (FVC) has been related with greater mortality in cancer, cardiac pathologíes[1] and lower survival rates in adults with respiratory symptoms or disease.[2,3] This goes to show that John Hutchinson in 1846 was right on the mark when he defined this parameter as "vital" capacity.

Respiratory diseases that run their course with airway obstruction, especially chronic obstructive pulmonary disease (COPD) and asthma, are extremely prevalent. Despite their morbidity and mortality and the important consumption of resources involved in their management, both diseases are underdiagnosed, up to more than 70% in COPD as shown in a recent study in Spain.[4]

The diagnosis of COPD is based on the detection of airway obstruction and one of the most useful tools for its determination is the implementation of spirometry in Primary Care (PC). Several studies show the usefulness of spirometry to detect subjects at high risk for developing COPD,[5,6] but few analyze the impact of spirometry in the treatment of COPD.[7] In this issue of *Archivos de Bronconeumología*, M. Monteagudo et al[8] analyze the impact of spirometry testing in the standard clinical practice of COPD in Primary Care and how it influences COPD treatment. Twenty-one centers intervened in this cross-sectional observational study with the participation of 801 patients, for whom only 53% of spirometries were available, FEV_1 being the only parameter. Thus, it was impossible to correctly stratify the patients into degrees of severity, a limitation that was admitted by the authors of the study.

Once again, the underuse of spirometry in the diagnosis and follow-up of COPD is revealed. Only in half of the patients was COPD diagnosis confirmed by forced spirometry and there was evidence of great variability in its use between the 21 centers that participated in the study. This diversity was also studied in the audit that Pellicer et al[9] carried out in 10 hospitals in the province of Valencia that diagnosed COPD. Fifty-four percent of the patients with COPD diagnosis did not undergo spirometry before hospital discharge. This study also states that COPD diagnosis in the hospital setting does not meet the minimal standard of acceptable quality of care, stating that there are great differences in the diagnostic management of this disease between the different specialists and levels of health-care.

M Monteagudo et al[8] associated the use of spirometry with better patient control, although they did not associate it with an integral approach to the disease, as recommended by the clinical guidelines. Patients with spirometry presented more registered exacerbations but, however, a lower number of hospitalizations. This could explain why the authors defend better follow-up and registry of this group of patients. The majority of the patients had follow-up visits with their general practitioner in Primary Care, whereas 35% were controlled by the nursing staff. It was confirmed that being controlled by a pulmonologist and/or nurse was positively associated with follow-up spirometries.

Another aspect to highlight is that 38% of patients who were smokers had not received any type of anti-smoking advice and had less follow-up spirometries. Even lower is the percentage of patients who received "healthy lifestyle" advice on diet, exercise, etc. When the authors evaluated the treatment, they found a greater use of short-acting β-2-adrenérgics in patients without spirometry (60 vs 52%) and (70 vs 63%) in the use of glucocorticoids. The authors could not analyze the quality of the spirometry, and it must be noted that in many cases only FEV_1 is registered. Moreover, each spirometer had its own reference values and no data was provided as to whether the spirometers were subjected to any type of quality control. This all goes to show that, as the authors highlight, quality health care standards are far from being reached in COPD.[10]

In spite of national[11] and international[12] clinical guidelines recommending the use of forced spirometry as a diagnostic tool in COPD, it is not only underused in all healthcare settings, but many times it is not adequately utilized. This was demonstrated in the study by M. Monteagudo et al,[8] where the minimal values of spirometry (FVC, FEV_1 and FEV_1/FVC ratio) could not be compiled, nor were data for bronchodilators, and in many instances it was not known which reference values were used while only percentage FEV_1 values were collected.

The healthcare challenge is early diagnosis of respiratory diseases, especially in those with greater prevalence like COPD and asthma. The dissemination of quality spirometry is an objective within our reach in the near future, but quality controls must be implemented in order for spirometry to be a reliable exploration, where both numerical and graphic data can be accessed. We must strive for a more extensive use of spirometry in all healthcare settings, without sacrificing quality.

The growing impact of information and communication technologies (ICT) in medicine is a reality, and there is no doubt that spirometry will not lie outside these technological changes.[13] It is necessary for spirometry to occupy its deserved place in clinical histories, due to both its historical and clinical use. Only by integrating lung function in computerized registers can we guarantee adequate quality control, and the expansion of spirometry as a basic tool for the evaluation of health.

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References

1. Mannino DM, Buist SA, Petty TL, Enright PL, Redd CS. Lung function and mortality in the United Status: data from the First Matinal Health and Nutritional Examination Survey follow-up study. Thorax. 2003;58:388-93.
2. Burney PGJ, Hooper R. Forced vital capacity, airway obstruction and survival in a general population sample from the USA. Thorax. 2011;66:49-54.
3. Lee HM, Le H, Lee BT, López VA, Wong ND. Forced vital capacity paired with Framingham Risk Score for prediction of all-cause mortality. Eur Respir J. 2010;36:1002-6.
4. Soriano JB, Ancochea J, Miravitlles M, García-Río F, Durán-Tauleria E, Muñoz L, et al. Recent trends in COPD prevalence in Spain: a repeated cross-sectional survey 1997-2007. Eur Respir J. 2010;36:758-65.
5. Naberan K, de la Roza C, Lamban M, Gobartt E, Martín A, Miravitlles M. Use of spirometry in the diagnosis and treatment of chronic obstructive pulmonary disease in primary care. Arch Bronconeumol. 2006;42:638-44.
6. Castillo D, Guayta R, Giner J, Burgos F, Capdevila C, Soriano JB, et al, FARMAEPOC group. COPD case finding by spirometry in high-risk customers of urban community pharmacies: a pilot study. Respir Med. 2009;103:839-45.
7. Dales RE, Vandemheen KL, Clinch J, Aaron SD. Spirometry in the primary care setting: influence on clinical diagnosis and management of airflow obstruction. Chest. 2005;128:2443-7.
8. Monteagudo M, et al. Variabilidad en la realización de la espirometría y sus consecuencias en el tratamiento de la EPOC en Atención Primaria. Archiv Bronconeumol. 2011;47:226-33.
9. Pellicer C, Soler-Cataluña JJ, Andreu A, Bueso J. Calidad del diagnóstico de la enfermedad pulmonar obstructiva crónica en el ámbito hospitalario. Arch Bronconeumol. 2010;46:64-9.
10. Soler-Cataluña JJ, Calle M, Cosío BG, Marín JM, Monsó E, Alfageme I, Comité de Calidad Asistencial de la SEPAR;Area de Trabajo EPOC de la SEPAR. Estándares de calidad asistencial en la EPOC. Arch Bronconeumol. 2009;45:196-203.
11. Peces-Barba G, Barberà JA, Agustí AGN, Casanova C, et al. Guía clínica SEPAR-ALAT de diagnóstico y tratamiento de la EPOC. Available from: http://www.separ.es/publicaciones/normativas.html. Arch Bronconeumol. 2008;44:271–8.
12. Pauwels RA, Buist AS, Calverley PM, Jenkins CR, Hurd SS, GOLD Scientific Committee. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop summary. Am J Respir Crit Care Med. 2001;163:1256-76.
13. Telemetric developments in respiratory monitoring. J. Roca, B. Vallespín, F. Burgos. The Buyers' Guide to Respiratory Care Products, 2008.

References

(1) Council of the EU 3053rd Employment sphaca. Innovative approaches for chronic diseases in public health and healthcare systems. 2010. 2013.

(2) WHO.2010. World Health Statistics 2010 report. 2013.

(3) 2008-2013 WHO. Non-communicable Disease Action Plan for Cardiovascular Diseases, Cancers, Chronic Respiratory Diseases, Diabetes. 2008-2013 WHO. 2013.

(4) Goodwin Nea. Integrated care for patients and populations: Improving outcomes by working together. [London, The King's Fund / Nuffield Trust]. 2012.

(5) Bousquet J, Anto JM, Sterk PJ, Adcock IM, Chung KF, Roca J et al. Systems medicine and integrated care to combat chronic noncommunicable diseases. Genome Med 2011;3(7):43.

(6) Epping-Jordan JE, Galea G, Tukuitonga C, Beaglehole R. Preventing chronic diseases: taking stepwise action. Lancet 2005 November 5;366(9497):1667-71.

(7) NEXES project (EU Grant 225025 and CIP-PSP program, 2008 2012. Supporting Healthier and Independent Living for Chronic Patients and Elderly (NEXES). 2012.

(8) WHO report.2005.ISBN 92 4 156280 3. Preparing a Health Care Workforce for the 21st Century:The Challenge of Chronic Conditions. 2005.

(9) Shaw Sea. What is integrated care? Nuffield Trust, London . 2011.

(10) Lloyd Jeal. Integrated Care. A Guide for Policymakers. Alliance for Health and the Future. London . 2006.

(11) Kodner Deal. Integrated care: meaning, logic, applications, and implications – a Discussion Paper. International Journal of Integrated Care 2002;2(12).

(12) Lewis Rea. Where Next for Integrated Care Organisations in the English NHS. Nuffield Trust and The King's Fund . 2010.

(13) Nolte Eea. Managing chronic conditions: Experience in eight countries. Brussels, European Observatory on Health Systems and Policies. 2008.

(14) Roca J, Alonso A, Hernandez C. Integrated care for COPD patients: time for extensive deployment. Breathe 5, 26-35. 20-5-2008.

(15) Casas A, Troosters T, Garcia-Aymerich J, Roca J, Hernandez C, Alonso A et al. Integrated care prevents hospitalisations for exacerbations in COPD patients. Eur Respir J 2006 July;28(1):123-30.

(16) Forum of International Respiratory Societies (FIRS). UN meeting in 2014 -http://www.thoracic.org/media/firs.php. 2013.

(17) Vestbo J, Hurd SS, Agusti AG, Jones PW, Vogelmeier C, Anzueto A et al. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. Am J Respir Crit Care Med 2013 February 15;187(4):347-65.

(18) Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. PLoS Med 2006 November;3(11):e442.

(19) Murray CJ, Lopez AD, Black R, Mathers CD, Shibuya K, Ezzati M et al. Global burden of disease 2005: call for collaborators. Lancet 2007 July 14;370(9582):109-10.

(20) Anto JM, Vermeire P, Vestbo J, Sunyer J. Epidemiology of chronic obstructive pulmonary disease. Eur Respir J 2001 May;17(5):982-94.

(21) Averame G, Bonavia M, Ferri P, Moretti AM, Fogliani V, Cricelli C et al. Office spirometry can improve the diagnosis of obstructive airway disease in primary care setting. Respir Med 2009 June;103(6):866-72.

(22) Celli BR. ATS standards for the optimal management of chronic obstructive pulmonary disease. Respirology 1997;2 Suppl 1:S1-S4.

(23) Miravitlles M, Soriano JB, Garcia-Rio F, Munoz L, Duran-Tauleria E, Sanchez G et al. Prevalence of COPD in Spain: impact of undiagnosed COPD on quality of life and daily life activities. Thorax 2009 October;64(10):863-8.

(24) Rabe KF, Hurd S, Anzueto A, Barnes PJ, Buist SA, Calverley P et al. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. Am J Respir Crit Care Med 2007 September 15;176(6):532-55.

(25) Soriano JB, Ancochea J, Miravitlles M, Garcia-Rio F, Duran-Tauleria E, Munoz L et al. Recent trends in COPD prevalence in Spain: a repeated cross-sectional survey 1997-2007. Eur Respir J 2010 October;36(4):758-65.

(26) Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet 2009 August 29;374(9691):721-32.

(27) Eaton T, Withy S, Garrett JE, Mercer J, Whitlock RM, Rea HH. Spirometry in primary care practice: the importance of quality assurance and the impact of spirometry workshops. Chest 1999 August;116(2):416-23.

(28) Schermer T, Eaton T, Pauwels R, van Weel C. Spirometry in primary care: is it good enough to face demands like World COPD Day? Eur Respir J 2003 November;22(5):725-7.

(29) Schermer TR, Jacobs JE, Chavannes NH, Hartman J, Folgering HT, Bottema BJ et al. Validity of spirometric testing in a general practice population of patients with chronic obstructive pulmonary disease (COPD). Thorax 2003 October;58(10):861-6.

(30) Hill K, Goldstein RS, Guyatt GH, Blouin M, Tan WC, Davis LL et al. Prevalence and underdiagnosis of chronic obstructive pulmonary disease among patients at risk in primary care. CMAJ 2010 April 20;182(7):673-8.

(31) Garcia-Aymerich J, Escarrabill J, Marrades RM, Monso E, Barreiro E, Anto JM. Differences in COPD care among doctors who control the disease: general practitioner vs. pneumologist. Respir Med 2006 February;100(2):332-9.

(32) Walters JA, Walters EH, Nelson M, Robinson A, Scott J, Turner P et al. Factors associated with misdiagnosis of COPD in primary care. Prim Care Respir J 2011 December;20(4):396-402.

(33) Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJ. Global and regional burden of disease and risk factors, 2001: systematic analysis of population health data. Lancet 2006 May 27;367(9524):1747-57.

(34) Halbert RJ, Natoli JL, Gano A, Badamgarav E, Buist AS, Mannino DM. Global burden of COPD: systematic review and meta-analysis. Eur Respir J 2006 September;28(3):523-32.

(35) Miravitlles M, Soriano JB, Garcia-Rio F, Munoz L, Duran-Tauleria E, Sanchez G et al. Prevalence of COPD in Spain: impact of undiagnosed COPD on quality of life and daily life activities. Thorax 2009 October;64(10):863-8.

(36) Tresserras R. [Planning driven by health priorities. Master planning criteria]. Med Clin (Barc) 2008 December;131 Suppl 4:42-6.

(37) Ministerio de Sanidad y Politica Social. Estrategia nacional en EPOC del Sistema Nacional de Salud. 2009.

(38) Schirnhofer L, Lamprecht B, Firlei N, Kaiser B, Buist AS, Halbert RJ et al. Using targeted spirometry to reduce non-diagnosed chronic obstructive pulmonary disease. Respiration 2011;81(6):476-82.

(39) Cockcroft DW. Direct challenge tests: Airway hyperresponsiveness in asthma: its measurement and clinical significance. Chest 2010 August;138(2 Suppl):18S-24S.

(40) Turton JA, Glasgow NJ, Brannan JD. Feasibility and acceptability of using bronchial hyperresponsiveness to manage asthma in primary care: a pilot study. Prim Care Respir J 2012 March;21(1):28-34.

(41) Eliasson O, DeGraff AC, Jr. The use of criteria for reversibility and obstruction to define patient groups for bronchodilator trials. Influence of clinical diagnosis, spirometric, and anthropometric variables. Am Rev Respir Dis 1985 October;132(4):858-64.

(42) Anthonisen NR, Lindgren PG, Tashkin DP, Kanner RE, Scanlon PD, Connett JE. Bronchodilator response in the lung health study over 11 yrs. Eur Respir J 2005 July;26(1):45-51.

(43) Sutherland ER, Cherniack RM. Management of chronic obstructive pulmonary disease. N Engl J Med 2004 June 24;350(26):2689-97.

(44) Bateman ED, Hurd SS, Barnes PJ, Bousquet J, Drazen JM, FitzGerald M et al. Global strategy for asthma management and prevention: GINA executive summary. Eur Respir J 2008 January;31(1):143-78.

(45) Pellicer CC, Soler Cataluna JJ, Andreu Rodriguez AL, Bueso FJ. Diagnosis of COPD in hospitalised patients. Arch Bronconeumol 2010 February;46(2):64-9.

(46) Damarla M, Celli BR, Mullerova HX, Pinto-Plata VM. Discrepancy in the use of confirmatory tests in patients hospitalized with the diagnosis of chronic obstructive pulmonary disease or congestive heart failure. Respir Care 2006 October;51(10):1120-4.

(47) Torrubia Fernandez MJ, Comin OA, Moreno VM, Carrizo Sierra SJ, Marin Tigo JM. [Spirometry and echocardiography use in hospitalised patients due to COPD or heart failure]. An Med Interna 2008 May;25(5):222-5.

(48) Miller MR, Crapo R, Hankinson J, Brusasco V, Burgos F, Casaburi R et al. General considerations for lung function testing. Eur Respir J 2005 July;26(1):153-61.

(49) Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A et al. Standardisation of spirometry. Eur Respir J 2005 August;26(2):319-38.

(50) Steenbruggen I, Mitchell S, Severin T, Palange P, Cooper BG. Harmonising spirometry education with HERMES: training a new generation of qualified spirometry practitioners across Europe. Eur Respir J 2011 March;37(3):479-81.

(51) Borg BM, Hartley MF, Fisher MT, Thompson BR. Spirometry training does not guarantee valid results. Respir Care 2010 June;55(6):689-94.

(52) Perez-Padilla R, Vazquez-Garcia JC, Marquez MN, Menezes AM. Spirometry quality-control strategies in a multinational study of the prevalence of chronic obstructive pulmonary disease. Respir Care 2008 August;53(8):1019-26.

(53) Menezes AM, Perez-Padilla R, Jardim JR, Muino A, Lopez MV, Valdivia G et al. Chronic obstructive pulmonary disease in five Latin American cities (the PLATINO study): a prevalence study. Lancet 2005 November 26;366(9500):1875-81.

(54) Walters JA, Hansen EC, Johns DP, Blizzard EL, Walters EH, Wood-Baker R. A mixed methods study to compare models of spirometry delivery in primary care for patients at risk of COPD. Thorax 2008 May;63(5):408-14.

(55) White P, Wong W, Fleming T, Gray B. Primary care spirometry: test quality and the feasibility and usefulness of specialist reporting. Br J Gen Pract 2007 September;57(542):701-5.

(56) Hankinson JL. Office spirometry: does poor quality render it impractical? Chest 1999 August;116(2):276-7.

(57) MacIntyre NR. The American Association for Respiratory Care and the National Lung Health Education Program: assuring quality in spirometry. Respir Care 2004 June;49(6):587-8.

(58) Levy ML, Quanjer PH, Booker R, Cooper BG, Holmes S, Small I. Diagnostic spirometry in primary care: Proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations: a General Practice Airways Group (GPIAG)1 document, in association with the Association for Respiratory Technology & Physiology (ARTP)2 and Education for Health3 1 www.gpiag.org 2 www.artp.org 3 www.educationforhealth.org.uk. Prim Care Respir J 2009 September;18(3):130-47.

(59) Masa JF, Gonzalez MT, Pereira R, Mota M, Riesco JA, Corral J et al. Validity of spirometry performed online. Eur Respir J 2011 April;37(4):911-8.

(60) Kenagy J. Designed to Adapt: Leading Healthcare in Challenging Times2009: Second River Healthcare. 2013.

(61) WB R. Health Care as a Complex Adaptive System: Implications for Design and Management. The Bridge, Spring 17-25., 2008.

(62) Tinetti ME, Studenski SA. Comparative effectiveness research and patients with multiple chronic conditions. N Engl J Med 2011 June 30;364(26):2478-81.

(63) Jithoo A, Enright PL, Burney P, Buist AS, Bateman ED, Tan WC et al. Case-finding options for COPD: results from the Burden of Obstructive Lung Disease study. Eur Respir J 2013 March;41(3):548-55.

(64) NHLBI Workshop. A Case-finding Strategy for Moderate-to-severe COPD in the United States: Executive Summary www.nhlbi.nih.gov/ meetings/workshops/case-finding-exesum.htm Date last accessed: 2011. Date last updated: 2009. 2011.

(65) I.Cano, A.Alonso, F.Burgos, C.Hernandez, JL.Martinez-Roldan, J.Roca. A multi-tier ICT framework to deploy Coodinated Care. Journal of Medical Internet Research (submitted) 2013.

(66) Garrido JM, Schlesinger R. Principles of Modern Operating Systems: Jones and Bartlett Publishers; 2008. 208.

(67) Liedtke J. Toward real microkernels. Commun ACM. 1996;39(9):70-7. 2013.

(68) FP7-ICT-270086 Synergy-COPD. Modelling and simulation environment for systems medicine (Chronic obstructive pulmonary disease -COPD- as a use case) www.Synergy-COPD.eu. 2010.

(69) Salas T, Rubies C, Gallego C, Munoz P, Burgos F, Escarrabill J. Technical Requirements of Spirometers in the Strategy for Guaranteeing the Access to Quality Spirometry. Arch Bronconeumol 2011;47(9):446-469.

(70) SIBEL. Interoperabilidad compatible con HL7(CDA de espirometría) http://www.sibelgroup.com/es/productos/respiratorio/espirometros/datospir-touch. 2012.

(71) Francisco García-Río, Myriam Calle, Felip Burgos, Pere Casan, Félix del Campo, Juan B.Galdiz et al. Normativa SEPAR Espirometría. Arch Bronconeumologia 2013 on line.

(72) Hankinson JL, Reynolds JS, Das MK, Viola JO. Method to produce American Thoracic Society flow-time waveforms using a mechanical pump. Eur Respir J 1997 March;10(3):690-4.

(73) Gardner RM, Hankinson JL. Standardization of spirometry--1987 ATS update (American Thoracic Society). J Occup Med 1988 March;30(3):272-3.

(74) Burgos F, Disdier C, de Santamaria EL, Galdiz B, Roger N, Rivera ML et al. Telemedicine enhances quality of forced spirometry in primary care. Eur Respir J 2012 June;39(6):1313-8.

(75) Enright PL, Johnson LR, Connett JE, Voelker H, Buist AS. Spirometry in the Lung Health Study. 1. Methods and quality control. Am Rev Respir Dis 1991 June;143(6):1215-23.

(76) Enright PL, Skloot GS, Cox-Ganser JM, Udasin IG, Herbert R. Quality of spirometry performed by 13,599 participants in the World Trade Center Worker and Volunteer Medical Screening Program. Respir Care 2010 March;55(3):303-9.

(77) Decramer M, Celli B, Tashkin DP, Pauwels RA, Burkhart D, Cassino C et al. Clinical trial design considerations in assessing long-term functional impacts of tiotropium in COPD: the UPLIFT trial. COPD 2004;1(2):303-12.

(78) Spirometry Monitoring Technology - SPIROLA. NIOSH - Spirometry in Occupational Medicine.U.S.Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.www.cdc.gov/niosh/spirometry/spirola.htlm .

(79) Janssens W, Liu Y, Liu D, Kesten S, Tashkin DP, Celli BR et al. Quality and reproducibility of spirometry in COPD patients in a randomized trial (UPLIFT). Respir Med 2013 May 25.

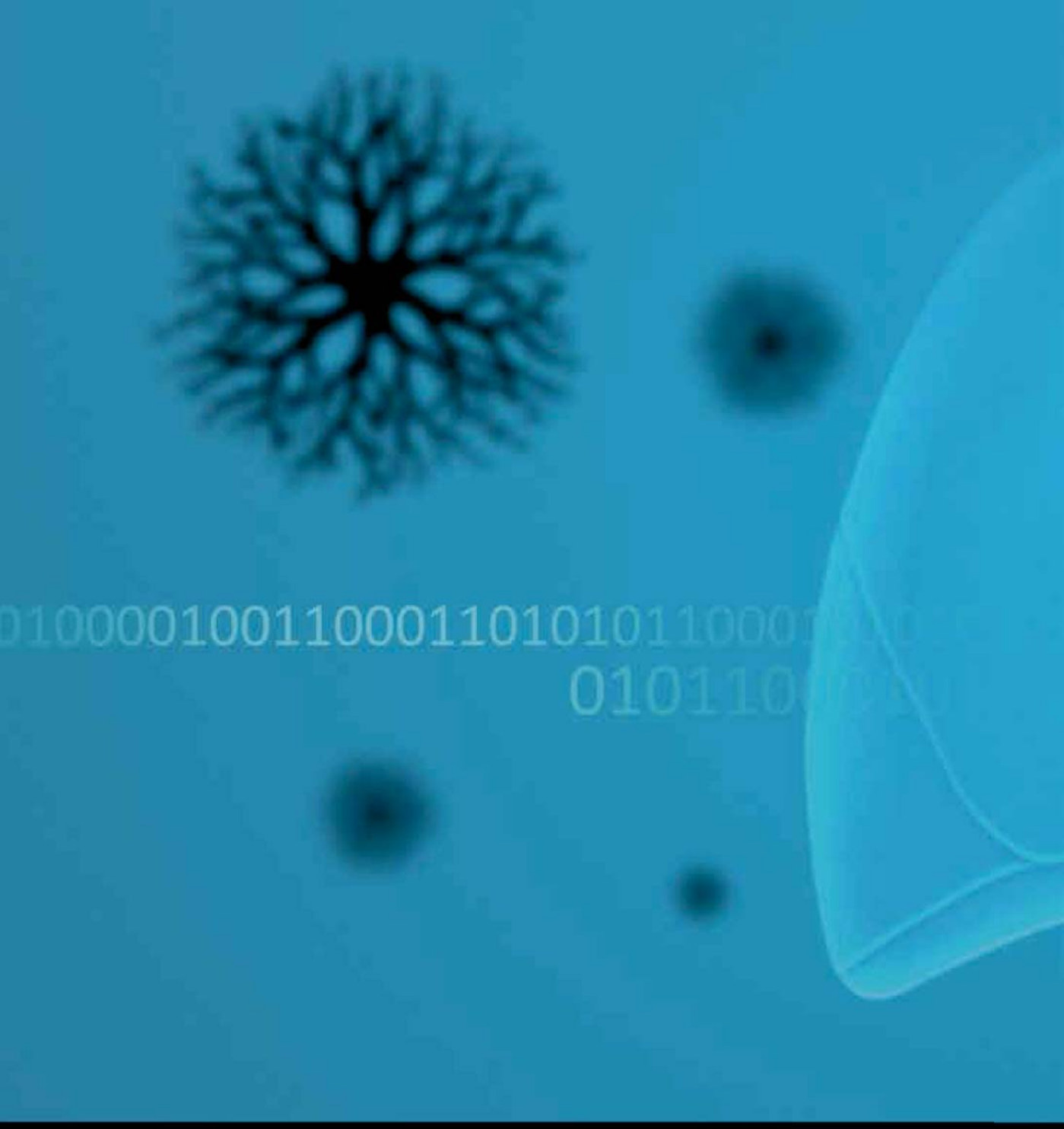
(80) Lopez de Santa ME, Gutierrez L, Legorburu C, Valero M, Zabala M, Sobradillo V et al. [Spirometry: quality in the respiratory medicine clinics of a public health care area]. Arch Bronconeumol 2002 May;38(5):204-8.

(81) Steenbruggen I, Mitchell S, Severin T, Palange P, Cooper BG. Harmonising spirometry education with HERMES: training a new generation of qualified spirometry practitioners across Europe. Eur Respir J 2011 March;37(3):479-81.

(82) Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV et al. HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc 2006 January;13(1):30-9.

(83) Ismaël Ghalimi. Business Process Management Initiative (BPMN) vs Unified Modeling Language (UML) www.intalio.com. 2002.

(84) Marina Malanda N., Galdiz Iturri J.B., Lopez de Santa María Miró E. Estudio multicéntrico para el análisis de la efectividad de la telemedicina en programas de aseguramiento de la calidad de las espirometrías. Plan de Calidad para el Sistema Nacional de Salud del Ministerio de Sanidad y Política Social. Agencia de Evaluación de Tecnologías Sanitarias del País Vasco; 2012. Informes de Evaluación de Tecnologías Sanitarias: OSTEBA Nº 2009/03. 2012.



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