IS PLUG-AND-PLAY SPIROMETRY THE FUTURE?

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CURRENT HEALTH TRENDS EXPAND THE NEED FOR SPIROMETRY

Patients with major respiratory disorders currently impose a large burden on healthcare systems worldwide and this burden is expected to increase over the next decade. Spirometry plays a central role in the diagnosis, monitoring and management of these patients [1, 2].

The role of spirometry is predicted to expand across healthcare tiers and beyond respiratory medicine because of two main factors. Firstly, there is strong evidence that the two main spirometry variables, maximum expired volume (forced vital capacity) and forced expiratory volume during the first second of the test (FEV1) [1, 2], are positively associated with survival rate in the general population. Secondly, novel strategies addressing integrated management of patients with prevalent noncommunicable diseases indicate the need to assess chronic patients for highly clustered comorbid conditions, such as chronic obstructive pulmonary disease (COPD), coronary artery disease, and type II diabetes mellitus and metabolic syndrome [3]. This is because the presence of these comorbid conditions has implications on patients’ clinical features and a well-established influence on prognosis [3, 4]. Moreover, due to the recognised under-diagnosis of COPD [5], spirometry has also a role in case-finding strategies [5–8].

These trends indicate a need to develop strategies facilitating ubiquitous spirometry in the healthcare system, including administration of the tests by professionals (respirologists) with a wide scope of skills and self-administration by patients. However, it must be emphasised that while equipment may be “plug and
play”, spirometry will still require adequate training of personnel for accurate, reliable and safe spirometry results. In this scenario, the potential of the plug-and-play concept, but also its limitations, must be assessed. It is of note, however, that ubiquitous spirometry in an integrated care scenario has two main pre-requisites. Firstly, applicability and high-quality testing administered by different user profiles; and, secondly, accessibility of the tests carried out across layers of care by different providers.

THE PLUG-AND-PLAY CONCEPT: POTENTIAL, LIMITATIONS AND ADOPTION

The plug-and-play concept is a technological one defined by the Merriam-Webster Dictionary as “a feature of a computer system by which peripherals are automatically detected and configured by the operating system”. This definition implies that the computer system is operational for the end-user without the need for intermediate technology-driven steps to prepare the equipment for use.

In the early days of the application of computer technologies in the clinical arena, hardware was a collection of modules, each with their own functionalities. In order to make the different modules work as an operational measurement system, several interventions were required that reduced enormously the usability of the systems and constrained the use of such equipment to specialised diagnostic areas where technological support was available.

Over the last few years, the boom in smartphone applications (“apps”) and the introduction of the Universal Plug and Play (UPnP) protocol [9] have facilitated the emergence of highly automated computer systems not requiring device configuration by the user. Moreover, the extensive use of smartphone apps is triggering a technological and social revolution that has rapidly expanded the potential for ubiquity of clinical testing beyond the traditional diagnostic areas often allocated in specialised hospital departments.

It should be noted, however, that several bottlenecks will need to be removed before such generalisation occurs. We can identify three major areas requiring attention and further work both on technological and regulatory aspects, namely:

- quality assurance of the technology used for testing;
- legal consequences of evolving concepts of the definition of medical devices and ethical aspects governing data transfer; and
- interoperability of equipment and testing among respirologists, namely physicians, allied health professionals, community workers and patients/relatives often located in different healthcare tiers and using proprietary health information systems (HISs).

The early phases of the current process of transition from usual care to a coordinated (integrated) healthcare scenario [10] pose exciting challenges in several dimensions that should be approached using the concepts of complex systems management [11, 12]. Such a transition involves re-engineering of fundamental aspects of the health system with profound organisational changes associated with emerging roles for professionals and citizens. Moreover, the cultural changes in terms of information management and decision making processes are significant.

It has been demonstrated that highly automated and user-friendly measurement systems may generate further dysfunction if they are not provided by interoperability at the health system level such that high-quality testing information is accessible across healthcare tiers. What are the concepts of interoperability?

Traditional telemedicine approaches were focused on the transfer of information between end-users and a remotely located professional. Thereafter, the initial deployment experiences of information and communication technology (ICT) platforms supporting home-based services relied on the implementation of consolidated standards for interoperability between the ICT platform and the proprietary HIS used by the healthcare provider using well-defined, but often costly, integration strategies.

Recently, interoperability within a healthcare sector including several providers triggered the development of health information exchange platforms including sophisticated, and always costly, integration strategies. However, full development of interoperability at the health system level, supporting unplanned relationships of patients with several providers, requires open ICT architectures with flexible, low-cost modalities of integration. Moreover, recent experience of extensive deployment of integrated care services for chronic patients supported by ICT platforms strongly suggests the need for collaborative tools involving development of novel strategies for knowledge sharing among actors in the health system [11].

In short, we currently believe that extensive adoption of plug-and-play measurement systems will occur, hopefully in the near future, in the context of a knowledge-sharing scenario supporting coordinated care for chronic patients.

We acknowledge that spirometry can, in the future, be a strong candidate for extensive adoption including a plug-and-play strategy. However, some specifics of the test, such as its patient-effort dependence, risk of contraindications and its current evolving condition in pulmonary medicine, will strongly modulate the way toward such an extensive deployment.
SPIROMETRY IN PULMONARY MEDICINE TODAY

During the last decade, spirometry has evolved from being used almost exclusively in lung function laboratories to having worldwide recognition as a basic test in primary care and in many medical offices (office spirometry). However, some limitations are analysed below.

The technology supporting spirometry strongly depends on the clinical setting. For example, in a lung function laboratory of a tertiary hospital, spirometry is often part of a patient’s extensive assessment, including carbon monoxide pulmonary transfer capacity, plethysmographic lung volumes, etc., and will require a totally different technological design to a primary care centre performing a few tests per day.

In tables 1 and 2 and figures 1–12, we show different types of measurement equipment currently used for spirometry. A detailed description of all those modalities can be found in refs 13–15. Parallel to the extension of the use of spirometry outside the lung function laboratory, equipment has evolved in terms of miniaturisation, usability, portability and price. It is of note, however, that some of the portable devices do not strictly meet the quality criteria that should be satisfied all spirometers, as extensively documented [14, 15].

Tables 1 and 2 and figures 1–12 show that there is a wide arsenal of equipment on offer for diagnostic and/or monitoring purposes. However, two necessary factors for an efficient expansion of spirometry across the health system are

- high-quality testing; and
- accessibility of high-quality tests across the healthcare sector.

High-quality spirometry at all care levels requires adoption of appropriate quality control strategies.

Unfortunately, built-in warning messages and flags to detect poor quality tests (start/end of the test, cough, etc.) are insufficient to ensure automatic quality control of spirometry due to lack of precision of algorithms. As a result, these automatic systems are not currently useful for quality control when spirometry is performed by nonspecialist professionals. However, access to high-quality tests across healthcare tiers is needed for two purposes: to prevent testing duplicates and to allow longitudinal comparisons.

Despite the optimistic trends regarding extensive use of spirometry that have been described here, we acknowledge that there is poor availability and insufficient use of

<table>
<thead>
<tr>
<th>TABLE 1. Spirometry technology</th>
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<tr>
<td><strong>Need to calibrate</strong></td>
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<tr>
<td>Pneumotachometer (Lilly, Fleisch) Turbine</td>
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<tr>
<td>Pneumotachometer (ultrasound) Turbine</td>
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<tr>
<td>PiKo* (pressure/flow sensor) Disposable pneumotachometer (pre-calibrated)</td>
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<tr>
<td>Disposable turbine (pre-calibrated)</td>
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<td>New sensors (under research)</td>
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*: nSpire Health Inc. (Hertford, UK).

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<th>TABLE 2. Historical and currently used equipment for spirometry</th>
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<tr>
<td><strong>Stead-Wells spirometers</strong></td>
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<tr>
<td>Water seal</td>
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<tr>
<td>Dry rolling seal</td>
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<tr>
<td><strong>Bellows-type spirometer</strong></td>
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<tr>
<td>Volume-displacement spirometer</td>
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<tr>
<td><strong>Pneumotachographs</strong></td>
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<tr>
<td>Measure the difference in pressure before and after a breath with known resistance</td>
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<tr>
<td>Fleisch types use a series of parallel capillaries; Lilly types use a membrane</td>
</tr>
<tr>
<td><em><em>Pitot (preVent</em>)</em>*</td>
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<tr>
<td>Open-ended barrel</td>
</tr>
<tr>
<td>Impact pressure is measured in the paired lumens of the rip and is based on a bidirectional differential pressure</td>
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<tr>
<td><strong>Turbine</strong></td>
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<tr>
<td>The harder the patient blows, the faster the turbine rotates</td>
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<tr>
<td>Rotations are measured (usually by infrared)</td>
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<tr>
<td><strong>Ultrasound</strong></td>
</tr>
<tr>
<td>Measure flow using ultrasound</td>
</tr>
<tr>
<td>Require no calibration</td>
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<tr>
<td><strong>Mass flow sensors</strong></td>
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<tr>
<td>Measure the electronic resistance through a hot wire</td>
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<tr>
<td>Resistance is dependent on the temperature of the wire</td>
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<tr>
<td><strong>Pressure/flow sensor technology</strong></td>
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<tr>
<td><strong>Lip reverberation</strong></td>
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<td>Under research</td>
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*: MGC Diagnostics (St Paul, MN, USA).
spirometry at all levels, even in hospitals [16, 17], leading to underdiagnosis of chronic respiratory diseases such as COPD. Compared with patients with heart failure, COPD patients are less likely to have a confirmatory test, even in those cases where the two conditions, heart failure and COPD, coexist [17, 18]. Consequently, dissemination of current trends on management of chronic patients [3] and training for spirometry in primary care through standardised courses are two important aims [19].

**ENHANCED SPIROMETRY CAN HAVE A MAJOR IMPACT ON HEALTH MANAGEMENT**

The best pulmonary function laboratories disregard ≥10% of patients’ data because of technical inaccuracies. But, in population-based studies, the figure may rise substantially and, in some cases, up to 40% of data might be censored [20]. It is well accepted that in nonspecialist settings, the inclusion of tests of suboptimum quality might increase our degree of uncertainty for clinical decision making. Consequently, high-quality (enhanced) spirometry (“quality diagnostic spirometry”) should be ensured at all levels of care.

The international (American Thoracic Society (ATS)/European Respiratory Society (ERS)) recommendations for spirometry [14, 15], which establish well-defined quality control criteria for both equipment and tests, do not include indications on strategies to ensure sustained quality assurance that are clearly needed in clinical settings where nonexpert professionals are likely to perform the tests. Moreover, it is common that adherence to ATS/ERS recommendations for both equipment and testing is lower than expected, even in specialised environments. The lack of appropriate strategies to enforce the use of those recommendations has been identified as a main barrier to achieving high-quality spirometry. This is fully endorsed by the results of the PLATINO study [21, 22], which used a centralised quality control assessment of spirometry. Moreover, as alluded to earlier, the problem is most relevant when tests are performed by nonexpert professionals, notably in primary care centres [20].

Recently, new models for quality control have been proposed to achieve similar standards to those seen in clinical trials or research. Adoption of those models can be decisive for a substantial improvement and sustainability of the quality of spirometry [21, 23].

**ACCESS TO TESTING ACROSS THE HEALTHCARE SYSTEM**

The concept of electronic health records (EHRs) has evolved profoundly...
The EHR is currently defined as a systematic collection of the patient’s health information using a digital support, which should facilitate information sharing across different healthcare levels.

The EHR can be allocated within the HIS of one provider delivering formal care, but chronic patients use to have more than one EHR since they are most often attended by several healthcare providers. Moreover, self-management of health information (personal health record (PHR) or personal health folder (PHF)) by the patient or by his/her relatives is a growing in Western countries.

The PHR/PHF is increasingly and successfully used for patients’ empowerment for self-management with a beneficial impact in terms of enhancing their adherence to therapy and preventive strategies, but the PHR/PHF could also be a way to enhance functional interoperability among healthcare providers, as well as between formal and informal care. Unfortunately, that is not the current situation. Interoperability issues at the health system level constitute a major limitation for extensive deployment of ICT-supported healthcare services. Moreover, spirometry is poorly implemented in the EHR, which fully explains why interoperability has not been perceived as an issue for it so far.

The spirometry equipment is a medical device that measures either volume or flow signals during the manoeuvre, generating different parameters that are most often stored in a proprietary format, limiting interoperability. 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 [24].

CDA for spirometry contains patients’ 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 normalised dataset organised in such a way that facilitates integration of spirometry into any HIS, and paves the way for access to spirometry by
health professionals working with different providers and/or at different healthcare tiers.

Acknowledgement of those major limiting factors to the transfer of lung function testing from specialised to primary care constitutes the first step in designing adequate strategies for change. The growing awareness of the limiting role of the lack of interoperability will overcome the current limitations in this area. It seems reasonable to predict that it should not take long to have truly interoperable spirometry accessible from any level of healthcare beyond the current PDF reports attached to HISs.

**PotentiaL role of informal care in spirometry**

Healthcare interventions outside a formal care scenario can be controversial but data from some pilot studies assessing the potential role of spirometry in pharmacy offices to support COPD case-finding programmes, with harmonised interplay with primary care, seem to generate promising results (table 3) [7, 25].

**conclusions**

As a diagnostic test, provided operators have appropriate training and competence, spirometry can be a simple, noninvasive, safe, reliable and inexpensive procedure for diagnosis and follow-up. Consequently, potential benefits of transferability of spirometry from specialised diagnostic units to community care are acknowledged by both health professionals and managers. However, key organisational and technological aspects that would make such transferability possible, while ensuring accessibility of the tests across the health system, are not yet in place. By solving the challenges involved in the transfer of spirometry from specialised centres to community care, we are paving the way for reshaping several other diagnostic and follow-up testing procedures within an integrated care scenario. Successful adoption of those changes should facilitate plug-and-play spirometry becoming a reality.

**statememt of interest**

None declared.

**table 3. spirometry scenarios**

| Formal care | Lung function laboratories (hospital) Primary care GP office |
| Informal care | Case-finding projects (i.e. community pharmacy) Self-management and personal spirometers |

GP: general practitioner.

**References**

17. Damarla M, Celli BR, Mullerova HX, et al. Discrepancy in the use of confirmatory tests in patients hospitalized with the...


