

Review



European Cystic Fibrosis Society Standards of Care: Quality Management in cystic fibrosis

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Abstract

Since the earliest days of cystic fibrosis (CF) treatment, patient data have been recorded and reviewed in order to identify the factors that lead to more favourable outcomes. Large data repositories, such as the US Cystic Fibrosis Registry, which was established in the 1960s, enabled successful treatments and patient outcomes to be recognized and improvement programmes to be implemented in specialist CF centres. Over the past decades, the greater volumes of data becoming available through Centre databases and patient registries led to the possibility of making comparisons between different therapies, approaches to care and indeed data recording. The quality of care for individuals with CF has become a focus at several levels: patient, centre, regional, national and international. This paper reviews the quality management and improvement issues at each of these levels with particular reference to indicators of health, the role of CF Centres, regional networks, national health policy, and international data registration and comparisons.

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Keywords: CF registries; Standards; Models of care; Quality management; Outcomes in CF

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1. Introduction

Since the earliest days of cystic fibrosis (CF) treatment, detailed summaries of large clinical groups have been employed to determine and describe the best approach to treatment, based on improved outcomes [1,2]. A comprehensive approach to therapy, routine monitoring, and attention to individual profiles and prognostic subgroups were highlighted in these early papers on CF management. The early years also included a cautionary tale, when mist tent therapy was cited as the key component responsible for remarkable survival in one large clinic, as documented in the newly established US CF Registry [3,4]. Over the following decade, however, it became clear that the scientific evidence of a beneficial effect was lacking for mist tent therapy [5]. Nevertheless, the improved outcomes were real, and emphasis was eventually, and more appropriately, placed on the comprehensive management package, including early diagnosis, patient and parent education, frequency of patient visits, daily physical therapy and aggressive antibiotic therapy. It was also during this period that a new focus on

growth and nutrition was evolving. Again, it began with reports from a large clinic where greatly improved outcomes were observed in patients with CF who were prescribed a high-fat diet in place of the historical low-fat diet [6,7]. But it was only when the CF registry data for two large, university-based clinics with similar demographics and approaches to other aspects of treatment were compared that the possibility of a normal diet and the goal of normal growth in patients with CF were widely embraced [8].

Although the benefits of specific treatments must be supported by evidence from well-controlled studies, there is great value in compiling and comparing outcomes in large clinical populations in order to document changes over time and to identify patterns and practices that may be associated with benefit or concern. Of particular importance are national registries that account for all, or a large and well-defined proportion of, CF patients in a region. National, annually updated CF registries in the USA since 1966 [9] and Canada since 1970 [10] were instituted primarily to describe population patterns of diagnosis, demographics and mortality. Over the years additional information was added to track

important correlates of CF prognosis, such as lung function and growth. Near the turn of the century, the US CF registry began to compute centre-specific summaries, which allowed CF Centres to locate themselves in the range from low to high performance for several key measures. The CF Foundation (CFF) Quality Initiative [11] was launched to support Centres in a concerted effort to improve poor outcomes and emulate the successful strategies of Centres with consistently good outcome measures. Several European countries have established CF registries, as have Australia and New Zealand, and there is an ongoing effort to orchestrate a European CF registry combining existing national registries with data from countries without a registry [12]. The European Cystic Fibrosis Society Patient Registry [13] was founded in 2004 and was based on the entry of defined demographic and clinical data. Later demographic data from CF registries collected during the European 6th framework Coordination Action project (2006–2010) provided evidence on disparities in care between Western and Eastern European countries. By the beginning of 2013, 20 European countries participated, representing more than 18,000 patients with CF. Annual reports are available [14], and the first comprehensive analysis has been carried out [15].

Several quality management programmes have evolved, with Centre comparison as a primary motivation. Early registry development in Germany was called the Cystic Fibrosis Quality Assurance (CFQA) project [16], and occurred long before the idea of publishing Centre-specific summaries was deemed acceptable in other regions. Whereas most registries report survival into the middle adult years, a report from South America [17] is a sobering reminder that attention to the quality and delivery of care is of primary importance.

As well as large Centre databases and national registries, there have been initiatives from the pharmaceutical industry to collect longitudinal data following large multicentre drug trials, to provide Phase IV analysis of treatment effects, and to study other prognostic factors. The Epidemiologic Study of Cystic Fibrosis (ESCF) [18] was a multicentre observational study that funded the collection of large amounts of clinical data on patients in participating Centres in the USA and Canada. The representativeness and continuity of the ESCF were complicated by funding issues, so that age and regional distributions and patterns over time were not always easy to interpret. But their analyses certainly intensified the interest in comparative studies and addressed many questions that will be more appropriately addressed by analysis of national registries, as more and more of them become poised to participate.

Issues of patient confidentiality and authorship in any publication must be addressed at an early stage of the planning of such studies. The equivalence of standard measures across populations, and even within populations, cannot be assumed and is another challenge in comparisons using registry data. The history and issues of benchmarking quality of CF care using registry data have been summarized in a recent review paper by Schechter [19].

The ongoing Early *Pseudomonas* Infection Control (EPIC) study is an example of an observational study, supported in part and ‘at arm’s length’ by the pharmaceutical industry, that combines registry follow-up with a study-targeted young American CF population. The study aims to answer specific questions about the early stages of the CF disease process and treatment options [20]. An Australian study of patients with CF identified at newborn screening highlights the difficulty of defining metrics for assessing progress, and by extension quality management, in the youngest patients [21]. Follow-up of well-defined groups of young patients with CF, especially those diagnosed by newborn screening, gives the best chance of describing and refining the best treatment practices [22].

Effective quality management at all levels must recognize the contributions and the needs of all partners in the process, from the medical experts and care personnel, to the patient and family members, and the analysts and interpreters of results. The processes for provision of data and access to data must be transparent and audited regularly. There must be a balance between the process and proposed outcomes so that all Centres can participate at a level compatible with their size, funding and stage of development. Analysis of changes over time and region, with appropriate recognition of known and potential confounders, will provide knowledge and guidance for the continuing improvement of care and outcomes in CF.

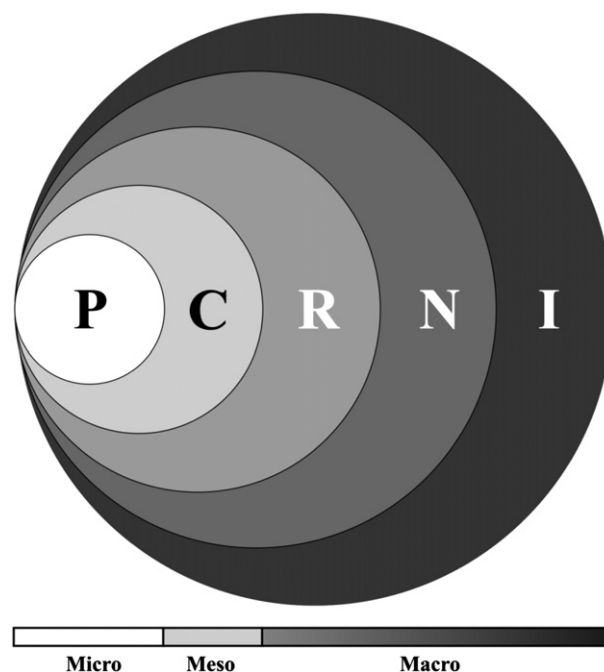


Fig. 1. Levels of quality management in CF. P, patient; C, cystic fibrosis Centre; R, regional governance, quality groups; N, national healthcare policy, registries, benchmarking; I, international guidelines and recommendations. The Dartmouth approach illustrates the different levels in clinical care: the microsystem level (patient, family cystic fibrosis care team); the mesosystem level (hospital); and the macrosystem (healthcare organizations, networks, governance) [27].

Quality management is closely linked to the goal of quality improvement. Quality improvement in healthcare has been defined as ‘an interdisciplinary process to raise the likelihood of the delivery of best practices for preventive, diagnostic, therapeutic, and rehabilitative care to maintain, restore, or improve health outcomes of individuals and populations’ [23]. Quality improvement is a science [24] and includes numerous distinct strategies for changing patient and provider behaviour, as well as redesigning systems of audit and feedback, case management, support for self-management, patient registries and computerized decision support [25]. But, the single, most basic approach involves iterative cycles of outcome measurement, identification of problems, implementation of potential solutions and repeated measurement [26].

Quality management in CF takes place at different levels: patient, Centre, regional, national and international (Fig. 1). The Dartmouth approach of systems embedded in systems acknowledges different levels of clinical care: the micro-system level involves the patient, their family and the specialist CF care team; the mesosystem level is the hospital/CF Centre in which the care is provided; and the macrosystem level includes healthcare organizations, networks and governance [27]. This paper reviews quality management issues at each of these levels.

2. Quality management at the patient level

2.1. Use of registry data

Patients are at the centre of all efforts to improve quality of care. This implies that they take an active part with CF teams in the continuous process of quality improvement. The use of CF registry data in daily care has been shown to be helpful in this respect [28–31]. Classical outcome indicators describing nutritional status and lung function are shared with patients at the site of the visit [32] and are expected to help promote different strategies to improve quality of care, with positive consequences on quality of life and life expectancy.

2.2. Patient-centred approach

Patients are the subject of care, but also experts on life with CF and their expertise can complement that of the CF healthcare professionals. The patients and their family are involved in quality improvement at all levels and their collaboration is a fundamental prerequisite. Full respect, trust and transparency should exist between partners, with co-responsibility for success and compliance with treatment. There should be an openness and willingness to learn from each other.

Different steps are included in this quality improvement process. Electronic files based on appropriate software (e.g. Port-CF, MUKO.dok., ECFS Registry) are a necessary precondition. Appropriate data and follow-up parameters may be grouped or individually presented to show changes

before and after therapeutic measures have been taken. These electronic files and follow-up charts may inform periodic CF team sessions and regular quality improvement conferences, centred on individual patients/parents.

International and national guidelines form the basis of different steps of therapy. Annual therapy goals can be set together with the patients/parents; therapy contracts may even be negotiated.

In the respiratory and nutritional fields, positive experiences highlight the successful implementation of quality improvement steps in CF patients and patient groups. For example, the natural progression in decline in forced expiratory volume in 1 s (FEV₁) [33,34] can be counteracted by different therapeutic interventions, such as anti-infectious and anti-inflammatory therapy and also by emerging new treatments for subgroups of patients [35–37]. Adherence to pulmonary guidelines [38], and education and training of physicians, families and patients [39] are successful quality improvement interventions that improve important outcomes. Key objectives are prevention and early treatment of exacerbations. For this, a patient checklist to be included in the electronic files is helpful to increase patient awareness of the early signs of exacerbation. Algorithms on what to do when FEV₁ declines are an additional useful instrument and should also appear in the electronic files and be transparent to patients.

A similar experience has also been reported for nutritional interventions. Many patients do not follow nutritional guidelines and recommendations [40,41]. This has a negative impact on the disease because adequate nutritional counselling, increased caloric intake and a good nutritional status are linked to favourable outcomes. In single cases an individually adapted strategy may be adequate. Quality improvement efforts have included individual and standardized nutrition plans and also behavioural and nutrition interventions to improve nutritional status in patients with CF [42,43].

Additional quality improvement projects, such as Centre care networking, individual quality improvement projects, group efforts and benchmarking are based on connecting patient data, registry data and individual efforts. There is also space for telehealth and patient-driven initiatives. Thus, quality improvement at the patient level is a central and decisive part of quality management in CF, accompanied by further and wider approaches at other levels.

2.3. Public reporting

Appropriate CF care and continuous improvement of clinical management are necessary to augment the well-being and quality of life of patients with CF [44]. Patient registries are of utmost importance not only from the experts’ point of view but also from the patients’ perspective. As well as providing reliable and comparable data in a given country, they also represent a valuable tool to lobby appropriate CF care. Registry data should be made available to patients and national health authorities [45]. In many European countries,

CF – a rare disease – competes for adequate share of the national health budget. It is important, however, that the data are presented in a patient-friendly way [46], and that patient representatives are trained in interpreting them.

In the USA, patient outcomes of each CF Centre have been laid open since 2006 (www.cff.org/CCNP/CareCenterSelector/Index.cfm). Interestingly, this effort did not lead patients to move to better performing Centres in any meaningful numbers.

2.4. Quality of life assessment

Over the past 20 years, a number of instruments have been developed to measure patient health status and to assess how patients feel or function with regard to their health conditions [47]. The questionnaires that measure quality of life in patients with CF (the revised CF questionnaire [CFQ-R] and the Cystic Fibrosis Quality of Life (CFQoL) questionnaire) are considered valid instruments with demonstrated reliability, internal validity, and sensitivity. As pulmonary exacerbations are clearly associated with worse symptoms of lung infection and health perception, these questionnaires represent an important tool to be used with clinical questions and national and international surveys, among other endpoints (clinical efficacy measures, surrogate endpoints or biomarkers) [48]. The European Medicines Agency recommends that in addition to demonstration of efficacy of treatment, a demonstration of benefit on health-related quality of life should be performed in CF trials [49].

2.5. Patient satisfaction assessment

‘Patients feel confident when looked after by medical personnel who are experienced in the care of their condition’ [50]. Therefore, quality improvement measures that start from patient satisfaction are under development in several countries. In Germany a nationwide study was conducted that examined patients’ experiences and satisfaction with the care provided at their Centres [51]. The response rate of 71–74% is a reflection of how interested patients are in contributing to improvements in the quality of their care.

However, quality improvement measures focusing on patient satisfaction are only useful if the results are discussed between CF teams and patient representatives. A way to organize such an ongoing and continuous reflection is to establish discussion groups that meet regularly. Such discussion groups may also offer a straightforward tool to improve care management in those countries where quality assessment and improvement measures on a national level are just about to start. Discussion groups do require a lot of good will on the part of the caregivers, as well as training of the patient representatives involved.

A summary of the elements of patient-centred quality management is shown in Table 1.

Questions and Answers

- Q1 What is the contribution of electronic patient files and follow-up charts in quality management in CF care?
- A1 Electronic patient files and follow-up charts are a basis for sharing data with patients, for individual comparison, Centre charts and for definition of therapy goals.
- Q2 How can appropriate respiratory and nutritional measures be installed and controlled individually in CF care?
- A2 By following national and international standards and definitions and using defined normal values in different age cohorts, best practice can be marked and individual aims can be set and managed.
- Q3 What is the contribution of patient-reported quality of life data and patient satisfaction questionnaires in quality improvement work?
- A3 Patient-reported quality of life data are an important subjective adjunct to description of quality at satisfaction and compliance level. Patient satisfaction questionnaires are opening up an additional dimension of interaction between patient and CF Centre in quality improvement.

3. Quality management at the Centre level

3.1. Centre care, certification and peer review

CF Centre care and the use of national and international patient registries have become essential features of health-care and information exchange in the field of CF in many countries. Since 1995, the German CFQA project has collected demographic data and outcome parameters and the registry has evolved from a standard registry into an instrument of quality management. The German CFQA project also serves as the backbone in supporting quality assurance groups and as a benchmark project [30]. Quality management is now a major tool in CF Centres and is maintained by national registries. The analysis of registry data could lead to the certification of CF Centres as well as to the guided planning of structures and strategies in CF care. It could also serve as a basis for political action in the healthcare system and for improvements in quality awareness at all levels (individual, Centres, quality groups, political, charity institutions) [52].

The CF Trust peer-review programme assesses services against national standards of care, identifies shortfalls and helps CF services to improve the care they provide. A

revised programme for 2012 will result in peer-review reports being made available to the public for the first time, providing comprehensive, independently verified information about the performance of individual CF services [53].

It is now recommended that CF patients should be cared for by a multidisciplinary team of specialist doctors, nurses and allied health professionals at a recognized specialist CF Centre.

3.2. Models of care, consensus documents

Different models of care have been outlined. The definition of the CF Centre, number of patients treated at the Centre (both lower and upper limit) as well as the number and expertise of staff members are given by different national and international consensus documents, including the Centre Framework paper in this supplement [50,54,55].

Questions and Answers

Q1 Do we have a nationwide definition of the specialist CF Centre? Can we agree on patient numbers and required staffing levels at CF Centres?

A1 The level of expertise required to treat the complex multisystem symptoms and complications of CF can only be acquired by a multidisciplinary team of trained, experienced, specialist health professionals who routinely see a critical mass of patients at a specialist CF Centre.

Q2 Do we have an agreement about key markers for evaluation of performance of specialist Centres?

A2 The following are examples of key markers used in many countries:
i microbiology, rate of new and chronic infections, lung function data, age groups
ii nutritional data (body mass index percentile, body mass index, age groups).

[For more details see Section 6].

Q3 How can data collection and public reporting of care Centre data be a part of the quality improvement initiative?

A3 By sharing data, the partnership between patients and caregivers can be strengthened. The analysis of data and establishment of national peer-review programmes could be used for the certification of individual CF Centres. It could also serve as a basis for political action in the healthcare system and for improvements in quality awareness at all levels.

Table 1

Patient-centred quality management.

Practical points and tools

- Electronic patient documentation
- Patient follow-up charts
- CF team sessions, discussion of single patients
- Setting quality goals
- Patient and Centre checklists
- Adherence to guidelines
- Planned intervention
- Education and training of physicians, families and patients

CF, cystic fibrosis.

4. Quality management at the regional and national level

The fundamental requirements for a functional and effective healthcare system is for all parties – patients, families, payers, healthcare professionals, healthcare system leaders and communities – to produce better outcomes for patients, better professional development and better performance for the healthcare organizations [56]. Quality and safety are the consequence of the functional interaction between healthcare providers and patients at the microsystem level, but physical resources, adequacy of funding and health policies influence both.

4.1. Health policies

Public health policies at the macrosystem level (either national or regional levels, depending on the country) include: 1) quality accreditation of care organizations, based on professional practice evaluation; 2) risk management, for instance to decrease iatrogenic disease and improve hygiene precautions; 3) professional development through continuous training and rewards.

Private policies, such as those developed by pharmaceutical companies or patient and family foundation initiatives, may complement or interfere with national public health policies. National or regional health policies and private initiatives need to converge into consistent incentives to sustain the engagement of professionals in continuous quality improvement over time. An example of this is the link between newborn screening and subsequent Centre care of the newly identified patients based on consensus [57].

From the European public health policy perspective CF is classified as “rare disease” (i.e. occurring with the prevalence lower than 5 in 10,000 individuals) according to the “Regulation (EC) No 141/2000 of the European Parliament and of the Council from of 16 December 1999 on orphan medicinal products”. In this regard CF Centres should be in compliance with the European Union Committee of Rare Disease Experts guidelines for “Centres of Expertise for rare diseases” so that these could cooperate within the frame of European Reference Networks for Rare Diseases. This macrosystem measure is important since rare diseases (hence

CF) have received a special status in Articles 54–55 of the European “Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare”. Such special status is potentially very important for CF centres located within the European Union in terms of reimbursement of CF care for patients originating from another Member State, including provision of transnational sharing of expertise, exchange of staff and eventually also of CF patients in selected instances (e.g. in those cases who could benefit from highly specialized care in a better resourced centre, or when local conditions would be temporarily unfavourable, or for patients from less favoured regions of the European Union). Finally, the rare diseases status also facilitates development and registration of orphan medicinal products (e.g. CFTR modulating therapies) by the industry and the European Medicines Agency, respectively.

4.2. Strategies of quality management at the national level

As the EuroCareCF analysis of demographic data from 35 countries shows, there is no single approach or strategy that works in all situations. However, there are principles that can help to develop a strategy suited to the situation in a particular region [58]. A strategy is a process, a way of agreeing what is to be done and by whom, and of ensuring that quality work is carried forward [59]. Strategies and experiences in several European countries are listed in Table 2.

4.3. Quality improvement learning collaboratives and learning and leadership collectives

Learning and leadership collectives (LLC) involve several care Centres in a yearly quality improvement programme. The programmes are based on the Dartmouth Institute Clinical Microsystem Approach (an action guide for accelerating the rate of quality improvement in CF care), and involve the training and coaching of the multidisciplinary care teams through four phases

- preparation phase
- 5P analysis (i.e. product, price, programme, process, people) and assessment of the Centre
- action phase, and
- transition phase.

Health systems in the USA, Germany, Sweden, the UK and France pursue quality improvement through learning strategies. Clinical outcomes attributed to quality improvement learning collaborative (QILC) include: identification and adoption of systematically studied evidence-based practices, decreased neonatal infection rates, cost-conscious prescriptive practices, improved patient safety, decreased emergency department waiting times and improved management of persons with chronic illness [19,29,60].

Key factors associated with successful collaboration for quality improvement include availability of resources to support changes, multidisciplinary involvement, agreed aims and agenda, project ownership among members, and the essential role of leadership. These conditions depend on personal contact between participants, wide networking, mutual respect among all parties, accessibility of data and information sharing. Diversity among members strengthens the collaborative by contributing a range of perspectives [61].

The CFF (USA) has developed LLCs [2]. The Dartmouth Institute Clinical Microsystems approach was used as the framework to improve the quality of CF care in the USA. Modelling on the US-CFF quality improvement initiative, a pilot QILC was initiated in France in 2011 and demonstrated that the US approach including national coordination and coaching is appropriate [62] with a few adjustments, namely the need for a part-time member of staff in each Centre whose role is one of a local coach, working closely with the physician leader of the CF Team.

An external evaluation highlighted the existence of obstacles, such as limited time and resources, staff and organizational changes, and lack of accurate and up-to-date information to measure outcomes [19,62]. These shortcomings were positively balanced by success factors, mainly motivation of the CF team, a culture of patient-centred care, patient and parent involvement, physician leadership and clear agreed goals.

4.4. Ranking and learning from best practice (benchmarking)

Benchmarking involves the identification of healthcare programmes associated with the most favourable outcomes as a means to identify and spread effective strategies for care delivery [56,60]. Variation in processes and outcomes suggests differences in the efficiency of delivery of care, and offers the opportunity to gain knowledge of the level of success that may be obtained with currently available therapies.

Quality benchmarks in CF use key nutritional and respiratory assessments such as body mass index (BMI), FEV₁%, bacterial status and complications. Patient registries include annual data derived from the data collected at each

Table 2
European quality management strategies and experiences.

Country	Quality management strategies	Principles — initiatives
France	LLC and best practice	Continuous professional development
Germany	Benchmarking and best practice, Centre certification	Quality of patient outcomes
Italy	Peer reviews and accreditation	Patient and family involvement as peers
UK	Peer reviews and LLC (site visits)	Quality of patient outcomes and processes (adherence to guidelines)

LLC, learning and leadership collaborative.

visit to the CF Centres. Where well-established patient registries exist with high-quality data, ranking of the Centres offers the opportunity to identify potential best practice for treating patients with CF.

The next step is to attempt to determine how their excellence was achieved [19,31]. The US CFF supported a benchmarking programme that used registry data to identify clinically excellent CF Centres and then to study their structural and cultural organizational features in addition to the specific practices that contribute to their outcomes. The underlying principle is that the practices and/or characteristics identified at high-performing Centres are drivers (and not just markers) of outcomes, which can be translated and applied to other Centres that are not performing so well.

A number of pitfalls complicate attempts to ascertain best practice [19]. Attention has to be paid to biases between Centres due to case mix. For example, Centres following patients with proportionately milder mutations may have better indicators than Centres following more severe patients (e.g. those registered on a transplantation list). Centres with small numbers of patients may present great variation in their indicators depending on the health status of just a few patients. Adult care Centres are fed by paediatric programmes, which determine the baseline disease status as well as the education of patients. Socioeconomic factors affect the population of patients in some Centres according to their location. It is important to consider case-mix adjustment to control for disproportionate distributions of sociodemographic and disease-specific risk factors at some programmes and locations, even if this may introduce new bias into the comparison.

Beyond the registry data, several key themes emerged from the benchmarking work: 1) the presence of a well-functioning care team working with a well-thought-out systematic approach to providing consistent care; 2) high expectations for outcomes among providers and families; 3) early and aggressive management, avoiding reliance on rescue therapies; 4) patients/families who are engaged, empowered and well informed on disease management and its rationale [63].

The most frequently used criteria for benchmarking and peer review are as follows:

- physician leadership
- multidisciplinary care team
- access to care
- infection control
- sweat test quality
- follow-up care guidelines
- patient and family satisfaction survey.

4.5. Guidelines

CF care at the national/regional level has to adapt international guidelines (USA and Europe) to the local context. Adaptation means translation into the local language, adaptation to the context of the organization of care, dissemination through the Centres, and assessment of their implementation in the CF Centres. A successful experience

[39] of appropriating international guidelines is illustrated by Cincinnati Children's Hospital, which set up a framework for adherence to prescribing guidelines in an outpatient setting, educating clinicians and sharing goals with families.

4.6. Peer review and quality accreditation programmes

Peer-review programmes enlist professionals to monitor the quality of patient care provided by their colleagues, in order to identify opportunities to improve the quality of patient care. They are designed to monitor the quality of the healthcare services offered to patients, to identify opportunities to improve patient outcomes, and to identify and prevent malpractice [64].

In the EU there are different quality improvement accreditation programmes involving the peer-review method. The activity of preparing and undergoing accreditation has been shown to promote change in health organizations. It is important to:

- assure a minimum standard of care in every Centre; the standard must be set at the maximum achievable level, in the national/regional context, in order to stimulate improvement over the time;
- foster exemplary care, encouraging and supporting care Centre development;
- support new Centres in starting their activity;
- improve clinical outcomes.

At the national/regional level, a key recommendation is that a multidisciplinary committee, including patient and family representatives, should be established in order to start and develop programmes of peer-review accreditation according to published European standards. These programmes should be adapted to local needs and resources, to stimulate CF Centre improvement over time. Table 2 shows examples of national peer-review programmes.

4.7. Information systems at the national/regional level

According to the World Health Organization [65], information systems need to apply consistently across the whole quality improvement programme so that comparisons in outcomes and progress can be made between parts of the programme. These information systems also need to be transparent, so that the widest possible range of stakeholders has access to the same information. The scope of the information includes: the availability to healthcare workers of information about best practice; the way in which the information is given to service users by those providing care; and the access by communities and individuals to information that will help them manage their own health. Any of these areas might require change as part of a strategy for quality improvement [65].

4.8. Measurements

In the course of a yearly collaborative quality improvement programme, key indicators and their current value are shared

with the Centres involved, patients and families. This fosters harmonization and quality control of the data in the Centres. Results must be interpreted carefully and scientific measures should be applied to identify trends and factors of variability for the accurate monitoring of quality improvement work [66].

The attention paid to the measures during Plan–Do–Study–Act (PDSA) cycles and to the underlying causes of variations in measures between Centres [60,66] is key to continued quality improvement.

4.8.1. PDSA cycles

Quality management is carried out using PDSA cycles, leading from a quality improvement plan (plan), to measuring appropriately and surveying quality indicators to changes in practice (do), to finding out about best practice (study), and finally, to induce new quality-improvement steps that will meet standards and guidelines and approach quality goals (act).

The results of quality improvement initiatives are not reported in the same way as traditional clinical research. Quality improvement reports tend to address ‘messier’ problems, involve more complex interventions, and require far greater attention to context. The ‘messiness’ of problems in quality improvement is a reflection of the real-life setting and the focus on routine care rather the controlled environment of a clinical trial. For example, an improvement project might ask: can patient outcomes be improved by changing the referral and appointment system to ensure timely access and better coordination between specialist and primary care services? [67].

To drive improvement efforts, an annual report of patient outcomes, based on one value derived from the different measurements of the year and issued several months after the end of the period is not appropriate. Actual data that are updated at each visit and displayed on graphs incorporating the evolution in processes, delivery of care and patient outcomes are essential to provide feedback on the implementation of treatment/service improvements plans. This requires a CF information system to collect patient data regularly and

to track the care delivered at each visit, and database management that issues reports for the team on weekly, monthly and quarterly bases.

Standardization, completion and quality control of the data collected at the Centres are essential to the relevance of the measure. Part of the improvement shown by the indicator comes from a higher quality of data collected. BMI or FEV₁% are significantly dependent on the conditions of measurement (e.g. before or after a meal, related to the scale used, before or after physiotherapy).

Over the past 20 years, the concept of improvement of healthcare systems has moved away from top-down control, compliance and punishment towards bottom-up development, self-regulation and incentives. Quality measurement has shifted from resource inputs to performance outputs. Emphasis has moved from quality control and assessment to the definition of agreed and valid standards, systematic and reliable measurement of performance, implementation of action for change, repeated measurement and continuous improvement in a cycle or upward-moving spiral [68]. Thus, the new quality improvement tools of benchmarking, learning from best practice, PDSA cycles, LLC and accreditation are more adequate to accomplish quality improvement in CF. These methods are summarized in Table 3.

5. Quality management at the national level

5.1. Quality improvement

Not uncommonly, practitioners in a specific clinical setting will fail to prescribe recommended treatments; the reasons for under-utilization of recommended efficacious therapies are often site specific and relate to structural or educational barriers. Through an iterative process of quality improvement, one can begin to identify and intervene on the barriers to effect change in care.

5.2. Registries in quality improvement

In order to begin work in quality improvement, one needs to have a measure of the scope of the clinical problem. One of the key components of quality improvement is access to high-quality data regarding patient characteristics, treatments and clinical outcomes. Such data sources have historically been patient registries. Registries permit investigators and stakeholders to document variation in care where variation would not be anticipated. CF is ideally suited for evaluation of quality improvement research because of the existence in many countries of comprehensive patient registries. Some of the very early patient registries in CF were set up [9,10] to establish a more unified understanding of CF and to measure quality improvement. In 1966, the CFF Patient Registry (CFFPR) was started for this purpose and now contains detailed data on more than 26,000 individuals with CF [9]. The CFFPR has been used to evaluate survival and temporal changes in survival [69], predictors of survival [70], impact of sputum microbiology [71] and complications related to CF

Table 3

Tools and methods to achieve quality improvement [56].

-
- Delineate healthcare process
 - Collect data over time to document variation in care practices and clinical outcomes
 - Document unwanted and unnecessary variation
 - Collect information regarding customer/beneficiary knowledge (e.g. measurements of illness burden, functional status, quality of life; recipients’ assessment of the quality of their care)
 - Adopt widespread public sharing of information
 - Improve communication by building teams and enhancing group learning using specific skills (e.g. situation, background, assessment and request [SBAR])
 - Create a leadership plan acknowledging: leading, following and making changes in healthcare
 - Build knowledge (locally useful) then take initiative and use adaptive action, reviewing and reflecting
 - Make small tests of change (e.g. Plan–Do–Study–Act cycles)
-

[72]. Similar advances have come from other registries (e.g. the UK CF Registry) identifying use of gentamicin as a particular risk factor for renal failure in CF [73] and highlighting the relationship between diabetes control and survival [74]. More recent publications from the USA have addressed process of care and access to care, which are key topics in quality improvement [29,75]. Johnson et al. evaluated US CF Centres, ranking these Centres based on the median FEV₁ within each of three age groups (6–12 years, 13–17 years and ≥ 18 years). They found that those Centres that saw their patients more frequently, with attendant lung function tests, sputum microbiology and more antibiotic use, consistently ranked higher [75]. These investigations can then lead to the design of interventions that improve care practice and patient-centred high-value outcomes.

5.3. Guidelines in CF for quality improvement purposes

One of the key elements of quality improvement is a clear understanding of what constitutes appropriate and high-quality care. One of the goals of quality improvement is to ensure that recommended treatments are indeed offered and utilized by patients in whom the treatments have demonstrated efficacy. Guideline documents have been published to help the CF community evaluate the existing evidence and establish standards of care (e.g. care of the infant and treatment of lung infections) [57,76]. These documents provide a systematic approach to evaluating the literature and a set of recommendations that can then be integrated into benchmarking. Such documents represent the standards for current care in CF, creating a roadmap to continued success in the management of this disease. One of the key challenges of guidelines is that they can differ in their recommendations. These differences may be due to differences in healthcare systems, interpretation of data, and interpretation of risks and benefits of interventions. Guidelines are clearly fluid and will change over time as more information is gathered regarding approaches to CF care.

5.4. Nationwide benchmarking in CF for quality improvement purposes

In many countries patient advocacy groups have set goals to improve the survival and outcome of individuals with CF. These groups represent the earliest phase of quality improvement in CF. As a result of these efforts, quality of care for people with CF has improved significantly, with an associated improved survival [46]. Development of patient registries has been the engine behind this success. Although improving survival is a key goal in quality improvement and benchmarking, other important metrics should also be tracked. There have been several key advances in this area over the past decade. German CF Centres have made quality improvement a major focus in their CF care [16,30]. This project was able to demonstrate first the temporal improvements in outcome and then improvements in care but

importantly, it demonstrated variation in care practices among the 93 Centres in Germany. The project then developed benchmarking indicators and a PDSA cycle [60]. As results from this work translate into change in care practice, continued improvement in CF outcomes will be realized [31]. In another example, in 2006 in a move toward benchmarking, the US CFF made Centre-specific performance indicators transparent to the public, promoting this action as an initiative to ‘accelerate the rate of improvement’ through benchmarking. Top-performing Centres were used as models of best practice with the hope of disseminating successful processes to other Centres, and thus reducing national variability in practice patterns and outcomes. The US CFF also launched a series of action-oriented training programmes (LLCs) to increase the capacity for quality improvement across the CF clinical care network [77]. Each Centre participating in one of the LLCs performed a quality improvement project over the course of a year. Examples included a project to standardize pulmonary exacerbation care [78] and benchmarking to improve the screening rates for CF-related diabetes [29].

5.5. Role of quality improvement in newborn screening

Newborn screening provides a unique opportunity for quality improvement in CF. Identifying individuals at birth provides several windows of opportunities to intervene early in the disease. Such interventions could lead to the prevention of structural lung disease occurring prior to clinical symptomatology in CF babies [79]. Newborn screening allows CF providers and researchers to more formally understand the early events that lead to later clinical disease [35] and evaluate the role of earlier interventions [80]. Recent work made possible by newborn screening was employed to establish a definition of exacerbation in very young children [21]. Understanding best practices, how to benchmark care, and how best to track children with CF identified by newborn screening will be essential to further advance the care of these patients. Guidelines and standards of care are now available for the management of this particular CF population and will remain essential [57]. National data registries will need to change accordingly to track clinical interventions and outcomes. A key challenge remaining relates to the limited data for treatments early in disease and the challenges to establish treatments in this patient population. In addition from a larger perspective, newborn screening poses new challenges and opportunities to ensure early and timely access to care for persons with CF and potentially access to new promising therapies for eligible patients.

Challenges will also remain given the differences in algorithms for newborn screening. All screening tests involve trade-offs between sensitivity and specificity. Marked differences have been noted in positive predictive value depending on the approach taken [81,82]. One of the key issues with regard to choosing different protocols for newborn screening will be the identification of carriers and understanding the natural history of the rarer genotypes identified through

newborn screening. Integration of data from newborn screening into patient registries will help to clarify some of the key issues that arise from screening.

Questions and answers

- Q1 How does one ensure that high-quality accurate data are recorded in registries?
 A1 One could consider doing random on-site audits in addition to electronic data audits.
- Q2 Should patient registries go through routine validation steps given the role they have in measuring and assessing quality of care?
 A2 Validation could include data audits but also validation of data steps involved in generated specific high-value outcome measures (e.g. FEV₁% predicted).
- Q3 How can registries achieve standardized definitions of data elements and standardized reporting to ensure improved comparisons when performing comparisons between countries?
 A3 This could be achieved by creating an international working group on registry standardization.
- Q4 How can registries reduce the time from data entry to feedback of results to Centres and patients?
 A4 One solution could entail real-time data entry.
- Q5 What are the essential data elements related to newborn screening that need to be collected in registries to establish appropriate quality measures in the future?
 A5 Potential variables include age of screening, approach taken for screening and results of screening
- Q6 How do countries address variable newborn screening protocols within their borders?
 A6 This could be addressed by having a clear outline of all approaches to newborn screening and to have a data element that clearly lists the approach taken for each individual.
- Q7 How should patient registries be employed to formally evaluate newborn screening protocols?
 A7 One strategy would be to compare the introduction of newborn screening with interrupted time series analysis in nations, provinces or states with differing times of introduction of these protocols.

Table 4

Proposed indicators for healthcare services.

Area	Proposed indicator
CF Centre definition	Funding of CF Centre guaranteed by the provider of medical care Number of patients followed Establishment of links with consultants with expertise in the fields recommended in the standards of care consensus Presence of referral and assessment protocol with a transplant Centre Availability of a radiology department with CT scanning facilities Availability of a pulmonary function laboratory Availability of a microbiology service with established contacts with a CF microbiology reference laboratory Availability of diagnostic capability including sweat testing and <i>CFTR</i> gene mutation analysis Availability of guidelines for the treatment of CF complications 24-hour access to the CF Centre for telephone advice, emergencies or consultations
Members of the team	Presence of CF Centre Director Presence of CF Consultant Presence of CF Clinical Nurse Specialist Presence of CF Physiotherapist Presence of CF Dietitian/Nutritionist, Presence of CF Social Worker Presence of CF Psychologist Presence of CF Clinical Pharmacist Presence of CF Clinical Microbiologist Presence of consultant, registrar, staff grade specialist nurse, physiotherapist, dietitian, social worker, psychologist, secretary, pharmacist for the full-time equivalent [90]
Outpatient care	Frequency of visits Place of visit Presence of CF physician and nurse at every visit Accessibility of all members of the team at every visit Execution of recommended routine tests, as appropriate for the age of the patient Revision of treatment and medications Implementation of segregation policy according to patient microbial status Admission or home intravenous treatments within 24–48 h
Inpatient care	Number of beds to allow immediate admission Presence of infection control policy Availability of single rooms with en-suite toilet and bathroom Availability of hand-washing facilities Availability of concomitant review by allied health professionals Assessment of hyperglycaemia and overnight oxygen saturation at each admission for infective exacerbation Regular sputum microbiology Regular spirometry measurement Physiotherapy (including sputum mobilization techniques), twice daily Availability of facilities for supervised physical exercise Availability of protocols for dosing and administration of antibiotics, treatment of a pneumothorax, management of haemoptysis, diagnosis and treatment of ABPA and CF-related diabetes Weekly discussions in the multidisciplinary meeting of inpatients and those receiving intravenous antibiotic therapy

6. Quality management at the international level

“More radically, I would suggest that we don’t need international comparisons. Rather, what we need is international learning.” K. Walshe (2003) [83].

(continued on next page)

Table 4 (continued)

Area	Proposed indicator
Shared care	Number of patients followed in the satellite CF unit Presence of input in the satellite CF unit from: dietitian, physiotherapist and nurse, each with a special interest in CF Presence of CF-dedicated clinics in the CF satellite unit Periodic contact (once/twice a year) between CF care and satellite CF unit annual assessment performed by the CF Centre
Transitional care	Availability of a system to allow transition from paediatric to adult care Presence of continuity of diagnostic and treatment protocols Agreement between transition Centres on infection control policies Review of children and parents before the handover of care Introduction to the new Centre before transition takes place Presentation of differences between the transition Centres performed before transition Written report on the patient by all disciplines attached to paediatric care Welcome of the patient on first day of transition to the new Centre
Annual assessment	History of all medical and life events since the previous annual review Full clinical examination Review by a CF specialist physiotherapist Spirometry in patients over 5 years of age Nutritional review by a CF specialist dietitian Time with social worker and/or psychologist if required Blood tests, sampling for faecal pancreatic elastase, faecal fat, chest X-ray, liver ultrasound, sputum or swab as indicated in the 'Standards of care' paper Oral glucose tolerance test as indicated in the 'Standards of care' paper Surveillance of bone mineral density Repetition of sweat test for patients new to the Centre Identification of genotype, if not already done, for patients new to the Centre Confirmation of pancreatic insufficiency for patients new to the Centre Introduction of the Centre to patients new to the Centre
Lung function tests	Spirometry at every visit (FVC, FEV ₁ , FEF _{max} , FEF _{25–75}) Pulmonary function tests other than spirometry when clinically indicated Execution of tests in a large ventilated room, using methods to reduce cross infection Segregation of patients according to their microbial status
New diagnoses	Ability to visit the patient within 24 h from diagnosis Implementation of initial assessment specifications Initiation of educational programme Initiation of treatment programme Diagnosis in adulthood Availability of tests indicated in the 'Standards of care' paper

ABPA, allergic bronchopulmonary aspergillosis; CF, cystic fibrosis; CT, computed tomography; FEF, forced expiratory flow; FEV₁, forced expiratory volume in 1 s; FVC, forced vital capacity.

6.1. International comparisons: state of the art

Comparisons of quality management practices across countries pose the same problems as comparisons within the same country, but add the complexity of differences in healthcare systems and data collection practices. Dreachslin et al. [84] identified the main obstacles to international data

quality comparisons as a lack of a uniform clinical database, common definitions and data collection practices.

6.1.1. Choice of indicators and their definition

The choice of indicators is crucial when quality management comparisons are carried out on patients' health status and on healthcare systems. Various indicators have been suggested and it is therefore important to consider the validity and necessity of measures, as defined by Kerr [85,86]. Diagnosis, healthcare services, and the outcomes of morbidity and mortality are suggested indicators [84]. However, quality assessment and improvement also require expert judgement and therefore quality indicators are not the panacea; learning through the sharing of experiences and networking is also important [87]. There is also a risk that a focus on indicators in certain areas will exclude consideration of other equally important areas and that long term outcomes may not be included [88].

The transferability of quality indicators for healthcare systems across countries is feasible, but most often it is subject to adaptation according to the specific context of the different countries [86]. Particular attention should be paid to the level of detail in the definition of international indicators of quality management. In an attempt to have uniformity across countries there is a risk that indicators will become uninformative and result in the collection of information that is too generic [84]. Similarly, some indicators might reflect only local needs, and are therefore unsuitable for international comparison [87].

Uniformity should be present for inclusion and exclusion criteria: potential selection bias in patient registration and information recording might affect the outcome of comparisons. It is therefore advisable to investigate whether inclusion/exclusion criteria or different processes of registration might be responsible for any differences found. To avoid the biases that might be introduced by case-mix in outcome measures, the recording of 'near misses' could be used instead [88].

Finally, data collection procedures and data quality should be part of the quality management process. In fact, data quality is an essential aspect of research, and one must remember the old adage 'garbage in, garbage out'. At the national level, the reduction of missing data eased the comparison and improved the follow-up in one study [31]. For this reason, data auditing processes are advised [88].

6.1.2. PDSA cycles

It is well recognized that reporting of differences would be a useless ranking exercise if not followed by a change in behaviour/practices [88]. It is important to define a strategy for identifying differences between countries, exploring why these differences exist and building what Stern et al. called a learning process and quality improvement procedure [31].

It is evident, though, that such a process is rather complicated in international settings, where different factors might lead to different outcomes and therefore confounding effects might lead to different outcomes or different quality indicators. Clearly, data analysis has a fundamental role: comparisons can be carried out in a mere descriptive way by means of summary tables and comparative graphs. However, a

Table 5

Proposed indicators for health outcomes and processes.

Area	Indicator	Stratification	Limits
Outcome	Median age	By sex	
	Proportion of patients aged 18 years or more		
	Median FEV ₁ % predicted	By sex and age	Patients aged 6+ years
	Median BMI percentile	By sex and age	
	Number of deaths in current year	By sex	
	Median age at death (deaths in current year)	By sex	
	Mean BMI	By sex and age	Patients aged 18+ years
	Mean BMI percentile	By sex and age	Patients aged 2–17
	Mean FEV ₁ % predicted	By sex and age	Patients aged 6+ years
	Mean, minimum, maximum, quartiles of age		
	Proportion of patients over 18 years		
	Proportion of patients deceased during current year		
	Mean and median age at death		
	Proportion of patients living with lung transplant		
	Proportion of patients living with liver transplant		
	Mean, minimum, maximum, quartiles of FEV ₁ % predicted	By age	Patients without lung function
	FEV ₁ % predicted groups (<40/40–80/>80%)	By age	Patients without lung function
	Prevalence of chronic infection by <i>Pseudomonas aeruginosa</i>		
	Prevalence of chronic infection by <i>Burkholderia</i> spp.		
	Prevalence of chronic infection by <i>Staphylococcus aureus</i>		
	Prevalence of infection by non-tuberculous mycobacteria		
	Prevalence of infection by <i>Stenotrophomonas maltophilia</i>		
	Mean, minimum, maximum, quartiles of Z-scores for height	By age	
	Mean, minimum, maximum, quartiles of Z-scores for weight	By age	
	Mean, minimum, maximum, quartiles of Z-scores for BMI	By age	
	Proportion of patients with BMI <18.5	By age and sex	Patients aged 18+ years
	Prevalence of allergic bronchopulmonary aspergillosis		
	Prevalence of pneumothorax		
	Prevalence of haemoptysis		
	Prevalence of malignancy		
	Prevalence of liver disease		
	Number of patients living with transplanted lung(s)	By age and sex	
	Number of patients living with transplanted liver	By age and sex	
Number of deaths in current year	By age and sex		
Age at death groups for deaths occurred in current year	By sex		
Cause of death for deaths occurred in current year			
Processes	Number of new diagnoses in current year		
	Percentage of new cases diagnosed by newborn screening in current year		
	Median age at diagnosis		
	Median age at diagnosis for new diagnoses		
	F508del genotype (homozygote/heterozygote/other/not genotyped)		
	Mean, minimum, maximum, quartiles of age at diagnosis		
	Age at diagnosis groups		
	Proportion of patients who underwent neonatal screening		Patients aged 5+ years
	Proportion of patients with DNA analysis		

BMI, body mass index; FEV₁, forced expiratory volume.

deeper understanding of the differences between countries should be carried out after also adjusting for potential confounders. Moreover, after factors responsible for different quality management levels have been identified, discussion on the appropriateness of transferring practices across countries are necessary, as what works in one country might not work in another, or it might simply not be transferable [88].

Finally, some authors advocate the need for a governance body that oversees the data quality improvement process and sets up the appropriate measuring criteria, data collection procedures, data analyses methods, and rewarding schemes [88,89].

6.2. International comparisons: a consensus

In order to set up an international quality improvement process, agreement at the international level must be reached on the following aspects: choice of indicators of quality monitoring, choice of most suitable repository to store such indicators, data analysis approaches (such as acknowledgment of selection bias and confounding factors), implementation of PDSA cycles and governance of quality management process. The following sections outline the consensus reached for each of these aspects, and suggestions are made for areas in need of work.

6.2.1. Choice of indicators

Comparisons on the following areas of quality management should be carried out internationally: healthcare services, outcomes and data quality.

6.2.1.1. Healthcare services. Indicators for evaluation of healthcare services have been proposed and used in the medical literature, but in CF their use has not been well documented, especially in international settings.

In the previous consensus statement on the standards of care for CF, Kerem et al. [50] identified key services, facilities and personnel to be adopted by specialized CF Centres, recommended routines of CF care for outpatient, inpatient, shared and transitional care, and recommended follow-up tests to be carried out at annual assessment. These standards of care have paved the way for the definition of indicators for international comparison, in particular for the area of healthcare services. Table 4 lists candidate indicators derived from the recommendations updated in the present standards of care paper (see Section 3, *Quality management at the Centre level*) [90].

ECFS encourages the creation of an international working group, composed of experts in evaluation of healthcare systems, CF specialists and data managers of CF databases, with the aim of evaluating whether these candidate indicators have the required characteristic for international comparisons. In particular, evaluation of the proposed indicators should concentrate on the following aspects:

- Do such indicators have the desired characteristics: validity, necessity, transferability?
- Do such indicators have an adequate level of detail? Are they informative or are they too vague? Do they reflect only local needs?
- Is there a risk of tunnel vision with the choice of such indicators?
- Are long-term indicators available and usable?

6.2.1.2. Health outcomes. In the CF literature, comparisons of health outcomes have been carried out nationally [30,31,52,91] and internationally [8,22,58,92–99]. Comparisons have been performed mainly for survival, lung function and nutrition. Median age at death, median predicted survival, FEV₁, forced vital capacity, occurrence of lung infections, weight, height and BMI have been used as indicators for comparisons.

All these indicators have desirable characteristics: there is a large consensus in the scientific CF community on their ability to reflect the patient's health status; they are routinely recorded in the clinical notes because they are used for the clinical management of the patient; they have an adequate level of detail to express the patient's health status; they do not reflect only local needs; they focus on various aspects of CF; and some of them take into account long-term outcomes. The main problems with the use of such indicators have been in terms of transferability: international comparisons through their use have proven difficult due to different timings of measurements (e.g. recording of best vs. last FEV₁ of the year), dissimilar

definitions (e.g. chronicity of infections) [100], different detection rates (e.g. genotyping) or frequency of sampling (e.g. microbiological testing) [100,101], potential patient selection bias [58,100,101], amount of missing data [100].

ECFS urges the international CF community to come to an agreement on core aspects of CF health outcomes, and report national-level indicators on such aspects on a routine basis, primarily through national CF registries. A proposal on sharing such information was put forward in 2009 [102] and a choice of Centre-level indicators was outlined. This proposal has been further developed and other indicators have been proposed [103].

Another example of international comparison of health outcomes and health processes (e.g. diagnostic practices) is given in the annual data report of the European Cystic Fibrosis Society Patient Registry [14,100]. Table 5 summarizes the indicators on health outcomes and health processes that should be considered and improved for international comparison purposes [100,102].

6.2.1.3. Data quality. Data quality should be part of an international quality monitoring process. Improvement of the level of accuracy of information recorded should be attained by motivation and proper training of the individuals in charge of data retrieval and data recording, by implementation of automatic systems for error detection, and by implementation of efficient procedures for error correction. Initiatives for sharing international learning and expertise on data quality control processes should be encouraged, such as the one initiated by the European Cystic Fibrosis Society Patient Registry [13].

6.2.2. Data analysis and metadata sharing

Outcomes of international comparisons are particularly prone to differences that might be due to confounding factors and to differences in patient selection. These confounders should be accounted for in the data analysis phase. Statistical methods for confounding control and case-mix adjustment can be used, although their implementation might be difficult in such a complex context, but at least simpler methods such as stratification and subgroup analysis should be used whenever necessary. It is essential that potential sources of patient selection bias are carefully scrutinized so that fair comparisons are carried out across countries in groups of patients that are as homogeneous as possible.

Another fundamental aspect of data analysis is the disclosure of all important technical information that might affect results. Reference values used to compute standard deviation scores for anthropometric measurements, or equations used to compute percentage of predicted values for lung function tests, specification of inclusion/exclusion criteria are examples of technical information that should be specified.

6.2.3. Data collection and choice of repository

The previous sections have described the elements needed for international comparisons: choice of indicators

for healthcare services, processes and outcomes, the implementation of data analysis methods accounting for confounding effect and selection bias, the sharing of knowledge on data quality, the sharing of technical information on data analyses. All these elements could be conveniently gathered in a unique repository, such as the one proposed by Sims [104].

International agreement should be reached on the choice of such a repository, and on the choice of the kind of information to be stored, as well as the level of detail. Examples of information stored are: aggregated results of indicators chosen for international comparisons, documentation of methodology used for data collection and data analysis, material useful for the exchange of experiences with different initiatives for quality improvement.

6.2.4. Implementation of PDSA cycles and governance of quality management processes

For the quality monitoring process to be effective, the PDSA cycle should be appropriately implemented and an efficient governance system should be set up.

It is recommended that international agreement is reached on how the governance process should be organized and sustained. A defined group of dedicated people, with the ability to introduce changes and measure the impact of those changes, should be set up. If the indicators chosen for international comparisons are not present in the existing databases (e.g. patient registries, administrative databases, routine health statistics reports), national registries should be urged to collect such information and to create a specific repository to store aggregated information.

Stimulation of participation in quality monitoring programmes, promotion of networking and experience sharing for the learning process, and audit on indicators and on data collection procedures are among the tasks of this group.

6.2.5. Patient involvement in international comparisons

Patient involvement at each level of the quality monitoring process is fundamental: quality improvement is for the patients' benefit and their empowerment and contribution to the process are essential.

Active involvement of patients is successfully attained in many countries through the sharing of information in which technical jargon is avoided. The distribution of fact leaflets, patient-friendly versions of annual data reports, and web pages of CF registries dedicated to the patients are examples of how the CF and registry specialists have granted the patients access to information in a transparent and comprehensible way. Patients thus have the opportunity to be an active part of healthcare, and through their representatives in the governance bodies can influence the implementation of the changes necessary to improve quality.

Conflict of interest

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