Anticipating the outcomes and care choices for people living with COPD

See linked articles by Cleland et al. on pg 255 and Seamark et al. on pg 261

*Dianne Goeman¹, Julia Walters², Carolyn Ross³

¹ Senior Research Fellow, Royal District Nursing Service, Helen Macpherson Smith Institute of Community Health, St Kilda, Victoria, Australia
² NH & MRC Primary Care Research Fellow, Menzies Research Institute, Tasmania
³ Associate Professor and Assistant Dean, Faculty of Nursing, University of Alberta, Alberta, Canada

*Correspondence: Dr Dianne Goeman, Royal District Nursing Service, Helen Macpherson Smith Institute of Community Health, 31 Alma Road, St Kilda, Victoria 3182, Australia
Tel: (03) 9536 5318 Fax: (03) 9536 5300
E-mail: dgoeman@rdns.com.au

In this issue of the PCRJ are reports of two qualitative studies from the UK investigating aspects of organisation of care for COPD. Cleland et al.¹ in Aberdeen, Scotland investigated stakeholder views of a community-based anticipatory care service (CBACS) for COPD, and Seamark et al.² in East Devon investigated the opportunity for advance care planning (ACP) in COPD. While ACP for people with advanced COPD is widely understood both in the UK and in other developed countries as addressing patients’ holistic needs including psychological, social and financial needs, an anticipatory care service in COPD is less well defined. Cleland et al. describe the role of a CBACS as not only responding to symptoms but also addressing health promotion to prevent exacerbations. The aim of such a service is therefore to deliver better outcomes for people living with COPD and to reduce hospital admissions, emergency department attendance, and urgent general practitioner (GP) visits. Seamark et al.² address the narrower (often neglected) aspect of ACP, which requires patient understanding about prognosis and options for end-of-life care.

Qualitative research methods are ideally suited for exploring people’s perceptions and attitudes using strategies such as focus groups and/or in-depth interviews — as was the case in these two studies. In the Seamark study, the qualitative approach is used to understand patient views about when and who should introduce the topic of advance care planning; and in the Cleland study it is used to examine the attitudes of a range of stakeholders — patients, carers and healthcare providers currently delivering COPD care — to a potential new service. The results of qualitative research, although limited in generalisability, can be a powerful tool for sensitising policymakers and practitioners to the perceptions of health service users and healthcare professionals. In turn, this disclosure can be the impetus for changes in healthcare delivery and health professional education which are needed to provide more cost effective care for chronic diseases such as COPD.¹

Although a CBACS for COPD with the potential to reduce hospitalisation was broadly acceptable to stakeholders, key benefits identified were patient education, patient-centred care and patient empowerment.¹ This fits with a shift in focus by policy makers in the community healthcare sector to implement models of care that are ‘person-centred’, ‘goal-oriented’ and enabling.⁵ A ‘person-centred’ approach to care encourages working with clients and/or their carers to achieve greater independence and wellbeing and the maintenance of independence for as long as possible, provided management can be done in a safe and effective way.²

Cleland et al.¹ did not directly address the fact that these objectives are also those of existing health care providers who care for COPD patients in general practice and in outreach services for COPD such as assisted-discharge service and hospital in the home.³ The findings did suggest that a CBACS could engage directly with existing services, but necessary linkages were not clearly defined. There was no consensus on the professional groups that would contribute to any new service, and resources for such a new service were recognised as limited. Stakeholders working in primary care and community nursing made it clear that they had no capacity to assume additional clinical, managerial or organisational responsibilities, although there were concerns for GPs if other healthcare professionals assumed leadership in a CBACS. Increasingly it is recognised that improved competencies for inter-professional collaboration can increase the consistency, continuity, and cost effectiveness of care. In Canada, the UK, New Zealand and the USA, policy makers are calling for changes in health professional education to improve collaborative practice.⁶

Findings from the study by Seamark et al.² confirm both the need for, and the well-documented difficulty implementing, ACP for patients with COPD. No patients could recall discussion in hospital about issues of resuscitation, the possibility of being ventilated, or planning for future exacerbations. The lack of follow-up instructions at the point of hospital discharge is a critical gap in transition of care recently reported in an 11-country survey.⁷ The logistic barriers to ACP inherent in the chaotic nature of hospital admission are understandable and probably not amenable to change. Patients’ preference for their GP as someone they knew and with whom they could engage in ACP discussions in a non-hospital setting is supported by other studies.⁷ However, this may be problematic, since GPs are already seen as being poorly placed with respect to both time and resources in order to deliver asthma or COPD education.¹
These two qualitative papers contribute to the development of new and innovative models of providing aspects of COPD care and shared decision-making. Their findings suggest that there is a need for ongoing debate regarding workforce issues and the development of appropriate competencies even in the highly centralised UK National Health Service. However, there are also other models – for example, the use of a hospital-based dedicated healthcare professional to promote discussion of ACP with patients directly (‘Respecting Patient Choices’1,2) currently in use in Australia and the USA. The role of other models should also be investigated.

Nevertheless, given the growing burden of disease from COPD resulting from changing demographics,1 it is clear from both papers1,2 that patient choices will be necessary, and that changes to traditional health service delivery (including the roles of health service providers) will be required, in order to accommodate the projected increase in demand.

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References

2012 and never been KISSed: we need to improve the care of children with asthma

See linked article by Jonsson et al. on pg 276

*Andrew Busha, Louise Flemingb

a Professor of Paediatric Respirology, Imperial College, London, UK; and Consultant Paediatric Chest Physician, Royal Brompton Hospital, London, UK
b Clinical Senior Lecturer, Respiratory Paediatrics, Imperial College, London, UK

*Correspondence: Professor Andrew Bush, Department of Paediatric Respiratory Medicine, Royal Brompton Hospital, Sydney Street, London SW3 6NP, UK. Tel: +44 (0)207 351 8232 Fax: +44 (0)207 351 8763 E-mail: a.bush@rbh.nthames.nhs.uk

‘KISS’ – ‘Keep It Simple, Stupid’ – is sound advice in virtually every clinical situation. In medical school, we focus on getting the basics right and doing the simple things well before rushing headlong into the expensive and elaborate. Asthma in children is common, is the subject of evidence-based guidelines, and in most cases just requires the KISS approach: get the diagnosis right; give an appropriate level of treatment; make sure the child and family know what it is all about, especially how to use the medication delivery device; and as far as possible eliminate trigger factors from the environment.

And yet, in this issue of the PCMJ, Jonsson et al. demonstrate not merely that the easy is not being done, but indeed, given the opportunity to seize the wrong end of the stick, primary care is doing this with assiduous attention! So not merely do they report a litany of sins of omission, but all practices had a nebuliser to treat asthma immediately. Firstly, the authors are to be congratulated on performing this study and having the chutzpah to publish the results. Secondly, how many asthma clinics (primary, secondary or even tertiary) inside or outside Sweden would be confident in their performance if submitted to the same scrutiny? Certainly, our experience with really severe asthma is that in at least half of cases there is a need to get the basics right rather than infusing the latest toxic biological.

This having been said, the results are depressing. The authors studied a large number of children and showed that only a minority had received competent care. Most would acknowledge that...
environmental factors are important, but documentation of environmental tobacco smoke (14%), pet exposure (30%), and the indoor environment (5%), was at best pitiful. The hallmark of asthma is airflow obstruction which varies spontaneously over time and with treatment, yet the vast majority had never performed even the simplest physiological test. Documentation of even the most basic aspect of patient education, namely checking the child could actually use the prescribed medication device, was also lamentable. Finally, even an asthma attack severe enough to merit the prescription of inhaled corticosteroids (ICS) only triggered ‘education’ but no inhaler checks and no measurement of pulmonary function. One expects asthma nurses to be more meticulous than doctors, (and certainly much more than professors!), but the results reported here reflect little credit on the nurses either. True, access to an asthma nurse meant that the child was more likely to have spirometry performed, but this was the only one of 16 comparisons which showed any difference – scarcely a powerful endorsement of the role of the asthma nurse.

One problem with interpreting these data is that children as young as six months were lumped together with school age children, and possibly that these interventions had been done but not documented – the latter a charitable view to which we do not subscribe. In future papers it might be better to avoid this, given the evidence that many young children will have pure episodic viral wheeze, which has completely different pathophysiology and management, in particular pharmacological.\(^1\)\(^2\)\(^3\)\(^4\)\(^5\) Having said this, it cannot be said to be good practice to give a parent of a child of any age an inhaler without knowing that both spirometry and BMI are (a) easy to measure, and (b) directly related to prognosis. This was no mere paper exercise, but led to genuine year-on-year improvements. Should primary care (and for that matter, secondary and tertiary care) be doing the same for asthma?

If we are going to attempt quality improvement, what should we measure? Even more fundamental, what do you have to provide before you can call yourself an asthma clinic? As far as we are aware, this pretty fundamental question has never been answered or even been acknowledged as a question worth answering. One obvious difference between CF and paediatric asthma is the difficulty of finding things to measure which can be done easily and which relate to prognosis in asthma. Possibly the number of children collecting more than one canister of short-acting \(\beta_2\)-agonist per month might be one, but probably there are very few of these.\(^1\)\(^1\) So unfortunately and distastefully, the answer will likely have to concentrate on process not outcome. But unlike our political masters, we should at least try to ensure that the processes we look at bear some relationship to a good outcome.

Table 1 is therefore a non-evidence-based attempt to define what an asthma clinic in any developed world context should provide, together with benchmarks against which care could be measured; none requires expensive apparatus or is very time-consuming, and the use of computerised proformas and databases would hopefully ensure that what had been done had been documented, thus allowing a ready audit of performance. Noteworthy is that we have not specified who should see the children in the clinic. There is no evidence-based reason why a doctor and a nurse should be involved – and to judge from the data of Jonsson et al., a folie a deux is more expensive and equally ineffective as a folie a un… We have also stayed neutral on doctor versus nurse-led clinics; there is no doubt which is likely cheaper. Of course, it could be argued that there is no evidence that any children suffer harm from neglect of these aspects of care, but these criteria will never be subject to a randomised controlled trial. We wonder what choice we would make for our own children – between a clinic which offers all these aspects of care as against one

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### Table 1. Possible requirements for a paediatric asthma clinic

<table>
<thead>
<tr>
<th>Element of care</th>
<th>Measurement</th>
<th>Age group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosis</strong></td>
<td>Has the presence or absence of polyphonic wheeze been documented?</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>Has variable airflow obstruction been documented with physiological testing?</td>
<td>School age children</td>
</tr>
<tr>
<td><strong>General Paediatric Care</strong></td>
<td>Are height and weight being measured regularly?</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>Are the data plotted on a growth chart?</td>
<td>All</td>
</tr>
<tr>
<td><strong>Asthma Baseline Control</strong></td>
<td>Has asthma control been documented using an appropriate questionnaire at least every six months?</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>Has lung function been measured at least every six months?</td>
<td>School age children</td>
</tr>
<tr>
<td></td>
<td>Has inhaler technique been taught, and checked at least every six months?</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>Have tobacco related issues been discussed?</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>Has the home environment, including pet exposure, been discussed?</td>
<td>All, but especially school age children</td>
</tr>
<tr>
<td></td>
<td>How many canisters of (\beta_2)-agonists are being dispensed per month?</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>Does this number of canisters merit inhaled corticosteroid prescription?</td>
<td>School age children, pre-school children with multiple-trigger wheeze</td>
</tr>
<tr>
<td></td>
<td>What is the prescription pick-up rate of prophylactic medications?</td>
<td>School age children, pre-school children with multiple-trigger wheeze</td>
</tr>
<tr>
<td><strong>Acute asthma attacks</strong></td>
<td>Are second opinions being sought at a guideline recommended level of treatment?</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>Are number of urgent contacts with medical care documented?</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>Are number of prednisolone bursts documented?</td>
<td>All</td>
</tr>
<tr>
<td></td>
<td>Has basic asthma care been documented as having been reviewed after a prednisolone burst (prescription uptake, inhaler technique, environment)</td>
<td>All</td>
</tr>
</tbody>
</table>
that offers none of them.

Over-diagnosis of asthma is a concern worldwide; one recent systematic study showed that 30% of adults were wrongly diagnosed. Of course there is no diagnostic test for asthma, but if wheeze has never been heard, and variable airflow obstruction never demonstrated, then the physician should have heightened alertness for another diagnosis (in particular, that most difficult diagnosis of ‘the normal child’). Measuring growth and recording the results is not merely good practice, but the only way of detecting faltering growth due to uncontrolled asthma, excessive ICS dosages or a coincidental diagnosis. The other two sections in our Table relate to on-going care. The basic components of assessing baseline control of asthma are well rehearsed in guidelines. The response to acute deterioration of asthma is largely ignored, and almost uniformly feeble. Asthma ‘exacerbations’ are not benign, but are associated with an accelerated rate of lung function decline in children not treated with ICS (though note that only half of those with an exacerbation bad enough to be given nebulised therapy were then given ICS, this may have been a correct decision in pre-schoolers with wheeze). Elsewhere it has been argued that a better term would be ‘asthma lung attacks’, and that such an attack should prompt a focussed re-appraisal of all aspects of management. Unfortunately there is no evidence that this ever happened in the present study.

So how have we got into the position of treating a really common condition like asthma with expensive medications — the cumulative cost of which runs to billions of euros — without really having any idea of who is doing a good job and who is not? And what are we going to do about it? Perhaps the fact that paediatric asthma is common, and usually appears to be more of a ‘nuisance’, has led us to become blasé about the condition. So we need a wake-up call; children have impaired quality of life because of asthma, some still die from asthma, and childhood asthma is a risk factor for later COPD. Asthma UK estimate that 75% of asthma admissions are avoidable, and we would add the corollary, only if you try to avoid them. Children with asthma deserve proper care, and they and their families deserve care that offers none of them.

Editorials

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Using COPD multidimensional indices in routine clinical practice: DOSE meets all criteria

*Niels H Chavannes*, Rupert CM Jones*, Dirkje S Postma*, Stephen Rennard*

* Correspondence: Associate Professor Niels H Chavannes,
  Leiden University Medical Center, Leiden, The Netherlands
  Tel: +31715268444 Fax: +31715268259
  E-mail: n.h.chavannes@lumc.nl

How should we employ multidimensional indices of COPD? Ideally, they should serve to work towards ‘optimal COPD care’, based on the concept that here-and-now goals should be integrated with goals to improve long-term outcomes and reduce future risk. However, this integration has (until recently) been overlooked, largely because multidimensional indices have usually been developed in selected patient groups and thus lack external validity in the community.

In this issue of the PCRJ, Josef Sundh and colleagues present a large study assessing the merits of the DOSE (dyspnea, obstruction, smoking, exacerbations) index in predicting mortality in both primary and secondary care patients. This is an important paper, since it adds knowledge to the existing applicability of DOSE which previously has been shown to predict hospitalisation, respiratory failure and exacerbation risk. The authors investigated 1,111 COPD patients aged 34-75 years, randomly selected from 70 Swedish primary and secondary care centres. 562 patients had complete data on all DOSE index components, i.e. MRC dyspnoea scale, forced expiratory volume in 1 second (FEV1) expressed as percent predicted (FEV1 %pred), smoking status, and exacerbation rate. Over the course of five years, 116 patients (20.6%) died. Mortality was higher in patients with a DOSE index score ≥4 (42.4%) than for lower scores (11.0%) (p<0.0001). Compared with a DOSE index score of 0–3, the hazard ratio for mortality was 3.48 (95% CI 2.32 to 5.22) for a score of 4–5, and 8.00 (95% CI 4.67 to 13.7) for a score of 6–8. Thus, the DOSE index has now been shown to be associated with mortality in COPD patients in both primary and secondary care, and can be used to assess prognosis in addition to other clinically relevant issues.

Originally, DOSE was designed as a predictor of health status, whereas both BODE (BMI, Obstruction, Dyspnoea, Exercise) and ADO (Age, Dyspnoea, Obstruction) were derived as predictors of mortality. ADO has the disadvantage that it is affected by age; younger people with worse COPD based on MRC or FEV1 score better than their older counterparts. This is counterintuitive, since one would expect younger people with advanced COPD to have more serious disease than older people. BODE has been studied extensively, yet has the major practical drawback that it requires a 6-minute walking test. This stems from its original development in a rehabilitation setting. However, the majority of COPD patients are managed in primary care where this test is not usually performed — although it could be, provided trained personnel and a 30m hallway were available.

To use any given index in primary care it should be able to identify individuals with the highest current burden of disease who are at risk of future morbidity and mortality. General criteria for the use of an index in routine clinical practice are that it should be:

(i) simple to record and calculate,
(ii) the component items should be easy to assess and record,
(iii) the component items should be clinically important in their own right,
(iv) it should be a predictor of a major measure of disease severity e.g. health status or mortality, and
(v) the index should be predictive of future exacerbations and health care consumption.

What is new in this current paper by Sundh et al.? Oga et al. previously reported on 150 patients from secondary care in Japan, and compared the DOSE, BODE and ADO indices in relation to mortality. They found that all three indices were significantly predictive of 5-year mortality, but that the BODE and ADO indices performed somewhat better than the DOSE index. This is hardly surprising, since BODE and ADO were originally developed as indicators of mortality, whereas the DOSE index was originally designed to predict health status. The Sundh paper extends this observation in a larger cohort of over 500 patients from both primary and secondary care, providing firm evidence that the DOSE index is a very good predictor of respiratory disease-specific mortality. Furthermore, the Chi-square values in the regression model used by Sundh et al. show that the DOSE index Chi-square value was 146, followed by MRC dyspnoea scale (116), air flow obstruction (91), exacerbation frequency (75.5), and smoking (54). This order was similar to that found in the original DOSE paper. Thus, when considering commonly used severity markers against both health status (as in the original paper) or mortality (as in the Sundh paper), the DOSE index is a stronger predictor than any of its individual items. In addition, while smoking is much vaunted as a predictor of mortality, smoking was not statistically significantly associated with mortality in the univariate analysis. The vast majority of patients with COPD are current or former smokers. However, smoking only accounts for 40-70% of the attributable risk for COPD. In the USA, for example, 20% of COPD patients are non-smokers, and 20% of COPD mortality occurs in non-smokers. It is therefore worth investigating whether or not DOSE would be less useful in these individuals.

There are different ways to assess the value of indices in predicting mortality. In the Sundh paper the DOSE index score was examined in categories, whereas in the Oga paper the DOSE score was used as a continuous variable and Cox’s proportional hazards were used. The
Pandemic influenza vaccination for healthcare workers in primary care: good progress, but higher uptake required

See linked article by Hothersall et al. on pg 302

*Colin R Simpson*a, Jim McMenamin*b

*a Allergy and Respiratory Research Group, Centre for Population Health Sciences, The University of Edinburgh, Edinburgh, UK 
*b Health Protection Scotland, Glasgow, UK

*Correspondence: Dr Colin Simpson, Allergy & Respiratory Research Group, Centre for Population Health Sciences, The University of Edinburgh, Doorway 3, Medical School, Teviot Place, Edinburgh, EH8 9AG, UK. 
Tel: +44 (0)131 651 4151 Fax: +44 (0)131 650 9119 E-mail: c.simpson@ed.ac.uk

There were three global epidemics of influenza in the last century – in 1918-19, 1957-58 and 1968-69 – which resulted in considerable morbidity and mortality; the number of deaths in these pandemics has been estimated at 20 to 40 million, 1 million and 1 million, respectively. The lack of herd immunity to the novel influenza viruses implicated (i.e. H1N1, H2N2 and H3N2) is believed to have been a key factor contributing to these very high numbers of deaths.

The World Health Organization (WHO) subsequently declared the influenza A, subtype H1N1 virus (which emerged in Mexico in March 2009) a pandemic in June 2009.1 Production of pandemic H1N1 2009 influenza monovalent vaccines began soon after confirmation of outbreaks in Europe and the USA, and in the autumn of 2009 a worldwide vaccination programme began. The pandemic vaccine was shown to be highly effective.2 However, significant global numbers of cases occurred prior to the implementation of the pandemic vaccination programme. Whilst the illness severity was in the main mild, early estimates of mortality attributable to the first pandemic wave revealed an estimated 201,200 respiratory deaths, 80% of which occurred in people aged under 65.3 Such estimates make no allowance for the illness burden seen from the same pandemic virus as it became part of the seasonal influenza pool.

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uptake rates of seasonal influenza vaccination have remained low, leading to a number of radical solutions being suggested such as mandatory vaccination. During the early stages of the 2009 H1N1 influenza pandemic, uncertainty over pandemic severity and concerns for the integrity of healthcare systems and national infrastructure prompted the WHO to recommend that healthcare workers be prioritised for rapid immunisation. Internationally, there was wide variation in 2009 pandemic vaccine coverage amongst healthcare workers, ranging from 9% to 92%.

In this issue of the PCRJ, a study by Hothersall and colleagues set out to determine vaccine uptake and attitudes of primary care healthcare workers to the H1N1 2009 pandemic influenza vaccine in Shropshire Primary Care Trust (PCT). For healthcare workers willing to be vaccinated, most believed the vaccination would bring personal benefit and benefit to colleagues or patients. They were also more likely to have been vaccinated for seasonal influenza in the past, and were willing to be vaccinated in the future. The key issues for those healthcare staff unwilling to be vaccinated included uncertainty surrounding the safety of the vaccine – in particular, fears over Guillain-Barré syndrome, adjuvants, and thiomersal – and concern over vaccine effectiveness. Furthermore, there was a lack of awareness amongst these staff of the possible health risk they posed to themselves, their patients and their colleagues, by remaining unvaccinated.

In the UK National Health Service (NHS), front line healthcare workers and social care staff, as well as pregnant women and those with chronic diseases, were the first groups to be offered the vaccine. For NHS healthcare organisations in England, very good data on vaccine coverage of healthcare workers were captured via the ImmForm web system. From these data, we know that although coverage rates in 2009/10 increased considerably from the previous year's seasonal vaccination in 2008/9 (from 13.0% to 40.3%), there was low uptake found amongst nurses employed by hospitals and community health services (35% vs. 49% amongst general practitioners). There was also wide variation in coverage amongst PCTs (lowest – 17.0%; highest – 92.0%). In order to determine what led to higher rates of coverage, qualitative studies using face-to-face and telephone interviews were conducted in organisations achieving over 50% and under 25% uptake. From the results, it was determined that on an organisational level, better uptake could be achieved if there was:

- provision of flexible and accessible delivery of vaccine to front line staff
- good leadership, with senior colleagues leading by example (being publicly vaccinated etc.)
- a culture of influenza vaccine promotion in the workplace characterised by strong pro-immunisation messages from staff physicians, supervisors, co-workers and other opinion leaders
- and good planning, governance and project management – e.g. setting up a comprehensive implementation plan well ahead of the flu season and the use of targeted approaches underpinned by good information on uptake.

With strong evidence to suggest that nosocomial infection with influenza leads to more severe disease, in the event of any future influenza pandemic it is imperative that the lessons learnt from the 2009/10 pandemic are implemented to help increase coverage amongst front line staff in order to protect vulnerable patients. Misperceptions regarding vaccine safety – which are attributable, in part, to other vaccine scare stories such as MMR – remain a key barrier to uptake amongst healthcare workers. Since there is little appetite to adopt mandatory vaccination, the development of a national vaccination strategy for healthcare staff (and the public) is necessary. Furthermore, education programmes – delivered to those refusing the vaccine, and undergraduates undertaking health professional and clinical degrees – are necessary if myths surrounding vaccines are to be addressed and confidence increased.

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Notification about seasonal influenza vaccination: what is the best way to increase uptake?

*Fiona Mowbray*, G James Rubin  

King’s College London, Institute of Psychiatry, London, UK  
Emergency Response Department, Health Protection Agency, UK  

*Correspondence: Dr Fiona Mowbray, Institute of Psychiatry, King’s College London, Department of Psychological Medicine (PO62), Weston Education Centre, Cutcombe Road, London SE5 9J1, UK. Tel: +44 (0)1980 616968 Fax: +44 (0)1980 612968 E-mail: fiona.mowbray@kcl.ac.uk

Each year, countries undertake public health campaigns to encourage their population to have the seasonal influenza vaccine in an effort to reduce the number of people who will suffer from influenza and influenza-related complications. Influenza vaccines are generally considered to be safe, and are effective in reducing hospital admissions, complications and mortality in at-risk patients. Ensuring that patients are aware of the availability of the vaccine and are able to make an informed choice about whether to be vaccinated is an important responsibility for primary care physicians. Although the generally poor uptake of seasonal influenza vaccination is well-recognised around the world, the issue is particularly topical now given the disappointing uptake of vaccines during the recent H1N1 influenza pandemic.

In this issue of the *PCRJ*, Van Rossem et al. report findings of an investigation into whether patients of family practices in Belgium want to be notified about the availability of the influenza vaccine. Approximately 80% of the total study population reported wanting to be notified, a fact which Van Rossem et al. rightly note should encourage us to be proactive in inviting patients to be vaccinated. Yet around 20% of patients did not wish to be notified. This figure increased to 34% among those who had never previously been vaccinated. The authors suggest that this reflects the fact that “some people have already made up their mind about their refusal to be vaccinated” implying that “subjects who had never been vaccinated” had “less need [sic] for notification.”

But are we right to assume that such patients have truly exercised informed choice, or do these patients actually have more, not less, need for information and advice? Studies investigating the reasons why some eligible patients do not receive the vaccine have identified a number of important risk factors, many of which do not sit well with our scientific understanding of the risks and benefits of the vaccine. These reasons range from lack of awareness that the vaccine is available and confusion as to who qualifies to receive it, through to perceptions that influenza is not a particularly serious illness, that the vaccine causes influenza, or that the vaccine is likely to cause long-term health effects. Regardless of personal desires about influenza vaccination notification, it remains the responsibility of health care professionals to ensure that members of the public – particularly those who fall into a risk category – are provided with adequate information about the availability of the vaccine and about the true risks and benefits involved in having it. A proactive notification strategy, as advocated by Van Rossem et al., is to be applauded – though notification combined with information that specifically targets those misunderstandings or barriers that prevent people from receiving the vaccination may be even better.

Targeting particular vaccination misunderstandings can be a difficult task, and recent research shows that simplistic attempts to correct misconceptions via leaflets could potentially do more harm than good. Fortunately, Van Rossem et al. have also highlighted a better way of delivering this information by demonstrating the important role that the family physician plays with regards to the uptake of influenza vaccination. Among those who wanted to be notified of vaccination opportunities in their study, 85% reported that they wanted to be notified by their family physician, mostly during a regular consultation. Preference for this is supported by research that shows a significant increase in levels of vaccination following a personal invitation or recommendation from a family physician. But while a face-to-face discussion with a trusted healthcare worker may be the best way of encouraging patients to accept vaccination, we must be mindful that healthcare workers themselves are notoriously bad when it comes to having their seasonal flu vaccination. Within the UK, uptake of the vaccine by healthcare workers languishes at about 37%. A study by our team investigated the reasons given by healthcare workers for not having the pandemic or seasonal influenza vaccine and found that they were more likely than the general public to cite a belief that the vaccine is dangerous, has side effects or is ineffective. Relying on healthcare workers to communicate about the benefits of a vaccination that they themselves are unwilling to have may be less effective than we might hope.

The study by Van Rossem et al. has contributed valuable information about the popularity of influenza vaccine notification and preferred notification methods. Evidence-based methods for increasing the impact of this notification should now be a priority. Based on this and existing research it appears that there is a need to produce and disseminate clearer messages to both the general public and healthcare workers about the benefits of the vaccine, the risk of side effects, and who is eligible to be vaccinated.

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**Understanding the true burden of COPD: the epidemiological challenges**

See linked article by McKay et al. on pg 313

*Sundeep S Salvi*, Roslina Manap*, Richard Beasley*

*a Chest Research Foundation, Pune, India,  
b Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur, Malaysia,  
c Medical Research Institute of New Zealand, Wellington, New Zealand  
*Correspondence: Dr Sundeep S Salvi, Director, Chest Research Foundation, Marigold Complex, Kalyaninagar, Pune 411014, India  
Tel: +91 9921211000  Fax: +91 2027035371  
E-mail: ssalvi@crfindia.com

According to the World Health Organization (WHO), an estimated 3 million people die due to chronic obstructive pulmonary disease (COPD) every year, making it the fourth leading cause of death in the world.1 Around 90% of these deaths occur in low- and middle-income countries, with India and China alone estimated to account for 66% of total global COPD mortality.2 By 2020, it is anticipated that COPD will become the third leading cause of death in the world.3 The largest number of deaths will be in the South East Asian region, where mortality due to COPD is expected to grow by 160%,4 totalling more than the combined numbers of deaths due to malaria, tuberculosis and HIV/AIDS.

However, these data may well underestimate the problem. Tan et al.5 estimated COPD prevalence in the Asia Pacific region to be 6.3%, compared to the rate of 3.9% extrapolated from WHO data. Similarly, COPD prevalence in China was found to be 2.5 times greater6 than that estimated by WHO. Despite this apparently huge burden, there are few good quality epidemiological studies on COPD prevalence in South East Asia. For several decades the major health burden has been communicable diseases such as tuberculosis, malaria and HIV/AIDS; governments, lay people and physicians have been slow to recognise the impact of COPD. Yet with the increasing morbidity and mortality from COPD – which has already overtaken most communicable diseases as a leading cause of death – there is now a need for more intensive research and analysis of the epidemiology of COPD in this region.

In this issue of the *PCRJ*, McKay and colleagues report a systematic review on the prevalence of COPD in India.7 India is one of the largest countries in Asia with an estimated population of over 1.2 billion, where small increases in the percentage prevalence of a disease can translate into large increases in the number of cases. This huge population is exposed to a large number of COPD risk factors. Tobacco smoking rates in India vary from 13.3% to 59.5% amongst men and 0.2% to 22% amongst women.8 Around 70% of smokers in India smoke ‘bidis’ instead of cigarettes, which contain crude tobacco (0.15–0.25g) loosely packed in hand-rolled dried leaves of tendu (*Disopyros melanoxylon*). The smoke from bidis contains 5 times more tar than the smoke from cigarettes, making bidis smoking a far greater risk factor for COPD than cigarette smoking.9 But more importantly, over 70% of homes in India use biomass fuel for cooking and heating, which again poses a greater risk factor for COPD than tobacco smoking.10 The prevalence of other risk factors such as early childhood lower respiratory tract infections, post-pulmonary tuberculosis, chronic poorly controlled asthma, poor socioeconomic status and a growing ageing population is also very high.

McKay et al. reviewed a total of 16 papers on COPD prevalence published from 1980 onwards. Disappointingly, they could not identify a single study that provided a rigorous estimate of COPD prevalence using a relatively standard spirometry-based definition, and were therefore unable to perform a meta-analysis.5 Five of the 16 studies examined the prevalence of chronic bronchitis as a surrogate for COPD using validated questionnaires, while the remaining studies defined COPD using less traditional and non-standard methods. The results of this study beg some important questions:

- What are the standard research tools and methodology needed to define COPD in population studies?
- And why has a country like India not been able to conduct such a study?

Unlike asthma (a term coined by Hippocrates over 3000 years ago), COPD is a relatively new disease that has undergone remarkable changes in its terminology over the last 350 years. In the early 1800s, the terms ‘bronchitis’ (introduced by the British physician Charles Badham) and ‘emphysema’ (introduced by the Frenchman Laennec) were proposed. For the next 100 years ‘emphysema’ was used largely by American physicians, and ‘chronic bronchitis’ by the British, and in
later years this confusion was compounded by the use of additional
terms such as chronic airflow limitation (CAL) and chronic obstructive
airways disease (COAD). In 1965, Briscoe argued that this confusion
should end, and the term ‘chronic obstructive pulmonary disease’ or
‘COPD’ was formally approved.10

The next major challenge was to define COPD, a process which
evolved slowly compared to the rapid advances that took place in our
understanding of the disease pathogenesis and its clinical
characteristics.11 Most definitions included the presence of (largely
non-specific) respiratory symptoms and histopathological changes,
neither of which were useful for epidemiologists carrying out COPD
population studies. For many years the respiratory health
questionnaire designed by the British Thoracic Society (“presence of
productive cough lasting for more than 3 months during 2
consecutive years”) remained the main epidemiological tool to define
the prevalence of chronic bronchitis as a surrogate for COPD in
population studies. It was soon realised that this tool was neither
sensitive nor specific for diagnosing COPD.

After the success of the Global Initiative for Asthma (GINA), the
Global Initiative for Obstructive Lung Disease (GOLD) was launched in
1997. Its primary objectives were to streamline the definition of COPD
and offer guidelines on diagnosis and management to physicians
worldwide. The first GOLD consensus report was published four years
later.12 For the first time, spirometry was recommended as the gold
standard diagnostic test for COPD, though there was an additional
category of patients (called GOLD stage 0) that had respiratory
symptoms commensurate with COPD despite having normal
spirometry. But in 2006, the GOLD committee excluded this category.
Presence of airflow limitation was now the sole defining criteria for
COPD.

The Burden of Obstructive Lung Disease (BOLD) was formed in
2002 to set quality standards for defining COPD in epidemiological
studies.13 The BOLD Committee recommended the use of a respiratory
questionnaire and good quality spirometry to determine the presence
of COPD. Consistent with the GOLD guidelines, it recommended
using a post-bronchodilator FEV1/FVC ratio of < 0.7 to diagnose
COPD. Until the GOLD guidelines were introduced, spirometry was
rarely used to study the prevalence of COPD – and even when it was,
many studies lacked quality assurance measures and used only pre-
bronchodilator values; a significant number of asthma patients were
therefore falsely labelled as having COPD. Spirometry has remained a
poorly used diagnostic tool in most countries across the world. In
India, up to 70% of patients with COPD have never had a spirometry
test (personal observation). The need for post-bronchodilator
spirometry in epidemiological studies requires training of field
workers, not only to perform spirometry according to ATS/ERS quality
standards but also to administer short-acting bronchodilators via
inhaleders. Despite all these challenges, the BOLD study has now been
conducted in 21 countries across the world. This has not only helped
us understand the burden of COPD using standardised, validated
tools, but has also given us an opportunity to compare prevalence
rates between different countries.

However, new challenges have emerged. BOLD defined COPD as
a post-bronchodilator FEV1/FVC ratio of < 0.7, in accordance with
GOLD, as well as the American and European Respiratory Societies.14
Canadian Thoracic Society15 and the British NICE guidelines.16 But the
fixed FEV1/FVC ratio of < 0.7 has been criticised because it
underdiagnoses COPD in younger shorter patients and over-diagnoses
COPD in older taller patients.1718 To overcome these issues, use of the
lower limit of normal (LLN) FEV1/FVC ratio (i.e. subjects below the 5th
percentile of the predicted FEV1/FVC value for their race, gender, age
and height) was recommended by the ATS and ERS in 2005 as the
defining criterion for COPD.19 Another major limitation is that a post-
bronchodilator FEV1/FVC ratio < 0.7 may occur in other respiratory
disorders such as long-standing asthma and bronchiectasis. This has
led to the recommendation that spirometry be used with caution for
disease diagnosis, and that the term ‘COPD’ should only be used in
the appropriate clinical (diagnostic) context.20 This issue is particularly
important in epidemiological studies in developing countries, where
undiagnosed or poorly treated asthma and bronchiectasis secondary
to tuberculosis and other respiratory infections may be more
prevalent.

Over the last seven years, debate has continued on which COPD
diagnostic criterion is the best – the post-bronchodilator fixed
FEV1/FVC ratio < 0.7, or the LLN FEV1/FVC ratio. BOLD, ATS and ERS
have subsequently revised their guidelines to use the LLN criterion. Yet
recent evidence suggests that the LLN criterion not only
underestimates COPD,21 but also excludes a substantial population
with important clinical manifestations and a high consumption of
health care resources.2223 And if the LLN criterion has to be used,
should it be pre-bronchodilator or post-bronchodilator? Pre-
bronchodilator LLN values overestimate COPD prevalence by 31%
compared to post-bronchodilator LLN values.24 The ERS Task Force has
recently recommended using post-bronchodilator LLN values to define
COPD.25 In addition, the LLN criterion depends on reliable reference
values derived from the healthy local population; many countries
don’t have their own reference values for spirometry, and even if they
do, they are in all likelihood based on values obtained from
asymptomatic never-smokers. In populations such as the Asia Pacific
region, where smoking is not the overwhelming cause of COPD, the
‘apparently healthy population’ may include many who suffer from
asymptomatic undiagnosed airflow limitation due to factors other
than tobacco smoking, which may lead to significant underdiagnosis
of true COPD in these population studies.

Since many countries lack reliable locally-generated predicted
values for spirometry, and given the other issues associated with the
LLN criterion, the GOLD guidelines have continued to define COPD
using the fixed post-bronchodilator FEV1/FVC ratio < 0.7, whilst
acknowledging the fact that it underdiagnoses and over-diagnoses at
extremes of adult age. As Mannino comments: “Splitting hairs over
the most precise definition of COPD while many people with disease
are undiagnosed and untreated because primary care providers are
confused by the multiplicity of these definitions, is a disservice to
patients and the medical community...”26 Whether we use the fixed
ratio or the LLN, each has its own drawbacks and limitations.
However, the major concern is that the difference in prevalence rates
of COPD between these two criteria may be as high as 200%.2627
Irrespective of which criterion is used in the future, we still have to
accept that we are only diagnosing fairly advanced COPD. Early or
mild COPD, which primarily starts as a disease of the small airways,
cannot be diagnosed either by the fixed ratio or the LLN criteria. We
will therefore be missing a substantial number of patients who might
otherwise benefit from early diagnosis, early preventative strategies
and even early therapeutic interventions.

There are many challenges in determining the true prevalence of
COPD in population studies. To summarise, these include:
A lack of awareness about COPD amongst healthcare policy makers, clinicians, medical researchers and lay people. There is a real need to conduct high quality COPD prevalence studies

COPD is a relatively new term for an old disease that has evolved after an identity crisis. There is still a grey area about what 'COPD' actually means.

Performing post-bronchodilator spirometry requires specialised training and a good quality assurance programme. There are logistical challenges if prevalence studies have to be conducted in remote areas that are not easily accessible.

There is poor consensus regarding which spirometric criterion (fixed ratio or LLN) should be used to define COPD. Both have their drawbacks, and produce prevalence rates that may differ by up to 2-fold.

The current spirometric criteria are poorly specific for COPD and will identify individuals with other respiratory disorders such as chronic asthma and bronchiectasis.

Both currently used spirometric diagnostic criteria do not diagnose early or mild COPD.

What about the future? Unless reliable epidemiological data is generated from countries across the world, especially from the South East Asian region, health policy makers will not be able to take appropriate decisions regarding effective preventative and management strategies for COPD. In order to generate this information, countries like India will have to follow currently accepted (albeit imperfect) diagnostic guidelines. The BOLD protocol is currently the most acceptable methodology to define COPD prevalence in different countries, and this is currently being studied in four cities across India. In the meantime, clinicians, epidemiologists and researchers must strive to work towards a definition of COPD that should be unambiguous, unbiased and reproducible in different settings. It should also be simple to use, capable of identifying most if not all patients likely to suffer from the disease, and be able to exclude other respiratory conditions with airflow obstruction. It is only then that we will understand the true burden of COPD, which will help drive appropriate policy decisions at local, national and global levels to reduce the morbidity and mortality that COPD currently poses to mankind.

Conflicts of interest The authors declare that they have no conflicts of interest in relation to this article.

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