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MODELS OF CHRONIC DISEASE MANAGEMENT IN PRIMARY CARE FOR PATIENTS WITH MILD TO MODERATE ASTHMA OR COPD

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LIST OF ABBREVIATIONS

APHCRI	Australian Primary Health Care Research Institute
ATS	American Thoracic Society
CI	Confidence interval
COPD	Chronic Obstructive Pulmonary Disease
DIMCA	Detection, Intervention and Monitoring of COPD and Asthma Programme
DALY	Disability-adjusted life year
ECRHS	European Community Respiratory Health Study
EPC	Enhanced Primary Care
FEV_1	Forced expiratory volume in 1 second
FVC	Forced vital capacity
GINA	Global Initiative for Asthma
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GP	General practitioner
GPwSI	General practitioners, with a special interest
HRQoL	Health-related quality of life
IPCRG	International Primary Care Respiratory Group
ICSI	Institute for Clinical Systems Integration
MBS	Medicare Benefits Schedule
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NICECOPD	Northern Ireland Cost and Epidemiology of Chronic Obstructive Pulmonary Disease
NZ	New Zealand
PCO	Primary Care Organisation
PCT	Primary Care Trusts
PD_{20}	Administered dose of a substance in the inhaled aerosol which causes FEV_1 to fall by 20%
PEF	Peak expiratory flow
PIP	Practice Incentives Programme
PHCRED	Primary Health Care Research, Evaluation and Development
QALY	Quality-adjusted life-year
RCT	Randomised controlled trial
RSD	Residual standard deviation
SIGN	Scottish Intercollegiate Guidelines Network
SMD	Standardised mean difference
UK	United Kingdom
US	United States of America
WHO	World Health Organisation
YPDGP	York Peninsula Division of General Practice

1. BACKGROUND AND RATIONALE

BACKGROUND

A key objective of APHCRI Stream Four was to systematically identify, review, and synthesize knowledge about primary health care organisation, performance monitoring, funding/costs and service delivery and consider the application of this knowledge in the Australian context.(1) It was hypothesised that the knowledge gained would then provide a basis to inform future primary health care policy. In response to these aims, this narrative review, under the topic "Chronic Disease Management", reviews models of disease management for the chronic lung diseases asthma and chronic obstructive pulmonary disease (COPD), in adults, in the primary health care sector. The review was undertaken by the Discipline of General Practice, in conjunction with the Discipline of Public Health, The University of Adelaide and the Central Northern Adelaide Health Service. Members of the review group and their affiliations are identified in Appendix 1.

DEFINITIONS

The World Health Organisation (WHO) described chronic diseases as diseases which "are permanent, leave residual disability, are caused by non-reversible pathological alteration and may require a long period of supervision, observation, care and special rehabilitation".(2) Chronic diseases lead to a gradual deterioration in health, causing premature morbidity and mortality, and are large contributors to the overall burden of disease. As the population ages, the incidence and prevalence of chronic diseases increase.(3) The WHO has estimated that 60% of all deaths and 46% of the global burden of disease are due to chronic diseases.(4) In Australia, they account for the top 10 causes of total burden of disease and injury (disability-adjusted life years (DALYs)), responsible for about 43% of the overall burden.(5) This recognition has led to an increased interest in improving chronic disease prevention, diagnosis, control and the quality of care provided.(6)

Disease management has been defined as "a population-based approach to health care that identifies patients at risk, intervenes with specific programmes of care, and measures specific outcomes".(6) Chronic disease management aims to provide opportunities to identify, and through initiation of management strategies, reduce subsequent exacerbations of the chronic disease, with the ultimate aim of improving the patient's health and health-related quality of life (HRQoL). This may translate into a reduction in the demand for future chronic care services.(7) It is possible that many chronic diseases may be preventable, or their onset delayed, by measures implemented early during the course of a disease. Chronic disease management in primary care involves appropriate prevention, early identification and adoption of best practice management strategies in the primary health care setting.(8)

Primary health care has been defined by APHCRI as "socially appropriate, universally accessible, scientifically sound first level care, provided by a suitably trained workforce, supported by integrated referral systems and in a way that gives priority to those most in need, maximises community and individual self-reliance and participation involving collaboration with other sectors".(1) Thus, it is considered to include general practice, state-funded community heath services, private allied health services, pharmacies and complementary therapists but not specialist or acute care outreach services.(9)
Models of chronic disease management or models of care, describe the delivery of health care within the health system. Models of care have been defined as "designs for the provision of a particular type of health care service that consist of defined core

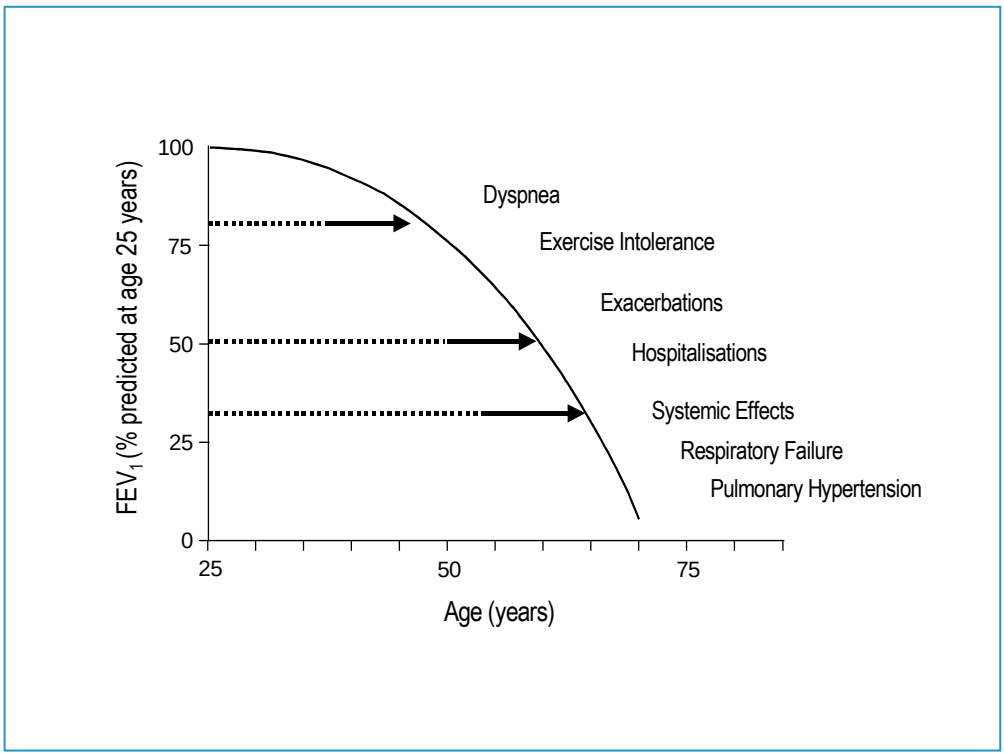
elements and principles and have a framework that can be implemented and evaluated".(10) More specifically, models of care should be evidence-based, based upon assessment of patient and health provider needs, incorporate evaluation of health-related and interventional outcomes and involve a multidisciplinary approach if applicable.(10)

RATIONALE

This review was undertaken with the recognition that much of the prevention, diagnosis, intervention and management of chronic lung disease in the community occurs in primary care. In primary care, programmes and initiatives designed to detect and manage mild to moderate chronic illness can be recognised and evaluated, to determine their uptake, effectiveness and cost, and provide an evidence base for future care. It must be emphasised that primary health care, with general practice providing a central role, is the first and often the only point of contact for patients with mild or moderate chronic lung disease within the Australian health system.(8) Primary care is where the best current opportunity would appear to exist, to modify the natural history of the disease process before serious ill health and disability become established – in asthma and in COPD where smoking persists despite primary prevention through tobacco control.

The decline in lung function for susceptible smokers with COPD is demonstrated in the diagram by Fletcher and Peto (Figure 1).(11) Susceptible subjects have an accelerated rate of decline of lung function compared to non-smokers. It is often not until late in the disease course that symptoms become severe, but by that time, patients may have large decrements in their lung function.

Figure 1. Time-course of chronic obstructive pulmonary disease



Source: Adapted from Fletcher and Peto(11)

This review explores models of chronic disease management for the mild to moderate lung diseases, asthma and COPD, in primary care. The review is focused at the disease-specific level, although some of the programmes have been used more widely in the community. A discussion of large integrated health care health maintenance organisations such as the United States of America (US) 'Evercare' or 'Kaiser Permanente' has not been included in this review.(12-14) Nor have generic models of care, such as the Chronic Care Model, been included.(15) Interventions relevant to severe lung disease, such as home oxygen therapy, discharge planning, hospital at home, or mechanical ventilation, are provided predominantly by secondary and tertiary health care facilities and so were not considered. A review of Australian national and state/territory level initiatives in primary health care with critical issues identified has previously been performed.(9)

SCOPE

The scope of the review was limited to the following inclusion criteria:

- asthma and COPD
- adults
- mild to moderate disease
- models of chronic disease management in primary care

It was necessary to narrow the scope of the review to enable it to be completed in a timely manner. By consensus, we narrowed the focus to adults with mild to moderate asthma and COPD as mild to moderate lung disease predominantly reflects the disease presenting in the primary health care setting. Paediatric asthma and moderate to severe chronic lung disease have previously attracted the majority of research attention.

Asthma has been defined as a chronic inflammatory disorder of the airways associated with airway hyperresponsiveness, airflow limitation and respiratory symptoms including wheezing, coughing and chest tightness.(16) In 1999, asthma was recognised by the Australian government as a National Health Priority Area due to the significant burden that this disease places on the Australian community in health, social, economic and emotional costs. The prevalence of current asthma in Australia has been estimated at 11.6% in 2001 with the prevalence of adults reporting ever being diagnosed with asthma ranging from 17% to 25%.(17)

Chronic obstructive pulmonary disease has been defined as a disease state characterised by airflow limitation that is not fully reversible.(18) The progressive airflow limitation leads to a gradual deterioration in health status.(18) The disease is predominantly attributed to cigarette smoking. Symptoms include cough, sputum production, shortness of breath and wheezing often leading, in severe disease, to marked limitation in physical mobility and hence activities. However, symptoms vary between individuals.(19) Currently, COPD presents as a major social and health issue, worldwide. In Australia, it is the third leading cause of DALYs, behind ischaemic heart disease and stroke but ahead of other National Health Priority Areas, diabetes mellitus (seventh leading cause of disease burden) and asthma (ninth).(5)

The number of patients with asthma and COPD is continuing to increase, yet both asthma and COPD are under-recognised and under-managed in the community.(20) It has been estimated that only 25 to 50% of patients with these diseases have been diagnosed.(21) These diseases must be priorities for health reform focused on prevention and improved collaborative management if we are to reduce the overall burden of chronic disease. Early detection of asthma and COPD, before disease progression, may provide an opportunity for early intervention with evidence-based management strategies, potentially reducing the loss of lung function, improving prognosis and reducing the burden on secondary and tertiary care.(21) However, diagnostic respiratory criteria vary between major respiratory societies and countries, leading to differing prevalence estimates and different estimates of target populations for possible intervention.(22)

OBJECTIVES

A primary research question was initially formulated:

"What do we know about models of chronic disease management for patients with mild to moderate chronic lung disease in the primary health care sector?"

A series of questions across four domains (organisation, implementation and evaluation, funding/costs and service delivery) were developed as follows:

Organisation

a. How is primary health care currently organised both nationally and internationally for patients with mild to moderate chronic lung disease?

b. What is the evidence base to support these organisational structures for chronic lung disease?

c. What is known about integrating innovative models of care across the primary health care/acute care interface for patients with mild to moderate chronic lung disease?

d. How do organisational structures facilitate management of comorbidity?

Implementation and Evaluation

a. Do primary health care organisations providing care to patients with mild to moderate chronic lung disease monitor performance?

b. What evidence is there to support monitoring and assessment for patients with mild to moderate chronic illness?

Funding/costs

a. How is primary health care financed for patients with mild to moderate chronic lung disease?

b. What is the evidence to support these models for patients with chronic lung disease?

c. How do these current financing models facilitate management of comorbidity for patients with mild to moderate chronic lung disease? What alternative innovative models are available?

d. What kinds of efficient and perverse incentives are generated by these various models of organisation and financing?

Service delivery

a. What are the federal and state approaches to service delivery for primary health care for patients with mild to moderate chronic lung disease?

b. What evidence is there to support these approaches for patients with chronic lung disease?

c. How do these approaches to service delivery facilitate management of comorbidity for patients with mild to moderate chronic lung disease?

During the initial scoping of the literature, the primary research question was subsequently modified as shown in Table 1. To produce the key research question as follows:

Final key research question

"What do we know about models of chronic disease management for adult patients with mild to moderate asthma or COPD in the primary health care sector?"

A hypothesis was generated, to be tested on the basis of the current available evidence identified. Models of chronic disease management were then considered for relevance to the hypothesis.

HYPOTHESIS

"Models of chronic disease management, when applied in primary care, can lead to the recognition of risk factors and the early detection, diagnosis and management of the chronic respiratory diseases, asthma and COPD, enabling the implementation of evidence-based strategies which may potentially alter the future disease burden."

Table 1. Modifications of the primary research question

Date	Original question	Changed question	Rationale
30.10.2005	What do we know about models of chronic disease management for patients with mild to moderate chronic lung disease in the primary health care sector?	What do we know about models of chronic disease management for patients with mild to moderate asthma or COPD in the primary health care sector?	Narrow the focus of the question to include asthma or COPD only.
02.11.2005	What do we know about models of chronic disease management for patients with mild to moderate asthma or COPD in the primary health care sector?	What do we know about models of chronic disease management for adult patients with mild to moderate asthma or COPD in the primary health care sector?	Narrow the focus of the question to exclude children.
22.02.2006	What do we know about models of chronic disease management for adult patients with mild to moderate asthma or COPD in the primary health care sector?	Hypothesis generated: "Models of chronic disease management, when applied in primary care, can lead to the recognition of risk factors and the early detection, diagnosis and management of the chronic respiratory diseases, asthma and COPD, enabling the implementation of evidence-based strategies which may potentially alter the future disease burden."	

A general framework for synthesis of narrative reviews is suggested by the Cochrane Collaboration and described in the Cochrane manual as follows:(23)

- what is the direction of effect?
- what is the size of effect?
- is the effect consistent across studies?
- what is the strength of evidence for the effect?

Due to time and budget constraints, the initial questions posed for this review were subsequently modified, simplified and reduced to allow hypothesis testing with consideration to the Cochrane Collaboration suggested synthesis above.

The following final secondary research questions under the four domains of organisation, implementation and evaluation, funding/costs and service delivery formed the framework for the review:

Organisation

What is the evidence base to support the models of chronic disease management for mild to moderate asthma and COPD?

Implementation and Evaluation

What is the evidence that the models of chronic disease management for mild to moderate asthma and COPD have been implemented and evaluated and what impacts have they had on clinical outcomes?

Funding/costs

How are the models of chronic disease management funded and are they cost-effective?

Service delivery

What are the barriers, advantages and disadvantages of the application of these models in primary care for patients with mild to moderate asthma and COPD?

2. METHODOLOGY

APPROACH TO THE REVIEW

The content for the review was obtained from an extensive literature search for evidence relating to models of care for asthma or COPD relevant to the primary health care setting. Multiple searches of electronic databases and the World Wide Web were conducted to identify both peer reviewed papers and 'grey' literature. Citation titles were initially scanned and abstracts of selected titles of potential relevance read, for possible inclusion in the review. Duplicate references were discarded. A large number of citations were retained for later sub-searches to identify those relevant to the individual models of disease management reviewed. The full text was obtained for potentially relevant studies/papers or for those citations where the potential relevance could not be determined from the title or abstract. The reference lists of relevant studies/papers were read for other references of possible relevance to the review ('snowballing'). An iterative strategy was employed. Indexes of key journals were repeatedly read for new articles of relevance to the review, which were added to the reference lists.

APPRAISAL OF THE EVIDENCE

We employed a narrative approach to appraise and summarise the literature, due to the heterogeneity of the studies identified. Using our best judgement, we included conclusions of meta-analyses, systematic reviews, narrative reviews, reports and individual studies. All levels of evidence, as currently defined by the National Health and Medical Research Council, (NHMRC) Australia (Table 2.) were considered for their potential relevance to the review, since it was anticipated that comments and reviews could lead to the identification of important issues surrounding the various models of care identified.(24) However, although all levels of evidence were considered, we gave preference to systematic reviews, meta-analyses and randomised controlled trials (RCTs) to evaluate the effectiveness and impact on health outcomes for the models of care reviewed. We used the results of focus groups, and qualitative studies to identify potential barriers and advantages in implementing the models of care. As high quality evidence was not always available, with some papers descriptive in nature, we were unable to synthesize the data into a meta-analysis.

Table 2. Rating scale for quality of evidence (National Health and Medical Research Council, Australia)

Grade	Definition
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III - 1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III – 2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control analytic studies, or interrupted time series with a control group.
III - 3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test and post-test.

Source: National Health and Medical Research Council. A Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines. Commonwealth of Australia.

Key informants from national professional bodies and key primary care personnel were contacted to identify models of care they considered important or to provide information with regard to additional reports, policy documents or guidelines. As it is often difficult to distinguish between interventions and models of care, and much debate could occur regarding the interpretation of both terms, we did not distinguish between the two. Rather, key topics and issues, highlighted by the primary health care providers and policy makers interviewed, served as a basis for informing the hypothesis.

INCLUSION CRITERIA

Diseases
Mild or moderate asthma or COPD.

Setting
Primary care.

Types of participants
Adults. Models of care specifically for children were excluded, although models including children and adults were considered

Language
Papers published in languages other than English were excluded.

Dates
The searches were limited to the years 1990 to 2005 as the first local Divisions of General Practice were established in 1992. The searches were performed in November and December 2005 and January 2006, although new reference material was continually added to the reference list as it was identified.

Comparator countries

International models of care were restricted to countries comparable with Australia, namely industrialised English-speaking countries including the United Kingdom (UK), Finland, US, Canada and New Zealand (NZ).

SEARCH STRATEGY

A broad search strategy was employed. A skilled university librarian was engaged to assist in the development of a subject search strategy, based on exploded 'MeSH' terms for COPD, asthma and primary health care, to be used with the National Library of Medicine PubMed online database of scientific literature (Appendix 2). For Ovid databases, subject search terms (Table 3) were incorporated into established search strategies, developed by the University of York, Centre for Reviews and Dissemination, to identify reviews, meta-analyses and RCTs.(25) Websites hosting databases of existing meta-analyses and systematic reviews were also searched.

Search terms

Standard search terms are given in Table 3. Additional broad search terms were used for databases where simple searches were required.

Table 3. Search terms

Standard search terms

1. Exp Lung disease, obstructive/ includes
   a. Asthma
   b. Bronchitis
   c. Pulmonary disease, chronic obstructive
2. Exp Adult/
   a. Aged
   b. Middle aged
3. Exp Patient care management/ includes
   a. Comprehensive health care
   b. Critical pathways
   c. Delivery of health care
   d. Disease management
   e. Patient care team
   f. Patient-centred care
   g. Patient selection
   h. Physician's practice patterns
   i. Point of care
4. Family practice/

Additional search terms

'COPD', 'asthma', 'primary care', 'management'

The subject search strategy was modified according to the databases searched and for searches of the 'grey' literature. The 'grey' literature included Australian federal and state government sponsored websites and Australian national and state lung disease or asthma websites such as The Australian Lung Foundation for identification of papers, reviews, reports and conference proceedings which may not have been published in peer-reviewed literature.

A list of the databases searched is given in Appendix 3.

Where several papers on the same topic, written by the same author, with similar information were identified, the most recent was retained unless earlier papers contributed additional knowledge. The references were downloaded to a citation management database (EndNote®).

ADDITIONAL TABLES

Models of chronic disease management for asthma or COPD, relevant to the primary care setting, were identified from the initial searches. Each model was then considered for its relevance to the hypothesis, and importance as identified by our key informants. The literature pertaining to the various models of care identified, was retrieved, and critically reviewed and summarised for possible inclusion in the review. The following tables were constructed (Appendix 4):

- a descriptive table for prevalence estimates from population studies (cohort, cross-sectional)
- a guidelines table describing guidelines for asthma or COPD relevant to primary care
- a descriptive table for meta-analyses, RCTs and comparative studies

Details extracted to a descriptive tables for prevalence estimates

Study, country, disease, plan of the study with inclusion criteria, design and methods, participants, prevalence, total sample size.

Details extracted to a guidelines table

Guideline acronym, guideline title, date released, country, chief author, adaptation, guideline developers, source(s) of funding, conflicts of interest, disease, guideline category, intended users, objectives, target population, cost analysis preformed, methods used to assess quality of the evidence, methods used to analyse the evidence, methods used to formulate recommendations, method of guideline validation, clinical algorithm, implementation plan developed, evaluation and uptake of guideline, patient information.

Details extracted to a descriptive table for meta-analyses, randomised controlled trials and comparator studies

Study, type of article, time/place of study and duration of follow-up, participants and sample size, setting, main aim and target group involvement, study design and outcomes, results/findings/subgroup effects, strengths, limitations of the study/study quality for RCTs, conclusions/implications.

OUTCOMES

- models of chronic disease management including origin of the intervention, time and place, local policy environment, study design
- implementation strategies including organisational factors, for example, training
- evaluation strategies including study design, measurement of effects with consideration to sub-groups (gender, age, ethnicity)
- estimated quality of the RCTs(26)
- costs and cost-effectiveness, sources of funding
- barriers to implementation
- advantages
- disadvantages

LIMITATIONS OF THE REVIEW

Due to time constraints, other available electronic databases were not searched. The search strategy did not attempt to extract all literature on the topics and it is likely some publications of relevance to the hypothesis were missed. However, the searches were verified for near completeness by an increasing number of duplicates retrieved during later searches.

Due to the lack of comparability between the American Managed Health Care System and the Australian Health Care System, we gave lower priority to literature from the US. We also gave preference to more recent papers to reflect current understanding of the management of chronic lung disease.

Although we extensively searched the 'grey' literature, most evidence was taken from meta-analyses or RCTs. However, we recognise that the external validity of RCTs is questionable, with these studies only being relevant to the select minority of patients participating in the study.(27) A study by Herland, to determine whether clinical study patients with asthma or COPD are representative of 'real life' patients with obstructive lung disease, concluded that evidence-based treatment decisions promulgated in disease management guidelines for obstructive lung disease are based on studies which include a very small and highly selected fraction of the 'real life' patient population.(28)

PROJECT TEAM MEMBER CONTRIBUTIONS

One reviewer (AC) developed the original concept and wrote the initial proposal. Two reviewers (JC and AC) performed the literature searches. A single reviewer (JC) reviewed the evidence and wrote the report. This was necessary due to financial and time constraints but increased the inherent potential for bias. Additional intellectual content was provided by three reviewers (AC, JM and RP). All reviewers approved the final report.

3. RESULTS

LITERATURE SEARCH AND IDENTIFICATION OF MODELS OF CHRONIC DISEASE MANAGEMENT

The initial scoping of the literature was conducted to address the key research question "What do we know about models of chronic disease management for adult patients with mild to moderate asthma or COPD in the primary health care sector?" The following major topic categories with models of chronic disease management were identified and are detailed in Table 4.

1. Health care delivery and management
   Models of chronic disease management/interventions that promote the use of evidence-based medicine for the assessment and management of patients with mild to moderate asthma and COPD in primary care.

2. Health care prevention and monitoring
   Models of chronic disease management/interventions promoting early recognition of risk factors and early diagnosis of asthma and COPD, and/or ongoing monitoring of disease progression, aiming to reduce future disease exacerbation.

3. Exercise and breathing reconditioning**:**
   Models of chronic disease management/interventions spanning the continuum of care, valid in the primary care setting, which could impact on the future progression and/or the future burden of asthma and COPD.

4. Alternative or complimentary therapies
   Non-medical models of chronic disease management /interventions offered in the primary care sector relevant to mild to moderate asthma or COPD.

The topic categories were not mutually exclusive; for example, guidelines were multi-factorial consensus statements providing advice on general practitioner (GP) management, patient centred management, outpatient management and general interventions. A practice nurse could provide self-management education to patients, conduct specialised respiratory clinics, and perform spirometry.

Table 4. Major topic categories and models of corresponding chronic disease management

Topic category	Model of chronic disease management
Health care delivery and management	General practitioners with a special interest in respiratory care Practice nurses Nurse-led respiratory clinics Patient education Patient self-management Clinical practice guidelines Academic detailing Audit and feedback: Clinical decision support After hours care Community-based pharmacy outreach programmes Information systems to access key data on individuals or populations Shared care: health partnerships Telephone consultations for asthma review Telemedicine in the home
Health care prevention and monitoring	Case-finding/screening/diagnosing/monitoring in chronic disease Questionnaires Spirometry in primary care Smoking cessation Vaccination
Exercise and breathing reconditioning	Exercise training Breathing retraining Psychotherapy Pulmonary rehabilitation
Complementary or alternative therapies	Numerous including: Acupuncture, Allergen avoidance, Chiropractic manipulation, Diet modification, Homeopathy, Humidity control, Hypnotherapy, Ionisation, Massage, Music therapy, Reflexology, Relaxation therapy, Yoga

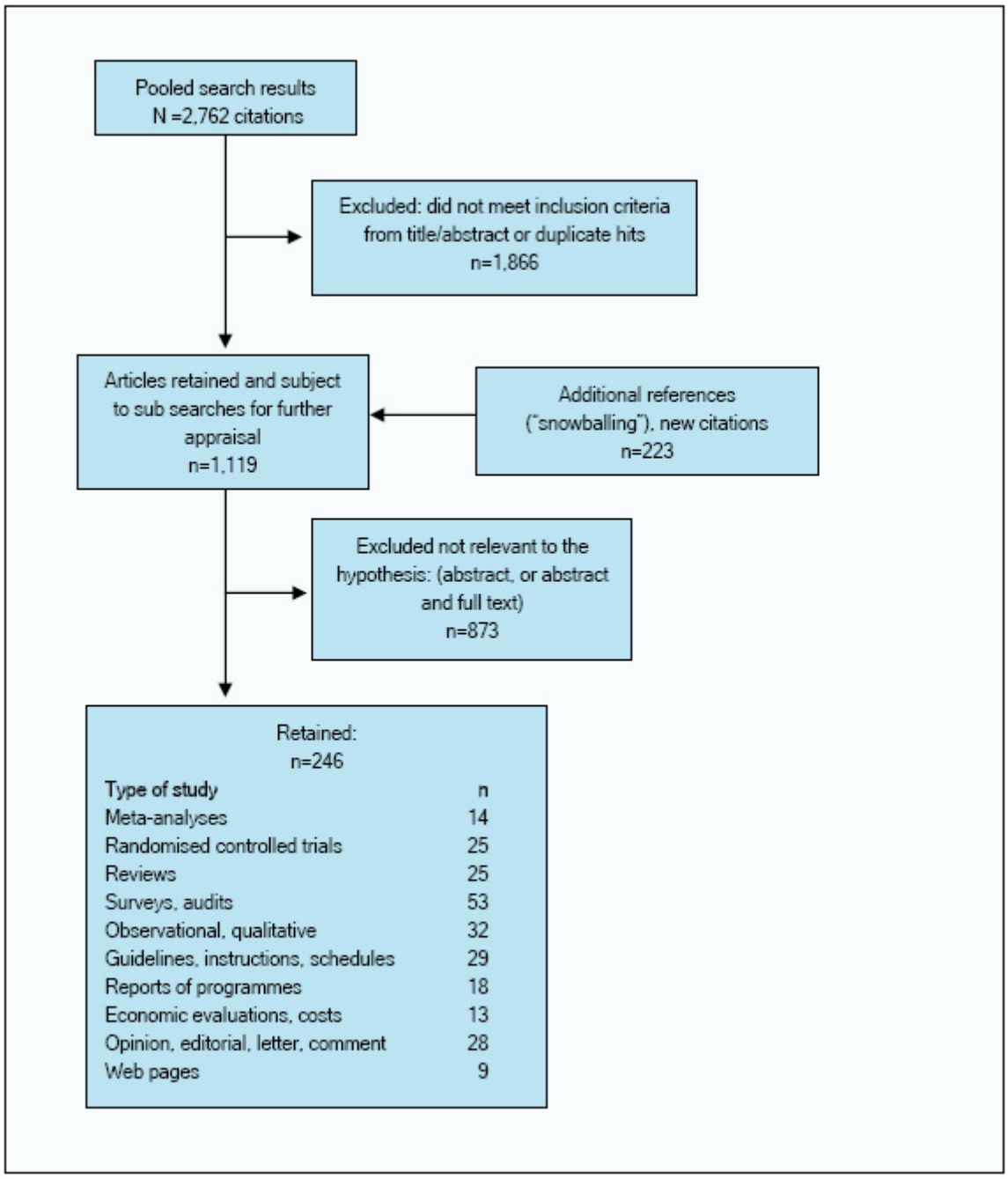
This narrative review focused on literature informing those models of care considered relevant to the hypothesis. The following topic categories and models of care were reviewed:

- health care delivery and management
  - GPs with a special interest (GPwSI) in respiratory care
  - practice nurses involved in asthma and/or COPD management through nurse-run clinics, patient education, patient self-management
  - clinical practice guidelines

- health care prevention and monitoring
  - case-finding, screening, diagnosis, monitoring of chronic lung disease through spirometry programmes in primary care

Figure 2 describes the results of the pooled searches. Additional references were added to the combined reference list over the course of the study duration until July 2006. A large number of citations were initially excluded as the studies involved children, were primarily aimed at the management of severe disease or conducted in secondary or tertiary referral facilities. A collection of citations of potential relevance to the review (n=1,119) was retained and subjected to secondary searches to identify those relevant to the different models of disease management reviewed. From the secondary searches, 246 citations have been included in this review.

Figure 2. Flow chart – Literature search results



1. GENERAL PRACTITIONERS WITH A SPECIAL INTEREST IN RESPIRATORY CARE

With the ageing of the population and the increasing burden of chronic disease, models of chronic disease management are required that are able to adapt to the changing focus from acute to chronic care.(29) Models based in primary care, and implemented by GPs, could potentially enable early management of disease reducing the subsequent burden on secondary and tertiary care facilities. 'Special interest' can be applied to a GP who is particularly interested in one area of practice through to having postgraduate qualifications and/or expertise in a particular area of general practice.(30) General practitioners, with a special interest in respiratory care, may

potentially provide a service in family practice that reduces demand for specialist services while improving the diagnosis and care of chronic disease.(31)

Research question 1. Organisation

What is the evidence base to support respiratory GPwSI?

In Australia, specialising GPs, either formally or informally, have developed specific skills and interests within the general practice setting.(30) Wilkinson noted that 28% of telephone directory general practice listings in Sydney and Brisbane, advertised special services.(30) General practitioners within Australia have developed expertise in many specialist areas such as asthma, skin cancer, hypnotherapy or acupuncture. Dedicated Medicare Benefits Schedule (MBS) item numbers are available for some aspects of care provided. As an example, the General Practitioners' Asthma Group, Australia, under the auspices of the National Asthma Council, was created in the early 1990s, and now has over 300 members. The group act as liaison officers, involved in the co-ordination and dissemination of new technology and information for GPs about asthma care.(32)

In the UK, a key goal of the recent National Health Service (NHS) Plan 2000 has been to formalise the role of 'Primary Care Specialists' who take referrals from fellow GPs for specific specialties.(33) The main aim of the service is to provide intermediate care to reduce hospital referrals and demand on secondary and tertiary care services.(30) Primary Care Organisations (PCOs) have promoted GPwSI in areas prioritised by government policy. A new primary care government contract in the UK, with a focus on respiratory disease, will provide an incentive for an increase in the number of respiratory GPwSI.(31)

The literature search identified two cross-sectional surveys discussing GPwSI respiratory services.(31,34) A model for respiratory GPwSI services was proposed by Williams.(35) An economic perspective of GPwSI services by Kernick emphasised the fact that there was no evidence to support GPwSI services in terms of cost-effectiveness.(36) An economic evaluation of GPwSI in the UK by Coast, included a study of GPwSI-run dermatology clinical service, was cited due to the paucity of information about respiratory GPwSI programmes.(37)

The Jones study, conducted in 1991, involved a postal survey being sent to all English general practices containing members of the "General Practitioners in Asthma Group" and with a special interest in asthma care.(34) A special interest in asthma care was defined by the practice's use of a written management protocol for asthma before 1990, and at least one member learning about best practice management of asthma. The responses to the questionnaire were compared with those from practices using a written asthma protocol after 1990 or those without an asthma protocol. The effects on the type of asthma care delivered, prescribing patterns and prescribing costs of having a special interest in asthma were evaluated. Subgroup analysis was conducted with comparisons between and within groups with age considered.

A survey (response rate 69%) involving the distribution of a semi-structured questionnaire to a random sample of English and Welsh PCOs to determine the role, barriers and monitoring of a respiratory GPwSI service was conducted in 2003.(31) Only 6% of PCOs surveyed had established, and 32% were planning, a respiratory GPwSI service.

The principal reasons identified for appointing a respiratory GPwSI included:

- to reduce pressure on secondary care
- in response to a government directive
- for drug cost containment or because of local patient pressure

Infrastructure and support considered necessary for a respiratory GPwSI service included:

- clinical support (nurses, physiotherapists)
- medical equipment (spirometer, oximeter)
- training and ongoing professional development for the GPwSI
- office and administrative support.

Research question 2. Implementation and Evaluation

What is the evidence that respiratory GPwSI services have been implemented and evaluated and have influenced clinical outcomes for patients with mild to moderate asthma or COPD?

There is little information regarding the evaluation and impact on clinical outcomes of respiratory GPwSI services. In the Jones' survey, responses from those practices with a special interest in asthma demonstrated higher asthma diagnosis rates, greater respiratory nurse hours, more asthma patients on an asthma register, a greater likelihood of having implemented a recall system and a greater likelihood that patients were reviewed by both doctor and nurse.(34) However, the study was limited by the variation within groups and the number of months of use of a written asthma protocol (13 to 82 months). Differences between practice prescribing and diagnosis appeared to be positively related to the number of practice nurse hours.

The Pinnock survey reported that 97% of responding PCOs monitored or were planning to monitor the impact of respiratory GPwSI through: admission rates for COPD and asthma, emergency department attendances, quality of respiratory care, practice prescribing for respiratory disease, patient satisfaction, waiting times and home oxygen therapy.(31) However, no outcomes data relating to the monitoring were provided.

Research question 3. Funding/costs

How are respiratory GPwSI funded and is the service provided cost-effective?

The UK NHS Plan of 2000 envisaged GPwSI either being employed by Primary Care Trusts (PCT) or Acute Trusts, usually on a sessional basis, or delivering services as independent contractors. Individual PCT are now responsible for remuneration arrangements for GPwSI in the UK, often on a session-by-session basis.(38)

In Australia, access to some MBS item numbers is restricted to GPs with appropriate training.(30) Medicare item numbers for care planning and case conferencing provide additional remuneration but have been perceived as being complex and more applicable to moderate to severe disease.(39)

We were unable to identify any studies evaluating the cost-effectiveness of respiratory GPwSI services. A cost-analysis of GPwSI services in relation to prescription drug costs was performed in conjunction with the Jones' survey.(34) Those practices using a written protocol for asthma were more active in asthma prescribing and so had higher

respiratory drug costs. These practices had lower costs for other therapeutic drugs such as cough medicines and nasal decongestants. Overall, prescribing costs were not different between practices using, and not using, a written asthma protocol. However, there was considerable variation in costs between individual practices, with low prescribing costs associated with lower practice nurse hours. No costs for the provision of the GPwSI were provided.

A cost evaluation of providing a GPwSI service in the UK was performed by Coast for dermatology clinical services.(37) Costs to the NHS for patients attending the GPwSI service were £208 compared with £118 for hospital outpatient care. Costs to patients and carers were £48 and £51 respectively, and costs of lost production were £27 and £34 respectively. The incremental cost-effectiveness ratios for GPwSI care over outpatient care were £540 per one point gain in the dermatology life quality index and £66 per 10 point change in the access scale. The study concluded that a GPwSI dermatology service was more costly than hospital outpatient care, but provided improved access for patients and similar health outcomes. It is not known if similar costs apply to respiratory GPwSI services.

Economic and related questions to be considered before establishment of GPwSI services have been highlighted by Kernick:(36)

- what is the aim of the service change?
- is the shift acceptable to stake holders?
- is there an evidence base for the proposed shift, which captures costs and outcomes?
- what are the local cost implications?
- what are the local values placed on the potential changes?
- what seems the best increment in service development to undertake?
- are new resources available, or is disinvestment in secondary care required?
- if disinvestment from secondary care is required, is this practical and can the released resources be identified?
- what benefits are forgone in the services from which the resources are being disinvested?
- are there implications for other services that may have been overlooked?

Research question 4. Service delivery

What are the barriers, advantages and disadvantages of respiratory general practitioner services?

The major barriers to implementing a respiratory GPwSI service identified in the Pinnock survey were:(31)

- competition with other local priorities
- inadequate funding for respiratory GPwSI
- inadequate infrastructure support funding
- respiratory disease not being a local priority
- respiratory disease not being a national priority
- lack of local interest/expertise from GPs
- already have a respiratory nurse
- opposition from secondary care
- lack of local patient pressure

Possible advantages for GPs, general practices and the community include:(30)

- variation in work and opportunity for career development
- provision of advice to other GPs
- reduced GP burnout
- improved retention of GPs
- possible increased financial compensation for the practice

Disadvantages for GPs, practices and the community have been hypothesised to include:(30)

- loss of some generalist skills
- reduced pool of GPs in the community
- possible suboptimal care if standards are not maintained
- fewer GPs available for less attractive or less well-remunerated areas or services such as socially deprived regions or visits to nursing homes

Key findings and implications for policy makers

1. There is an absence of evidence that respiratory GPwSI services improve the management of mild asthma in primary care (only 1 cross-sectional survey performed approximately 15 years ago provided lower level evidence of outcomes).

2. There is no evidence either to support or refute the hypothesis that respiratory GPwSI services improve the management of mild to moderate COPD in terms of improved patient outcomes.

3. There was limited evidence that a GPwSI service increased respiratory drug costs but reduced costs for other drugs such as cough medicines.

4. The overall costs and cost-effectiveness of a respiratory GPwSI service, clinical outcomes, acceptability by patients and physicians and standards of care require evaluation. The direct costs of establishing a GPwSI service for dermatology patients have been calculated and were substantial.

5. Economic and related issues require consideration prior to the establishment of respiratory GPwSI services.

2. PRACTICE NURSES

In Australia, both registered and enrolled nurses work as practice nurses, providing nursing services within general practice and contributing to chronic disease management and population health activities in the community.(40),(41) It has been estimated that there are approximately 5,500 to 6,500 nurses employed in general practice in Australia with the number increasing by approximately 15% to 17% per annum.(42)

The Australian Government recognised the need for improved chronic illness care in its National Chronic Disease Strategy released in November 2005 and is proposing to expand the role of practice nurses by an extension of the practice nurse subsidy.(43)

Research question 1. Organisation

What is the evidence base to support practice nurse management for patients with mild to moderate asthma and COPD?

Role of the practice nurse

The responsibilities of practice nurses are usually determined by GPs and are influenced by factors such as the practice population, nurse' qualifications and skill levels, practice structure, professional standards and national incentives and programmes.(40) The employment of practice nurses with special skills and knowledge, enable practices to offer clinics in specific areas such as asthma care and asthma education.(44) Nurse practitioners may also have a role as practice nurses, working collaboratively with GPs and the general practice team.(45)

Nurses as educators

Patients with chronic illness require regular communication with their health care providers to focus on prevention of exacerbations and maintain function.(29) This includes systematic assessments, attention to treatment guidelines, and patient support. However, providing to a patient with a chronic disease, individualised care that is evidence-based in a 15 minute visit may be difficult for many GPs.(46) It has been estimated that it takes an hour to provide education and correct misinformation to an asthma patient, and education may be required over more than one session.(47) Practice nurses are in a position to undertake education and spirometry testing of respiratory patients, providing health promotion information, education and instruction on inhaler medication and technique, and performance and feedback of spirometry.(48)

While patient education has been emphasised over recent years, for chronic disease management to be effective, it must not only improve patient knowledge but must result in changed patient behaviour. The rationale is that an informed patient can participate in decision-making regarding their own care.(49) Self-management requires the ability to recognise and self-assess a change in symptoms, to learn problem solving skills and adjust behaviour to reach a desired goal, for example, by adjusting medication or making appropriate life-style changes.(50) However, the need for regular review of the condition should also be recognised. Many studies of asthma patients have demonstrated a poor clinic attendance which may be due to a lack of understanding by patients of their condition, to minimal symptoms or failure to recognise symptoms experienced or that self-management programmes have not considered patients' perceptions and preferences.(51-53)

General practitioner' perceptions of the practice nurse role

Focus groups, conducted to identify GPs' views on chronic-disease management, indicated Australian GPs' perceived practice nurses as involved in many tasks including: playing a key role in providing patient education, generating recalls and reminders, undertaking routine clinical tests, assisting with paperwork, coordinating care and undertaking reception duties.(54)

Respiratory practice nurses: Australian experience

Practice nurses or community nurses, with or without specialist respiratory training; have been involved in asthma management in Australian general practice for several years. The "National Service Improvement Framework for Asthma", recognised that the majority of an asthma patient's care occurs in the community, with GPs and community nurses, pivotal in the provision of continuing care.(43) Nurse-run general practice-based asthma clinics have been established, but often in conjunction with research

studies or asthma campaigns.(55) A 1997 survey of Australian Divisions of General Practice reported that 24 Divisions (28%) were involved in asthma projects with 58% of the projects centred around asthma education.(47)

Respiratory practice nurses: Overseas experience example United Kingdom

Practice nurse positions have increased rapidly in the UK since the late 1980s, largely in response to the 1990 GP contract which paid doctors to provide chronic disease clinics.(56) Also contributing to the expansion were the results of a pre-and-post audit by Charlton of a nurse-run asthma clinic which demonstrated improvement in health outcomes for moderate to severe asthmatics.(57)

In the UK, the practice nurse role in the management of asthma in primary care involves the running of asthma clinics, either individually or in conjunction with a GP.(51),(58) A UK survey of the roles and responsibilities of practice nurses found that all responding practice nurses reported undertaking chronic disease management with over 80% of respondents claiming involvement in asthma management and 9.6% in COPD care.(59) The discrepancy in the number of practice nurses claiming involvement in asthma care compared to COPD care probably has resulted from the world-wide focus on asthma since the early 1990s with COPD care only being emphasised over recent years. The practice nurse's duties included care for asthma patients, making decisions about diagnosis, initiating treatment or adjusting treatment regimes.

Other nurse-led primary care services in the UK include NHS Direct, a 24 hour, telephone health advice and information service and NHS walk-in centres, which provide access to health information, advice and treatment for a range of minor illnesses.(56)

Training and Competency

Overseas examples, United Kingdom and New Zealand

Postgraduate certificate community nursing courses including general practice nursing are available in the UK to nurses with a degree in community nursing. In NZ, the professional development of practice nurses is supported by a professional college which provides an education and accreditation programme.(40),(60) Practice nurse accreditation was confirmed in 1998.

Australia

Competency standards for registered and enrolled nurses in general practice were released by the Australian Nursing Federation in 2005.(44) These standards provide a professional framework for performance measurement and professional development for both employers and practice nurses in Australia. Universities such as The University of Adelaide, South Australia and the University of Wollongong, New South Wales, are now offering graduate diplomas or graduate certificates in nursing science/general practice nursing. The uptake of these courses is yet to be determined and it will be several years before nurses completing the courses are available to work as skilled general practice nurses.

Research Question 2. Implementation and Evaluation

What is the evidence that the service provided by practice nurses for patients with mild to moderate asthma and COPD has been implemented and evaluated and what impact has it had on clinical outcomes?

The literature review identified eight systematic reviews or meta-analyses including randomised studies in which a nurse was involved in the primary care management of patients with a diagnosis of COPD or asthma.(6, 51),(61-66) Some studies were common to more than one meta-analysis. For example, a meta-analysis by Tsai included RCTs for asthma, depression, heart failure and diabetes, with the majority of the asthma RCTs previously considered for inclusion in the Gibson meta-analyses.(66) One RCT included in the Tsai meta-analysis and not considered in the Gibson meta-analyses provided additional information.(67)

A review by Vrijhoef, of the effects of quality of care when the specialised nurse has a central role included two RCTs involving asthma patients (also included in a Gibson meta-analysis) and 3 RCTs of patients with COPD (also included in the Monninkhof meta-analysis).(68) A review by Sudre, of education programmes for asthma, documented objectives, methods and content of patient education programmes prior to 1998.(69)

Twelve randomised trials, not included in the systematic reviews, were identified from the literature searches.(70-81) An RCT by Bourbeau was not considered as the study involved patients with severe COPD.(82)

Costing information was provided in the meta-analyses when documented in the included RCTs. Costs were also reported in five RCTs.(80,83-86) An evaluation of the cost of an asthma programme in Australia was performed by Pearce.(87)

Six reviews informing general practice asthma management provided additional information:

1. A review of asthma clinics in general practice.(55) One of the cited studies was included and another excluded from the Gibson meta-analysis for self-management education in asthma.

2. The Scottish Asthma Management Initiative, a programme to provide Scottish general practices with an opportunity to examine asthma management through audit, feedback and education.(88,89)

3. An evaluation of: UK NHS walk-in centres and NHS Direct.(90, 91)

4. A review of patient self-management of chronic disease in primary care.(50)

5. An evaluation of the role of self-treatment guidelines in self-management education for adult asthmatics.(92)

6. A review of the cost-effectiveness of asthma self-management.(93)

Non-randomised studies identified included:

- a Swedish before-and-after study(94)
- an audit of a nurse-led clinic for COPD(95)
- a qualitative study of the views of GPs, practice nurses and asthma on self-management(96)
- an evaluation of patients' perceptions of a self-management programme for COPD(97)

Two reviews of various aspects of education: a review of printed patient education interventions(98) and a review of individual versus group education(49) were considered. A project to evaluate specialist nurse' education of practice nurses in asthma management was conducted in the UK.(99)

Respiratory clinics for asthma or COPD

Systematic review

A Cochrane systematic review by Fay, to assess the effectiveness of primary care-based, nurse-run asthma clinics identified only one trial suitable for inclusion.(51) This South Australian RCT, conducted by Heard, studied the effects on asthma morbidity of general practice-based, respiratory nurse-led asthma clinics.(100) The clinics provided counselling, education, an asthma management plan, spirometry and a diary card plus a GP consultation. Eight general practices (42 GPs) included 191 adults and children with asthma. The severity of asthma was not described, but most (90%) patients had taken reliever medication and approximately 80% preventer medication, during the 6 months prior to trial commencement. Each patient was asked to attend 3 clinic sessions over a 6 month period.

After 6 months, asthma clinics were associated with a reduction in nocturnal symptoms, an increase in ownership of peak flow meters and an adverse effect of an increase in the number of patients commencing or resuming smoking. No differences between intervention and control groups were found for all other outcomes: time lost from work/school, provision of written action plans, rescue and preventer medication use, waking up in the morning due to asthma, hospital admission, emergency department visits, GP home visits and discussion of asthma triggers with the GP. However, both control and intervention groups demonstrated improvement in some outcomes over time (days lost from work/school, symptoms, use of an action plan, taking reliever medication). Asthma clinics were concluded to be not more effective than standard general practice in reducing asthma morbidity for this patient group. There was poor compliance with the intervention regimen with nearly one third of the intervention patients not attending 3 clinic visits (13% not attending any visits), which may have influenced the results. The study was subject to potential bias in that patients were randomised rather than practices so that a GP could provide health care to both intervention and control group patients.

Other studies

A review by Pilotto of asthma clinics in general practice(55) identified three UK studies in addition to the Charlton audit cited earlier and the Heard RCT, namely, a cross-sectional study,(101) a cohort study(102) and a before-and-after study.(103) The review concluded that nurse-run asthma clinics in primary care have not demonstrated a clear benefit over standard general practice care.(55) The authors stated that several unanswered questions remain:

1. Are there differences in outcomes for people with mild, moderate and severe asthma managed in an asthma clinic, by a GP, or under an asthma plan?

2. What is the ratio of cost to benefit for the models of care?

3. Are asthma clinics accepted by patients and GPs?

4. If asthma clinics produce positive changes for patients, how long do the changes last?

5. Will GPs provide the resources and time to establish asthma clinics?

Pilotto attempted to answer some of the questions posed in a more recent South Australian RCT.(70) Eleven general practices were randomised. The study included 170 adult asthma patients with 153 patients followed-up for 6 to 9 months. All patients had attended general practice because of asthma within the previous 9 months. A risk-screening questionnaire indicated that approximately one third of the participants had more severe asthma than the other two thirds. Patients initially received spirometry, a review, inhaler medication instruction, written educative materials, and smoking cessation advice if required. Patients from intervention practices attended respiratory nurse-run asthma clinics (3 clinics over 3 months, each clinic visit followed by a GP consultation, consistent with the Australian asthma 3+ plan).(104,105) Patients from control practices received usual GP care. Participants attending the asthma clinics did not demonstrate additional improvements in HRQoL or lung function compared to those receiving usual care. The intervention had no substantial impact on smoking cessation or the small number of patients (intervention n=8, control n=6) possessing a written action plan at the end of the study period. The number of outpatient attendances by the intervention group was greater than for the control group. Poor compliance with asthma clinic attendance was again demonstrated, with only 48% of the intervention patients attending all scheduled clinic visits.

A programme to support general practice asthma management in Australia involved the establishment of asthma clinics, run by an asthma educator, in an urban area of Victoria.(87) The asthma educator saw each patient three times over a 6 week period. The severity of asthma for the patients attending the clinics was not indicated but reimbursement for applying the asthma 3+ plan is only available for cases of moderate to severe asthma. The clinics were evaluated, in a survey conducted by Pearce, through questionnaire responses, completed by GPs and patients, to items on: quality of care, patient understanding, patient satisfaction and efficiency in asthma management. The clinics were well received by patients with all patients rating the clinics as at least helpful and GPs indicating that they thought patient understanding of disease improved; although no baseline assessment of patient knowledge prior to the intervention was available for comparison. The impact on health care utilisation, HRQoL, lung function and medication use was not discussed.

Overseas studies included a randomised trial conducted in primary care clinics in the US comparing outcomes for primarily Hispanic patients with asthma, diabetes or hypertension, assigned to nurse practitioner-led or physician-led management.(71) No differences in health status outcomes between nurse practitioner- or physician-led groups were reported after 6 months. The only data separately analysed for the asthma subgroup was mean peak expiratory flow (PEF), which was found to be not significantly different. Changes from baseline and asthma severity were not reported.

A Swedish survey compared the outcomes of patients recruited from 7 primary health care centres attending an asthma nurse practice clinic with those receiving traditional GP asthma care.(94) The asthma practice nurse booked her own appointments including regular follow-up visits, providing information about asthma prevention, inhalation techniques and medication, and performing spirometry and PEF measurements. A questionnaire on asthma symptoms, medication use, health status and HRQoL was distributed over 3 months to a random sample of 20 adult patients from each centre. The response rate was 82% in the asthma nurse practice group but only 53% in the GP group. Patient records were also audited for records of PEF, spirometry and reversibility testing. More patients in the asthma nurse group reported using peak flow meters, having a written action plan, having automatic asthma appointments and receiving knowledge about asthma. They also reported fewer asthma attacks, less nighttime wakening and less limitation in activity. No differences in HRQoL, or asthma medication use were detected. However, the study was limited and probably biased by the poor response rate of the standard care patients. It was unknown how many patients in the standard care group actually received the questionnaire, particularly in practices where no dedicated staff member was responsible for asthma care.

A recent review of the national asthma programme in Scotland through a telephone survey, conducted in 2002, indicated that the majority (93% of responding practices) ran an asthma service with 74% employing a trained asthma nurse to offer asthma review.(88, 89) Despite most practices having nurse-run asthma clinics, less than 40% provided patients with written action plans or had proactive care procedures for targeting patients most at risk.

Evaluations of UK NHS nurse-led walk-in centres and NHS Direct were completed in 2002.(90,91) Prescriptions for asthma medications were largely for inhalers. About a quarter (26%) of the consultations to walk-in centres and four fifths (82%) to NHS Direct resulted in referral, sometimes to Emergency Departments. Walk-in centres improved access for some patients, but attracted a more affluent population with relatively low levels of health need, than general practice. Users of walk-in centres were highly satisfied with their care. For a cohort of 1,000 patients the costs of a walk-in centre visit plus any referral onward were higher than those of general practice and appeared to generate additional demand for health services.

We could find no RCTs comparing nurse-run primary care clinics with usual standard care for mild to moderate COPD. An RCT comparing conventional care with a disease management programme for patients with moderate to severe COPD was implemented in primary care in NZ.(72) The programme included monthly clinic visits by the patient to the practice nurse to review goals and quarterly visits to the GP. Additional advice was provided by a specialist respiratory physician and a respiratory nurse to enhance intensive chronic disease management. Patients received an action plan and education on symptom management, smoking cessation, medication and the use of inhalers. The specialist respiratory nurse made at least one home visit to the patient. Conventionally treated patients visited their GP as required. All patients had access to a pulmonary rehabilitation programme. The disease management programme reduced hospital admissions and bed days. Important parts of the programme were considered to be patient participation and information sharing among health care providers. With such a multiple intervention strategy, it is difficult to evaluate which particular component of the programme was effective in improving outcomes and whether the programme

would be efficacious in patients with mild to moderate COPD with fewer respiratory symptoms and few hospital admissions.

A poorly analysed, retrospective pre-post audit of a nurse-run UK clinic for COPD has not been considered to provide evidence for this review.(95) Only 37.5% COPD patients attended the clinic, no demographic or disease specific information was provided and no statistical analysis performed, so no conclusions could be drawn as to the clinic's effectiveness.

Education and self-management in asthma and COPD

Self-management of a chronic condition involves patients making day-to-day decisions about their illnesses.(50) Behaviour changes have been measured by changes in health status and the use of health services. Two types of education, self-management interventions involving nurses in primary care can be identified:

1. Education of patients, tailored to individual patient needs, and providing knowledge to promote self-management or shared care partnerships.(49) Education and instruction on self-management for patients with asthma and COPD, can be provided as written, verbal, visual material or audio interventions and delivered to individual patients or groups by a nurse, pharmacist, health educator or medical practitioner.(61)

2. Education of practice nurses or GPs in primary care on chronic disease management, who, in turn, educate patients.

1a. Education and self-management in asthma

Many different asthma self-management models have been developed.(52) Examples include "credit card" versions, a brief credit card sized version of a management plan, or "traffic light systems" where zones of severity with appropriate patient responses are identified diagrammatically as traffic lights.(52) Studies of patient preferences have been performed in children or in moderate to severe disease rather than in mild to moderate disease.(106)

Meta-analyses

Three meta-analyses were identified:

- a meta-analysis by Weingarten, of interventions used in disease management programmes, included 9 asthma studies, 7 of which were also included in the following Gibson meta-analyses(6)
- a meta-analysis by Gibson of 12 trials where health outcomes were studied after the provision of asthma information and compared with usual care(61)
- a meta-analysis by Gibson of 36 trials where health outcomes after education on self-management was combined with regular practitioner review and an action plan and compared to usual care(62)

A variety of interventions were evaluated in the included trials from – hospital-based clinics to general practice-based interventions. Education and self-management interventions included education plus self-monitoring and recording of symptoms in a diary, review by a doctor and/or a written action plan. The number of education sessions and the time period over which the sessions were conducted varied between trials from one 1 hour session, to three 3 hour sessions, to seven 90 minute sessions over 7 weeks. Included patients often had moderate to severe asthma. It was concluded that the use of limited asthma education did not improve health outcomes in

adults with asthma although perceived symptoms appeared to improve.(61) Education in asthma self-management coupled with regular medical review and a written action plan in adult asthmatics improved HRQoL and reduced hospitalisations, emergency room visits, unscheduled visits to the doctor, days off work or school, and nocturnal asthma. Lung function remained unchanged.(6,62)

Although the systematic review by Gibson supported education and self-management with regular medical review and a written action plan for asthma the relevance of this intervention to primary care has been questioned.(107) The included trials were heterogeneous, recruiting patients from hospital clinics after inpatient or emergency room attendance, from general practice, and from advertisements in newspapers and on radio, which may have resulted in selection bias. Many trials had extensive exclusion criteria, at least 5 trials excluded smokers, 4 trials randomised less than 50 subjects, and loss to follow-up was over 40% in five studies. The reduction in hospital attendance seen may have been partly balanced by patients attending asthma clinics. Several studies provided free medical treatment during the trials, but self-management plans may have less impact when patients have to purchase their own drugs.(107) Follow-up during the studies was short (maximum 12 months).

Reviews

Two reviews by Bodenheimer and van der Palen of self-management for adult asthmatics were identified.(50),(92) The review by Bodenheimer included studies of asthma, diabetes and arthritis with asthma studies common to the Gibson and van der Palen reviews. Of 27 studies of adult asthma, 12 measured clinical outcomes, 11 evaluated outcomes and health care costs, and 4 measured costs alone. Eleven of the 23 studies measuring clinical outcomes demonstrated asthma symptom improvement, although only one study reported improvement in lung function. Self-management action plans appeared to be an important component to produce an improvement in health outcomes. Self-management interventions were less effective in mild to moderate disease compared with severe disease. Long-term improvements were measured in one study only (after 5 years) and were only partially maintained. Of the 15 studies measuring cost outcomes, eight found reduced hospital or emergency department visits while seven failed to demonstrate cost savings. Several conclusions were reached by the authors concerning limitations of self-management in chronic disease:

- it is unknown how long benefits are maintained over time
- studies of self-management using volunteers and highly selected patient groups as research subjects may be inapplicable to the general population
- the essential criteria which determine the success of self-management education remain to be determined

The review by Van der Palen evaluated 15 studies for evidence to support self-management guidelines for asthma.(92) Seven studies were randomised. The studies were not double-blinded and only two were placebo controlled. Selective sampling of participants was common. The review concluded that evidence for the efficacy of guidelines to guide self-management behaviour was far from complete. The two placebo controlled studies showed only little or no effect of self-treatment guidelines.

Randomised controlled trials

Randomised controlled studies not included in the Cochrane reviews have provided evidence for some improved outcomes from education and self-management interventions for patients with asthma. An RCT to assess the effects of individual self-management education on clinical, biological, and adherence outcomes in mild to moderate asthma, conducted in the UK, found that education and training in self-management improved adherence with inhaled therapy and perceived control of asthma.(73) An advanced practice nurse conducted the asthma self-management intervention, a 30 minute, individual session reinforced at the first 2 of 5 biweekly visits over 7 weeks. Compared with the control group, the intervention group had improvements in adherence to inhaled corticosteroid therapy (30% versus −5%, p=0.01) and self-reported control of asthma (14% versus 5%, p=0.04), with a possible improvement in HRQoL (37% versus 21%, p=0.06). There was no change in symptom severity, lung function or morning PEF during the study.

A randomised multi-centre study performed in France compared the outcomes of a population of adult asthma patients attending an educational programme (10 hours over 1 year) with a control population.(74) The severity of asthma was not indicated and the study was not blinded. The self-management programme included an individual assessment of the patient's needs plus two group educational sessions conducted by trained physicians, nurses and physiotherapists. The primary goal was to evaluate, over a period of 1 year, the benefit of the programme in terms of compliance with treatment, health-related HRQoL, psychological and behavioural measures. Symptoms and HRQoL scores improved over time in the 'educated' group; use of asthma medications decreased to a greater extent in this group.

In the Netherlands, the effect of education and self-management in patients with asthma was studied in an RCT, although education was performed by the GP rather than a practice nurse.(67) Nineteen general practices were randomly allocated to usual care (n=104 patients) or to a self-management programme (n=110 patients). All patients were pre-treated to obtain optimal disease control before trial commencement. Smokers with a smoking history of 15 or more pack years were excluded. Self-management training including education and instruction on the use of an action plan, occurred during four individual training visits at the GPs surgery over 3 months. Follow-up consisted of biannual visits over 21 months. Patients recorded PEF and asthma symptoms weekly and were instructed how to self-manage their disease in response to alarm symptoms or fall in PEF readings. Outcomes included the percentage of successfully treated weeks defined by acceptable asthma control in terms of perceived dyspnoea. Self-managed patients recorded a greater number of successfully treated weeks than usual care (78% versus 72%). The number of oral steroid courses was greater in the self-management group, possibly due to over-treatment or over-registration of prescriptions by GPs. There was a significant improvement in the emotions domain of HRQoL for the self-managed group. No difference between usual care and self-managed care over 2 years was reported for the mean number of exacerbations, courses of antibiotics and other domains of HRQoL.

Only one study considered long-term follow-up, following patients for up to 5 years. Maximum follow-up in the other RCTs of self-management for asthma was 2 years. What improvements persist over longer time periods and whether patients would accept additional education and self-management plans is not well established. One study attempted to assess patients' thoughts of self-management plans.(74) They

appeared to be well accepted as a means of communication, although the number of patients with this perception was not indicated.

Other studies

A qualitative study of the views of GPs, practice nurses and consumers on guided self-management plans for asthma from South Wales, revealed that most of the health professionals surveyed opposed their use and most patients felt the plans irrelevant.(96) Nurses considered patient education and ongoing monitoring important but only provided self-management plans to patients with well-controlled asthma and not to patients with newly diagnosed asthma or patients not undergoing regular review. Nurses were concerned that patients would self-manage and not return for review for monitoring of inhaler technique and medication use. Nurses considered that information should be individualised rather than standardised or hospital clinic generated. Patients considered self-management plans irrelevant and thought the recording and monitoring of asthma symptoms unnecessary. They considered practice nurses would provide crisis care if required.

Education and self-management in COPD

Evidence of the effectiveness of education and self-management for COPD patients was provided mainly by meta-analyses and RCTs. Education could be conducted by nurses, respiratory health workers, physiotherapists, pharmacists and psychologists. The studies were conducted almost exclusively in patients with moderate to severe disease with little information available relating to mild disease, where possible intervention could potentially have maximal impact in producing life-style change moderating disease progression.

Meta-analyses

Four meta-analyses were identified.(6),(63-65) The Weingarten meta-analysis included studies of patients with moderate to severe COPD which were primarily based in a hospital setting and hence outside of the scope for this review.(6) Most programmes studied an intervention of education combined with pulmonary rehabilitation. The pooled effect size for programmes with patient education or patient reminders indicated the COPD programmes had no significant effect on disease control.

Severity of COPD was moderate to severe. The meta-analysis is mentioned as subgroups based on disease severity were analysed separately. Overall, mortality was not significantly reduced A Cochrane meta-analysis by Monninkhof, of self-management education, included eight RCTs and one controlled trial.(63) The trials also included patients predominantly with moderate to severe disease with only 1 trial stating that patients with mild disease were randomised. Education consisted of group education (4 studies), individual education (4 studies) and written material (1 study) with total duration of the intervention from less than 1 hour to 26 hours. Follow-up varied from 6 to 12 months. The studies showed no effect of self-management education on hospital admissions, emergency department visits, days lost from work and lung function, with inconclusive results for HRQoL. Self-management education reduced the need for rescue medication and led to an increase in the use of steroids and antibiotics. Due to insufficient data, the authors could make no recommendations regarding the intervention.

Education, support and home care provided by practice nurses or specialist respiratory nurses during home visits for patients with COPD were reviewed in a Cochrane meta-analysis by Smith.(64) The Cochrane review included 4 RCTs, 2 of which were common to the Monninkhof systematic review.(64) by home visits, although subgroup analysis suggested that patients with moderate COPD might have improvements in mortality

and HRQoL from a nursing outreach programme, which was not evident in severe disease. Outreach nursing was associated with an increase in costs. No reduction in hospital admissions or changes in lung function or exercise performance were reported.

A systematic review by Taylor, of nurse-led chronic disease management in COPD, included 4 RCTs reviewed in the Smith meta-analysis plus 5 additional RCTs.(65) The interventions were either brief (1 month) or longer term (approximately 1 year) for patients also with predominantly moderate to severe COPD. The interventions involved case-management and included home visits by a nurse or trained respiratory health worker for education and support often after a hospital admission; or a disease specific self-management programme delivered by a trained professional, usually a nurse. Based on 9 RCTs, the review found that interventions aimed at improving the management of chronic COPD did not improve outcomes such as HRQoL, psychological wellbeing, impairment and disability, number of exacerbations, pulmonary function, mortality, number of outpatient visits, unscheduled readmissions or patients' symptoms.(108) Patient's knowledge of COPD may have increased after the nurse-led interventions and the number of emergency room visits could be reduced by long-term interventions. It was concluded there was little evidence to support the widespread adoption of chronic disease management by respiratory nurses, including case management for COPD patients.

Reviews

Only one review of self-management interventions in COPD was identified and this included trials in advanced COPD.(109) Effects of self-management on the use of health resources were equivocal.

Randomised controlled trials

Randomised controlled trials not included in the meta-analyses mainly included patients with moderate to severe COPD. Only 2 studies evaluated outcomes in patients with mild to moderate COPD. Both of these studies also included patients with asthma.(75,76)

The effectiveness of an education programme by a practice assistant for patients with mild to moderate asthma or COPD and experiencing symptoms was examined in an RCT conducted in the Netherlands.(75) The intervention, consisting of from 1 to 4 semi-structured consultations with the GP assistant, each lasting 30 minutes, over a period of 1 year was compared to usual care. After 1 and 2 years of follow-up, inhalation technique was significantly improved in the intervention group. However, no differences were observed in the other outcomes of: HRQoL, compliance, smoking cessation, self-efficacy or coping. Subgroup analysis by diagnosis and gender also was unable to detect differences between intervention and control groups.

A German study reported a reduction in exacerbations and improved symptom monitoring over 6 months in an educated (4 x 2 hour sessions) group of patients (N=192) with mild to moderate COPD or asthma compared to a control group.(76) However, the effects were more pronounced among the asthma group. The methodology was poorly described with few details provided, so the study was rated as having a low quality. An earlier report of the study was not available in English. There was no difference in medication use between treated and control groups for COPD patients and only borderline differences in the number of exacerbations and symptom monitoring. Peak flow monitoring was significantly greater for the educated group ($p=0.002$).

Two other RCTs were identified but all included patients with moderate or severe COPD. They are noted, as they were primary care-based and due to the lack of studies in mild COPD.

An RCT of COPD patients cared for by primary care physicians in the US included 151 patients (83.5% with moderate COPD based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria(18),(110) and the remainder with severe COPD.(77) The patients were randomly assigned to usual care, nurse-assisted medical management or nurse-assisted collaborative management. Four nurses underwent 8 hours of training in management based on the GOLD guidelines. Those involved in collaborative management received an additional 8 hours of training including healthy behaviour, lifestyle and self-management education. The nurse-led interventions did not result in improvements in health status or health care utilisation when compared with usual care over 6 months.

An RCT by Monninkhof, studying the effects of a comprehensive self-management programme in patients with COPD, has been noted as it was a combination hospital-based - primary care-based programme in stable patients.(78) The patients had moderate to severe COPD characterised by a mean forced expiratory volume in 1 second (FEV_1) of 57% of the predicted value and 65% of patients using inhaled corticosteroids although they were reported as "fairly well stabilised". The self-management intervention consisted of a skill-oriented patient education programme conducted by a respiratory nurse (five 2 hour group sessions over 4 months plus written handouts on self-treatment) and a near-home fitness programme (weekly visits) conducted by a physiotherapist. The control group received usual care. No differences in HRQoL, symptom scores or walking distances between the two groups were detected after 1 year.

A qualitative study of the views of 20 randomly selected patients (10 males, 10 females) included in the Monninkhof study described above was performed by interviewing patients at home.(97) Patients highlighted the fitness programme as an important aspect of the self-management programme. Most patients reported that they evaluated exacerbations by adjustment of medications. Patients felt safe during the programme due to the frequent follow-up and 24 hour access to hospital.

2. Nurses as educators of other health professionals

The role of respiratory nurses as educators in primary care, educating GPs and practice nurses in asthma management was studied in an RCT of 44 East London general practices (N=319 asthma patients) from a deprived multi-ethnic area.(79) The study combined the education of patients after discharge with educational outreach and clinical support for GPs. The general practices were randomised to an intervention group, which received 2 visits from a specialist nurse to discuss guidelines and prompts for patient review, or to a control group. Patients with doctor diagnosed asthma, who had required Emergency Department or GP out of hours attendance for acute asthma in the previous 2 years were included in the study. Patients from intervention general practices attended a nurse-run clinic for discussion of asthma self-management and provision of a written management plan, a peak flow meter and rescue medication. The control group of general practices received a single visit from the respiratory nurse to discuss standard guidelines for asthma. The intervention delayed the time to the first attendance with acute asthma and reduced the number of patients attending with acute asthma. No differences were detected in self-management behaviour, HRQoL,

asthma symptoms, or rescue medications after 2 or 12 months of follow-up. Minority ethnic groups appeared to derive less benefit from the intervention.

Converse findings were reported in a study surveying 41 UK general practices, evaluating the effect of nurse educators educating practice nurses who subsequently educated patients with mild asthma.(99) Nurse specialists conducted six teaching sessions on asthma care for all practice nurses in the intervention practices. The nurse specialists also visited the practices, assisting in patient management. Two cross-sectional surveys of practice patients with asthma, conducted at baseline and after 3 years of the intervention, reported that the practice nurse education model of care was ineffective in improving patients' asthma outcomes of HRQoL, emergency department attendance or hospital admissions.

Approach to education

Individual or group approaches to patient education in both asthma and COPD, the training received by the instructors, the total course duration, the structure of the programme, the aids and instruments used and the objectives of the programme require evaluation and comparison. A systematic review of the objectives, methods and content of patient education programmes for adults with asthma attempted to identify the most effective components of the programme.(69) The review included reports of education programmes for asthma published between 1979 and 1998. Seventy seven projects including 94 interventions involving 7,953 patients were analysed. In 56% and 60% respectively, of the identified reports, the general and educational objectives of the education intervention were not stated. Other outcomes of interest such as: duration of education, number of sessions, who delivered education, whether training was conducted in groups or was individualised were described in less than half the reports. Where these outcomes were described, great variation between studies existed, for example, training duration ranged from 0 (self-education) to 58 hours, the number of sessions from 0 to 36, training tools such as peak flow meters, diary cards or books varied with the intervention. The authors concluded that excessive variability in education programmes reduced the possibility of identifying the most effective components.

A review of individual versus group education concluded that both formats could improve patients outcomes, but that it was not possible to determine which was more effective due to the wide variation in effectiveness among individual programmes.(49)

A review of printed patient education material(98) identified 1 RCT involving asthma patients.(111) This study compared the effects of an audio-taped asthma education programme, an asthma education brochure and a combination of both, with standard provider education on asthma medication adherence for 44 adult asthmatic patients. Standard education was not described. The study methodology was poorly documented. Adherence to medication improved slightly (from 15 to 19%) in the three intervention groups between baseline and 6 months and decreased by 22% in the control group. No differences were reported for the outcomes of asthma control, HRQoL and asthma self-efficacy. Subgroup analysis demonstrated a negative response to audio-taped sessions by male patients. The study was severely limited by the poor documentation and small numbers of included patients.

Research Question 3. Funding/costs

How are practice nurses funded for the management of mild or moderate asthma and COPD and is their management cost-effective?

Practice nurse funding, costs to general practices and cost-effectiveness

Practice nurse funding

Since 2001, the Australian federal government has promoted the role of practice nurses through the introduction of the Practice Incentives Programme (PIP) - Practice Nurse Payment to selected general practices. The payment targets areas where patient access to medical services is limited by workforce shortages or by the practice being in a rural or remote region.(44) New Medicare rebates can also be accessed for some services provided by practice nurses. These are known as enhanced primary care (EPC) health assessments, where nurses assist GPs in chronic disease management.(44) However, restrictions apply: Asthma Incentive Payments only apply to patients with moderate to severe asthma.

An alternative model of primary care funding is provided in the UK.(112) The new system aims to improve the salary structure for practice staff and to recognise and promote staff knowledge and skills. A job weighting is applied according to knowledge, skills, physical, mental or emotional effort in performance of the job and any extra demands imposed by the working environment. Pay progression is linked to the demonstration of continuing professional development.

Costs to general practices

It is important to identify the costs to general practices of introducing practice nurse-led disease management programmes, and whether these costs outweigh the potential savings in health care utilisation and productivity.(86)

A recent Australian study of GPs' views on providing health care for people with chronic illness reported that many GPs, particularly those in solo practices, felt they could not afford to employ a practice nurse despite the incentive rebates listed above or even by sharing a nurse between practices.(54) In addition, the complexity of the incentives, the paperwork involved and the changes to criteria have acted as disincentives for many GPs.(54)

The Pearce evaluation of external asthma educator-run clinics, where the income was generated through MBS Item Numbers, reported that the costs incurred by the practices were met and exceeded.(87) However, the Division of General Practice offered a subsidy of 50% of the cost of the programme and was essential in providing financial and administrative support. The programme was claimed to be cost-neutral for the Division.

Cost-effectiveness of a practice nurse

There is little information about the cost-effectiveness of a practice nurse in the care of adults with mild to moderate asthma or COPD in primary care. Most RCTs did not attempt costing or cost-effectiveness evaluations.

Meta-analyses

Fay(51)

No costing data were reported in the single trial included in this meta-analysis

Gibson (a)(61)
The costs of limited patient education programmes included in the meta-analysis were measured in two of the included studies. Both studies were conducted in secondary care facilities and one demonstrated cost savings

Gibson (b)(62)
Two studies contributed cost information to the meta-analysis of self-management education in asthma. Overall, the review concluded that a self-management intervention led to a significant reduction in indirect costs (standardised mean difference (SMD) –0.1; 95% confidence interval (CI) –0.69 to –0.11), but increased direct costs (SMD 0.39; 95%CI 0.10 to 0.68). Total costs were not significantly different. Both studies were conducted in outpatient clinics.

Smith (64)
Hospital service utilisation could not be analysed due to missing data. It was concluded that the home-based intervention incurred substantially higher health care costs than standard outpatient care for COPD, without measurable health care gains for the patient.

Taylor(65)
A cost-effectiveness analysis was not performed but no improvement in HRQoL was detected and the evidence for a reduction in hospital admissions, days spent in hospital and the number of visits to the GP were equivocal.

Randomised controlled trials

Gallefoss(83)
The Gallefoss RCT reported the results of a subset of COPD patients from an earlier study included in the Gibson meta-analysis for self-management education in asthma. The RCT, however, analysed data from both asthmatics and patients with COPD, since 32% of the patients demonstrated 20% reversibility in FEV_1 after inhalation of bronchodilator, the education intervention was described as "asthma education" and the costs of hospital care for asthma and anti-asthmatic medications were included in the analysis. The authors concluded that patient education over the 12 month follow-up improved patient outcomes and reduced costs.

Kauppinen(84)
The cost-effectiveness of a conventional versus an intensive education self-management programme for mild asthma was evaluated in Finland. At baseline, all patients received education in guided self-management. Ongoing education was provided for the intervention group every 3 months for a period of 1 year. Health-related quality of life improved for both groups. The intervention produced a significant improvement in FEV_1, but this was associated with an increase in costs of FIM 406 (AU$114) per patient. The authors concluded that the intervention was not superior to usual care.

Monninkhof(80)
A cost minimisation analysis was conducted during the Monninkhof RCT. The self-management programme was calculated to be almost twice as expensive as usual care for patients with moderate to severe COPD, incremental cost difference = €838 (AU$1440) in favour of usual care with an incremental cost difference of €179 (AU$308) per person per year, yet produced no discernable difference in HRQoL, symptom scores or walking distance.

Pinnock(85)
The cost-effectiveness of telephone or face-to-face asthma reviews, conducted in general practice in the UK, for adults who had recently been prescribed a bronchodilator was studied by Pinnock. Telephone reviews were significantly shorter (mean duration (SD) 11.19 (4.79) minutes versus surgery reviews 21.87 (6.85) minutes). Total health care costs over 3 months per patient were similar. Mean cost per consultation was lower in the telephone group (mean cost (SD) telephone consultation £7.19 (£2.49) versus surgery £11.11 (£3.5)). Morbidity and HRQoL at 3 months were similar for the two groups. The authors concluded that telephone consultations enabled more patients to be reviewed at no additional cost.

Schermer(86)
A randomised controlled economic evaluation compared guided asthma self-management conducted by a GP with usual asthma care for 193 adults with stable asthma (98 self-management, 95 usual care).(86) Nineteen family practices in the Netherlands were randomised. Self-managed patients gained 0.039 quality-adjusted life years (QALY) (95% CI, 0.003 to 0.075) over 2 years follow-up compared with usual care; 0.024 QALY (95% CI, -0.022 to 0.071). However, baseline HRQoL scores were higher in usual care patients, possibly leaving less room for improvement in this group. Differences in HRQoL scores at baseline gradually disappeared during follow-up, which may indicate that HRQoL was maximised in both groups. Self-managed patients experienced 81 (95% CI, 78 to 84) successfully treated weeks over 2 years compared with 75 (95% CI, 72 to 78) successfully treated weeks for the usual care group. No differences in total costs between groups were calculated. Cost substitution occurred with the self-managed patients consuming less respiratory medication than usual care patients but spending more on allergen avoidance measures. The major cost difference between self-management and usual care arose due to the time spent by family physicians to educate and train asthma patients.

Other studies

The review of asthma clinics in general practice by Pilotto identified seven economic evaluations of asthma self-management programmes including the Kauppinen evaluation cited above.(55) Three studies included only paediatric patients. The remaining three studies reported that the self-management intervention was cost-effective when indirect costs were included.

A narrative review of the cost-effectiveness of self-management education in asthma discussed clinical studies in adults and children performed prior to 1997.(93) It was reported that the studies had several flaws, often poorly covering: costs associated with asthma self-management, dropouts, and study length with a variety of cost-effectiveness variables used. However, it was concluded that asthma self-management was cost-effective compared with usual care with education directed at patients with moderate to severe asthma, the most costly health-resource users, providing the largest savings to society.(93) No attempt was made to synthesise the studies into a meta-analysis.

The impact of adult asthma self-management education on health service use was discussed in the Bodenheimer review.(50) Eight studies reported reduced hospital or emergency department use, while 7 studies were unable to demonstrate cost savings. Most studies demonstrating cost savings included an asthma management plan.

Other studies have described lower productivity costs due to self-management, but comparing studies was difficult due to variations in study design, differences in disease severity, cost and outcomes estimation and the different countries of origin.(55),(86)

Research question 4. Service delivery

What are the barriers, enhancing factors and disadvantages of employing practice nurses to assist in the management of mild to moderate asthma and COPD, and are practice nurses trained to fulfil their role?

Several questions can be considered in relation to practice nurses and with regard to service delivery for mild to moderate asthma or COPD:

1. How do GPs view the role of the practice nurse?
2. Can practice nurses reduce the GP burden of chronic disease management?
3. How does the practice nurse view his/her role with regard to training?
4. What is the patient's view?
5. What barriers to the development of the practice nurse' role can be identified?
6. What factors enhance the role of the practice nurse?
7. What are the advantages of employing a practice nurse for the management of mild to moderate asthma and COPD?

1. How do GPs view the role of the practice nurse?
Focus groups provided some insight into the perceptions of GPs.(54) Some GPs considered chronic disease management to be complicated, time consuming and costly, with telephone discussions unpaid and home visits uneconomical. Others considered chronic care rewarding due to additional time spent with patients. However, despite these differing views, GPs considered themselves to be care coordinators and patient advocates, with practice nurses providing assistance rather than being leaders of chronic care management.

2. Do practice nurses' impact on the general practitioner's burden of disease management for asthma or COPD?
Much of the literature focused on the role of the practice nurse to save GP time rather than on how they can enrich patient services.(40) We identified 2 studies evaluating the effect of a practice nurse on GP workload for the treatment of mild to moderate asthma or COPD.

A 12 month before-and-after audit of the effect of a nurse-run asthma clinic on practice workload and patient morbidity reported that GP consultations fell by approximately one half (818 to 414) after the implementation of the clinic. However, this was offset by the 496 nurse consultations during the 12 months study duration.(57)

The effect on GPs' workloads, of adding a trained practice nurse (nurse practitioner) to the general practice, was evaluated in an RCT performed in the Netherlands.(81) The

nurses performed diagnostic tests, assessed social factors, educated patients and coordinated care with other health care professionals or community services. The control group did not receive nurse-led care. Target patients included those with asthma or COPD. The study found the workload of GPs increased, at least in the short-term, by the addition of a trained nurse practitioner as some patients had previously unrecognised problems that required the GPs attention. The nurses provided additional care rather than substitute GP care. Other studies in different disease groups have reported conflicting results, with some reporting reductions in GP workloads and others no effect.(81)

3. How does the practice nurse view his/her role with regard to training?

An Australian review of general practice nursing, reported that the practice nurse is usually a part-time registered nurse who has little post-basic formal education, which is unlikely to be general practice specific. The review indicated that practice nurses fulfil diverse roles varying according to nurse abilities and interests and the practice's patient population.(113)

A postal questionnaire, distributed to 187 practice nurses (92% practices) in a UK local area in 1994, documented nurses' perception of their role in the management of patients with asthma.(48) Nurses without advanced asthma qualifications did not feel fully confident in their responsibility for asthma patient management.

4. What is the patient's view?

Focus groups have provided consumer perceptions of the role of the practice nurse.(40) A key message expressed by consumers was that expansion of the practice nurse role must not jeopardise individual patient choice in seeking primary health care through their GP, or result in increased costs to the consumer. Twelve focus groups conducted in New South Wales and South Australia (76 consumers with a chronic illness) exploring patient perceptions about the quality of general practice care indicated that they considered practice nurses important for providing information and undertaking some clinical care.(114) However, patients emphasised the importance of their GP as their main health care provider and care coordinator.

5. What barriers to the development of the practice nurse' role can be identified?

A number of barriers and issues have been identified by nurses and GPs affecting the practice nurse role. Although not specifically related to mild to moderate respiratory disease, nevertheless, these issues are still pertinent. Two Australian reviews, a review of nursing in Australian general practice(40) and a review of developments in primary health care integration,(115) identified extensive barriers and enhancing factors covering organisational (health system), legal, financial, social, professional, knowledge and education, workforce and public issues to the development of the practice nurse role including:

- deficiencies in skills and training
- role clarification; where practice nurses are involved in both clinical and non-clinical activities, non-clinical activities such as educating patients or self-management training may take lower priority
- legal implications and risk management
- reimbursement; organisational support issues
- team-work issues; GPs may not have clear understanding how the employment of practice nurses translates into economic efficiencies
- professional recognition

- shortage of qualified practice nurses

Barriers to the development of the nurse practitioner role in primary care were explored in focus groups of GPs conducted in the UK.(116) Significant concerns were raised by the GPs in relation to the nurse practitioner role in general practice

- threats to GP status, job and financial security
- nursing capabilities, including training and scope of responsibility
- structural and organisation barriers, including the inability of nurses to independently prescribe medications

Factors identified as enhancing the role of practice nurses include:(40)

- the shift from secondary towards primary care
- group practices
- funding for health priority areas
- government initiatives
- shortage of GPs
- employment conditions
- consumer needs

Key findings and implications for policy makers

1. Current studies have not demonstrated a clear benefit of nurse-run asthma clinics in primary care, compared to usual care, in altering asthma morbidity, HRQoL, lung function, medication use or increasing smoking cessation.

2. Anecdotal evidence suggests that patients attending asthma clinics may have increased ownership of peak flow meters.

3. Patients demonstrate poor compliance with asthma clinic appointments.

4. There is an absence of evidence to determine the effectiveness of nurse-run clinics for patients with mild to moderate COPD.

5. Practice nurses may not be adequately trained to provide respiratory care.

6. Practice nurses provided additional rather than substitute GP care.

7. Patients view their GP as their main health care provider.

8. Self-management education, accompanied by regular medical review and an action plan, may produce short-term benefits to asthma patients but these interventions are unlikely to alter lung function.

9. The evidence for improved outcomes with self-management education or nurse-led chronic disease management in COPD is equivocal. The studies predominantly included patients with moderate to severe disease. The results from the two studies supporting an improvement in outcomes included asthma patients, which could have confounded the results.

10. Nurse-led interventions are likely to be associated with increased costs and increased referral to other health care providers.

11. Many constraints and barriers to the development of the practice nurse role have been identified.

3. CLINICAL PRACTICE GUIDELINES

Since the late 1980's many disease management clinical practice guidelines, protocols, statements, position papers, and "best practices" have been developed and published.(117) A clinical practice guideline refers to "a systematically developed statement to assist practitioners' decisions about appropriate health care for specific clinical circumstances."(118) Disease management guidelines provide a tool to communicate what is considered best practice to health care providers to promote optimal management, reduce variation in clinician performance and improve patient outcomes.(119, 120)

Clinical guidelines should be based on high quality evidence.(119) However, as evidence is often lacking, consensus statements are commonly used.(118) It has been estimated that less than 50% of recommendations in guidelines are evidence-based.(121) Thus, clinical guidelines may not always reflect current medical knowledge and may be liable to bias by the views of the developers.(122)

Research question 1. Organisation

What is the evidence base to support clinical guidelines for the diagnosis and management of mild to moderate asthma and COPD?

Guidelines for the management of asthma and COPD have been developed by the Thoracic or Respiratory Societies of many countries, with international guidelines being available since 2001.(123) Many can be accessed electronically.(124) Clinical guidelines have predominantly been developed for moderate to severe asthma and COPD with often only brief reference to primary care,(16,18,125) but recently, evidence-based guidelines have been written for the primary care diagnosis and management of chronic respiratory disease.(126-128)

The literature searches identified the following major clinical guidelines and Australian guidelines containing specific reference to primary care:

- three national guidelines with reference to primary care for the diagnosis and management of stable COPD: the GOLD guideline, the UK National Institute for Clinical Excellence guideline and the Finnish Medical Society Duodecim guideline.(18,110,125,129) A synthesis of these guidelines is provided by the National Guideline Clearing House.(130) The Finnish Medical Society Duodecim have also developed a guideline for the long-term management of asthma(131)

- a combined American Thoracic Society (ATS), European Thoracic society guideline for COPD, based on the GOLD guideline with additional recommendations in relation to specific aspects of disease management(132)

- a guideline developed by the Institute for Clinical Systems Improvement (ICSI) US, for COPD, with specific reference to family practice(133)

- the Australian COPDX plan. A GP management hand-book, a GP friendly algorithm, and a COPD action plan have more recently been developed.(134)

- the International Primary Care Respiratory Group (IPCRG) guideline for the diagnosis of respiratory disease in primary care(126)
- the IPCRG guideline for the management of COPD in primary care adapted from the GOLD guideline(127)
- the IPCRG guideline for the management of asthma in primary care, an adaptation of the Global Initiative for Asthma (GINA) guidelines(128)
- an ICSI guideline for the diagnosis and outpatient management of asthma(135)
- a New South Wales action plan for health, providing a practical guide and standards for the treatment of chronic respiratory disease, including asthma and COPD, with specific reference to general practice(136)
- the National Asthma Council, Australia, Asthma Management Handbook which includes a description of the Australian Asthma 3+ Plan for the management of moderate to severe asthma in general practice.(105) A qualitative evaluation of this plan was recently performed.(137)
- a New Zealand guideline for the diagnosis and treatment of adult asthma(138)
- a North England guideline on the primary care management of asthma (139)
- the Scottish Intercollegiate Guidelines Network (SIGN) guideline for the management of asthma(140)
- a British guideline for the prevention, identification and management of occupational asthma: evidence review and recommendations(141)

A comparison of major guidelines and Australian guidelines according to criteria from the US National Guideline Clearing House is given in Appendix 4.

The guidelines, other than the recent IPCRG guidelines, were predominantly highly complex documents, providing guidance over several domains, most with clinical algorithms to guide decision-making. Domains covered included: definition and classification of disease severity, assessment, diagnosis and monitoring of disease and disease management. Components of disease management consisted of treatments, symptom relief, prevention and management of exacerbations and complications, patient education, smoking cessation, multidisciplinary care plans (COPDX), patient self-management and action plans.

Research question 2. Implementation and Evaluation

What is the evidence that clinical guidelines for mild to moderate asthma and COPD have been implemented and evaluated and have influenced clinical outcomes?

Implementation and evaluation

Implementation

Dissemination and implementation is essential if guidelines are to be useful; and evaluation of guideline impact on medical practice is required to determine the effect

of implementation on disease management or the need for update of the guideline.(118). As an example, asthma guidelines have been written with the aim of improving asthma management to ensure that the patient is symptom free, with normal physical activity, normalised lung function, exacerbations kept to a minimum and mortality reduced or abolished.(142) A recent study of asthma deaths in UK reported that routine asthma care did not follow guideline recommendations in two thirds of the patients who died from asthma.(143)

Poor implementation of guidelines in primary care may be due to the perception that current guidelines are too complex, focused on secondary and tertiary care and so irrelevant to the primary care setting.(124),(144) For guidelines to be implemented in primary care, the evidence provided must be relevant and clear about the applications and the limitations of their recommendations.(145)

General practitioners' require evidence for patients that cover a range of diagnostic, prognostic and interventional issues broader than those of patients included in the RCTs on which many guidelines have been based.(145) The complexity of many current guidelines highlights the advantage of the recent IPCRG clinical guidelines developed by GPs for the primary care setting. The IPCRG guideline for diagnosing respiratory disease, bases the early identification and diagnosis of respiratory disease on the symptoms likely to be encountered by GPs in primary care rather than on spirometry which is not always available.(126) Dissemination and implementation of the IPCRG guidelines was proposed during guideline development, and has involved widespread distribution of the guidelines and the development of education programmes, monitoring and feedback.

Various strategies have been used to implement guidelines.(146) Many involve the use of a combination of educational materials, conferences or group education and reminders, with multiple methods more likely to be successful.(147) Although implementation strategies were not always planned during guideline formulation, many have since been developed. For example, a desktop tool for asthma was developed by the South Australian York Peninsula Division of General Practice (YPDGP) in collaboration with the Discipline of General Practice, The University of Adelaide, after factors leading to emergency asthma care were identified.(148) The tool combined evidence-based asthma guidelines with a patient education resource and has been provided to all general practices, hospitals and pharmacies within the YDPGP region.

A systematic assessment of clinical practice guidelines for the management of COPD identified several problems with implementing respiratory guidelines in primary care:(149)

- the guidelines focused strictly on COPD and asthma with little reference to comorbidities
- efforts at dissemination and implementation were poor for some of the guidelines (some guidelines did not have an implementation strategy included in their development)
- guideline development was often sponsored by multiple pharmaceutical companies, with ethical implications and potential conflicts of interest not always stated
- costing and cost-effectiveness information were not available for all guidelines

- guidelines were only partly multi-disciplinary, often with little consumer input
- it was not always clear if GPs were consulted or included in guideline development, for example, the GOLD guidelines listed a large number of organisations and participants but were not explicit asto whether GPs were included
- discrepancies between guidelines were apparent. A comparison of the Finnish, GOLD and NICE guidelines for COPD demonstrated differences in the approach to medical history taking and physical examination.(130) Although all three guidelines based the classification of disease severity on the results of spirometry, the guidelines differed in the stages of disease severity proposed and their indications for reversibility testing. A recent cross-sectional study comparing severity gradings of COPD patients according to the Australian COPDX plan and the GOLD guideline demonstrated differences resulting in underestimates of the severity of HRQoL and in exercise performance for some patients, with the Australian guideline.(150)
- evidence ratings varied between guidelines and all guidelines used expert opinion when evidence was lacking
- evidence for treatment effects varied with the guidelines for example, theophylline - from no evidence of effect (Finnish guideline) to effective (GOLD guideline)

Evaluation

Despite the enormous effort and expense that has gone into guideline development there are relatively few evaluation studies to assess the impact of asthma and COPD guidelines on primary care clinical practice and these have had mixed results.

The literature search identified four randomised trials studying patient outcomes after asthma guideline dissemination and implementation in primary care.(151-154) We failed to identify any RCT on the effect of guideline implementation on the management of COPD in primary care. Other studies identified included: an audit of medical records after general practice- based education on asthma guidelines to physicians, and a before-and-after study of the impact of an asthma clinical guideline.(155, 156) A descriptive survey of the implementation of the asthma guideline in Finland, 6 years after the launch of the Finnish Asthma Programme, described the structures and processes developed in that country for the management of asthma.(157) Guideline evaluations have also been performed in Canada, UK, The Netherlands, NZ, the US and Europe.(158-163) The lack of penetration of guidelines into general practice was highlighted by surveys in Switzerland and Australia.(164-166)

Randomised Trials

As longer guidelines may be inappropriate for busy GPs, a UK study involved the dissemination of a shortened asthma guideline to general practices.(151) The study compared the impact of the dissemination of full guidelines, reduced guidelines and reduced guidelines supplemented by feedback on practice performance. Outcome measures were patient respiratory symptom scores and patient satisfaction. The reduced version of the guideline did not increase adherence to guideline recommendations in comparison with the traditional guideline format. The addition of providing feedback had minimal effect.

The effect of guidelines on the management of asthma and angina in primary care in the UK was assessed by Eccles.(152) General practices were randomised to receive either a guideline on asthma or a guideline on angina. Patient records were audited to determine the impact of the guidelines on disease management. The authors reported that the computerised guidelines had no effect on any outcome evaluated including: drugs prescribed for asthma, compliance with medication, consultation rates, lung function, inhaler technique, and education relating to smoking or asthma.

A medical record audit conducted in the UK assessed whether guidelines on asthma and diabetes, disseminated to GPs through education and "prompts", improved quality of care.(153) After 1 year, improvement in asthma practices over diabetes practices was detected in the recording of only one of six variables studied: review of inhaler technique, although asthma practices improved their prescribing of prophylaxis medication for asthma. However, there were improvements in both asthma and diabetes practices for three asthma outcomes over baseline: review of inhaler technique, smoking habit, and symptom review, a possible "Hawthorne" effect. Consultation rates before implementation of the guidelines were low but increased after guideline implementation. The study concluded that guidelines disseminated via practice-based education produced a marginal effect for asthma patients. However, the recording of outcome variables varied enormously between practices and was generally poor. The use of a "prompt", a stamp reminding GPs about annual review for asthma patients, improved the recording of outcome variables for asthma.

Compliance with the GINA guidelines as assessed by respiratory symptoms and inhaler technique was also improved in family practice if a "prompt" in the form of a flow sheet incorporating the guidelines was placed in patients' medical records.(154) The medical records of randomly selected patients (N=122) from family physician patient registers in a US community of 17 practices, were reviewed. Reviews occurred before, and 6 months after, placement of the flow sheet. However, the implementation was accompanied by an adverse effect of a reduction in the rate of reported frequency of counselling patients about smoking cessation (pre, post intervention; 66.7%, 28.5% ($p<0.0001$)).

Other studies

Other studies evaluating the use of guidelines in the primary care management of asthma and COPD demonstrated mixed results with regard to changing patient care and outcomes.

A pre-post study in the Netherlands evaluated the effectiveness of an intensive small group education and peer review programme, conducted by an experienced GP, for GPs. The intervention aimed to introduce national guidelines on asthma/COPD care to GPs and evaluate the effect on patient outcomes and GP knowledge. Apart from more peak flow meters in the practices and an improvement in GP self-estimated skills, intensive small group GP education on guidelines, and peer review in asthma and COPD care, did not change the patient care provided or patients' health status.(155)

Conversely, a before-and-after American study in a primary care department of a managed care organisation reported that, after the mandatory implementation of an asthma clinical guideline, emergency visits and hospital admissions for asthma significantly decreased and the percentage of patients receiving asthma education significantly increased.(156) Lung function and prescriptions for controller medication remained unchanged.

In Finland, the recognition of asthma as a community problem requiring governmental action resulted in the launch of the Finnish Asthma Programme in 1994.(157) This programme emphasised asthma guideline implementation and follow-up. The goals of the programme included: early diagnosis, active treatment, guided self-management, decrease in smoking, implementation of rehabilitation, education and promotion of scientific research. The role of primary care in asthma was recognised as important, with recommendations made that a trained GP or nurse should act as coordinator of all local asthma activities in all health centres. Six years after the launch of the programme, a descriptive evaluation of asthma care was conducted, which provided information on the implementation of the asthma guideline. Most (83%) of the health centres had a dedicated GP responsible for asthma education of colleagues and nurses and acting as a contact person for specialised care and treatment of asthma patients. Asthma education for the professionals had been organised in 71% of the health centres in the previous 2 years. First-line treatment consisted of an inhaled corticosteroid. Guided self-management was used in 98% of the health centres, although its components were not clear to the doctors. Most (95%) of the health centres had spirometers, which were predominantly used at least weekly. Poor patient compliance, lack of personnel, lack of time and lack of competency amongst nursing staff were major barriers to effective asthma management identified by GPs.

The impact of dissemination of an asthma management guideline was evaluated by a community survey conducted in three Canadian towns 1 year after an intensive asthma education program was provided to physicians with an interest in asthma in one of the towns.(158) The more intensive education programme, to promote the national asthma management guidelines, did not translate into improved asthma control in the community.

An observational, parallel group, cluster-controlled study evaluated the impact of the British Thoracic Society COPD guideline on the health status and HRQoL of general practice patients and health care resource use.(159) There were some significant differences in medication use between active (guideline-based) and control groups (usual care), with more patients in the control group requiring long-acting beta2-agonists during the study and more patients in the active group receiving short-acting beta2-agonists, inhaled anticholinergics and theophylline. However, use of the guideline had no impact on lung function or health care resource use over 12 months. Patients in both groups experienced significant improvements in symptom scores, as measured by a respiratory questionnaire, over the study period.

The effectiveness of the implementation of UK guidelines for the treatment of asthma or angina in primary care was audited after active implementation of guidelines in one district and passive implementation in another.(160) Asthma outcomes assessed included smoking status and inhaler technique. There were improvements in all outcome criteria between baseline and follow-up audits, irrespective of whether the guideline was actively or passively disseminated. The estimated increase in medical records compliant with guidelines was small (4%, 95%CI; 0, 8).

In the Netherlands, a before-and-after study over 1 year (1993-1994) was performed to evaluate patient health outcomes after the implementation of asthma and COPD guidelines in general practice.(161) The project involved an implementation programme of a series of educational meetings for GPs to discuss guidelines and their recommendations. Identification of barriers, documentation of the care provided, education, feedback on compliance with the guidelines, and peer review were also

provided. After guideline implementation, the mean PEF of intervention patients improved. However, the intervention group had significantly fewer patients with comordity than the comparison group (intervention versus comparison; 15% versus 31%, $p<0.001$) and tended to have a greater number of asthmatics (71% versus 61%, $p=0.07$), which could have confounded the study results.

The NZ guideline for the diagnosis and treatment of adult asthma was evaluated by a simple fax-back questionnaire sent to GPs 2 weeks after dissemination of the guideline.(162) A 58% response rate was obtained. Almost one third of the GPs did not recollect receiving the guideline, only 12% read it in detail and 20% indicated they thought it would change their practice. Implementation of guideline recommendations was impaired by the lack of acceptance of the guideline by GPs.

A cross-sectional retrospective analysis determined adherence with asthma guidelines, from accessing paid claims for pharmacy, institutional and medical services for asthma Medicaid recipients in Kentucky for 1996.(163) The majority of asthmatic patients in this population were not prescribed therapy in accordance with guidelines. The authors postulated that: either the guidelines had not been adequately disseminated, physicians had not embraced them, or barriers existed to their implementation by patients and health care providers.

A European survey (seven countries) to assess levels of asthma control as reported by patients, in order to reflect the extent to which guideline recommendations were being implemented, was conducted by household screening.(167) Current asthma patients were identified in 3,488 households, with 2,803 patients (80.4%) completing the survey. Almost half of the patients reported daytime symptoms and 30% had asthma-related sleep disturbances at least once a week. Only 23% of patients had used inhaled corticosteroids during the previous 4 weeks, and 60% of patients had never undergone pulmonary function testing. The study concluded that the GINA guidelines were not being fully implemented and that there was insufficient monitoring of asthma and its treatment.

A cross-sectional Australian study was performed to analyse asthma management 10 years after the 1989 launch of the National Asthma Campaign.(164) A cohort of young asthmatics (n=435) responding positively to the question "Have you ever had asthma?" was surveyed about their asthma management. Although 10% of the sample owned a peak flow meter, only 1.6% reported using it in the last 3 months. There was a decline in the number of asthmatics with a written action plan from the period 1993 to 1999/2000. The authors concluded that asthma management in this cohort fell well short of guideline recommendations.

A prospective cross-sectional survey of 455 GPs and 243 residents, fellows and staff physicians from the Departments of Internal Medicine, Community Medicine, and Geriatrics of Geneva University Hospital in Switzerland, response rate 45%, was conducted to evaluate their knowledge of guidelines for the management of COPD.(165) The survey reported major deficits in knowledge: 55% of physicians used spirometric criteria to define COPD, one third knew the correct diagnostic GOLD criteria, 25% prescribed inhaled corticosteroids for severe COPD, but 46% ignored the indications for their use. There was no difference between questionnaire responses for the various physician groups.

The COPDX guideline and the NZ guideline for the diagnosis and treatment of adult asthma were disseminated by a mail-out of periodicals to GPs (Medical Journal of Australia, The NZ doctor).(134) Following the mail-out, the Discipline of General Practice at The University of Adelaide organised a series of focus groups for GPs, to assess their perceptions of the guideline and discuss changes of the guideline format that would make it more acceptable to GPs. Preferences identified by the groups included electronic rather than paper formatted guidelines, and reminders to implement the guideline. The key recommendations of the COPDX guideline have since been summarised by the Discipline of General Practice in a brief GP-friendly algorithm, freely available electronically, providing information relating to the diagnosis and management of COPD.(168,169)

We were unable to find any reports of specific evaluations of the COPDX guideline in primary care, although the recent Matheson community survey reported that only 48.7% of subjects with COPD had ever been prescribed medication for their breathing problems and few had undergone lung function testing, indicating poor uptake of the guideline in primary care.(166)

Research Question 3. Funding/costs

How much does it cost to implement clinical guidelines for the primary care management of asthma or COPD, and is guideline implementation cost-effective?

Few studies were identified where the costs or cost-effectiveness of implementing clinical guidelines in primary care were identified. An RCT by Baker reported practice costs of implementing guidelines for asthma and angina in the UK.(170) The costs of three interventions used in a trial of guideline implementation, namely guidelines alone, shortened guidelines presented as prioritised review criteria or review criteria with feedback were estimated. The less costly approaches, dissemination of guidelines or guidelines with prioritised review criteria, were as effective as providing guidelines with review criteria and feedback. Direct costs were incurred by the NHS and general practices in delivering guideline implementation strategies. Although costs incurred by most practices were small, some practices spent several thousands of pounds on implementation activities.

The cost of implementing the 1999 Canadian Asthma Consensus Guidelines including asthma education and spirometry in Canadian general practices was estimated at approximately CA$78 dollars per patient (group sessions) and CA$100 per patient (individual sessions) in the first year of implementation.(171) The costs of providing enhanced asthma care were found to be significant, with physicians usually inadequately reimbursed (or not reimbursed) for these interventions.

Research question 4. Service delivery

What are the barriers, advantages and disadvantages of the use of guidelines for case finding, diagnosis and management for mild to moderate respiratory disease in primary care?

Reasons for the lack of guideline implementation in primary care practice have been suggested by several authors to be as follows:(172-174)

- GPs may be inundated with many often bulky guidelines for the management of various diseases
- most respiratory guidelines have been developed for secondary and tertiary disease management and may not appear relevant to primary care
- GPs may not agree with parts of asthma guidelines
- physicians may prefer to use clinical judgement rather than objective measures in diagnosing respiratory disease, for example, in COPD guidelines, lung function measures are important for diagnosis with limited reference paid to outcome measures of interest to patients such as the frequency of exacerbations requiring hospitalisation(119)
- effective implementation strategies have not always been designed
- adequate resources to implement guidelines are not always available, for example, performance of spirometry in primary care where reimbursement is inadequate or spirometric testing is not available
- patient non-compliance with guideline recommendations

Advantages of implementing guidelines for asthma and COPD in primary care:

- clinical practice guidelines may improve some outcomes in primary care if they encourage interventions of proven benefit(156)
- clinical practice guidelines may reduce variation in clinician performance and improve the quality of physician decision making(175)

Disadvantages of implementing guidelines in primary care(175)

- evidence for the guideline recommendations is often lacking
- recommendations are influenced by the opinions and experience of the guideline development group
- flawed guidelines may encourage ineffective or harmful care
- other perspectives than best practice patient care may influence guideline development, for example, many guidelines have been sponsored by multinational pharmaceutical companies
- patient preferences may not be considered during guideline development
- guidelines focus attention on specific issues and hence may affect public policy or funding decisions in particular areas

Key findings and implications for policy makers

1. There has been a poor uptake of respiratory clinical guidelines in primary care. Many barriers and disadvantages to the implementation of guidelines have been identified as described above.

2. In addition to the barriers listed above, reasons for the poor uptake may also include:

    - under-diagnosis or under-recognition of the respiratory disease by the GP
    - a lack of effective therapies of proven benefit for patients with mild to moderate asthma and COPD
    - the major costs of treatment occur in moderate to severe disease, where most research attention has been focused, and on which the majority of guidelines are based

3. Randomised trials evaluating the implementation of asthma guidelines in primary care only provided evidence supporting improvements in very few health outcomes after guideline implementation. The three trials reviewed all included sample size estimations and were sufficiently powered to detect changes. The use of prompts, however, appeared to improve compliance with guideline recommendations.

4. We were unable to identify any RCT evaluating health outcomes after guideline implementation for COPD patients in primary care.

5. Patients presenting to primary care may not be similar to those included in RCTs providing evidence to guidelines; for example, primary care patients may be older, more complex and present with a broad range of signs and symptoms.

6. Randomised controlled trials provide information about the effectiveness of interventions in often highly selected patient populations. General practitioners require evidence about how an individual patient will respond to the intervention.(145) Guidelines focused on a single disease may not be applicable to patients with multiple comorbidities.(176)

7. Clinical practice guidelines may decrease the physician's freedom to address individual patient issues.

8. If guidelines are not continually updated to reflect the latest evidence they may potentially promote inappropriate treatment modalities.

9. Considerable time and effort is required by GPs to fully implement guidelines and GPs may not be adequately resourced to enable implementation of guidelines in everyday practice.

10. New primary care focused clinical practice guidelines for asthma and COPD have recently been developed but their impact on health outcomes is not yet available.

4. SPIROMETRY IN PRIMARY CARE

Spirometric evaluation of lung function is important in the diagnosis, differentiation and management of respiratory illnesses such as asthma and COPD and for the assessment of lung health in smokers or those exposed to occupational and environmental hazards.(177) Over recent years, emphasis has been placed on the detection and treatment of respiratory disease in primary care, with spirometry an important part of the evaluation.(178)

Research question 1. Organisation

What is the evidence base to support the use of spirometry in primary care?

Spirometry for case finding, diagnosis and monitoring

Mild to moderate airway obstruction has been reported to occur in approximately 25% of adult smokers aged between 35 to 59 years but is underdiagnosed and misdiagnosed.(179, 180) It has been suggested that underdiagnosis and misdiagnosis may be due to underutilisation of spirometry in primary care.(181)

Guidelines recommend lung function testing using spirometry:(18, 133, 182)

- to confirm the diagnosis by assessing airflow obstruction and the reversibility of airflow obstruction by a comparison with predicted normal values
- to monitor the effects of treatment after this has been initiated or changed
- to regularly assess maintenance of airway function, so that information about disease severity and control can be communicated back to the patient

In asthma, response to inhaled bronchodilator, and reversibility testing, peak flow monitoring or laboratory-based tests to measure bronchial hyperresponsiveness are required for confirmation of diagnosis based on a history of symptoms.(16, 183) Regular monitoring of pulmonary function is important for asthma patients who may not perceive their symptoms until obstruction is severe.(135) Spirometry is the 'gold' standard as the measurement of PEF with conventional peak flow meters is dependent on patient effort, patient motivation and respiratory muscle strength. There is also poor agreement among different brands of peak flow meters.(184, 185)

For a diagnosis of COPD, the updated GOLD guideline proposes four different stages, based on the severity of airflow obstruction as determined by spirometry (Table 5.)(110)

Table 5. GOLD staging system for COPD severity

Stage	Description	Findings (based on post bronchodilator FEV_1)
0	At risk	Normal spirometry Chronic symptoms (cough, sputum production)
I	Mild COPD	FEV_1/FVC <70% FEV_1 ≥80% predicted With or without chronic symptoms
II	Moderate COPD	FEV_1/FVC <70% FEV_1 50% to <80% predicted With or without chronic symptoms
III	Severe COPD	FEV_1/FVC <70% FEV_1 30% to <50% of predicted value With or without chronic symptoms
IV	Very severe COPD	FEV_1/FVC <70% FEV_1 <30% predicted or FEV_1 <50% predicted plus chronic respiratory failure

Source: National Institutes of Health. Global initiative for chronic obstructive lung disease workshop report(110)
GOLD, Global initiative for chronic obstructive lung disease
COPD, chronic obstructive pulmonary disease
FEV_1, forced expiratory volume in one second
FVC, forced vital capacity

With the development of robust, small portable spirometers, case finding of mild to moderate asthma and COPD in primary care is possible. However, spirometry correlates poorly with HRQoL and symptoms of shortness of breath, fatigue, cough and wheezing.(126,186) Underdiagnosis may be due to a lack of symptom awareness by the patient or GP, patient reluctance to seek health care or attribution of symptoms to other causes such as ageing.(19,187-189) Physicians may have a negative attitude towards COPD due to the patient's usual smoking history and may make no attempt to devise a management plan.(190) The lack of a consistent correlation of airflow limitation with HRQoL reduces the ability to predict disease course and hence the possibility of early detection.(186)

The literature search identified:

- two systematic reviews involving the use of spirometry in primary care(191),(192)
- two additional RCTs, not included in the systematic reviews, evaluating the use of spirometry by GPs for the diagnosis or management of COPD and asthma (193),(194)
- thirteen surveys, not included in the two systematic reviews (Appendix 4) where spirometry was used to confirm airway obstruction, COPD or asthma.(166,195-206)
- the cost-effectiveness of spirometry for case finding in primary care was reported in the Wilt systematic review, during development of the NICE guideline, and during a cross sectional case finding study conducted in primary care. (191),(207),(208)

- barriers, difficulties or advantages associated with the use of spirometry were identified by several authors(209-215)
- information on a new method of funding spirometry in primary care in the UK aiming to reward practices offering higher quality care(216)
- spirometry as a predictor of future health care costs in COPD was evaluated in a population study(217)
- adverse effects of inhaled corticosteroids in mild asthma or COPD were evaluated in two systematic reviews(218, 219)

The comprehensive Wilt systematic review obtained information from searches of MEDLINE® and the Cochrane Database for articles published in English from 1966 to May 2005.(191) This evidence-based report included 10 cohort studies for prevalence estimates where spirometry had been used for case-finding, 7 RCTs for spirometry as an aid to smoking cessation, 52 additional RCTs, 6 meta-analyses for therapies and 5 cohort studies for prognosis.

The Bize systematic review identified four RCTs which included spirometry testing as a biomedical feedback to smokers for improving smoking cessation.(192) Three of the four RCTs were also included in the Wilt systematic review. In one of the four trials, spirometry results alone and in three trials, spirometry plus exhaled carbon monoxide measurements were provided as feedback to patients. An odds ratio of 1.21 (95%CI 0.60 to 2.42) favouring smoking cessation was obtained when spirometry results alone were used as feedback. The authors' concluded that, due to the scarcity of evidence, they could make no recommendations regarding the use of spirometry for feedback but that current evidence did not support the hypothesis.
Since the publication of the two systematic reviews, two new RCTs have been published. One study evaluated the use of spirometry in asthma and COPD in standard general practice.(193) A second trial reported the use of spirometry in asthma management: the effects of early intervention with inhaled budesonide on lung function as measured by spirometry in persistent mild asthma.(194)

Five population surveys,(166, 195-198) included spirometry following a symptom assessment or HRQoL questionnaire to confirm either airway obstruction, asthma and COPD. Eight population surveys were identified where bronchial hyperresponsiveness confirmed a diagnosis of asthma.(199-206)

Research question 2. Implementation and Evaluation

What is the evidence that the performance of spirometry in primary care has been implemented and evaluated, and that it has influenced the clinical outcome of patients with mild to moderate asthma or COPD?

Systematic reviews

The Wilt systematic review concluded that, compared with clinical evaluation alone, spirometry was helpful in diagnosing COPD and was a useful aid to confirming the diagnosis in individuals with symptoms suggestive of COPD.(191) A study by Buffels, included in the Wilt review, compared spirometry with a respiratory questionnaire for detection of COPD. This study reported the positive predictive value of a questionnaire to be low (sensitivity, 58%; specificity, 78%) and that 42% of the newly diagnosed cases of obstructive lung disease would not have been detected without the performance of spirometry.(220)

The literature review demonstrated that the prevalence of diagnosed asthma and COPD varied according to the population and country studied, and to the definitions of disease and symptoms used in the studies.(191) Airflow obstruction increased with increasing age of the population and smoking history and was dependent on ethnicity, height and weight.(191),(221) Applying GOLD criteria to a representative US survey, Wilt reported that 7.2% of the survey population were at risk of COPD (GOLD stage 0), 7.2% had mild airway obstruction (GOLD stage 1), 5.4% moderate obstruction (GOLD stage 2) and 1.5% severe to very severe obstruction (GOLD stage 3) for an overall prevalence of 21.3%.

Other studies

An Adelaide community study (North West Adelaide Health Study) included 4,002 subjects randomly selected from the telephone directory and identified 9.4% with current asthma based on spirometric reversibility criteria.(199) An earlier account of this study reported 11.6% participants with asthma, 9.3% with a doctor's diagnosis of asthma. The results of spirometry testing indicated that 19.2% of the total asthmatic group was previously undiagnosed.(188)

A Canadian study reported that spirometry was useful in identifying incorrect diagnoses.(196) From before-to-after knowing the results of spirometry the diagnosis of airflow obstruction changed in 20% subjects studied, with 9% patients newly diagnosed and 11% patients having a diagnosis of airflow obstruction removed.

A recent community-based, random sample of 1,224 adults from three electoral regions in Victoria identified 3.5% adults with COPD (stage 2 or 3 GOLD criteria) and 8.9% with asthma only, with more than 40% of the subjects with COPD being previously undiagnosed. (166)

A UK study of 168 patients (aged at least 50 years) on general practice asthma registers and undergoing spirometry, identified (British Thoracic Society guidelines) 34% with normal spirometry, 24% with active asthma and 34% with COPD.(222) Only 40% of the COPD diagnosed patients had previously been diagnosed. Most (79%) newly diagnosed COPD patients had mild to moderate disease.

In the Netherlands, a study of 1,155 subjects from 10 general practices with known COPD and asthma patients excluded, revealed that during a screening stage detection programme, approximately 50% of the general undiagnosed population had symptoms and signs of COPD or asthma.(19) A second stage of the study demonstrated that persistently decreased lung function or a rapid decline in lung function was observed in approximately 20% of the general undiagnosed adult population.(19)

Contrary to these results, Lusuardi concluded that office spirometry did not improve the diagnosis of asthma or COPD in the primary care setting.(193) This randomised study, involving 74 GPs from 57 Italian pulmonology centres enrolled 333 subjects aged 18 to 65 years with symptoms of asthma or COPD who had not previously been diagnosed. The GPs attended educational sessions on guidelines for asthma and COPD and practical sessions on spirometry provided by pulmonary specialists prior to commencement of the study. The subjects were randomised to receive conventional evaluation with or without spirometry. During the study, 30% of subjects diagnosed with COPD by the GP had normal spirometry ($FEV_1/FVC \geq 0.7$ and $FVC \geq 80\%$ of predicted). Diagnosis based on a conventional evaluation of symptoms and physical examination produced similar results to that obtained from conventional evaluation plus spirometry. However, the sample size was inadequate to prevent a possible type

II error. Use of spirometry by GPs decreased progressively during the study even though it was rated as useful by the majority of GPs.

Impact on clinical outcomes

Asthma

The importance of screening or case finding in primary care is to detect those individuals where intervention will reduce or delay subsequent exacerbation.(191) However, this is dependent on the availability of effective intervention strategies for the detected patients.(21) It could be expected that spirometry testing would be more useful in changing asthma management due to the reversibility of FEV_1 with bronchodilators. Spirometry is usually recommended as part of an overall asthma management plan involving the use of written action plans, patient education, nurse counselling and GP consultation and review.(223),(100)

The literature search identified 33 meta-analyses where spirometry (usually FEV_1) was included as one of the outcome measures to determine the efficacy of a particular drug regime or treatment effect for chronic asthma (including patients with mild to moderate asthma). Other outcome measures included were symptom scores, HRQoL, PEF, relief or rescue medications and the number of exacerbations or emergency department visits. These have not been cited, as it is difficult to determine from these studies if spirometry alone can influence asthma management. An overview of Cochrane systematic reviews on the use of long-acting beta2-agonists in asthma was also identified.(224) Only 1 meta-analysis used lung function measurements alone as the outcome measure.(225) This meta-analysis concluded that caffeine appeared to improve airway function modestly for up to 4 hours in people with asthma. This review has implications for pulmonary function testing rather than for asthma management. The meta-analyses provided evidence for the management of asthma, which could be incorporated into disease management guidelines. Yet current guidelines differ in their recommendations and are, at present, often not well implemented in primary care practice.(224)

One trial was identified where spirometry alone was used to demonstrate an effective intervention for mild asthma.(194) The outcomes of early intervention with inhaled corticosteroids on decline in lung function as measured by spirometry were assessed in an RCT in patients with persistent mild asthma. The study included both adults and children. Results suggested that early intervention with an inhaled corticosteroid (budesonide, 200 to 400 micrograms once daily) slightly reduced the loss of lung function (FEV_1) over a period of 3 years. The difference in FEV_1 values between patients treated with budesonide and those treated with placebo developed during the first 6 weeks of treatment. The results may have been confounded by almost half of the patients in the placebo group receiving non-study corticosteroids during the study period.(226) The inhalation did not prevent the decline of post-bronchodilator FEV_1 values in either treated or control groups. The authors hypothesised that either: there was a steroid insensitive component to airway changes or that a higher dose of inhaled steroid was required. The study was sponsored by the supplier of the corticosteroid, a multi-national pharmaceutical company, so the possibility of bias could not be eliminated.

The question of adverse effects of long-term corticosteroid inhalation in mild respiratory disease remains to be determined, with only 3 years of follow-up data available to date. The safety of inhaled corticosteroids was studied in a systematic review and meta-analysis of RCTs of patients with COPD.(218) The validity of the reporting of adverse events was limited by short study durations (mean follow-up

period 22.3 months) and small sample sizes. In addition, patients unable to tolerate treatment during a run-in phase were eliminated in many studies. Observational evidence identified a dose-related risk of cataract and open-angle glaucoma. A Cochrane review by Jones reported that in patients with asthma or mild COPD, there was no evidence of an effect of inhaled corticosteroid at conventional doses on bone mineral density or vertebral fracture over a 2 year period.(219) However, higher doses were associated with evidence of increased bone turnover.
The effect of early treatment with inhaled steroids on lung function in asthma confirms the results of a previous study where spirometry, indicated a favourable effect on lung function and QALYs but only in subjects with asthma.(227) A prospective study in general practice by Dompeling reported, that in patients with mild asthma, inhaled steroid treatment improved bronchial hyperresponsiveness as measured by spirometry.(228)

A prospective controlled trial of an adult asthma programme, where adult asthmatics used home monitoring of peak flow readings and an educational intervention to self-manage their disease, compared the outcomes with those from a control group of patients using symptoms and spirometric data for following physicians' management plans.(229) Severity of asthma was not explicitly stated, but applying criteria for asthma severity from the GINA guidelines, mean FEV_1 would indicate the patients had moderate persistent asthma.(16) Patients in both groups' demonstrated significant improvements in morbidity indicators such as days lost from work and acute asthma attacks and in lung function over 6 months of follow-up. However, knowledge of spirometry appeared to produce smaller improvements in outcomes compared to improvements achieved through home monitoring of PEF and education. It was noted that 34% of patients were unable to self-assess their symptom severity and modify their medications according to their therapeutic plan.

An intervention including spirometry did not alter the outcomes for asthma patients when compared with standard general practice care in the RCT by Heard.(100) An additional RCT by the same group, of the effectiveness of asthma clinics, which included the performance of spirometry, a discussion of spirometry results between patient and GP, plus nurse education with encouragement to develop an action plan, also concluded that the intervention and standard general practice care produced similar effects on HRQoL and lung function.(70)

A study in the Netherlands employed an expert consensus panel to evaluate spirometry interpreted by trained GPs and to assess the influence of spirometry on GP decision-making. Trained GPs were able to differentiate between normal and obstructive disease patterns although spirometry suggestive of rare disease was often missed. Decision-making appeared to be influenced by spirometry by reducing diagnostic uncertainty and increasing referral to specialist care.(230)

A retrospective audit of patient case records was conducted in the UK to determine whether spirometric readings obtained during primary care asthma clinic attendance influenced subsequent management.(231) Evidence that spirometry altered management decision-making was identified in only 4% of cases. The availability of spirometry results did not guarantee that the findings were incorporated into patient management.

A Canadian study of screening spirometry in primary care asked the physician if the patient's management would be changed based on the results of spirometry.

Management changes described by physicians were usually to counsel patients to stop smoking or to alter medications.(196)

Currently, the Discipline of General Practice, The University of Adelaide is undertaking an RCT aiming to examine the potential benefits of spirometry in the general practice management of asthma in children and adults in primary care. This study should provide additional information.

COPD

The systematic review by Wilt included an assessment of the evidence for the use of spirometry for the management of COPD. The effect of the use of spirometry on smoking cessation rates was studied, as smoking cessation is the only intervention that has been demonstrated to reduce or delay the decline in airflow limitation.(191) The review reported that the evidence identified was limited and flawed. The independent effect of spirometry on smoking cessation rates was only assessed in one study, which failed to demonstrate a benefit. Six additional studies were identified which approximated the independent effects of spirometry but these indicated spirometry was of limited use in predicting future smoking cessation. Overall, spirometry appeared to have little or only a small effect on smoking cessation rates. A similar conclusion, that feedback on the physical effects of smoking by physiological measurements including spirometry did not result in increased smoking cessation compared with standard treatment, was reached by Bize. (192)

Little evidence was identified to assess the potential adverse effects of spirometry in relation to smoking cessation. The Wilt review reported that the single study stratifying smoking cessation rates by spirometry reported an adverse effect of less smoking cessation in patients with abnormal spirometry. (191)

Spirometry appears unlikely to be useful in mild to moderate COPD for monitoring response to therapies or altering treatments in primary care, as benefits of therapies are greatest in patients with the most severe disease. The Wilt review reported that no inhaled medications have been reported to improve outcomes when prescribed to COPD patients with FEV_1 >50% of predicted value and that many patients have been prescribed inhaled medications for COPD yet have normal spirometry findings.(191),(210) However, in primary care, spirometry may be useful to identify a threshold level at which treatment could be initiated, or to prevent incorrectly diagnosed subjects from receiving COPD-specific therapy.(191) Spirometry also provides prognostic information for COPD although other factors such as body mass index and dyspnoea have been found to be better prognostic indicators.(191)

A descriptive evaluation of a recent pilot study of a mobile spirometry service offered education on spirometry, data interpretation and COPD management to general practice staff from 6 practices known to have a spirometer, plus spirometry clinics with bronchodilator and steroid reversibility assessments.(232) Ninety eight patients were referred to the nurse-run spirometry service over a 3 month period with 6% having normal lung function. Benefits to patients included improved diagnosis, and greater referral to specialist services.

Research Question 3. Funding/Costs

How much does the performance of spirometry in primary care cost and is it cost-effective?

Direct costs

The cost of the performance of spirometry in primary care has been estimated by the UK National Collaborating Centre for Chronic Conditions during development of the NICE guideline.(125) The cost per test of spirometry performed by a practice nurse in the UK, based on a test time of 10 minutes, a spirometer lifetime of 5 years and the performance of from 1 to 10 spirometries per week was estimated at £9.91 in 2001 (AU$24.89). However, this test time does not allow for reversibility testing.

In Australia, spirometry is funded through the MBS.(233) Most general practice spirometry is covered under Item Number 11506 for "the measurement of respiratory function involving a permanently recorded tracing performed before-and-after the inhalation of bronchodilator - each occasion at which one or more tests are performed".(233)

To estimate the direct costs of the performance of spirometry in primary care involves not only an estimation of the cost of the clinical equipment and GP or practice nurse test time but the costs of reporting the test, and is dependent on the number of tests performed during the effective useful clinical lifetime of the equipment.

An estimate of the costs of spirometric testing, including response to inhalation of bronchodilator and according to whether the test is performed by a general practitioner or a practice nurse, is provided in Table 6. The majority of the costs described are variable costs and are approximates only.

- the costs are based on performance of spirometry according to the Australian COPDX plan(134)
- calculations were made assuming 2 patients per day or 500 patients per year undergo spirometry testing and a useful clinical life of the equipment of 5 years
- the total cost represents the minimum cost of spirometry, based on a total test time of 23 minutes (4 minutes pre-bronchodilator test time, 15 minutes between pre-and-post bronchodilator tests, and 4 minutes post-bronchodilator test time)
- additional time must be allowed for preparation, including priming of the spacer in diluted detergent, clean-up, interpretation of test results and reporting
- no maintenance or calibration time is required for the 'ndd EasyOne™' spirometer although other spirometers may require regular maintenance
- the cost of four metered dose inhaler actuations (400 micrograms) of salbutamol, to assess bronchodilator response, is included(134)
- attendance, by the GP or practice nurse, at a spirometry training course is essential for the performance of clinically useful spirometry and interpretation of the results

Test time estimates of 4 minutes (standard deviation 1.1) were calculated during a previous cross-sectional study involving the spirometric measurement of lung function in 651 smokers aged 35 to 70 years from general practices in the Netherlands.(208) An allowance of 4 minutes for 3 acceptable spirometric manoeuvres represents the time taken if all variables are optimal, and would underestimate test time in sub-optimal

situations, such as poor reproducibility, poor exhalation, cough or the patient unwilling or unable to cooperate with the performance of the test. The COPDX plan recommends reversibility testing 15 to 30 minutes after bronchodilator is given.(134) Thus, a minimal time allowance of 15 minutes between pre-and-post bronchodilator testing has been made.

A training time of 6 hours or 1 day (attendance at one spirometry training course) has been included, assuming practice staff' perform 500 spirometric tests per year over a 5 year period. Training includes instruction on performance, quality assurance and interpretation and infection control. Attendance at a refresher course may be required for practice staff performing fewer spirometry tests and would increase total cost.

The direct cost of performing spirometry in general practice in Australia has been estimated to range from $36.01 to $76.20 depending on whether the test is performed by a GP or practice nurse (see Table 6.). The cost of performing spirometry could be reduced in asthma clinics, where several patients could be tested simultaneously. The MBS fee (Item Number 11506) is $17.75 which is reimbursed at 85%.(233)

The cost of spirometry training may be covered by external sources such as the Divisions of General Practice, the National Asthma Council, or through pharmaceutical or medical equipment companies. Assets may be depreciated over their effective clinically useful life in accordance with current government policy.

Table 6. Estimated direct costs of performing spirometry in primary care in South Australia according to the Australian COPDX Plan

Item	Item details	Cost ($) per test	Cost ($) per test
		Practice Nurse	General Practitioner
Salary cost: nurse/GP per hour*	$21.60/$125.80 per hour	8.28	48.22
Spirometer (ndd EasyOne™ Stand Alone ND2001-4) †‡	$3,250	1.30	1.30
Consumables (mouth piece)		2.75	2.75
Bronchodilator (salbutamol) (4 actuations)	$16.39 each inhaler 200 meter doses per inhaler	0.33	0.33
Volumatic spacer (single use)		10.69	10.69
Cleaning/preparation costs	$21.60 per hour 5 minutes per test	1.80	1.80
General practitioners time to report test	125.80 per hour 5 minutes per test	10.48	10.48
Printer (Canon Pixma iP2200) †‡	$88.00	0.04	0.04
Printer consumables (ink cartridge, paper)	$76.75	0.03	0.03
Training (time)	6 hours	0.05	0.30
Training (course cost)	$650 per course	0.26	0.26
TOTAL COST		**36.01**	**76.20**

*Based on a total test time of 23 minutes
†Based on an effective clinically useful life of the equipment of 5 years
‡Based on the performance of 500 spirometry tests per year

Funding spirometry in primary care: UK model

An alternative method of funding spirometry is provided in the UK. A new General Medical Services contract became effective during 2004, providing financial rewards to practices meeting agreed clinical indicators and constructing patient disease registers.(216) Clinical indicators were selected where good evidence of benefit was available.(216) Asthma clinical indicators attract a total of 45 points of which 15 are available for measures of variability or reversibility. For COPD, 33 points are available, 17 for a diagnosis confirmed by spirometry including reversibility testing and a record of FEV_1 in the previous 15 months.

Cost-effectiveness

The National Heart, Lung, and Blood Institute recommends spirometry be performed in all current or former smokers aged at least 45 years and anyone with symptoms of chronic cough, excessive dyspnoea on exertion, or wheezing.(234) Costs to be considered in determining the cost-effectiveness of screening adult smokers for lung disease include those of the spirometry testing, of implementing and maintaining

screening and smoking cessation programmes, and of their consequences, that is, reduced morbidity (perhaps lower short- and medium-term health care costs) and mortality (perhaps higher long-term health care costs).(235)

The impact on health care cost of widespread spirometry in primary care has been reported in the Wilt systematic review.(191) It was estimated that providing routine spirometry to all adult smokers, ex-smokers and non-smokers with respiratory symptoms would require 110 million adults in the US to undergo spirometry at a cost in excess of US$1 billion. Based on the estimated prevalence of respiratory symptoms in the US, levels of airflow obstruction and the effectiveness of drug therapy for COPD, they estimated that applying spirometry to a clinic population of 10,000 adults would identify 6,588 for spirometric testing, detect 129 candidates for therapy and result in benefits to 8 individuals through a reduction in exacerbations.

The incremental costs and health outcomes of spirometry testing smokers or ex-smokers, aged over 35 years, presenting to their GP with symptoms of COPD were calculated by the NHS.(125) The cost evaluation included the following costs:

- cost of spirometry (a cost of spirometry of £9.91 was included)
- diagnosis costs, for example, chest radiograph, assessment of breathlessness, full blood count and the calculation of body mass index
- intervention costs (smoking cessation programme)
- costs of care: costs for mild, moderate and severe COPD
- QALYs
- costs were discounted at 6% and health outcomes (life expectancy and QALYs) were discounted at 1.5%

Opportunistic case-finding in primary care was found to be a relatively cost-effective strategy.(125) Based on a probability of having COPD of 27%, the incremental cost of spirometry per life year gained was estimated at £713.16 and the incremental cost per QALY gained at £814.56. However, considerable uncertainty existed around the main parameters included such as: the discount rate, the prevalence of COPD, smoking cessation success rate, concordance with smoking cessation programmes, cost of diagnosis and cost of the intervention, thereby creating considerable uncertainty in the model. The model assumed that spirometry had a 100% sensitivity and specificity and was performed by trained and competent staff, which is not always currently true in general practice.(236)

A cost-evaluation study, performed in Canada, analysed trends in spirometric testing by GPs.(237) Expenditure on spirometry rose by 37% to C$14.1 million from 1989-1990 to 1994-95, with a quarter of the cost increase attributed to an increase in the total number of tests performed by more physicians performing spirometry. In addition, flow-volume loops were being substituted for simple spirograms, possibly due to the higher fee attracted. It was postulated that the spirometry increase could have been due to the availability of relatively inexpensive electronic spirometers or to an increasing awareness of guidelines, although there was wide variation in use of spirometry between regions.

A primary care study in the Netherlands involving case-finding by spirometry screening of smokers has estimated a direct cost of detecting one smoker with airflow obstruction (FEV_1 <80% of predicted) of between 5 to 10 Euros (A$8.35 to $16.70)

based on a mean test time of 4 minutes with one airway obstruction identified for every 23 minutes of test time.(208)

An earlier prospective study in the Netherlands, to detect subjects in the general population with early COPD or asthma, involved spirometry screening and a subsequent 2 year monitoring of all subjects with positive results on screening. The costs of lung function assessments (based on 1996 reimbursement fees (US$18.51)), organisation, transportation, and patient time were included. The average cost per detected case was estimated to range from US$469 to US$953(19)

The usefulness of airflow obstruction to predict future health care use was studied in an audit of the medical records of a population-based cohort of COPD patients in the US.(217) Airflow obstruction was found to be a significant but weak predictor of future health care resource utilisation. Prior hospitalisation, home oxygen use, the presence of comorbid conditions and symptoms of dyspnoea, however, were found to be better predictors of costs.

The cost of screening spirometry in Australia is currently being studied by the Discipline of General Practice at The University of Adelaide. An RCT is being conducted to obtain evidence relating to the incremental costs and health outcomes of the performance of spirometry for asthma monitoring in primary care.

Research question 4. Service delivery

What are the barriers, advantages and disadvantages of the use of spirometry for case finding diagnosis and management for mild to moderate respiratory disease in primary care?

Barriers and disadvantages of spirometry in primary care

1. Quality control and training

The reliability of spirometry is dependent on equipment selection, test performance and correct interpretation of the results.(236) An RCT to determine the quality of spirometry performed in primary care practice in NZ demonstrated that 4 months after completion of two sessions of formal training, less than one third of the spirometry fulfilled ATS criteria for acceptability and reproducibility (2 acceptable blows).(236) A significant training effect was observed, with training found on logistic regression analysis to be the major determinant of an acceptable spirometric manoeuvre. Analysis of spirometry testing revealed that 18.9% of patients' tests by trained GPs and 5.1% by usual GPs had three acceptable blows based on ATS criteria. Only 13.5% of tests (trained GPs) and 3.4% of tests (untrained GPs) met full acceptability and reproducibility criteria. This occurred despite built-in quality assurance features of the spirometer. In addition, the GPs' interpretation of the test results were judged by experienced chest physicians to be correct in only 53% of tests independent of training.(236, 238)

An Australian national survey of spirometer ownership and usage in general practice by Johns (response rate = 19.5% general practices) found that 64.2% of responding practices owned a spirometer with 67% of these practices performing 1 or more tests per week.(209) The duration of training in spirometry varied from less than 2 hours for 40% of the responding general practices, to 3.5 days for 6.7%.

Two 2.5 hour training sessions performed 1 month apart for GPs and practice assistants resulted in the performance of spirometry test that gave test results marginally but statistically higher than pulmonary function laboratory measurements in the Netherlands.(239) The percentage of non-reproducible tests ranged from 4 to 35% in general practice compared with 13 to 20% for the laboratories. It was concluded that on average, with adequate training, the validity and quality of spirometric tests in general practice was satisfactory.

2. Calibration of equipment
The Johns survey reported that accuracy checks of spirometers, if performed, were infrequent with 44% of GPs performing accuracy tests annually, 17% monthly, 5% weekly and only 1% daily.(209) While some of the new portable spirometers have been demonstrated to maintain calibration, the ATS and others recommend that the accuracy of the spirometer be verified on a regular basis.(240)

3. Compliance
Successful spirometry is dependent on maximal patient effort and cooperation. Acceptable spirometry was obtained for 78% of the elderly subjects tested using a 'Vitalograph® S' dry bellows spirometer during a population-based study in Finland.(203) Patient-related factors responsible for unsuccessful spirometry have been reported to be illness, dementia, or non-cooperation/refusal or contraindications to forced expirations.(203) However, the patients included in the study were elderly. In a community study of middle aged male smokers acceptable spirometry was obtained for 87.2% of participants.(197)

4. Risk of overdiagnosis and misdiagnosis
Spirometry (especially FEV1) correlates poorly with symptoms.**(241)** Using the GOLD severity classification table for COPD, apart for grade Stage 0, a diagnosis of COPD is based on cut-points of FEV1 and requires no symptoms.**(242)** The ratio of FEV1/FVC decreases with age. Hence, criteria that are not relative to the predicted value may result in overdiagnosis of COPD in the elderly.**(242)** Comorbidity may also result in a lower FEV1. A Norwegian study of asymptomatic, never smoking adults over 70 years of age reported that 35% performing acceptable spirometry would have been classified as at least COPD Stage 1 according to GOLD criteria.**(213)** The percentage misclassified increased with age, so that approximately 50% of over 80 year olds would have been classified as having COPD. Thus, screening spirometry will result in the overdiagnosis of COPD, which will incur an economic cost to the community and a cost to the patient if treatment is prescribed. Hardie has estimated that up to 10% of the elderly population might receive a misdiagnosis of Stage 2 COPD resulting in prescription of regular bronchodilators and possible inhaled glucocortico-steroids.

In a commentary on the current literature Enright concluded that until more studies are performed with results demonstrating improvements in outcomes following treatment for COPD patients with mild to moderate disease, screening spirometry should be reserved for symptomatic smokers.(210)

Case finding through spirometry can also result in misdiagnosis due to mislabelling of patients with COPD. The GOLD classification Stage 0 (at risk) is defined by chronic cough and sputum production, but normal spirometry. The concept that Stage 0 can predict future COPD was tested retrospectively in the Copenhagen City Heart Study.(214) During this study, a general population sample performed spirometry at baseline and after 5 and 15 years. After 15 years, only 20.5% of smokers with GOLD

Stage 0 at baseline could be classified as having COPD GOLD Stage 1. Further analyses using multivariate logistic regression confirmed that GOLD Stage 0 was not predictive of subsequent airways obstruction. Stage 0 was also not a stable feature because of variability of symptoms, which may explain the lack of predictive value. This study indicated that Stage 0 was unsuitable for pointing out the population "at risk" for development of COPD in a random population in general and among smokers in the general population in particular.

5. Uptake of spirometry

Studies have documented a poor uptake of the use of spirometry in primary care. The Wilt review reported that many adults (over 80%) reporting a clinical diagnosis of chronic bronchitis or emphysema have not undergone recent spirometry.(191) A cross-sectional study by Tsuyuki of the management of asthma among primary care physicians in Canada reviewed charts of 3,072 patients from 45 GPs.(243) Despite the fact that previous emergency department visits or hospitalisations were experienced by 20% of the sample, only 25% of patients had documented evidence that they had performed spirometry. A survey by Bolton, of the use of spirometry in general practice in Wales, reported over 80% of general practices owned and used a spirometer.(244) However, only 58% of practices reported they were confident in the use of the spirometer and a low 34% reported confidence in interpretation. Walters found, during an Australian pilot cross-sectional study of COPD patients and general practitioners in Tasmania, that spirometry had been performed by only 41% of patients diagnosed with COPD by a GP but in all cases where a specialist was involved in patient care.(212) General practitioners preferred to diagnose on clinical grounds rather than through spirometry.

6. Barriers to the performance of spirometry as identified by GPs

Barriers to the performance of spirometry in primary care were identified during both the pilot study and the later GP spirometer ownership survey by Walters:(209),(212)

- high cost of spirometer (53% of responding practices)
- insufficient Medicare rebate (33% of responding practices)
- insufficient time to perform the test (21% of responding practices)
- did not employ a practice nurse (23% of responding practices)
- lacked confidence in interpreting results (18% of responding practices)
- believed spirometry was not useful (6% of responding practices)
- lack of access to a well maintained spirometer
- lack of expertise in performing the test
- patient reluctance to attend a referral centre for spirometry
- increased cost to patients and longer consultations
- time waiting for post bronchodilator spirometry

Advantages of the performance of spirometry in primary care (209, 211, 215, 245)

- spirometry can identify previously undiagnosed asthma and COPD through screening smokers or subjects at risk
- spirometry can diagnose early chronic respiratory disease where intervention by new therapies may result in reduction in progression of disease
- spirometry can prevent misdiagnosis of COPD or asthma. In a community study of adults with a GP diagnosis of asthma, 41% of a sample demonstrated no reversibility of airflow obstruction, with 62% of these subjects currently taking

asthma medications. Only 52.2% of the subjects reported ever having undergone pulmonary function testing.(215)
- exercise retraining in mild COPD may benefit patients with comorbid cardiac disease
- the performance of spirometry can distinguish asthma from COPD, correcting misdiagnosis and possible mistreatment
- spirometry is a relatively simple, inexpensive and available test
- may provide easier access for patients if spirometry is performed in primary care
- shorter travelling distance for patients if spirometry is performed in primary care

Key findings and implications for policy makers

1. To determine future demand for resources for COPD, consensus must be reached on the definition of asthma and COPD.(242)

2. Spirometry is useful for the differential diagnosis of asthma and COPD, but using some defining criteria, could triple the number of adults being labelled as "at-risk" or with COPD.

3. Most evidence does not support the use of spirometry for screening in primary care.

4. Spirometry screening is likely to result in overdiagnosis of chronic lung disease, particularly in the elderly, and could result in prescription of medications for asymptomatic mild disease or for incorrectly diagnosed patients.

5. There are economic implications of widespread screening spirometry and a lack of a cost-effectiveness analyses in favour of screening.

6. Evidence suggests that spirometry results alone have not altered management of COPD in primary care. Only smoking cessation and influenza vaccination have been found to be effective in preventing symptom development in COPD.(191)

7. There is some evidence that early intervention with an inhaled corticosteroid in mild to moderate asthma may slightly reduce the loss of lung function (FEV_1) over a period of 3 years but the question of adverse effects of long-term corticosteroid inhalation in mild respiratory disease remains to be determined.
8. There is no current evidence that spirometry, as an isolated intervention, has aided smoking cessation.(246)

9. More widespread spirometry in primary care could lead to greater referral to respiratory specialist services.

10. Misdiagnosis from poor spirometry technique or non-compliance of patients may be a problem, so the reliability of spirometry measurements cannot always be guaranteed.

11. GPs or practice nurses may not have the training, knowledge or expertise to judge quality and interpret the results of spirometry.

12. Performance of spirometry in general practice produces extra workload and is poorly reimbursed.

13. Alternatives to general practice-based spirometry include: mobile community based spirometry services, pulmonary function laboratory provision of a spirometry service direct to GPs, local specialist respiratory nurse-run asthma clinics or the use of an alternative, more reliable, more easily performed test for the diagnosis of chronic lung disease.

14. Many barriers to the routine use of spirometry in primary care have been identified, such as, overdiagnosis, absence of quality assurance, costs, time constraints, lack of training and insufficient financial incentive.

4. DISCUSSION

This narrative review has been performed to consider models of chronic disease management for mild to moderate asthma and COPD in primary care. The literature review served as a basis for enquiry and analysis; informing questions developed for the selected models of chronic disease management.

When we commenced the review, we were overwhelmed by the volume of literature produced by the early searches. We tried to cope with this by identifying our own initial biases and prejudices so that we avoided tunnel vision. From a key research question, we developed a hypothesis to either confirm or reject: that models of chronic disease management, when applied in primary care, could lead to the recognition of risk factors and the early detection, diagnosis and management of mild to moderate asthma and COPD. Thus, we did not approach the extensive literature with a blank slate and the hypothesis provided us with a method of reducing the literature, as it helped us to judge what to read and what not to read.

We conducted an extensive literature search of black and grey literature to identify the current available evidence. In order to test the hypothesis, we evaluated models of chronic disease management in primary care: GPwSI services in respiratory care, practice nurses, clinical guidelines and the use of spirometry. Preference was given to the highest quality evidence available, while acknowledging that selected patients included in RCTs may not always reflect the patients presenting routinely in primary care. Due to time and financial constraints, this review did not attempt to capture all literature on the topic. Some papers may have been inadvertently omitted simply because of the volume of literature to be searched. We did not attempt to synthesize the evidence into a meta-analysis due to the variety of papers identified.
Although we preferred to review high quality evidence, it became apparent during the performance of the review that there was no neat hierarchy of evidence to support the hypothesis in relation to each of the models of chronic disease management reviewed. The little evidence available mainly related to moderate to severe disease managed in secondary and tertiary-referral facilities or was initiated by secondary and tertiary care facilities. Some studies included children. Inclusion criteria were often narrow, such as excluding smokers or the elderly. With the limited time frame for this review, it was impossible to re-evaluate each meta-analysis, so that only studies relevant to this review were included. Nor was this information readily available with some studies not indicating the severity of disease of the included patients. Many descriptive or viewpoint papers were identified, and we were unsure whether papers got in to the literature because they described the best programmes or were produced by the

keenest writers. However, these viewpoints provided some insights into the barriers perceived and experienced by GPs and general practices which would require consideration during policy development.

Randomised controlled trials were often limited by their short study duration. Short-term evaluation was usually routine due to the problems of financing longer-term studies and maintaining staff and interest from both research staff and consumers during the course of a study. However, demonstration of early successful implementation does not necessarily ensure longer-term effectiveness, particularly when side effects or adverse events may not appear for many years into the future.(120) The study quality of the RCTs identified was variable and reduced by the fact that the nature of the interventions meant that few studies could be double-blinded.

There was an absence of evidence supporting the hypothesis in relation to GPwSI services. We were unable to identify any meta-analyses or RCTs. One survey, conducted approximately 15 years ago, reported improved asthma care with GPwSI services but the results appeared to be influenced by the amount of time practices employed a practice nurse and there was a large amount of variability between practices. Evidence from evaluations of GPwSI services in other diseases indicated these were associated with considerable costs.
Evidence informing the hypothesis in relation to practice nurses was primarily obtained from studies in asthma. Practice nurse-run asthma clinics did not appear to provide additional benefit over usual GP care and appeared to be associated with some cost increases. There was an absence of evidence with regard to practice nurse-led COPD clinics.

The role of practice nurses may involve education of respiratory patients including instruction in disease self-management strategies. For asthma management, education alone did not appear to provide additional benefit. The evidence however, supported education combined with disease self-management programmes in improving health outcomes for asthma. The highest-level evidence was principally related to the management of moderate to severe asthma rather than to mild to moderate disease.

Evidence for the effectiveness of education and self-management programmes to improve health outcomes in COPD was equivocal, and the studies were predominantly conducted in moderate to severe disease. The results of two studies of self-management programmes for patients with mild to moderate COPD were possibly confounded by the inclusion of patients with asthma.

There was no evidence to support nurses educating other health professionals in disease management for mild to moderate asthma, and a lack of evidence in COPD, although one study suggested that some outcomes could be improved for patients with acute asthma. Interventions such as education and disease self-management programmes could be associated with increased costs.

Patients and GPs preferred practice nurses providing additional care. The evidence did not support the view that practice nurses could substitute for GP clinical management with nurses often poorly educated to provide respiratory care.

The evidence to support improved management of mild to moderate asthma or COPD in primary care through the use of guidelines was largely equivocal which may have

been a consequence of poor implementation strategies or to guidelines being primarily developed to advise the management of moderate to severe disease. The evidence from implementing new primary care guidelines developed by GPs for GPs is not yet available.

Although spirometry leads to improved diagnosis of asthma and COPD in primary care and is an important test in distinguishing between asthma and COPD, the studies did not support its widespread application as a screening tool. Disadvantages associated with spirometry screening in primary care included the lack of a consistent definition for COPD, probable overdiagnosis of disease particularly in non symptomatic patients, the lack of effective treatment for mild to moderate COPD and the cost of implementing widespread screening. Spirometry as a motivational tool for smoking cessation did not appear to be effective. There was limited evidence to suggest that the results of spirometry could alter clinical management for mild asthma. Inhaled corticosteroids may have a small benefit on lung function in asthma although questions about the long-term effects of this therapy have not been answered.

The failure for many of the RCTs reviewed to demonstrate consistent improvements in health outcomes could be due to the fact that patients with mild to moderate disease may have few symptoms and so have less room for improvement than patients with severe disease. In addition, improvements in some outcomes, such as a reduced rate of decline of lung function, may only be detectable over several years. To demonstrate improvements in outcomes for these patients would require well-designed, high quality studies including large numbers of patients with follow-up periods of much longer duration than the general 1 to 2 years of current studies.

This review highlighted the fact that narrative reviews address the perennial questions: the art rather than the science of health services policy. The perennial questions include: population versus individual perspective, hospital versus community care, scientific versus humanitarian practitioner and
better patient health versus cost-containment

The lack of consistent evidence across studies, with many providing equivocal evidence or only one or two improved health outcomes amongst the many outcomes investigated, highlighted the fact that these perennial questions are never finally solved, but interim, unstable and provisional resolutions are arrived at for particular contexts of time and place and person. Models of disease management are often developed to fill service gaps or in response to short-term views of policy makers rather than as planned responses to local needs.(31) Models of care may be being implemented by health care providers with limited resources in the interests of enhancing care at reduced costs.(10) However, many interventions required additional funding and administrative support to assist busy GPs.

5. CONCLUSIONS

Disappointingly, this review of the literature of models of chronic disease management in primary care for mild to moderate asthma and COPD has provided little high quality evidence to support or refute the hypothesis in relation to the various models of disease management reviewed. Most of the evidence relating to primary care was equivocal. Few available studies, variation in study design, short follow-up periods and the fact that very few studies included patients with mild to moderate disease made it difficult to reach conclusions. Numerous barriers were identified in relation to the

implementation of many of the chronic disease management programmes. Before these models can be successfully implemented in primary care, appropriate support, both financial and administrative, must be provided.

Since mild to moderate asthma and COPD are such important health problems in the community, and can progress into disabling conditions yet may present with few symptoms in the early disease stages, there is a pressing need for large well-designed randomised primary care-based clinical trials of sufficient statistical power to be conducted – and an even more pressing need to clarify what is likely to be the most fruitful primary care approach to these conditions.

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7. APPENDICES

ADDENDUM

September 2006

Information from Section 4 "Spirometry in primary care" of this narrative review, including the estimated cost of performing spirometry in primary care, has been provided to The Australian Lung Foundation to inform a budget submission to the Australian Government, the Commonwealth Treasury. This submission resulted from a previous submission to the Federal Government's Backbench Committee on Health and Ageing, Inquiry into Health Funding, in July 2006.

APPENDIX 1

PROJECT TEAM

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STOCKS Nigel	Professor, Head, Discipline of General Practice, Director Primary Health Care Research Evaluation and Development (PHCRED) Program, Director Australian Sentinel Practices Research Network (ASPREN), School of Population Health and Clinical Practice, Assistant Dean (student) Medical School, Faculty of Health Sciences, University of Adelaide. 5005 South Australia

APPENDIX 2

DETAILS OF SEARCH STRATEGIES

Search strategy for PubMed

obstructive airway disease OR chronic obstructive lung disease OR chronic obstructive pulmonary disease OR chronic airflow obstruction* OR copd OR coad OR chronic bronchitis OR pulmonary emphysema* OR asthma OR asthmas OR exercise induced asthma OR exercise-induced asthma) AND (primary care OR primary health care OR primary health care OR primary medical care OR primary practice* OR family care OR family medicine OR family practice OR family practices OR general practice* OR primary practitioner* OR family practitioner OR general practitioner OR family physicians OR family physician OR physicians, family) AND ((care plan OR care plans OR care planning OR medical plan OR medical plans OR medical planning OR case* management OR critical path* OR patient-centered OR patient centered or patient-centred OR patient centred OR health care OR health care OR health service* OR managed care OR telemedicine OR remote consultation* OR teleconsult*) AND (organization OR organization* OR organisation OR organisation* OR model*) OR (models of care OR care model* OR models, organizational OR organi* model* OR models, theoretical OR patient care management/organization and administration)) AND (adult OR adults OR aged OR elderly OR middle age*) NOT (child OR children OR infant OR infants OR adolescents OR adolescent OR adolescence OR pediatric OR paediatric)

Ovid MEDLINE(R) 1966 to November 2005

1. controlled.ab.
2. design.ab.
3. evidence.ab.
4. extraction.ab.
5. randomised controlled trials/
6. meta-analysis.pt.
7. review.pt.
8. sources.ab.
9. studies.ab
10. or/1-9
11. letter.pt.
12. comment.pt.
13. editorial.pt.
14. or/11-13
15. 10 NOT 14
16. exp lung disease, obstructive/
17. asthma, exercise-induced/
18. 16 OR 17
19. exp adult/
20. exp patient care management/
21. family practice/
22. 20 OR 21
23. 15 AND 18 AND 19 AND 22

APPENDIX 3

Databases and websites searched

- CHSRF - Canadian Health Services Research Foundation
- CMA infobase - Canadian Medical Association
- The Cochrane Library
- Current contents
- EFPC - European Forum for Primary Care (European Public Health Alliance)
- EMBASE
- EPOC - Cochrane Effective Practice and Organisation Care Group
- EPPI-Centre - The Evidence for Policy and Practice Information and Co-ordinating Centre, University of London
- ERIC - Education Resources Information Center
- Health Evidence.ca - Effectiveness of public health and health promotion interventions, Canada.
- HSTAT - Health Services/Technology Assessment Text
- Informit - Australia
- IngentaConnect
- Joanna Briggs Institute
- King's Fund (UK)
- LocatorPLus - National Library of Medicine
- NGC - National Guideline Clearing House, US
- NICE - National Institute for Health and Clinical Excellence, London
- NICS - National Institute of Clinical Studies, Australia
- NPCRDC - National Primary Care Research and Development Centre, UK
- OMNI - Organising Medical Networked Information, UK
- OVID CINAHL - Cumulative Index to Nursing & Allied Health Literature
- OVID ECONLit
- OVID MEDLINE
- OVID PsycINFO
- PHC RIS (Primary health care research and information service)
- PROS (Population research and Outcome Studies)
- PubMed (National Library of Medicine)
- ReFeR (Research findings electronic register)
- SIGN (Scottish Intercollegiate Guidelines Network)
- Sinapse (Sooner Information Network)
- WorldCat

Other websites:
Australian State Government Departments of Health, Department of Health Canberra, Australian Lung Foundation, National Asthma Council Australia and individual State Asthma Foundation websites.

APPENDIX 4

Prevalence estimates for asthma and COPD by study

Study	Country	Disease	Plan of study Inclusion criteria	Design and methods	Participants Age (years) Smoking	Prevalence (%)	Total sample size
Appleton S., 2005(199)	South Australia	Asthma	Case-finding Diagnosis FEV_1 reversibility criteria: ≥12%, ≥15%, ≥9% pred. ≥400ml	Cohort study	≥18	Current asthma, 9.4% FEV_1 reversibility ranged from 2.0% (≥400mL) to 6.2% (≥9% of predicted).	4,002 Randomly selected community population. Questionnaire followed by interview and spirometry.
Devereux G., 1996(200)	United Kingdom	Asthma	Case-finding Diagnosis Methacholine challenge; positive airways responsiveness (PD_{20} ≤6,400 micrograms)	Cross-sectional study	20-44 Males	27.7% (West Cumbria) 28.2% (Newcastle)	608 Postal survey of randomly selected men followed by spirometry and methacholine challenge on a random sample of respondents.
Dow L., 2001(201)	United Kingdom	Asthma	Spirometry FEV_1/FVC ≤0.7 Reversibility; FEV_1 ≥15% increase post bronchodilator and FEV_1 increase ≥200ml PEF variability ≥20% over one or more days	Cross-sectional study	≥65	1.7% Asthma in previously untreated adults. Disease mostly moderate to severe.	280 General practice patients not receiving treatment for respiratory disease. Questionnaire followed by spirometry.
D'Souza W., 1999(202)	New Zealand	Asthma	Case-finding Methacholine challenge	Cross-sectional study	20-44	24.9% Positive airways responsiveness.	1,257 Random sample of respondents to a respiratory screening questionnaire.
Isoaho R., 1994(203)	Finland	Current asthma	Case-finding Asthma verified by: Diurnal variation in PEF by ≥20% FEV_1 ≥15% increase post bronchodilator, Methacholine challenge PEF at least 15% decrease	Cross-sectional study	≥64	Males: 2.9% Females: 3.8%	1,196 Rural population study Symptom questionnaires followed by spirometry.
Macy E., 2005(204)	United States	Asthma	Management of mild asthma Reversibility FEV_1 ≥12% increase	Cross-sectional study	18-64 Asthma patients	62.1% Patients with previously diagnosed low-risk asthma had their asthma confirmed.	400 Randomly selected patients with low-risk asthma.

Study	Country	Disease	Plan of study Inclusion criteria	Design and methods	Participants Age (years) Smoking	Prevalence (%)	Total sample size
			post albuterol or ≥15% increase				
			post advair or positive methacholine challenge				
Thiadens HAI., 2000(205)	The Netherlands	Asthma	Case-finding Diagnosis Bronchial obstruction (FEV_1 <FEV_1 %pred. minus 1.64 RSD) Bronchial hyperresponsiveness PD_{20} ≤15.6 μmole methacholine	Cross-sectional study	18-75	36.9% patients with symptoms of acute bronchitis in general practice had asthma based on questionnaire, spirometry and methacholine challenge.	192 Patients who had contacted GP with coughing. Questionnaire and spirometry performed at baseline, 2 and 8 weeks. Medical records were checked after one year.
van Schayck CP., 2000(206)	The Netherlands	Asthma	Case-finding Diagnosis Spirometry Bronchial obstruction defined as FEV_1 <FEV_1 %pred. minus 1.64 RSD on two occasions Asthma-related symptoms Histamine challenge	Cross-sectional study	25-70	7.4% Airflow obstruction and symptoms suggestive of asthma 34% of these patients had presented their symptoms to the general practitioner.	1,155 DIMCA† project Random sample patients from general practice without known lung disease Questionnaire and spirometry.
Celli BR., 2005(195)	United States	Airway obstruction	Case-finding Diagnosis FEV_1/FVC <0.7	Cross-sectional study	30-80 years Non-smokers	Never smokers: 9.1% Ever smokers: 21.9% 68.5% obstructed never smokers had no prior respiratory diagnosis.	4,544 (NHANES III)* General population sample of non-smokers who had completed a health questionnaire. Never smokers represented 42% NHANES III survey population selected to be a representative sample of the US population.
Dales REI., 2005(196)	Canada	Airway obstruction	Case-finding Diagnosis (FEV_1/FC <0.7) Management	Cross-sectional study	≥35 years ≥20 packs cigarettes over lifetime	17.4% (9% new diagnosis, 11% diagnosis of airflow obstruction removed.) Doctor planned to change management based on spirometry in 15% patients. Documentation that management had changed was present in	1,034 Ever smokers attending primary care for any reason. Interviewer-administered respiratory questionnaire Spirometry

			minimal number of patients.				
Study	Country	Disease	Plan of study Inclusion criteria	Design and methods	Participants Age (years) Smoking	Prevalence (%)	Total sample size
Geijer RM., 2005(197)	The Netherlands	Airway obstruction	Case-finding Diagnosis GOLD Stage 1 (mild): FEV_1/FVC <0.7 and FEV_1 ≥80% predicted GOLD Stage 2 (moderate): FEV_1 50-79% pred.	Cross-sectional study, part of a cohort study	40-65 Male Smokers No known lung disease.	29.9% previously undetected airflow obstruction (mild: 25.9%, moderate: 4.0%) Prevalence increased with age and increasing pack years.	702 Ijsselstein study Smokers were identified by letter. Subjects with documented lung disease excluded. HRQoL questionnaire Spirometry
Matheson MC., 2006(166)	Australia	Asthma COPD	Case-finding Diagnosis (GOLD)+ Stage 2; FEV_1/FVC <0.7 and FEV_1 <80%pred. Reversibility; FEV_1 ≥12% post bronchodilator FEV_1 increase ≥200ml	Cross-sectional study	45-70	COPD: 6.8% (GOLD stage 2 or 3) (10% of these had prior doctor's diagnosis of COPD) Current asthma: 12.5% 28.7% current asthmatics had COPD	1,224 General population sample. Questionnaire Spirometry Methacholine challenge Transfer factor
Murtagh E., 2005(198)	United Kingdom	Asthma COPD	Case-finding Diagnosis FEV_1 <80% predicted Reversibility; FEV_1 ≥15% post bronchodilator	Cohort study	40-69	COPD: 6.3% Asthma: 7.2% Prevalence of COPD increased with age.	722 (NICECOPD study)** General population sample. Postal questionnaire to determine risk factors, symptoms and prior diagnosis followed by spirometry with reversibility testing in a sample of 350 symptomatic and 450 asymptomatic patients.

† DIMCA: Early detection, Intervention and Monitoring of Asthma and COPD
‡ ECRHS: European Community Respiratory Health Survey
+ GOLD: Global initiative for chronic obstructive lung disease
* NHANES III: National Health and Nutrition Examination Survey
** NICECOPD: Northern Ireland Cost and Epidemiology of Chronic obstructive Pulmonary Disease

COPD:Chronic obstructive pulmonary disease, FEV_1: Forced expiratory volume in 1 second, FVC: Forced vital capacity, HRQoL: Health-related quality of life, PD_{20}: Provocative dose of a substance that reduces FEV_1 by 20%, PEF: Peak expiratory flow, %Pred: Percentage of predicted value, RSD: Residual standard deviation

Guidelines table (Asthma). Information and categories from the National Guideline Clearinghouse

Acronym	GINA						SIGN		
Guideline title	Global strategy for asthma management and prevention	Diagnosis and outpatient management of asthma	Long-term management of asthma	Asthma Management Handbook 2002	The diagnosis and treatment of adult asthma	Evidence-based guideline on the primary care management of asthma	British guideline on the management of asthma. A clinical national guideline	Guidelines for the prevention, identification and management of occupational asthma	Management of asthma
Date released	1995 Jan (revised 2005)	1998 (revised 2005)	2001 (revised 2004)	2002 updated from 1998	2002	1996 (revised 2001)	2003 (revised 2005)	2004	2006
Country	United States	United States	Finland	Australia	New Zealand	United Kingdom	United Kingdom	United Kingdom	United Kingdom
Chief Author	O'Byrne P.,(16)	Sveum R.,(135)	Keistinen T.,(131)	Tomlins R.,(105)	Town I. (138)	Eccles M.,(139)	Not stated(140)	Newman Taylor AJ.,(141)	Van der Molen T.(128)
Adaptation	No adaptation	No adaptation	No adaptation	Not stated	No adaptation	Adapted from the North of England Asthma Guideline	No adaptation	No adaptation	Adapted from GINA
Guideline developer(s)	National Heart, Lung, and Blood Institute, World Health Organisation	Institute for Clinical Systems Improvement (ICSI)	Finnish Medical Society Duodecim - Professional Association	National Asthma Council Australia	New Zealand Guidelines Group	North of England Asthma Guideline Development Group	British Thoracic Society, Scottish Intercollegiate Guidelines Network (SIGN)	British Occupational Health Research Foundation	International Primary Care Respiratory Group (IPCRG)
Source)s) of funding	Altana, Andi-Ventis, AstraZeneca, Aventis, Bayer, Boehringer Ingelheim, Chiesi Group, GlaxoSmith Kline, Merck, Sharp & Dohme, Mitsubishi-Pharma Corporation, Nikken Chemicals, Novartis, Schering-Plough, International, Viatris.	Minnesota health plans: Blue Cross and Blue Shield of Minnesota, Health Partners, Medica, Metropolitan Health Plan, PreferredOne, UCare Minnesota. In-kind support provided ICSI	Finnish Medical Society Duodecim	Allan and Hanburys AstraZeneca, Australia Dairy Corp. Aventis, Pharma, Boehringer Ingelheim Dunlop, Dyson, Essex Pharma, GlaxoSmith Kline, MBF, Medibank Private, Merck Sharp & Dohme, Micro Medical, Novartis, Proctor and Gamble, 3M Pharmaceuticals, Sharp	The New Zealand Ministry of Health	Northern and Yorkshire Regional Health Authority. Medical audit advisory groups of Durham, Northumberland, and South Tyneside Family Health Services Authorities	Scottish Executive Health Department. Dissemination project received financial assistance from: GlaxoSmith Kline, AstraZeneca, 3 M, MSD, Schering - Plough, italograph, IVAX and Clement Clarke	British Occupational Health Research Foundation	Altana, AstraZeneca, Boehringer Ingelheim, EAMG, GlaxoSmithKline, Merck, Sharp and Dohme, Mitsubishi Pharma, Novartis, UCB Pharma, Zambon.
Conflicts of interest	Not stated	Nil	Not stated	Not stated	Stated	None	Stated	Not stated	Stated
Disease	Asthma	Asthma	Asthma	Asthma	Asthma	Asthma	Asthma	Allergic	Asthma

								occupational asthma	
Guideline category	Diagnosis Evaluation Management Prevention Treatment	Counselling Diagnosis Evaluation Management Treatment	Evaluation Management Treatment	Diagnosis Management Treatment	Diagnosis Evaluation Management Treatment	Treatment Management	Diagnosis Evaluation Management Prevention Treatment	Diagnosis Management Prevention Risk assessment Treatment	Treatment Management
Intended users	Practice nurses Physicians Public health departments Respiratory physicians	Practice Nurses Allied Health Health Care Providers Health Plans Hospitals Nurses Physicians	Health care providers Physicians	General practitioners, Community pharmacists Asthma educators Health professionals Students	Practice nurses Health care providers Patients Physicians	Primary health care professionals	Practice nurses Nurses Pharmacists Physicians	Practice nurses Patients Physicians Respiratory Physicians	Primary health care professionals
Objectives	Comprehensive recommendations on asthma management Improve HRQoL Disseminate information Promote research Provide knowledge base	Assessment of asthma severity (lung function measurement) Control of persistent asthma (inhaled corticosteroids) Promote partnerships between patients and health care providers through education and use of action plans	To collect, summarise, and update the core clinical knowledge essential in general practice. Describe the scientific evidence underlying treatment recommendations	Practical guide for: Detection/diagnosis (spirometry) Management Treatment Review (3+ Visit Plan) Develop action plan Patient education	Provide an evidence-base for diagnosis, management and treatment of asthma in New Zealand adults Aid evaluation of evidence and make informed decisions to improve health outcomes	Provide recommendations (evidence-based when possible) to guide primary health care professionals in management of adult patients with asthma	Comprehensive recommendations on asthma management for patients of all ages in both primary and secondary care	Improve prevention, identification, and management of occupational asthma in primary care and in occupational health. To reduce the incidence of asthma caused by substances at work by 30% by 2010	Relieve symptoms Prevent and treat exacerbations Allow normal activity Prevent mortality Prevent disease progression Avoid adverse effects from medications Education, advice Smoking cessation
Target population	All patients with asthma world -wide	Patients over 5 years of age with asthma-like symptoms or diagnosis of asthma	Patients with asthma	Adults and children with asthma	Adults 16+ years	Adult patients with asthma	All patients with asthma	Patients with asthma	Adults and children with asthma
Cost analysis performed	Yes	No	No	No	No	No	No	No	No
Methods used to assess quality of the evidence	Rating scheme A: Randomised controlled trials - rich body of data. B: Randomised controlled trials - limited data C: Non-randomised trials D: Consensus	According to a rating scheme	Rating scheme A. Strong evidence. high-quality studies, homogeneous results. B. Moderate evidence. At least one relevant, high-quality study or multiple adequate	Rating system 1: Systematic review of randomised controlled trials 2: One or more randomised controlled trials 3: Controlled trials without randomisation 4: Observational	Rating scheme According to SIGN	Rating scheme (I): Based on well designed randomised controlled trials, meta-analyses, or systematic reviews (II): Based on well designed cohort or case-control studies (III): Based on	Rating scale 1: Meta-analyses, systematic reviews RCTs with a low risk of bias. 2: Systematic reviews of case control or cohort studies. 3: Non-analytic studies 4: Expert opinion	Rating scheme According to SIGN and BTS	Three star system of the Royal College of General Practitioners

			studies. C. Limited evidence. At least one adequate study. D. No scientific evidence. Expert panel evaluation.	studies 5: Opinions, descriptive studies or reports of expert committees		uncontrolled studies or consensus			
Methods used to analyse the evidence	Review of meta-analyses Systematic reviews with evidence tables	Systematic review with evidence tables	Review of published meta-analyses Systematic reviews	Incorporating key elements of evidence-based guidelines and consensus opinion	Review of published meta-analyses Systematic reviews	Qualitative of published data	Systematic reviews	Review of published meta-analyses Systematic reviews with evidence tables	Evidence-based guidelines, together with epidemiological evidence
Methods used to formulate recommendations	Expert consensus	Not stated	Not stated	Consensus opinion	Expert consensus	Consensus methods	Expert consensus	Expert consensus	Expert consensus
Method of guideline validation	External peer review Internal peer review	Clinical validation-pilot testing Internal peer review	Peer review	Peer review	Clinical validation External peer review Internal peer review	External reviewers	External peer review Internal peer review	External peer review	Peer review by guideline group
Clinical algorithm	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Implementation plan developed	Yes	Yes	No	Not stated in guideline	Yes	No	Yes	No	No
Evaluation, and uptake of guideline	Yes, various studies	Evaluation occurs throughout a pilot phase	Yes	Yes	Yes	Evaluation of a computerised guideline	Number of hits and downloads from websites collected	No	No
Patient information	Yes	Yes	No	Yes	No	No	Available from website	Yes	No

Source: National Guideline ClearinghouseTM Agency for Health care Research and Quality, US. http://www.guideline.gov/

GINA: Global initiative for asthma, ICSI: Institute for Clinical Systems Improvement, IPCRG: International Primary Care Respiratory Group, SIGN: Scottish Intercollegiate Guidelines Network

Guidelines Table (COPD). Information and categories from the National Guideline Clearinghouse

Guideline acronym	GOLD			COPDX		NICE		
Guideline title	Global strategy for the diagnosis, management and prevention of COPD. Standards for the diagnosis and treatment of patients with COPD.	Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	The COPDX Plan: Australian and New Zealand guidelines for the management of chronic obstructive pulmonary disease	NSW Action plan for health. A practical guide for the optimal treatment of chronic respiratory disease	National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care	Diagnosis of respiratory diseases in primary care	Management of chronic obstructive pulmonary disease (COPD)
Date released	GOLD 2001,(18) updated 2005,(110) ATS/ERS 2004	2001, revised 2005	2002 (revised 2005)	2003 GP hand book 2003 GP algorithm 2004	2003	2004	2006	2006
Country	United States Europe	United States	Finland	Australia	Australia (New South Wales)	United Kingdom	United Kingdom	United Kingdom
Chief author	Buist S.,(119) ATS/ERS Celli B.,(132)	Mickman J.,(133)	Kinnula V.,(129)	McKenzie D.,(134)	Department of Health,(136)	NICE., (125)	Levy ML.,(126)	Bellamy D.,(127)
Adaptation	ATS/ERS updated from GOLD, ATS and ERS guidelines	No adaptation	No adaptation	Adapted from GOLD	Adapted from GOLD and recommendations of the National Asthma Council, Australia	No adaptation	Adapted from GOLD	Adapted from GOLD
Guideline developers	National Heart, Lung, and Blood Institute - Federal Government Agency [US] World Health Organization American/European Thoracic Societies	Institute for Clinical Systems Improvement	Finnish Medical Society Duodecim - Professional Association	Thoracic Society of Australia and New Zealand and the Australian Lung Foundation	Respiratory Clinical Expert Reference Group (NSW)	National Collaborating Centre for Chronic Conditions - National Government Agency [Non-US]	International Primary Care Respiratory Group (IPCRG)	International Primary Care Respiratory Group (IPCRG)
Source(s) of funding	Altana, Andi-Ventis, Astra Zeneca, Aventis, Bayer, Boehringer Ingelheim, Chiesi, Glaxo SmithKline, Merck, Sharp and Dohme, Mitsubishi Pharma, Nikken Chemicals, Novartis, Pfizer, Schering-Plough, Zambon	Minnesota health plans provide direct financial support	Finnish Medical Society Duodecim	Boehringer Ingelheim GlaxoSmithKline Air Liquide Health care Pty Ltd BOC Medical	Not stated	National Institute for Clinical Excellence (NICE)	Altana, AstraZeneca, Boehringer Ingelheim, EAMG, GlaxoSmith Kline, Merck, Sharp and Dohme, Mitsubishi Pharma, Novartis, UCB Pharma, and Zambon	Altana, AstraZeneca, Boehringer Ingelheim, EAMG, GlaxoSmith Kline, Merck, Sharp and Dohme, Mitsubishi Pharma, Novartis, UCB Pharma, Zambon
Conflicts of interest	Not stated	Nil	Not stated	Not stated	Not stated	Stated	Stated	Stated
Disease	COPD	COPD	COPD	COPD	COPD, Asthma	COPD	Respiratory diseases	COPD

Guideline category	Diagnosis Evaluation Management Prevention Treatment	Diagnosis Evaluation Management Treatment	Diagnosis Management Treatment	Diagnosis Management Treatment	Diagnosis and severity Prevention Detection, Management Treatment Education	Diagnosis Evaluation Management Treatment	Diagnosis	Classification of disease severity Management Treatment
Intended users	Practice nurses Allied health personnel Nurses Physicians Public Health Departments	Practice nurses Allied health personnel Health plans Nurses Patients Pharmacists Physicians	Health care providers Physicians	Not stated but distributed to general practitioners	General practitioners Pharmacists Asthma educators Students Other clinicians	Practice nurses Allied health professionals Patients Physicians Public health departments Students	Primary care health professionals	Primary care health professionals
Objectives	Management and prevention of COPD in all countries Increase awareness of COPD Decrease morbidity and mortality Encourage research	Increase use of spirometry for diagnosis Increase smoking cessation advice Reduce exacerbations Education and improved management	To improve knowledge in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.	Confirm diagnosis Optimise function Prevent deterioration Develop support network and self-management plan Manage exacerbations	Evidence-based clinical standards, targets and milestones for asthma and COPD	Management of COPD for use in the National Health Service in England and Wales	Early identification and diagnosis of chronic respiratory disease through questionnaires and diagnosis guides	Management of COPD in primary care
Target population	Adults with COPD	Stable and acute COPD patients	Adults with COPD or possible COPD	Adults over 35 years with smoking history	Patients with chronic respiratory disease	Adults with a clinical diagnosis COPD	Adults and children with suggestive symptoms presenting to primary care	Adults with diagnosed COPD
Cost analysis performed	Yes	Yes	No	No	Planned	Yes	No	No
Methods used to assess quality of the evidence	Weighting according to a rating scheme A: Randomised controlled trials Rich body of data B: Randomised controlled trials, limited data C: Nonrandomised trials Observational studies D: Panel consensus	Weighting according to a rating scheme	Levels of evidence A: Strong research based evidence. Multiple relevant, high-quality scientific studies with homogeneous results. B: Moderate research based evidence. At least one relevant, high-quality study or multiple adequate studies. C: Limited research based evidence. At least one adequate scientific study D: Expert panel evaluation	Levels of evidence according to the National Heart, Lung and Blood Institute	Levels of evidence according to the National Heart, Lung and Blood Institute	Hierarchy of evidence Levels of evidence Ia, ib, IIa, IIb, III, IV and recommendations graded from A-D	Three star system of the Royal College of General Practitioners	Three star system of the Royal College of General Practitioners
Methods used to analyse the	Review of published meta-analyses.	Review of published meta-analyses	Review of published meta-analyses	Incorporating key elements of evidence-	Not stated	Review of published meta-analyses	Incorporating key elements of evidence-	Incorporating key elements of evidence-

evidence	Systematic review with Evidence tables		Systematic review	based guidelines, together with evidence from published papers		Systematic review with evidence tables	based guidelines, together with epidemiological evidence	based guidelines, together with evidence from published papers
Methods used to formulate recommendations	Expert consensus	Not stated	Not stated	Expert consensus	Expert consensus	Expert consensus	Expert consensus	Expert consensus
Method of guideline validation	Comparison with guidelines from other groups External peer review Internal peer review	Clinical Validation-Pilot Testing Internal Peer Review	Peer review	Peer review by members of the Thoracic Society of Australia and New Zealand and Australian Divisions of General Practice	Not stated	External peer review Internal peer review	Peer review by guideline group	Peer review by guideline group
Clinical algorithm	No	Yes	No	Yes	Yes	Yes	Yes	Yes
Implementation plan developed	No	Yes	No	Yes	Yes	Yes	Yes	Yes
Evaluation and uptake of guideline	Not performed	Not stated	Unknown	Not performed	Planned	Not performed	Planned	Planned
Patient information	Yes	No	No	COPD action plan	No	Yes	Not relevant	No

Source: National Guideline ClearinghouseTM Agency for Health care Research and Quality, US. http://www.guideline.gov/

COPD: Chronic obstructive pulmonary disease
ATS: American Thoracic Society, ERS: European Thoracic Society, GOLD: Global initiative for chronic obstructive lung disease, ICSI: Institute for Clinical Systems Improvement, IPCRG: International Primary Care Respiratory Group, NICE: National Institute for Health and Clinical Excellence, NSW: New South Wales

Descriptive table for meta-analyses, randomised controlled trials and comparative studies

Study	Type of article	Time/place Duration of follow-up	Setting, Participants, Patient age, sample size	Main aim Target group involvement	Study design/Outcomes	Results: findings/subgroup effects	Strengths	Limitations of the study/ Study quality for RCTs (Jadad scale)	Conclusions/ Implications
General practitioners with a special interest									
Jones KP., 1995(34)	Peer-reviewed journal article	1991 United Kingdom	Primary care Members of the General Practitioners in Asthma Group N=163 (70% practices)	Define the characteristics of general practices with a special interest in asthma. To estimate the resulting prescribing costs. Questionnaire developed by the General Practitioners in Asthma group.	Postal survey Quantitative and qualitative analysis Comparison of responses from practices using a written asthma protocol before 1990 (Group A) with those using a written asthma protocol after 1990 (Group B) and those with no protocol (Group C).	Large variations in costs. Prescribing costs for respiratory drugs were greater for Group A, but costs of other drugs were less. No overall increase in total drug cost for group A.	Provision of some cost information.	Large variations within groups. Duration of use of an asthma protocol by Group A practices varied 13 to 82 months. Asthma nurse hours varied from 0-2.9 per 1000 patients Respiratory drug prescribing costs were proportional to respiratory nurse hours.	Provision of a GPwSI service may be associated with some respiratory drug cost increases.
Nurse-led interventions									
Respiratory clinics for asthma and COPD									
Fay JK., 2002(51)	Peer-reviewed journal article	2002 Australia	Primary care Adults and children attending primary care-based clinics for asthma N=195 Patients recruited from 8 general practices	Determine the effectiveness of organised asthma care via primary care-based asthma clinics.	Cochrane review of 1 RCT. Comparison of nurse-run asthma clinics versus standard general practice. Intervention: Asthma education conducted by respiratory practice nurses (3 hour session, 3-visits over 6 months). Outcomes: Action plans Health care use Peak flow meters Symptoms Smoking Time off work/school	After 6- months, asthma clinics associated with: Reduction in nocturnal symptoms (Odds ratio (OR) 0.38 (95% CI 0.16-0.91) Owning a peak-flow meter (OR 8.3 (95%CI 2.96-23.27) Commencing or resuming smoking (OR 3.97 (95%CI 1.11-14.25) No difference between control and intervention groups for other outcomes.	Meta-analysis Asthma clinic attendance reduced nocturnal waking. Symptoms in both intervention and control groups improved during the study.	Only one RCT included in the meta-analysis. Short duration (6 months). The number of patients commencing or resuming smoking increased in the intervention group. The same GPs saw both intervention and control patients so there was a possibility of contamination of the control group. Quality=2.	There is limited evidence of benefit for primary care-based asthma clinics. Asthma clinics were not more effective than standard general practice for reducing asthma morbidity. More studies are required.
Lindberg M., 2002(94)	Peer-reviewed journal article	Sweden Multi-centre	Primary care Patients attending asthma clinics. Retrospective audit of patient records. Patient questionnaire	Comparison between nurse-led asthma care and traditional care	Comparative study Case note audit, patient survey Outcomes: Costs Asthma symptoms Lung function testing	Retrospective review Nurse-led care was associated with improved documentation of: Lung function Reversibility testing, Smoking	Nurse-led care May have improved patient's ability to self-manage their disease.	Survey data only. Only 20 records were reviewed for details of nurse-led care compared with 132 non-nurse-led care. Low response rate in the	Nurse-led asthma clinics may improve some outcomes of asthma care and may be associated with reduced costs

Study	Type of article	Time/place Duration of follow-up	Setting, Participants, Patient age, sample size	Main aim Target group involvement	Study design/Outcomes	Results: findings/subgroup effects	Strengths	Limitations of the study/ Study quality for RCT (Jadad scale)	Conclusions/ Implications
			Retrospective audit N=152 (nurse-led care n=20, traditional care n=132) Patient questionnaire: N=347		Asthma appointments	habits. Nurse-led care associated with improved: Peak flow measurement Knowledge Symptoms		traditional care group (53%) may indicate that not all patients in this group received the questionnaire.	
Martys CR., 1992(103)	Peer-reviewed journal article	1989-1990 United Kingdom Single-centre 1 year	General practice Asthma 161 pre-clinic, 238 post-clinic patients with asthma.	Assessment of asthma care after GP-led asthma clinic	Audit of medical records. Outcomes: Number of asthmatic patients Medication use Smoking history Hospital admissions for asthma	Results: Improvement in documentation of: Peak flow measurement Smoking history No improvement in: Asthma review Recording of medication Treating acute asthma	Improvement in recording of some outcomes. No improvement in objective changes	Different patients assessed before and after the intervention.	Clinic session became fully booked with the increasing emphasis placed on identifying asthma patients, leading to a reduction in the percentage of patients reviewed.
Mundinger MO., 2000(71)	Peer-reviewed journal article	1995-1997 United States Multi-centre 6 months	Primary care Patients with asthma, hypertension and diabetes included N=1981 (38.7% patients screened)	Comparison of outcomes after nurse practitioner or physician-led care	Randomised comparative study Outcomes: Patient satisfaction HRQoL Health care service use	Results: Patient outcomes were comparable with both physician-led and nurse practitioner-led care.		Subgroup analysis: Peak flow was the only outcome analysed for asthma patients.	Significance of findings in relation to asthma outcomes was not reported.
Pearce C., 2004(87)	Peer-reviewed journal article	Australia Multi-centre	Primary care Patients attending asthma clinics	Evaluate costs and knowledge after attendance to asthma clinics	Qualitative survey post intervention Outcomes: Quality of care Patient and GP satisfaction Patient knowledge Costs	Patients appeared to improve their knowledge of asthma and rated the clinics as at least helpful. Program was cost neutral	The Division of General Practice was essential to provide support and financial assistance.	Effectiveness of the clinic was not evaluated. No comparison with baseline or a control group.	The General Practices did not have the administrative or financial capacity to develop clinics without assistance from The Division of General Practice
Pilotto LS., 2004(70)	Peer-reviewed journal article	Australia Multi-centre 6-9months	Primary care Adults from 11 general practices N=170 Intervention n=80 Control n=90 153 participants completed follow-up	Assess the ability of nurse-run asthma clinics in general practice compared with usual medical care to improve HRQoL of asthma patients. GPs invited patients to participate.	RCT Intervention: Nurse-run asthma clinics followed by GP visit Outcomes: Lung function Patient compliance HRQoL Smoking cessation	No difference between intervention and control for: HRQoL scores Lung function Owning an action plan Smoking cessation Intervention group more likely to attend hospital outpatient departments but took fewer days off work.	Symptoms in both intervention and control groups improved during the study.	Poor compliance: only 36% intervention patients attended three clinic appointments. Only 10% intervention patients and 7% control patients had written action plans at the end of the study. Quality=3.	Participants attending nurse-run asthma clinics did not achieve greater improvements in HRQoL or lung function compared with usual GP care. No substantial impact on smoking cessation.

Study	Type of article	Time/place Duration of follow-up	Setting, Participants, Patient age, sample size	Main aim Target group involvement	Study design/Outcomes	Results: findings/subgroup effects	Strengths	Limitations of the study/ Study quality for RCT (Jadad scale)	Conclusions/ Implications
Rea H., et al. 2004(72)	Peer-reviewed journal article	1999-2000 New Zealand Multi-ethnic, deprived population Multi-centre 12months	Primary care and hospital 66 GP practices approached, 51 practices randomised. Adults from 35 practices participated in study. N=135 Intervention n=83, Control n=52 Dropouts n=18 Practice nurse participation varied across sites.	Comparison of effect of a disease management programme, including a COPD management guideline, a patient-specific care plan and collaboration between patients, general practitioners, practice nurses, hospital physicians and nurse specialists with conventional care.	RCT Before and after comparison of collaborative disease management intervention versus control Outcomes: Hospitalisations Lung function Walk test difference HRQoL	Intervention group: Reduction in mean hospital bed days. Improvement in pulmonary function, walking distance, and two dimensions of HRQoL (fatigue and mastery) compared with conventional care.	Disease specific program reduced hospital admissions and hospital bed days for selected patients.	Patients not evenly distributed between the practices (11 practices had no eligible patients and an additional 5 practices did not participate). Only 19% patients screened were enrolled in the study. Multi interventions: unable to isolate helpful interventions. Moderate to severe disease. Comorbidity affected recruitment. Many patients required complex management. Quality=3.	Multi-faceted disease specific management program appeared to reduce hospital admission and bed days in moderate to severe COPD. Key elements were patient participation and information sharing among health care providers.
Education and self-management in asthma and COPD									
Coultas D., et al. 2005(77)	Peer-reviewed journal article.	2000-2001 United States Multi-centre 6 months	Primary care (17 sites) Adults with COPD selected from electronic database. N=151 ≥ 45 years ≥ 20 pack years FEV_1/FVC <70% FEV_1 <80% pred.	Investigate the effectiveness of nurse-assisted home care (patient education, patient self-management) and enhanced follow-up. 4 nurses underwent 8 hours training based on the GOLD guideline. 2 nurses underwent an additional 8 hours of training in collaborative management.	RCT. Comparison of three groups (usual care, medical management or collaborative management). Outcomes: HRQoL Health care utilisation	Results: No change in: HRQoL or health care utilisation between groups.	Multivariate analysis was performed to adjust for baseline differences.	Power to detect change was low due to failure to complete study because of: Unavailability for follow-up or patient death. Sources of bias: Randomisation-baseline characteristics not equally distributed. Quality=3.	Patient education and efforts to improve patient self-management in COPD by nurse-led intervention did not improve health status or health care utilisation in COPD.
Gibson P., 2002a(61)	Peer-reviewed journal article	RCTs conducted over 20 years	Hospital based (3 studies), home-based (4 studies), asthma clinic based (4 studies), general practice-based (1 study). Adults Asthma education by	Assess the effects of limited (information only) asthma education on health outcomes in adults with asthma.	Cochrane review and meta-analysis of 12 RCTs. Outcomes: Hospitalisations Emergency visits Doctor visits Lung function Medication use Symptoms	Results of the meta-analysis: No significant effect on: Hospitalisations; over a 12 month period Doctor visits Lung function Medication use Asthma symptoms. Significant reduction in Emergency room	Meta-analysis	Methodological quality of included studies- variable. Trials conducted over a period of 20 years. Outcome assessment usually not blinded. Limited information sessions did not improve asthma knowledge over an extended	May reduce emergency room visits for high risk individuals. However, limited asthma education did not appear to improve health outcomes.

Study	Type of article	Time/place Duration of follow-up	Setting, Participants, Patient age, sample size	Main aim Target group involvement	Study design/Outcomes	Results: findings/subgroup effects	Strengths	Limitations of the study/ Study quality for RCT (Jadad scale)	Conclusions/ Implications
			nurse, pharmacist, health educator or medical practitioner. Exclusion criteria: Peak flow monitoring Action plan		Knowledge Costs	visits by a mean of 2.8 (94%CI 1.18 to 4.34) per year for high users. Patients felt better.		period. However, no information on duration of education, mode of delivery, level and type of interaction could be obtained.	
Gibson P., 2002b(62)	Peer-reviewed journal article	RCTs conducted between 1986-2001	Studies were: Hospital based (10 studies), asthma clinic based (13 studies), general practice or primary care-based (13 studies) N=6090 Dropout rates ranged from 0-54%	Assess the effects of asthma self-management programmes, when coupled with regular health practitioner review, on health outcomes in adults with asthma.	Cochrane review and meta-analysis of 36 RCTs. Outcomes: Hospitalisations Emergency room visits Doctor visits Days off work Nocturnal asthma Lung function Medications HRQoL Costs	Results of the meta-analysis: Self-management education reduced: Hospitalisations Emergency room visits Unscheduled doctor visits Days off work Nocturnal asthma HRQoL. Lung function was unchanged. Less intensive interventions were less efficacious.	Meta-analysis performed where possible	Variable contamination of control groups in some studies. Outcomes not always reported in a way that they could be included in the meta-analysis.	Self-management education improved health outcomes. Interventions should include a written action plan, self-monitoring and regular medical review. Intervention resulted in reduction in indirect costs but increased direct costs.
Hesselink AE., et al. 2004(75)	Peer-reviewed journal article	1998-1999 The Netherlands Multi-centre 2 years	Primary Care 12 General practices. Asthma, COPD or mixed disease. N=276 Intervention n=139 Usual care n=137 After 2 years: Intervention n=96 Usual care n=80 Ages 16-75 years	Investigate the effectiveness of an education programme for patients with asthma or COPD or mixed disease reporting use of respiratory medications and experiencing symptoms in past year.	RCT Comparison of changes from baseline between intervention and usual care after 1- and 2 years follow-up. Outcomes: Dyspnoea Symptoms HRQoL Medications	Results No changes after follow-up in: Symptoms HRQoL Compliance Smoking cessation Self-efficacy or coping. More patients in intervention group had correct inhalation technique. No differences in outcomes by disease groups or gender.	Intervention improved inhalation technique.	Patients had mild to moderate disease with good HRQoL scores at baseline so room for improvement was limited. Few patients stopped smoking. Quality=3.	Individual training program. Inhalation technique improved in intervention group. No change in smoking cessation or any other health outcomes with the intervention.
Janson SL., 2003(73)	Peer-reviewed journal article	Date? US Single-centre N=65 1-week run-in period 6-week study period	Clinical laboratory Mild to moderate asthma patients prescribed an inhaled corticosteroid N=65 adults Intervention n=33 Control n=32	Effects of individual self-management education and an action plan on clinical, biological, and adherence outcomes in asthma. Education conducted by experienced practice	RCT Comparison of changes from baseline for intervention and control groups.. Self-management behaviour change Corticosteroid use Asthma symptoms	Intervention improved: Adherence to inhaled medication (30% vs. −5%, p = 0.01) Perceived control of asthma (14% vs. 5%, p= 0.04). No change in lung function, peak flow, symptom severity.	Some behaviours improved with the intervention.	Study did not determine which component of the intervention was most responsible for the clinical improvements in the intervention group. Quality=2.	In asthmatic patients treated with inhaled corticosteroids, education and training in self-management improved adherence with inhaled therapy, perceived control of

Study	Type of article	Time/place Duration of follow-up	Setting, Participants, Patient age, sample size	Main aim Target group involvement	Study design/Outcomes	Results: findings/subgroup effects	Strengths	Limitations of the study/ Study quality for RCT (Jadad scale)	Conclusions/ Implications
			Ages 18-55 years Non-smokers	nurse. 5-visits over 7 weeks.	HRQoL	Borderline improvement in HRQoL.			asthma, and sputum eosinophilia.
Jones KP., 1995(102)	Peer-reviewed journal article	1988-1991 United Kingdom Two centres 3 years	General practice Asthma patients aged 5-65 years N=141	Comparison of asthma care in two similar practices; proactive nurse-run care in one practice and reactive care in the other.	Cohort comparative study Outcomes: Questionnaire responses Lung function Medication use	PEF improved in both groups.	No differences in outcomes between the two practices was detected	Only 33% intervention group and 40% control group patients saw the asthma nurse during follow-up. The nurses worked an extra 5 hours per week leading to additional costs.	Proactive care was not more effective than reactive care and incurred considerable costs.
Magar Y., 2005(74)	Peer-reviewed journal article	1999 to 2001 France Multi-centre 1 year	Education centres. Asthma patients with at least 1 asthma attack per week or bronchodilator once per week N=238 patients randomised Ages 18-60 years After 1 year: Intervention n=104 Control n=89	Assessment of a therapeutic education programme including education, personalised action plan. Educators were trained physicians, nurses or physiotherapists. Educator training: 3 sessions (7 days over 4 to 6 months. Patients: initial interview followed by 2 X 2.5 hour group sessions.	RCT Comparison of changes from baseline. Outcomes: Clinical (symptoms, medication) Psychological (anxiety) Behavioural (smoking)	Results: Significant improvement in the educated group for: Symptom free days Number of awakenings HRQoL Decreased use of corticosteroids No difference in smoking cessation rates between educated and uneducated groups.	The results are consistent with those of the Cochrane review; training programmes and a written asthma action plan are more effective than other forms of self-management.	No measure of lung function provided and no cost evaluation. Some outcomes, (medication and HRQoL score) improved for both treated and control groups. Control patients also received some education e.g. in inhaler use and avoidance of trigger factors. Quality=2.	Self-management education with action plan produced some beneficial effects for patients with asthma.
Monninkhof EM., 2002(63)	Peer-reviewed journal article	RCTs conducted between 1986-2000	Outpatient clinics or primary care COPD N=1106 completed studies Inclusion criteria for studies: FEV_1 varied from <80 to <65% pred. Follow-up 2-12-months.	Assess the efficacy of COPD self-management/ education programmes on health outcomes and use of health services.	Cochrane review and meta-analysis of 8 RCTs and 1 controlled trial. Outcomes: HRQoL Symptoms Exacerbation rate Health care service use Medications Days off work Lung function Exercise capacity	Results of the meta-analysis: No effect of self-management education on: Hospitalisations Emergency room visits Days off work Lung function HRQoL. Self-management education reduced the need for rescue medication but increased use of steroids and antibiotics.	Meta-analysis performed where possible	No double-blind studies. Quality of studies was variable but rated good for 5 studies. Varying diagnostic criteria and outcome measures. Mode of education varied between studies. Although the need for rescue medication was reduced, this effect was measured in only one study.	Data insufficient for forming recommendations. Self-management behaviour should be focused on behavioural change.
Monninkhof E., et al. 2003 and 2004(78, 80)	Peer-reviewed journal articles	1999-2000 The Netherlands Single-centre 1 year	Hospital outpatient clinic for education and primary care for fitness training. Patients with stable	Assess the effects of a self-management intervention (education and fitness training) in patients with stable COPD	RCT Comparison of changes from baseline and between groups at the end of the study. Outcomes:	Results: After 1 year, no differences between groups in: Walking distance Symptom scores	In a pre-trial period, COPD medication was optimised, patients received	Moderate to severe COPD Mean HRQoL score at baseline were relatively high so room for improvement was limited.	The nurse-led self-management intervention did not result in improvements in

Study	Type of article	Time/place Duration of follow-up	Setting, Participants, Patient age, sample size	Main aim Target group involvement	Study design/Outcomes	Results: findings/subgroup effects	Strengths	Limitations of the study/ Study quality for RCT (Jadad scale)	Conclusions/ Implications
			moderate to severe COPD. N=248 Intervention n=127, Control n=121 Ages 40-75 years		Walking distance Symptoms exacerbation rate HRQoL Self-confidence Subgroup analysis: Patient reported symptoms Economic analysis.	HRQoL. The intervention group reported more exacerbations. No subgroup differences detected.	inhaler instruction and smoking cessation advice so these did not confound the study.	Quality=3.	HRQoL, walking distance, symptoms or exacerbation frequency for COPD patients receiving optimal treatment. The programme was twice as expensive as usual care.
Smith B., et al. 2001(64)	Peer-reviewed journal article	RCTs conducted between 1987-1999 Follow-up 7-12 months	Respiratory or practice nurse home-based care, education and support programme. COPD 624 patients randomised FEV1 <60% pred.	Evaluate the effectiveness of outreach respiratory health care worker programmes for patients with COPD.	Cochrane review and meta-analysis of 4 RCTs. Outcomes: Lung function HRQoL Mortality Costs Hospitalisations GP or nurse visits Carer satisfaction HRQoL	Results of the meta-analysis: Overall mortality not reduced by the intervention. Sub-group analysis: Mortality reduced in patients with less severe disease. HRQoL improved in one study. No change in lung function, exercise performance or hospitalisations.	Meta-analysis performed where possible	Poor quality of studies due to non-blinding. Hospitalisation and costs assessed in one study and increased for outreach care Inadequate data on carer HRQoL and satisfaction.	Outreach programs are resource intensive with little benefit on HRQoL or mortality.
Sudre P., et al. 1999(69)	Peer-reviewed journal article.	RCT (n=42) and non-randomised studies (n=11). Reports published 1979–1998.	48 interventions for outpatients. 10 interventions for inpatients Asthma 77 projects 94 interventions N=7953	Evaluate objectives, methods and content of patient education programmes for adults with asthma	Systematic review of education interventions for asthma Outcomes: General and educational objectives Duration of education Number of sessions Who delivered education Group or individualised training	Results: 56% reports did not specify general objectives, 60% did not specify educational objectives. Training duration ranged from 0 (self-education) -58 hours, Number of sessions from 0-36. Training tools varied.	Insufficient documentation of asthma education programmes for adults precludes their replication	Information about who delivered the education, whether education was conducted individually or in a group, and what teaching tools were used was missing in a substantial proportion of reports.	Excessive variability of education programmes reduces the possibility of identifying their most effective components
Taylor SJ., et al. 2003(65)	Peer-reviewed journal article	RCTs conducted between 1987-2003 Follow-up ranged from 1-month to 1 year	Inpatient, outpatient or community based nurse-led interventions. Adults with COPD (moderate to severe for most studies).	Determine the effectiveness of innovations in management of chronic disease involving nurses for COPD patients.	Meta-analysis of 9 RCTs Outcomes: HRQoL Psychological wellbeing Impairment and disability Exacerbation rate Lung function Mortality Health care use	Results of the meta-analysis: Brief interventions: Little evidence of benefit. Longer term interventions: No difference in: Psychological wellbeing Impairment and disability Exacerbation rate Lung function Mortality	Meta-analysis involved extensive effort to identify studies.	Most trials included small numbers of patients No sample size calculation in 5 trials Evidence from individual trials was assessed as low or with wide confidence intervals. Evidence for most interventions was sparse.	Little evidence to support nurse-led: home care programs, case management programs or self-management programs for COPD.

Study	Type of article	Time/place Duration of follow-up	Setting, Participants, Patient age, sample size	Main aim Target group involvement	Study design/Outcomes	Results: findings/subgroup effects	Strengths	Limitations of the study/ Study quality for RCT (Jadad scale)	Conclusions/ Implications
					Knowledge Social support Symptoms	Outpatient visits Social support Symptoms Nurse-led interventions may improve patients' knowledge and reduce emergency visits.			
Thoonen BPA., et al. 2003(67)	Peer-reviewed journal article	Date? The Netherlands 2 years	Primary care Patients with mild to moderate asthma. 19 general practices (50%of invited practices) N=193 Intervention n=110, Usual care n=104 Ages 16-60 years FEV1 >40% pred.	Determine the effectiveness of asthma self-management in general practice. Education: 4 individual training visits of 30, 20, and 2 x 10 minutes, respectively, at the GP's surgery over 3months. Personalised self-management plan	RCT Comparison between intervention and usual care. Outcomes: Asthma control (changes in spirometry including reversibility) HRQoL Lost activity days	Results: Intervention associated with small improvement in successfully treated weeks (perceived dyspnoea) Reduction in the number of activity limited days Limited improvement in one domain of HRQoL. No change in: Lung function Number of oral steroid courses was higher in the intervention group.	Asthma self-management is at least as effective as usual care.	Number of oral steroid courses higher in the intervention group possibly due to: over registration by the GP, a larger number of patients requiring pre-treatment due to worse asthma control or over-treatment in the self-management group. Baseline HRQoL was lower for some domains for the intervention group but HRQoL high in both groups at baseline leaving little room for improvement. Quality=3.	Improved self-management of asthma through attendance to individual training sessions provided by GPs reduced the burden of illness as perceived by patients with asthma.
Weingarten SR., et al. 2002(6)	Peer-reviewed journal article	RCTs published between 1987-2001 United States	Chronic diseases including asthma (10 programmes) and COPD (7 programmes)	Evaluate the characteristics and effectiveness of disease management programmes of patient education, provider education and provider feedback.	Meta-analysis of RCTs	Results: Asthma programmes: Provider feedback; No significant effect of 1 programme on disease control. Patient education; Significant effect of 2/3 programmes on disease control. Patient reminders; No significant effect of 1 programme on disease control. COPD programmes: Patient education, patient reminders; No significant effect from 3 programmes on disease control.	Patient education in asthma produced a small but significant improvement in disease control not detected in COPD.	Few programmes for asthma and COPD. Quality, quantity and heterogeneity of studies limited conclusions.	Patient education in asthma produced a small but significant improvement in disease control.

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Worth H., et al. 2004(76)	Peer-reviewed journal article	Date? Germany 6 months	Outpatient setting 4, 2 hour group sessions Patients with mild to moderate asthma or COPD N=192 Asthma: Intervention n=78 Control n=34 COPD: Intervention n=46 Control n=34	Evaluation of a structured education programme for mild to moderate asthma and COPD.	RCT Before and after study. Outcomes: Symptom monitoring Peak flow monitoring Self medication Hospital days Number of exacerbations HRQoL	Results: Significant difference in monitoring of symptoms and peak flow after education. Significant reduction in hospital days and exacerbations. No change in medication use, lung function or HRQoL.	Study reported an improvement in self-control after education.	No description of methodology provided and an earlier report was not available in English so low quality rating. Borderline changes in hospital days. No difference between treatment and control groups for medication utilisation. Quality=1	Education may modify patient behaviour in the management of asthma and COPD by improving self-control and self-management of the disease. Improvements were greater fro asthma patients.
Nurses as educators of other health professionals in primary care									
Griffiths C., et al. 2004(79)	Peer-reviewed journal article	Date? United Kingdom Multiethnic area of East London. Multi centre. 1 year.	Primary care 44 General Practices 2 Specialist nurses. Asthma N=324 Intervention n=175, Control n=149. Ages 4-60 years	Determine whether asthma specialist nurses, using a liaison model of care, reduce unscheduled care in a multiethnic area. Specialist nurses liaising with GPs and practice nurses instructed practices in use of guidelines and reviewed patients. Patients provided with a written action plan and rescue medication. Control: single visit from specialist nurse to discuss guidelines.	Cluster RCT Participants were interviewed at baseline and 2-, 6-, 9- and 12-months. Outcomes: Unscheduled asthma care Time to first attendance for unscheduled care Self-management behaviour HRQoL	Results: The specialist nurse intervention delayed first attendance for unscheduled asthma care (hazard ratio 0.73 (95% CI 0.54-1.00) Reduced GP visits for acute asthma . No difference in: Self-management behaviour HRQoL Symptoms Rescue medication use No ethnic differences identified	98% participants completed follow-up. Control was best standard practice.	Limited power to detect difference in ethnic subgroups. No costing analysis performed. Quality=2.	Asthma specialist nurses using a liaison model of care reduced unscheduled care for asthma in a deprived multiethnic district of London.
Premaratne UN., et al. 1999(99)	Peer-reviewed journal article	1993-1996 United Kingdom Multi-centre.	Primary care 41 general practices with a practise nurse. N=24,400 patients surveyed. Response rate 50.0% Ages 15-50 years	Evaluate the effectiveness of an asthma resource centre in educating practice nurses who educate asthma patients. Intervention: 6 teaching sessions for practice nurses followed by nurse specialist visits to practice	Audit of medical records data and patient interviews before and after the randomised intervention. Outcomes: HRQoL Prescribing rate Hospitalisation Emergency room visits	Results: No difference in overall patient HRQoL between intervention and control groups or after controlling for age, gender, number of partners in the practice. No significant differences in hospitalisations, emergency	Study had sufficient power to detect a change.	Survey data High turnover of practice nurses during the study (67% intervention practices had practice nurse staff changes). Quality=1.	This model of service delivery of specialist nurses educating practice nurses did not improve the outcomes for asthma patients in primary care.

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				nurses to assist with patient management.		room visits, or steroid prescribing rates.			
Cost-effectiveness of a practice nurse									
Gallefoss F., et al. 2002(83)	Peer-reviewed journal article. Earlier report included in the Gibson meta-analysis.	1994-1995 Norway Single centre 1 year	Outpatient and primary care Mild to moderate COPD (also included patients with asthma) N=62 Intervention n=31 Control n=31 Dropouts n=9 <70 years FEV_1 40-80% pred.	Cost-benefit and cost-effectiveness analysis of self-management in patients with COPD	RCT Outcomes: Direct costs Medication use Hospitalisation Patient satisfaction	Results: Mean total costs (direct, indirect): Intervention = NOK 10600 Control = NOK 19900 Intervention group had lower costs for GP visits and hospital admissions. Both groups were satisfied with their treatment.	Intervention associated with cost savings.	Study included patients with both asthma and COPD. The mean age of patients was younger than usually associated with COPD. Quality=3	Difficult to determine the effect of the intervention in COPD patients due to the inclusion of patients with asthma.
Kauppinen R., et al. 1998(84)	Cost-effectiveness RCT Peer-reviewed journal article	1991-1993 Finland Single centre 1 year	Hospitalised patients with asthma were recruited Newly diagnosed asthma N=150 Intervention n=78 Usual care n=72 Dropouts n=12 FEV_1 ≥80% pred.	Comparison of education and self-management versus usual treatment. All patients received education at baseline.	RCT Outcomes: Lung function HRQoL PEF PD_{15} Health care service use Sickness days Medication	Results: Both intervention and control groups improved in all clinical and HRQoL outcomes except for spirometry. Intervention was associated with significantly increased direct costs but no difference in indirect costs.	Lung function improved in the intervention group after 12 months follow-up.	Both intervention and control patients received education in disease self-management at baseline. Longer follow-up may be required before conclusions around cost-effectiveness of intervention can be drawn. Quality=3	The education programme did not prove to be cost-effective.
Pinnock H., et al. 2005(85)	Peer-reviewed journal article	2001 United Kingdom Multi-centre 3 months	Primary care Symptomatic asthma Telephone review group: Practice review group: 4 general practices N=278 Telephone review n=137 (74% were reviewed) Practice review n=141 (48% were reviewed)	Cost-effectiveness of telephone (nurses made up to four attempts to ring patients) or surgery (patients invited to make an appointment for asthma review). Health service costs were calculated using unit cost estimates from the UK multiplied by the use of health care resources recorded over 3-monts.	RCT Outcomes: Number of patients reviewed Nurse time and telephone costs, GP or practice nurse visits Aborted telephone calls Emergency visits Hospitalisations Medications Calculation of: Overall costs Consultation cost Health care resource use	Results: No significant differences in: Total costs Health care resource use Cost of consultation Drug use. More telephone consultations over 3months due to shorter duration compared with surgery consultations (mean durations telephone 11.2, surgery 21.9 minutes, p<0.001) Cost per consultation was significantly less for the telephone group.	Experienced nurses performed reviews. Detailed individual patient data collected.	Short duration of study. Patients may have been reluctant to attend practice for review. Quality=2	Telephone consultations enabled a greater proportion of asthma patients to be reviewed at no additional cost.

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Schermer TR., et al. 2002(86)	Peer-reviewed journal article	1996-1999 The Netherlands Multi-centre 2 years	Primary care Adults with stable asthma 19 general practices were randomised. 49 physicians. N=193 Intervention n=98 Usual care n=95	Economic evaluation of asthma self-management in primary health care	Parallel group RCT Outcomes: Number of successfully treated weeks Lung function HRQoL Resource use Medication Calculation of direct health care cost Programme cost Productivity cost	Results: No significant difference in total costs between intervention and usual care. Number of limited activity days was 1.2 for self-management and 3.9 for usual care. Self-management was associated with a gain in 1.5 QALYs over 2 years relative to usual care. More referrals to respiratory physicians among self-management group.	52% probability that self-management was cost-effective compared to usual care.	Uncertainty around the cost-effectiveness estimate was large. Practices were randomised to avoid cross-contamination but prevailing habits by family physicians cannot be ruled out. Quality=2	Most important expenditure necessary was time taken to educate patients. Self-management led to substitution costs – reduced cost of medications but greater cost of allergen avoidance measures.
Practice nurse' impact on the general practitioner's burden of disease management for asthma or COPD									
Charlton I., et al. 1991(57)	Peer-reviewed journal article	1987-1990 United Kingdom Single-centre 12months	Primary care Asthma patients using prophylactic asthma medication. N=115 patients (46 children) 48% asthma patients	Effect of a nurse-run asthma clinic on workload and patient morbidity.	Before-and-after audit. Outcomes: Number of GP consultations Number of nurse visits consultations Number of prescriptions for asthma medications	Results: Consultations with general practitioners fell from 818 to 414 during the study period. This was offset by 496 consultations with the nurse. Overall costs remained stable.	Nurse asthma clinic reduced the number of GP consultations.	Audit data. A group of patients (9%) were non compliant with clinic attendance.	Establishment of the clinic was associated with more patients being labelled as asthmatic and commencing medication.
Laurant MGH., et al. 2004(81)	Peer-reviewed journal article	1998 The Netherlands Multi-centre 28 days	Primary care Nurse practitioners Asthma and COPD management 7 General practice groups (33% groups) N=48 GPs Intervention n=30 Control n=18 5 nurses randomly allocated to GPs	Evaluate the impact of nurse practitioners with experience as community nurses, on workload of GPs	RCT before and after study Outcomes: Subjective workload Number of contacts per day Type of consultation Time of day of consultation	Results: COPD or asthma Significant increase in objective workload of GPs after the intervention. No change in out of hours contact time.	The increase in surgery contacts was partially offset by a small (non-significant) reduction in the number of contacts during evenings.	Study was performed in only one region of the Netherlands, which may limit the generalisability. Quality=3	Adding nurse practitioners to general practice teams did not reduce GPs workload in the short-term. GPs reported no subjective benefits in terms of workload. Nurses provided supplemental care not substitute care.
Clinical guidelines									
Baker R., et al. 2003(151)	Peer-reviewed journal article	1998-2000 United Kingdom	Primary care 81 General practices 1482 Asthma patients	Evaluate the impact of guidelines, prioritized review criteria and	Cluster RCT General practices randomised Outcomes relevant to asthma:	Results: The dissemination of guidelines in the format of prioritized.	Large number of practices and patients included	Participating practices and patients were all volunteers reducing the generalisability.	Difficult to implement the recommendations of guidelines in

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		Multi-centre		feedback on implementation of recommendations for asthma and angina	Adherence to ten guideline recommendations about asthma.	review criteria did not increase adherence to recommendations in comparison with the traditional guideline format. Provision of feedback had minimal additional effect	in the study. Hence, study findings are likely to be valid.	Quality=3	primary care. Other interventions such as computerised reminder systems may be more effective.
Eccles M., et al. 2002(152)	Peer-reviewed journal article	2000-2001 United Kingdom Multi-centre 2 years	Primary care 60 General practices Adults with asthma n=2363 patients Adults with angina n=2276 patients	Effect of computerised evidence-based guidelines on management of asthma and angina in adults in primary care.	Before-and-after cluster RCT General practices randomised Outcomes: Process of care (lung function, inhaler technique) Medications prescribed Patient reported outcomes	Results: The computerised decision support system had no significant effect on consultation rates, process of care measures (including prescribing), or any patient reported outcomes for either condition.	Large numbers of patients included. The computerised decision support system was based on pre-existing software currently available.	Levels of use of the software were low. Practice staff had limited training in the functioning and use of the computerised system. Quality=3	Difficult to integrating guidelines into clinical encounters where busy practitioners manage patients with complex, multiple conditions.
Feder G., et al. 1995(153)	Peer-reviewed journal article	1992-1993 United Kingdom Multi-centre 1 year	Primary care 24 General practices Adults with asthma or diabetes from disease registers Age >16 years N=480 patients	Determine whether locally developed guidelines on asthma and diabetes, disseminated through practice based education improved quality of care in general practices.	RCT Each practice received one set of guidelines but provided data on the management of both asthma and diabetes. Outcomes: Recording of key variables in patient's records; Symptoms PEF Inhaler technique Smoking	Results: Both groups of practices improved recording of: Review of inhaler technique Smoking habit Review of asthma symptoms. In practices receiving asthma guidelines, further improvement was seen in only 1 outcome: Quality of prescribing.	The use of prompts for the recording of clinical information recommended by guidelines improved implementation of the guidelines.	Both asthma and diabetes practices improved recording of asthma outcomes of inhaler technique, smoking habit, and review of asthma symptoms. Quality=2	For asthma patients, the effect of the intervention was marginal for asthma. The education programme for GPs during guidelines dissemination was associated with considerable costs.
Guest JF., et al. 2005(159)	Peer-reviewed journal article	1999-2001 United Kingdom Multi-centre 1 year	Primary care 26 General practices (13 active and 13 matched controls). COPD patients >40 years 3 or more prescriptions for beta2-agonists in the preceding 6 months, History of wheeze	Determine the impact of the British Thoracic Society COPD guidelines on health status, healthcare resource use and HRQoL.	Observational, parallel group, non-randomised cluster-controlled study. Outcomes (audit of medical records): Healthcare resource use Drug utilisation data Outcomes (questionnaire): HRQoL	Results: No significant differences between active and control practices in: Lung function Healthcare resource use Minor improvements in 2 domains of HRQoL for one instrument for active group. Some differences in medication use between groups.	Guidelines had no detectable impact on patients' airway function and healthcare resource use. Patients experienced minor benefits in health status.	Only 41–45% of eligible patients completed study with 16-19% of these patients failing to attend clinic visits. Practices not randomised to treatment. Study may be have been confounded by variations in primary care expertise in COPD between active and control practices.	COPD patients managed according to the British Thoracic Society guidelines experienced only minor improvements in HRQoL, but no other significant benefits.
			N=1466 509 patients completed the study.						

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Jans MP., et al. 2001(161)	Peer-reviewed journal article	1993-1994 The Netherlands Multi-centre 1 year	Primary care 19 General practices Asthma and COPD patients not under the care of a chest physician Ages 16-70 years N=607 patients Only 370 patients completed study Intervention: n=280 Usual care n=90	Evaluation of a project to implement guidelines in general practice involving identification of barriers, documentation of care specific education, feedback on compliance with guidelines, and peer review	Before-and-after study, non-randomised. Comparison with usual care. Outcomes: PEF Variation in PEF Number of days with respiratory symptoms HRQoL	Results: Intervention group significant improvements in; PEF Variation in PEF Respiratory symptoms Pain Comparing changes within intervention group and changes in control group, only PEF remained significantly improved.	The comprehensive implementation program improved PEF and some symptoms.	Only motivated patients included in study. High drop-out rate (39%). Differences between intervention and comparison groups at baseline may have affected results.	Comprehensive implementation programme improved PEF and some asthma and COPD symptoms, but in comparison with a reference group, the effect on PEF was small.
Lesho EP., et al. 2005(156)	Peer-reviewed journal article	Date? United States Single-centre 1 year pre versus 1 year post	Primary care Asthma Age >6 years N=330 patients before implementation N=334 after implementation	Evaluation of clinical practice guidelines including an asthma guideline after implementation involving education of GPs and tool kits containing management algorithms.	Before-and-after study, non-randomised. Outcomes: Asthma medication use Emergency Department visits Hospital admissions	Results: After implementation, significantly more patients received education. Significant decreases for asthma exacerbations in number of; Nebuliser treatments Emergency room visits Hospital admissions	The asthma guidelines improved some processes and all outcomes measured.	The guidelines did not improve compliance with treatment recommendations.	Outcomes were improved after implementation of an asthma guideline.
Ruoff G., 2002(154)	Peer-reviewed journal article	2000 US Single-centre 6 months	Family practice Asthma patients randomly selected N=122 All ages	Evaluation of the effects of implementation of a flow sheet, incorporating GINA guidelines on physician performance in the management of asthmatic patients.	Before-and-after study, non-randomised. Audit of medical records for documentation of outcomes. Outcomes: Education Smoking cessation program Allergy testing Vaccine prophylaxis Nocturnal awakening Physical activity Health care use Infections Control of asthma triggers	Results: After implementation of a flow sheet, documentation improved for 13 out of 14 clinical indicators. There was a reduction in documented counselling of patients about smoking cessation.	Use of a flow sheet in primary care practice improved documented compliance of guideline clinical indicators for the management of asthma.	After flow sheet implementation, there was a reduction in documented counselling of patients about smoking cessation. The study did not measure quality of care or whether actual clinical outcomes improved.	Compliance with asthma management quality indicators appeared to improve after flow sheet implementation.

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Smeele IJ., et al. 1999(155)	Peer-reviewed journal article	Date? The Netherlands Multi-centre 1 year	Primary care Asthma/COPD 34 Groups of GPs randomly allocated to intervention or control groups. Patients >25 years with symptoms of respiratory disease. N=544 433 patients completed study Intervention n=210 Control n=223	Determine if small group education of GPs to introduce national guidelines and peer review can improve care for patients with asthma or COPD.	RCT Before-and after study Outcomes: Knowledge Symptoms PEF Number of exacerbations Smoking habits HRQoL	Results: Only significant changes for self estimated skills (+16%, 95% confidence interval 4% to 26%) and presence of peak flow meters in practice (+18%, $p < 0.05$). Subgroup analysis: No significant differences for older patients, those with more severe disease or patients not using anti-inflammatory medication. Quality=2	Power of study was sufficient to detect a change.	Limited number of GPs included. Quality=2	Intensive small group education and peer review in asthma and COPD care did not seem to be effective in changing care provided by GPs in accordance with guidelines, nor in changing patients' health status.
Wright J., et al. 2003(160)	Peer-reviewed journal article	Date? United Kingdom Multi-centre Audits at 6 monthly intervals for 18months	Primary care Asthma and angina 180 General practices	Determine effectiveness of a multifaceted implementation of guidelines in primary care.	Non-randomised, comparative study. Active dissemination of guidelines in one district and passive disseminated in another. Outcomes: Smoking status Inhaler technique	Results: Improvements in all outcome criteria between baseline and follow-up audits, regardless of whether the guideline was actively implemented or passively disseminated.	The only significant improvement associated with active implementation was smoking status in angina patients.	The estimated increase in the proportion of medical records complying with guidelines was 4%.	Improvements occurred irrespective of whether the guideline was actively or passively disseminated.
Spirometry in primary care									
Bize R., et al.(192)	Peer-reviewed journal article	RCTs conducted between 1966-2004	General practice or clinic settings Smokers where a physical measurement was used to provide feedback as motivation for quitting smoking. 4 RCT used spirometry results.	Determine the effectiveness of biomedical risk assessment as feedback to aid smoking cessation.	Cochrane systematic review and meta-analysis Outcomes: Abstinence from smoking	Results: No significant effects were identified when spirometry results alone or spirometry plus exhaled carbon monoxide measurement were used as feedback.	Broad inclusion criteria used for the systematic review. Existing evidence does not support the intervention.	The studies were heterogeneous with regard to recruitment. Studies generally were inadequate with regard to documentation of randomisation and sample size estimation.	Insufficient evidence for recommendations. Existing evidence of lower quality does not support the hypothesis that biomedical risk assessment increases smoking cessation.
Chavannes N., et al. 2004(230)	Peer-reviewed journal article	Date? The Netherlands Multi-centre	General practice Obstructive respiratory disease and mixed obstructive	To compare the achievements of trained GPs in spirometric diagnosis with those of an	Comparative study Outcomes: Diagnostic accuracy (bronchial obstruction (from mild to	Results: GPs obtained for normal and obstructive curves; high diagnostic odds ratios 65.0	Study combined standardised case material with multi-level	It is unknown if similar results would be obtained a real-life setting, with actual patients and less or even untrained	Trained GPs differentiated between normal and obstructive disease.

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		1 year	restrictive disease N=39 GPs 3 GPs dropped out of study	expert consensus panel. Determine the impact of spirometry on GPs' decision-making.	severe), rare respiratory pathology, normal lung function) Incorrect test manoeuvre.	and 48.9 respectively. GPs were less effective at diagnosing rarer pathological curves (diagnostic odds ratio of 3.8). Scoring of an incorrect test manoeuvre; an intermediate diagnostic odds ratio of 24.4	analysis to evaluate a complex diagnostic tool, spirometry.	GPs.	Spirometry suggestive of rare or mixed disease was often missed. Spirometry influenced GP decision-making by reducing uncertainty, but increased use of additional diagnostics and referral to specialist care.
Ignacio-Garcia JM., et al. 1995(229)	Peer-reviewed journal article	1990-1991 Spain Single-centre 6 months	Outpatient clinic Asthma Ages 14-65 years N=94 70 patients completed the study Intervention n=35 Control n=35	Determine the usefulness of PEF plus an education program and medication self-management plan in reducing morbidity in adults with moderate asthma compared with control (spirometry feedback, symptom management).	RCT Outcomes Change in lung function Morbidity parameters	Results: Both intervention and control groups improved lung function during follow-up, but spirometry feedback appeared less effective than PEF, education and self-management.	Asthma outcomes appeared to improve with self-management intervention.	Small number of patients studied. Short follow-up period. 34% patients found it difficult to self-assess their asthma severity. PEF results were unreliable in a small group of patients (3.4%). Quality=2	Spirometry feedback appeared less efficacious than PEF and education self-management but difficult to tell which part of the intervention was more important.
O'Byrne PM. , et al. 2006(194)	Peer-reviewed journal article	1996-1998 32 countries Multi-centre 3 years treatment followed by 2 years open treatment	Ages 5-66 years Patients had asthma symptoms weekly N=7,241 patients 7,165 were available for analysis budesonide n= 3,597 placebo n=3,568	Evaluate the role of early intervention with inhaled budesonide in patients with mild asthma.	RCT Comparison of low doses of inhaled corticosteroids or placebo initiated within the first 2 years of a diagnosis of asthma. Outcomes: Lung function (FEV_1 %pred.)	Results: Inhalation of budesonide: Significantly improved FEV_1 Reduced the mean decline from baseline for FEV_1 at 1 year and 3 years (-0.62% and -1.79% for budesonide and -2.11% and -2.68% for placebo, ($p < 0.001$)). The decline was more marked for male patients, active smokers, and patients > 18 years old.	Large worldwide, long-term, double-blind, placebo-controlled trial.	Concomitant treatment was administered throughout the study; 45% of the placebo group had received inhaled oral or systemic corticosteroids. Multinational drug company sponsored the trial. Quality=4	Early intervention with inhaled budesonide within the first 2 years of asthma diagnosis in patients with persistent asthma improved FEV_1. The effects of longer-term administration are unknown.
Wilt TJ., et al. 2005.(191)	Report	1966-2005	Report prepared to provide evidence to inform the work of the American Thoracic Society, The	Evidence-based assessment report on the use of spirometry for case finding, diagnosis, and management of COPD	Systematic review of the literature to determine: Prevalence of COPD If spirometry increases smoking cessation	Prevalence of spirometry varied according to definition, population, and country. Spirometry appears to be of limited use in predicting future	Systematic review. Spirometry plus clinical examination	Evidence regarding effect of spirometry on smoking cessation was limited and flawed. Costs of routine screening	It was estimated that routine screening spirometry in the US of 10,000 smokers, ex-smokers and non-

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			American Academy of Family Physicians, American College of Physicians and American Academy of Pediatrics Task Force.		If baseline severity or change in spirometry leads to changed management in COPD If spirometry provides independent prognostic value.	smoking cessation. There appeared to be little or no improvement in symptoms with inhaled medication after detection of disease through spirometry. On average respiratory status and survival would not be improved through spirometry.	improved diagnostic accuracy and was useful to diagnose individuals with suggestive symptoms who might benefit from pharmacologic treatment.	spirometry for smokers, ex-smokers and symptomatic non-smokers would exceed $1 billion dollars.	smokers with suggestive symptoms would identify 6,588 for spirometry, detect 129 candidates for therapy and result in benefits to 8 patients.

95%CI: 95% Confidence interval, FEV1: Forced expiratory volume in 1 second, FVC: Forced vital capacity, GP: General practitioner
GPwSI: General practitioner with a special interest, HRQoL: Health-related quality of life, OR: Odds ratio, PEF: Peak expiratory flow
%Pred: Percentage of predicted value, PCOs: Primary Care Organisations, QALY: Quality-adjusted life year, RCT: Randomised controlled trial