ScotPHN report

Scottish Public Health Network (ScotPHN)

A needs assessment of home oxygen services

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Preliminaries

Foreword

The number of patients receiving home oxygen has increased steadily over recent years. The reasons behind the increasing demand and the likely future trends in demand and need for the service are not fully understood. This has important implications for the planning of future services.

NHS National Services Scotland (NSS) asked the Scottish Public Health Network (ScotPHN) to undertake a national needs assessment of the home oxygen service to increase understanding of the clinical need, how this is likely to change over time and to contribute clinical and public health views to current discussion between the Scottish Government, NSS and NHS Boards on future service delivery.

This piece of work has highlighted how complex the provision of home oxygen is. A range of factors including the different patient groups, the large number of conditions where home oxygen is prescribed, current service configuration, new technological developments and so forth, have to be considered. There needs to be appropriate input from technical, clinical, public health, planning and financial expertise in the development of the service.

This report provides valuable information for this stage of the development of the service. It is hoped that any future service configuration will include the collection of more robust data, which in turn will inform planning for a continued, robust home oxygen service that appropriately meets the needs of the people of Scotland.

In order to inform current discussion, this project has been undertaken within tight time constraints and I would like to sincerely thank its authors, Rachael Wood, Ian Grant and Andrew Millard, for their significant contribution to the project within very challenging deadlines.

As with any needs assessment, the work exists as if at a single point in time. However, the implications of this work are already beginning to be considered in a wider context. Reflecting this, we are very happy to include additional comments (as appendix 6) concerning factors to be considered in the implementation of the recommendations of this needs assessment which were received from the Directors of Pharmacy. We are also grateful to them for their assistance within the overall timescale for the project.

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Introduction

What is home oxygen and who uses it?

Home oxygen refers to the provision of an enriched oxygen supply for patients outwith a hospital setting, for example in their home or for use whilst out and about. Home oxygen can be used in a variety of ways by a variety of patient groups. Patterns of usage have traditionally been categorised as:

- Long term oxygen therapy (LTOT)
- Ambulatory oxygen therapy (AOT)
- Short burst oxygen therapy (SBOT).

LTOT can be defined as continuous use of home oxygen for at least 15 hours per day over long periods. It is usually used by patients with chronic respiratory failure/hypoxaemia to reduce complications such as development of pulmonary hypertension and right sided heart failure and improve survival. These patients can include premature babies with chronic neonatal lung disease, children with complex neuromuscular disease resulting in weakened breathing, young adults with cystic fibrosis, older people with chronic obstructive pulmonary disease, and patients with a wide range of other problems.

AOT refers to the provision of home oxygen whilst people are mobile either within or outwith their homes. Whereas LTOT involves the provision of static equipment within patients' homes, AOT involves the provision of portable equipment designed to be transported by the patient whilst they move around. Patients prescribed AOT will usually also be receiving LTOT through a static supply.

SBOT is usually defined as repeated intermittent use of home oxygen for short periods such as 10-20 minutes. SBOT is usually used to relieve intermittent shortness of breath in patients who do not meet the criteria for LTOT.

An additional category of Nocturnal Oxygen Therapy (NOT) is also sometimes used. NOT refers to the provision of continuous oxygen therapy just whilst patients are asleep. This is usually used for patients with neuromuscular problems or obstructive sleep apnoea/hypopnoea syndrome, often in conjunction with some form of ventilatory support such as non-invasive ventilation.

Patients with terminal illness form an additional distinct group of home oxygen users. These patients may use home oxygen on a short burst or long term basis at the end of their lives to palliate severe breathlessness. Other patterns of home oxygen use that do not fit well with the standard classification include intermittent LTOT which is most commonly used for children with severe neurodisability and recurrent exacerbations of respiratory problems, and intermittent emergency use which can be used to relieve cluster headaches or to treat recurrent severe asthma prior to specialist help arriving.

How is home oxygen delivered?

A range of different static devices can be used to deliver home oxygen. Oxygen can be supplied to patients' homes in large static cylinders with empty cylinders being replaced with full ones as required. Alternatively, equipment such as an oxygen concentrator can be used. Oxygen concentrators work by intaking room air,

extracting nitrogen and other gases, and outputting a concentrated flow of oxygen. Oxygen concentrators require periodic servicing to ensure continued correct functioning but not frequent replacement in the same way that cylinders do. In addition, concentrators are less expensive than cylinders for patients using relatively high amounts of oxygen (around 4 hours use per day at usual flow rates) as the daily cost of a concentrator is constant regardless of the duration of use whereas the cost of cylinders is directly related to the volume of oxygen used. Specialised concentrators have recently become available for patients with particular needs. BabyOx concentrators are designed to accurately deliver low flow rates, usually for young children. The BabyOx service also provides specialised portable cylinders for young children on home oxygen so that their parents can get out and about and maintain family life despite having an oxygen dependent child. Conversely high flow concentrators are designed to deliver very high flow rates to patients with high oxygen requirements. Historically, static cylinders were used for most patients but more recently there has been a shift towards static cylinders being used for SBOT and palliative care with concentrators being used for LTOT.

Portable oxygen equipment used to deliver AOT is usually in the form of portable cylinders. These are much smaller and lighter weight than traditional static cylinders and are designed to be carried by the patient in a backpack or pushed along on a trolley. As with static cylinders, portable cylinders need to be refilled/replaced when empty. Liquid oxygen is an alternative form of portable oxygen supply used by some patients with high AOT requirements (because of high flow requirements and/or spending long periods out of the home) eg mobile young people with cystic fibrosis. Patients using liquid oxygen usually have a reservoir tank/base unit at home from which they can fill their portable cylinders. The base unit needs to be replenished on a regular (usually fortnightly) basis as the liquid oxygen is used up (or evaporates). Storing the gas in liquid form means that the canisters of liquid oxygen can deliver higher flow rates over longer periods of time than standard portable cylinders. Liquid oxygen is considerably more expensive than standard portable cylinders however and is associated with some specific risks eg cold burns when filling the portable cylinders. Most patients using a portable form of oxygen will also have a static supply (cylinders or concentrator) at home.

Ongoing technological development means that new forms of home oxygen equipment continue to become available. Homefill concentrators were made available in Scotland in 2008 in response to a shortage of portable cylinders at that time. These concentrators have an integrated compressor so that patients can refill portable cylinders themselves at home, removing their reliance on deliveries of pre-filled cylinders. Small portable concentrators are also now available: these are generally used on a temporary basis rather than as an individual's usual source of oxygen (see below).

Whatever device is used to deliver oxygen, patients actually obtain their oxygen by wearing nasal prongs or a facial mask leading to specialised tubing that attaches to a valve on the device which can be turned up or down to regulate the flow of oxygen. Oxygen conservers are relatively new devices that can be used in conjunction with other oxygen delivery equipment. Conservers regulate the flow of oxygen through the respiratory cycle so that oxygen flow is switched on when patients inhale and switched off when patients exhale. They improve the efficiency of devices such as portable cylinders but are not suitable for all patients eg those with weak inspiratory effort (Murphie et al 2008). Conservers are not currently generally available in Scotland although they have been occasionally provided to patients with particular needs. Some newer devices such as the Homefill system have integral conservers as part of the equipment.

How is the home oxygen service currently configured?

Oxygen cylinders (both static and portable) are provided on GP prescription with the cylinders being dispensed by specific community pharmacies (or occasionally dispensing practices). Only one private company, BOC, currently supplies cylinders to pharmacies in Scotland. Prior to dispensing oxygen, pharmacies must be registered with their local NHS Board.

Since 1989, all other forms of oxygen equipment (all concentrators and liquid oxygen) provided to patients have been made available through the home oxygen service run by NHS National Services Scotland Health Facilities Division (usually known as Health Facilities Scotland or HFS). HFS maintains a national contract with a private sector company (currently Dolby Medical) that is actually responsible for delivery, installation, upkeep, and removal of all equipment. All concentrators are serviced every 3 months and liquid oxygen is usually delivered to patients' homes on a fortnightly basis.

GPs can initiate prescriptions for oxygen cylinders themselves or at the request of secondary care clinicians. HFS by contrast only accepts referrals from consultants (usually adult respiratory physicians, neonatologists or paediatricians) or clinical nurse specialists with specific authority delegated from a consultant.

Dispensing pharmacies are reimbursed for the cost of providing oxygen cylinders by NHS National Services Scotland Practitioner Services Division (PSD). They are reimbursed both for the gross ingredient cost (the actual cost of the oxygen) and for additional costs associated with cylinder provision (such as rental of cylinders and delivery to patients' homes). Further additional costs can be paid by NHS Boards but these are locally negotiated and generally small in comparison to the costs paid by PSD. HFS receives a lump sum directly from the Scottish Government as reimbursement for provision of the home oxygen service. The sum provided is determined by the Government and does not necessarily equate to actual costs incurred.

In addition to the provision of home oxygen equipment on a medium to long term basis to individual patients, HFS is also responsible for administering the holiday element of the home oxygen service and managing the supply of portable concentrators for other purposes. As part of the holiday service, HFS is responsible for arranging a temporary oxygen supply for patients travelling to/within Scotland. This could comprise a standard or portable concentrator supplied directly through HFS or cylinders supplied by a local pharmacy. HFS also helps patients from Scotland who are travelling to other parts of Britain to coordinate their required temporary oxygen supply by liaising with local home oxygen providers. In addition to using some of the available portable concentrators for holiday cover, HFS also distributes these devices to out of hours services and hospital departments where they are used to avoid unnecessary admission and facilitate early discharge of oxygen dependent patients respectively. HFS also retains some concentrators in central stores as part of pandemic influenza planning.

Origins and purpose of this national needs assessment for home oxygen

The provision of home oxygen is complex. The patient groups requiring home oxygen are highly heterogeneous; a wide range of clinicians from primary and secondary care is involved in initiating and maintaining treatment; the actual supply of home oxygen is split between community pharmacies and HFS for historical

reasons; and the service is expensive to deliver. In 2008, prompted in part by the then shortages in portable oxygen cylinders, the Scottish Government commissioned an external working group to examine the provision of home oxygen. In its report (Scottish Government, 2010) the group focused mainly on the technical and practical aspects of the service however the report also noted the requirement for greater consideration of the clinical and public health aspects of home oxygen delivery.

In addition, as noted above, HFS is directly funded by the Scottish Government for provision of its part of the home oxygen service. The amount of funding provided to HFS has remained relatively static over time whilst the actual costs of providing the service have increased markedly hence an increasing funding shortfall has been developing. If current trends continue, the shortfall for HFS in 2011/12 is predicted to be over £2.5 million. HFS has relatively little control over the costs of the service as it is required to provide the services requested by prescribers. Prescribers themselves have no direct responsibility for the costs of the services provided.

A working group convened in October 2009 considered ways to address the funding shortfall accruing to HFS. The group reported back to the NHS Directors of Finance meeting in March 2010 and the NHS Board Chief Executives meeting in April 2010. The group's reports contained specific proposals to reduce the long term costs associated with provision of the home oxygen service, such as switching patients to more efficient delivery mechanisms where clinically appropriate, however it noted that even if all feasible cost reduction strategies were implemented, a substantial funding shortfall would persist.

As the financial pressures associated with provision of home oxygen are predominantly being experienced by HFS, NSS has a considerable interest in developing robust proposals for the ongoing development of home oxygen services. NSS is keen to ensure that any future changes to the provision of home oxygen are focused on meeting population needs and maintaining high quality care as well as achieving a sustainable financial situation. In early 2010, NSS therefore asked the Scottish Public Health Network (ScotPHN) to conduct a national needs assessment for home oxygen. This needs assessment project subsequently commenced in July 2010 and was asked to produce its final report by November 2010. Its primary purpose is to contribute clinical and public health views to the discussions about the future delivery of home oxygen services currently underway between the Scottish Government, NSS, and territorial NHS Boards.

Aim and objectives

Aim

- To undertake a national needs assessment for home oxygen services in Scotland that provides enhanced understanding of the appropriateness of current service provision and likely future trends in need for the service and hence to contribute to decision making around the future of home oxygen services.

Objectives

- To summarise the development and current configuration of home oxygen provision in Scotland
- To review the epidemiology of the main conditions underlying provision of home oxygen
- To briefly summarise the evidence on the clinical effectiveness of home oxygen
- To review trends in the provision of home oxygen in Scotland
- To consider user and provider views on home oxygen
- To review the provision of home oxygen in other settings, in particular England and Wales
- To draw conclusions on the appropriateness of current provision of home oxygen in Scotland and likely future trends in need for the service

General approach and methods

The general principles of health care needs assessment

The objective of any health care needs assessment (HNCA) is to specify services and other activities which impinge on health care relating to a specific disease or diseases. In general, the principal activities involved in HCNA are:

- an assessment of incidence and prevalence;
- an analysis of the effectiveness and/or cost-effectiveness of services; and
- establishing the existing service baseline to help guide service development and redesign.

From these three components, health care planners and commissioners, together with other stakeholders, can determine the policy direction they wish to pursue. There can also be other objectives in HNCA. These might include:

- improving access and the allocation of resources at local, regional and national levels;
- targeting resources at area(s) of highest need; and
- securing the active participation of key stakeholders and players in understanding the need for change and how it can be achieved.

Undertaking such work usually requires a collaborative approach bringing together people with the necessary knowledge base and those with the appropriate technical skills. Broadly speaking, this requires that there is an:

- *Epidemiological Needs Assessment:*
    - incidence and prevalence;
    - effectiveness and cost effectiveness of services; and
    - description of baseline services.

- *Corporate Needs Assessment:*
    - reporting the demands, wishes and alternative perspectives of interested parties, for example service users and their carers, and stakeholders including professional, political and public views.

- *Comparative Needs Assessment*
    - comparing and contrasting the services in the population under study with those provided elsewhere.

Taken together a HCNA should, insofar as there is appropriate data available, describe the capacity of the population to benefit from a service or intervention and to make suggestions as to how such benefits can be delivered. Health care need is not, however, the only important factor in planning and delivering health care. Consideration may be given to, for example, political direction, health care costs, legislation, competing NHS priorities, patient voices and public involvement, professional opinion, scarcity of resources or expertise and the existing pattern of services. Given the NHS is a public-funded institution, it is also important to recognise the importance of population perceptions and the impacts of political processes.

Scope of this needs assessment

Early in the project, discussions were had about the scope of this needs assessment and which aspects of care and/or patient groups should be included. It was determined that all forms of home oxygen therapy (LTOT, AOT, and SBOT) for both paediatric and adult patients in Scotland would be considered. Provision of home ventilation in addition to oxygen would not be considered and nor would use of oxygen in health care settings. It was recognised that home oxygen is a particularly difficult topic to address through a needs assessment as the patient groups served are so diverse. It was agreed therefore that when examining the epidemiology of the underlying conditions necessitating home oxygen, a manageable number of key conditions would be focused on.

Methods used in this needs assessment

Elements of the epidemiological, corporate, and comparative approaches to needs assessment were all adopted for this project.

Epidemiological approach

Epidemiology of underlying conditions
The epidemiology of key underlying conditions necessitating the provision of home oxygen was considered. The conditions focused on were:

- Chronic neonatal lung disease (CNLD)
- Severe neurodisability in children
- Cystic fibrosis (CF)
- Chronic interstitial lung disease (CILD) in adults, and
- Chronic obstructive pulmonary disease (COPD).

Brief literature scans were undertaken to identify information on trends in the burden of disease (incidence/prevalence/mortality) and to provide information on the natural history of disease, in particular the point at which home oxygen may be required and subsequent prognosis. For conditions with a dominant causative risk factors (eg smoking for COPD), information on trends in exposure to the risk factor was also sought. For all conditions, the quality of the evidence and its applicability to Scotland was considered.

Alongside the literature scans, available routine data were sought to provide information on:

- Prevalence of risk factors (CNLD, COPD)
- Incidence (CNLD, CF) and/or prevalence (CF, CILD, COPD) of disease
- Mortality from disease (CNLD, CF, CILD, COPD)
- Hospital admissions for disease (CNLD, CF, CILD, COPD)

As noted above, different data were sometimes available for different conditions. Routine data on severe neurodisability in children were not sought, mainly due to the inherent problems in defining the range of conditions that would be included in this category.

The data sources used were:
From the General Register Office for Scotland (GRO(S))

- Birth registrations
- Death registrations

- Mid year population estimates

From NHS National Services Scotland Information Services Division (ISD)

- Maternity hospital discharge records (SMR02): provides information on births (including gestation) in Scottish hospitals
- Neonatal 'sick baby' records (SMR11 – scheme phased out from 2002)
- Scottish Birth Record (SBR – scheme phased in from 2002): SMR11 and SBR together provide information on babies admitted to Special Care Baby Units with neonatal problems such as CNLD
- General (non-maternity, non-psychiatric) hospital discharge records (SMR01): ISD's linked file which brings all SMR01 records since 1981 together for an individual along with their death registration record if relevant was used to provide information on the total number of hospital admissions for particular conditions, average length of stay, readmission rates, and prevalence estimates (see below)

From the Scottish Newborn Screening Laboratory (SNSL)

- Neonatal blood spot screening records: provides information on the number of newborns detected through screening as having CF

From national surveys

- The Scottish Schools Adolescent Lifestyle and Substance Use Survey: provides information on smoking amongst 13 and 15 year olds in Scotland
- The Scottish Health Survey: provides information on smoking amongst adults aged 16 or over in Scotland
- The General Household Survey: provides longer time trend information on smoking amongst adults in Great Britain

Where relevant, both absolute numbers and rates were considered and data were broken down by appropriate age groups and sex. Data were obtained from 1989 (the time the HFS home oxygen service started) to the present wherever possible. The International Classification of Diseases (ICD) version 9 and 10 codes that were used to define the particular conditions and extract relevant hospital and death records are given in Appendix 2.

As noted above, ISD's linked file brings together all the SMR01 records since 1981 for an individual along with their death registration record if relevant. This is important as an SMR01 record is generated each time an individual is discharged from one episode of hospital care to another hence one admission to hospital could generate multiple SMR01 records if the patient requires transfer between different hospitals, facilities (eg high dependency unit and ward), or consultant teams. Using the linked file allows each admission ('Continuous Inpatient Stay', CIS) to be counted once and this approach was taken for this project. Analysing CISs rather than individual episodes of care also allows meaningful average length of stay for complete admissions to be calculated and also readmission rates (ie the proportion of individuals that are readmitted for the same condition with a specified period of time following discharge).

The linked file was also used to estimate trends in the prevalence of CF, CILD, and COPD in the Scottish population between 1989 and the present as follows. People were counted as a prevalent case in any one year if they had had at least one prior admission for the condition of interest since the start of the linked file in 1981 and were still alive on the 1 July of the year in question. In each year any individual prevalent case was counted once in the age and sex group relevant to them at that

time. Although substantial effort is put into ensuring the quality of hospital discharge data, some miscoding of the diagnoses that necessitated the admission does occur. The degree of miscoding has decreased over time hence is worse when working with historical as opposed to current data. Miscoding can occur in both directions eg an admission for asthma could be miscoded as one for COPD and vice versa. When admissions are miscoded to or from the conditions of interest to this project, the prevalence estimates will be erroneously inflated or deflated. To minimise this error, only first admissions for CF occurring when someone was <25 years of age and only first admissions for CILD or COPD occurring when the individual was >=25 years of age were picked up as indicating a prevalent case. An individual with CF is unlikely to get to 25 years of age without requiring any admissions for their condition and conversely admissions coded to COPD in children are likely to represent coding errors. It is recognised that this approach is relatively crude and does not eliminate all error. Nevertheless, this approach to estimating prevalence is useful for conditions such as CF, CILD, and COPD which are likely to require hospital admission as the disease progresses and once contracted are likely to remain for the duration of the person's life. It is worth emphasising that only individuals with disease severe enough to have required at least one admission will be counted as a prevalent case: individuals with early stage disease still to be diagnosed or being managed in the community will not be counted.

Effectiveness of home oxygen

At the time this needs assessment was being conducted, the British Thoracic Society (BTS) was in the process of developing guidelines for the use of home oxygen in adults (to be published in 2011) to complement their existing guidelines on use in children. The BTS guideline development process involves a detailed review of the literature on the effectiveness of home oxygen which it would have been inefficient for this needs assessment project to replicate. In addition, this project was being undertaken to a highly constrained timescale. Rapid scans of relevant literature were therefore undertaken rather than detailed systematic reviews. Existing reviews were examined in preference to primary studies in most cases.

The following questions were used to focus the literature scans:

- How effective is LTOT in improving important outcomes such as breathlessness, exacerbations of/admissions for underlying disease, pulmonary hypertension, right sided heart failure, or mortality?
- How does effectiveness vary by factors such as underlying diagnosis, patient age, duration of oxygen use per day, and mechanism of oxygen delivery (eg cylinder vs concentrator)?
- What are the marginal benefits and disbenefits of AOT?
- How effective is SBOT in improving important outcomes such as breathlessness, exacerbations of/admissions for underlying disease, or mortality?
- How common are the complications of home oxygen (restriction of activity, impairment of communication, dry mouth/nose, fire/burns)?
- Is any evidence available on the cost effectiveness of home oxygen?
- What is known about the provision of home oxygen relative to population need for the service?

Publications from the following organisations were searched to identify relevant reports/reviews:

- Scottish Government
- British Thoracic Society (BTS)
- Scottish Intercollegiate Guidelines Network (SIGN)

- National Institute for Health and Clinical Excellence (NICE)
- Royal College of Physicians
- Royal College of Paediatrics and Child Health
- NHS Quality Improvement Scotland (QIS)
- Cochrane Collaboration

The bibliographies of the identified reports/reviews were used to identify key primary papers and additional Medline and PubMed searches were performed using the keywords (home, oxygen, continuous, short, long, intermittent, ambulatory, therapy), for the period 2007-2010, to identify any recent literature not captured by the earlier reports.

Additional information on providers' views on the effectiveness of home oxygen was obtained through the semi-structured interviews conducted for this project (see below).

Current and previous provision of home oxygen in Scotland
Information was sought on trends in the provision of home oxygen in Scotland. Information on oxygen cylinders dispensed through community pharmacies or dispensing practices is available though ISD's Prescribing Information System (PIS). PIS provides complete information from 2004 onwards on the number of prescriptions dispensed, the total number of cylinders dispensed (as more than one cylinder may be dispensed per prescription), and the gross ingredient cost (actual cost of the oxygen) of the dispensed cylinders. When pharmacies dispense oxygen, they are also eligible for reimbursement of the additional costs associated with cylinder provision (such as for rental of cylinders and delivery to patients' homes). Information on these additional costs was obtained from NHS National Services Scotland Practitioner Services Division (PSD) which is responsible for making the payments.

Traditionally, the PIS has contained high quality data on the medicine/product dispensed but limited or no information on the patient for whom the prescription is intended. This reflects the fact that PIS is primarily a by-product of information required to reimburse pharmacists for the medicines they have dispensed. Over recent years, however, efforts have been made to include patients' Community Health Index (CHI) number in PIS. The CHI is in effect a list of all patients registered with a GP in Scotland and contains information on patients' age and sex as well as other demographic details. Including CHI on PIS therefore allows calculation of not just the number of prescriptions dispensed but also the number of individual patients receiving a particular medicine over a period of time along with their age and sex profile. PIS records for oxygen cylinder prescriptions dispensed in the 3 month period May to July 2010 that contained the patient's CHI were examined for this project to provide estimates of the number of patients receiving home oxygen cylinders at that time and their age, sex, and NHS Board profile.

Information was also sought on the provision of concentrators and other oxygen equipment through HFS. HFS and Dolby together maintain a database that provides information on all patients in receipt of a concentrator or other equipment and other information such as the number of requests for temporary oxygen provision to cover holidays. The database provides information on some issues such as patients' age and type of device provided but not others such as patients' gender, underlying diagnosis, or whether the patient is also in receipt of oxygen cylinders through community pharmacies. The database is used to actively manage the home oxygen services provided by HFS and Dolby so the basic data (eg number of patients in

receipt of a concentrator) are presumed to be of high quality. The quality of other variables such as patients' age is unknown.

To estimate how long patients usually use a concentrator for, all patients first provided with a concentrator during 2004 were examined. These patients were followed up to see how long the concentrator remained installed in their homes (Dolby removes concentrators promptly when they are no longer required, in adult patients this usually means after the patient's death).

Information on the costs of provision of home oxygen was also sought from HFS. Costs can be divided into the direct costs of providing oxygen equipment (which are paid to the contractor) and additional costs such as those relating to reimbursement of patients' additional electricity costs incurred through running a concentrator in their home and salary costs for the staff running the home oxygen service within HFS. Cost data was available from 1993/94 onwards.

Finally, the numbers of patients on the different forms of home oxygen in NHS Boards across Scotland were used to calculate estimated home oxygen provision rates per 10,000 population for each Board.

Corporate approach

NSS conducted a survey on behalf of the Scottish Government in 2006 eliciting patients' and community pharmacists' views on home oxygen provision. The results of this survey were summarised in the 2010 report of the working group on home oxygen (Scottish Government, 2010). In addition, as part of their review, the working group directly solicited the views of relevant patient groups on home oxygen provision and they also commissioned an external agency to undertake a substantial research project. The research project included a thorough assessment of user and provider views on home oxygen provision through interviews with and a survey of patients and carers and a Delphi survey of providers including GPs, consultants, specialist nurses and physiotherapists, palliative care clinicians, community pharmacists, and NHS Board representatives (Ferguson et al, 2010). This extensive previous work was summarised for the purposes of this project and no further direct elicitation of user views on home oxygen was undertaken.

A series of semi-structured interviews with clinicians responsible for the prescribing of home oxygen to patients was undertaken in September 2010 as part of this needs assessment project to supplement the information already available. A purposive sample of 18 interviewees chosen to reflect key professional groups from a range of both urban and rural locations across Scotland was identified: all 18 took part in an interview. A further three interviews were undertaken with staff from the Scottish Government and National Services Scotland to provide information on current service configuration and the availability of data on home oxygen provision. Further details on the interview sample are provided in Appendix 3: the clinical groups covered were:

- Managed clinical network leads
- Consultant physicians and paediatricians/neonatologists
- Specialist and practice nurses
- General practitioners

Members of the wider healthcare team involved in the ongoing care of patients on home oxygen and suppliers were not included in the interviews due to time and resource constraints.

All interviews were guided by an interview schedule relevant to the professional being interviewed and a sample schedule is provided in Appendix 4. The main areas focused on in the interviews related to:

- Decision making around initiating home oxygen therapy
- Clinical monitoring of patients on home oxygen
- The effectiveness of different forms of home oxygen
- The influence of factors such as changing patterns of hospital based care, availability of new technology, and policy/guidelines on demand for the service
- The current adequacy and appropriateness of home oxygen provision
- Potential future service developments

All interviews were audio recorded and subsequently transcribed before clinical groups' views were systematically analysed with common themes and areas of discrepancy identified. Interviews were coded using the NVivo version 8 computer package to enable comparison of responses. Initial themes were identified in this way and responses were compared for each question using matrix analysis.

Comparative approach

Information on the provision of home oxygen in England and Wales, and particularly on the restructuring of the service that occurred in 2006, was obtained from the relevant NHS website (http://www.homeoxygen.nhs.uk/1.php) and in particular the Home Oxygen Service Manual (Department of Health 2007) and the BTS document on the clinical aspects of the home oxygen service in England and Wales (British Thoracic Society 2006). Information on the numbers of patients in the regions of England and Wales receiving different forms of home oxygen was obtained from the Department of Health in London.

A rapid literature scan was also carried out to identify any available information on the configuration of home oxygen services (eg eligible prescribers, types of patients served, types of devices available, overall provision rates) in countries outwith Great Britain.

Epidemiology

A wide range of conditions can underlie a requirement for home oxygen. Essentially any conditions that cause chronic respiratory failure/hypoxaemia can result in a patient potentially requiring LTOT. Respiratory conditions that impair the ability of the lungs to deliver oxygen to the blood stream are the most common underlying problems. These can include chronic neonatal lung disease, cystic fibrosis, interstitial lung disease, pulmonary vascular disease, severe chronic asthma, and chronic obstructive pulmonary disease. Paediatric patients with inadequate lung development/pulmonary hypoplasia, for example due to diaphragmatic hernia, can also require long term oxygen therapy.

Heart disease in adults such as chronic heart failure can also result in hypoxaemia and hence provision of LTOT although the effectiveness of LTOT in patients with heart disease is unclear. LTOT is occasionally used in paediatric patients with acyanotic congenital heart disease although again its effectiveness is unclear. LTOT is not indicated in babies with cyanotic congenital heart disease.

Conditions that result in hypoxaemia because of weak or inefficient respiratory movements are an important additional category of patients that may require LTOT. Specific underlying conditions include muscular dystrophies and severe obstructive sleep apnoea/hypopnoea syndrome. Skeletal problems such as kyphoscoliosis (curvature of the spine) can also indicate LTOT if they are severe enough to prevent the lungs from expanding and working efficiently. These neuromuscular and skeletal problems often indicate LTOT (or possibly just nocturnal oxygen therapy) in addition to some form of ventilatory support such as non-invasive ventilation whereas respiratory and cardiac conditions usually indicate LTOT alone. The respiratory conditions noted above are the most common problems resulting in a requirement for ambulatory oxygen therapy in addition to LTOT. These respiratory conditions (at an earlier stage in disease progression) often also underlie the provision of SBOT.

Other patient groups can also be prescribed home oxygen although their pattern of use may not fit well with the usual LTOT/AOT/SBOT classification. Patients with terminal illness, particularly lung cancer, may use home oxygen on a short burst or long term basis at the end of their lives to palliate severe breathlessness. Children with severe neurodisability who are prone to recurrent severe respiratory infections but are being managed at home to avoid frequent admissions and preserve family life are commonly prescribed LTOT which they use just during their periods of infection/exacerbation (intermittent LTOT). Adults with cluster headaches and patients with recurrent severe asthma can also be prescribed home oxygen to use in emergency situations, to reduce the severity of headache or whilst an ambulance is on its way (intermittent emergency oxygen).

It is worth emphasising that the conditions most frequently underlying provision of home oxygen vary markedly depending on the age group considered (Balfour-Lyn et al 2009). The prognosis of children on home oxygen can also be quite different from that of adults, with some children (mainly those with chronic neonatal lung disease) expected to improve over time and 'wean off' their oxygen whereas most adults requiring home oxygen have progressive disease (Primak et al 2010).

As the potential range of conditions underlying provision of home oxygen is so wide, only the epidemiology of a small number of key conditions that are likely to account for the majority of demand for home oxygen was considered in detail for this report.

The specific conditions considered (in order of increasing age when usually affected/requiring home oxygen) were:

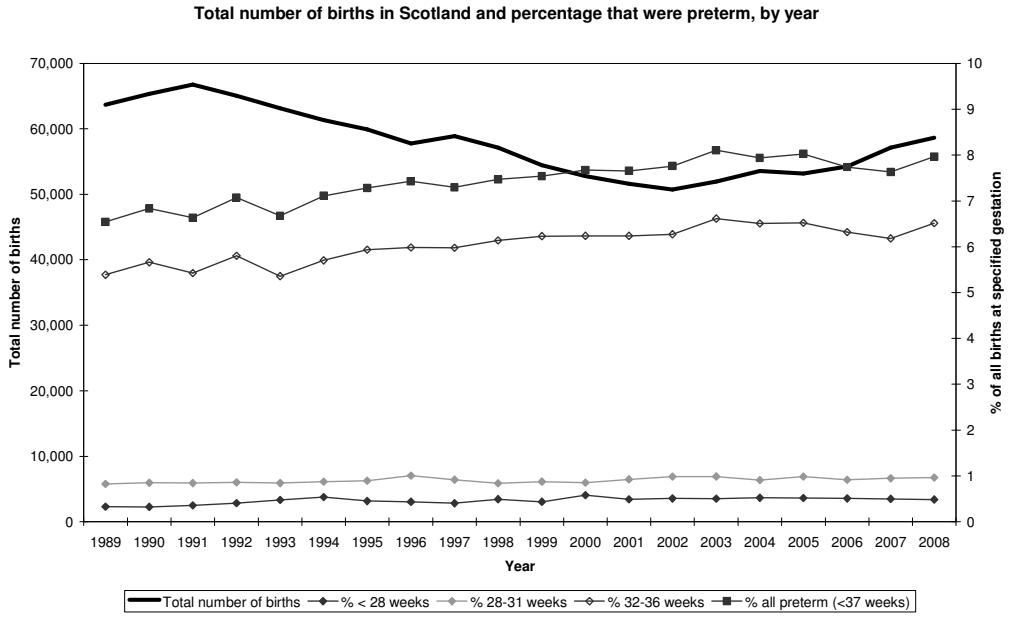
- Chronic neonatal lung disease (CNLD)
- Severe neurodisability in children
- Cystic fibrosis (CF)
- Chronic interstitial lung disease (CILD) in adults, and
- Chronic obstructive pulmonary disease (COPD).

Chronic neonatal lung disease

Chronic lung disease was the most commonly diagnosed condition (44%) in a cross-sectional survey of children in England and Wales receiving home oxygen therapy (Primak et al 2010). Although the aetiology of CNLD (also known as bronchopulmonary dysplasia, BPD) is not fully understood, it usually arises in premature babies who have had neonatal respiratory distress and required mechanical ventilation (Marshall et al 1999; Banks-Randall and Ballard 2005; Tapia et al 2006). There is debate about the precise diagnostic criteria for CNLD but one commonly used definition states it should be diagnosed when a baby who is at least 28 days old still requires supplementary oxygen at 36 weeks corrected gestation (Shennan et al 1988; Patrinos 2002).

As CNLD occurs predominantly in babies born prematurely it is useful to examine trends in premature births in Scotland. The total number of births in Scotland declined over the 1990s to a low of 51,548 in 2002 but has since been increasing again, reaching 60,366 in 2008. The proportion of births that are premature (born at less than 37 completed weeks of gestation) has increased over time, from around 6.5% in the late 1980s to almost 8.0% in 2008. The proportion of births that are extremely premature (<28 weeks gestation) has also increased over that time period from around 0.35% to around 0.5%. The absolute number of babies born at less than 28 weeks gestation (the group at highest risk of CNLD) has therefore fluctuated over time but overall has increased from 209 in 1989 to 284 in 2008. The current upward trend in both overall number of births and the proportion that are premature means this figure is likely to continue to increase over the short term.

Figure 1



Data sources: Total births from birth registrations, GROS, % premature from SMR02, ISD

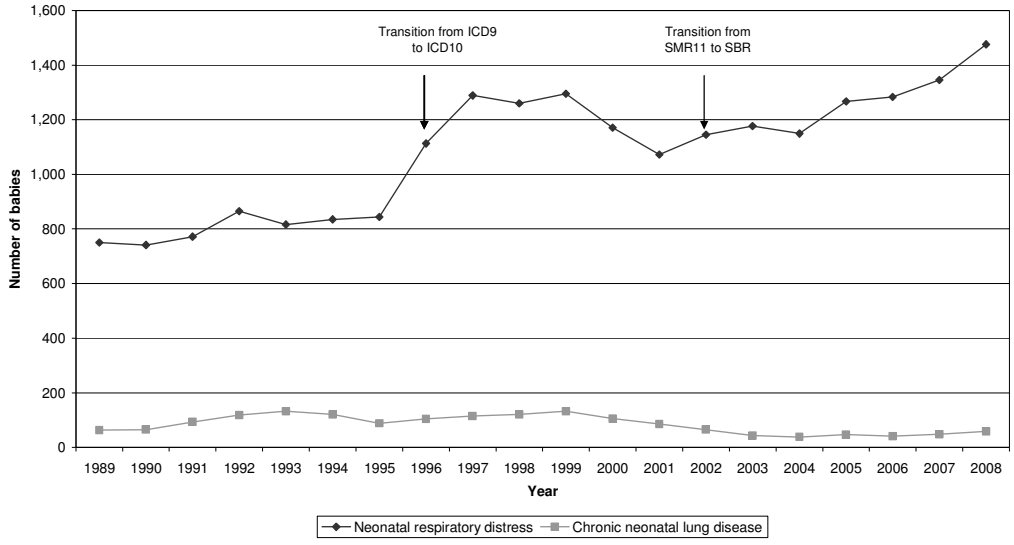
In international studies, the incidence of CNLD amongst surviving premature infants has been found to range from 12% to 35%, with incidence increasing with increasing prematurity (Egreteau et al 2001; Kamper et al 2004; Hentschel et al 2005; Tapia et al 2006; Larroque et al 2008). In a UK observational study of babies weighing

<1250g admitted to a Nottingham neonatal intensive care unit in 1997, 29% developed CNLD (still oxygen dependent at 36 weeks corrected gestation) (Manktelow et al 2001). In the Nottingham study, data were collected at three time points: 1987, 1992 and 1997. Although incidence of CNLD increased between 1987 and 1992, the trend in the data for 1992-1997 suggests that the risk of developing CNLD may have fallen, but the change did not reach statistical significance. A recent US study, based on admissions to hospitals, suggests that the absolute incidence of CNLD actually fell 3.3% (p =0.0009) annually between 1993 and 2006 (Stroustrup and Trasande 2010).

Trends in the number of babies treated in Scottish neonatal units for neonatal respiratory distress and CNLD are shown below. Trends are difficult to interpret as there is no direct correlation between the diagnostic codes used to identify these conditions/hospital stays before and after 1996 (ie before and after the change from the International Classification of Diseases (ICD) version 9 to ICD 10) and also the data collection system used to record these hospital stays changed from SMR11 (sick baby record) to SBR (Scottish Birth Record) from 2002 onwards. Nevertheless, it appears that over recent years when the number of premature births has been increasing, the number of babies with neonatal respiratory distress has also been increasing but the number of babies with CNLD has been relatively constant. This probably reflects improvements in the care of very premature babies such as the use of antenatal steroids and the use of surfactant and less traumatic ventilation (Geary et al 2008).

Figure 2

Number of babies with a hospital stay for neonatal resiratory distress or chronic neonatal lung disease, all Scotland by year

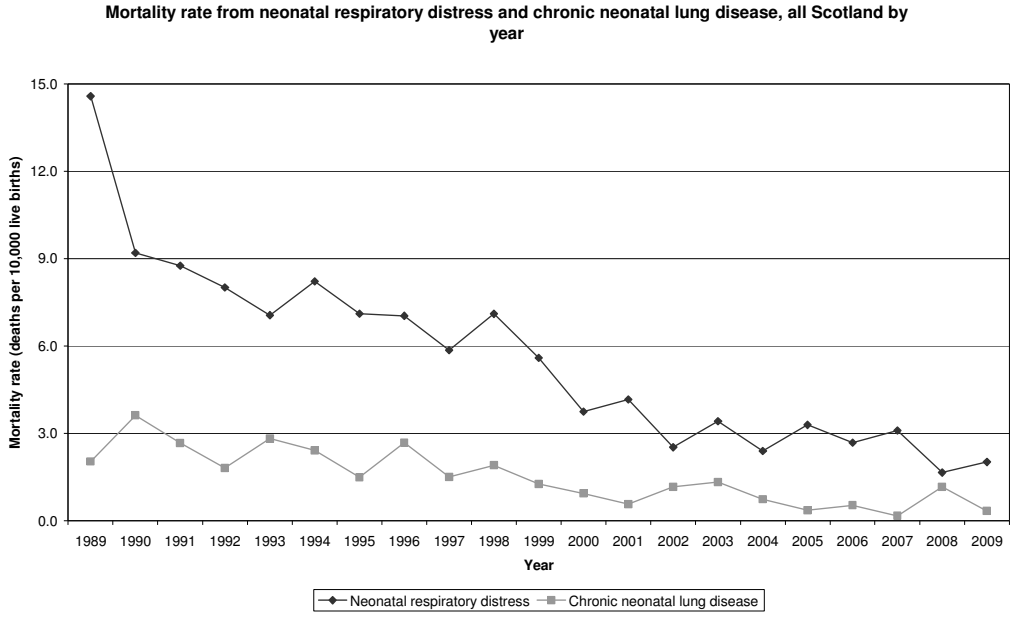


Data sources: SMR11 and SBR, ISD

The prognosis of CNLD depends on its severity and the coexistence of other morbidities of prematurity such as intraventricular hemorrhage/periventricular leukomalacia. The number of babies in Scotland dying from neonatal respiratory distress or CNLD, and the mortality rates from these conditions has shown a clear downward trend over the period studied (Figure 3). The majority of deaths from neonatal respiratory distress occur in the neonatal period (age <1month) whereas most deaths from CNLD by definition occur in the post-neonatal period (age 1-11

months). This falling mortality from CNLD in the face of relatively static incidence indicates that more babies are surviving through infancy with this condition.

Figure 3



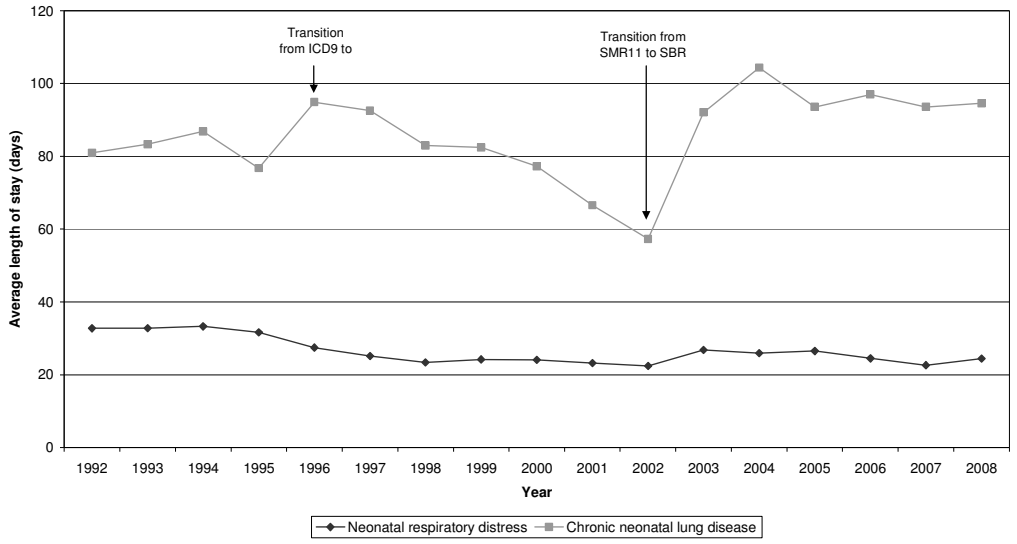
Data sources: death and birth registrations, GROS

Most surviving infants eventually 'outgrow' their CNLD and although this can take much longer in some babies than others (Patrinos 2002). LTOT is recommended for infants with CNLD to reduce or prevent pulmonary hypertension, reduce intermittent desaturations, reduce the risk of sudden infant death, and promote growth and neurodevelopment (British Thoracic Society 2009).

The availability of LTOT in the home is an important factor in facilitating the discharge from hospital of infants with CNLD who are oxygen dependent but otherwise well enough to go home. Trends in the average total length of stay for babies with CNLD in Scotland (ie the average age at which these babies get home from hospital) were examined. There are substantial difficulties in interpreting trends in length of overall hospital stay for neonatal respiratory distress and CNLD due to the disjunction between ICD9 and 10 codes for these conditions and particular difficulties in accurately identifying total length of stay using SBR data. For the period 1996-2002 (SMR11 data coded using ICD10 and hence the most reliable period), there is evidence that overall length of hospital stay for babies with CNLD fell substantially, from around 95 days to 57 days. More recent data suggests that this decline may now have plateaued but as discussed this is uncertain.

Figure 4

Average length of stay for babies with neonatal respiratory distress and chronic neonatal lung disease, all Scotland by year



Data sources: SMR11 and SBR, ISD

Overall, therefore, it seems likely that there are more premature babies being born but due to improvements in the ventilation of very small babies, the number developing CNLD is relatively constant. Babies that do develop CNLD however are more likely to survive and to be discharged from hospital at a younger age and hence to require home oxygen therapy.

Severe neurodisability in children

Severe neurodisability is a relatively poorly defined state but generally refers to children with substantially delayed development in a number of domains (eg gross motor, fine motor, communication, vision, etc) with an underlying neurological condition. Complications of prematurity are important causes of neurodisability. Other underlying conditions include static conditions such as cerebral palsy (which itself may be linked to prematurity) and the less common progressive neurodegenerative conditions. Regardless of the precise underlying condition, these children tend to have multiple co-morbidities including feeding and respiratory problems. For a number of reasons, they are prone to recurrent chest infections that can be associated with hypoxaemia and which significantly worsen their overall condition (Morton et al 1999; Seddon and Khan 2003). The outlook for these children is generally poor with high mortality rates. To avoid recurrent hospital admissions, children with severe neurodisability can be provided with home oxygen for use during periods of infection (intermittent LTOT). Provision of home oxygen for these children is more often driven by quality of (family) life issues rather than clear evidence of impact on clinical outcomes (BTS 2009). In a recent cross-sectional survey of people of people receiving home oxygen in England and Wales, 14% of children reported neurodisabilites. Neurodisability was the second most commonly reported diagnostic category after chronic neonatal lung disease (Primrak et al 2010).

There is very little published data on the overall incidence and prevalence of neurodisability in the UK or elsewhere (Bax et al 2003). It is known, however, that severe neurodisability is relatively common after very preterm birth. In the current published literature, rates of severe neurodisability vary between 18 and 40% in very young children for those born at 25 weeks of gestation (Hack & Fanaroff 1999). Two UK studies of 580 and 283 children born at 25 or fewer completed weeks of gestation found prevalence rates of severe neurodisability of 24% at one year follow up (Wood et al 2000). It is unclear how improvements in the care of very preterm babies (increased survival vs possibly decreasing risk per baby) are influencing the overall incidence of severe neurodisability.

The overall prevalence of cerebral palsy has been estimated as 2-2.5 per 1000 live births (all gestations) in the UK and US (Pharoh et al 1998; Reddihough and Collins 2003; Dolk et al 2010). There is no evidence that these overall rates are currently changing significantly (Pharoah et al 1990; Marlow 2004). Survival of children with cerebral palsy depends on the degree of functional impairment (Heming et al 2005). Around half of all children with severe cerebral palsy in the UK survive into their teens and around a quarter survive into their 30s (Hutton and Pharoah 2006).

It is difficult to predict future trends in severe neurodisability in Scotland with certainty. It seems likely, however, that even if incidence remains broadly static, the prevalence (overall number of children living with severe neurodisability at any one time) will increase somewhat due to improved survival of children with complex problems.

Cystic fibrosis

Cystic fibrosis is one of the UK's most common life-threatening inherited diseases. CF is inherited in an autosomal recessive manner and is caused by a defect in a single gene on Chromosome 7 which is responsible for controlling the movement of salts in the body (O'Sullivan and Freedman 2009). In patients with CF, the lungs and digestive system become clogged with thick sticky mucus resulting in chronic infections and inflammation in the lungs and difficulty digesting food (Strausbaugh and Davis 2007). CF can manifest in different ways in different patients with the severity of lung and digestive problems being quite variable. Over time however, serious decline in lung function is almost inevitable and a high proportion of CF patients will require home oxygen. At least 80% of deaths in CF patients are due to respiratory problems (Strausbaugh and Davis 2007).

Neonatal screening for CF based on detection of immune reactive trypsin (IRT) in the heel prick blood spot sample obtained when babies are around 5 days old was introduced in Scotland during 2003. The number of babies found to have CF through the screening programme is shown below. The small number of babies identified clinically as having CF who screened negative and were subsequently notified to the national screening laboratory is also noted. There may also be an additional small number of babies with CF who were never screened, for example because they presented clinically (e.g. with meconium ileus) before 5 days of age.

Table 1: New cases of CF detected through newborn screening, all Scotland 2004-2009

	2004	2005	2006	2007	2008	2009
Number of babies tested for CF	54,612	54,643	55,703	58,100	60,354	59,341
Number with raised IRT who went on to be diagnosed with CF	32	21	32	18	28	25
Additional new cases of CF not identified by screening that were notified to the SNSL	3	2	3	2	1	0
Total known incident cases of CF	35	23	35	20	29	25
Incidence rate of CF per 10,000 births	6.4	4.2	6.3	3.4	4.8	4.2

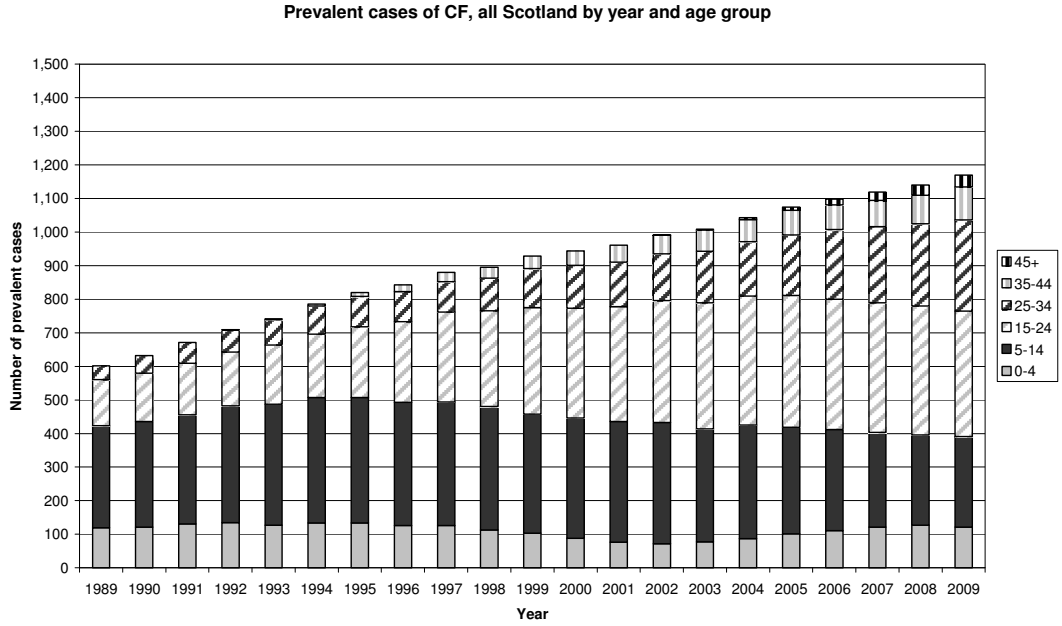
Data source: Scottish Newborn Screening Laboratory (SNSL), Yorkhill Hospital, and GRO(S) birth registrations

Cystic fibrosis is most common in populations of northern European descent and the UK has one of the highest rates of CF in the world (Farrell 2008). The gene carriage rate in northern European populations is around 1 in 25 persons giving an expected incidence of disease of around 1 in every 2,500 live births (Dodge et al 2007; O'Sullivan and Freedman 2009). By definition (as it is an autosomal condition) the incidence of CF is comparable in males and females. It can be seen from Table 1 that the incidence has fluctuated somewhat from year to year as would be expected due to the small numbers involved but overall is broadly in line with the expected incidence in Scotland of around 25 cases per year or 4 per 10,000 births.

ISD's linked database, which brings together all hospital admissions and, if relevant, death records for individual was used to estimate the prevalence of CF ie the number of people living with the condition at any one time. It is important to note that this

approach only captured patients admitted to hospital for their CF (with first admission occurring when they were aged <25 years) and that there will be some degree of error in the figures due to the use of imprecise of incorrect ICD codes to record patients' underlying condition on hospital discharge records.

Figure 5



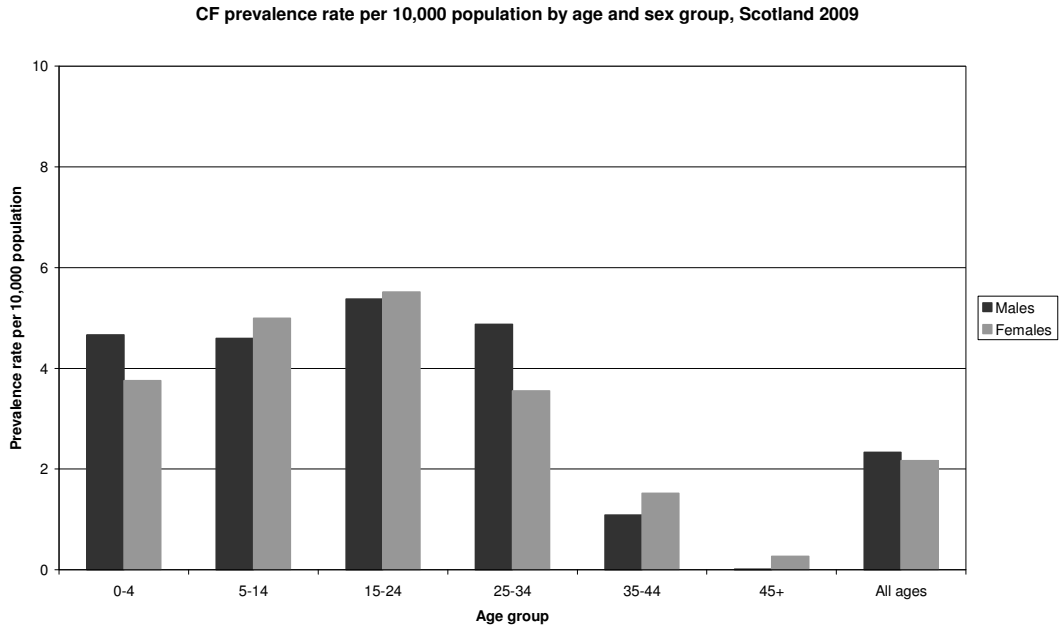
Data source: linked database, ISD

It can be seen that the prevalence of CF has almost doubled over the period of study from a total of 602 persons in 1989 to 1,169 in 2009. The majority of this increase has been due to increased numbers of people aged 15 years and over living with CF and hence reflects improvements in survival of CF patients achieved over the last 20 years (Dodge et al 1997; Dodge et al 2007). Slight reductions in the birth prevalence of CF following the introduction of newborn screening (due to earlier diagnosis and hence improved opportunity for prenatal testing of subsequent pregnancies) has been noted in other settings (Massie et al 2010) but this effect is not yet apparent in Scotland from these data.

Data from a UK wide register of all people living with CF (the UK CF Survey) suggested that in 2003 there were 8,224 people in the UK living with CF (Dodge et al 2007). A separate estimate looking just at data on Scottish residents suggested there were around 750 people living with CF in Scotland in 2003 (Gray 2003). The prevalence estimates derived from routine hospital discharge figures shown above are slightly higher than these other estimates but generally broadly comparable. There are known data completeness issues with the UK CF Survey, with not all areas of Scotland contributing to the register (Gray 2003; Dodge et al 2007).

The current prevalence rate of CF by age and sex (Figure 6) shows that prevalence is relatively constant up to 24 years of age then steeply declines with increasing age, reflecting the high mortality of CF patients as they age. As would be expected, prevalence rates are similar in males and females.

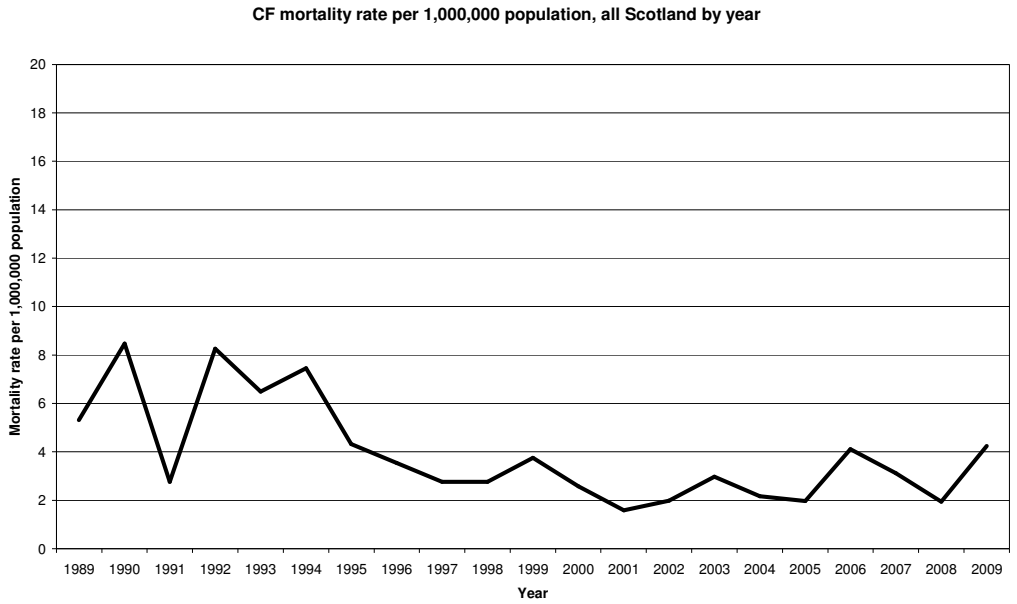
Figure 6



Data source: linked database, ISD and mid year population estimates, GRO(S)

Mortality from CF fell over the early 1990s although the decline appears to have plateaued over recent years. The average age at death has increased substantially over the past 20 years however. In keeping with the prevalence data shown above, deaths in people aged <15 years are now unusual but equally survival beyond 45 remains uncommon: most deaths occur in the 15-34 age group.

Figure 7

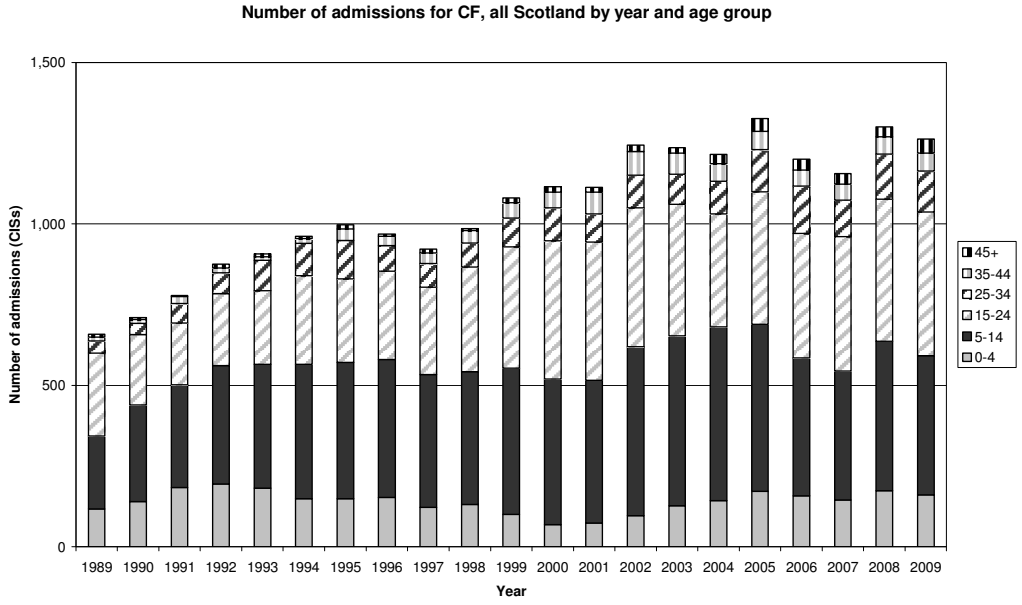


Data sources: death registrations and mid year population estimates, GROS

This trend towards improved survival and older age at death has been noted in many studies (Lewis et al 1999; Kulich et al 2003; LAIA 2005; Slieker et al 2005). There is some evidence that further improvements in survival of CF patients can be anticipated as Scotland still has higher mortality amongst CF patients than other higher income countries such as England and Wales and the US (Fogarty et al 2000). The current median life expectancy for CF patients in the UK as a whole has been estimated as around 40 years (Dodge et al 2007) although as noted this is likely to be somewhat lower in Scotland.

The number of hospital admissions for CF has increased steadily over time (Figure 8). Admission rates are highest in the 5-14 year age group although all age groups (with the possible exception of the 0-4 year group) have seen an increase in admission rates over time.

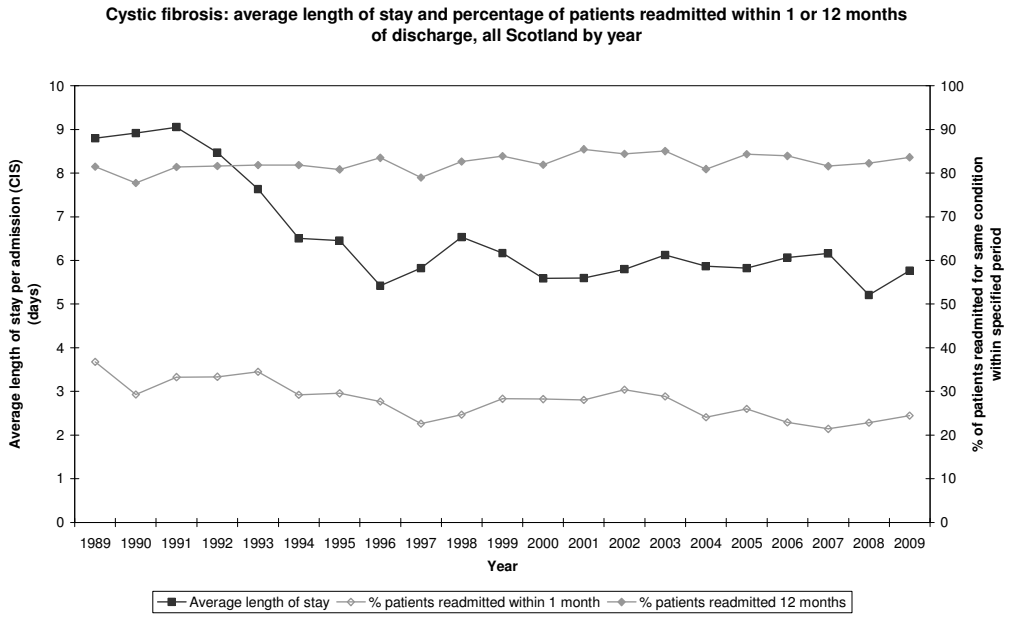
Figure 8



Data source: linked database, ISD

The average length of stay for CF admissions fell substantially over the early 1990s but has been relatively constant over recent years. Readmission rates are consistently very high for CF patients (Figure 9).

Figure 9



Data source: linked database, ISD

Overall there is evidence that the incidence of CF is relatively constant but survival is increasing hence the number of people living with CF into young adulthood is also increasing. CF patients are high users of hospital services, with frequent admissions.

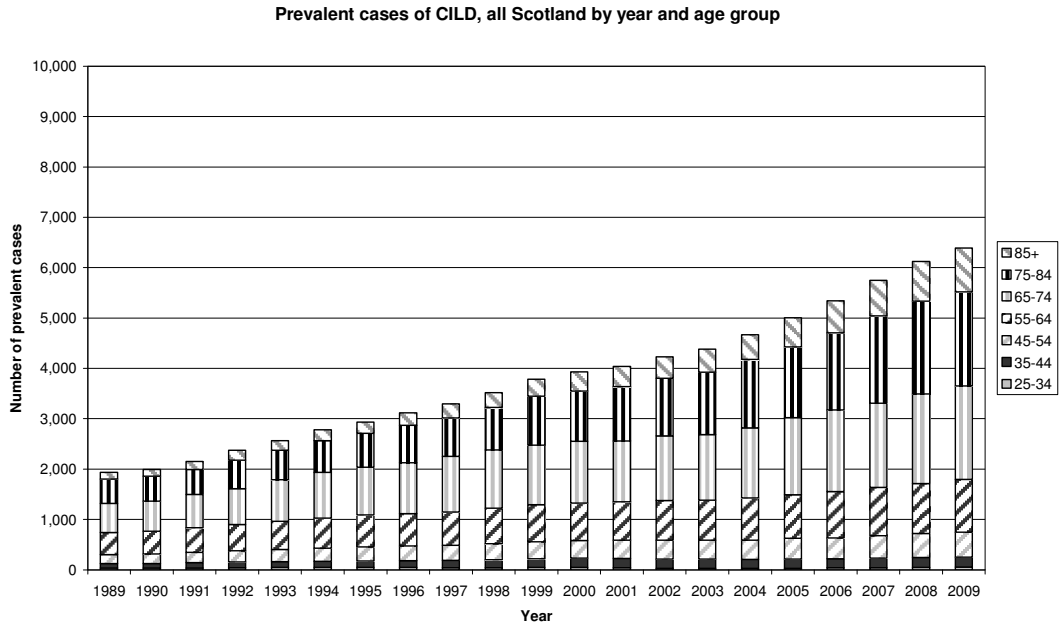
It is of interest to consider how the improved survival of patients with CF will translate into requirements for home oxygen. It is likely that some of the additional years of life that have been gained are relatively healthy and independent years but equally an unknown proportion may be additional years lived with severe disease that requires support such as home oxygen. Use of home oxygen by children with CF is relatively uncommon: only around 1-2% of paediatric CF patients are on home oxygen (Balfour et al 2005; Douglas et al 2008). Use will clearly be much higher in adult patients as their disease progresses.

Chronic Interstitial Lung Disease

Chronic interstitial lung disease (CILD) in adults encompasses a range of conditions characterised by inflammation and/or scarring of the lung interstitium (the tissue surrounding the lung air sacs/alveoli) and hence reduced ability of the lungs to pass oxygen into the blood stream (American Thoracic Society 2000). CILD can be idiopathic (have no identifiable cause eg idiopathic pulmonary fibrosis) or associated with/caused by autoimmune disease (eg sarcoidosis), exposure to organic or inorganic dusts (bird fancier's lung, coal workers pneumoconiosis), or certain infections, drugs or radiotherapy (Raghu et al 2004). Smoking is associated with some forms of CILD but not all (Britton and Hubbard 2000; Nagai et al 2000). In general the clinical spectrum of CILDs is changing with disease caused by occupational exposure becoming less common and idiopathic disease becoming more prominent (Hubbard et al 1996, 2000a; Baumgartner et al 2000). CILD can occur in children but it is rare and has not been considered further here (Demedts et al 2001).

Information on incidence of CILD is not readily available from routine data sources but prevalence estimates derived from hospital admission and death data are shown below.

Figure 10



Data source: linked database, ISD

It can be seen that the overall prevalence of CILD has apparently increased substantially over the past 20 years, from 1,933 cases in 1989 to 6,394 cases in 2009. All adult age groups have shown an increase in prevalence but it is the oldest age groups that have seen the highest absolute and relative increases in numbers of cases and prevalence rates.

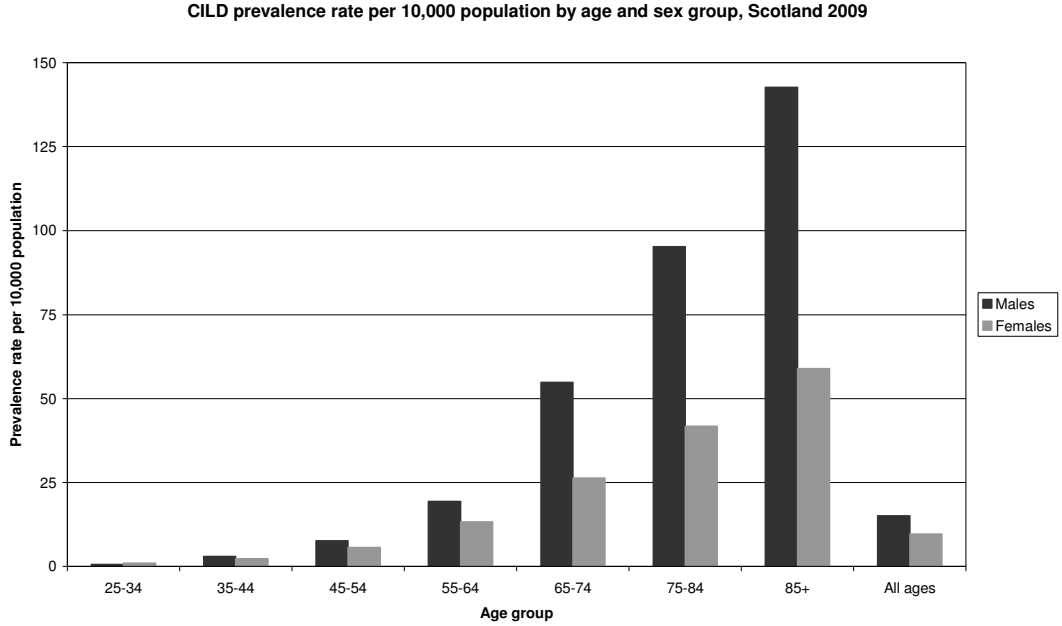
Consistent data on trends in the overall incidence and prevalence of CILD are hard to find in the literature and problems with inconsistent diagnostic classifications have been noted (Demedts et al 2001). Trends in particular subtypes of CILD can show different patterns. There is some evidence that incidence of and deaths from

idiopathic pulmonary fibrosis have increased over recent years in the UK (Johnston et al 1990; Hubbard et al 1996; Gribben et al 2006) whilst incidence of sarcoidosis has remained relatively constant (Gribben et al 2006). A study based on new cases of all forms of CILD identified through outpatient or hospital admission data in Denmark suggested that the overall incidence of CILD had increased by around 33% between 1995-2000 and 2001-2005 (Kornum et al 2008), broadly similar to the increase in prevalence over that time period shown above.

There is unresolved debate over how much of the apparent rise in CILD incidence and prevalence over recent years is due to genuine increase in disease and how much can be explained by improved awareness, better diagnosis, and more precise diagnostic classification/coding (Kornum et al 2008). The criteria and terminology for CILD have been variable and confusing; however, major improvements have resulted from the recent development of an internationally agreed classification system (Wells and Hirani 2008). Evidence from recent population based studies suggests that the incidence and prevalence rates of CILD are on the increase, particularly when this international classification system is used (Raghu et al 2004).

Most types of CILD are first diagnosed between the ages of 40 and 70 years although median age at first diagnosis, relative numbers of men and women affected, and subsequent prognosis/disease progression can vary markedly between different specific disease types (Turner-Warwick 1990; Gribben et al 2006). In Scotland, overall prevalence increases sharply with age and is consistently higher in men than women (see below). Around 60% of prevalent cases are men and men and women have seen a similar increase in prevalence over recent years.

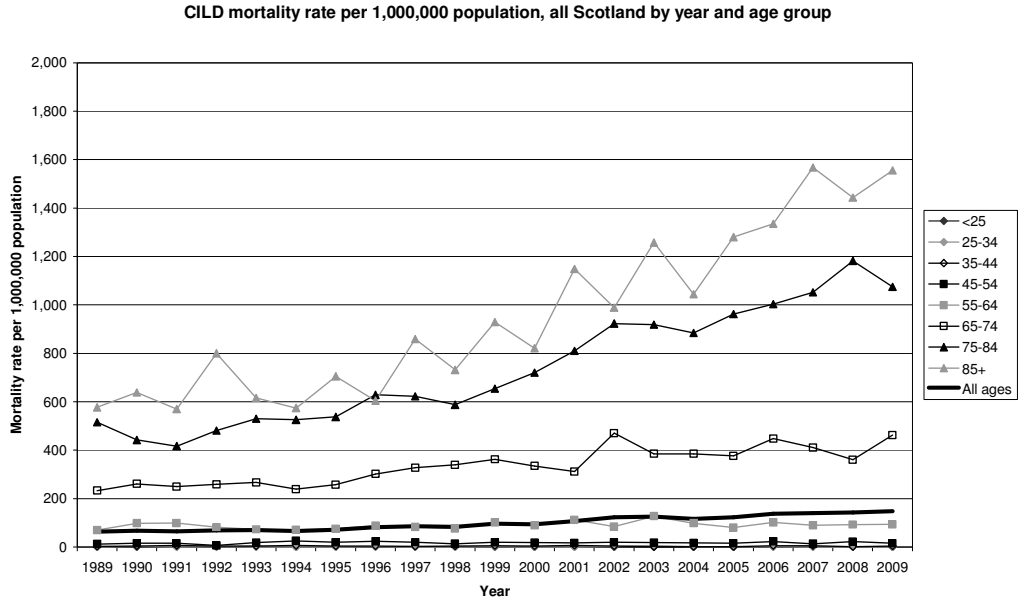
Figure 11



Data source: linked database, ISD

The number of deaths from CILD has increased steadily over recent years from 321 in 1989 to 770 in 2009. Mortality rates increase with age, hence are highest in the 85+ age group (Figure 12).

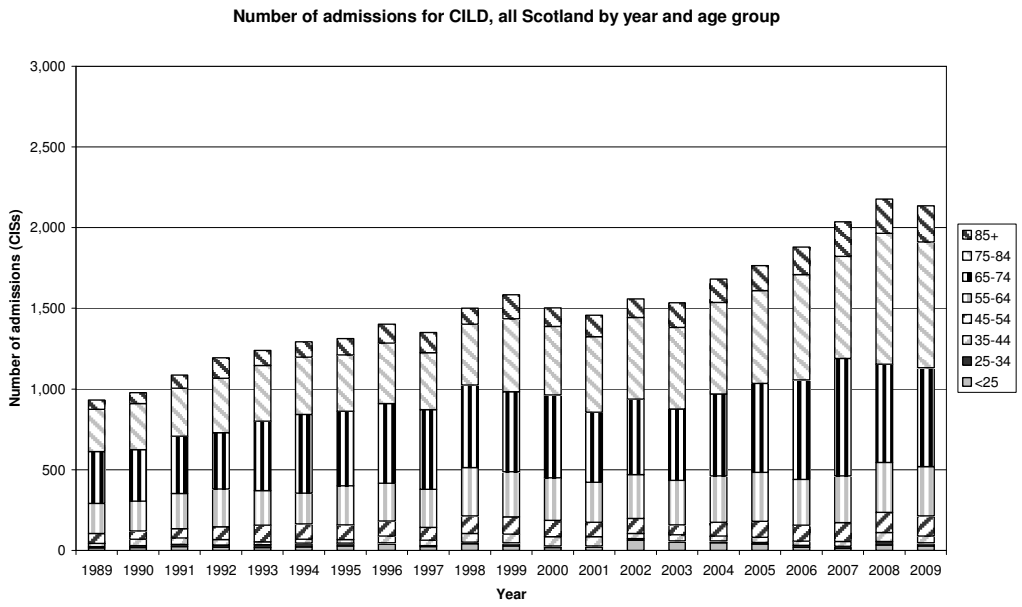
Figure 12



Data sources: death registrations and mid year population estimates, GROS

The number of admissions for CILD has more than doubled over the past 20 years (Figure 13). The 75-84 year age group has consistently had the highest overall admission rate and has experienced the most marked increase in admission rates over time.

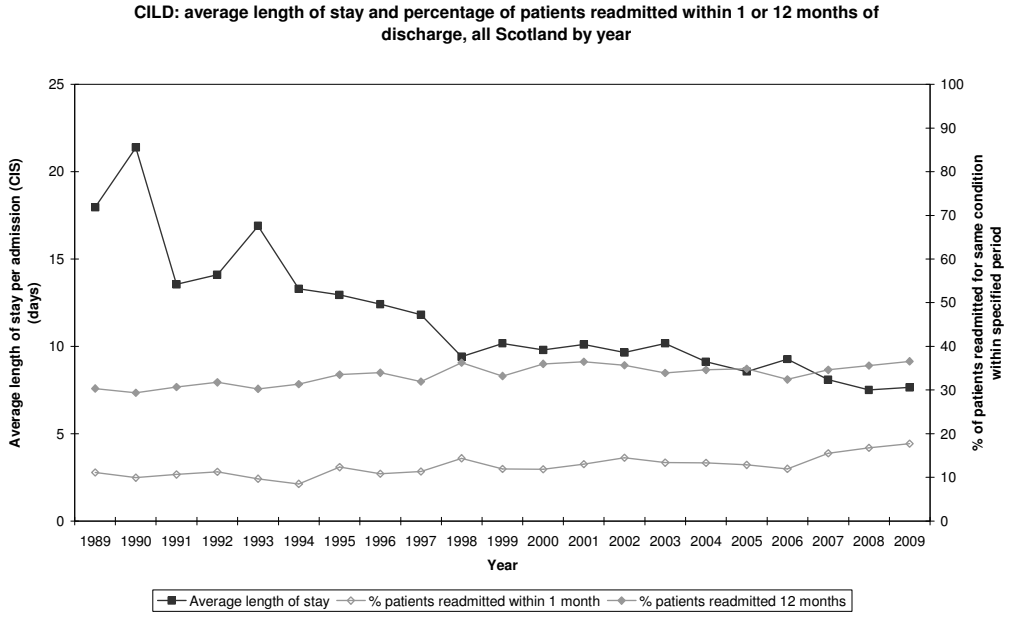
Figure 13



Data source: linked database, ISD

The average length of stay for CILD admissions has fallen substantially over the period examined. Readmission rates have increased slightly, with over a third of patients now readmitted due to their CILD within a year of discharge.

Figure 14



Data source: linked database, ISD

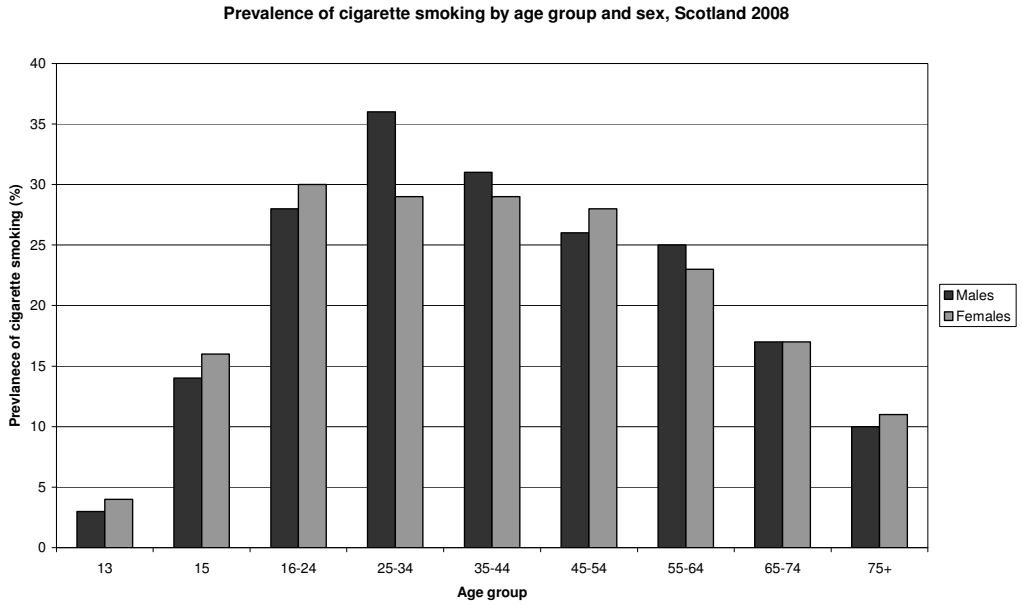
Overall, there is evidence of upward trends in the prevalence of, admission for, and mortality from CILD over the last 20 years. The relative contributions of improved/more precise diagnosis and genuine increase in the burden of disease to these increases are not clear. CILD is increasingly a disease of elderly people and remains somewhat more common in men that women.

Chronic Obstructive Pulmonary Disease

COPD comprises chronic bronchitis, emphysema and/or small airways disease/bronchiolitis. In chronic bronchitis the airways are narrowed by inflammation and excessive mucous production and in bronchiolitis the small airways are narrowed by inflammation. In emphysema the alveoli (small air sacs within the lungs) are damaged and enlarged. These pathological abnormalities tend to be progressive over time and when severe can reduce the ability of the lungs to efficiently transfer oxygen into the bloodstream. Smoking is by far the commonest cause of COPD (Rabe et al 2007), with at least 80% of COPD deaths thought to be attributable to smoking (NHS Health Scotland and ScotPHO 2007; NCGC 2010). The risk of COPD increases with increasing exposure to smoking ie both duration and daily amount of smoking. There can be a long lag time of up to several decades between starting smoking and developing clinically apparent COPD. Other risk factors such as occupational exposures and α1 anti-trypsin deficiency are important in a minority of COPD cases (Balmes et al 2003; Celli et al 2005; Behrendt et al 2005; Rabe et al 2007).

Current smoking rates in men in Scotland increase sharply through the teenage years up to the 25-34 age group then progressively decline through the older age groups (Figure 15). Smoking rates in women peak in the 16-24 age group then are relatively static through young adulthood before declining in the older age groups. Smoking rates in women are higher than those in men in the youngest and oldest age groups but the reverse is true in young adulthood. This pattern reflects both the usual smoking trajectory though individuals' lives of starting smoking as a teenager or young adult then a proportion quitting as they get older, a healthy survivor effect (ie smokers being less likely to survive into old age than non-smokers), and overall smoking rates in successive cohorts.

Figure 15

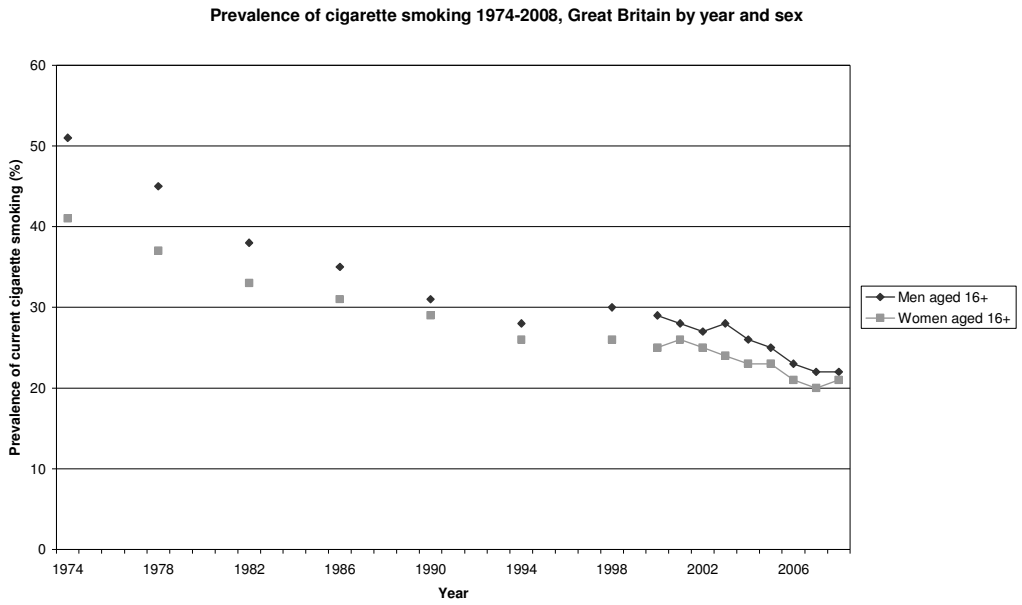


Data sources: SALSUS for ages 13 and 15 and Scottish Health Survey for ages 16+

Overall, smoking rates in men (aged 16+) have progressively declined over time since reaching their peak at the end of the Second World War (Figure 16). At that time, over 60% of adult men smoked cigarettes and around a further 20% smoked

tobacco in other forms eg pipes hence overall tobacco exposure rates were over 80%. Smoking rates in women never reached the extremely high levels seen in men. Cigarette smoking rates in women were relatively stable at around 40% from the end of the war to around 1970 then have progressively declined since then. Use of forms of tobacco other than cigarettes has always been uncommon in women. In both men and women the greatest decline in smoking prevalence occurred over the 1970s and 1980s with the rate of decline progressively slowing since then (ScotPHO 2008). The General Household Survey provides information on smoking prevalence rates in Great Britain from the 1970s onwards as shown below: rates for Scotland have consistently been found to be 3-4% higher than those for Great Britain as a whole. Whether the recent ban on smoking in public places will re-accelerate the decline in smoking prevalence is yet to be seen.

Figure 16

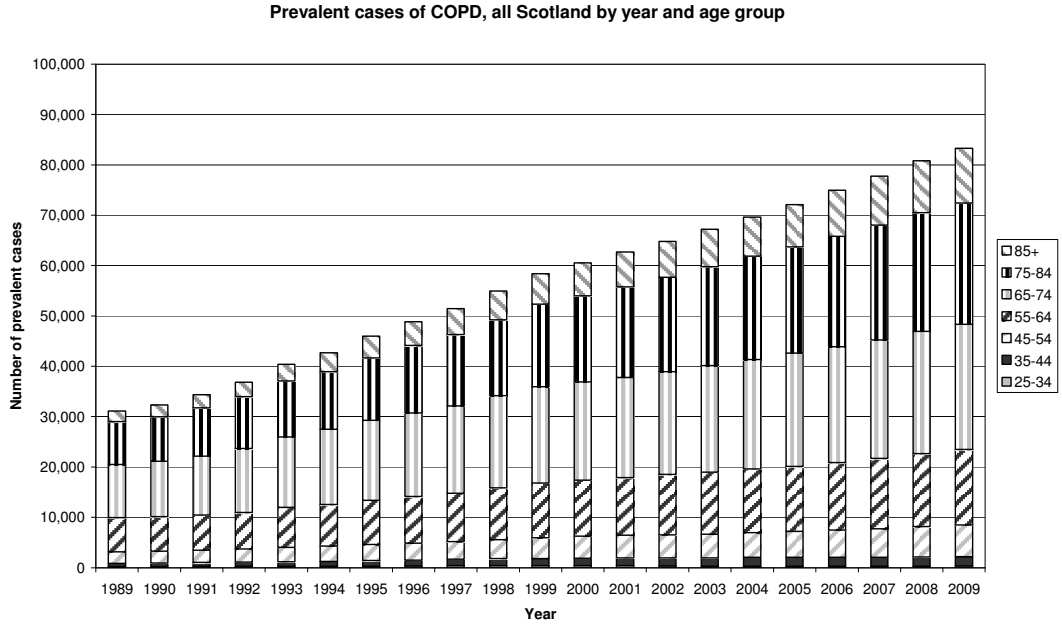


Data sources: General Household Survey

Understanding how age, period, and cohort effects on smoking will influence the future incidence and prevalence of smoking related disease is highly complex. Cohort analyses have shown that sequential cohorts of men born since at least 1900 and women born since the 1920s have had lower smoking exposure than previous cohorts but that this effect appears to have stopped for men and women born from around 1960 onwards (Kemm 2001; Davy 2006). In other words, over recent years, sequential cohorts of older people (arbitrarily defined as people reaching the age of 70 years as this is the age by when COPD is usually evident), have had lower smoking rates than previous cohorts and this effect has been going on longer for men that women. Furthermore, this trend is likely to continue for around a further 20 years then stabilise unless other factors (such as the recent ban on smoking in public places) influence the situation. As overall smoking rates have declined in the population, smoking has become more concentrated in people living in relatively deprived areas hence inequalities in smoking related disease are likely to have increased and this trend will continue. It is also worth reiterating that despite the great progress that has been made in reducing smoking rates in Scotland, overall smoking rates are still high, with over one quarter of the adult population being a current cigarette smoker.

From the above, the age specific risk of smoking related disease would be expected to have declined over recent years. Information on the incidence of COPD is not readily available from routine data sources but prevalence estimates have been derived. These data suggest that the prevalence rate of COPD has actually increased over recent years, particularly in the oldest age groups. This, in conjunction with population ageing and increased numbers of older people, means that the estimated number of people living with COPD has increased substantially over the last 20 years from 31,149 cases in 1989 to 83,314 cases in 2009 (Figure 17). There is no evidence yet of this increase in prevalence slowing down. The increase in prevalence has been more marked in women than men. In 1989 44% of prevalent COPD cases were women: in 2009 this had increased to 53%.

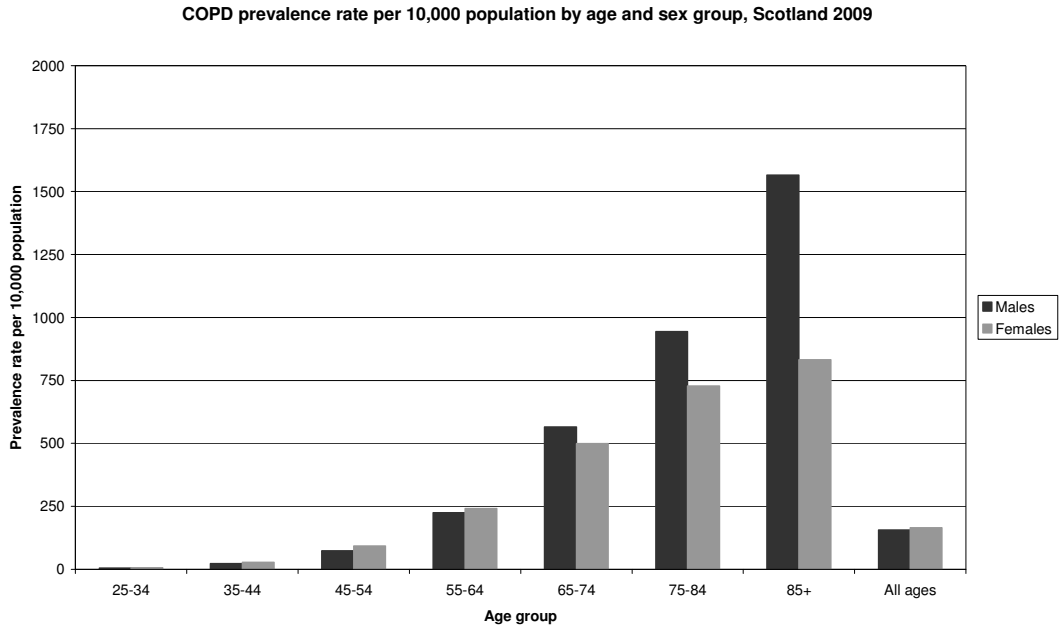
Figure 17



Source: linked database, ISD

As shown below, current prevalence rates are marginally higher in women than men in adult age groups up to 55-64 years but substantially higher in men in the oldest age groups. This pattern reflects historical smoking patterns with today's older men having had considerably higher exposure to smoking than women but younger men and women having had more similar smoking rates. These overall prevalence estimates, and the change observed in the sex distribution of COPD, agree very well with previously published information (Cleland et al 2006; Audit Scotland 2007; Rabe et al 2007; ScotPHO 2010a; NHS QIS 2010). In addition to the age and sex distributions shown here, COPD is known to be commoner in people living in urban and deprived areas (King's Fund 2004; NCGC 2010).

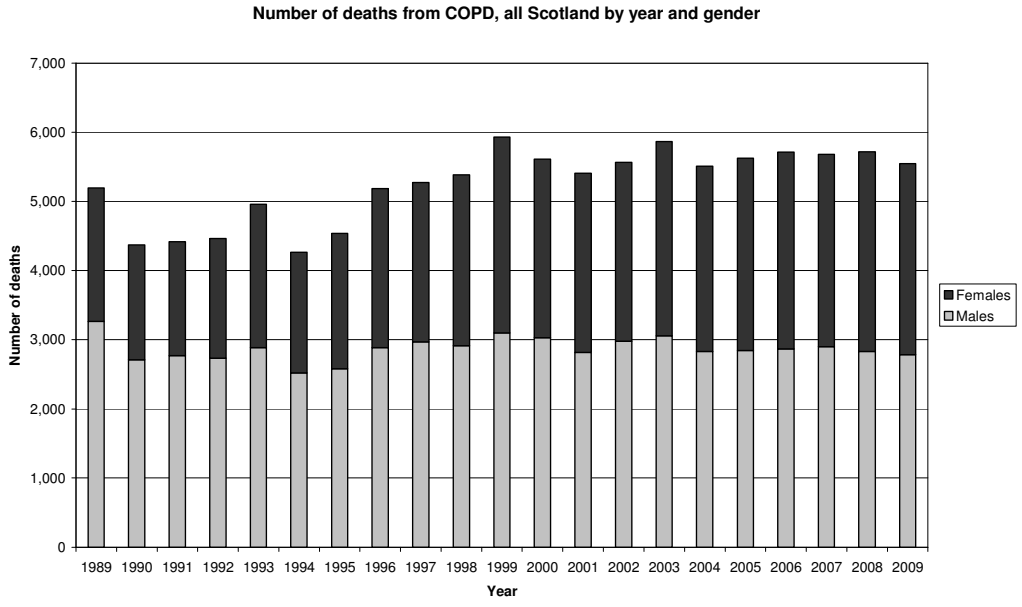
Figure 18



Source: linked database, ISD

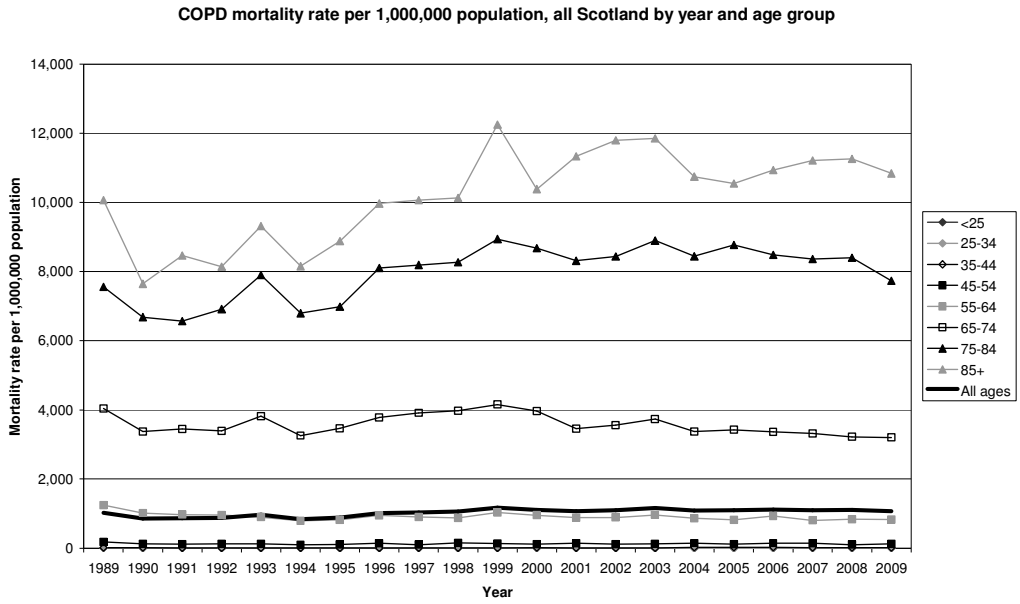
COPD is the fifth leading cause of death in the UK and fourth worldwide (NCGC 2010). The number of deaths in Scotland from COPD increased slightly over the 1990s but has been relatively constant over the last 10 years. 5,548 deaths were attributed to COPD in 2009. The increase in the number of deaths over the 1990s was predominantly due to an increase in deaths in women and in the oldest age groups.

Figure 19



Data sources: GRO(S) death registrations

Figure 20



Data sources: death registrations and mid year population estimates, GRO(S)

It can be seen that the number of deaths from COPD is relatively small compared to the number of prevalent cases when compared to some of the other conditions studied such as CF and CILD, reflecting the longer survival associated with COPD. Five year absolute survival from COPD diagnosis has been estimated as 78% in men and 72% in women with clinically mild disease defined as not requiring continuous drug therapy (NCGC 2010). Survival is much lower in patients with severe disease, particularly those with chronic hypoxaemia and/or those on LTOT however (Calverly 2000; Halpin 2001; Gibbons 2002; NCGC 2010).

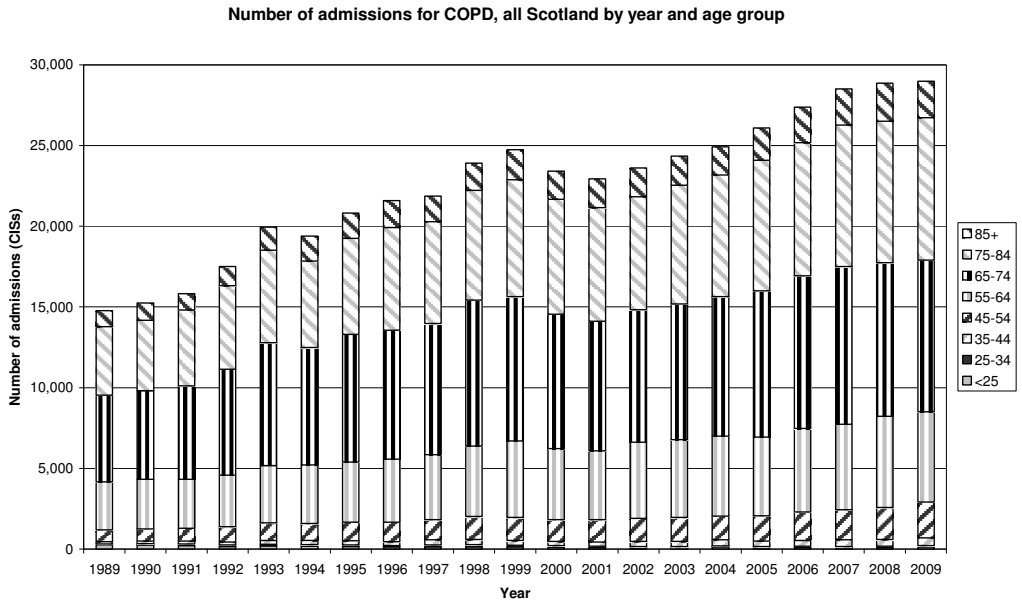
The fact that mortality from COPD has been relatively constant over recent years whilst estimated prevalence has continued to rise may be explained by a number of factors eg

- Improved awareness and diagnosis (eg diagnosis at an earlier stage of disease)
- Increasing incidence (eg in women)
- Improved survival
- Issues around the coding of hospital discharge and death data.

The relative contribution of these possible explanations is difficult to disentangle and all are likely to explain at least some of the rise in prevalence.

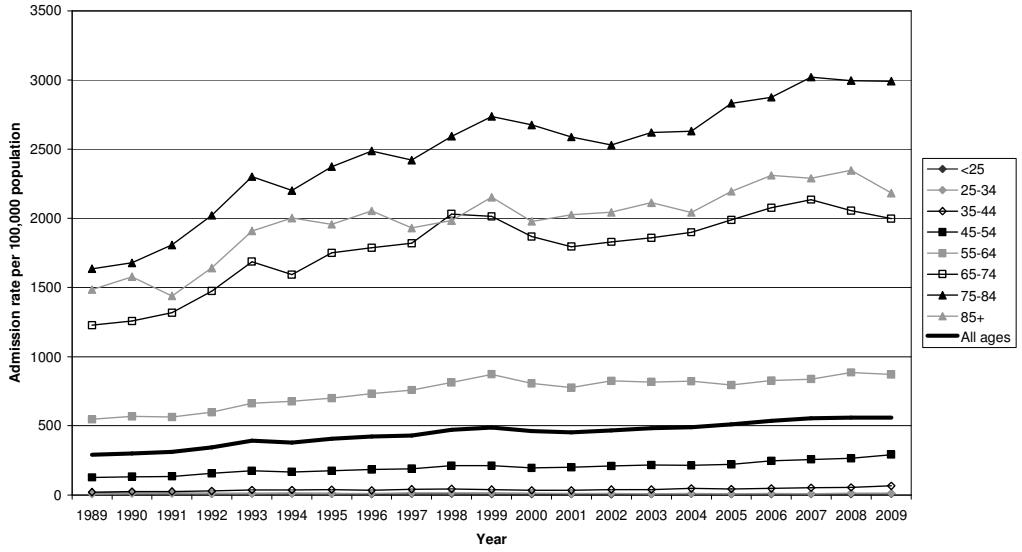
COPD is one of the commonest causes of hospital admission in Scotland (Audit Scotland 2007). The number of admissions for COPD has increased persistently over the past 20 years with all age groups from 45-54 years upwards experiencing an increasing number of admissions. The 75-84 year age group has consistently had the highest overall admission rate and has experienced the most marked increase in admission rates over time.

Figure 21



Data sources: ISD linked database

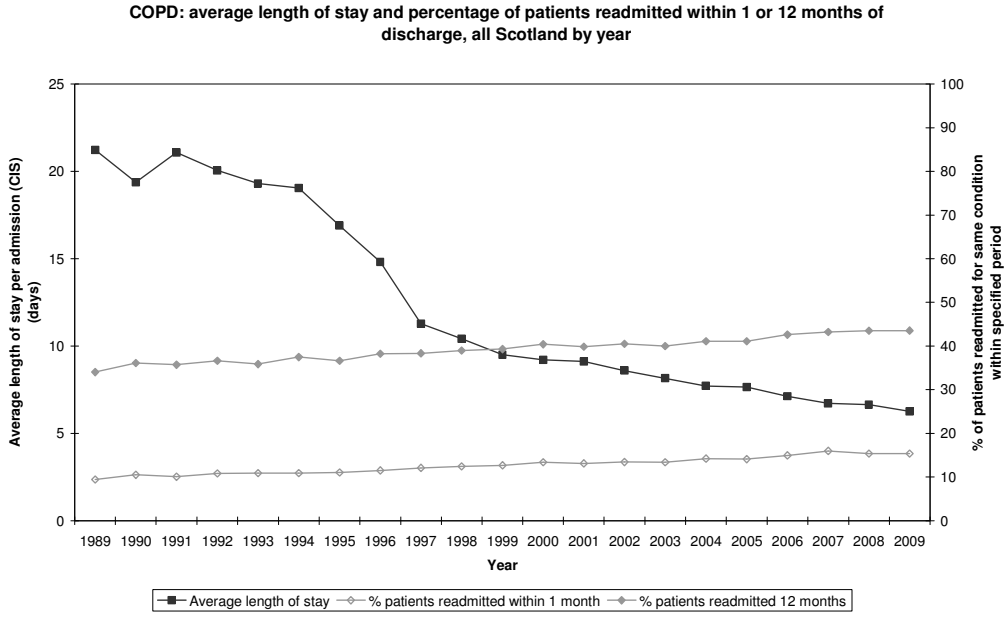
Figure 22



Data sources: ISD linked database and GRO(S) mid year population estimates

An increase in admissions may be due to more patients being admitted or the same patients being admitted more frequently. The average length of stay for COPD admissions has fallen substantially over the period examined. Readmission rates have increased moderately, with around 43% of patients now readmitted due to their COPD within a year of discharge.

Figure 23



Data sources: ISD linked database

Overall, there is evidence that mortality from COPD has been relatively stable in both men and women over the last 10 years although the number of prevalent cases and the total number of admissions for COPD continue to increase. Disease has become equally common in women and men and more common in older people. Hospital stays for COPD have got substantially shorter and readmission rates have shown a moderate increase over the last 20 years.

COPD is currently a very common condition in Scotland and is likely to remain so for the foreseeable future. If current prevalence rates stay the same over the short term, population ageing will mean that the absolute numbers of (older) people living with diagnosed COPD will continue to rise (Audit Scotland 2010). It is likely that the age specific incidence and prevalence of COPD will fall over the longer term, however, due to historical trends in smoking. These trends will counterbalance the effect of population ageing and result in stable or possibly even falling overall prevalence over time. There is a trend towards more active case finding and early diagnosis/management of COPD driven by factors such as the Quality and Outcomes Framework of the GP contract (see http://www.isdscotland.org/isd/3305.html) and published standards on management of COPD (NHS QIS 2010). This will tend to increase apparent prevalence by unmasking the large numbers of patients with relatively early stage COPD who were previously undiagnosed. The shift in the burden of COPD from men to women is likely to continue due both to smoking trends and demographics (higher number of older women) and increasing socio-economic inequalities in smoking related disease are likely.

Effectiveness

This summary of the evidence on the clinical effectiveness of home oxygen therapy is drawn from a rapid review of previously published reviews and clinical guidelines and recent key research papers as discussed in the methods chapter.

Most home oxygen services around the world have been developed since the early 1980s when two key research reports indicated that LTOT had a positive effect in reducing mortality from chronic lung disease (Nocturnal Oxygen Therapy Trial Group 1980; Medical Research Council Working Party 1981). There is more evidence about which patients require LTOT, its efficacy and its supply, than about the other forms of oxygen therapy (NCGC 2010). There is considerably less agreement about the clinical indications for home oxygen therapy in children than there is for adults (Balfour-Lynn et al 2005).

Clinical effectiveness of long term oxygen therapy

The strength of the evidence on the clinical effectiveness of LTOT varies by the condition being treated.

Chronic neonatal lung disease

There have been no randomised trials of the use of LTOT in infants however it has been suggested that home oxygen might in part be responsible for improved survival in chronic neonatal lung disease (CNLD) both through its role in the treatment or prevention of pulmonary hypertension (Balfour-Lynn et al 2005; 2009) and its role in reducing episodes of unrecognised and untreated hypoxaemia and hence modifying the increased risk of sudden death seen in infants with CNLD (Gray et al 1994; Poets et al 1998).

Home oxygen in children with CNLD has also been shown to be associated with improved weight gain (Groothuis and Rosenberg 1987; Chye and Gray 1995) and reduced reversible obstructive lung disease (Balfour-Lynn et al 2005; 2009). LTOT in babies with CNLD is also likely to be beneficial for neurodevelopment (Kotecha and Allen et al., 2002), though as many factors may contribute to suboptimal neurodevelopment in this group of children, the relative contribution of CNLD remains uncertain (Balfour-Lynn et al 2009).

Home oxygen may also facilitate earlier discharge from hospital for oxygen dependent children and enhance quality of family life without increasing health care costs (Greenhaugh et al 2004; MacLean and Fitzgerald 2006). It has also been suggested that caring for babies on supplementary oxygen at home is preferable to a prolonged hospital stay (Balfour-Lyn et al 2005; 2009). It reduces the risk of nosocomial infection and is felt to be good for parent-child relationships (Hallam et al 1996; Kotecha and Allen 2002).

Severe neurodisability in children

As discussed in the epidemiology section, neurodisability is the second most common reason for prescribing long-term home oxygen in children. The rationale behind this prescribing is often unclear however. Current British Thoracic Society guidelines support the use of intermittent LTOT in children with severe neurodisability

and recurrent respiratory problems (in particular aspiration pneumonia) associated with hypoxaemia but recognise that this is driven primarily by quality of (family) life issues rather that any definite evidence of impact on specific clinical outcomes (Balfour-Lynn et al 2005; 2009). Having oxygen available in the home can be highly valued by the parents of children with severe neurodisability due to its potential to reduce the frequency of hospital admission however hard data on the impact of home oxygen on admission rates is lacking.

The BTS guideline notes that there is no evidence to support or refute the anecdotal reports that supplementary oxygen can reduce seizure duration in children with neurodisability and associated epilepsy (Balfour-Lynn et al 2009).

Cystic Fibrosis

There is surprisingly little evidence for the benefit of LTOT in cystic fibrosis patients or on when therapy should be started (Urquhart et al 2005; Balfour-Lyn et al 2009). In one (old) study, while oxygen led to an improvement in school or work attendance, there was no effect on mortality rate, frequency of hospitalisation, or disease progression (Zinman et al 1989). A Cochrane systematic review concluded that there was no evidence of beneficial effect of LTOT on survival or lung or cardiac functioning in CF patients and hence inadequate data to guide the prescription of chronic oxygen supplementation to CF patients with advanced lung disease (Elphick & Mallory 2009). This review did note however that oxygen therapy for CF patients during sleep and exercise improves oxygenation, exercise duration and peak performance.

The potential adverse psychological effect of starting oxygen at home must also be considered. It is often taken as an indicator of a serious deterioration in the child's condition and has been described as an ''emotional life event'' for a patient with cystic fibrosis (Balfour-Lynn et al 2009). This evidence underpins current thinking that LTOT should be used in patients with cystic fibrosis to improve tissue oxygenation and prevent complications associated with hypoxaemia rather than primarily to produce survival benefits (Davis and Di Sant'Agnese 1984; RCP 1999; Balfour-Lynn et al 2005). Current BTS guidance states that LTOT should be considered for hypoxic children with cystic fibrosis as a means to improve school attendance and for those who obtain symptomatic relief (BTS 2009).

Chronic interstitial lung disease

Breathlessness is a pronounced feature of CILD and patients usually progress from mild breathlessness on exertion to severe breathlessness even at rest. There is little specific evidence on the effectiveness of home oxygen in CILD. One American study found no significant difference in survival between those on oxygen therapy and those not (Douglas et al 2000). A recent Cochrane review concluded that there is currently no evidence that oxygen therapy influences long-term survival in patients with idiopathic pulmonary fibrosis or other forms of CILD (Crockett et al 2001). Equally, although nocturnal hypoxaemia is common in patients with idiopathic pulmonary fibrosis, and may be associated with daytime impairment of quality of life, there is no specific evidence that supplemental oxygen is useful in this setting (Clark et al 2001).

Despite this lack of evidence, home oxygen is frequently used in CILD. Due to the natural history of disease, CILD patients are often initially provided with ambulatory oxygen then progress to LTOT with or without additional AOT (Duck 2007; Wells and Hirani 2008). Current clinical guidelines recommend that patients with CILD

associated with chronic hypoxaemia and right heart failure should be considered for home oxygen therapy (Wells and Hirani 2008) but also note that as to date there is no therapy proven to improve survival or otherwise significantly modify the clinical course of idiopathic pulmonary fibrosis, all patients should be considered for recruitment to high quality clinical trials of therapy and/or for lung transplantation if appropriate.

Chronic Obstructive Pulmonary Disease

As COPD progresses, many patients develop low arterial oxygen levels even when they are clinically stable. This is a poor prognostic feature independent of the severity of the disease indicated by other lung function tests (Calverly 2000). Chronic hypoxaemia results in a number of detrimental physiological changes. If left untreated, the five-year survival rate of hypoxaemic patients is less than 50% (Halpin 2001; Gibbons 2002; NCGC 2010).

There is good evidence that long-term oxygen therapy improves survival in people with COPD who have severe hypoxaemia. The Nocturnal Oxygen Treatment Trial (NOTT) and a Medical Research Council (MRC) trial evaluated long-term oxygen therapy in patients with COPD with severe hypoxemia. Both studies demonstrated a survival benefit with supplemental oxygen, but only in those who were instructed to use it 15–24 hours per day (MRC 1981; NOTT Group 1980). These studies also demonstrated that LTOT also reduces polycythaemia (increase in haemoglobin content of the blood) and pulmonary hypertension, increases exercise capacity, improves sleep quality, increases renal blood flow, and improves neuropsychological functioning (RCP 1999, Croxton et al 2006). To get the benefits of LTOT, patients should breathe supplemental oxygen for at least 15 hours per day. Greater benefits in patients with COPD are seen in patients receiving oxygen for 20 hours per day (NCGC 2010).

A Cochrane review (Cranston et al 2005) of four randomised controlled trials (RCTs) looking at the impact of long-term oxygen therapy on survival of COPD patients concluded that:

- Long-term oxygen therapy improves survival in COPD patients with severe hypoxaemia.
- Long-term oxygen therapy does not appear to improve survival in COPD patients with mild to moderate daytime hypoxaemia and/or arterial desaturation at night.

Survival curves for oxygen-treated subjects in subsequent uncontrolled studies have generally produced results that are consistent with the data from similarly treated groups of the NOTT and MRC studies (Croxton et al 2006). Nevertheless, Croxton et al (2006) observed that only four randomized controlled trials have measured effects of LTOT on mortality in patients with COPD (NOTT Group 1980; MRC 1981; Górecka et al 1997; Chaouat et al 1999). These trials involved a total of only 501 subjects, and few participants were women. No positive results have been reported since 1981.

Based on the above evidence, current clinical guidelines recommend the use of home oxygen in COPD patients with chronic hypoxaemia. Guidelines suggest that the need for oxygen therapy in COPD patients should be assessed in all patients with very severe airflow obstruction (FEV1 <30% predicted), cyanosis, polycythaemia, peripheral oedema, raised jugular venous pressure, and/or oxygen saturation ≤ 92% breathing air. Assessment should also be considered in patients with severe airflow obstruction (FEV1 30-49% predicted) (RCP 1999; NCGC 2010; NHS QIS 2010).

The original reports of the MRC and NOTT trials did not show a reduction in hospitalisation among patients given LTOT however several subsequent observational studies have reported a significant reduction in hospitalisations with LTOT. Two studies compared the hospitalisation rates before and after the initiation of LTOT (Crockett et al 1993; Ringbaek et al 2002), and one study compared rates with a historical control (Clini et al 1996).

There is a lack of evidence about the impact of LTOT on COPD patients' overall quality of life (RCP 1999). In an ancillary study to the NOTT study, there was no improvement in quality of life over 6 months in patients with hypoxic COPD treated with oxygen compared to age-matched controls without COPD (Heaton et al 1983). In a study based in London, no change in quality of life was detected using a disease-specific health measure in patients with severe COPD using an oxygen concentrator (Okubadejo et al 1996). These studies may be criticised for not including COPD patients not using LTOT as controls: the results do not preclude the possibility that LTOT prevented or slowed a decline in quality of life in COPD patients. Other cross sectional studies have noted poorer quality of life among COPD patients using LTOT compared to those not using oxygen (Janssens et al 1997; Sant'Anna et al 2003) but conversely it is difficult to account for the underlying impact of disease severity in these studies. At least one qualitative study has commented that LTOT can improve some patients' sense of self-determination and control over their symptoms but conversely contribute to dependency and impaired quality of life in other patients (Cornford 2000) hence impact of quality of life is likely to vary substantially between patients.

Overall effectiveness of LTOT

Overall, therefore, it can be seen that the evidence for the impact of LTOT on relatively easily measurable clinical outcomes such as survival varies according to the underlying condition being treated. There is RCT level evidence that LTOT significantly improves survival of patients with COPD associated with severe hypoxaemia (SaPO2 ≤7.3kPa) if it is used appropriately (for at least 15 hours per day). Evidence for an effect on survival in patients with more rapidly progressing disease such as CF or CILD is generally lacking. There is additional evidence that LTOT improves other outcomes such as exercise capacity and frequency of hospital admissions in COPD patients but again RCT level evidence for effects in other conditions is lacking. This may reflect a simple absence of evidence rather than definite negative effect and disease specific clinical guidelines often support the use of LTOT in hypoxaemic patients. There is a total lack of RCT level evidence for the effectiveness of LTOT in children, partially due to the difficulties of conducting trials in children, however there are high quality clinical guidelines for the use of home oxygen in children which reflect the available observational evidence and current expert opinion.

There is very little hard evidence of a positive effect on overall quality of life associated with the use of LTOT and some evidence that starting LTOT can be a significantly distressing event (eg for CF patients). This should be set against the generally very positive views of patients currently using LTOT and their carers who often highly value the service. There is additional uncertainty about the clinical effectiveness of LTOT in conditions that have not been considered in detail here. A major RCT is underway in the UK to examine the clinical and cost effectiveness of LTOT in patients with chronic heart failure (see http://www.hta.ac.uk/1726) which will provide helpful additional information. Other high quality information on the clinical effectiveness of LTOT will become available over time. A US based trial (the Long

Term Oxygen Treatment Trial - see http://clinicaltrials.gov/ct2/show/NCT00692198) looking at the effectiveness of LTOT in COPD patients with moderate hypoxaemia or exercise desaturation commenced in 2009. In addition, the British Thoracic Society guideline on the use of home oxygen in adults is due to be published in 2011. This will provide a vital source of authoritative guidance based on all levels of evidence and expert clinical opinion and will complement the existing guideline on use of home oxygen in children.

Reliance on the MRC and NOTT trials

Much of the clinical effectiveness evidence for LTOT rests on the two seminal trials reported around 30 years ago (NOTT 1980; MRC 1981). These trials included 87 and 203 patients respectively with COPD and chronic hypoxaemia. Patients in the MRC trial also had evidence of right heart failure. The MRC trial compared LTOT provided for at least 15 hours a day with no home oxygen whereas the NOTT trial compared continuous (24 hours or as much as possible) home oxygen use with nocturnal oxygen therapy. Both trials showed a substantial survival benefit associated with the use of LTOT (around 50% cf 25% 5 year survival in the MRC trial and around 60% cf 40% 3 year survival in the NOTT trial). Not surprisingly, the strong positive effects of these trials have had a substantial effect on subsequent clinical guidelines and practice.

It is important to remember however that they included a highly selected group of patients and information on important potential confounders such as smoking cessation rates in the different trial arms was not reported (Cranston et al 2005). The trials have resulted in a clear focus on the degree of hypoxaemia as a key eligibility criterion for LTOT. This is appropriate to an extent but some authors have argued that other patients who may benefit from LTOT (such as those with pulmonary hypertension, low body-mass index, frequent exacerbations or co-morbid cardiac disease) are being denied therapy (O'Reilly and Bailey 2007).

Patient survival in the control arms of the two trials (patients receiving no oxygen in MRC trial and nocturnal oxygen only in NOTT trial) were similar. Whilst patients in the treatment arms of both trials showed a considerable survival benefit, survival was better in the NOTT trial (up to 24 hour usage, actual mean use per day of 19.4 hours) than the MRC trial (15 hours usage). The results of the two trials have, therefore, been taken together to indicate a probable relationship between average daily duration of oxygen use and outcomes although a definite threshold below which LTOT is unlikely to be effective is difficult to specify and the reliability of the relationship has been questioned (Petty and Bliss 2000). There are theoretical reasons why longer daily duration of oxygen use may be beneficial, including more effective reduction in pulmonary hypertension and avoidance of intermittent desaturations (Croxton and Bailey 2006). Current guidance that LTOT should be used for at least 15 hours a day clearly stems from the MRC trial.

Clinical effectiveness of ambulatory oxygen therapy

Ambulatory oxygen therapy refers to the provision of oxygen therapy whilst people are mobile ie doing exercise or undertaking activities of daily living. Ambulatory oxygen therapy can be prescribed in patients on LTOT, who are mobile and need to or can leave the home on a regular basis. AOT can also be used by patients who do not have chronic hypoxaemia and who show evidence of oxygen desaturation with exercise (BTS, 2006).

Clinical guidelines governing the provision of home oxygen in England and Wales (BTS 2006) suggest that ambulatory oxygen therapy is indicated for the following conditions:

- Chronic obstructive pulmonary disease
- Severe chronic asthma
- Interstitial lung disease
- Cystic fibrosis
- Pulmonary vascular disease
- Primary pulmonary hypertension

AOT is not recommended in patients with chronic lung disease and mild hypoxaemia without exercise de-saturation. It is also not recommended for patients with chronic heart failure (NCGC 2010).

There is relatively little evidence on the effectiveness of AOT in patients with exercise induced desaturation or patients with chronic hypoxaemia who are already on LTOT. Two Cochrane reviews have reported on the use of ambulatory oxygen for chronic obstructive pulmonary disease. Ram and Wedzicha et al (2002), on the basis of two eligible studies concluded that the evidence available to date did not allow any firm conclusions to be drawn concerning the effectiveness of long-term AOT in patients with COPD. A review of thirty one randomised controlled trials (total of 534 participants) examining the short-term benefit of ambulatory oxygen in COPD, provided some evidence that AOT improves exercise performance in COPD patients. The authors noted however that the clinical importance of this size of improvement is unclear (Bradley and O'Neill 2005). There is some evidence that AOT can improve the quality of life of COPD patients (Eaton et al 2002). Prior to widespread prescription of ambulatory oxygen, it is recommended that future research establishes the net long-term benefit of ambulatory oxygen in patients with different levels of hypoxemia or exercise-induced desaturation (Bradley et al 2007) and the relative cost effectiveness of AOT (McDonald et al 2005).

Clinical effectiveness of short-burst oxygen therapy

Short-burst Oxygen Therapy (SBOT) involves the intermittent use of oxygen at home for short periods of time. SBOT has traditionally been used for pre-oxygenation before exercise, breathlessness during recovery from exercise, control of breathlessness at rest, in palliative care and after an exacerbation of COPD to bridge the time to full LTOT assessment (DoH 2004). According to BTS (2006) guidelines, SBOT should be considered for episodic breathlessness, not relieved by other treatments in patients with the following conditions:

- severe COPD
- interstitial lung disease
- heart failure
- palliative care.

Although short-burst oxygen therapy is extensively prescribed (Kelly and Lynes 2008), there is little evidence that it is effective, despite patients often reporting subjective benefits (Stevenson and Calverley 2004; BTS 2006). A case has been made for its appropriate use in palliative care though the benefit described may simply be a placebo effect and some of its apparent symptomatic benefits may be due to the cooling effect of the oxygen on the face rather than a correction of hypoxia (Booth et al 2004). A very recent randomised control has suggested oxygen provides no additional benefit (compared to room air delivered through nasal

cannulae) in terms of reducing dyspnoea in terminally ill patients (Abernethy 2010; Higginson 2010).

Short-burst therapy may help to reduce the work of breathing and reduce the volume of air entering the lung each minute (minute ventilation) and, hence, the sensation of breathing (O'Donnell et al 1997). This may help during exercise, but is unlikely to be beneficial before or after it (Stevenson and Calverley 2004; Eaton et al 2006). The literature identifies a number of drawbacks that have been associated with SBOT including it may cause psychosocial dependence; it can restrict activity and impair communication; it may interfere with the relationships between carers and patients; and can cause drying of the user's mucus membrane (Kelly and Lynes 2008).

The evidence for short-burst oxygen therapy in patients with chronic obstructive pulmonary disease was the subject of a Cochrane review (O'Neill et al 2005). The review, which included eight RCTs, concluded that the prescription of SBOT for patients with chronic obstructive pulmonary disease is not evidence-based and a scientific rationale is required for continued prescription. The authors however acknowledged that potentially important clinical information on patient characteristics was not reported in the included studies; and this might have introduced bias as some of the participants may not have been suitable for SBOT. An assessment of the review concluded that although the recommendations appear reasonable, the review suffers from potential biases e.g. differences in methodology and reporting by the included studies, which means that it may not have been appropriate to pool the results, wide confidence intervals and small sample sizes which affect the reliability of the data synthesis (O'Neil et al 2005).

Compliance with home oxygen therapy

Longitudinal and cross-sectional studies in different countries have reported problems with compliance with LTOT outwith the context of a clinical trial (Law and Lehoux 2004). Most studies have reported that only 35-70% of patients prescribed LTOT use their oxygen for the recommended 15 or more hours per day (Walshaw et al 1990; Phillips et al 1994; Law and Theroux 2004; Jones et al 2007). In a Scottish study, compliance ranged widely with only 56% of patients using their concentrator for 15 or more hours a day (Morrison et al 1995).

Studies from England, Denmark and Australia have shown that adherence was particularly poor where non-chest physicians prescribed LTOT (Walshaw et al 1990; Ringbaek et al 2001; Jones et al 2007). Several other studies have suggested that severity of resting hypoxemia, specialist input in the effective use of home oxygen, and ongoing education from a nurse and physiotherapist may also be associated with good compliance with prescribed oxygen regimes (Walshaw et al 1990; Granados et al 1997; Ringbaek et al 1999; Neri et al 2006; Jones et al 2007). The difficulties involved in measuring compliance and the reliability of self-reported data, which all estimates were based on, were consistently reported in the above studies.

Ongoing smoking is also associated with poor compliance with home oxygen therapy (Cullen 2006). The proportion of patients smoking while on LTOT ranged from 8-51% in studies reporting this outcome (Law and Theroux 2004). UK studies have noted smoking rates of 11% in Scottish patients (Morrison et al 1995) and 20% in English patients (Restrick et al 1993) when first prescribed LTOT. Cigarette smoking has been demonstrated to interfere with the clinical effectiveness of LTOT and exacerbate hypoxemia (Calverley et al 1982; Kamplemacher et al 1998; Cullen

2006). Continuing to smoke after LTOT has been prescribed also raises issues of safety due to increased fire hazard.

The current literature on compliance with LTOT almost exclusively focuses on patients with hypoxemic COPD and there is very little evidence about adherence to LTOT in other patient groups such as CF patients. Differences in compliance between adult and paediatric patients are also unknown.

Several studies have examined patient's reasons for non-compliance with LTOT. Earnest (2002) demonstrated that adhering to oxygen therapy is difficult for patients and adapting to the use of oxygen is a complex process. Using oxygen, even under the best of circumstances, involves making compromises that, for some, may represent a profound loss of independence, autonomy, and self-perception. Cornford et al. (2000) reported fear of dependency and addiction influenced patients' adherence to LTOT. In a meta-synthesis of qualitative research studies on patients' views of LTOT, Cullen and Stiffler (2009) concluded that each oxygen user faces tremendous physical, psychological, and emotional challenges which affect their ability to adhere to their treatment guidelines.

Complications of home oxygen therapy

Home oxygen equipment is generally considered safe for use by patients given adequate patient education about safe handling, storage and maintenance procedures (Chang et al 2001). The key safety concern with home oxygen therapy systems is the risk of fire due to smoking or proximity to open flames and improper handling of the oxygen canisters, given that oxygen markedly enhances combustion (Weg and Haas 1998). Cylinders pose a fire and explosion risk in the home. Although a concentrator does not store oxygen, a patient is still at risk from burns if they smoke while wearing oxygen (Kelly and Lynes 2008) and it has been noted that as most burns occur at the delivery site (nasal cannulae) and not at the source, the different forms of home oxygen present similar risks (Chang et al 2001).

In a review of accidents and home oxygen in the UK, Maxwell et al (1993) found only seven published reports of accidental burns to patients due to smoking, although it is likely that this low number reflects substantial under-reporting (Chang et al 2001). Most reported cases of burns associated with home oxygen use occur in COPD patients who continue to smoke (Edelman et al 2008). Estimates of the percentage of adult home oxygen patients who smoke vary from 10-51% (Chang et al 2001; Law and Lehoux 2004; Edelman et al 2008) Morrison et al (1995), in a study of patients prescribed long term oxygen therapy in Scotland between 1989-1991, found that 14% of patients were still smoking. In the NOTT and MRC trials, smoking was not an exclusion criterion and it is of note that 38% and 43% of patients participating in the trials were current smokers (Lacasse et al 2006). It has been argued that it is tacitly accepted that many LTOT patients continue to smoke, with clinical guidelines often failing to clearly address the question of provision of oxygen to current smokers or the cost effectiveness and ethical issues involved in provision or withholding of treatment (Law and Lehoux 2004; Lacasse et al 2006; Edelman et al 2008; Kelly and Lynes 2008). When patients in Scotland are first provided with home oxygen equipment by HFS, they are asked for their agreement in writing not to smoke 'in the vicinity of' their oxygen supply.

Further complications of oxygen therapy have been summarised by Law and Lehoux (2004). Important clinical complications include oxygen toxicity, progressive carbon dioxide retention, and local irritation of the nasal area (American Thoracic Society

1995; Weg and Haas 1998). Weg and Haas (1998) suggest that topical measures may be effective for the drying, irritation and/or bleeding that can be caused by nasal cannulae, but state that routine humidification is not justifiable with low flow oxygen administration.

A number of technical problems have also been reported, including breakdown of equipment (Law and Lehoux 2004). Concentrators are more likely to suffer technical faults than cylinders (Ström and Boe 1991), underlining the need regular servicing.

Comparative effectiveness of different oxygen modalities

There is continuous technological development in terms of the range of different oxygen modalities available. Traditional static cylinders and standard concentrators have been available for many years but some of the other devices now available in Scotland are relatively new. The BabyOx service, high flow concentrators, portable cylinders, liquid oxygen, and portable concentrators were made available in Scotland in 2007 and Homefill systems in 2008. Oxygen conservers are still not widely available. This technological development raises questions about the relative clinical and cost effectiveness of different delivery mechanisms. For example, should patients who require LTOT and AOT receive a standard concentrator and portable cylinders or a Homefill system, should patients requiring AOT only receive portable cylinders or Liquid Oxygen, etc.

At the simplest level, there is no reason to assume that devices that deliver the same 'dose' of oxygen should have different potential efficacy. Different devices may be substantially more or less convenient to use however and this may impact on compliance and hence effectiveness. Different devices may also vary widely in terms of cost. Although patients on home oxygen are generally very positive about the service they receive (see chapter on User and Provider Views) they do note several issues associated with use of home oxygen, such as:

- Inconvenience of having to wait in for cylinder deliveries
- Fears around 'running out' of oxygen, particularly relevant to cylinders and liquid oxygen
- Inconvenience of having bulky/noisy equipment in the home
- Problems using portable cylinders due to their relatively large size and weight

The newer devices are often designed to get around such problems, for example the Homefill system frees patients from having to wait for their delivery of portable cylinders and worrying that they may run out prior to delivery but the system is relatively expensive to install (although may be efficient in the longer term due to avoiding the costs associated with repeated cylinder deliveries). Issues of providing home oxygen in remote rural areas also need to be taken into account in Scotland. Fortnightly delivery of cylinders to inaccessible areas that may get cut off in bad weather can be both expensive and risky. Equally, concentrators require an electricity source to run hence prolonged power cuts pose a risk in these areas. Concentrator patients are usually provided with 20 hours' worth of oxygen in special back up cylinders but responding within this time period may be challenging .in very remote areas hence further back up facilities may be required.

In general, there are few studies that directly compare the overall clinical and cost effectiveness of different basic modalities and take into account patient views and preferences (Dunne 2009). One very small study noted that Homefill cylinders appeared as good as standard portable cylinders in terms of maintaining oxygenation

during a walking test in COPD patients (Dunne 2009) and these systems seem to be highly valued by patients (Scottish Government 2010). The exception to this relates to oxygen conservers: conservers have been shown not to impair oxygen saturation when used with other devices such as portable cylinders and to extend cylinder life and reduce costs (Tiep et al 1985; Tiep and Lewis 1987; Braun et al 1992; Barker et al 1994; Weg and Haas 1998; Murphie et al 2008). Some patients find conservers difficult or unpleasant to use however and they are not suitable for patients without sufficient inspiratory effort to trigger the device (Law and Lehoux 2004; MacDonald et al 2005; Ferguson et al 2010).

Overall, it is accepted that different devices suit different patients due to their age, clinical condition, level of mobility within and outwith the home, geographical region, and personal preferences. The specific device(s) provided to any individual patient is usually determined after negotiation between the patient, the prescribing clinician, and the provider. It should be recognised that new devices can offer improvements in terms of patient convenience but many are more expensive than standard devices. Often the costs of providing oxygen are borne by multiple stakeholders eg HFS in terms of installing concentrators, community pharmacies and NHS Boards in terms of delivering cylinders, and patients in terms of their time in waiting for deliveries and different modes of provision may result in costs being shifted between these stakeholders. In addition, some devices may have high start up costs but then lower ongoing running costs. This emphasises the need to take a holistic view when deciding which devices should be made available (Law and Leroux 2004; Dunne 2009)

Cost effectiveness of home oxygen therapy

Cost effectiveness of home oxygen for infants and children

Research indicates that the use of home oxygen therapy for children can be financially efficient as well as family friendly. Home oxygen for children with hypoxaemia is expensive but potentially cost-effective as it facilitates earlier discharge from hospital and enhances quality of life in the home (MacLean and Fitzgerald 2006). Silverman et al (1992) found that LTOT for children was beneficial in terms of freed resources for neonatal units and reduces the total cost of care for an infant. Similarly, early discharge and the use of home oxygen therapy for prematurely born infants were not found to have a negative effect on the cost of care or the morbidity of the infants (Greenough et al 2004). It should be noted that these studies were observational and not an economic costing analysis.

Cost effectiveness of home oxygen for adults

A number of studies have addressed the question of whether provision of home oxygen for adult patients (usually specifically COPD patients) is overall cost incurring or cost saving to the health service. There is no doubt that provision of home oxygen is expensive (Ward et al 2000; Sullivan et al 2000), however the balance of evidence suggests that appropriate provision of LTOT for COPD patients is overall cost neutral or saving to the health service, mainly due to the reduction in frequency of hospital admissions.

Research carried out in Chile (Maquilon et al 2001) found that the costs of COPD patients who were on home oxygen were equivalent to the costs of patients with COPD who were on a waiting list for the service. This indicates that although the costs of home oxygen therapy are high, the costs of not providing the home oxygen

therapy are similar but dispersed throughout the system. Farrero (2001) reported a reduction in costs due to a decrease in the use of hospital services in patients with COPD though they did observe that their study design may have contributed to the results. More recently, a formal economic analysis in the US used a Markov model to estimate cost effectiveness of LTOT (Oba 2009). In this study, it was shown that the cost-effectiveness of continuous oxygen therapy in patients with severe resting hypoxemia was far more favourable than that of surgical therapies for COPD that were approved by Medicare and was comparable to or more favourable than commonly used medical therapies for COPD. Oba (2009) noted that the cost-effectiveness estimates of LTOT in his study could be very conservative because of the assumption in the study that LTOT would not reduce COPD-related hospitalisations. When estimates of reduction in hospitalisations were incorporated into the model, continuous oxygen therapy was more effective and less costly than no oxygen therapy because of a substantial saving from fewer hospital days (Oba 2009).

Relative cost effectiveness of different oxygen modalities

Some information relating to the relative cost effectiveness of different oxygen modalities is provided in the section on 'Comparative effectiveness of different oxygen modalities'. There is a specific issue in relation to the relative cost effectiveness of static cylinders as compared to standard concentrators. It has been shown that concentrators can be lower cost than cylinders for patients using moderate or high amounts of oxygen (Petty and Donohue 1993; Pelletier-Fleury et al 1996; Law and Leroux 2004). Based on current cost structures in Scotland, it has been estimated that providing concentrators becomes less expensive than providing cylinders when patients use 4 hours (or more) per day of oxygen at usual flow rates (Don Page – personal communication). Scottish guidance originally stated that patients should require/use oxygen for at least 15 hours a day to become eligible for a concentrator (Scottish Government 1989) but this figure was reduced to 8 hours a day in 2004 (Scottish Government 2004). There has been recent debate about the possibility of reducing this eligibility threshold further (eg to 4 hours per day) or removing it altogether. Reduction of the eligibility criterion to 4 hours use per day makes sense from a purely financial point of view but given the general lack of evidence of clinical effectiveness of oxygen therapy when used for less than 15 hours per day, even the reduction to an 8 hour threshold is questionable.

Cost effectiveness issues relating to the way home oxygen services are configured

A recently published economic evaluation (CRD 2010) compared the efficacy and cost of two health care systems delivering long term oxygen therapy at home for patients with COPD: non-profit associations versus profit-making health organisations. Non-profit associations were less costly than profit-making organisations without significant differences in survival outcomes.

Chaney et al (2002) evaluated the initial benefits of establishing an oxygen therapy clinic (OTC) to manage users of long-term oxygen therapy (LTOT). The authors concluded that the institution of a respiratory therapist-managed OTC to manage home oxygen patients can significantly decrease inappropriate supplemental oxygen use, which can result in significant cost savings while providing improved health-care delivery and timely identification of related and potentially modifiable comorbid conditions such as tobacco use and sleep-related breathing disorders. Other similar studies, summarised by Croxton and Bailey (2006), indicate how important factors such as robust initial patient assessment, ongoing clinical monitoring, and attention to other factors such as smoking are in ensuring that home oxygen is appropriately

delivered to patients with the capacity to benefit from the therapy and hence in ensuring maximum clinical and cost effectiveness.

Service provision

Cylinder provision

Information on static and portable oxygen cylinders dispensed through community pharmacies and dispensing practices is available through the national Prescribing Information System and the information on additional payments made to providers by NHS NSS Practitioner Services Division.

Table 2: Static oxygen cylinders dispensed and associated costs, Scotland 2004-2009

Static cylinders	2004	2005	2006	2007	2008	2009
Number of prescriptions dispensed	41,389	37,560	36,797	37,847	34,598	30,091
Number of individual cylinders dispensed	169,501	154,541	146,943	149,316	132,491	114,292
Gross ingredient costs[1] (£)	1,280,816	1,183,354	1,208,286	1,306,889	1,199,022	1,044,667
Additional costs[23] (£)	1,369,329	1,199,403	1,129,544	1,181,378	1,046,349	902,835
Total costs (£)	2,650,145	2,382,757	2,337,829	2,488,266	2,245,371	1,947,502

Data sources: PIS, ISD and payment information, PSD

Table 3: Portable oxygen cylinders dispensed and associated costs, Scotland 2004-2009

Portable cylinders	2004	2005	2006	2007	2008	2009
Number of prescriptions dispensed	6,282	10,710	13,294	16,453	18,847	19,166
Number of individual cylinders dispensed	18,634	32,701	39,559	53,494	60,185	59,113
Gross ingredient costs (£)	243,197	457,140	617,360	1,044,742	1,253,718	1,270,344
Additional costs[3] (£)	207,836	342,002	408,081	513,573	569,991	575,047
Total costs (£)	451,033	799,142	1,025,441	1,558,315	1,823,709	1,845,391

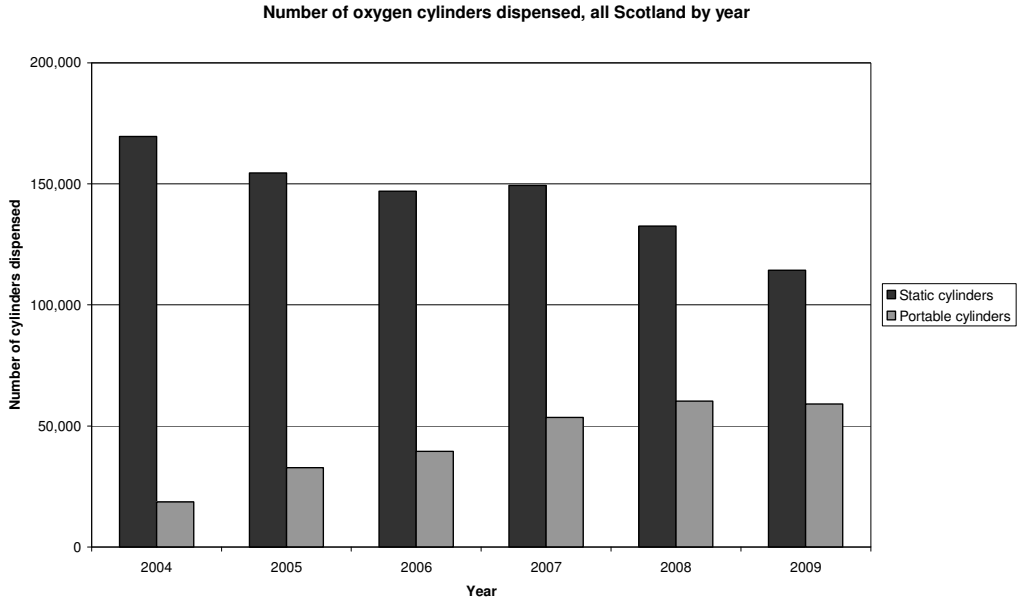
Data sources: PIS, ISD and payment information, PSD

It can be seen that the number of prescriptions for static cylinders and the total number of individual static cylinders dispensed has been falling steadily over recent

[1] Gross ingredient cost relates to the actual cost of the oxygen prescribed.
[2] Additional costs relate to other costs incurred in providing oxygen such as cylinder rental and delivery.
[3] Note that additional costs are only available for all cylinder provision combined. Separate figures for static and portable cylinders have therefore been estimated on a pro-rata basis using the number of prescriptions dispensed.

years. Conversely the number of portable cylinders dispensed has increased markedly, although there is a suggestion that this increase may now have reached a plateau.

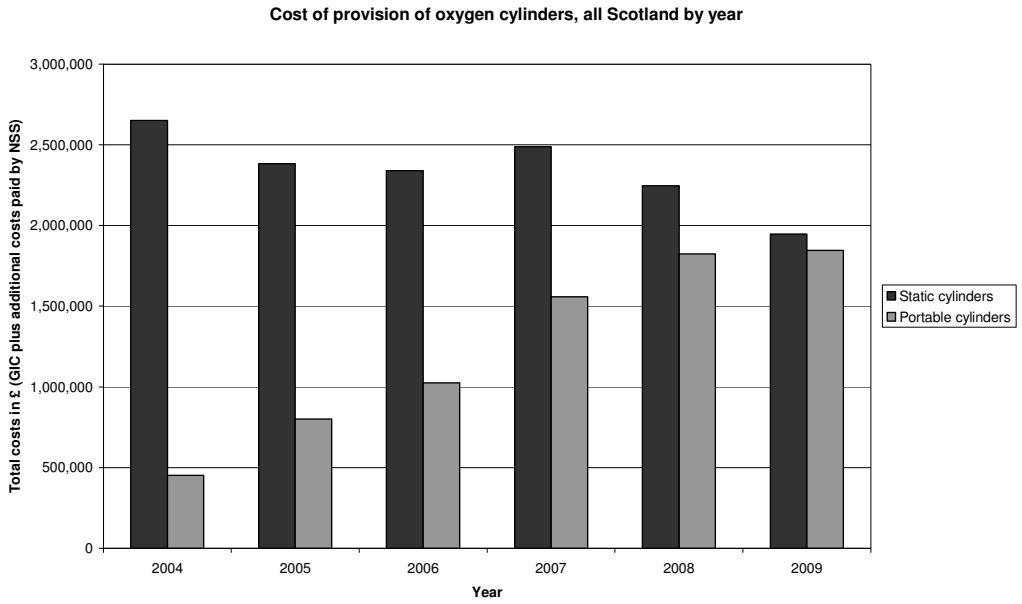
Figure 24



Data sources: PIS, ISD

The cost of static cylinder provision has consequently been falling whilst that of portable cylinder provision has been rising. As the gross ingredient cost (but not additional cost) per portable cylinder is considerably higher than that per static cylinder, the costs associated with provision of the two types of cylinder are now similar. The total cost incurred through dispensing of oxygen cylinders in 2009 was almost £3.8 million.

Figure 25



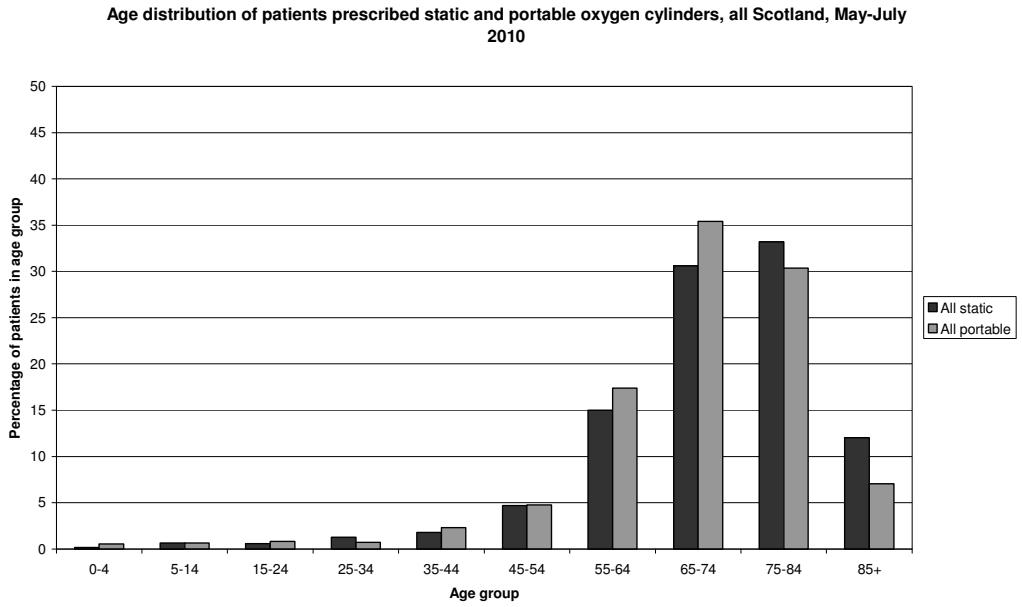
Data sources: PIS, ISD and payment information, PSD

As described in the methods section, the subset of prescribing data from May-July 2010 inclusive that contained the patient's CHI number was examined to estimate the total number of individual patients that were dispensed an oxygen cylinder during that time period and their age and sex profile. It was found that a total of 1,952 patients received at least one static cylinder during that time and 1,686 received at least one portable cylinder. There was a surprisingly high degree of overlap between these two groups (624 patients) hence the total number of patients that received any form of cylinder was 3,014.

For the period May-July 2010, the CHI was available on 83% of oxygen cylinder prescriptions. It should be emphasised, therefore, that incomplete CHI recording will tend to underestimate the number of patients that received a home oxygen cylinder during that time. Conversely, the population receiving home oxygen cylinders is constantly changing as new patients initiate therapy and others stop either because they recover or die. The three month window was chosen as it is likely that patients on home oxygen cylinders will receive a prescription at least every 3 months hence all patients on home oxygen for the duration of that period would have had the opportunity to be counted. However, whilst patients starting treatment during that period may have been counted, patients that stopped during the period may also have had the opportunity to be counted eg if they received a prescription at the start of the period then died a month later. This approach will therefore tend to overestimate the number of patients on home oxygen cylinders at any one time. It is unclear how these two opposing biases will work together but overall, this approach provides the best currently available estimates of the numbers of patients using home oxygen cylinders at any one point in time.

The age profile of the patients receiving cylinder oxygen is shown below. The majority of patients receiving cylinder oxygen are in the 65-74 and 75-84 year age groups. The age distribution of patients receiving static cylinders is slightly older than that of patients receiving portable cylinders as would be expected. Further analysis of the data shows that the age distribution of female patients is slightly older than that of male patients for each type of cylinder (static and portable), again in line with what may be expected.

Figure 26



Data source: PIS, ISD

Concentrator and other modality provision

Information on the provision of oxygen concentrators is available from Health Facilities Scotland. It can be seen from Table 4 that the provision of standard concentrators has increased steadily since the national service delivered by HFS started in 1989. There is no evidence of a significant additional increase in 2004 when the threshold for prescribing a concentrator was reduced from 15 to 8 hours oxygen use per day. Standard concentrators remain by far the most common type of static home oxygen modality provided by HFS: relatively few patients are currently using more specialised equipment such as BabyOx concentrators, although numbers using the newer modalities have increased sharply since their introduction from 2007. Two hundred patients were provided with a Homefill system in 2008 on a trial basis on the instruction of the Minister for Public Health in response to a shortage of portable oxygen cylinders which accounts for the sudden increase in the use of Homefill at that time. These machines have continued to be made available to patients by HFS. HFS and Dolby Medical staff have undertaken visits to all respiratory departments across Scotland over the last couple of years to ensure that clinicians are aware of the range of services offered.

Comparing the figures in Table 4 with those on the numbers of patients receiving oxygen cylinders presented above, it can be seen that currently around two thirds of patients in Scotland using a static supply of home oxygen are using a concentrator or other newer modality supplied through HFS and one third are using static cylinders. As previously noted, concentrator patients are usually provided with at least one static cylinder as a back up supply in case of power failure but as these cylinders are provided directly by Dolby and not through pharmacies they are not counted in the main cylinder figures presented above. About three quarters of patients using a portable form of home oxygen use portable cylinders: use of liquid oxygen, BabyOx, and Homefill systems is relatively uncommon.

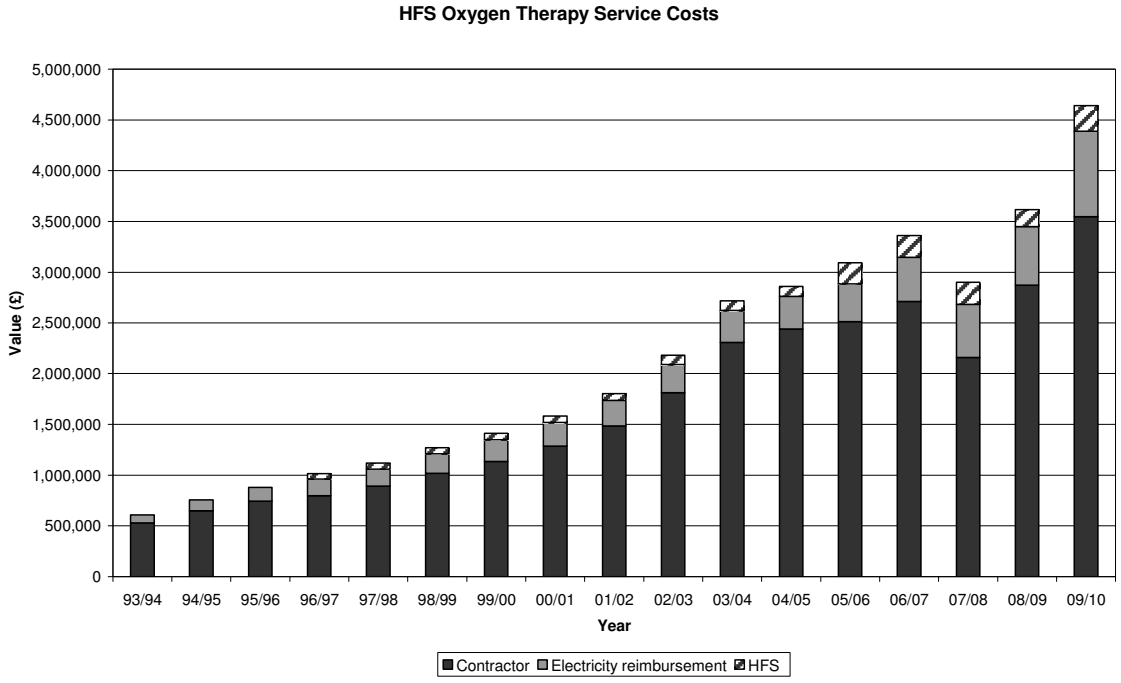
Table 4: Number of patients in receipt of different home oxygen modalities, all Scotland by year (as at 31 March)

Modality	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Standard Concentrator	120	295	415	626	847	1087	1283	1424	1652	1824	1987	2320	2499	2712	2916	3022	3088	3243	3473	3504	3725
Baby Ox																			29	135	250
High Flow Concentrators																			30	60	100
Homefill Systems																			7	231	236
Liquid Ox																			35	78	130

Data sources: Home oxygen database, HFS

The costs incurred through the provision of HFS's home oxygen service have also increased substantially over recent years. Overall costs can be broadly broken down into those paid to the commercial contractor that provides the equipment to patients, those paid by HFS directly to patients to reimburse them for the additional electricity costs they incur through running a concentrator in their home, and staff and other costs incurred within HFS itself. Total costs in 2009/10 were over £4.6 million pounds, with the majority of these costs due to contractor fees. The dip in contractor costs seen in 2007/08 was a real reduction achieved through re-tendering of the national contract at that time. A more detailed analysis of the contractor's costs in 2009/10 shows that, as would be expected, the majority related to installation and daily rental charges for standard concentrators. Despite being a relatively uncommonly used modality, provision of liquid oxygen accounted for over 10% of total contractor costs as this is noticeably more expensive to provide than other modalities, mainly due to the requirement for fortnightly deliveries.

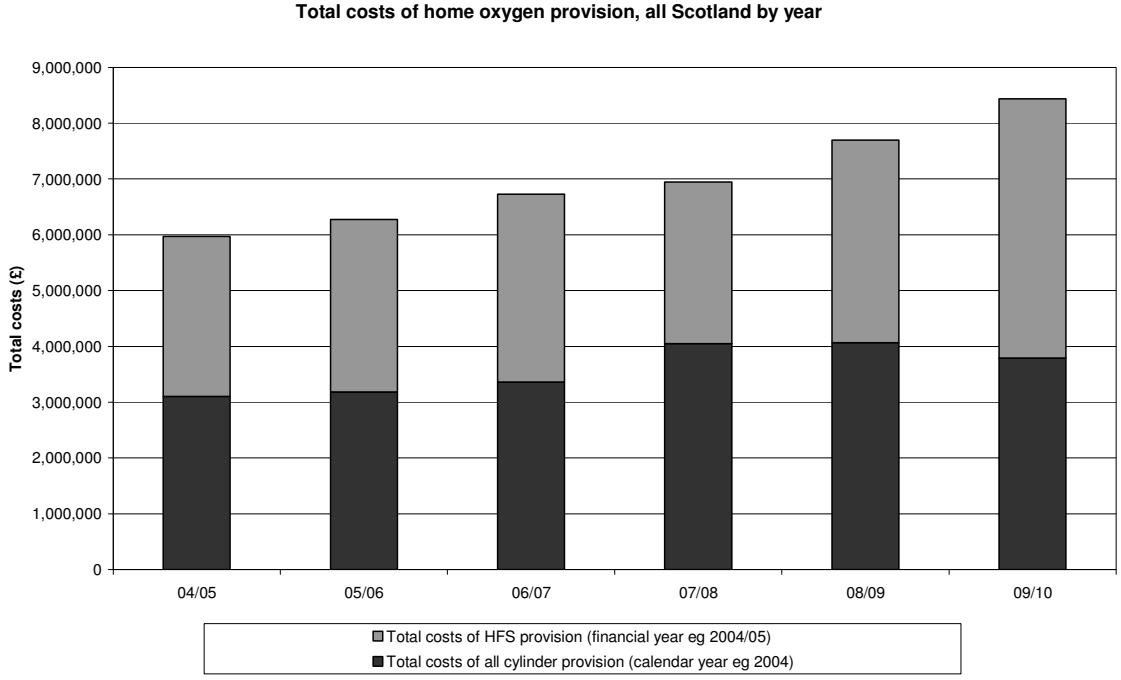
Figure 27



Data source: Home oxygen database, HFS

If the total costs of (static and portable) oxygen cylinder provision are added to the total HFS costs, it is evident that overall costs of home oxygen provision in Scotland have increased from around £6 million per year in 2004/05 to over £8 million per year currently. The majority of this increase in costs has been seen by HFS as the increasing costs of portable cylinder provision have been broadly offset by declining costs associated with static cylinder provision. If recent trends continue (ie static cylinder provision declining, portable cylinder provision reaching a plateau, and concentrator provision continuing to increase), the recent shift in costs of home oxygen provision towards HFS is likely to become more pronounced.

Figure 28

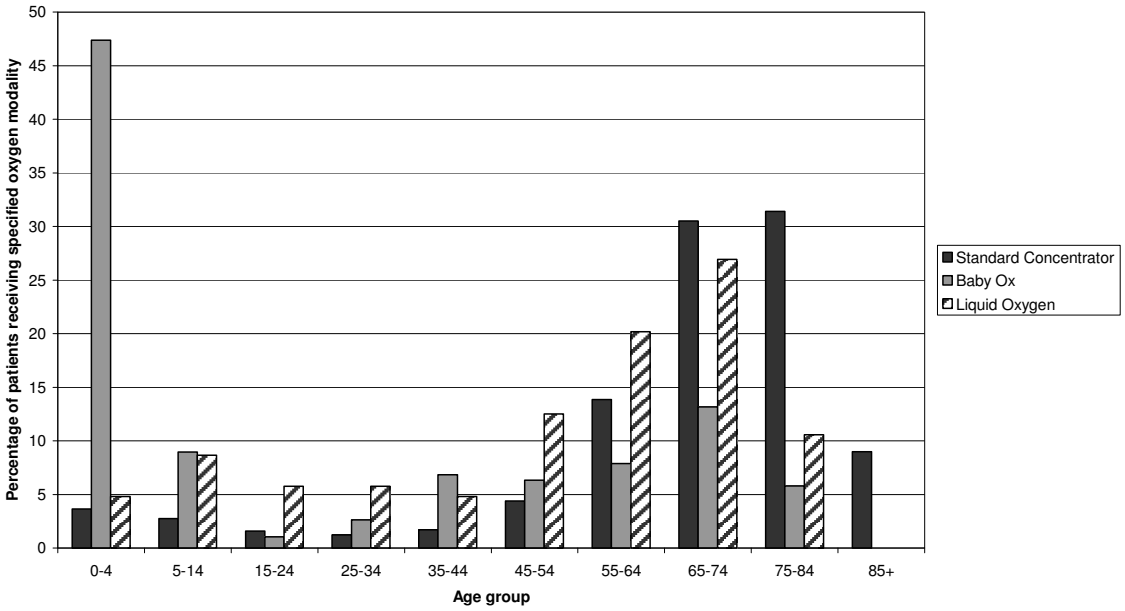


Data sources: Home oxygen database, HFS and PIS, ISD

The age profile of patients supplied with home oxygen equipment by HFS is shown below. It can be seen that most people using a standard concentrator are in the 65-84 year age range although there are small numbers of children, younger adults, and older adults using standard concentrators. The majority of patients using the BabyOx service are children, although again there are some older adults using this service. Liquid oxygen users have a different age profile again. The majority of liquid oxygen users are older adults but children and in particular younger adults also use this service. This would be expected as liquid oxygen is often used for people with high oxygen requirements but relatively high mobility as may be seen in younger adults with CF or chronic interstitial lung disease. The age profile of patients using high flow concentrators and Homefill systems was very similar to that of standard concentrator users.

Figure 29

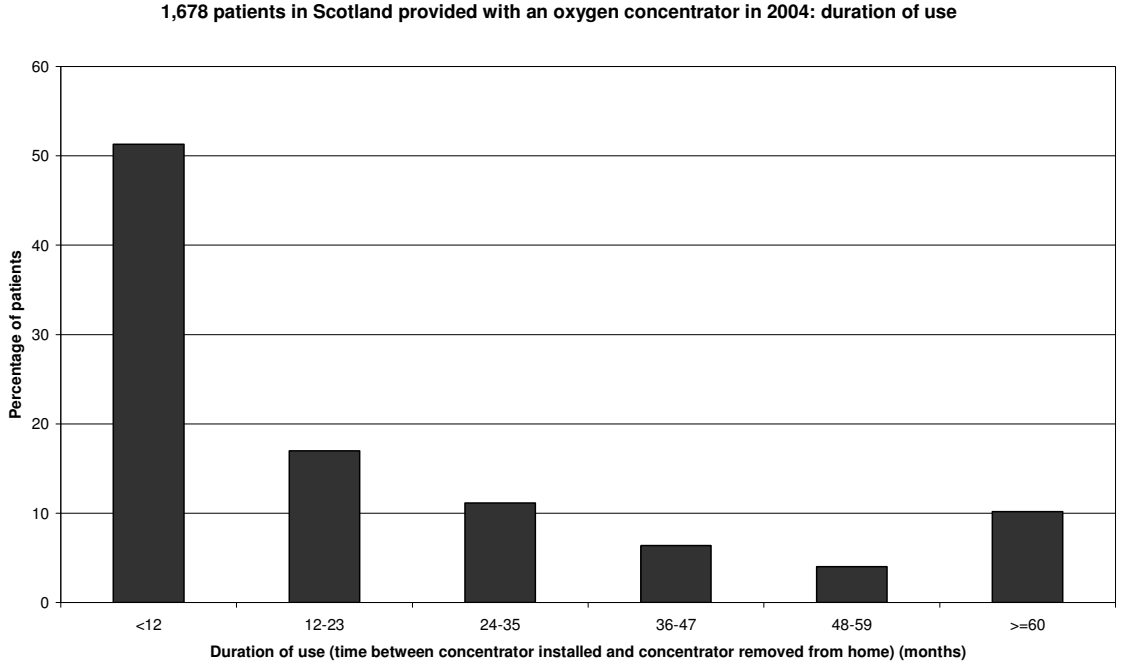
Age distribution of patients on different oxygen modallities, all Scotland as at 31 March 2010



Data source: Home oxygen database, HFS

Data on all patients provided with a standard concentrator by HFS in 2004 were examined to see how long patients used their concentrator for (ie the interval between the concentrator being installed in and removed from their home). The results below show that just over half of all patients used their concentrator for less than one year and around two thirds for less than two years. There does appear to be a subgroup of around 10% of patients using their concentrator for a relatively long period of time (over 5 years) however. Clearly, by necessity this analysis looked at a historical cohort and it is not known whether patients currently being started on oxygen concentrators have a similar pattern of duration of use.

Figure 30



Data source: Home oxygen database, HFS

Portable concentrator and holiday cover provision

The number of portable concentrators available to the service has increased sharply since their introduction in 2007. At the end of March 2010, 145 portable concentrators were available. Forty two of these were available to GP out of hours services (eg to avoid unnecessary admission of patients with exacerbations of respiratory disease or those who had unexpectedly run out of their usual home oxygen), and a further 32 were available to hospital departments (eg to facilitate early discharge of oxygen dependent patients). Twenty three were on semi-permanent loan to specific patients who undertook frequent travel and the remaining 48 were available to the general holiday provision service.

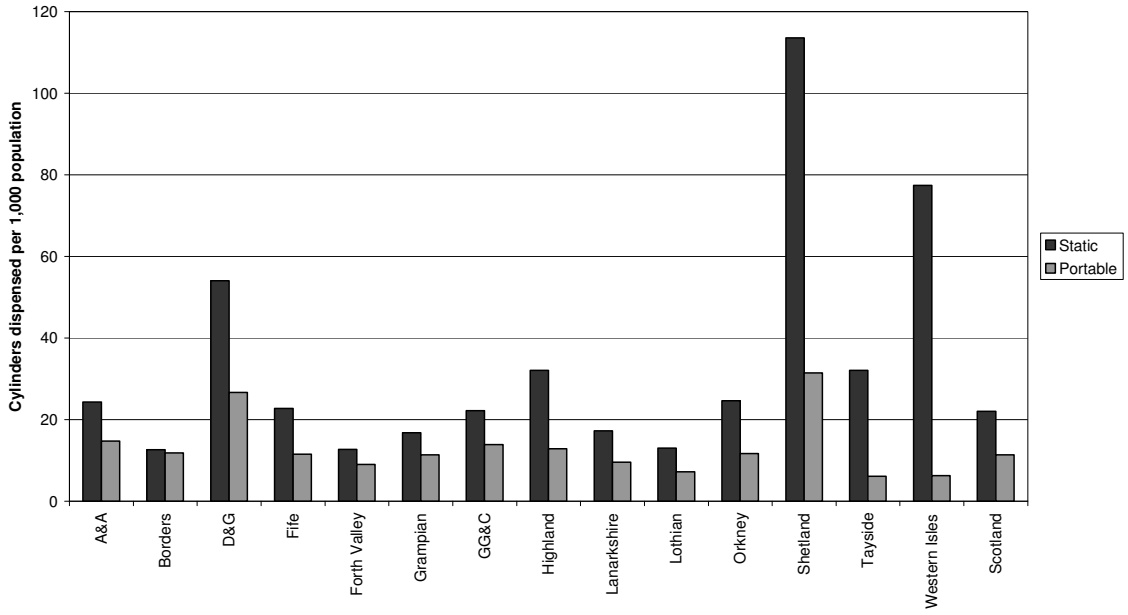
Increasing demand for temporary provision of domiciliary oxygen to cover holidays or other spells away from home (eg respite care) is evident. HFS received 313 requests for temporary provision between June and December 2007, 802 requests in 2008, and 1,318 in 2009. A further 1,013 requests had already been received by the end of August 2010. Patients requiring a temporary oxygen supply whilst away from their usual home are provided with a temporary/portable concentrator through HFS and/or cylinders from a local pharmacy.

Provision of home oxygen by NHS Board

The crude provision rate for static and portable oxygen cylinders by NHS Board is shown in Figure 31 below. The crude rate is simply the total number of cylinders dispensed in the Board in one year divided by the total (mid year) population of the Board area. It can be seen that in Scotland in 2009, around 22 static cylinders and 11 portable cylinders were dispensed over the course of the year for every 1,000 persons in the population. A considerable degree of variation is evident in crude rate between Board areas. Some NHS Boards, such as Lothian, appear to provide relatively low numbers of oxygen cylinders whereas others such as Shetland are relatively high providers. Other NHS Boards, such as Tayside, appear to provide relatively high numbers of static cylinders but relatively low numbers of portable cylinders.

Figure 31

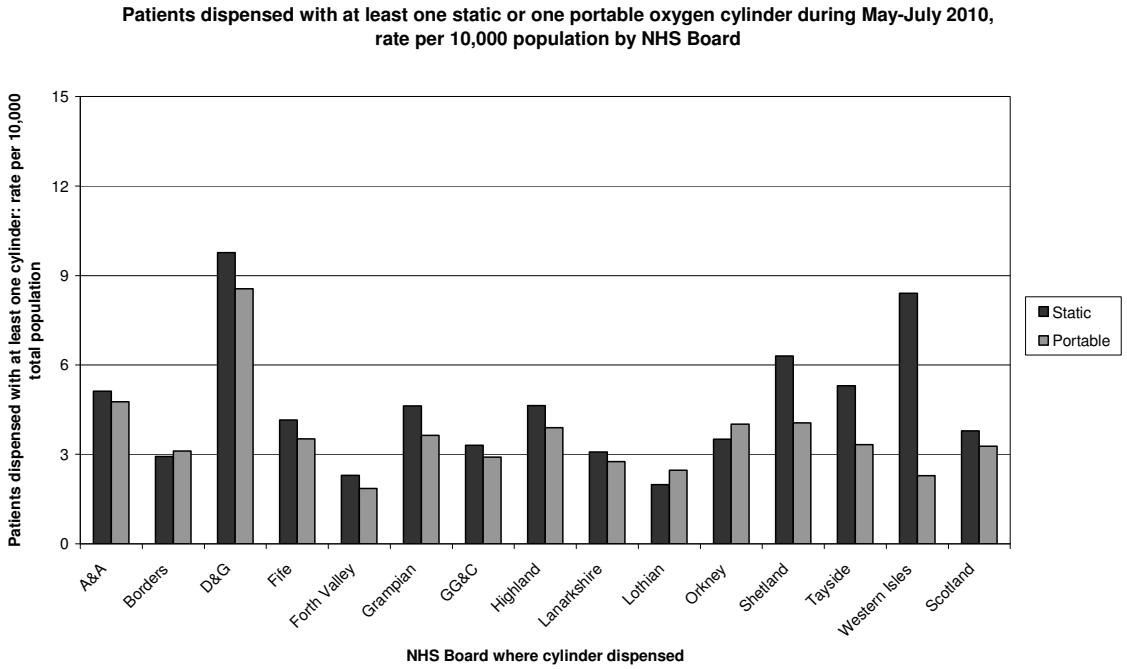
Static and portable oxygen cylinders dispensed: rate per 1,000 population by NHS Board, 2009



Data source: PIS, ISD and mid year population estimates, GRO(S)

Crude cylinder provision rates can be influenced by small numbers of patients who use large numbers of cylinders, particularly in smaller Board areas. Prescribing data with CHI available was therefore also examined to investigate how the estimated rate of individual patients dispensed with oxygen cylinders per head of population varied by NHS Board and the results are shown in Figure 32.

Figure 32



Data source: PIS, ISD and mid year population estimates, GRO(S)

As noted previously, the CHI number was available on 83% of all prescriptions for oxygen cylinders dispensed across Scotland in May-July 2010. CHI completeness varied between NHS Boards however as shown in Table 5.

Table 5: Percentage of all prescriptions for oxygen cylinders dispensed May-July 2010 that contained a valid CHI number

NHS Board	% CHI completeness
Ayrshire and Arran	82.2
Borders	88.2
Dumfries and Galloway	88.1
Fife	87.8
Forth Valley	83.4
Grampian	82.1
Greater Glasgow and Clyde	80.7
Highland	85.4
Lanarkshire	87.9
Lothian	79.1
Orkney	88.7
Shetland	**43.1**
Tayside	84.9
Western Isles	93.5
Scotland	**83.5**

Data source: PIS, ISD

It can be seen that, in general, NHS Boards had similar levels of CHI completeness (around 80-90%) except for Shetland which only had CHI recorded on 43% of all prescriptions for oxygen cylinders dispensed. This means it is likely that the number of patients receiving oxygen cylinders will be particularly under estimated in Shetland.

How the estimated numbers of patients receiving oxygen cylinders relate to the true number of patients receiving oxygen cylinders is extremely difficult to assess. Essentially this is because we do not know the 'pattern of absence' of CHI numbers. This 'pattern of absence' will lie somewhere between two extreme situations. At one extreme is an 'all or nothing' pattern. Here, if the CHI number is missing for one prescription for a given patient, CHI is missing for all prescriptions for that patient. This could arise, for example if CHI were missing from all prescriptions issued by some practices or dispensed by some pharmacies but otherwise completely recorded. At the other extreme, CHI is missing on a random basis. Here, if CHI is missing for one prescription for a patient that has no implications for whether CHI is missing for any other prescription for that patient.

These two extreme positions have quite different implications for the relationship between the estimated numbers (based on records with CHI) and the true numbers. If CHI were missing on an all or nothing basis, then the true number could be calculated by a straight scaling up of the estimate. For example, if CHI completeness were 80%, the true number would be the estimate multiplied by 1/0.8 or 1.25. If CHI is missing on a random basis, then the estimate will be much closer to the true number since each separate prescription provides an independent and additional 'bite at the cherry' of identifying the patient. If several prescriptions are involved for each patient, the estimate will be very close to the true number under the 'random missing' assumption.

Unfortunately, we do not know the actual pattern of absence of CHI: it will lie somewhere between the two extremes. However, if we assume that this 'pattern of absence' is unlikely to vary greatly between NHS Boards then the pattern of variation shown in Figure 32 will be fairly close to the true pattern of variation. The exception is likely to be Shetland. Here, because CHI completeness is much lower than in other Boards, and because Shetland is such a small Board with its own prescribing mechanisms, it may well have its own 'pattern of absence'. This would make the relationship between any estimated number of patients and the true number highly uncertain.

Results relating to cylinder oxygen provision by NHS Board (and particularly Shetland) should therefore be interpreted with caution. Overall, however, it appears that there is a degree of variation in the prescribing of both static and portable oxygen cylinders between different areas of Scotland, with Dumfries and Galloway and Shetland likely to have particularly high prescribing rates.

The variation in provision of static and portable home oxygen modalities by HFS by NHS Board was also examined and results are shown in Figure 33. For the purpose of this analysis, static modalities provided by HFS were defined as:

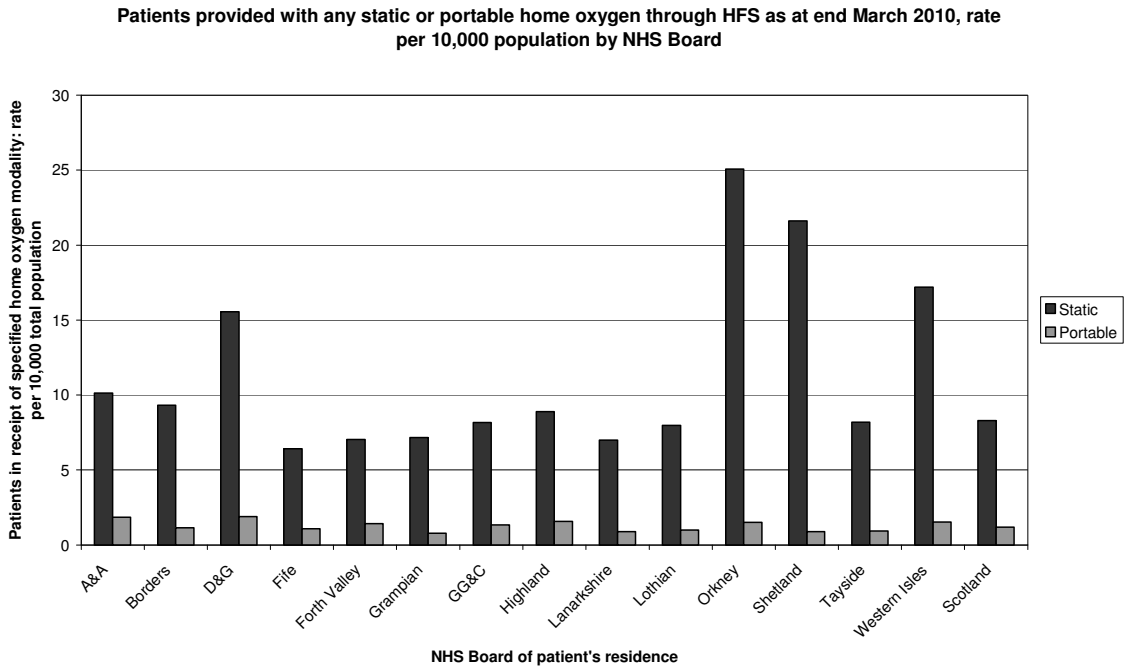
- Standard concentrator
- BabyOx
- High flow concentrator, and
- Homefill system

Portable modalities were defined as:

- BabyOx
- Homefill system, and
- Liquid oxygen

This reflects the fact that the BabyOx service and the Homefill system both provide static and portable forms of home oxygen.

Figure 33

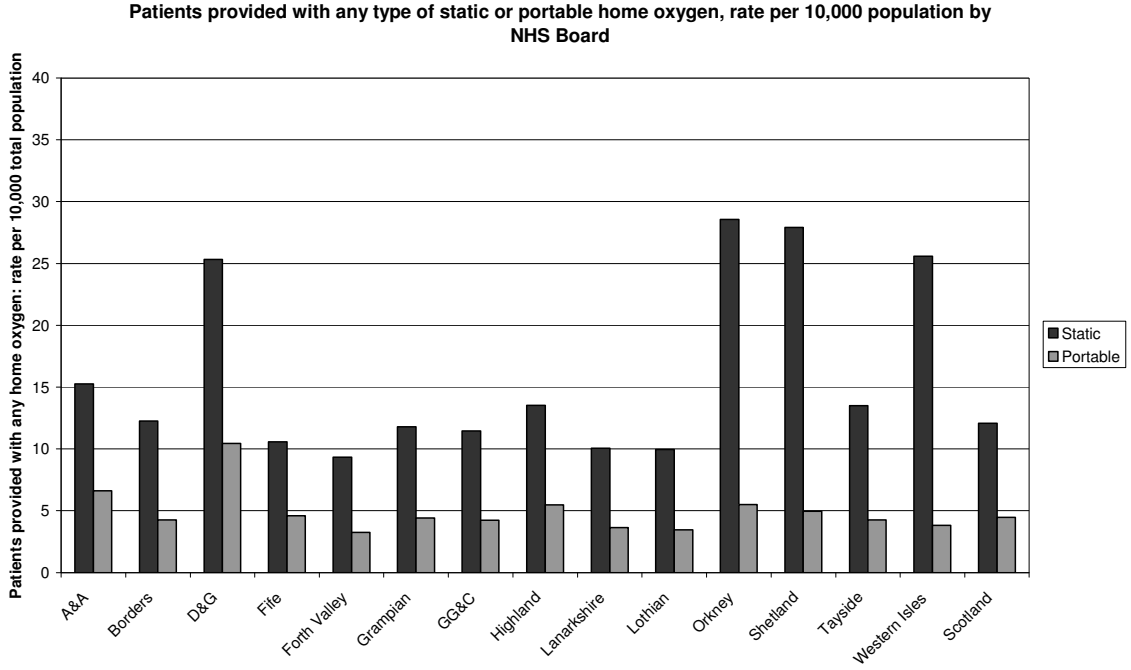


Data source: Home oxygen database, HFS and mid year population estimates, GRO(S)

It is apparent that many more patients receive static modalities than portable modalities through HFS. Overall, however, it is clear that whilst most Boards have relatively similar levels of static modality provision, some stand out as relatively high providers, notably Dumfries and Galloway and the island Boards. There is relatively little variation in provision rates of portable modalities between Boards. Rates of provision of portable modalities in the smaller and island Boards shown in Figure 33 are based on very small numbers so should be interpreted with caution, however.

Finally, the total overall provision (through community pharmacies or HFS) of any form of static and portable home oxygen was examined by NHS Board and the results are shown in Figures 34. These overall figures were obtained by simply adding the estimated numbers of patients in receipt of static and portable cylinders to the numbers of patients in receipt of static and portable modalities through HFS shown above. It should be remembered that these figures therefore include the subset of prescribing data which contains patients' CHI numbers with the attendant issues discussed above. The two data sources relate to slightly different time points (May to July 2010 for PIS data and end March 2010 for HFS data) and also define NHS Board differently (NHS Board of dispensing pharmacy for PIS and NHS Board of residence for HFS data). Nevertheless, these estimates provide the first attempts to quantify how the overall provision of home oxygen varies across Scotland.

Figure 34



Data source: PIS, ISD, Home oxygen database, HFS, mid year population estimates, GRO(S)

It can be seen that, overall, there is relatively little variation in provision of static or portable forms of home oxygen between the larger and generally more urban areas of Scotland. There is some evidence that provision of static home oxygen modalities is higher in the more remote and rural areas of Scotland, in particular in Dumfries and Galloway, and the island Boards. Provision of portable home oxygen also appears to be relatively high in Dumfries and Galloway. Reasons behind this pattern of provision across Scotland are unknown but the issues involved in managing patients in areas with more difficult access to hospital may play a part. As the majority of home oxygen is prescribed for older adults, provision rates by NHS Board were also calculated based on the population aged 65+ rather than the total population but this made minimal difference to the patterns observed.

It is worth noting that no information is available in Scotland on the reasons/diagnoses underlying prescription of home oxygen. It would be possible to investigate this through

a record linkage exercise and/or a patient/carer survey but this has not been attempted within the timescale of this project.

User and provider views

User views: literature review

National Services Scotland conducted a survey, on behalf of the Scottish Government, in 2006 on patients' and providers' views on home oxygen provision. The results of this survey were summarised in the 2010 report of the working group on home oxygen (Scottish Government 2010). In general, patients reported very high satisfaction with their home oxygen service. Of the 820 patients surveyed (who used a mixture of cylinders and concentrators), approximately three quarters (72%) of patients rated the home oxygen service (concentrator provision) as excellent and 25% as very good, while 59% and 29% rated the portable oxygen service as excellent and very good respectively. The majority of patients were satisfied with the amount of portable oxygen received each month (Scottish Government 2010).

As part of their review, the working group also directly solicited the views of relevant patient groups on home oxygen provision. Again generally high patient satisfaction was reported, with some caveats around limited choice of equipment type and problems with the size and weight of 'portable' cylinders noted. Lack of clarity around how to complain when problems arose was also mentioned. The Homefill system and conservers were commended as offering significant advances although it was felt these could be made more widely available (Scottish Government 2010).

The working group also commissioned an external agency to undertake a substantial research project which included a thorough assessment of user views on home oxygen provision through interviews with and a survey of patients and carers (Ferguson et al 2010). Thirty patients (or carers when the patient was too young or too ill) were interviewed and an additional 63 took part in a web based survey. High patient satisfaction levels were reported in this survey with 89% rating the service as excellent or very good. Interestingly, in light of the absence of formal research evidence on the impact on home oxygen on patients' quality of life, 75% of the sample indicated the service improved their quality of life, mainly by allowing more activity and independence. Patients commented that their home oxygen made it easier to manage everyday activities such as housework and spending time with family and overall contributed to an improved peace of mind and confidence. Highly variable knowledge amongst patients regarding appropriate use of their oxygen was noted however and a minority did not feel they derived any benefit from their home oxygen. Some specific frustrations with aspects of the service (and associated suggestions for improvement) were also reported e.g.

- Inconvenient delivery/collection of cylinders
- Inadequate supply of portable cylinders
- Cylinders being delivered inadequately filled
- Portable cylinders being large and heavy
- Noise associated with concentrators, and
- Difficulties accessing oxygen supplies in emergency situations out of hours.

Patients that had used various types of oxygen generally reported preferring concentrators to cylinders; ambulatory to the bigger 'portable' cylinders; and a conserver to no conserver. The vast majority (84%) of respondents reported having their oxygen

initiated by a consultant and 75% reported having their needs reviewed at least every 6 months however a minority reported receiving no meaningful ongoing review of their requirements. Patients often had a range of health and social problems and numerous professionals involved in their care and reported frustrations related to poor care coordination and communication between professionals. This seemed to be worse for adult patients than children and for patients with specific conditions e.g. COPD that were not in receipt of formal palliative care (Ferguson et al 2010).

Finally, the 200 patients in Scotland provided with Homefill devices in 2008 were surveyed 30 days after they had started using the device by Health Facilities Scotland. Patients were very positive about the Homefill system, universally preferring it to their previous devices (Ferguson et al 2010).

The generally high levels of patient satisfaction with home oxygen services in Scotland are also found in England and Wales. A large scale survey of users' views was undertaken in 2008 (n= 3065, response rate 66%) to assess patient satisfaction with the home oxygen service following its reorganisation in 2006. In general, high levels of satisfaction were noted with 88 per cent of patients believing that their quality of life had improved since receiving the service (Sexton et al 2008). Similar findings were reported by Cornford et al (2000) with patients receiving home oxygen reporting a positive impact their sense of self-determination and overall quality of life. The factors most strongly associated with patients' satisfaction were noted as the initial installation of equipment, ease of use of equipment, convenience of oxygen deliveries, and the availability of a telephone helpline for queries. Areas for improvement were noted as reliability of oxygen deliveries and communication with and education of patients and carers. The type of device used (e.g. cylinder vs. concentrator) did not have an impact of satisfaction (Sexton et al 2008).

Studies in the US looking at the care of children on home oxygen therapy have also reported high satisfaction rates among families. Thilo et al (1987) in a study of children with chronic neonatal lung disease reported that families responded 94% of the time that they would again take an infant home on oxygen. Bajal et al (2006) found high satisfaction rates among families (97%) with home oxygen therapy for their child at 7 day follow-up after hospital discharge. Similar findings were reported in two Swedish studies with the majority of patients reporting positive improvements in their quality of life (Ring and Danielson 1997; Thorbjorg et al 2006). Negative views of oxygen therapy in these studies concerned the oxygen machines themselves. Thorborg et al (2006) noted that of particular importance was how strenuous the initiation of the treatment was for everybody, carer and patient. Ring and Danielson (1997) observed strong feelings of social isolation among patients in their study caused by being restricted to their homes, mobility problems and being dependent upon a fixed routine.

Provider views: literature review

The 2006 NSS survey of patient and provider views on home oxygen provision in Scotland included returns from 164 community pharmacists, approximately one-third of pharmacists who dispensed oxygen at that time (Scottish Government 2010). The vast majority of community pharmacies considered the portable oxygen cylinder service to be working effectively at that time. From the same survey, Scottish Respiratory Nurse Specialists reported a variation in support for severe COPD patients across the country

as not all NHS Boards had community respiratory nurse specialist services for long term oxygen therapy users. The nurses also suggested that both portable cylinder carry bags and oxygen conservers should be made available on the NHS and that there was a need for clearer patient information on how to arrange their oxygen supply when going on holiday abroad (Scottish Government 2010). Many of these issues have been addressed in the time elapsed since this survey was undertaken.

As part of the research supporting the recent working group on home oxygen services, Ferguson et al (2010) undertook a 2 stage eDelphi survey to assess provider views on home oxygen provision. The survey involved 53 stakeholders (including respiratory consultants, GPs, specialist nurses, pharmacists, physiotherapists, and finance/planning staff) from 13 NHS Boards across Scotland. In general the professionals were more critical of the service than patients had been, with only 42% of respondents agreeing with the statement that 'The current domiciliary oxygen therapy service meets patients' needs'. There was clear consensus that respiratory consultants (or other relevant specialists) are the best placed to assess patients' needs for home oxygen apart from in obvious palliative care situations when primary care prescribing was considered appropriate. There was strong agreement that GPs should not be able to prescribe concentrators because GPs are unlikely to have the required degree of specialised knowledge and because they do not generally have access to specialist assessment tests such as arterial blood gas sampling in primary care settings. Despite this, there was clear agreement that not all patients started on home oxygen receive a secondary care based assessment of their needs. This must relate to patients started on static cylinders as HFS does not accept referrals to start patients on concentrators or other modalities from GPs.

Ferguson et al (2010) also reported problems with inadequately detailed prescriptions for oxygen, e.g. lack of information on flow rate, recommended duration of usage per day, and precise equipment to be supplied, particularly in relation to GP prescriptions for cylinders. There were clear concerns that ongoing monitoring of patients' oxygen requirements was suboptimal, particularly for those receiving SBOT and there was very high consensus that portable cylinders should be made more readily available and that individual patients should have access to more cylinders if needed. There was a consensus that simply transferring patients on cylinders onto concentrators was inappropriate without a thorough assessment of individual patient's needs and their ability to benefit from home oxygen. Patients' concerns regarding reliable access to oxygen out of hours were echoed by professionals, mainly attributed to problems with local arrangements for out of hours pharmacist cover. Providers indicated a desire for more explicit guidance around the provision of home oxygen with 67% disagreeing with the statement 'There is clear guidance for those prescribing oxygen'. Use of home oxygen by patients that continue to smoke and use of oxygen on public transport were noted as specific areas for which clear guidance was lacking.

Respondents to the eDelphi survey were not asked for their views on whether in principle Scotland should aim to bring together the different elements of home oxygen provision in a unified national service. Specific possible elements of a unified service were asked about however and responses were mixed. For example, 73% of respondents agreed that a national database of home oxygen patients would be beneficial whereas only 5% agreed that Scotland should adopt the Home Oxygen Monitoring Form used for all home oxygen prescriptions in England and Wales. Forty nine percent agreed that creating one centralised supplier for all oxygen products would

improve the service but 33% agreed that if all oxygen equipment was provided by one organisation this would significantly increase the risks of problems with suppliers. Based on these findings, Ferguson et al (2010) noted two possible options for the future development of home oxygen services – firstly separating the supply and support functions inherent to home oxygen provision and secondly introducing a national contract for cylinder supply. Making firm recommendations about these issues was beyond the scope of the research report.

Provider views: interview results

As outlined in the methods section and Appendix 3, a series of 18 interviews was conducted with key clinicians from across Scotland involved in the prescribing of home oxygen as part of this needs assessment project. The interviewees comprised:

- 6 consultant respiratory physicians
- 4 consultant paediatricians/neonatologists
- 5 specialist or practice nurses, and
- 3 General Practitioners

Of the above, 2 consultant respiratory physicians, 1 specialist nurse, and 2 GPs also held lead clinician roles within managed clinical networks for respiratory disease.

The interviews were designed to provide additional information to complement that available through the research commissioned by the recent working party on home oxygen. The main findings from the interviews are presented here for each of the main themes addressed, namely:

- Decision making around initiating home oxygen therapy
- Clinical monitoring of patients on home oxygen
- The effectiveness of different forms of home oxygen
- The influence of factors such as changing patterns of hospital based care, availability of new technology, and policy/guidelines on demand for the service
- The current adequacy and appropriateness of home oxygen provision, and
- Potential future service developments.

<u>Decision making around initiating home oxygen therapy</u>

Interviewees were asked how they made the decision to start a patient on home oxygen and in particular how they used objective tests such as blood gas sampling to support their decision. Patients in Scotland should only be started on a concentrator or liquid oxygen by a consultant level doctor as Health Facilities Scotland only accepts referrals from consultants. In theory, patients could be started on cylinder oxygen by their GP but BTS guidance for the home oxygen service in England states that this would only be appropriate in palliative care situations and any patients starting on LTOT using cylinders or on AOT using portable cylinders should be assessed by a consultant led team (BTS 2006) and this would generally be accepted as good practice in Scotland too. Current guidance also recommends that adult patients starting LTOT should have hypoxaemia proven on blood gas sampling and those starting AOT should have clear evidence of exercise desaturation. Testing in children prior to initiating home oxygen generally relies on pulse oximetry rather than blood gas sampling. The detail of current guidance is summarised below.

Guidance produced by the British Thoracic Society for the home oxygen service in England and Wales (BTS 2006) currently recommends that LTOT should only be started in adults in the following situation:

- The patient's underlying clinical condition has been confidently diagnosed
- Other aspects of the patient's condition have been optimally managed
- The patient has been clinically stable for at least 5 weeks
- Hypoxaemia has been demonstrated on at least 2 blood gas samples (from radial or femoral artery or arterialised ear lobe capillary sample) taken at least 3 weeks apart
- Hypoxaemia is defined as PaO_2 ≤7.3kPa (or between 7.3 and 8.0kPa if other problems such as polycythaemia or pulmonary hypertension evident) in a patient who has been breathing air for at least 30 minutes
- Correction of hypoxaemia (PaO_2 maintained at >8kPa) (and no dangerous rise in $PaCO_2$) demonstrated on further blood gas sampling after breathing supplemental oxygen for at least 30 minutes

The guidance recognises that patients with primarily neuromuscular/hypoventilation problems will require further specialised assessment before LTOT is provided. It also recognises that such rigorous testing may not be appropriate in palliative care situations.

The guidance also recommends that AOT should only be started when

- Pulmonary rehabilitation has been provided
- The patient's usual activity levels (and motivation to use AOT) and hence AOT requirements have been assessed
- Exercise desaturation has been demonstrated (defined as a fall in SaO_2 of ≥4% to a value <90%)
- Improvement in exercise capacity and/or breathlessness and correction of exercise desaturation with AOT has been demonstrated
- This means improvement in objective measurement of walking distance and dyspnoea using recognised scoring methods and maintenance of SpO2 above 90% during exercise
- A six minute walk test or shuttle walk test is usually used in these assessments

Again, the guidance recognises that this approach will be appropriate for LTOT patients likely to be high AOT users and non-LTOT patients being considered for AOT. Such rigorous testing may not be appropriate in situations where patients already on LTOT who rarely leave the house are being provided with supplementary AOT for very occasional use eg to facilitate visiting family, however.

No specific guidance is given on patient assessment that should be undertaken before prescription of SBOT as there is inadequate evidence on this issue.

The BTS guideline on the use of home oxygen in children is clear that assessment for home oxygen is very different in children compared to adults (Balfour-Lynn et al 2009). Measurement of oxygenation in children usually relies on pulse oximetry rather than blood gas sampling. When assessing children for home oxygen, SpO2 should be monitored for at least 6-12 hours during all activity levels (including sleeping and feeding) and adequate oxygen supplementation should be defined as achieving minimum target SpO2 (usually 93%) for at least 95% of the time.

Interviewees confirmed that LTOT was generally only initiated by specialists in secondary care, although it could be either nurses or doctors who made the decision

according to local service configuration. There was evidence that the specialists followed established guidance with regard to patient testing prior to starting LTOT. Arterial blood gas sampling was used when making the decision to start LTOT in adults with a PaO_2 <7.3kPa mentioned as the relevant threshold. Pulse oximetry was also mentioned as used in adults as a screening test to indicate the need for further blood gas testing or to assist in follow up monitoring once patients start LTOT. Pulse oximetry was also mentioned as the appropriate test for children, although different target saturations were noted as appropriate for different patient groups. Exercise testing was noted as appropriate when assessing patients for AOT. Overnight oxygen saturation monitoring, full blood count to detect polycythaemia, and ECG to detect pulmonary hypertension were also mentioned as appropriate tests in some circumstances. There was evidence that flexible approaches were taken to patient assessment in very remote areas.

"Well the child would be assessed for their oxygen requirement to determine the flow rate and that the oxygen is essential and that is usually by oximetry…" (Paediatrician)

"If, for example, I get a letter from a GP in one of the very remote parts of our patch, which could easily be three/four hours drive away from us, and if he says this patient has such and such a pathology, they would really struggle to get to a clinic, but I have checked their oximetry at home on several occasions and it is such and such a level…then I have sometimes used that as really the main criterion for prescribing someone oxygen." (Adult Respiratory Physician)

Some specialists indicated that, in their view, all LTOT patients should be considered for AOT but others noted that they did not consider AOT for LTOT patients who were housebound. Many interviewees noted that the decision to initiate AOT was relatively complex and depended on a balance between the extra ability to go out rather than being tied to the home, and the inconvenience and physical challenge of carrying portable cylinders.

"…it [starting AOT] has always been a matter of the balance of the benefit of oxygen against the inconvenience of having to use a cylinder." (Adult Respiratory Physician)

Several respondents indicated that decision making around initiating AOT for patients not already on LTOT was particularly difficult.

"That [starting AOT for non-LTOT patients] is such a harder decision…if the patient is clearly de-saturating, i.e. their oxygen levels are dropping dramatically on exercise, sometimes they do benefit." (Practice Nurse)

"Ambulatory oxygen is difficult. I would consider it in patients who don't meet the criteria for domiciliary oxygen, but are likely to de-saturate." (Adult Respiratory Physician)

Most interviewees reported using exercise testing when making the decision whether to prescribe AOT in at least some situations but equally a number of respondents indicated that there were situations where AOT was automatically provided to LTOT patients without formal exercise testing being undertaken. Paediatric patients were felt to almost all need ambulatory oxygen.

"…we're looking for a 4% de-saturation from the baseline before we would consider perhaps prescribing." (Respiratory Nurse Specialist)

"…not exercise testing because we're not doing non-LTOT ambulatory." (Adult Respiratory Physician)

The 3 GPs interviewed all indicated that they would not initiate LTOT without the advice of a relevant specialist. GPs differed in whether they would initiate SBOT in palliative care situations without the guidance of a specialist. GPs confirmed that they generally had access to pulse oximetry but not blood gas sampling and that GP prescription of portable cylinders tended to be on the advice of a specialist.

"So the only situation I would instigate oxygen at home would be on the advice of another practitioner who might be a hospital respiratory specialist or somebody who was involved with palliative care." (GP)

"…it is purely symptomatic [using SBOT in palliative care situations] and perfectly legitimate to have a go in that manner." (GP)

Finally, there was a theme about putting all the tests into the context of a wider clinical assessment.

"Most oxygen prescriptions arrive after a long period of decline in the patient's wellbeing and therefore the patients are probably already in the system to an extent." (GP)

"It's a clinical assessment […] So it's maximise medical therapy beforehand before we just rush in. […] we want them to be clinically stable." (Adult Respiratory Physician)

<u>Clinical monitoring of patients on home oxygen</u>

Clinical follow up of patients started on home oxygen was noted in the 1999 Royal College of Physicians report to be an area in particular need of improvement (RCP 1999). Follow up should ensure that patients continue to need their oxygen, are using their oxygen safely and in the required amount, and are deriving the expected benefit. The detail of current guidance on follow up is summarised here. The BTS guidance on provision of home oxygen recommends that all patients started on LTOT should have a consultant led review after 3 months and at least annually thereafter with blood gases measured on air and on supplemental oxygen. In addition, it recommends that all LTOT patients should have a home based review within 4 weeks of starting therapy and at least 6 monthly thereafter by a specialist nurse, physiotherapist, or technician with an assessment of their SaO2 on air and on oxygen (should be >=92% on oxygen) and their oxygen useage/compliance, with referral for specialist assessment if there are any concerns (BTS 2006).

The guidance also states that all patients started on AOT should be reviewed after 2 months by interview and review of diary card and oxygen usage to assess whether meaningful benefit is being obtained and the AOT should be continued. Lastly, all patients on AOT and SBOT also require at least annual reviews on an ongoing basis to ensure current provision continues to meet their clinical needs (BTS 2006).

Children on home oxygen are different to adults with regard to their follow up requirements as they (particularly neonates with CNLD) are generally expected to improve over time and eventually outgrow their oxygen dependence. When children are started on home oxygen, the relevant BTS guidance recommends that the family is visited by a community children's nurse or respiratory nurse specialist within 24 hours then offered hospital based review after 4-6 weeks (Balfour-Lynn et al 2009). Children with CNLD should have their SpO2 monitored around every 4 weeks. Older children with stable disease usually require less frequent monitoring. SpO2 is usually monitored overnight using a suitable pulse oximeter and the results discussed with the relevant clinician. Withdrawal of home oxygen can be considered once children are stable on flow rates of 0.1l/min. Home oxygen equipment should be left in the child's home for at least 3 months (or until the end of winter) after withdrawal in case of deterioration eg with a viral respiratory infection.

Interviewees were first asked if they felt they could reliably identify all the patients on home oxygen under their care. Some (adult and paediatric) specialist teams noted that they maintained a register of all patients on home oxygen and these registers were often maintained by specialist nursing staff. Other teams had no formal way of identifying home oxygen patients but felt that all relevant patients were seen for follow up through the normal clinic process. In primary care, the requirement specified in the Quality and Outcomes Framework for practices to hold a register of patients with COPD was noted as being helpful but this may not provide a complete record of all patients on home oxygen.

"We've got a sort of system in place in the hospital whereby we're informed of all the patients who are started on oxygen therapy by any of our consultants in the hospital and we've got a home oxygen register." (Respiratory Nurse Specialist)

"I guess we fall down here. We don't have a specific register as such…so if you say, 'Do you have a list to hand of all your patients on oxygen?' – 'No.' 'Are they all seen at a clinic?' then, as I said, with one or two exceptions, 'Yes.'" (Adult Respiratory Physician)

"We have a disease register for COPD, which is a requirement of the quality and outcomes framework for the GMS contract, but it doesn't specify who is on long-term oxygen." (Practice Nurse)

There was evidence of active follow up provided to patients on home oxygen. The precise model of follow up varied between paediatric and adult patients and between areas. Combinations of home based and clinic based follow up were used and nurse specialists were often mentioned as having a key role in follow up. Self monitoring by patients in their homes then discussion of the results with the specialist team was also an important aspect of follow up. Follow up appointments were noted as being opportunities for holistic assessment of patients' needs rather than just blood gas/saturations checking. GPs gave a clear view that formal follow up of home oxygen patients was the responsibility of secondary care (except where they had initiated oxygen as part of palliative care) although they often had considerable contact with patients on home oxygen.

"They [nurse specialists] check on the long-term oxygen patients every six months and they check their oxygen saturation, and they check on patients on oxygen cylinders once a year and check their oxygen saturation." (Adult Respiratory Physician)

[Talking about follow up provided by nurse specialists to LTOT patients] "…education and support, recording oxygen saturation and the flow rate, correction satisfactorily of low oxygen levels and the results are sent to both the hospital specialist and the GP." (Adult Respiratory Physician)

"We call them [paediatric patients on LTOT] in or give them a clinic pulse oximeter that they will then take home and do the study or do the recording and then we will download that on to computer software so we can analyse it and feed them back the results usually by telephone call." (Paediatrician)
"There aren't arrangements to monitor them in primary care. In fact the, the primary care position is that secondary care should be monitoring them. If secondary care is not monitoring them, then primary care will drive secondary care to monitor them." (GP)

<u>The effectiveness of different forms of home oxygen</u>

Interviewees were asked to give their opinions on the clinical effectiveness of different forms of home oxygen. There was a widespread view that long term oxygen therapy was effective in improving survival if given for more than 15 hours per day to appropriately selected adult patients, although it was acknowledged that the evidence applied to COPD most robustly. It was generally also accepted that LTOT improved patients' quality of life, although some respondents were more equivocal about that.

"The evidence that it improves their quality of life has always been a little less robust. I think in some patients, it may do; and in other patients, it will actually reduce their quality of life, but it makes them live longer." (Adult Respiratory Physician)

Although the basic evidence around LTOT being effective when used for at least 15 hours a day was clearly reflected by respondents as noted above, one adult physician mentioned at least 12 hours a day being adequate for some benefit. Paediatricians acknowledged the uncertainty around the effectiveness of LTOT in children, and gave different opinions as to required daily duration of use.

"Because babies have frequent periods of sleep, which is the time when they're at potential risk, the only way to deal with them is to give them 24-hour oxygen supplementation. And, when that requirement becomes less, particularly focus it on the period at night, when they can't be supervised." (Paediatrician)

"…long-term is effective? I suppose we're aware that low oxygen levels can have an affect on pulmonary hypertension and right ventricular hypertrophy, so the blunt answer to the question is, 'Yes', but what level is actually required to prevent that from happening is not known." (Paediatrician)

[Talking about the required daily duration of LTOT] "At least 8 and usually 24 [hours]" (Paediatrician)

Interviewees were generally very positive about the additional benefits of AOT in terms of freeing patients from being tied to their home, facilitating exercise, and improving quality of life although adult specialists noted that there were issues around the inconvenience of carrying bulky 'portable' cylinders and the stigma of wearing oxygen

equipment whilst out in public. One respondent also emphasised that AOT was only relevant to adult LTOT patients who were sufficiently mobile to leave their homes.

"They call it portable, but they really shouldn't, I don't think. They [adult patients on AOT] should be given some sort of device to carry it around with, possibly a little carriage or something that they could wheel around." (Respiratory Nurse)

"I think portable oxygen is beneficial but I think there's a large reluctance to wear it just because of the stigma attached to it." (Adult Respiratory Physician)

[Talking about the usefulness of AOT] "For a very few patients, yes. The majority of patients that need oxygen in my experience are pretty housebound." (GP)

Paediatricians were clear that AOT was very important for children to allow families to maintain normal activities and to allow older children to access school, although they recognised that there may not be formal research evidence on this issue.

"There is no evidence to say how effective it [AOT] is but I can see the benefits of it from a socialising point of view with a child. […] So yes, I think portable oxygen is important." (Paediatrician)

"I feel very strongly that they [oxygen dependent children] need oxygen when they need it…allowing them to be active and to develop and grow and learn." (Paediatrician)

Respondents' views on the effectiveness of SBOT for adult patients were much more varied and less certain. In general, there was scepticism about the objective clinical effectiveness of SBOT (in particular for non-hypoxaemic patients) but there was a recognition that in some situations patients did seem to derive subjective benefit.

"…really there is not evidence to support the use of short burst oxygen therapy." (Adult Respiratory Physician)

"I've no idea about the effectiveness of short burst oxygen…I think there are some patients who seem to benefit from it" (Adult Respiratory Physician)

"I think the patients that are on it find it effective…I think it's more of a psychological benefit than a physical benefit, although some patients feel that they do recover quicker from exertional dyspnoea if they use [SBOT]" (Respiratory Nurse Specialist)

Children tend to use intermittent emergency oxygen in very specific clinical situations rather than using SBOT in the way that some adult patients do and this difference was reflected in the paediatricians' responses.

"Short burst is less often indicated for children but when it is indicated, it is effective." (Paediatrician)

Some interviewees made particular comments on the effectiveness of home oxygen in palliative care situations. Again, there was considerable scepticism about the objective clinical benefit of using oxygen, especially in non-hypoxaemic patients, particularly amongst consultants. Other respondents expressed more equivocal views, suggesting oxygen may be useful to reduce breathlessness and patient anxiety. All groups

recognised difficulties inherent in 'denying' treatment to patients in distressing palliative care situations.

"Again, I think it's difficult to know. Can I put it like this – who am I to say to a palliative care patient who tells me that they're breathless and who says that the oxygen helps, 'No, you can't have it.' So I think it would be inhumane to deny them oxygen because it's a subjective feeling, breathlessness, and, of course, in this patient group, they're not going to have terribly long to live." (Adult Respiratory Physician)

"It [home oxygen in palliative care] can be helpful; I wouldn't put it stronger than that…but it is purely a symptomatic treatment." (GP)

"I'm not clear of the benefits of oxygen use in palliative care" (GP)

<u>The influence of factors such as changing patterns of hospital based care, availability of new technology, and policy/guidelines on demand for the service</u>

Interviewees were asked for their views on how factors such as changing patterns of hospital based care, availability of new technology, and the availability of specific policies/guidelines may have influenced the demand for and supply of home oxygen services over recent years.

One specific clinical advance was cited that reduced the need for home oxygen, namely giving antenatal steroids and the use of surfactant to reduce the risk of CNLD. The trend towards earlier discharge from hospital (for both paediatric and adult patients) was noted as increasing the need for home oxygen however (and equally the availability of home oxygen was noted as a factor in facilitating early discharge). Paediatricians from different areas of the country gave differing views on whether these opposing trends were resulting in an overall increase or decrease in the need for home oxygen for neonates. Particular new technologies that were noted to be helpful included portable pulse oximeters which allowed families to monitor babies' oxygen saturation overnight and thus avoid hospital admission for monitoring purposes.

One nurse specialist noted that increasing survival of CF patients was driving an increase in demand for home oxygen in this patient group. A paediatrician noted that CF patients usually started on oxygen when they became hypoxaemic and were being considered for a transplant.

There was a suggestion that the range of paediatric patients being considered for home oxygen had expanded over recent years with home oxygen now being more commonly used in children with heart disease associated with pulmonary hypertension.

There was a suggestion by a consultant that the development of nurse specialist led services for adult patients had led to more systematic assessment of patient needs and hence higher prescribing of home oxygen. A GP also commented that there had been a shift towards more active identification and management of patients with COPD. Reduced length of hospital stay for COPD patients was also noted as driving demand for more home oxygen for COPD patients.

"There has been a huge change [in the management of COPD patients]. First of all in its recognition. You find people have put down COPD but they had forgotten about it so

they are much better looked after, much more likely to have oxygen saturations done in the community, much more likely to have been monitored and FEV-ed in the community and much more likely to be treated early in the community and supported in the community. So there has been quite a revolution in COPD." (GP)

The increasing range of devices available for delivering home oxygen was generally welcomed by respondents. High flow concentrators were reported to be helpful for patients with high flow requirements and clearly better than the previous practice of piggybacking two or more standard flow concentrators together. The Homefill system was universally welcomed, with the only noted problem being under provision (waiting lists of over a year in Highland). The Homefill system was noted by one consultant as now being the preferred option for adult patients requiring both LTOT and AOT due to its advantages over portable cylinders.

"Homefill – great thing, absolutely. The cylinders are smaller, for a start, it's lighter, it lasts longer. It's got the pulse dose meter on top of it so, as long as the patient has enough inspiration to activate it, it's great. I haven't seen one patient that's not liked it." (Respiratory Nurse Specialist)

Liquid oxygen was noted as still the device of choice for certain patients, for example those with high flow requirements and high mobility. Oxygen conservers were seen as a useful adjunct, especially to AOT, and there was a demand for them to be made more widely available.

"We were able to demonstrate very clearly significant cost efficiency savings [when conservers were introduced], patients spent more time outside their home and their quality of life was better, so were able to argue the case and go back to the Board and say, 'It's cheaper to rent conservers for patients and they use a third of the oxygen.'" (Respiratory Nurse Specialist)

Respondents also noted a desire for wider availability of portable concentrators. The holiday service provided by HFS was broadly welcomed but some interviewees felt it could be better publicised.

Respondents were asked directly what impact they thought the reduction in eligibility criteria for an oxygen concentrator had had. A Scottish Government letter issued in 2004 reduced the eligibility criteria from 15 hours use of oxygen per day to 8 hours. One respondent noted that, as all LTOT patients should be using oxygen for at least 15 hours per day, this should have had minimal impact but the majority of respondents felt that in practice it had had significant impact. There was a view that the change had resulted in substantial numbers of patients switching from using cylinders to using concentrators, that often it was questionable whether these patients should be using oxygen at all but in practice it could be very difficult to withdraw it, and that the change had been driven by economic rather than clinical effectiveness considerations. It should be noted that the perception that large numbers of patients were switched from cylinders to concentrators when the eligibility threshold was lowered is not supported by the available data on concentrator provision as previously discussed.

"[The change] halved the number of people who were getting cylinders regularly and doubled the ones who were on concentrators." (GP)

"In many cases these patients have been on oxygen a long time and find it very difficult to be without oxygen." (Adult Respiratory Physician)

"Then I feel our hands are kind of tied really because they've already fulfilled the criteria on an economic basis, not on a… So it's evidence-based in terms of economics, but its evidence base in terms of physical prognostic benefit…" (Adult Respiratory Physician)

"There's no evidence that 8 hours of oxygen per day in a COPD patient works. What we're talking about here is the economic provision, the break-off point between whether cylinders or a concentrator is more cost-effective" (Adult Respiratory Physician)

One respondent noted that making portable cylinders available on GP prescription (which was introduced through the same Scottish Government letter) had significantly increased the use of portable cylinders by removing financial barriers to their provision and difficulties in accessing the cylinders.

Many respondents were aware of relevant clinical guidelines eg the BTS guideline on home oxygen use in children and the NICE 2010 guideline on management of COPD, but presented these documents as useful background information that guided their clinical practice rather than rigid protocols to be followed in all cases. A summary of policy and clinical guideline documents relevant to home oxygen provision is given in Appendix 5.

<u>The current adequacy and appropriateness of home oxygen provision</u>

The Royal College of Physicians report in 1999 summarised evidence from the late 1980s and early 1990s that suggested that significant numbers of patients on home oxygen at that time did not meet eligibility criteria and also that patients often made little use of prescribed AOT. These problems were linked to inadequate patient follow up (RCP 1999). More recent evidence from a number of countries suggests that inadequate follow up of (adult) patients started on home oxygen continues to be a problem (Ringbaek 2005, Jones et al 2007).

Interviewees were asked directly whether they thought that home oxygen is currently over or under provided in Scotland in relation to population need. There was some concern voiced that a degree of over provision remains an issue. Over provision was noted to be possible in a number of situations such as

- Inappropriate use of SBOT in non-hypoxaemic patients
- Patients being started on oxygen in a crisis situation, eg exacerbation of COPD, then receiving inadequate follow up to ensure that oxygen is still required
- Patients who have been on (inappropriately prescribed) cylinder oxygen for a long time being switched onto a concentrator following the change in eligibility criteria

In all of the above situations there was recognition that it can be extremely difficult to withdraw oxygen therapy from someone once it has been started if the clinician feels it is no longer appropriate.

"I suspect short burst is probably more prone to inappropriate prescribing but no-one really has evidence for what is appropriate and what's not appropriate." (Adult Respiratory Physician)

"At the moment, if a GP gives them a cylinder, it's not followed up, they don't do any safety checks, they give it to patients who are smoking like a lum – it's not safe. So we're trying to improve " (Adult Respiratory Physician)

"Most audits do show that oxygen concentrator use for patients has been over prescribed, but it's very hard to remove a concentrator from someone." (Adult Respiratory Physician)
Tighter regulation of prescribing of home oxygen therapy in primary care was suggested as the mechanism to reduce inappropriate provision, but respondents thought that GPs should retain the right to prescribe static cylinders in certain situations, particularly in palliative care and short term crises.

Under provision was also noted as an issue by some respondents. Although no-one reported problems in accessing home oxygen equipment for specific patients, there was a recognition that there may well be patients who could benefit from home oxygen who have not been identified or offered the service.

"I think the static cylinders and concentrators, provision is adequate in the sense that, if we want them, we can get them." (Adult Respiratory Physician)

"My guess is that there is probably more under provision than over provision. In other words, there are probably more patients who haven't been identified who might be helped by long-term oxygen than there are people who are inappropriately using oxygen" (Adult Respiratory Physician)

Two respondents noted that AOT was probably still generally under provided and another respondent suggested that some patient groups (such as those with kyphoscoliosis or pulmonary hypertension) may be less well served than those with COPD or CILD. Significant lack of availability of the Homefill system, oxygen conservers, half litre liquid oxygen cylinders for children, devices to assist with the carrying of portable cylinders, and portable concentrators were noted as practical issues.

<u>Potential future service developments.</u>

Interviewees were asked how they thought that home oxygen services in Scotland should develop in the future. As noted above, respondents to the eDelphi survey were not asked for their views on whether in principle Scotland should aim to bring together the different elements of home oxygen provision in a unified national service, and they gave mixed views on different possible elements of a unified service. The Scottish Government working group therefore recommended that the community pharmacy and HFS-provided elements of the service should be better coordinated but stopped short of saying they should be formally combined into a unified service. Prescribers' views on unifying the two aspects of the service were explored through the interviews to provide more information on this issue.

There was general support for the idea of a unified service for all forms of oxygen delivery equipment. However this was qualified in a number of instances by practical considerations about the delivery of cylinders across Scotland, and potential unintended consequences. Maintaining a flexible system so that individual patient needs and different requirements in remote and rural areas could be accommodated, and adequate piloting of any change to current service configuration, was seen as important.

Unifying the service was often seen as synonymous with transferring the authority to prescribe static cylinders (in the majority of instances) from primary to secondary care and also as facilitating specialist follow up of patients using cylinders. A unified service was thus thought to be a way of potentially increasing the clinical appropriateness of home oxygen provision whilst controlling the overall costs by addressing the alleged issue of over provision of static cylinders. A secondary care clinician suggested that this may cause conflict between primary and secondary care but this was not echoed by the GPs interviewed who were broadly supportive of a unified service.

"I think it certainly would [make sense] economically, and I think there's an argument for it clinically as well, for the prescription to be unified, and really for the prescription to be brought solely into secondary care. I know that won't be well-received in primary care" (Adult Respiratory Physician)

"I think that [a unified service] would be great because it would allow us to control the cylinder use a bit better, and make sure that people are being given it appropriately, and that they get the safety checks, and followed up appropriately, which is a major problem at the moment." (Adult Respiratory Physician)

"I think we would need to see a pilot of that kind of model being done somewhere that actually works and is successful" (Respiratory Nurse Specialist)

<u>Miscellaneous issues</u>

Respondents indicated a desire for clearer guidance on specific aspects of home oxygen provision such as

- Provision of duplicate equipment
- Use of oxygen on public transport and taxis, and
- Use of oxygen equipment in schools.

There is currently no explicit policy on provision of duplicate equipment in Scotland although this is occasionally done by HFS for patients who work, attend school, or routinely divide their time between two homes (eg in the case of children with separated parents). Some information on using oxygen in vehicles, including public transport, is included in the patient guide provided by HFS to all concentrator patients. The guide notes that patients need to obtain the permission of vehicle operators before using their oxygen and that operators have a requirement to be reasonably accommodating of their request under disability discrimination legislation. Through the national contract managed by HFS, Dolby Medical is required to undertake a formal risk assessment for all children using oxygen at school. Dolby also provides training for patients, carers, and staff.

Provision of home oxygen to patients when someone in the house continues to smoke was noted as a perennially difficult issue. Attitudes towards providing home oxygen to patients who continue to smoke varied, with some respondents seeing this as an absolute contraindication and others indicating that patients should be free to take the risk.

"We will not provide oxygen to somebody who smokes." (Adult Respiratory Physician)

"In some cases, we'll actually remove the patient's oxygen from their home environment [if they continue to smoke]." (Respiratory Nurse Specialist)

"Occasionally we actually ask patients to sign a form saying that they understand they shouldn't smoke and that, if they do, they're taking it on their own responsibility." (Adult Respiratory Physician)

Some confusion around who should take primary responsibility for training patients and their carers in the safe use of their home oxygen was noted, with a GP indicating this was a secondary care responsibility and a secondary care clinician indicating it was the responsibility of the equipment provider (Dolby or the pharmacist). A consultant expressed the view that there was room for improvement in training.

Many of the themes raised in the interviews echoed themes raised in the report of the working party on home oxygen (Scottish Government 2010). The working party report supported the continued trend away from use of static cylinders to use of concentrators, increased provision of the Homefill system, better information for patients on the holiday cover service, and increased provision of conservers. The working party report concentrated on the technical aspects of home oxygen services in Scotland but did note that there was a need for more robust clinical guidance on home oxygen provision, for example relating to patient assessment and ongoing monitoring.

Provision of home oxygen in other countries

Provision of home oxygen in England and Wales

Arrangements for the provision of home oxygen in England and Wales changed substantially in 2006 (Wedzicha 2006). Prior to the change, all home oxygen was prescribed by GPs with cylinders subsequently provided by community pharmacies and concentrators by specialist contractors. Concentrators had been available since the 1980s but use of concentrators in relation to cylinders had remained relatively low and portable cylinders and liquid oxygen were not widely available. The changes aimed to improve clinical assessment and monitoring of patients' requirements, reduce the use of SBOT to fund increases in LTOT, widen access to AOT, and simplify and control costs.

After the reconfiguration, England and Wales was divided into 11 home oxygen service regions, each with a contract with a single approved supplier. The supplier is responsible for provision of all home oxygen equipment in the region hence community pharmacies have ceased to have any role in provision of home oxygen. At present a total of 4 commercial company suppliers cover the 11 regions.

Who is prescribing home oxygen under the new arrangements is somewhat unclear. Clinical guidance states that '*Most orders (prescriptions) for home oxygen therapy will be initiated by a hospital specialist with an interest in respiratory disease…General Practitioners will continue to be able to prescribe home oxygen but it is expected that this will be mainly for palliative use.*' (British Thoracic Society 2006, p8). All home oxygen now has to be ordered using a standard Home Oxygen Order Form (HOOF) and in practice, the HOOF just requires the prescriber to tick a box stating that they are a 'registered healthcare professional' hence the degree to which this guidance is being followed is difficult to assess. There is evidence that suggests that consultants, nurses, physiotherapists, and GPs are all prescribing home oxygen depending on local service configuration (Ferguson et al 2010).

The HOOF form states the patient's oxygen requirements (LTOT/AOT/SBOT, flow rate and daily duration of use) then it is up to the contractor to determine the most appropriate modality to meet the patient's needs. The HOOF also requires the prescriber to indicate the patient's underlying condition/diagnosis using 20 pre-coded categories (COPD, CF, CNLD, etc). National standards are in place for the services provided by the suppliers which stipulate the range and quality of services they must provide. All suppliers must provide concentrators, static and portable cylinders and liquid oxygen. Criteria for prescription of LTOT, AOT, and SBOT are set out in the Home Oxygen Service Manual and related clinical guidance (Department of Health 2007, British Thoracic Society 2006). LTOT is recommended as suitable for patients with chronic hypoxaemia with oxygen usually given for at least 15 hours per day. AOT is recommended as suitable for mobile LTOT patients who need to get out of the house and patients who do not meet LTOT criteria but experience desaturation on exercise. The poor evidence base for prescription of SBOT is noted hence it should only be ordered '*if an improvement in breathlessness and/or exercise tolerance can be documented.*' (British Thoracic Society 2006, p8). Specific standards for initial clinical assessment prior to prescription and follow up arrangements are also provided and have been outlined in the previous chapter.

A number of practical difficulties were encountered during the transition to the new home oxygen service in England and Wales in 2006. These included problems with identifying all service users, communicating the change in arrangements efficiently, implementing the HOOF form, and impact on workload on GPs, pharmacies, and specialist units. These issues provide useful learning for other areas considering potential changes to their home oxygen service (Wales Audit Office 2008).

As the regional contracts started in 2006 were generally for a fixed term of 5 years, a new re-tendering process is currently underway. The home oxygen service regions are being slightly reconfigured and the invitation to tender to cover the new regions was issued in July 2010. It is anticipated that by the end of 2010 a list of approved suppliers that meet national standards will have been drawn up then each new region will appoint its single supplier following a local tendering process. The new contracts will generally become operational in 2011. As part of this process the management of the home oxygen contracts is moving from the Department of Health to the NHS and it is anticipated that each region will have a lead Primary Care Trust to oversee the tendering process and subsequent contract management. How the current proposed changes to the structure of the NHS in England (Department of Health 2010) will impact on this is not yet clear.

Data on provision of home oxygen in England and Wales were requested from the Department of Health. The Department provided data on the number of patients in receipt of different forms of home oxygen therapy as at May 2010 in each of the (newly reconfigured) regions. These data originated from the commercial companies providing home oxygen in England and Wales and have not been validated or quality assured by the Department. The Department also provided information on the total population of each oxygen region which had been obtained from the NHS Information Centre.

Data on home oxygen provision in England and Wales is not directly comparable to that available in Scotland. In England and Wales, all the data for a particular region comes from that region's oxygen supplier: there is no distinction between data on concentrator and cylinder provision as there is in Scotland. The particular issues around having to estimate the number of people in receipt of cylinders at any one time from 3 months of prescribing data that contains patients' CHI numbers do not apply to the England and Wales data. As different suppliers cover the different regions, there is not one national source of data on provision of any specific modality, however.

The exact modalities provided in England and Wales (and how they are recorded) are also somewhat different to the situation in Scotland. There is no BabyOx service in England and Wales hence infants and children receiving home oxygen are likely to be counted in the overall concentrator (and probably also lightweight cylinder – see below) categories. Similarly, patients in receipt of high flow concentrators are not counted separately and will appear in the 'concentrator' total. Homefill Systems are not currently available in England: a very small number have been provided in Wales and data on these patients are provided separately.

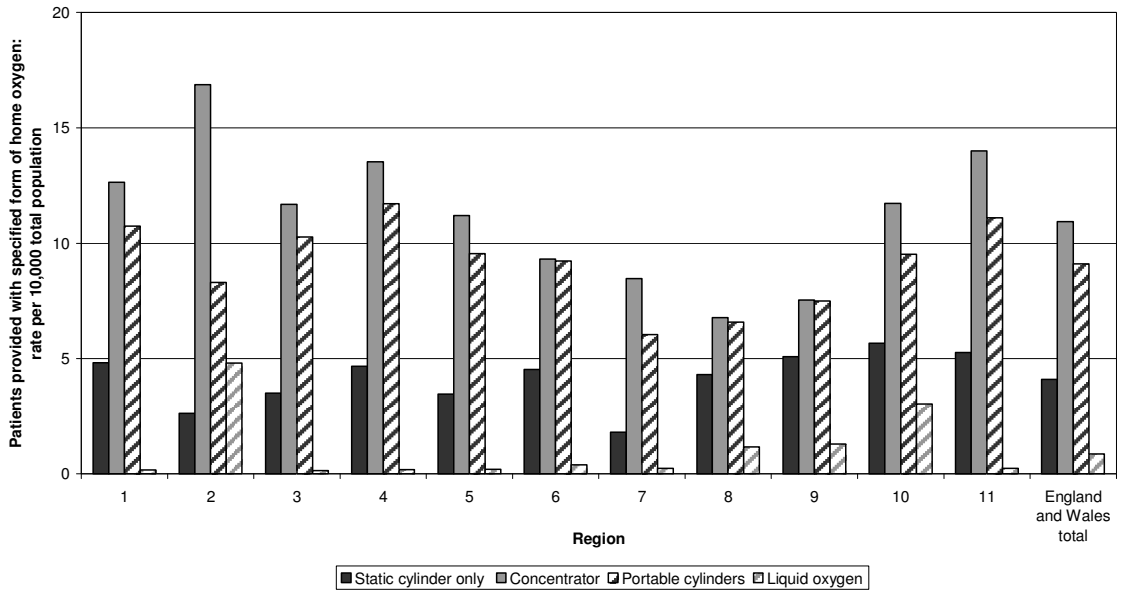
In England and Wales, as in Scotland, essentially all patients in receipt of a concentrator are provided with at least one static cylinder as a back up supply in case of power failure. Unlike in Scotland, however, because in England and Wales one supplier is responsible for provision of all modalities, all concentrator patients are also counted in the static cylinder patient total in the England and Wales figures. To get an estimate of

the number of patients just in receipt of static cylinders, the number of concentrator patients is therefore subtracted from this total. Finally, the England and Wales figures provide separate data on patients in receipt of portable cylinders and those in receipt of lightweight cylinders. The lightweight cylinders are small ultra portable cylinders suitable for patients with low flow requirements and in practice are usually given to infants and children. These patients would therefore mainly be counted in the BabyOx (rather than the portable cylinder) totals in the Scottish data.

Figure 35 shows how provision of four key home oxygen modalities varies between the regions in England and Wales.

Figure 35

Patients provided with home oxygen, rate per 10,000 population by region of England and Wales, May 2010



Data source: Department of Health

It can be seen that in all regions, concentrators are provided to the highest number of patients with fewer patients receiving just static cylinders. Relatively high numbers of patients are provided with portable cylinders and, as in Scotland, relatively few patients are provided with liquid oxygen. There is a moderate degree of variation in provision of the different modalities per head of population between the regions. The pattern of provision of the different static and portable modalities also varies between the regions, with some making relatively more use of static cylinders (as opposed to concentrators) and some making considerably more use of liquid oxygen (as opposed to portable cylinders). It should be re-emphasised that these data are unvalidated and the figures for static cylinder only patients are estimates as discussed above, however they do provide the best currently available estimates of the provision of home oxygen across England and Wales.

It is difficult to directly compare these data with the data available on provision of home oxygen in Scotland as discussed above. It is of particular interest, however, to explore how provision in Scotland compares to that in the rest of the UK. Roughly comparable

snapshot figures from Scotland in spring 2010 suggest the following provision of home oxygen at that time:

- Overall provision of static cylinders 3.8 patients per 10,000 population
- Overall provision of concentrators 8.3 patients per 10,000 population
- Overall provision of portable cylinders 3.7 patients per 10,000 population
- Overall provision of liquid oxygen 0.3 patients per 10,000 population.

It should be re-emphasised that the Scottish figures relating to cylinder provision are derived from prescribing data over three months with incomplete CHI recording and hence are only estimates of the number of patients in receipt of cylinders at any one time, and the figures relating to concentrator and liquid oxygen provision by HFS are unvalidated. The number of patients on standard and high flow concentrators, the BabyOx service, and with a Homefill system have been added together to get the 'concentrator' total to ensure maximum comparability with the Department of Health figures. Similarly, the number of patients with portable cylinders and a Homefill system have been added together to get the 'portable cylinders' total.

These figures should not be used to provide precise estimates of the differences in home oxygen provision between Scotland and England and Wales due to all the caveats around the data and their comparability. A reasonable interpretation of the figures would suggest, however, that provision of static cylinders in Scotland is broadly similar to that in England and Wales as a whole; provision of concentrators is slightly lower; provision of portable cylinders is substantially lower; and provision of liquid oxygen is broadly similar to that in most regions in England and Wales. The number of patients with a portable form of home oxygen in England and Wales is around 75% of the number in receipt of a static modality whereas in Scotland the comparable figures is likely to be closer to 40%. The total number of portable oxygen cylinders provided in the different countries cannot be compared as figures for Scotland relate to the cumulative number of cylinders dispensed over a period of time whereas figures for England and Wales relate to the number of cylinders on loan to patients at a particular point in time.

Why provision of concentrators appears to be slightly lower and provision of portable cylinders appears to be substantially lower in Scotland than in England and Wales can only be speculated about. The situation is likely to be highly complex with elements of both over and under provision in each of the countries, but these data provide some reassurance that large scale over provision (ie provision of home oxygen to patients unlikely to derive clinical benefit) is unlikely to be a widespread problem in Scotland. The relatively tighter control on who can prescribe home oxygen in Scotland may be having some influence on provision rates, as may historical (now resolved) shortages of portable cylinders, and the way that the HOOF form works.

Provision of home oxygen in other countries

The research report conducted for the Scottish working group on home oxygen (Ferguson et al 2010) summarised the available literature on provision of home oxygen services in other countries. In Northern Ireland, GPs prescribe all forms of home oxygen, often on the advice of a secondary care team. Concentrators are then supplied directly by a contractor whereas cylinders are supplied by community pharmacies in a similar way to that which is currently seen in Scotland. Concern has been raised that

there is insufficient control over prescription of home oxygen in Northern Ireland, with guidelines for clinical assessment often not being followed (O'Neill 2004).

Australia's health service is based on a publicly funded compulsory insurance model. This allows tight specification of which services provided by health care professionals/organisations will be funded/reimbursed. There is considerable variation between the different states in the range of services available. LTOT prescribed by a respiratory or cardiology consultant is usually funded. AOT is funded to a limited extent in some states. If patients are prepared to pay for their care they can purchase any available home oxygen service prescribed by any doctor (McDonald et al 2005). Canada has a similar system with insurance systems funding various elements of home oxygen therapy in the different states. In Nova Scotia, designated consultants can prescribe LTOT and AOT which is then provided (sometimes on a co-payment basis) to patients. Requirements for ongoing patient review are built into the system that attempt to ensure that only patients that continue to meet eligibility criteria continue to receive home oxygen (see http://www.gov.ns.ca/health/ccs_strategy/home_oxygen.asp accessed 15.10.2010).

It is clear many, if not all, high income countries provide some form of home oxygen service (Garattini et al 2001). In general, health care systems make efforts to ensure that this expensive resource is appropriately used by limiting who can prescribe home oxygen, setting eligibility criteria linked to initial patient assessment and follow up requirements, and restricting the range of equipment that is made available through public funding. In some countries, ability to access home oxygen is influenced by patients' location of residence and ability to pay in addition to their clinical need. Information on overall population provision rates of different forms of home oxygen in different countries is not readily available.

Variation in provision of home oxygen within countries

There is some research evidence on variation in provision of home oxygen services within individual countries. Studies from Denmark (Ringbaek 2006), Spain (Cienfuegos 2000), the USA (Oba et al 2000), Tasmania (Jones et al 2007), and Australia (Serginson et al 2009) have shown a mixture of over/inappropriate provision of home oxygen linked to inappropriate initial assessment and ongoing monitoring, and under provision linked to rural residency, low availability of respiratory consultants, and variably restrictive eligibility criteria. Several studies have shown the potential for service development projects to improve the clinical appropriateness of home oxygen provision and in some instances also reduce costs (Jones et al 2007; Deeming et al 2008). Other studies have shown substantial variation in the prescription of home oxygen between individual clinicians, in particular those prescribing home oxygen to children (Ellsbury et al 2004; MacLean and Fitzgerald 2006). Taken together this evidence emphasises the complex nature of home oxygen provision. Elements of both under and over provision are likely to be present in any one system but the way that local services are configured and that the service as a whole is managed can influence the clinical and cost effectiveness of services.

Summary, conclusions and recommendations

This national needs assessment for home oxygen services in Scotland took place from July to November 2010. The project aimed to provide enhanced understanding of the appropriateness of current service provision and likely future trends in need for the service and hence to contribute to decision making around the future of home oxygen services. All forms of home oxygen therapy (Long Term Oxygen Therapy, Ambulatory Oxygen Therapy, and Short Burst Oxygen Therapy) for both paediatric and adult patients in Scotland were considered. Elements of the epidemiological, corporate, and comparative approaches to needs assessment were all incorporated into the project, with information sought on:

- The epidemiology of key conditions underlying the provision of home oxygen
- The clinical effectiveness of home oxygen
- Trends in the provision of home oxygen in Scotland
- User and provider views on the home oxygen service
- Provision of home oxygen in other areas, in particular England and Wales.

Provision of home oxygen is highly complex. A wide range of patient groups from all ages and suffering from a large number of different conditions can receive home oxygen. Consequently, a wide range of health professionals from different specialities within secondary care and from primary care is involved in the care of home oxygen patients. Current service configuration is also complex, with provision of oxygen cylinders and other equipment such as concentrators being split between community pharmacies and Health Facilities Scotland respectively. Technological developments mean that new forms of home oxygen equipment continue to become available.

The clinical need for home oxygen

The epidemiology of the following conditions was considered in detail:

- Chronic neonatal lung disease (CNLD)
- Severe neurodisability in children
- Cystic fibrosis (CF)
- Chronic interstitial lung disease in adults (CILD)
- Chronic obstructive pulmonary disease (COPD)

These conditions account for a high proportion of the patients currently requiring home oxygen in the different age groups (infants → children → young adults → older adults).

These conditions vary greatly in the number of people they affect, for example fewer than 100 babies develop CNLD in Scotland every year whereas it is estimated that around 80,000 people are living with COPD that is sufficiently severe for them to have required at least one admission to hospital. The available evidence suggests that the prevalence of (number of people living with) each of the conditions studied has increased in Scotland over recent years. A number of reasons lie behind the increases in prevalence:

- Increased incidence (more new cases)
- Increased survival (people living longer with their disease)
- More active case finding/more accurate diagnosis/recording

- Demographics (more premature babies being born and more older people in the population).

These increases in prevalence are likely to continue at least over the next 10 to 20 years. In the longer term, the prevalence of disease primarily caused by smoking, in particular COPD, may stabilise or even start to fall. There have been considerable changes in the general management of these conditions over recent years; in particular the length of hospital admissions has got considerably shorter hence patients are increasingly being cared for at home. In general, infants requiring home oxygen can have a good prognosis and 'grow out' of their oxygen requirement over time. By contrast, older people requiring home oxygen often have progressive disease, and possibly multiple co-morbidities, and once started on home oxygen remain on it for the remainder of their lives. Other conditions that may require home oxygen were not reviewed in detail for this project, however recent clinical guidance has recommended the use of home oxygen in a wide range of conditions, for example certain forms of congenital heart disease, congenital diaphragmatic hernia, unpredictable severe asthma, and cluster headache.

- *For the foreseeable future it seems likely that the clinical need for home oxygen therapy (LTOT and AOT) will increase. The range of patients served will continue to encompass all age groups, including the very young and very old, and probably an increasingly complex range of underlying conditions. Planning for the future delivery of home oxygen services should take this into account.*

The effectiveness of home oxygen

The evidence on the effectiveness of home oxygen therapy depends on the type of use (LTOT, AOT, SBOT) and the underlying condition being treated. The best evidence relates to the use of LTOT in patients with COPD who are severely hypoxaemic (PaO_2 ≤7.3 kPa). In this group there is randomised controlled trial evidence that use of home oxygen for at least 15 hours per day improves important clinical outcomes including exercise capacity, sleep quality, frequency of hospitalisation, and overall survival. The evidence on the impact of LTOT on these patients' overall quality of life is more equivocal however.

There is generally less evidence on the effectiveness of LTOT in other patient groups. This relative lack of evidence does not necessarily mean that home oxygen is ineffective in these groups, and current consensus expert opinion does recommend LTOT for a range of patient groups including infants with CNLD, children with severe neurodisability associated with frequent respiratory problems, young adults with CF, and older adults with CILD. Some important trials are currently underway that will provide new information on the effectiveness of LTOT in particular additional patient groups, for example adults with heart failure.

Home oxygen is an expensive service to provide, however there is evidence that LTOT is cost neutral or possibly even cost saving to the NHS as a whole due to the reduction in need for hospitalisation that it allows. The way that services are currently configured means that the costs and savings associated with home oxygen provision are experienced by different elements of the health service.

There is relatively little evidence on the clinical effectiveness of AOT, either when used in isolation or when used in conjunction with LTOT, and further research is required. It seems likely, however, that AOT has potential benefits for selected patients in terms of improving exercise tolerance, allowing patients to maintain their independence, and ensuring that oxygen is used for a sufficient duration every day.

There is evidence (mainly relating to adults with COPD) that at least some patients find it difficult to use their LTOT and/or AOT for the recommended period of time every day that is required to derive maximum clinical benefit. This reflects the fact that use of (even ambulatory) home oxygen can be restrictive and stigmatising. This emphasises the need for robust follow up of patients prescribed home oxygen to ensure they continue to benefit from their therapy.

The effectiveness of SBOT is highly questionable, particularly in non-hypoxaemic patients. Short term, 'as required' use of home oxygen (which can be provided from cylinders or a concentrator) does have a role in the care of hypoxaemic terminally ill patients who are experiencing breathlessness and in the care of temporarily hypoxaemic patients experiencing an exacerbation of an underlying respiratory condition to help them avoid hospital admission. There is little, if any, other role for SBOT. The way that home oxygen services are configured should ensure that patients do not get left on 'as required' home oxygen for long periods without appropriate further assessment to determine whether they should be offered LTOT, AOT, or no ongoing home oxygen at that time.

The use of home oxygen is generally considered to be acceptably safe but there are specific issues around increased risk of fire and the potential for oxygen to worsen CO_2 retention in some patients that need to be managed.

- *The provision of home oxygen should be guided by the available evidence on its clinical effectiveness and associated consensus professional statements and clinical guidelines. Patients' preferences and motivation to use home oxygen and safety considerations should also be important factors in determining provision at the individual level.*

- *The way that home oxygen services are configured and managed should promote robust patient assessment before prescribing home oxygen and subsequent regular follow up to ensure that home oxygen is provided to patients able to benefit from it. This should facilitate the appropriate use of LTOT and AOT and discourage the use of SBOT except for in the specific circumstances outlined above.*

Provision of home oxygen in Scotland

It is estimated that in the spring of 2010 around 6,300 patients across Scotland were in receipt of a static home oxygen modality: 31% of these patients were in receipt of static cylinders, 60% were in receipt of a standard concentrator, and the remaining 9% were in receipt of a newer modality (BabyOx, high flow concentrator or Homefill system). At the same time, around 2,300 patients across Scotland were estimated to be in receipt of a portable home oxygen modality: 73% of these patients were in receipt of portable cylinders, 6% were in receipt of liquid oxygen, and the remaining 21% were in receipt of

a newer modality (BabyOx or Homefill system). Almost all patients on a portable modality would be expected to also be on a static modality although the actual degree of overlap between the two groups is not known.

The overall cost of providing home oxygen in 2009 was around £8.4 million. Provision of static and portable cylinders through community pharmacies accounted for around £3.8 million and provision of all other modalities though HFS accounted for around £4.6 million. HFS costs also include provision of portable concentrators to out of hours services and hospital departments, and provision of a temporary oxygen supply to patients travelling within Scotland. All these costs relate solely to the direct provision of oxygen equipment: they do not cover other issues such as prescribing clinicians' time.

Over recent years, there has been a shift away from ineffective provision of SBOT and towards effective provision of LTOT and AOT. Consequently, the provision of static cylinders (often but not always used for SBOT) has been falling and the provision of standard concentrators and portable cylinders has also been increasing (although there is a suggestion that the increase in portable cylinder provision may be plateauing). The provision of newer modalities such as the BabyOx service has also been increasing since they were introduced in 2007/08. Total costs associated with provision of home oxygen have increased year on year. The increase in costs has been mainly borne by HFS as the declining costs associated with static cylinder provision have somewhat offset the increasing costs accruing to Boards due to increasing portable cylinder provision.

Overall there is relatively little variation in the provision of static or portable forms of home oxygen between the larger and generally more urban NHS Boards across Scotland. There is some evidence that provision of static home oxygen modalities is higher in the more remote and rural areas of Scotland, however, in particular in Dumfries and Galloway and the island Boards. Provision of portable home oxygen also appears to be relatively high in Dumfries and Galloway. This variation is likely to reflect local service configuration, and possibly issues associated with the care of patients in areas with relatively lower access to hospital based care, rather than variation in clinical need across the country.

- *Some variation in home oxygen provision is inevitable and not all variation will be inappropriate. Further exploration of the reasons underlying the observed variation should be considered as it may help to elucidate the balance of over and under-provision of the different types of home oxygen across Scotland.*

There is a specific issue in Scotland relating to eligibility criteria for concentrators. Previous guidance stated that patients should require/use oxygen for at least 15 hours a day to become eligible for a concentrator but this figure was reduced to 8 hours a day in 2004. There has been recent debate about the possibility of reducing this eligibility threshold further (for example to 4 hours per day – the approximate point at which a concentrator becomes less expensive than cylinders) or removing it altogether. Reducing the eligibility threshold to 4 hours use per day makes some sense from a financial point of view but given the current lack of evidence of effectiveness of oxygen therapy when used for less than 15 hours per day, it would be of questionable clinical benefit.

- *The provision of home oxygen should be primarily driven by clinical effectiveness considerations. When a patient is provided with home oxygen, the exact modality used should take into account a range of factors including the relative cost of the different options. Clinicians should be provided with relevant information and guidance to facilitate their decision making. This approach should be emphasised rather than the setting of specific eligibility criteria for different home oxygen equipment.*

User and provider views on home oxygen

There is a large amount of information available on the views of users and providers of home oxygen therapy from previous work carried out in Scotland and from the interviews conducted with home oxygen prescribers as part of this project. This information is very helpful in guiding the development of home oxygen services.

In general, patients and their carers are very positive about their home oxygen therapy, with the substantial majority indicating high satisfaction with the service, although the potential for response bias (patients that express their views not being representative of all patients) should be borne in mind. Patients have raised some practical concerns, for example the inconvenience of having to wait in for cylinder deliveries and the relatively large size and weight of currently available portable cylinders.

- *The recommendations of the recent working party on home oxygen, which focused on the technical and operational elements of the service for example making carrying devices for portable cylinders more widely available to patients, should be implemented promptly.*

Prescribers' views in relation to the current delivery of home oxygen services in Scotland suggest that the initiation of LTOT and subsequent patient follow up is broadly in line with currently recommended best practice. There appears to be less consistency around decisions to offer AOT, although AOT is clearly felt to be beneficial for some patients, for example all children on LTOT. At least some GPs continue to initiate SBOT, mainly in palliative care situations. This now appears to be relatively uncommon, although it should be emphasised that the GPs interviewed for this project all had a special interest in the management of respiratory disease and may not be representative of all GPs across Scotland.

Overall, clinicans have expressed some concerns about over-provision of home oxygen (provision to patients who do not have the ability to benefit from the therapy). These concerns relate almost exclusively to patients inappropriately started on (or left on) SBOT. Clinicians have also noted that under-provision (lack of provision to patients who could benefit) is likely to be as real an issue as over-provision. Both over- and under-provision are likely to have decreased over time.

There is a clear view across professional groups that the decision to commence a patient on home oxygen should, in the vast majority of cases, be taken by an appropriately qualified specialist. There is also a consistent view that all patients started on home oxygen should have robust follow up to ensure they continue to require and benefit from their home oxygen.

Prescribing clinicians interviewed for this project expressed general support for bringing together the provision of all forms of home oxygen into a single national-level service. Unifying the service was often seen as synonymous with transferring the authority to prescribe static cylinders (in the majority of instances) from general to specialist services and also to facilitate more robust follow up of patients on cylinders. A unified service was thus thought to be a way of increasing the clinical appropriateness of home oxygen provision and potentially controlling its overall costs by addressing the alleged issue of over provision of static cylinders. The potential risks and unintended consequences involved in moving to a unified service were acknowledged, however. Maintaining a flexible system so that individual patient needs and different requirements in remote and rural areas could be accommodated, and adequate piloting of any change to current service configuration, was seen as important.

- *Appropriate configuration and management of home oxygen services will include reasonable controls on who can start patients on home oxygen in different clinical situations in addition to reasonable requirements for initial patient assessment and follow up. The presumption should be that home oxygen will be initiated by designated clinicians with specialist knowledge and skills in the majority of cases. All GPs should retain the ability to start a patient on home oxygen in exceptional circumstances however.*

There is a clear desire from prescribers for increased access to certain types of home oxygen equipment, in particular Homefill systems and conservers. Both of these devices can be more efficient to provide over the longer term than standard concentrators and portable cylinders and are well received by patients hence increasing their provision would be beneficial. The recent working party on home oxygen also recommended increasing the availability of these devices.

- *Homefill systems and conservers should be made substantially more widely available across Scotland.*

Professionals have repeatedly indicated a desire for detailed clinical guidance to be developed on the provision of home oxygen, including guidance on:

- Who can prescribe home oxygen
- Appropriate clinical assessment required before starting home oxygen (LTOT, AOT, and SBOT)
- Follow up of patients on the different forms of home oxygen
- Who is responsible for training patients and carers in the safe use of home oxygen
- Provision of duplicate equipment
- Use of oxygen on public transport and in taxis
- Use of oxygen equipment in schools
- Provision of home oxygen to patients who continue to smoke.

- *Detailed clinical guidance on the provision of home oxygen in Scotland should be developed. The Scottish Government should consider which organisation would be best placed to develop such guidance.*

Provision of home oxygen across Great Britain

Direct comparison of the provision of home oxygen in Scotland to that in England and Wales is difficult. The available data suggest, however, that provision of static cylinders in Scotland is broadly similar to that in England and Wales as a whole; provision of concentrators is slightly lower; provision of portable cylinders is substantially lower; and provision of liquid oxygen is broadly similar to that in most regions in England and Wales. The number of patients with a portable form of home oxygen in England and Wales is around 75% of the number in receipt of a static modality whereas in Scotland the comparable figures is likely to be closer to 40%.

There is no independent benchmark specifying the 'correct' level of home oxygen provision that Scotland's figures can be compared to. Provision levels in England and Wales will reflect a complex mixture of over- and under-provision as they do in Scotland. These comparative figures do give an important insight into the effect that service configuration (for example who can prescribe home oxygen) can have on overall provision rates, however.

- *Active management of home oxygen services in Scotland should continue to involve periodic comparison of provision rates in Scotland to those seen in other similar countries.*

Overarching recommendations

- *Home oxygen is a potentially effective but also a complex and expensive service to provide. In general the way services are configured significantly impacts on their clinical appropriateness and hence effectiveness and efficiency. Unifying all elements of home oxygen provision in Scotland into one national level service could bring potential benefits in terms of increased clinical appropriateness and efficiency and should be carefully considered by the Scottish Government, NHS National Services Scotland, and territorial NHS Boards. Consideration of how a unified service should be configured was outwith the remit of this needs assessment. Detailed consideration of the various options (and their benefits and risks) will be required before any changes are planned or implemented. This process should involve all stakeholders including suppliers, the wider healthcare team, and service users.*

- *One potential benefit of a unified service would be better data on home oxygen provision. Currently the available data are fragmented and provide suboptimal detail for planning, monitoring and epidemiological purposes. Careful consideration should be given to enhancing the information available on home oxygen provision, including for example information on patients' underlying conditions, initial and subsequent clinical assessments, outcomes, and costs per patient per modality. Data should be used to actively manage home oxygen services and hence ensure maximum effectiveness and efficiency. Steps should be taken to ensure that the ongoing management of home oxygen services receives appropriate input of technical, clinical, public health, planning, and financial expertise.*

- *The development of a single national service would carry potential risks in terms of disruption to suppliers. These risks should be carefully considered and mitigated as part of any service development/planning process. Lessons learned from the service reconfiguration in England and Wales should be studied to avoid any similar problems arising in Scotland.*

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Appendices

Appendix 1: Project group membership

Name	Organisation	Role
Marion Bain	NSS	Medical Director / Chair of project group
Rachael Wood	ISD	Consultant in Public Health Medicine / Project lead author
Ian Grant	ISD / ScotPHO	Researcher / Project co-author
Andrew Millard	ScotPHN	Researcher / Project co-author
Irene Barkby	NSS	Executive Nurse Director
Simon Belfer	NSS	Director of Finance
John Haughney	QIS	NHS QIS Clinical Advisor / GP
Paul Kingsmore	HFS	Director
Una MacFadyen	Stirling Royal Infirmary	Consultant Paediatrician
Willie McGhee	HFS	Oxygen Therapy Service Project Manager
Bill McNee	University of Edinburgh / NHS Lothian	Consultant Respiratory Physician
Donald Page	ISD	Technical Services Pharmacist
Phil Mackie	ScotPHN	Lead Consultant
Ann Conacher	ScotPHN	Co-ordinator

NSS	NHS National Services Scotland
ISD	NSS Information Services Division
ScotPHO	Scottish Public Health Observatory
ScotPHN	Scottish Public Health Network
QIS	NHS Quality Improvement Scotland
HFS	NSS Health Facilities Scotland

Appendix 2: ICD 9 and 10 codes used to define specific conditions for the purposes of extracting relevant hospital and death records.

	ICD9	**ICD10**
Neonatal respiratory distress	769	P22.0, P22.8, P22.9
Chronic neonatal lung disease	770.7	P27.1, P27.8, P27.9
Cystic Fibrosis	277.0	E84
Chronic interstitial lung disease in adults	495, 500, 501, 502, 503, 504, 505, 508.1, 508.8, 515, 516.0, 516.2, 516.3, 516.8, 516.9	J60, J61, J62, J63, J64, J65, J66, J67, J70.1, J70.3, J84.0, J84.1, J84.8, J84.9
Chronic obstructive pulmonary disease	490, 491.0, 491.1, 491.2, 491.8, 491.9, 492, 496	J40, J41, J42, J43, J44

Both hospital discharge and death records allow the recording of multiple diagnoses/causes of death. Records with one of the relevant codes occurring in any position were included in the analyses carried out for this project.

Appendix 3: Sample for semi-structured interviews

Professional group and role	Work location
GP and MCN clinical lead	Lothian
GP and MCN clinical lead	Tayside
GP	Lanarkshire
Adult Respiratory Physician	Lothian
Adult Respiratory Physician	Forth Valley
Adult Respiratory Physician MCN Chair	Glasgow & Clyde
Adult Respiratory Physician	Highland
Adult Respiratory Physician MCN clinical lead	Borders
Adult Respiratory Physician	Lothian
Paediatrician or neonatologist	Lothian
Paediatrician or neonatologist	Grampian
Paediatrician or neonatologist	Lothian
Paediatrician or neonatologist	Forth Valley
Nurse -respiratory	Glasgow & Clyde
Nurse -respiratory	Glasgow & Clyde
Nurse – respiratory and MCN clinical lead	Dumfries and Galloway
Nurse - Paediatric	Glasgow & Clyde
Nurse - Practice	Fife

Appendix 4: Sample interview schedule

Separate interview schedules were used for GPs/practice nurses, adult respiratory physicians/adult specialist nurses, and paediatricians/neonatologists/paediatric specialist nurses. All used the same preamble. A sample of one of these, for adult respiratory physicians, is given below.

National Needs Assessment for Home Oxygen Service – interview schedule

Introduction

A range of paediatric and adult patient groups are provided with oxygen at home, either through static cylinders via GP prescription or through concentrators or other equipment via Health Facilities Scotland. Patterns of oxygen use vary with some patients using 'short burst' oxygen for brief periods as and when required and others using 'long term' oxygen for many hours every day. The duration of oxygen use also varies with some patients using it for a few weeks as part of their palliative care and others using it for a number of years. Some patients receive portable forms of oxygen (such as portable cylinders via GP prescription) in addition to their main 'at home' supply to assist their mobility and independence.

The Scottish Public Health Network is undertaking a national needs assessment for home oxygen. As part of this project, interviews are being conducted with key individuals with a role in the provision of home oxygen such as yourself. The interviews aim to enhance understanding of decisions to provide home oxygen, provider views on the effectiveness and adequacy of home oxygen, and the impact of changing models of care and developing technology on the service.

I anticipate this interview will take no longer than one hour. Could you please confirm that you are happy for it to be recorded and subsequently transcribed for analysis?

Adult respiratory physician's interview

1. How does your team decide who to give HO?
   - Long term oxygen
   - Additional ambulatory oxygen

2. Do you use specific objective tests to support your decision making?
   - Oximetry
   - Spirometry
   - Arterial blood gas sampling
   - Exercise testing
   - Other

3. How does your team identify all their patients on HO?
   - Disease register?
   - HO register?
   - Other

4. What arrangements are in place to clinically review patients that are on Home Oxygen?
   - Monitoring: of what, when, by whom?

5. What are your opinions about the effectiveness of the different types of HO?
   - Long term (in particular how many hours of use per day required for objective clinical benefit?)
   - Portable oxygen
   - Short burst
   - Palliative care use

6. How have recent developments in the way care is provided affected HO provision?
   - Early patient discharge
   - Hospital at home
   - For specific patient groups eg COPD patients

7. How have new devices affected the provision of HO?
   - Portable cylinders
   - High flow concentrators
   - Homefill systems
   - Portable Concentrators
   - Liquid Oxygen
   - Oxygen Conservers
   - BabyOx
   - Holiday Service through HFS

8. What impact has national guidance had on your team's provision of HO?
    - SG letters – especially HDL 2004 (01) (reduction in eligibility criteria for concentrators from 15 to 8 hours oxygen use per day; introduction of portable cylinders on GP prescription)
    - NICE guidance on COPD (2010 version)

9. Do you have any local clinical guidelines for the provision of HO?
    - Are you aware of any local rules for using/carrying oxygen on public transport (including taxis)

10. What are the arrangements locally for training patients and/or carers in the safe use of HO?
    - How is safe use of HO monitored?

11. Do you think home oxygen is currently over or under provided in relation to population need?
    - Is it available to all those who need it?
    - Is it provided to any who do not need it?
    - Do you think the adequacy of provision varies by type of oxygen therapy (eg short burst/long term/ambulatory) and/or device used to deliver oxygen (eg concentrators/static cylinders/new devices)
    - Do you think any specific elements of the home oxygen service currently provided by the NHS should be made more widely available or cut back?

12. How do you think the HO service should be developed in the future?
    - Unified cylinder and concentrator service

13. Do you have any comments on modality assessment (included as Appendix F in the 2010 report of the working party on home oxygen)?

Appendix 5: Summary timeline of policy and clinical guideline documents relevant to the provision of home oxygen

2010

- Scottish Government published home oxygen working party report (Scottish Government 2010) and associated research report (Ferguson et al 2010)
- NICE published updated guidance on Chronic Obstructive Pulmonary Disease, originally issued in 2004
- NHS QIS published clinical standards for COPD services
- NHS QIS issued best practice statement on home oxygen therapy for children
- BTS published guideline on non-CF Bronchiectasis

2009

- BTS published guideline on use of home oxygen in children

2008

- Scottish Government issued letter in response to shortage of portable oxygen cylinders (PCA(P) 15 (M)6 2008)
- BTS published guideline on interstitial lung disease
- National Pulmonary Hypertension Centres of the UK and Ireland published consensus statement on the management of pulmonary hypertension
- SIGN and BTS published guideline on management of asthma (availability of home oxygen for recurrent severe asthma attacks)
- SIGN published guideline on diagnosis and management of headaches in adults (use of home oxygen in cluster headaches)

2007

- Scottish Government issued letter in response to Air Products Ltd withdrawing from oxygen provision in Scotland (leaving BOC as sole suppliers of cylinder oxygen) (PCA(P) 37 M(14) 2007)

2006

- Scottish Government issued letter on new arrangements for supply of home oxygen for patients travelling to England and Wales following the service reorganisation there (HDL(2006)63)
- Scottish Government issued letter amending the QOF points available to GPs for management of a number of conditions including COPD (PCA(M)(2006)13)
- BTS issued standards for clinical component for Home Oxygen Service in England and Wales

2005

- Scottish Government issued letter in response to shortage of portable oxygen cylinders (PCA(P)(2005)23)

2004

- Scottish Government issued letter reducing the eligibility criteria for a concentrator from 15 hours to 8 hours oxygen use per day and noting that portable cylinders would be made available on prescription (HDL(2004)01 and subsequent addendum)

- Scottish Government issued letter noting the addition of portable oxygen cylinders to the Scottish Drug Tariff (and hence their availability on GP prescription) HDL(2004)11
- NICE published guidance on Chronic Obstructive Pulmonary Disease (updated in 2010)
- New GP contract brought in with new system of Quality and Outcomes Framework payments to GPs based on their management of various conditions including COPD.

2003

- Scottish Government issued letter notifying the changes to be introduced in 2004 through HDL(2004)01 PCA(P)2003/07/PCA(M)2003/19

2002

- European Industrial Gases Association published guidance on safe use of medical oxygen systems for supply to patients with respiratory disease (IGC Doc 89/02/E)

2001

- Cystic Fibrosis Society issued guidance on standards of care for children and adults with Cystic Fibrosis

1999

- Royal College of Physicians published landmark report on domiciliary oxygen therapy services

1996

- Scottish Government issued letter outlining charging policy relating to provision of oxygen cylinders by pharmacies (PCS(P)(1996)01)

1989

- Scottish Government issued letter noting the establishment of the national home oxygen (concentrator) service to be provided by Health Facilities Scotland (then Common Service Agency) (1989(GEN)33)

1985

- Oxygen concentrators made available on prescription in England and Wales through the drug tariff

1981

- Results of NOTT and MRC randomised controlled trials on the benefits of LTOT in COPD patients published

Appendix 6: Response on behalf of the Directors of Pharmacy on the Home Oxygen Services report (December 2010)

Dear Marion

I am responding on behalf of the Directors of Pharmacy Group to this report.

The Directors of Pharmacy Group welcomed the opportunity to comment on the draft report generated by ScotPHN. A number of issues which they raised have been fed back to the lead author for the report and amendments incorporated where possible. These have focused principally on two key sections of the report:

Providers and Users section - further detail has been included on the eDelphi survey which engaged the wider health care delivery team and presented a mixed response when asked about specific elements of a unified service. The section also now clarifies that the interviews undertaken for this report focused only on clinicians engaged in the prescribing of oxygen. The specific input of the Community Pharmacy community (as providers of the service and, in the current arrangements, the most likely clinicians to interact with these patients on a regular basis) remains an outstanding gap in the report. The report's author acknowledges the absence of Community Pharmacy input due to the omission of CP membership on the ScotPHN Steering Group.

Overarching Recommendations - modification has been made to this section to clearly state that moving to a national service / national approach could bring benefits but requires to be taken forward through a robust option appraisal process with the engagement of all key stakeholders.

If this report is accepted as it stands, the Directors of Pharmacy consider the following key areas require careful consideration in the implementation phase:

1. There are currently significant pressures on NHS Board service provision budgets for home oxygen. Any redesign would need to ensure maximum effectiveness and efficiency.
2. Engagement of the community pharmacy service providers and senior pharmacy management in any discussion on improving/redesigning service delivery must be sought.
3. The option appraisal of service delivery models would require to make appropriate arrangements to meet patient needs, irrespective of location. Currently there are aspects of the service provision locally negotiated by NHS Boards to ensure the clinical needs of patients are met.
4. Provision for out of hours services and robust contingency planning for bad weather/supply shortages is critical to this service model.

The NHS Scotland Directors of Pharmacy Group requests that these key areas are addressed in furthering this piece of work.

Regards

Marion Bennie

ScotPHN report

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