



## Research Article

# COPD burden and healthcare management across four middle-income countries within the Breathe Well research programme: a descriptive study

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## Abstract

**Background:** Chronic obstructive pulmonary disease is one of the world's leading causes of morbidity and mortality, with many low- and middle-income countries still experiencing an increase. Effective management requires a strong primary healthcare system, to prevent, diagnose in a timely way, and manage prevalent disease for a long period of time through to end of life, but this is inadequate in many middle-income countries.

The Breathe Well programme was a multinational collaboration between the University of Birmingham, United Kingdom, and partner institutions in four middle-income countries: Brazil, China, Georgia and North Macedonia. This review, conducted at the start of the programme, aimed to set the context for our research programme and future research, health care and policy needs by describing these four national health systems, risk factors, current burden and management of chronic obstructive pulmonary disease patients.

**Design and methods:** A descriptive review based on publicly available data identified from MEDLINE, national and international websites, supplemented by local expert opinion. For each of the included middle-income countries, we present and discuss the ability of the healthcare systems to effectively diagnose and manage chronic obstructive pulmonary disease, the barriers and limitations, including history of the healthcare system, organisation and

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governance, financing and medicines. The health and health care of chronic obstructive pulmonary disease patients are further illustrated by a hypothetical patient case developed with local clinical experts.

**Results:** While the sizes and features of the populations differ, the number of doctors tends to be low across most countries, the number of smokers high, the out-of-pocket expenses also high and the provision of diagnosis and management for chronic obstructive pulmonary disease in primary care suboptimal. Primary prevention including smoking cessation is insufficient across the participating countries. Cost and availability of care and medications are common barriers to effective chronic obstructive pulmonary disease management.

**Limitations:** This study is not a comprehensive systematic review. It provides a useful broad description of the subject, but we did not seek to produce detailed accounts.

**Discussion:** While there is vast diversity in settings and context, some challenges appeared to be shared: a lack of human and material resources in the primary care systems with an apparent power imbalance between primary and secondary care, pushing care burden to secondary care and potentially worsening geographic and economic health inequities. High cost (relative to average earnings) and low accessibility of long-term medications lead to high out-of-pocket expenditure, affecting quality and equity. There is generally suboptimal primary prevention with high smoking rates and high levels of air pollution. Improvement of prevention, diagnosis and management of chronic obstructive pulmonary disease via stronger primary care could help reduce health inequalities.

**Future work:** This study provided useful context for prioritising research questions within the Breathe Well programme and beyond. Research recommendations included assessment of resource-effective methods for primary prevention, screening and community-led management of chronic obstructive pulmonary disease cases, as well as mapping the educational needs of primary care staff which were then prioritised by local stakeholders including patients, clinicians, healthcare managers and policy-makers. It will be essential to update information on local context at regular intervals to ensure currency of research plans.

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## Introduction

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease characterised by inflammatory remodelling of airways and lung tissue causing progressively reduced lung function and increased susceptibility to infections. It forms an increasing public health problem and is the third leading cause of death globally.<sup>1</sup> Middle-income countries face particular challenges due to high and often increasing rates of tobacco smoking, high levels of air pollution and healthcare systems that regularly struggle to keep pace with a shifting burden of disease.<sup>2</sup>

While tobacco smoking is the strongest risk factor for developing COPD, there is a growing body of evidence on the impact of air pollution, exposure to indoor biomass fuel and occupational exposure to irritating inhalants.<sup>3</sup> Still, tackling tobacco use remains key to lowering COPD morbidity, especially in populations where tobacco smoking is widespread. This is valid both for prevention and to slow disease progress and reduce disability.<sup>2</sup> Primary care is in a privileged position to offer smoking cessation information and programmes, early diagnosis and treatment of manifest disease, and an ability to follow up and track progress in a local, patient-focused manner. The emphasis on primary care is also reflected in the gold-standard recommendations for COPD management,<sup>2</sup> the United Nations Sustainable Development Goals<sup>4</sup> and

the World Health Organization's (WHO) Universal Health Coverage (UHC) strategy.<sup>5</sup>

The Breathe Well programme was a 3-year international venture funded by the National Institute for Health and Care Research (NIHR) aiming to build capacity for COPD research and management in primary care in middle-income countries (MICs), specifically around earlier identification and community-based treatments. Breathe Well brought together primary care and public health research groups from four MIC members of the International Primary Care Respiratory Group chosen for their contrasting cultures but common problems in managing COPD: China, Brazil, Georgia and North Macedonia. They worked in partnership with the University of Birmingham to develop strategies to map their COPD situation and identify locally relevant research. The overall aim of the programme was to prioritise locally relevant research studies, develop and conduct population-based studies and build capacity for future research.<sup>6</sup>

## Aim

As part of the initial phase of mapping and building understanding of the different healthcare contexts, this review was conducted to provide a description and summary of the four different health systems, with a specific emphasis on COPD management, illustrated by

hypothetical patient cases. This detailed review, completed within the first 6 months of the programme, aimed to provide essential background information for finalising the research questions for prioritisation within the programme and the detail needed for developing research protocols. Thus, it fed into all of our stated research aims.

## Methods

This study aimed to provide detailed understanding of the health and health care relevant to COPD in each of our participating countries and feed into decision about health needs and gaps in healthcare provision, and subsequently research questions prioritised and delivered.

A descriptive literature review was conducted by a single reviewer (A d'E) to identify relevant published literature (up to mid-2017) to inform the key elements of the description. MEDLINE and other relevant internet sources were searched using key words such as 'COPD', 'China', 'Brazil', 'North Macedonia', 'Georgia', 'prevalence', 'smoking' and 'healthcare' to identify the most recent relevant reviews, commentaries and primary studies describing the populations, COPD-related health, healthcare system, financing and clinical management within each country. Where information was unavailable, expert opinion was sought from the co-investigators from each country. No explicit criteria were used to systematically assess the literature as this was not intended to be a systematic review, rather general judgement on the appropriateness and timeliness of included studies and routine data were applied. No additional reviewers were involved in searching or sifting the literature.

Key information on population size, gross domestic product (GDP)/capita, doctors/1000 (as a proxy for extent of medical provision), life expectancy, healthcare expenditure/financing and UHC (provided by the UHC service coverage index 2021) was tabulated and described for each country.

Data and description for each country also included COPD-relevant data on smoking prevalence, COPD prevalence, attributable disability-adjusted life-years (DALYs) and COPD healthcare characteristics [diagnosis in primary care, availability of spirometry, COPD inhaler medications, pulmonary rehabilitation, smoking cessation, home non-invasive ventilation (NIV) and annual reviews].

A brief history of each health system is followed by descriptions of its organisation and governance, financing, medicines, COPD data and management. Finally, we

conclude the findings with a fictional patient vignette for each country to illustrate the key features of COPD management, which was developed by the lead author in discussion with the clinical leads from each country. We chose a range of different age, sex, exposure and other characteristics for our vignettes.

Important definitions and sources of data collected are covered in [Table 1](#).

## Findings

A comparison of the populations, healthcare systems, COPD epidemiology, medicines and management is provided in [Table 2](#). While the sizes and features of the populations differ, the number of doctors tends to be low across most countries, the number of smokers high and the provision of primary care diagnosis and management for COPD suboptimal.

### Brazil

#### Brief history of health system

The health system in modern Brazil traces its roots back to the industrialisation of the 1930s. Social security systems were based around occupations and provided insurance with varying coverage for care from mainly private providers. During the military rule in the 1960s and 1970s, the state commissioned private providers to build hospitals. Funding for care provision was predominantly managed by subsidies to employers' and unions' insurance programmes, and through philanthropy. In parallel with the path towards democracy in the 1970s and 1980s, the view of health care gradually developed towards a more rights-based approach and in 1986 health was recognised as a universal citizen right. During the following years, the Unified Health System (Sistema Único de Saúde; SUS) began to take shape, and today forms the backbone of Brazilian health care. In parallel, a gradual decentralisation has taken place and new grassroots actors have been introduced, notably in the form of the community-based Family Health Programme (now called the Family Health Strategy; FHS).<sup>11,12</sup>

#### Organisation/governance

The national health system SUS organises public and private providers under a common umbrella. Primary care is mainly publicly run while particular diagnostic specialist services are dominated by private actors, contracted by the SUS. The SUS is designed as a decentralised system where the Ministry of Health (MoH) issues policies that are adapted by local health authorities at state (i.e. regional)

TABLE 1 Important definitions

MIC	Middle-income country as per the World Bank 7
Primary care	Primary care is defined as primary care services provided to individual patients, not including wider public health policy such as tobacco taxation, but including clinic-facilitated services such as smoking cessation <sup>7</sup>
Family physician	Medical doctor working in primary care as per above. May be a specialised family physician (such as in a general practitioner in the UK) or a generally trained doctor
Catastrophic health expenditure	Expenditures threatening the subsistence of the household, typically through out-of-pocket (OOP) payments
GDP/capita (PPP intl \$)	GDP, purchasing power parity in international dollars
Total healthcare expenditures/GDP	Total healthcare expenditure as share of GDP. Includes all healthcare spending, both private and public. Includes public health measures when conducted within the healthcare system
Share public financing	Amount of the total healthcare spending accounted for by public resources, either through publicly administered health insurance or through taxation
OOP of total financing	OOP; proportion of total national health expenditure paid for directly by patients, not including health insurance (private or public), as a share of the total national healthcare spending
Insurance coverage	Proportion of the population covered by public (or publicly mandated) health insurance
COPD proportion of DALYs	DALYs; the share of DALYs made up by COPD morbidity according to the Global Burden of Disease project <sup>8</sup>
COPD prevalence	Age-standardised COPD prevalence as per the Global Burden of Disease project, <sup>8</sup> used in preference to local studies due to consistency of methodology across the different countries
UHC Health Coverage Index	Composite measure calculated by the WHO. <sup>9</sup> UHC service coverage index is measured on a scale from 0 (worst) to 100 (best) based on coverage of essential services, service capacity and access

and municipal levels. At each level, a health council offers insight and opportunity for participation for various stakeholders, meant to improve social integration.<sup>11</sup>

Brazil has implemented a community-based system for primary care, the FHS. Introduced on a small scale in the 1990s, it had grown to encompass 62% of the population by 2019, mainly in rural locations.<sup>13</sup> FHS provision is managed by teams consisting of a family physician, a nurse, a nurse assistant and four to six community health agents. Each team has primary care responsibility for up to 1000 households, including some disease prevention (e.g. health promotion). Each community agent is responsible for approximately 150 households and lives in the area. The agent visits every household at least once per month, checking for signs of ill health and keeps track of appointments. As such, the concept has proven effective in increasing coverage and utilisation of health care, especially among lower socioeconomic and rural populations.<sup>12</sup>

Secondary and tertiary care is provided by a mix of public and private providers, with private providers both being subcontracted by the SUS and available through out-of-pocket (OOP) spending or private insurance plans. Within the SUS, private providers are particularly

dominant in diagnostic services: 2010 data shows 35% of hospital beds being publicly owned, while 39% of the private sector's beds were available to the SUS through subcontracting.<sup>11,14</sup>

The secondary and tertiary care system is excessively 'siloed', that is separate subsystems lacking co-ordination. Communication between primary and secondary/tertiary care has also been described as lacking.<sup>12</sup> The issue has for a long time been recognised by the authorities and in 2007 the MoH set up a department dedicated to improving co-ordination, co-operation and communication between providers.<sup>11</sup>

In addition to the SUS, the state operates several targeted health programmes, focusing on, for example ethnic minorities, or people with mental health problems. A notable agency is the National Health Promotion Policy, designed to promote public health and reduce socioeconomic health disparities.<sup>14</sup>

## Financing

All care under the SUS is free of charge for users at the point of delivery. It is tax-funded and receives about half of its funds from the federal government, while the other half is split between state and municipal budgets. In total,

TABLE 2 Comparison of health systems and COPD management

	Brazil	China	Georgia	North Macedonia
<b>Demographics (2022)<sup>10</sup></b>				
Population	214 million	1.41 billion	3.7 million	2.1 million
GDP/capita (PPP intl \$)	16,100	19,300	17,000	17,900
Life expectancy (years)	76	77	73	76
<b>Healthcare financing (2020)<sup>9</sup></b>				
Health care/GDP (%)	10.3	5.6	7.6	7.9
Doctors/1000 people	2.3	2.0	7.1	2.8
Share public financing (%)	41	56	45	60
OOP of total financing (%)	22	35	47	39
UHC service coverage index (2021)	80	81	68	74
<b>Epidemiology<sup>8</sup></b>				
Smoking female/male (%)	6.9/10.9	3.6/49.7	7.0/51.8	31.0/47.1
COPD prevalence/100,000 ##17 (%)	5.3	12.0	11.6	10.2
COPD proportion of DALYs (%)	2.2	5.2	1.7	1.8
COPD DALYs attributable to smoking (%)	48.8	50.5	47.8	64.8
Second-hand smoke (%)	7.2	12.0	11.4	11.9
Outdoor particulates (%)	7.4	25.4	11.7	19.3
Occupational exposure (%)	12.3	20.0	14.3	8.0
Indoor solid fuel use (%)	2.4	7.6	6.0	3.7
Ozone pollution (%)	4.4	6.9	6.9	2.6
<b>COPD management<sup>8</sup></b>				
Primary care diagnosis of COPD	Yes	No	No	No
Spirometry through primary care	No	Yes	No	No
Home oxygen	Yes	Yes	Yes	Very limited
Home NIV	Unknown	No	No	No
Nebulisers/drugs	No	Yes	Yes	Yes
Pulmonary rehab	Yes	No	No	Yes
Smoking cessation – drugs	Yes	No	Limited	No
Smoking cessation – CBT	Yes	Yes	Yes	No
Annual review	No	No	No	Yes

CBT, cognitive-behavioural therapy; intl, international; PPP, purchasing power parity.

a Data on COPD management provided by Breathe Well investigators from respective countries.

public spending accounts for approximately 41% of total health expenditures<sup>9</sup> (see [Table 2](#)).

The private sector has historically been encouraged and as previously mentioned provides a large share of care, both

subcontracted by the SUS or as OOP/private insurance services. Private health insurance is more popular among higher-income groups and in total covers around a quarter of the population. Overall, around 80% of the population relies on the publicly funded SUS for care.<sup>13</sup> The majority of

private (i.e. non-SUS) health care (around 70%) is funded by employers.<sup>12</sup>

### Medicines

Medicines are provided free of charge when part of SUS services, including primary care; covered products are regulated by the MoH.<sup>14</sup> However, cost remains a problem for patients where the local care system does not stock the relevant medicines, resulting in them having to turn to private providers, buy directly from pharmacies or over the counter. Overall, about half of all patients with chronic diseases receive free medicines. Most commonly, these are related to cardiovascular diseases, while patients with respiratory diseases such as COPD and asthma pay OOP in 60% of cases. Patients having been prescribed a medication in private care can get these paid for if they are for chronic conditions, although this requires an application to be made to the SUS.<sup>15,16</sup>

### Chronic obstructive pulmonary disease management

Chronic obstructive pulmonary disease accounts for about 2% of all morbidity in Brazil, measured in DALYs. Compared to the other partner countries, smoking is responsible for a high proportion of COPD burden, with occupational exposure and outdoor air particulates coming in second. This is noteworthy, as recent smoking rates are comparatively low.<sup>8</sup>

Chronic obstructive pulmonary disease is generally diagnosed and treated by pulmonologists in hospital and regional specialist centres. Patients either get referred through primary care or seek hospital care from the start. Spirometry with reversibility testing is the adopted standard of diagnosis and is usually performed by trained technicians at health facilities to which the patients are referred by pulmonologists. There is usually one unit performing spirometry per administrative area (e.g. city), although availability of services tends to be geographically inequitable with better access in the south and southwest.<sup>17</sup> Both primary care physicians and pulmonologists can prescribe COPD inhalers such as long-acting beta-agonist (LABA) and inhaled corticosteroids (ICSs), while home oxygen and pulmonary rehabilitation are exclusive to secondary care.

While the role of diagnosing COPD is thus put on secondary care, general practitioners maintain close contact with the patient and are generally responsible for long-term continuity. General practitioners also refer patients to smoking-cessation cognitive-behavioural therapy and prescribe nicotine replacement therapy (Sonia Maria Martins, personal communication).

### Patient case

Miguel de Silva is a 63-year-old from a middle-sized city in Brazil. He has begun to notice difficulties in climbing the stairs to his apartment and is bothered by a persistent cough. He mentions this to the local community health agent during one of her routine visits, and she books a visit to the local family physician. The family physician has heard about COPD but does not feel confident in diagnosing and treating it and diagnoses Mr de Silva with asthma. He prescribes a short-acting beta-agonist (SABA), which gives some momentary relief. All this is free of charge.

Mr de Silva continues to smoke and 2 years later falls ill with fever, productive cough and shortness of breath. His son calls an ambulance that takes him to a SUS hospital. He receives emergency care for a COPD exacerbation and improves within a few days. In the hospital, he is cared for at a general ward, and discharged with a referral to a pulmonologist whom he sees 2 months later. A spirometry confirms the presence of moderate COPD, and he is prescribed a combination of a SABA and a steroid (as per international guidelines). Initially he has to pay OOP for these medications, but after about a month the paperwork to get it for free has gone through. The hospital care is free of charge through the SUS. He is strongly advised to stop smoking and is recommended to ask for support at his family physician if he feels the need.

He contacts his family physician for long-term follow-up, who has not received any information from the hospital, but is aware of the smoking cessation programme in the municipality. He refers Mr de Silva, who manages to stop smoking through a 12-week programme with information, counselling and nicotine substitution.

### China

#### Brief history of health system

The health system in modern China traces back to 1949, when the Communist Party took power and attempted to create a health system built on government-owned facilities and practically free provision of service. This early system also successfully made use of community health workers (so-called barefoot doctors), increasing coverage in rural areas. In combination with state-led public health programmes and economic development, China began an epidemiological transition similar to the West.<sup>18</sup> As part of a general push towards privatisation and free markets in the early 1980s, funding for the health care and public health systems dropped dramatically. Facilities were largely privatised while those that remained state funded adopted a for-profit financing structure. As economic and

geographic disparities increased, trust in the health system dropped.<sup>19</sup> The 2000s saw reforms shifting focus back to public funding to increase health coverage. A primary care system was established, and in 2008 health insurance was introduced for approximately 95% of the population.<sup>20</sup> Yet, private healthcare provision is increasing, particularly in tertiary care facilities (although the majority is publicly provided), and recent reforms once again intend to utilise market forces and increase private ownership in the health system.<sup>18</sup>

### Organisation/governance

China's health system is the responsibility of the central government through the National Health Commission (NHC). Responsibility is further split between national, provincial and local level.<sup>14</sup>

Health authorities manage the system at provincial, city and county levels, usually internally organised similar to the NHC. Each level delivers care and runs hospitals and facilities, including public health and disease prevention. Decision and policy-making are generally exercised at provincial level.

Care provision is also split between rural and urban areas. The rural system is based around county hospitals which oversee township- and county-level clinics at the primary care level. These institutions are also responsible for basic public health work with the rural population. In urban areas, city hospitals act as a backbone for a similar system of community health institutions, while also providing medical education and research. In both cases, more complicated and/or rare cases are referred upwards in the system to larger hospitals at the city, county and state level, with primary, secondary and tertiary hospitals found at all levels, but with more advanced care concentrated higher in the hierarchy.<sup>21</sup> This drives considerable regional health inequities between rural and urban populations.<sup>14</sup> In general, the Chinese care delivery system has been described as hospital focused with a relatively high share of care being provided at hospitals instead of at primary care level.<sup>18</sup>

Furthermore, as previously mentioned, the private sector provides a large proportion of care, both in collaboration with the national health system and as separate entities. In 2018, 64% of hospitals were privately owned and increasing, as per the ambition of the Chinese government to attract private investment.<sup>14</sup>

In parallel, there are systems and providers for traditional Chinese medicine, organised similarly and overseen by

State Administration of Traditional Chinese Medicine. These services are generally provided through a separate system of facilities (although sometimes co-located).<sup>22</sup>

### Financing

The total healthcare expenditure made up 5.6% of GDP in 2020, of which public spending comprised 56%<sup>9</sup> (see [Table 2](#)).

The health insurance system covers upwards of 95% of the population, consisting of several different brackets and financing of the insurance varies by situation. For example, rural citizens can choose to enrol in the New Rural Cooperative Medical Scheme, which provides co-payment from a pool of state- and premium-sourced resources.<sup>22</sup>

In 2020, 35% of expenditure was OOP payments, that is uninsured patients, uncovered services, private providers or co-payments in combination with insurance.<sup>9</sup> Attempts are being made to reduce OOP and the share is dropping. In particular, effort is made to reduce catastrophic impact of OOP payments (i.e. expenditures threatening the subsistence of the household), with such public 'last resort' insurance policies covering about 6% of the population in order to prevent severe economic impact on the most vulnerable.<sup>14</sup>

### Medicines

All pharmaceutical activities in China are overseen by the China Food and Drug Administration (CFDA). Like healthcare provision, suborganisations of CFDA are responsible at local levels. A National Essential Medicines List (NEML) is provided by state authorities, with the aim of keeping costs down and to ensure availability.<sup>22</sup> The list is similar to the WHO list of essential medicines and consists of a few hundred products that are purchased through provincial public bidding and are not allowed to be resold with profit. Resale of medicines otherwise carries a profit cap of 15% at the consumer stage. The list has been widely adapted and has improved access to essential medicines throughout the country.<sup>23</sup>

The general concept is that provision is built on market principles while patients are reimbursed through their respective insurance policy, which all have their own list of covered drugs and a differing proportion of co-payment. In addition, some pharmaceutical products are provided completely free of charge from the state, including tuberculosis medications and basic child immunisation. HIV medication is provided to vulnerable groups free of charge.<sup>22</sup>

Drug costs and OOP expenses for drugs have been increasing over the past 30 years. While these problems are recognised and actions like NEML and increased insurance coverage have been helpful, costs still put a substantial financial burden on many patients. In 2015, medications made up 88% of outpatient and 59% of inpatient OOP spending accordingly,<sup>24</sup> and medical debt is a major source of financial difficulties.<sup>25</sup>

Other challenges in pharmaceutical provision are drug safety and counterfeiting, particularly in rural areas and overuse of antibiotics.<sup>22</sup>

### Chronic obstructive pulmonary disease management

Chronic obstructive pulmonary disease is a major and increasing cause of morbidity in China. Smoking rates are high among men (see [Table 2](#)), and, in the whole population, exposure to air pollution is a common risk factor. Indoor pollution from solid fuel, outdoor particulates, occupational exposure and second-hand smoke all add notably to the burden of disease. All in all, COPD causes about 4% of total morbidity (DALYs), highest among the included countries.<sup>8</sup> While there is a growing academic awareness about the burden of COPD, there is still a lack of knowledge among the general population and physicians that results in late discovery and makes misdiagnosis and mistreatment common.<sup>26</sup> Use of primary care is low with patients generally preferring to go directly to hospitals,<sup>18</sup> while responsibility for long-term follow-up lies with primary care providers. A lack of knowledge and inadequate communication between different care levels prevent long-term management from functioning properly. When diagnosed, investigation seldom (but increasingly, with ambitious ongoing investment) involves spirometry and patients are overprescribed SABAs, while treatment with ICSs and long-acting inhalations (e.g. LABA) is rare.<sup>27</sup>

### Patient case

Mrs Wang Fang is 72 years old and lives in a rural area in western China. She lives in her family home, where the younger generations practise farming. She has a long history of smoke exposure, both through solid-fuel cooking and passive smoking as her husband and three sons share the habit.

She has been bothered by frequent coughing since her mid-50s, but it is only in the last few years that she has begun to notice shortness of breath when working around the home. As no one in her social network knows about COPD and chronic respiratory diseases, she assumes her symptoms are due to normal ageing.

No contact with health care is made until she becomes seriously ill, and even if she had chosen to contact a village doctor, the chances are that they would not be able to diagnose her properly due to low levels of awareness of respiratory diseases. One day she is experiencing fever and severe shortness of breath and is helped by her son to a county hospital, about 30 minutes away. She is admitted to a pulmonary ward, where she receives treatment for a COPD exacerbation with theophylline, anticholinergics, antibiotics and oxygen therapy. After 6 days, she is released with a preliminary (non-spirometry-verified) COPD diagnosis, and a prescription for 4 more days of antibiotics and a long-term prescription of a LABA. The county hospital requires the equivalent of a few hundred US dollars in co-payment for her stay.

However, the medication would cost several hundred US dollars per year, with her rural insurance covering about half. Since she has received no information on the cause and mechanisms behind her disease or a definite diagnosis, and now feels quite well, she does not start medication. No follow-up is arranged, and no changes in living conditions are made. Eight months later, she once again falls ill and is admitted to a month-long hospital stay with intensive care at a tertiary hospital. This will cost her family several thousand US dollars in co-payment.

## Georgia

### Brief history of health system

Georgia gained independence with the fall of the Soviet Union in 1991 and inherited its health system model. Health care was given free at the point of care and was centrally organised in a hierarchy from district to state hospitals, owned and employed by the state. There was a strong focus on hospital care, with little attention to the primary level. Following independence, the healthcare budget dropped dramatically, while a previously centralised Union of Soviet Socialist Republics governance system handed over the control to largely unprepared local authorities. In 1994, the system was reformed and introduced health insurance, user fees and a focus on defining the responsibilities and cover of the public health system. A system for payments from employers and payrolls was introduced but did not manage to raise enough funds to be a meaningful contribution. The new system was deemed to have failed and was abandoned in 2004. It was replaced by a system covering only vulnerable groups, about a quarter of the population, offering them around 70% discount on care. In 2008, the system was once again reformed, and a programme was initiated where private insurance companies provided compulsory insurance regulated by the state. Those unable to pay received vouchers from



the state for insurance payments. OOP still made up the majority of health spending, with a large part being informal payments. Meanwhile, the infrastructure was privatised with facilities sold to insurance companies and other private investors, while their operation was regulated by the state. In 2013, the Georgian government launched a new universal healthcare programme (UHC) and replaced the insurance companies' plans with a state-owned and state-operated insurance system. This decreased OOP and increased financial accessibility, which, in combination with increased state health sector funding, has improved the situation, although major challenges still exist.<sup>28,29</sup>

### Organisation/governance

The Ministry of Labour, Health and Social Affairs (MoLHSA) serves as the highest authorising organisation in the Georgian health system. It is responsible for overarching planning of health priorities, drafting laws and regulating the sector and its workforce. MoLHSA works in close co-operation with the Ministry of Finance (MoF) that is responsible for budget outlines including benefit packages. The National Centre for Disease Control and Public Health is the highest public health organisation, serving under MoLHSA. Most providers are privately operated on contract from the MoLHSA and under reimbursement from the MoF. However, parallel systems exist for some (generally vulnerable) groups with publicly owned hospitals and free care, similar to the pre-independence system.<sup>28,29</sup>

Primary care is weak; primary care centres have insufficient coverage, trust in primary care is low and they do not act as gatekeepers to secondary care. Patients thus underutilise primary care and overuse secondary care, creating difficulties in continuity and economic efficiency. Other inefficiencies include a disproportionate number of doctors to nurses per capita and a bed utilisation rate of approximately 37%.<sup>29</sup> Advanced care is focused to the capital region in and around Tbilisi.<sup>29</sup>

### Financing

Georgia's total healthcare spending was expected to account for 7.6% of GDP in 2020 – low in comparison with similar-income countries as well as the rest of Europe<sup>9</sup> (see [Table 2](#)). The proportion has increased and is expected to keep increasing as the healthcare sector sees increased investment in combination with an ageing population.<sup>29</sup> The public share is low by European standards, with approximately 55% of spending being private. Private expenditure is however decreasing because of a push to improve public provision. Of private spending, about 80% is OOP, the rest being private insurance.<sup>9,28</sup> Over 40% of total OOP spending relates to pharmaceuticals, which are mainly bought without prescription.<sup>29</sup>

Georgians without secondary care coverage are covered by the UHC, which provides free primary care for the most vulnerable. Secondary care is partially covered with co-payments, except for some vulnerable groups. Still, care is often paid for completely OOP, which may be due to a lack of trust in primary care, driving people to enter the system at the secondary care level.<sup>14</sup>

### Medicines

The pharmaceutical sector is regulated by the MoLHSA, through the National Drug Policy. Supply of pharmaceutical products is generally adequate, although there can be long distances between pharmacies in some rural areas and the aforementioned high prices mean products are unaffordable for some patients. Proposed reasons for the high cost include a malfunctioning import market dominated by several large companies, and poor regulation on private retail.<sup>29</sup>

All pharmacies are private, but certain medications including antibiotics require prescription. In general, medications are paid completely OOP or covered by private insurance, but for vulnerable groups some medicines for chronic disease are now covered and OOP costs can be as low as 25% of the total.<sup>14,28</sup>

### Chronic obstructive pulmonary disease management

Like many eastern European countries, Georgia has a high smoking prevalence rate (see [Table 2](#)). While few women are regular smokers, more than half of men are. Other major contributors to the burden of COPD are indoor and outdoor air pollution and occupational exposure.<sup>8</sup>

Similar to the overall healthcare system, provision of COPD care relies heavily on secondary and tertiary care, due to a lack of awareness as well as equipment for diagnosis and treatment in primary care centres. Consequently, COPD is mainly managed within secondary care, where spirometry is commonly performed.<sup>30</sup> A recent study indicated increased compliance with international COPD management guidelines, but mainly in secondary care.<sup>30</sup> There are ongoing efforts to increase awareness among family physicians regarding COPD and tobacco-related illness, as part of the Tobacco Control State Program, although coverage is still limited. An over-reliance on secondary care also increases inequalities regarding access, due to the geographical location of hospitals.<sup>28</sup>

### Patient case

Mr Giorgi Beridze is a 63-year-old carpenter in Tbilisi and, as is common among his countrymen, a heavy smoker. Over the past 10 years, he has experienced recurrent coughing

and a shortness of breath when climbing scaffolding or carrying heavy loads. However, being unable to pay for private health insurance, the high OOP cost of visiting a health facility meant that he has not sought care.

Since he is now covered by the UHC (rolled out since 2013), he decides to seek care. He does not trust the competence of his local family physician but goes to him first since secondary care is not fully covered by his public insurance.

The family physician identifies the problem as pulmonary but does not have the competence to correctly diagnose and treat his condition. He does however recognise Mr Beridze's smoking habit as a risk factor for respiratory illness, since he is one of about 700 health workers to have received training as part of the Tobacco Control State Program. He advises his patient to quit smoking (but has no other means of helping him) and refers him to a pulmonologist at a tertiary level hospital.

The pulmonologist suspects COPD and performs a reversibility test with spirometry, confirming a diagnosis of moderate COPD. Mr Beridze is prescribed the recommended LABA inhaler and is given information about his disease. His insurance covers part of the visit, the rest is paid OOP. He continues to smoke, but does choose to continue medication, for which he pays OOP.

## North Macedonia

### Brief history of health system

North Macedonia's current health system evolved from the system implemented by the previous Yugoslavian government. When North Macedonia gained independence in 1991, efforts were made to retain the universal coverage and strong public health institutions. However, old infrastructure, an overdependence on large hospitals and low trust among the population caused patients to turn to the private market. This led to an increase in OOP, widening health inequities and workforce migration from the public to the private sector.

Efforts were taken to improve system efficiency, cutting hospital beds and staff and promoting the private sector to complement the public provision. As part of these efforts, primary care provision was privatised in 2007, and in 2012, the government began to integrate public and private care. While problems with high OOP, understaffing and old infrastructure remain, North Macedonia has experienced a strong improvement in health outcomes since gaining independence, with marked reductions in communicable disease burden and general mortality. Still,

mortality remains among the highest in Europe, possibly explained by a combination of lifestyle factors, poor health promotion and inadequate non-communicable disease treatment.<sup>31</sup>

### Organisation/governance

North Macedonia has mandatory universal health insurance and buys care from both public and private providers through the Health Network (HIF) launched in 2012. The HIF in turn is run by the MoH under governmental oversight. All providers, both public and private, must be certified by the MoH. The government collaborates with an appointed board consisting of, among others, the MoF, representatives of healthcare professionals and a representative of the insured population. Public health policy and programme delivery mainly lie under the Institute of Public Health, serving directly under the MoH. The HIF also has responsibility for promoting public health, through its contracted providers. With few exceptions, the health system is strongly centralised with few local-level councils. From local authorities there is a growing interest in localising decision-making; efforts have however been hampered by organisational and human resources and mostly include public health programmes. Primary care is provided by local, private institutions that are publicly commissioned. Patients are free to choose a provider and care is free of charge. Secondary care is regionalised in larger hospitals, while particularly complicated cases are referred to tertiary care in the capital, Skopje. Hospitals suffer from poor utilisation with a bed occupancy of only around 60% (of a relatively low number of beds) due to lack of doctors in the public sector as well as organisational issues.<sup>31</sup> Subsequently, patients are referred from secondary to tertiary level hospitals in Skopje, where capacity and high private expenditure limit utilisation of specialist services.

### Financing

Overall, 7.9% of North Macedonia's GDP was spent on health care in 2020, which is below the European average. In the same year, 60% of spending was public, also below the European mean.<sup>9</sup> As mentioned, North Macedonia has a system of compulsory public health insurance, paid for by all salaried citizens, providing universal coverage of public healthcare services. In practice, the majority (approximately 80%) of funding is provided by the state directly rather than via insurance payments due to the nation's large informal economy. For the unemployed, the state covers the costs of health insurance. Funds are distributed by the HIF to cover health services in primary, secondary and tertiary health care. At the primary level, selected doctors are paid on a capitation basis.<sup>31</sup>

Private insurance makes up a negligible share of health spending while OOP is relatively high, accounting for approximately 40% of national health spending in 2020.<sup>9</sup> OOP consists of co-payment in the HIF, direct payment for private services, drugs not prescribed via HIF or informal payments.<sup>31</sup> A study by the World Bank estimated that 40% had made informal payments to receive either faster or better-quality health care as well as buying medicines that were not on the public-funding-approved Positive List.<sup>32</sup> Co-payments in HIF are generally 20%, while some services such as primary care and gynaecology and paediatrics are free.<sup>31</sup>

### Medicines

Medicines are regulated by the Agency for Medicines and Medical Devices (MALMED) together with MoH and HIF. All medicines sold in the country must be authorised by MALMED and distributed through approved companies, including pharmacies. Furthermore, the MoH maintains the Positive List outlining medications to be covered by insurance. The Positive List of medicines has not changed in more than 15 years.<sup>33</sup>

Private sector pharmacies are deregulated, which has led to a skewed distribution with ample coverage in cities and a low concentration in rural areas. The HIF signs contracts with pharmacies for provision of medicine related to HIF care. In total, insurance payments cover approximately 20% of medication costs related to a treatment within the HIF,<sup>31,32</sup> and high costs for medications is a major driver of health inequities with pharmaceuticals accounting for 96% of health expenditure.<sup>33</sup>

### Chronic obstructive pulmonary disease management

The majority of COPD morbidity is attributed to smoking which causes about two-thirds of all COPD, the highest among the compared countries (see [Table 2](#)). Outdoor air pollution and indoor solid fuel usage are the second and third highest causes, respectively.

There is a distinct lack of published studies on COPD management in North Macedonia, but personal communication with Breathe Well investigators suggests care to be inadequate. Family physicians have insufficient familiarity with diagnosing, treating and preventing COPD and are generally not authorised to do so, but are expected to refer patients to pulmonologists. Access can be difficult due to a lack of pulmonologists, and geographical accessibility and long-term follow-up are challenging, as COPD care is not available at local care centres. Furthermore, COPD medications are expensive

resulting in high OOP, causing poor long-term compliance to treatment with associated risks of disease progression and exacerbations. Smoking cessation medication is limited although cytosine can be purchased over the counter. There are some empirical studies supporting this, including a 2018 study suggesting a need for more standardised care programmes for COPD,<sup>34</sup> and a 2019 WHO report suggesting the need to resource primary care to better manage chronic respiratory conditions.<sup>35</sup>

### Patient case

Mrs Marija Aleksova is a 77-year-old widow living in the North Macedonian countryside with her two sons. She was a cigarette smoker in her youth but quit smoking many years ago. In recent years, her stamina has worsened, and she finds it increasingly difficult to look after the house. She is also bothered by prolonged colds with productive cough and shortness of breath. On her sons' advice she consults her family physician who suspects COPD. The family physician has no means of performing spirometry but prescribes oral steroids and a SABA inhaler. Two months later, Mrs Aleksova feels somewhat better but still suffers from a cough and shortness of breath. As her family physician did not manage to get her an appointment with a pulmonologist at a secondary hospital, her sons pay for a private consultation (100% OOP) with a pulmonologist within a week. She performs a spirometry with a reversibility test, which confirms moderate COPD. For this she is prescribed medications from the pulmonologist, in accordance with best practice and arranges a follow-up appointment after 6 months. Because the medicines are not prescribed by a public pulmonologist, the family physician cannot prescribe medicines through the HIF and she is left to pay for them OOP.

After 3 months on LABA inhalers, she feels noticeably better and quits her medication as they are too expensive for her, unaware of the need for long-term therapy. Due to expenditure, she declines follow-up with the private pulmonologist. She is feeling better, and she is not visiting her family physician too.

### Discussion

All four countries herein described have some form of publicly operated health system. In some cases, such as the primary care system in Brazil and China, the public authorities both own and run the facilities. In other cases, such as North Macedonia's primary care system and all of Georgia's health system, the services are provided by the private sector commissioned by the state.

All four systems include some degree of mandatory financial support scheme managed by the authorities. For example, Brazil adopts a tax-based system with no public health insurance, while North Macedonia has compulsory insurance, provided and paid for by the state. There are however discrepancies in how much of the actual costs these systems end up covering. OOP expenditure (private expenditures not covered by any form of insurance) varies between 22% (Brazil) and 47% (Georgia) of total national healthcare spending. All four countries have OOP levels well above the global average of 16% in 2020, according to the WHO.<sup>9</sup> High OOP is indicative of financial barriers to access and increased risk of catastrophic expenditures due to disease and should be kept low for equity and care-utilisation reasons.

In general, there appears to be a distinct need for education around treating COPD in primary care. Doctors and health workers need to be educated on case-finding, diagnosis, treatment and follow-up, including improving access to spirometry which typically is conducted only after referral by secondary care physicians. It is also crucial that such upskilling is accompanied by financial incentives for improving COPD care; lack of financial incentives for care providers to improve their skillset and management was commonly mentioned by the Breathe Well collaborators as a key barrier.

Availability of medicines appears to be less of a problem in the four Breathe Well countries, although cost as mentioned remains an accessibility barrier. This seems to be particularly significant in Georgia and North Macedonia where the OOP spending generally makes up the majority of pharmaceutical costs.

The primary care systems in China, Georgia and North Macedonia appear to suffer from low public confidence, are underutilised and have insufficiently trained healthcare workers, resulting in a heavy burden on secondary care clinics. Likely impacts of this include increasing costs, reducing accessibility and delays in patients seeking healthcare treatment. Brazil also struggles with suboptimal management of COPD in primary care but has successfully implemented a novel community-based delivery model where community workers maintain a close connection to the local community and hence primary care services in general are well utilised.

Finally, there appears to be a general need for public health interventions addressing the high (although varying) smoking rates, and to a lesser extent (in the context of COPD) air pollution levels. Such upstream prevention is likely to be both more cost-effective and to

positively impact socioeconomic health equity compared to treatment of manifest illness.

### **Limitation and scope for future work**

This is a descriptive review relying on previously collected data and the statements of a few (initiated) professionals. As such, while we are confident that the article provides a useful broad description of the subject and the barriers in place for effective COPD management, we did not seek to conduct a systematic review or produce detailed accounts of the included healthcare systems, or the issues they face. The aspects of health care discussed herein reflect the priorities of multinational Breathe Well group, and accordingly do not aim to provide a complete understanding of health system strengthening (e.g. the WHO Six Pillars of health system strengthening<sup>36</sup>).

Likewise, while the included comparisons in-between healthcare systems provide a brief overview and summary of the different challenges faced by the included nations, this study by design lacks the granularity to draw any firm conclusions about future policy directions. Future research would do well to explore these differences and present specific challenges in more detail, including applying a more rigorous methodology and collect primary data to paint a more granular picture. Further, an improved understanding of the mentioned barriers in place is needed in order to effectively address them and ultimately improve COPD care in the included countries.

### **Research recommendations**

A series of potential research questions were identified from the prevalence data and healthcare provision information presented here and agreed with the country leads. It was also important that these recommendations were prioritised by patients, clinicians and policy-makers so that any research conducted was locally relevant, which is the subject of a further paper in this journal.<sup>37</sup> For example, the high smoking rates and lack of available smoking cessation drugs/support in North Macedonia meant that one of the prioritised research questions in our programme was the assessment of novel ways to promote smoking cessation in the primary care setting. A second question prioritised was the evaluation of a pulmonary rehabilitation programme adapted for the context in Georgia, where there were no such programmes in place. A third question prioritised in both China and Brazil on the most cost-effective ways to identify undiagnosed COPD reflected high smoking rates, low prevalence of diagnosed COPD and lack of ability to diagnose in primary care. Further questions prioritised for the future included the education of primary care doctors about COPD management.

## Summary

Overall, this review provides a useful summary of the state of COPD health care in four different MICs. While this is by no means a comprehensive analysis, we herein clearly show the need for health-system strengthening to better manage the substantial and increasing burden of COPD, and how these needs may differ substantially between different settings. In practical terms, this summary effectively provided the contextual information required for directing and prioritising research within and beyond the Breathe Well research programme.

## Additional information

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### Other contributions

Alexander d'Elia wrote the first draft of the paper, supervised by Rachel Jordan, and Peymane Adab, and with country-specific input from Chunhua Chi, Zihan Pan, Mariam Maglakelidze, Tamaz Maglakelidze, Katarina Stavrikj, Sonia Maria Martins, Rafael Stelmach. All authors were involved in the initial concept and discussions, and commented on and approved the final draft.

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### **Data-sharing statement**

No original data; queries should be addressed to the corresponding author.

### **Ethics statement**

Ethical approval was not required for this literature review.

### **Information governance statement**

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International Primary Care Respiratory Group and as expert funding panel member for Cancer Research UK. Nicola Gale declares membership of HS&DR Associate Board May 2016–May 2019. Kate Jolly declares Sub-committee chair of NIHR Programme Grants for Applied Health Research (payments to institution). Sue Jowett declares unfunded membership of the HTA Funding Committee Policy Group (formerly CSG) and the HTA Clinical Evaluation and Trials Committee. Alice Sitch declares grant funding to her institution from NIHR Birmingham BRC and AstraZeneca. Alice Turner declares grant funding to her institution from AstraZeneca and Chiesi, payment of honoraria from GSK and Boehringer, support for attending meetings and/or travel from AstraZeneca and Chiesi, membership of HTA Prioritisation Committee B (In hospital) April 2021–March 2024. Siân Williams declares her institution has received conference sponsorship and independent educational grants from Pfizer Global Medical Grants, AstraZeneca, GSK, Boehringer Ingelheim, Vitalograph, Caire Diagnostics and Thorasys. Peymane Adab holds grants from NIHR, MRC and Colt Foundation, has active membership with NIHR PHR as Chair of the Funding Committee, member of Prioritisation Group, PHR Remit Check committee, is Deputy Director of the NIHR SPHR, NIHR Senior Investigator, was a member of several ad hoc funding panels (Palliative and End of Life Care Research Partnerships call panel, NIHR/UKRI ‘Long COVID’ funding call panel, NIHR COVID-19 Recovery and Learning Funding Committee, UKRI Population Health Improvement Clusters Funding panel), is a member of the Irish Health Research Board Funding Committee, the Icelandic Research Fund, Wellcome Trust Early Career Advisory Committee, MRC Cancer Research Forward Look Oversight Group, Expert Advisory Group for NESTA funded ‘Blueprint to Halving Obesity’, member of Obesity Health Alliance Independent Obesity Strategy Working Group member of chair of several research advisory and oversight groups (Chair of TSC for NIHR Funded MapMe trial and NIHR Funded trial to evaluate HENRY, Member of: NIHR/MRC funded Natural Experiments Evaluations Project Oversight Group, International Advisory Board for NIHR-funded GHRC for Multiple Long-Term Conditions, International Scientific Board for UKPRP funded Groundswell, Research Advisory Group for NIHR PRP-funded qualitative study on depression and community-based weight management services), was output assessor for Panel A, subpanel 2 in 2021 Research Excellence Framework. Kar Keung Cheng, Chunhua Chi, Andrew Dickens, Alexandra Enocson, Tamaz Maghlakelidze, Mariam Maghlakelidze, Sonia Martins, Katrina Stavrikj and Zihan Pan have no conflicts to declare.

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## List of abbreviations

CFDA	China Food and Drug Administration
COPD	chronic obstructive pulmonary disease
DALY	disability-adjusted life-year
FHS	Family Health Strategy
GDP	gross domestic product
ICSs	inhaled corticosteroids
LABA	long-acting beta-agonist
MALMED	Medicines are regulated by the Agency for Medicines and Medical Devices
MIC	middle-income country
MoF	Ministry of Finance
MoH	Ministry of Health
MoLHSA	Ministry of Labour, Health and Social Affairs
NEML	National Essential Medicines List
NHC	National Health Commission
NIHR	National Institute for Health and Care Research
NIV	non-invasive ventilation
OOP	out-of-pocket
SABA	short-acting beta-agonist
SUS	Sistema Único de Saúde
UHC	Universal Health Coverage
WHO	World Health Organization

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