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Chronic obstructive pulmonary disease in the adult population within the Middle East and North Africa region: rationale and design of the BREATHE study

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Summary
The objective of the BREATHE study was to estimate the regional prevalence of chronic obstructive pulmonary disease (COPD) symptoms within the general population in the Middle East/North Africa (MENA) region and to document risk factors, disease characteristics and management using a standardised methodology.
This was an observational population-based survey performed in ten countries in the Middle East and North Africa (Algeria, Egypt, Jordan, Lebanon, Morocco, Saudi Arabia, Syria, Tunisia, Turkey and United Arab Emirates), together with Pakistan. A general population sample of 10,000 subjects ⩾40 years of age in each country or zone was generated from random telephone numbers. Structured interviews were proposed by telephone. A screening questionnaire was administered to each subject collecting information on respiratory symptoms and smoking habits. Subjects with chronic bronchitis or breathlessness and smoking ⩾10 pack·years fulfilled the epidemiological definition of COPD ("COPD" population). This population then completed a full disease questionnaire, the COPD Assessment Test (CAT) and a cost-of-disease questionnaire. A randomly selected sample was also assessed by spirometry.
In all, 457,258 telephone numbers were generated and contact was established with 210,121 subjects, of whom 65,154 were eligible and 62,086 accepted to participate. The overall response rate was 74.2%. 2,187 (3.5%) subjects fulfilled the criteria for the "COPD" population. Evaluable spirometry data were obtained from 1,847 (14.2%) subjects to whom it was proposed.

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The BREATHE study has collected a large amount of information on COPD variables from a representative sample of the general population of countries in the MENA region, which can be compared with other regional COPD initiatives.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is defined by the Global initiative for chronic Obstructive Lung Disease (GOLD) as "*a common preventable and treatable disease characterised by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and comorbidities contribute to the overall severity in individual patients*".[1] COPD is a leading cause of morbidity and mortality worldwide. In 2001, the Global Burden of Disease project of the World Health Organisation (WHO) identified COPD as the sixth leading cause of mortality in countries of middle- or low-income, accounting for 4.9% of total deaths.[2] A national study performed between 1980 and 2000 in the USA, identified COPD as the fourth leading cause of chronic morbidity and mortality.[3] In comparison to many other chronic diseases, death rates from COPD continue to rise steadily.[4,5] The WHO estimates that by 2020 COPD will become the third leading cause of death worldwide.[1] COPD is also an important cause of disability and extrapulmonary complications such as depression, diabetes, cardiovascular disease and osteoporosis.[6,7] Although around 90% of deaths due to COPD occur in low- or middle-income countries, very few data on the prevalence of this illness are available in these countries.[8] In contrast, the prevalence of COPD in high-income countries has been well documented. For example, prevalence rates of 18% and 9% have been reported for COPD stages I and II in Iceland,[9] 26.1% and 10.7% in Austria,[10] and 13.2% for stage I in Germany[11] using the BOLD (Burden of Lung Disease) methodology, an initiative set up to collect country-specific data on the prevalence, risk factors and social and economic burden of COPD using structured interviews based on questionnaires and spirometry.[12]

Although COPD is not a curable disease, elimination or reduction of risk factors can prevent the development or slow down the progression of the disease. The main risk factors for the development of COPD are cigarette smoking, increasing age, exposure to air pollutants resulting from the burning of wood or other biomass fuels, tuberculosis and occupational exposures.[13,14] The increase in prevalence of COPD is closely linked to the increase in prevalence of smoking worldwide, particularly among women and adolescents.[15,16]

The main obstacle to the implementation of effective public health strategies aimed at managing and preventing COPD is the lack of data relating to COPD prevalence and burden in low- and middle-income countries. In these countries, accurate prevalence assessment of COPD is very important for many reasons, including the ability to document the impact of COPD on disability, on quality of life, cost of the disease, but also to help in the management of the disease and public health planning through governments and health planners.

In the Middle East and North Africa (MENA) region COPD is underdiagnosed and detected at a late stage.[17] Many people in this region still consider smoking as a socialising factor and it is part of their daily lives. In this region, tobacco smoking, waterpipes (narghile, hookah), use of hashish, and the lack of laws and regulations that ban smoking and water pipes in coffee houses and other public places are major contributors to air pollution and second-hand smoke.[18,19] Waterpipe smoking is prevalent among women because there is less of a cultural stigma attached to it than to cigarette smoking.[20] In the 2011 WHO report on the global tobacco epidemic, smoking rates in the MENA region ranged from 15.1% in Morocco to 38.5% in Lebanon.[7] COPD is therefore a growing problem in MENA due to the lack of awareness of the risks associated with smoking.

In the MENA region, as elsewhere in the developing world, available data on the epidemiology of COPD are limited. Although several local studies have been performed,[21–24] these have not always been population-based or nationwide, and have varied with respect to the age group and the methods used. For these reasons, the data obtained are difficult to compare between studies and with those obtained from other regional initiatives into the epidemiology of COPD such as BOLD,[12] PLATINO[25] and *Confronting COPD*.[26]

For these reasons, we have carried out a large population-based epidemiological study of COPD in the MENA region (BREATHE) using a consistent standardised methodology which is inspired by that used in the *Confronting COPD* surveys in North America and Europe.[26] The objective of the study was to collect standardised population-based data on COPD throughout the region that can be compared to data from other regions of the world. The BREATHE project has collected information on prevalence, burden, management and resource consumption of COPD in eleven countries in the MENA region. This article describes the methodology used in the study.

Objectives

The primary objective of the BREATHE study was to estimate the prevalence of COPD symptoms within the general population of participating countries in the MENA region. Secondary objectives were to document risk factors, to characterise the COPD population, to describe the management and the burden of the disease and to estimate related resource consumption.

Study design

The BREATHE study was a cross-sectional, observational, population-based survey of COPD. The project was conceived as a series of six independent parallel studies

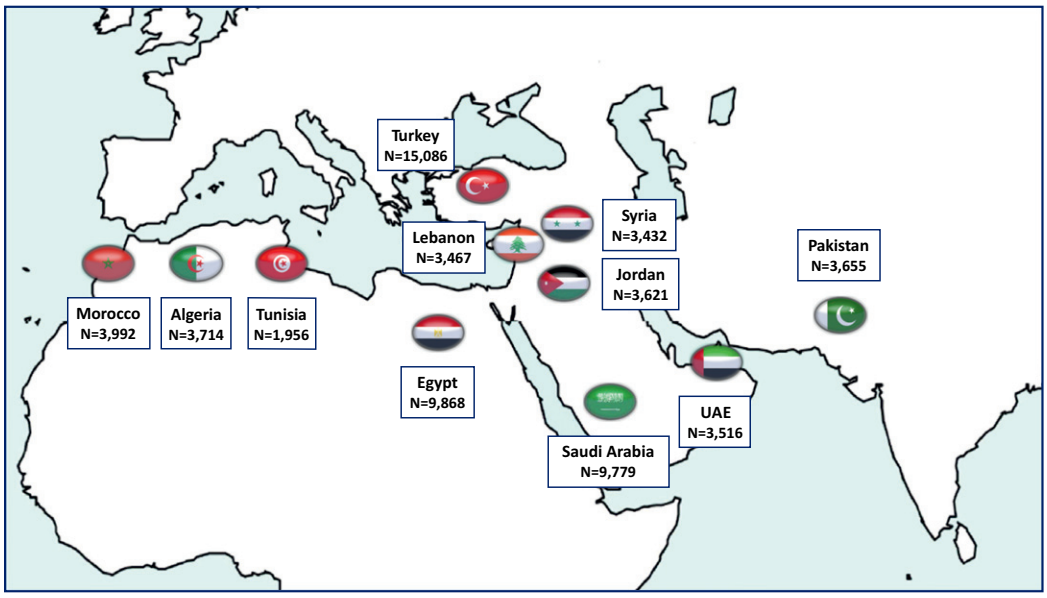

Figure 1. Participating countries and numbers of subjects enrolled in the BREATHE study.

performed using an identical protocol in four individual countries (Egypt, Pakistan, Saudi Arabia and Turkey) and in two zones including more than one country, namely North Africa zone (including Algeria, Morocco, and Tunisia) and Middle East zone (including Jordan, Lebanon, Syria, and UAE). In each of these geographical units, the study was implemented by a specific contract research organisation (CRO). The number of subjects recruited by country is illustrated in Fig. 1.

Feasibility study

Prior to initiating the main survey, a feasibility pilot study was performed in all target countries except Pakistan in order to investigate the performance of the telephone random-dialling method for recruiting subjects and to assess the acceptability of the questionnaires.

Recruitment of the study population

The study was carried out by telephone, allowing the systematic screening of a national sample in order to identify a national probability sample of individuals likely to have COPD. A sample of at least 10,000 subjects among the adult general population of each country or zone was generated using a random stratified sampling method. Telephone numbers (landline and mobile phones) were randomly generated using an assisted random-digit dialling procedure. Numbers were generated by bloc. In a first step, a bloc of 5,000 random phone numbers (landline and mobile) was generated by country or zone and these numbers were all called in order to evaluate the proportion of exploitable numbers. On this basis, the number of further blocs of numbers to be generated in order to achieve the target of at least 10,000 subjects could be estimated. Successive blocs of numbers were then selected until the pre-specified quota of 10,000 interviews was completed in each participating country or zone. In order to optimise the response rates, the next bloc of numbers was only released when the previous bloc had been completed. The process continued until a target sample of at least 10,000 subjects had agreed to participate in each defined country or zone (Table 1).

Subjects were contacted by dialling each telephone number on the list consecutively. In order to optimise contact, each number was dialled up to 15 times on different days including weekends and at different times including evenings until contact was established. After 15 attempts the outcomes were categorised as interview, formal refusal or not a valid number (out of service, professional number or fax or not reachable). When telephone contact was established, the interviewer assessed the eligibility of

Table 1
Number of subjects in each target sample

Country or zone	Target sample
Egypt	10,000
Pakistan	10,000
Saudi Arabia	10,000
Turkey	10,000
Middle East zone	
Jordan	3,500
Lebanon	3,500
Syria	3,500
UAE	3,500
North Africa zone	
Algeria	4,000
Morocco	4,000
Tunisia	2,000

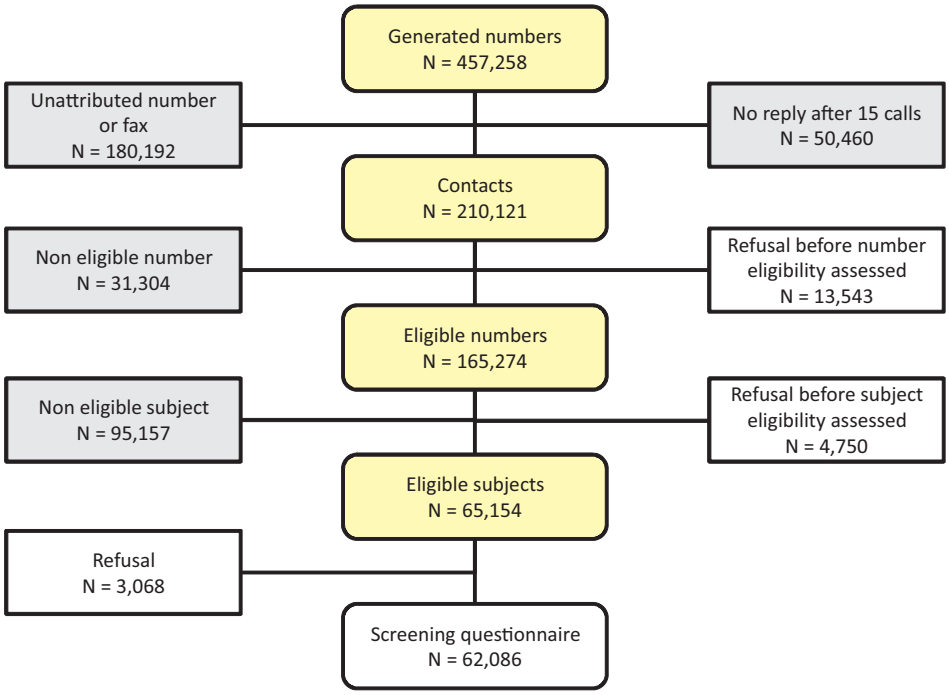

Figure 2. Details of the recruitment phase. Open boxes: subjects taken into account in the determination of the response rate.

the telephone number. Work telephone numbers were considered to be non-eligible. For eligible landline or mobile telephone numbers, the interviewer characterised the subjects in terms of age, gender and region.

Inclusion and exclusion criteria

During the screening phase, male or female subjects aged ⩾40 years, who agreed to participate in the study were enrolled. Subjects not domiciled in the country or those of foreign origin resident in the country for less than six months at the time of the interview or having comorbid mental illness were excluded. Eligible subjects were provided with standardised information about the study, not mentioning COPD in order to avoid potential bias, and were invited to respond to the screening questionnaire.

Subjects recruited

The total number of subjects involved in the recruitment phase for all participating countries is summarised in Fig. 2 and for each country separately in Table 2.

A total of 457,258 telephone numbers was generated and contact was established with a total of 210,121 subjects, of whom 65,154 were eligible to participate in the study. Finally, 62,086 eligible subjects accepted to participate in the study and constituted the screening population. The overall response rate, defined as the ratio between the number of subjects who completed the screening questionnaire and the number of potentially eligible subjects, was 74.2%, ranging from 37.3% in Pakistan to 95.5% in Algeria. As well as subjects who refused to participate, the potentially eligible subjects also included the sets of numbers whose eligibility could not be assessed and the individual subjects whose eligibility could not be assessed. Since these groups of undetermined eligibility will include an undefined number of non-eligible subjects, the response rate provided should be considered a conservative estimate.

In order to ensure representativeness of the population of each country as a whole, cross-stratification was performed to ensure representativeness by age and gender, and margin stratification to ensure representativeness by region (Table 3).

Data collection

Telephone interviews were conducted by ten to twenty interviewers per country. Each interviewer was trained about the study protocol and COPD. Each interview lasted around five minutes for the screening questionnaire and around forty-five minutes for the detailed questionnaire. In a first step, the interviewer administered a screening questionnaire using the Computer Assisted Personal Interviewing (CAPI) method or equivalent. No gifts or incentives were offered to participating subjects.

Subjects fulfilling the screening criteria (see below) were invited to complete a more detailed questionnaire on the disease (detailed COPD patient questionnaire), as well as two questionnaires assessing the severity of COPD (CAT questionnaire) and cost of disease (cost of disease questionnaire). A subset of subjects was asked to perform spirometry in selected centres or at home. All these questionnaires are detailed below. The screening and the detailed COPD patient questionnaires used in this study have been developed from the validated questionnaires provided

Table 2
Key steps of the recruitment phase by participating country

	Algeria		Egypt		Jordan		Lebanon		Morocco		Pakistan		Saudi Arabia		Syria		Tunisia		Turkey		UAE	
Generated numbers, n	**47,000**		**25,000**		**11,895**		**12,332**		**44,000**		**146,926**		**56,000**		**11,774**		**17,500**		**68,675**		**16,156**	
Blocs released	5		3		3		3		7		4		4		3		4		1		4	
Telephone type, n (%)																						
Landlines	12,697	(27.0%)	13,750	(55.0%)	10,824	(91.0%)	11,715	(95.0%)	25,848	(58.7%)	21,191	(14.4%)	10,528	(18.8%)	11,303	(96.0%)	10,999	(62.9%)	68,675	(100.0%)	14,379	(89.0%)
Mobile phone	34,303	(73.0%)	11,250	(45.0%)	1,071	(9.0%)	617	(5.0%)	18,152	(41.3%)	125,735	(85.6%)	45,472	(81.2%)	471	(4.0%)	6,501	(37.1%)	0	(0.0%)	1,777	(11.0%)
Call status, n (%)																						
Wrong number	17,039	(36.3%)	3,526	(14.1%)	3,181	(26.7%)	1,815	(14.7%)	18,518	(42.1%)	100,898	(68.7%)	9,047	(16.2%)	1,167	(9.9%)	1,620	(9.3%)	18,110	(26.4%)	5,271	(32.6%)
Unreachable ⩾15 times	11,517	(24.5%)	2,289	(9.2%)	1,673	(14.1%)	1,721	(14.0%)	5,627	(12.8%)	2,086	(1.4%)	10,984	(19.6%)	2,161	(18.4%)	4,521	(25.8%)	5,608	(8.2%)	2,273	(14.1%)
Refusal	70	(0.1%)	1,343	(5.4%)	383	(3.2%)	1,149	(9.3%)	584	(1.3%)	4,031	(2.7%)	835	(1.5%)	421	(3.6%)	324	(1.9%)	3,304	(4.8%)	1,099	(6.8%)
Contact	18,444	(39.2%)	19,185	(76.7%)	7,041	(59.2%)	8,796	(71.3%)	19,855	(45.1%)	27,457	(18.7%)	35,969	(64.2%)	8,446	(71.7%)	11,359	(64.9%)	44,957	(65.5%)	8,612	(53.3%)
Eligible numbers, n (%)	**18,444**		**19,185**		**7,041**		**8,796**		**19,855**		**27,457**		**35,969**		**8,446**		**11,359**		**44,957**		**8,612**	
Yes	14,165	(76.8%)	17,478	(91.1%)	6,491	(92.2%)	6,886	(78.3%)	9,217	(46.4%)	17,376	(63.3%)	33,336	(92.7%)	7,532	(89.2%)	4,222	(37.2%)	41,417	(92.1%)	7,154	(83.1%)
No	4,209	(22.8%)	364	(1.9%)	167	(2.4%)	761	(8.7%)	10,054	(50.6%)	6,050	(22.0%)	1,798	(5.0%)	493	(5.8%)	6,813	(60.0%)	236	(0.5%)	359	(4.2%)
Call back ⩾10	79	(0.4%)	241	(1.3%)	70	(1.0%)	100	(1.1%)	19	(0.1%)	927	(3.4%)	1,225	(3.4%)	132	(1.6%)	15	(0.1%)	1,902	(4.2%)	253	(2.9%)
Eligible subjects, n (%)																						
Yes	3,740	(20.3%)	10,020	(52.2%)	3,666	(52.1%)	3,629	(41.3%)	4,052	(20.4%)	4,843	(17.6%)	10,001	(27.8%)	3,466	(41.0%)	1,989	(17.5%)	16,108	(35.8%)	3,640	(42.3%)
No	10,346	(56.1%)	7,217	(37.6%)	2,755	(39.1%)	3,157	(35.9%)	5,146	(25.9%)	11,606	(42.3%)	22,110	(61.5%)	3,934	(46.6%)	2,218	(19.5%)	23,407	(52.1%)	3,261	(37.9%)
Refusal	15	(0.1%)	152	(0.8%)	45	(0.6%)	162	(1.8%)	45	(0.2%)	1,170	(4.3%)	144	(0.4%)	34	(0.4%)	33	(0.3%)	981	(2.2%)	124	(1.4%)
Call back ⩾10	11	(0.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	15	(0.1%)	18	(0.1%)	78	(0.2%)	0	(0.0%)	0	(0.0%)	41	(0.1%)	0	(0.0%)
Reasons of ineligibility, n (%)																						
Age < 25 yrs	3,533	(19.2%)	1,714	(8.9%)	961	(13.6%)	779	(8.9%)	1,641	(8.3%)	NA	(0.0%)	1,620	(4.5%)	1,340	(15.9%)	672	(5.9%)	4,046	(9.0%)	918	(10.7%)
Age [25–39] yrs	5,150	(27.9%)	5,227	(27.2%)	1,377	(19.6%)	1,381	(15.7%)	2,786	(14.0%)	NA	(0.0%)	7,396	(20.6%)	2,039	(24.1%)	1,103	(9.7%)	3,119	(6.9%)	1,804	(20.9%)
Quota reached	1,663	(9.0%)	276	(1.4%)	417	(5.9%)	997	(11.3%)	719	(3.6%)	NA	(0.0%)	13,094	(36.4%)	555	(6.6%)	443	(3.9%)	16,242	(36.1%)	539	(6.3%)
Subjects screened, n (%)	**3,714**	**(20.1%)**	**9,868**	**(51.4%)**	**3,621**	**(51.4%)**	**3,467**	**(39.4%)**	**3,992**	**(20.1%)**	**3,655**	**(13.3%)**	**9,779**	**(27.2%)**	**3,432**	**(40.6%)**	**1,956**	**(17.2%)**	**15,086**	**(33.6%)**	**3,516**	**(40.8%)**
Response rate	**95.5%**		**85.0%**		**87.9%**		**71.1%**		**85.8%**		**37.3%**		**81.1%**		**85.4%**		**84.0%**		**70.8%**		**70.4%**	

in the *Confronting COPD* study which was carried out in North America and Europe.[26] A method of translation, back-translation, medical review and linguistic validation was used in order to ensure trans-cultural validation of the questionnaires. All questionnaires were initially translated from English to classical Arabic, Turkish, French and Urdu by local experts. In North Africa, where some groups of the population could potentially not understand some items or words in classical Arabic or French, the questionnaires were translated into local dialectal Arabic or into Berber languages by the local expert.

Screening questionnaire

The screening questionnaire consisted of eighteen questions relating to patient demographics, smoking habits and respiratory symptoms (Table 4).

The objective was to identify eligible subjects who fulfilled the epidemiological case definition of COPD (see Box 1).

The screening questionnaire included six questions to collect data on the presence of respiratory symptoms that fulfilled the definition of chronic bronchitis or breathlessness (symptom criterion), one question to confirm whether COPD or chronic bronchitis or emphysema had been diagnosed (diagnosis criterion), and six questions to collect information on daily smoking, type of tobacco used and frequency of consumption (smoking criterion).

Four categories of subject populations were defined (see Box 1). The first category concerns eligible subjects fulfilling the smoking criterion as well as either the symptom criterion or the diagnosis criterion. This population was identified as the "COPD" population. The second category, identified as the "Possible COPD" population, corresponds to subjects fulfilling either the smoking criterion or the symptoms criterion or the diagnosis criterion. The third category, corresponding to subjects not fulfilling any of these criteria, was identified as the "Non-COPD" population. The fourth category, identified as the "Potential COPD" population, corresponds to those fulfilling at least one of these criteria and thus includes all the "COPD" population as well as subjects in the "Possible COPD" population fulfilling only a single criterion. The purpose of the "Possible COPD" category was just to constitute the "Potential COPD" category, and data for this group have not been analysed specifically.

The data collected in this questionnaire concerned a total of 62,086 subjects in all participating countries. These subjects are also described elsewhere in this supplement in articles dedicated to smoking habits[27] and distribution of COPD symptoms.[28]

Detailed COPD patient questionnaire

Subjects included in the "COPD" population were considered as positively screened and invited to undergo a more detailed telephone questionnaire on the disease (detailed COPD patient questionnaire). This questionnaire consists of seventy-seven questions collecting information on risk factors, disease history, clinical symptoms, impact on daily life and disease management. A total of 2,187 "COPD" subjects were enrolled and 1,392 of them completed the detailed COPD questionnaire (Table 5).

The data collected are presented in the articles dedicated to disease management,[29] to burden of disease,[30] to attitudes and beliefs towards COPD[31] and to healthcare resource consumption.[32]

Cost of disease questionnaire

All subjects in the "COPD population" were invited to complete a cost of disease questionnaire. This questionnaire aimed to assess the cost of COPD and its impact on quality of life and health. It was completed by 1,038 subjects, corresponding to around half (47.6%) of the "COPD" population.

Spirometry

An ancillary study collected data on respiratory function using spirometry from a subpopulation of subjects in order to assess severity of the disease and potentially to substantiate the diagnosis using the GOLD definition (post-bronchodilator FEV_1/FVC ratio < 0.7 AND $FEV_1 < 80\%$ predicted).

A randomly selected subgroup of subjects in the "Potential COPD" group in each country was invited to undergo spirometry. The target sample size was defined for each country according to local capacities in terms of health care resources and the area of residence. The aim was to recruit as many subjects as could be handled comfortably with the resources available. Spirometry was performed in specified centres or alternatively at home, if mobile spirometry equipment (*Vitalograph Alpha IV*®) and trained operators were available locally.

The target sample of the "Potential COPD" group was contacted in order to propose participation and obtain oral consent. For subjects who agreed to participate, an appointment was made for the spirometric assessment. When the subject attended the appointment, written informed consent was obtained according to local laws and subjects were assessed for comorbidities incompatible with performing spirometry. Spirometry was performed by a pulmonologist or experienced technician using a standardised protocol and equipment that met or exceeded the minimum performance standardised of the American Thoracic Society.[33] Lung function measurements were obtained, FEV1 and FVC being assessed according to the recommendations of the American Thoracic Society.[33] At the time of this visit, all subjects were also invited to complete the COPD Assessment Test during a face-to-face interview (see below) as well as a questionnaire on their air quality environment.

Spirometry was proposed to 12,967 (67.2%) of the "Potential COPD" group (Fig. 3). Of these, 5,213 (40.2%) agreed to participate and 1,892 (14.6%) actually attended their spirometry visit. Evaluable data were obtained from 1,847 subjects.

Table 3
Demographics of the study population (Screened) compared to the expected data (Expected) of the participating countries

	Algeria		Egypt		Jordan		Lebanon		Morocco		Pakistan		Saudi Arabia		Syria		Tunisia		Turkey		UAE	
	Screened	Expected	Screened	Expected	Screened	Expected	Screened	Expected	Screened	Expected	Screened	Expected	Screened	Expected	Screened	Expected	Screened	Expected	Screened	Expected	Screened	Expected
N	**3,714**	**4,000**	**9,868**	**10,000**	**3,621**	**3,500**	**3,467**	**3,500**	**3,992**	**4,000**	**3,655**	**10,000**	**9,779**	**10,000**	**3,432**	**3,500**	**1,956**	**2,000**	**15,086**	**10,003**	**3,516**	**3,500**
By gender																						
Women	1,823	1,978	4,960	48,888	1,777	1,699	1,796	1,770	2,027	2,028	1,496	4,802	3,392	4,463	1,773	1,704	998	998	8,694	5,143	1,687	1,109
(%)	(49.1%)	(49.4%)	(50.3%)	(48.9%)	(49.1%)	(48.5%)	(51.8%)	(50.6%)	(50.8%)	(50.7%)	(40.9%)	(48.0%)	(34.7%)	(44.6%)	(51.7%)	(48.7%)	(51.0%)	(49.9%)	(57.6%)	(51.4%)	(48.0%)	(31.7%)
Men	1,891	2,022	4,908	5,112	1,844	1,801	1,671	1,730	1,966	1,972	2,159	5,198	6,387	5,537	1,659	1,796	958	1,002	6,392	4,860	1,829	2,391
(%)	(50.9%)	(50.6%)	(49.7%)	(51.1%)	(50.9%)	(51.5%)	(48.2%)	(49.4%)	(49.2%)	(49.3%)	(59.1%)	(52.0%)	(65.3%)	(55.4%)	(48.3%)	(51.3%)	(49.0%)	(50.1%)	(42.4%)	(48.6%)	(52.0%)	(68.3%)
p-value	*0.73*		*0.03*		*0.52*		*0.15*		*0.93*		*<0.0,001*		*<0.0,001*		*0.0,005*		*0.16*		*<0.0,001*		*<0.0,001*	
By age (years)																						
40–49	1,688	1,699	4,312	4,431	1,609	1,571	1,376	1,220	1,752	1,760	1,802	4,748	5,909	5,461	1,764	1,592	837	840	5,752	3,933	2,016	2,380
(%)	(45.4%)	(42.5%)	(43.7%)	(443%)	(44.4%)	(44.9%)	(39.7%)	(34.9%)	(43.9%)	(44.0%)	(49.3%)	(47.5%)	(60.4%)	(54.6%)	(51.4%)	(45.5%)	(42.8%)	(42.0%)	(38.1%)	(39.3%)	(57.3%)	(68.0%)
50–59	1,125	1,122	3,314	3,043	1,018	923	991	892	1,022	1,020	1,089	2,854	2,677	2,400	977	951	513	508	4,606	2,868	1,095	865
(%)	(30.3%)	(28.0%)	(33.6%)	(30.4%)	(28.1%)	(26.4%)	(28.6%)	(25.5%)	(25.6%)	(25.5%)	(29.8%)	(28.5%)	(27.4%)	(24.0%)	(28.5%)	(27.2%)	(26.2%)	(25.4%)	(30.5%)	(28.7%)	(31.2%)	(24.7%)
⩾60	901	1,179	2,242	2,526	994	1,006	1,100	1,388	1,218	1,220	764	2,398	1,193	2,139	691	957	606	652	4,728	3,202	405	255
(%)	(24.3%)	(29.5%)	(22.7%)	(25.3%)	(27.5%)	(28.7%)	(31.7%)	(39.6%)	(30.5%)	(30.5%)	(20.9%)	(24.0%)	(12.2%)	(21.4%)	(20.1%)	(27.3%)	(31.0%)	(32.6%)	(31.3%)	(32.0%)	(11.5%)	(7.3%)
p-value	*<0.0,001*		*<0.0,001*		*0.04*		*<0.0,001*		*0.99*		*0.09*		*<0.0,001*		*<0.0,001*		*0.30*		*<0.0,001*		*<0.0,001*	
By region																						
p-value	*0.27*		*0.62*		*<0.0,001*		*<0.0,001*		*0.99*		*<0.0,001*		*<0.0,001*		*0.99*		*0.99*		*<0.0,001*		*<0.0,001*	

COPD Assessment Test

A second ancillary study investigated health status using the COPD Assessment Test (CAT).[34,35] The CAT has been translated into over fifty different languages as part of a large international programme available on the CAT website (http://www.catestonline.org/). The Arabic and Turkish versions used in this study were created and validated as part of this programme. As well as collecting data on the subjects included, this ancillary study also allowed further psychometric validation of the CAT questionnaire and determination of its internal consistency, reliability, reproducibility, discriminant validity and sensitivity in a previously unstudied population group. The CAT questionnaire was completed by three groups of subjects. The first group consisted of the first 5,681 subjects, which represent around 10% of the total number of screened subjects during the BREATHE survey, and who were all invited to complete the CAT at the end of the screening questionnaire. The second group consisted of all subsequent subjects who were identified as "COPD" (both smoking and symptoms/diagnosis criteria fulfilled) during the screening phase, and who completed the CAT at the same time as the detailed COPD questionnaire and the cost of disease questionnaire (Fig. 4). The third group consisted of all subjects who attended a spirometry visit in the ancillary spirometry study (see above), who completed the CAT during a face-to-face interview at the time of the visit. Since the spirometry study drew patients from the "Potential COPD" group, it was possible for these subjects to have already completed the CAT during the telephone interview, and two questionnaires are thus available for these subjects.

A total of 8,368 complete questionnaires were collected from 62,086 subjects, of which 5,639 derived from screening of the initially enrolled subjects, from the general population, 1,035 derived from the subsequently enrolled "COPD" population and 1,694 from the subjects assessed by spirometry. The latter group included 535 questionnaires from subjects in the "COPD" group and 174 in the "Possible COPD" group who had previously completed a questionnaire during the screening phase. Further details of the methodology as well as the results of the CAT study are described elsewhere in this supplement.[36]

Statistical analysis

Data are presented as proportions and means with standard deviations (SD), or medians with interquartile ranges (IQR). 95% confidence intervals (95% CI) were calculated for binomial data. Associations between categorical variables were estimated using the χ^2 test and the Mantel–Haenszel test for trends, as appropriate. Two-sided tests were used in all cases and a probability threshold of 0.05 was considered significant. Bonferroni correction was applied for multiple testing procedures, when appropriate. All statistical analyses were performed using SPSS Version 17 (IBM Corp, Armonk, NY).

Prevalence rates were estimated separately for each country by dividing the total number of positively screened subjects by the total number of screened subjects. Prevalence rates were adjusted for age and gender. The response rate was the overall number of screened subjects divided by the total number of potentially eligible subjects for whom contact could be established. More specific statistical approaches are described wherever appropriate in the other articles in this supplement.

Discussion

In this survey, over 60,000 subjects in eleven countries in the MENA region were screened for information on respiratory symptoms and smoking habits. The response rate was $\geqslant$70% in all countries (except Pakistan, where the conduct of the study was affected by geopolitical instability), suggesting that the data obtained should be relatively representative of the target populations in each country. Comparison of the demographic features of the screened subjects with national census data suggests that the survey population was indeed representative. It should be noted that the study was performed during a year (2011) of considerable political movement in several of the participating countries (Arab spring).

When planning the BREATHE study, a number of strategic decisions had to be taken. The first related to the reference frame. Previous large regional epidemiological studies on COPD have used either home-based interviews exclusively, such as *Confronting COPD,*[26] or systematic standardised spirometry, such as BOLD[12] or PLATINO.[25] The spirometry-based surveys have the advantage of providing reliable data on the number of COPD cases, since these are ascertained objectively by spirometry, but may suffer from suboptimal representativity as the evaluated subjects have to be able and willing to go to a health centre for spirometry evaluation. On the other hand, the interview-based surveys rely on respondent self-reporting for identifying COPD cases, which may be less accurate, but can provide more complete coverage of the population. In the BREATHE survey, our ambitious goal was to combine the advantages of both reference frames in a clustered design in which spirometry was proposed to a subgroup of respondents who reported features consistent with an epidemiological definition of COPD. In this way we hoped to optimise the estimate of the prevalence of COPD by combining the high-quality numerator of the spirometry studies with the high quality denominator of the interview-based study. This goal was only partially met. Although the response rate to the interviews of $\geqslant$70% was respectable, the proportion of subjects undergoing spirometry was low (14.2% of respondents to whom it was proposed). Our study illustrates the difficulty of collecting information necessitating specific paraclinical tests using random sampling of the general population. Approaches such as that used in the BOLD studies,[12] where specialist centres targeted individuals living in their catchment area, may be better adapted to collecting such data.

The second major strategic choice that had to be made related to data acquisition. We chose to contact respondents through random telephone dialling. Face-to-face interviews during household visits were not practical for the screening

Table 4
Questions presented in the screening questionnaire

1. (What is the gender/sex of the respondent)?
   a. Male
   b. Female
2. Where do you fall in the following age range?
   a. <25 years
   b. 26–39 years
   c. 40–49 years
   d. 50–59 years
   e. ⩾60 years
3. How many phone numbers do you have other than this one (mobile and landline)?
4. Do you suffer from any of the following health conditions?
   a. Diabetes
   b. Hypertension
   c. Any cardio-vascular diseases
   d. Renal disease
   e. Neurological disease
   f. Liver disease
   g. Asthma
   h. Migraine
   i. Eye diseases
   j. Digestive diseases
   k. Any other condition
      If yes, specify
5. Do you suffer from persistent bronchitis or coughing with phlegm or sputum from the chest for the last 2 years or more?
6. How many MONTHS in the past 12 months have you had bronchitis or chronic coughing with phlegm/sputum from the chest?
7. For how many years have you had bronchitis or chronic coughing with phlegm/sputum from the chest for at least 3 months?
8. At what age did you first develop bronchitis or coughing with phlegm or sputum?
9. Have you been repeatedly short of breath over the past 12 months?
10. At what age did you first develop shortness of breath?
11. Do you suffer from any of the following respiratory conditions?
    a. Emphysema
    b. Chronic bronchitis
    c. Chronic Obstructive Pulmonary Disease (COPD)
       or Chronic obstructive airways disease (COAD)
       or Chronic obstructive lung disease (COLD)
    d. α_1 antitrypsin deficiency
12. At what age did you first develop this respiratory condition?
13. Have you ever smoked cigarettes on a daily basis?
14. If yes in Q13, for how many years, in total, have you smoked cigarettes on a daily basis?
15. If yes in Q13, how many cigarettes do you/did you smoke per day, on average?
16. Have you ever smoked waterpipes on a daily basis?
17. If yes in Q16, for how many years, in total, have you smoked waterpipes on a daily basis?
18. If yes in Q16, how many hours do you/did you smoke waterpipes per day, on average?

Box 1. Definitions used in the study

Definition of chronic bronchitis: The GOLD definition of chronic bronchitis was used in the study: "the presence of cough and sputum production for at least 3 months in each of two consecutive years", not necessarily associated with airflow limitation.[1]

Epidemiological definition of COPD: "COPD" cases were defined as eligible subjects fulfilling BOTH the following criteria 1 and 2:

(1) EITHER
   (a) Diagnosis criterion: already diagnosed with COPD, emphysema or chronic bronchitis, OR
   (b) Symptom criterion: presenting EITHER with symptoms that fulfil the definition of chronic bronchitis OR with dyspnoea.

(2) AND
   Smoking criterion: lifetime smoking exposure of $\geqslant$10 pack·years.

Study populations: Four populations were characterised:

"COPD" population: eligible subjects fulfilling the epidemiological definition of COPD (both smoking and symptoms/diagnosis criteria fulfilled)

"Possible COPD" population: eligible subjects fulfilling either the smoking criterion or the symptoms/diagnosis criterion, but not both.

"Non-COPD" population: eligible subjects fulfilling neither criterion.

"Potential COPD" population: eligible subjects fulfilling at least one criterion. This group thus includes both the "COPD" and the "Possible COPD" groups.

Table 5
Classification of eligible subjects according to COPD criteria and number of detailed COPD interviews

	Gender, n (%)		Age groups, n (%)			Total, n (%)
	Men	Women	40–49 years	50–59 years	$\geqslant$60 years	
Subjects screened	31,673 (51.0%)	30,413 (49.0%)	28,815 (46.4%)	18,427 (29.7%)	14,844 (23.9%)	62,086 (100%)
Smoking and symptoms/diagnosis criteria fulfilled ("COPD" population)						
Yes	1,632 (5.2%)	555 (1.8%)	895 (3.1%)	726 (3.9%)	566 (3.8%)	2,187 (3.5%)
No	29,938 (94.5%)	29,769 (97.9%)	27,829 (96.6%)	17,656 (95.8%)	14,222 (95.8%)	59,707 (96.2%)
Possible COPD	11,254 (35.5%)	5,847 (19.2%)	7,306 (25.4%)	5,369 (29.1%)	4,426 (29.8%)	17,101 (27.5%)
No COPD	18,684 (59.0%)	23,922 (78.7%)	20,523 (71.2%)	12,287 (66.7%)	9,796 (66.0%)	42,606 (68.6%)
Missing data	103 (0.3%)	89 (0.3%)	91 (0.3%)	45 (0.2%)	56 (0.4%)	192 (0.3%)
COPD interviews						
Yes	1,052 (64.5%)	340 (61.3%)	535 (59.8%)	487 (67.1%)	370 (65.4%)	1,392 (63.8%)
No	580 (35.5%)	215 (38.7%)	360 (40.2%)	239 (32.9%)	196 (34.6%)	795 (36.4%)

phase due to the large areas with poor access to be covered in certain countries. Although this would probably have facilitated contact with respondents and potentially improved response rates, making household visits would have entailed many months of fieldwork in order to reach the target sample size set for the survey. A postal survey was rejected given the low response rate often associated with this form of data acquisition, and because literacy rates were low in some of the regions targeted. Nonetheless, it is recognised that anonymous data collection through a postal survey may generate more accurate data with regard to culturally sensitive items such as smoking habits than direct interview. Random telephone dialling was thus chosen for the screening phase of the study as it provides the best compromise to reach a representative sample of the target population with an acceptable response rate in a relatively short timeframe. It was recognised that contacting respondents by telephone may limit enrolment of women, who may not participate in telephone interviews because of cultural or religious barriers, and for this reason, enrolment was stratified by gender. In the event, the expected cohort of women was enrolled in all countries except Saudi Arabia and Pakistan, where women were somewhat under-represented.

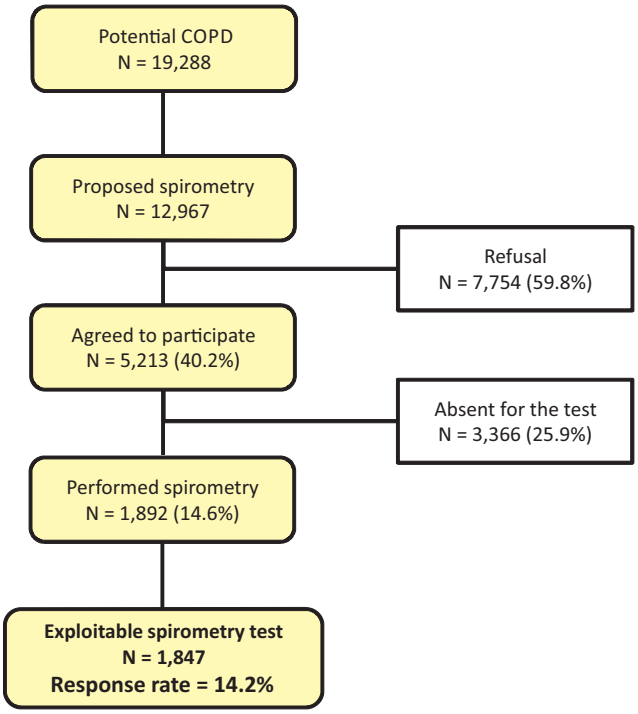

Figure 3. Study populations for the ancillary spirometry study.

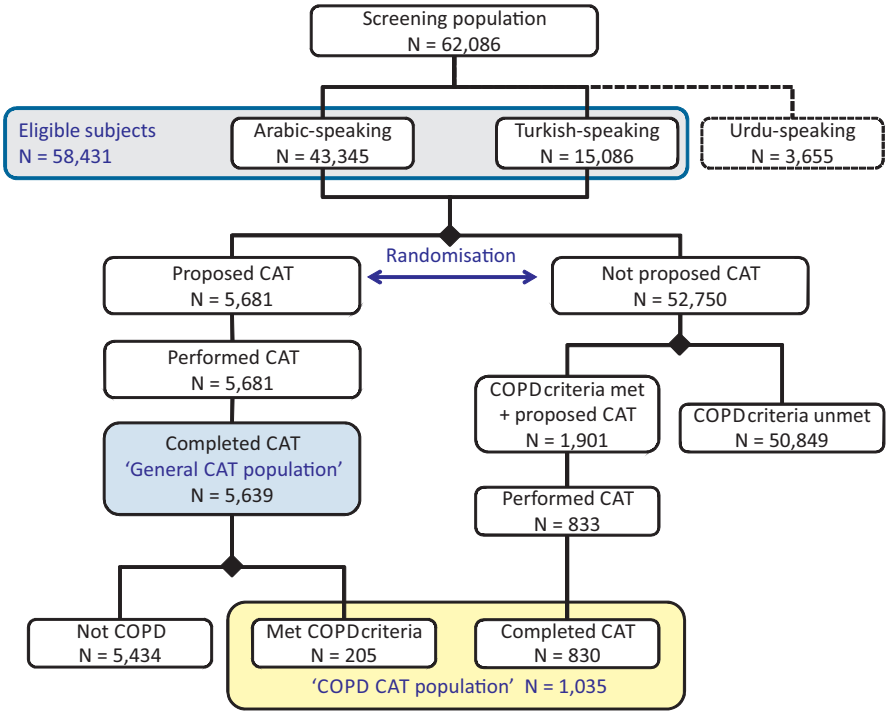

Figure 4. Study populations for the CAT study.

It was decided to exploit both mobile telephone numbers and landlines. In many countries in the region, landline coverage is poor, for example in Algeria where only 43.1% of households have access to a landline, compared to 92.7% of the population who have a mobile telephone.[37] Use of landlines only would thus have introduced a potential sampling bias due to the unequal distribution of landline coverage, for example leading to an over-representation of urban areas. The extent of landline and mobile telephone coverage in each participating country is provided in Table 6. On the other hand, respondents reached through a landline at home may be more receptive to being interviewed than those contacted outside on their mobile telephone. Indeed, during the feasibility study, the acceptance rate for

mobile telephone contacts in Turkey was poor. Since landline coverage is extensive in this country (81.6%), it was decided to exploit landlines only in Turkey.

Table 6
Landline and mobile telephone coverage in the general population of participating countries[a]

Country	Total population	Subscribers (% of general population)	
		Landline	Mobile
Algeria	34,080,030	43.1%	92.7%
Egypt	72,798,031	54.6%	87.0%
Jordan	5,103,639	47.7%	91.0%
Lebanon	3,759,135	71.9%	83.0%
Morocco	29,891,708	65.9%	87.8%
Pakistan	132,352,279	96.0%	86.0%
Saudi Arabia	22,678,262	56.2%	89.8%
Syria	17,874,589	96.4%	70.0%
Tunisia	9,910,872	54.7%	87.4%
Turkey	73,722,988	81.6%	79.5%
UAE	4,106,427	100.0%	78.0%

[a] Data were obtained from the relevant government sources in each country.

Interviewees were thus reached by both mobile telephones and landlines, proportionally to the telephone coverage in each country, with the exception of Turkey, where only landlines were used. The number of successive blocs of numbers released was adapted to each country according to telephone coverage and use patterns. In order to optimise representativeness, each successive bloc was only released when the previous one had been completed, either through a successful contact or through failure to establish contact after fifteen attempts. In each call centre, the most successful interviewers were systematically assigned to numbers that appeared difficult to contact or where respondents who had been asked to be called back were difficult to recontact.

This method proved to be successful and nearly 500,000 numbers were generated and dialled over a period of 56 weeks, resulting in over 200,000 contacts and the identification of 65,154 potentially eligible subjects. Less than five percent of these potentially eligible subjects contacted refused to participate. The large number of individuals screened allowed the constitution of a panel of 2,187 subjects fulfilling the epidemiological definition of "COPD" who reported both symptoms consistent with a diagnosis of COPD and regular smoking. It has been possible to collect a large amount of data from this panel through the in-depth survey questionnaires, and the panel thus constitutes, to our knowledge, the largest database of potential COPD patients identified from the general population in this region of the world.

The study methodology has a number of limitations, most of which are direct consequences of the sampling and data collection methods which were chosen to optimise the reach of the survey. For example, contacting potential participants by telephone necessarily excludes individuals who do not have telephones, who may be older or live in more remote rural areas. This may introduce some bias if, for example, these individuals present different risk factors. A related issue is that the criteria for the epidemiological definition of COPD required respondents to be smokers. This requirement, which was also used in the *Confronting COPD* surveys,[26] was motivated by the fact that smoking is by far the most important risk factor for COPD in industrialised countries. However, other risk factors, such as exposure to smoke from biomass fuel, may be very important in some regions of the MENA region. For this reason, the epidemiological definition used may underestimate the real prevalence of COPD symptoms. Finally, data were collected over the telephone by lay interviewers with no attempt to ascertain information on clinical symptoms, diagnosis or treatments used, which may have compromised accuracy. Similarly, since data were collected by direct interview rather than on an anonymous postal questionnaire, it is possible that the accuracy of some of the data, notably with respect to smoking habits, may be suboptimal.

In conclusion, the BREATHE study has collected a large amount of information on COPD related variables from an extensive cohort of members of the general population of countries in the MENA region using a standardised methodology comparable to that previously used in the *Confronting COPD* surveys in North America and Europe. The data collected allow the frequency of smoking and of respiratory symptoms in participating countries to be estimated and compared with precision. The detailed findings of the BREATHE study are described in other articles in this supplement.

Conflict of interest statement

AEH and NR are employees of GlaxoSmithKline Laboratories, which funded the BREATHE study and market a number of treatments for COPD. AL is a director of MS Health, the clinical and epidemiological research company responsible for implementation of the study, collection of the data and statistical analysis of the results of the BREATHE study on behalf of GlaxoSmithKline Laboratories. HS and AD are employees of Foxymed, a medical communication and consultancy company which participated in the exploration and interpretation of the results of the BREATHE study on behalf of GlaxoSmithKline Laboratories and prepared the manuscripts for publication. CN advised on the data management and statistical analysis of the results of the BREATHE study on behalf of GlaxoSmithKline Laboratories.

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