The national COPD screening programme in China: rationale and design

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The national COPD screening programme is the first large-scale prospective study to determine the net benefit of mass screening for COPD in China. The programme aims for remarkable achievements in management of chronic respiratory disease in China. https://bit.ly/3Hi475g

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Abstract

Background COPD is the most prevalent chronic respiratory disease in China. It is estimated that there is a large, as-yet undetected, high-risk population who will develop in COPD in future.

Methods and design In this context, a nationwide COPD screening programme was launched on 9 October 2021. This multistage sequential screening programme incorporates a previously validated questionnaire (*i.e.* COPD Screening Questionnaire) and pre- and post-bronchodilator spirometry to target the COPD high-risk population. The programme plans to recruit 800 000 participants (eligible age 35–75 years) from 160 districts or counties of 31 provinces, autonomous regions or municipalities across China. The filtered COPD high-risk population and early-detected COPD patients will receive integrated management and be followed-up for ⩾1 year.

Discussion This is the first large-scale prospective study to determine the net benefit of mass screening for COPD in China. Whether the smoking cessation rate, morbidity, mortality and health status of individuals at high risk of COPD could be improved along with this systematic screening programme will be observed and validated. Moreover, the diagnostic accuracy, cost-effectiveness and superiority of the screening programme will also be assessed and discussed. The programme marks a remarkable achievement in the management of chronic respiratory disease in China.

Background

COPD is the most prevalent chronic respiratory disease in China. According to the China Pulmonary Health study, one of the largest cross-sectional surveys on chronic respiratory disease in China, the prevalence of spirometry-defined COPD in Chinese adults was 8.6%, accounting for 99.9 million people [1]. Of note, a previous pulmonary function test had been conducted in only 9.7% of the entire study population, in 12.0% of the confirmed COPD patients and in 55.8% of the people with a self-reported history of COPD [1]. Besides, only 2.6% of the confirmed COPD patients were aware of their respiratory condition [1]. Another nationwide survey also reported an overall low rate of 10.8% pulmonary function test implementation in primary healthcare in China [2]. These data indicated large unmet needs, both from the perspectives of demand and supply, in the prevention and management of COPD in China.

Beyond the large number of confirmed cases, it is believed that there exists a much larger population at high risk of COPD not yet diagnosed as COPD, but which has a high probability of developing COPD in the future. However, the definition of this population has not gained a global consensus; the terms Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage 0 [3], pre-COPD [4] or early COPD [5] are sometimes used. In these cases, many research questions are unanswered, *e.g.* the precise definition of the pre-clinical stage of the disease, the prevalence and epidemiological characteristics of the high-risk population, the development and prognosis of the disease at an early stage, *etc*.

Meanwhile, the United States Preventive Services Task Force (USPSTF) [6, 7], the GOLD scientific committee [8, 9], the American College of Physicians, the American College of Chest Physicians, the American Thoracic Society (ATS) and the European Respiratory Society (ERS) [10] have all recommended against mass screening for COPD in asymptomatic adults, since no net benefit has been proven; the optimal screening strategies for COPD are still controversial [11–13]. In this context, an active or opportunistic case-finding scheme is proposed [14]. The case-finding method refers to identifying COPD patients among the population who are exposed to high-risk factors (*e.g.* cigarette smoke) and present with significant respiratory symptoms (*e.g.* cough, sputum, dyspnoea, wheeze) that are relevant to COPD [15]. If the approach is employed as part of routine care for those who visit clinics for respiratory disease, it is opportunistic case-finding; if the approach is adopted in target population with self-reported risk factor exposure and/or chronic respiratory symptoms, it is active case-finding [15]. Many countries, for example Finland [16], Denmark [17, 18], the United Kingdom [19–21], Poland [22–24], India [25], Nepal, Peru and Uganda [26–28] have attempted to find suitable screening strategies to improve early management of COPD. In China, the design, implementation, cost and effectiveness of a feasible COPD screening scheme must be determined.

In July 2020, the central government of China launched a national project and offered government funds for the purchase of portable spirometers for 50% of primary care institutions, and to provide primary care workers with professional training, aiming to improve their capabilities in the early detection and management of COPD [29]. A year later, in October 2021, the central government initiated another programme for national COPD screening, and authorised the National Center for Respiratory Diseases as the leading organisation [30]. The screening programme uses a previously validated questionnaire and a portable spirometer to target the COPD high-risk population, which is defined based on high-risk factor exposure, respiratory symptoms and pulmonary function. The screening is voluntary for residents, in an active case-finding framework. The programme has a multistage design, involving primary care institutes and superior specialised hospitals, with ultimate goals to facilitate early detection of COPD in a primary area, to prevent severe outcomes and to reduce the burden of the disease.

Materials and methods

Objectives

The major objectives of this national COPD screening programme are 1) to determine the prevalence and characteristics of population at high risk of COPD and those with underdiagnosed or misdiagnosed COPD; 2) to prospectively investigate whether smoking cessation rate, morbidity, mortality and health-related quality of life would be significantly improved with a systematic screening programme; and 3) to assess the cost-effectiveness, cost–utility and cost–benefit of the multistage screening scheme.

Design

This screening programme is cross-sectional at baseline; the filtered COPD high-risk population and confirmed COPD patients will be prospectively followed-up according to planned schedules.

Participants

Adults who are potentially at high risk of COPD with an age between 35 and 75 years are eligible to be recruited. Moreover, the participants should be residents who have lived in the survey area for >6 months in the past year. Participation in the screening programme is voluntary, but signed informed consent is required. The exclusion criteria are 1) experienced myocardial infarction, stroke or shock in the past 3 months; 2) experienced severe cardiac insufficiency, severe arrhythmia or unstable angina pectoris in the past 4 weeks; 3) experienced massive haemoptysis in the past 4 weeks; 4) received chest, abdominal or ophthalmic surgery in the past 3 months; 5) mental disorders (*e.g.* auditory hallucinations, visual hallucinations, seizures requiring medication, taking antipsychotics, *etc*.); 6) cognitive impairment (*e.g.* dementia, impairment of comprehension, *etc*.); 7) uncontrolled hypertension (*i.e.* systolic blood pressure >200 mmHg and/or diastolic blood pressure >100 mmHg); 8) heart rate >120 beats·min^{-1}; 9) aortic aneurysm; 10) severe hyperthyroidism; 11) pregnant or lactating women; and 12) experienced respiratory infection (*e.g.* tuberculosis, influenza, *etc*.) in the past month.

It is hypothesied that the statistical significance level (α) is 0.05, the admissible error (δ) is 0.08, the screening sensitivity (P) is 0.80, and the specificity (P) is 0.70. The following formula is used to estimate the sample size [31]:

$$n = \left[\frac{57.3 \times Z_{\alpha}}{\sin^{-1}(\delta/\sqrt{P(1-P)})}\right]^2$$

The required numbers of samples with true positive and true negative screening results are 311 088 and 409 637, respectively. If accounting an attrition rate of 10%, ⩾792 798 samples are needed.

Thus, this screening programme plans to recruit a total of 800 000 participants from 160 districts or counties (5000 for each site on average) in 31 provinces, autonomous regions or municipalities directly under the central government of China. The planned recruitment numbers are listed in table 1.

Implementation

The national COPD screening programme was launched officially on 9 October 2021. This programme incorporates multistage sequential screening strategies, as follows.

TABLE 1 The distribution of participants across the country

Province, autonomous region or municipality	Sites	Participants	Participants receiving post-bronchodilator spirometry test	Population aged 35–74 years	Percentage[#] (%)
Beijing	3	15 000	3000	11 860 964	0.13
Tianjin	3	15 000	3000	7 559 439	0.20
Hebei	5	25 000	5000	38 342 793	0.07
Shanxi	5	25 000	5000	18 466 697	0.14
Inner Mongolia	5	25 000	5000	14 081 188	0.18
Liaoning	4	20 000	4000	26 207 774	0.08
Jilin	4	20 000	4000	14 786 743	0.14
Heilongjiang	4	20 000	4000	20 154 123	0.10
Shanghai	3	15 000	3000	13 875 654	0.11
Jiangsu	5	25 000	5000	45 570 361	0.05
Zhejiang	5	25 000	5000	35 373 034	0.07
Anhui	5	25 000	5000	30 609 324	0.08
Fujian	5	25 000	5000	20 940 665	0.12
Jiangxi	5	25 000	5000	21 904 871	0.11
Shandong	10	50 000	10 000	53 892 301	0.09
Henan	10	50 000	10 000	46 540 628	0.11
Hubei	5	25 000	5000	31 316 764	0.08
Hunan	10	50 000	10 000	34 357 869	0.15
Guangdong	5	25 000	5000	57 427 593	0.04
Guangxi	5	25 000	5000	23 647 053	0.11
Hainan	8	40 000	8000	4 748 055	0.84
Chongqing	3	15 000	3000	16 765 758	0.09
Sichuan	8	40 000	8000	44 212 185	0.09
Guizhou	5	25 000	5000	17 314 408	0.14
Yunnan	8	40 000	8000	23 125 720	0.17
Tibet	2	10 000	2000	1 480 892	0.68
Shaanxi	5	25 000	5000	20 324 545	0.12
Gansu	5	25 000	5000	12 740 471	0.20
Qinghai	2	10 000	2000	2 836 927	0.35
Ningxia	5	25 000	5000	3 437 729	0.73
Xinjiang	3	15 000	3000	11 834 237	0.13
Total	160	800 000	160 000	725 736 765	0.11

Data are presented as n, unless otherwise stated. [#]: calculated as (the number of participants/the number of population aged 35–74 years)×100% in each province, autonomous region or municipality. Information from [32].

Step 1

Firstly, the organisers broadly promote the COPD screening programme through multiple media (*e.g.* television, mobile phone, broadcast, internet, newspaper, *etc*.) in communities. The residents who are interested and are willing to participate in the programme are instructed to complete an online screening questionnaire *via* their mobile phones. The COPD Screening Questionnaire (COPD-SQ; supplementary table S1) is a previously validated questionnaire; a score of ⩾16 indicates a higher probability of COPD [33]. The COPD-SQ has been recommended to be used in the primary care setting for COPD screening in China [34–36]. Those who have a COPD-SQ score <16 are considered non-COPD high-risk.

Step 2

The residents who have a COPD-SQ score ⩾16 and meet the inclusion and exclusion criteria should make an appointment for an on-site screening within 3 months. They will be asked to sign a paper informed consent form and complete another detailed survey questionnaire (including demographic information, smoking status, physical activities and medical history on respiratory disease) and undergo anthropometry measurement (including height, weight, waist and hip circumferences, blood pressure, heart rate and pulse oxygen saturation).

Step 3

A pre-bronchodilator pulmonary function test *via* a spirometer is administrated to participants. The collected indices mainly include forced expiratory volume in 1 s (FEV_1), FEV_1 % predicted, forced vital capacity (FVC), FVC % pred, FEV_1/FVC ratio, peak expiratory flow (PEF) and PEF % pred. Participants with COPD-SQ scores ⩾16 and pre-bronchodilator FEV_1/FVC ⩾0.70 are categorised as COPD high-risk population I. This population will receive customised and integrated management, which includes in-time intervention; telephone follow-up and secondary intervention at month six; and face-to-face follow-up and intervention at month 12.

Step 4

For those participants who have a COPD-SQ score ⩾16 and a pre-bronchodilator FEV_1/FVC <0.70, a post-bronchodilator pulmonary function test is performed. Participants with COPD-SQ scores ⩾16, pre-bronchodilator FEV_1/FVC <0.70 and post-bronchodilator FEV_1/FVC ⩾0.70 are grouped as COPD high-risk population II. This population will also receive customised and integrated management, which includes in-time intervention; face-to-face follow-up and secondary intervention at month six; and face-to-face follow-up and intervention at month 12.

Step 5

Participants with COPD-SQ scores ⩾16, pre-bronchodilator FEV_1/FVC <0.70 and post-bronchodilator FEV_1/FVC <0.70 will be suspected COPD patients. These suspected patients will be referred to a superior specialised hospital for definite diagnosis and further treatment.

Step 6

Participants having a verified post-bronchodilator FEV_1/FVC <0.70 in the superior hospital are confirmed COPD patients after excluding other obstructive lung diseases, according to the diagnostic criteria of COPD in the GOLD 2021 report [37]. Otherwise, if the participant has a post-bronchodilator FEV_1/FVC ⩾0.70 in the superior hospital, he or she belongs to COPD high-risk population II. The confirmed COPD patients will receive more intensive management, which includes: in-time intervention; telephone follow-up at month one; telephone follow-up and secondary intervention at month three; and face-to-face follow-up and intervention at month 12. If the participants are diagnosed with other respiratory diseases, they will be referred for specialised treatment in the superior hospital.

A clear definition of the study population is presented in supplementary table S2. The baseline survey and follow-up investigation plans and contents for respective target populations are described in supplementary tables S3 and S4. The in-time and secondary intervention measures are listed in supplementary table S5. The integrated management measures include health education, lifestyle guidance, symptom monitoring, suggestions on smoking cessation, vaccination, physical activity, *etc*. Implementation of the entire programme is illustrated in figure 1.

Ethics and registration

The project protocol, informed consent and questionnaires have been approved by the institutional review board at the China–Japan Friendship Hospital (Beijing, PR China; approval number 2021-145-K103). The programme has been registered at the ClinicalTrials.gov with identifier NCT05480176. All participants are required to provide written informed consent.

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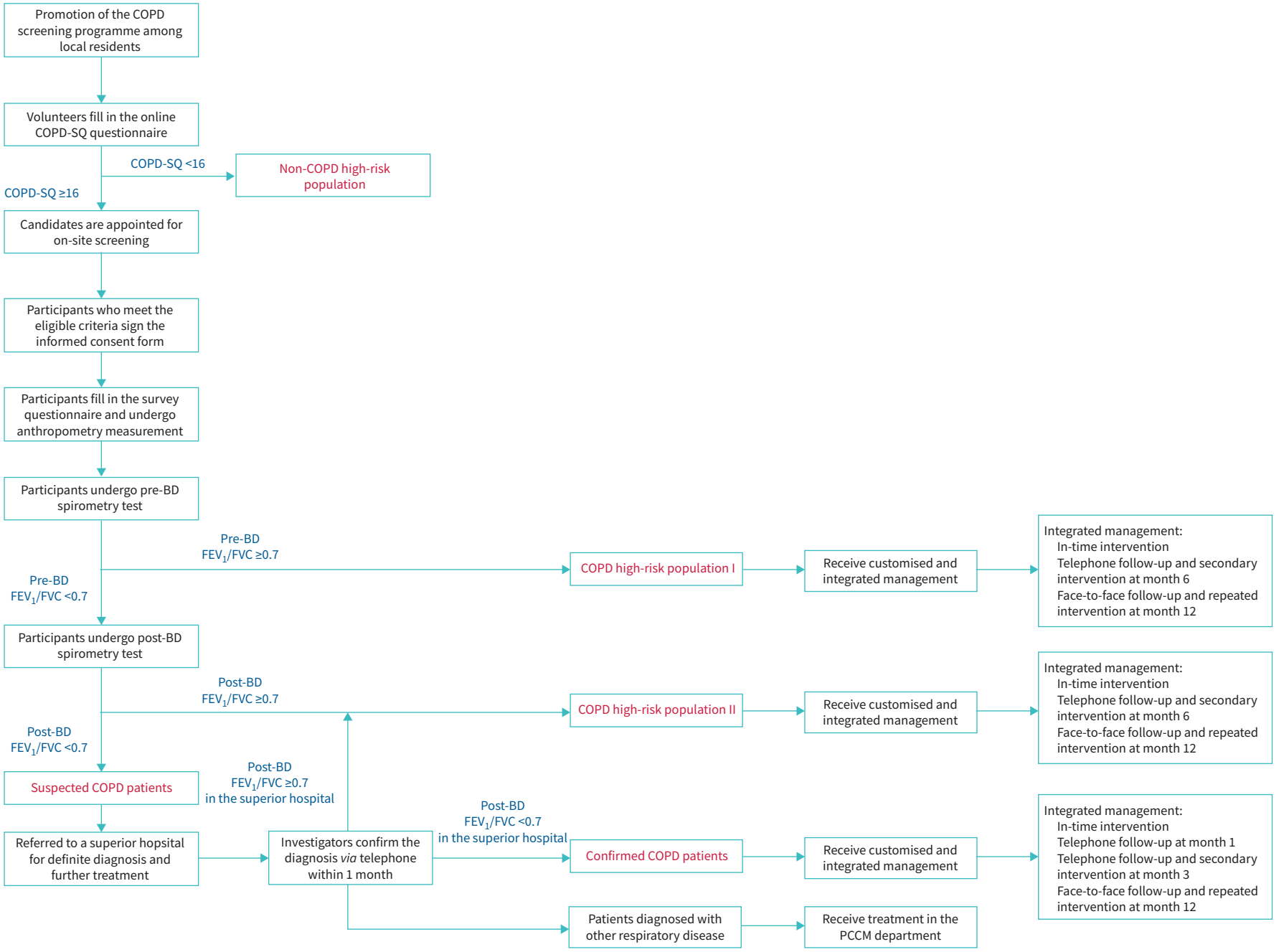

FIGURE 1 Workflow of the systematic COPD screening programme. This is a multistage sequential screening scheme, incorporating a previously validated questionnaire (*i.e.* COPD Screening Questionnaire (COPD-SQ)) and pre- and/or post-bronchodilator spirometry tests to target the COPD high-risk population. The filtered COPD high-risk population and early-detected COPD patients will then receive customised and integrated management measures. BD: bronchodilator; FEV_1: forced expiratory volume in 1 s; FVC: forced vital capacity; PCCM: pulmonary and critical care medicine.

Project and data management

This national COPD screening programme is led by the National Center for Respiratory Diseases, and is managed by the centres for disease control and prevention (CDCs) and/or tertiary hospitals at the province level. This screening programme has a four-level structured management team, responsible for the project and data quality. The structure and responsibilities of the management team are presented in figure 2.

The central management office, within the National Center for Respiratory Diseases, oversees the entire programme. The national quality control team consists of senior respiratory physicians, senior pulmonary function technicians, professional epidemiologists and managers from the information technology department. Their responsibilities include developing the national quality control scheme, organising and offering professional training, auditing all the quality control and training work, issuing a project newsletter each month and executing regular online and on-site monitoring.

The provincial quality control team consists of senior respiratory physicians and senior pulmonary function technicians who are responsible for developing the provincial quality control scheme, organising and offering professional training and executing regular online and on-site monitoring.

The district (for urban area) or county (for rural area) quality control team mainly include respiratory physicians and pulmonary function technicians. They are in charge of developing the district or county and local quality control schemes, organising and offering professional training and executing regular online and on-site monitoring.

At a local level, the quality control team consists of medical staff from the participating centres. They are responsible for auditing the local screening work and dealing with local quality control issues.

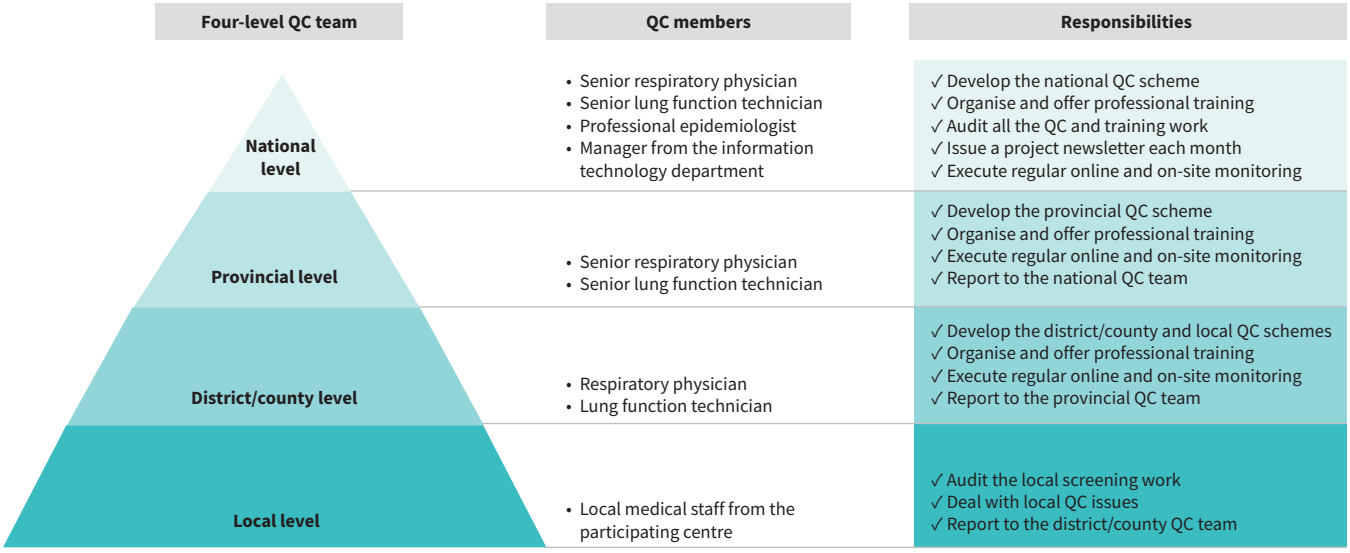

FIGURE 2 Settings of the four-level quality controls. This COPD screening programme has four-level (*i.e.* national, provincial, district (for urban area) or county (for rural area), and local) management teams, taking distinct responsibilities for project and data management. QC: quality control.

Comprehensive and professional training, *e.g.* calibration of the spirometer, technical standard operating procedure, quality control of the spirometry test, interpretation of the test data, diagnosis and management of COPD, *etc.*, are offered to local medical staff when the programme is initiated. The medical staff will obtain credentials when completing the training. Then the trained and certified technicians are capable of performing quality pulmonary function tests.

The pre- and post-bronchodilator spirometry manoeuvres are conducted in a seated position, and the participant is required to wear a nose clip and a disposable mouthpiece. Regarding the post-bronchodilator test, a short-term bronchodilator (salbutamol 400 µg) is administered by inhalation through a 500-mL spacer, then the spirometry is performed 20 min later. For each participant, three acceptable and repeatable tests are preferred; if not qualified, the test could be performed consecutively up to eight times. The spirometry data will be centrally reviewed and adjudicated. In addition, a daily calibration check for the spirometer using a 3-L syringe is required. The grading criteria used for quality assessment of FEV_1 (flow) and FVC (volume) are consistent with the ATS/ERS [38, 39] and Chinese [40] guidelines (supplementary table S6).

The national quality control team should review (online) ⩾5% of spirometry test results regularly for each province, autonomous region or municipality; the provincial quality control team should review ⩾10% of test results regularly for each district or county; and the district or county quality control team should check at least a third of test results each month for the region. The provincial quality control team should examine the first five test reports and assign appropriate grades for each participating centre. If the test qualified rate is <60%, the pulmonary function technicians should undergo a second round of training. Continuous education and technical support are available for the participating centres throughout the programme.

All data and original pulmonary function reports are entered and uploaded to a password-protected, electronic data collection system. Any missing value, outlier and illogical information will be sent to the local participating centres to be checked and amended.

Research questions and planned analyses

To achieve the study aims, this national COPD screening programme will address the following questions.

1) The prevalence and characteristics of population at high-risk of COPD, and those with underdiagnosed or misdiagnosed COPD;
2) the predictors of positive screening;
3) the most appropriate definition of COPD high-risk population;
4) the improvement of smoking cessation rate, morbidity, mortality and health-related quality of life alongside the screening programme;
5) the variation of respiratory condition alongside the screening programme;
6) the impact factors that are correlated with development of the disease;
7) the cost-effectiveness, cost–benefit and cost–utility of this multistage screening scheme;
8) the generalisability of this systematic COPD screening programme.

This national COPD screening programme could provide us with a platform for multiple studies and analyses. In short, descriptive analyses will be used to summarise the epidemiological and clinical characteristics of the study population. Sensitivity, specificity, positive predictive values, negative predictive values and the area under the receiver operating characteristic curve, along with 95% confidence intervals, will be used to examine and compare the diagnostic and discriminative accuracy of different definitions and screening approaches in the target population. Health technology assessment and health economic measurement will be employed to determine the cost-effectiveness, cost–utility and cost–benefit of current systematic screening strategies. Linear, logistic, Cox or other appropriate regression models will be adopted to assess the disease outcomes and corresponding impact factors. Due to the exploratory nature of the programme, the planned analyses are not limited to the aforementioned methods. The exact analysis methods could be decided when the analyses are conducted.

Discussion

This is an attempt to implement a nationwide COPD screening programme in a developing country, based on a continuously increasing disease burden and a potential large population of underdiagnosed or misdiagnosed COPD patients in China [1, 41]. This programme is an advance in COPD management (especially in the primary area) from the perspective of public health; however, the clinical and economic benefits of mass screening for COPD still have to be evaluated.

Strengths

There are multiple strengths to this national screening programme. First, currently there is a paucity of evidence that screening questionnaires and/or spirometry could improve smoking cessation rates, vaccination rates and COPD-related health outcomes (*e.g.* morbidity, mortality, health-related quality of life, *etc*.) [15, 42, 43]. To our knowledge, this is the first large-scale prospective study to determine and validate whether smoking cessation rate, morbidity, mortality and health status of individuals at high risk of COPD could be improved under a systematic screening and management scheme. Second, this programme attempts to target the population at high risk of COPD who could gain more benefit from systematic screening approaches combining questionnaires and pre- and post-bronchodilator spirometry. In other words, screening the symptomatic population with risk factor exposure and with suspected airway limitation might be the most cost-effective way, especially in countries or regions with limited resources. Third, this is not solely a disease screening programme, but also incorporates scheduled follow-ups and integrated management measures to respective populations (*i.e.* non-COPD high-risk population, COPD high-risk population I, COPD high-risk population II, suspected COPD patients and confirmed COPD patients), searching for the optimal management mode for screening-detected and early COPD patients. Fourth, in contrast to pure research projects, this is a central government-funded, National Center for Respiratory Diseases-led, multiple-agency (*e.g.* government sectors, CDCs, primary care institutions, specialised hospitals, *etc*.) programme, which could guarantee the implementation efficiency and quality control of the whole programme. Lastly, and importantly, this is real-world practice of population medicine in management of COPD in China, to maximise the long-term public health, societal and economic welfare of the entire population [44].

Limitations

There are several limitations to this programme. First, it was originally designed and initiated as a public health project, rather than a research study. Thus, the survey items are not as sophisticated as a typical case report form in observational or interventional clinical trials. However, supplementary studies could be embedded in the established platform. Second, false positive and false negative detections are inevitable in a large-scale screening programme. These issues and relevant impacts should be discussed in all aspects of those involved, *e.g.* patients, physicians, households, government agencies, *etc*. Third, performing quality spirometry in a primary area and the management of such a volume of data are real challenges. Continuous input in the form of professional training and rigorous quality control are very necessary throughout the implementation of the programme.

Further considerations

While the USPSTF, GOLD, and other scientific committees or societies recommend against screening asymptomatic adults for COPD, active case-finding (*i.e.* using screening questionnaires and spirometry without a bronchodilator) among target populations who have risk factor exposure and present with COPD-related symptoms is suggested; more relevant research is encouraged [7, 10, 37]. Screening questionnaires (with or without a measurement of PEF) [33, 45–50], innovative handheld spirometers [51, 52] and optimal multistage screening strategies [18, 20, 28, 53] have been explored worldwide. Country- or region-specific active case-finding approaches should be developed due to resource constrains and varied population characteristics. COPD screening should be compared with screening for malignant tumours, cardiovascular diseases and diabetes mellitus, to demonstrate its noninferiority to the other diseases.

Moreover, a combination of lung cancer and COPD screening using low-dose computed tomography (CT) is recommended in the GOLD 2022 report [37]. The benefit of annual low-dose CT screening in aged current or former smokers even with normal pulmonary function or with mild-to-moderate COPD has been reported in the United States [54]. Furthermore, combined screening for early lung cancer, COPD and cardiovascular disease has been initiated [55–57]. One-off low-dose CT screening has been demonstrated to be significantly associated with reduced lung cancer mortality and all-cause mortality in a large population in China [58]; thus a comparison between low-dose CT and the current active case-finding method is possible.

Conclusions

The COPD screening programme will mark a remarkable achievement in management of chronic respiratory disease in China. The diagnostic accuracy, cost-effectiveness and superiority of current systematic screening approaches will be assessed and discussed in future.

Provenance: Submitted article, peer reviewed.

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Ethics statement: The project protocol, informed consent and questionnaires have been approved by the institutional review board at the China–Japan Friendship Hospital (approval number 2021-145-K103). All participants are required to provide written informed consent.

Data availability statement: The raw data supporting the conclusions of this article can be made available from the corresponding authors on reasonable request.

Conflict of interest: The programme is conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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