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# Large-Scale Epidemiologic Studies of Cardiovascular Diseases in China

## Need for Improved Data Collection, Methods, Transparency, and Documentation

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#### **ABSTRACT**

With the advent of international precision medicine initiatives, it is important to evaluate existing large-scale studies to inform future investigation. This study sought to review, describe, and evaluate all large-scale cardiovascular disease (CVD) studies completed in China. We undertook a review of all large-scale CVD studies completed in China to describe and evaluate their design, implementation, and dissemination in published medical reports. Seventeen studies met the inclusion criteria. There were substantial variations in study design, geographic location, and data collection. Most studies lacked standard study names, did not publish their methods, and provided no publicly available data. Few studies included underdeveloped regions or minority groups. Most published articles contained only descriptions of the average population at risk of CVD, and no study predicted individual CVD risk or identified people at high risk. Future CVD studies in China may need to incorporate stronger systematic data collection methods, increased data transparency, clearer documentation, and standard study names to most gain from China's burgeoning field of CVD research.

The widespread availability of electronic data collection and processing facilitates the undertaking of increasingly large cohort studies. Global biobanks and precision medicine initiatives have been established in anticipation of expanding study capacities [1]. As such, it is important to assess past efforts to conduct large-scale public health studies that can inform the design, administration, and evaluation of future investigations.

Cardiovascular disease (CVD) is the global leading cause of death [2], and thus is a field that can benefit enormously from potentially high-impact, large-scale studies. Indeed, China's large population and central government organization can facilitate large-scale studies, many of which have already been undertaken [3,4]. To better inform the design and implementation of such studies, it is important to evaluate and critique prior efforts. However, prior studies have not systematically identified all large-scale, epidemiologic studies on CVD in China, nor have they described study approaches, designs, implementations, transparency, and publications. Such information, particularly regarding ways in which studies succeed or fail in collecting and reporting meaningful data, could inform future CVD research initiatives both in China and abroad, especially given that much information remains inaccessible to researchers outside of China. In addition, CVD information on the prevalence and incidence of cardiovascular risk factors and patients' knowledge and attitudes would be especially useful in designing future interventions.

We conducted a review of published reports to identify large-scale studies in China that addressed cardiovascular risk factors such as diabetes, hypertension, obesity, dyslipidemia, smoking, inactivity, and diet. We focused on studies that enrolled ≥100,000 participants to parallel the magnitude of other well-established large-scale epidemiologic studies [5-7], and to inform the design and implementation of China's PEACE MPP (Patient-centered Evaluative Assessment of Cardiac Events Million Persons Project), which is among the largest ongoing populationbased studies, that aims to enroll 5 million people in China [8]. We described study characteristics and assessed studies based on study design, demographic characteristics, geographic location, funding sources, and data collection methods. We further evaluated studies' statistical analyses and resulting publications in high-impact journals. We sought to understand the methodological approaches and publications of large-scale CVD research in China, and to use our findings to formulate recommendations for how future epidemiologic CVD studies might best be conducted and reported.

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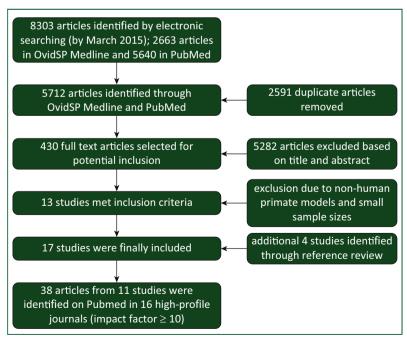
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#### **MATERIALS AND METHODS**

#### Search strategy and selection criteria

A standardized review protocol, including eligibility criteria and data extraction methods, was designed to form a detailed search strategy for papers. The protocol is described in detail in Figure 1. A systematic literature search was performed in OvidSP MEDLINE and PubMed using the combined text, acronyms and MeSH heading search strategy (["hypertension" OR "diabetes", "obesity" OR "dyslipidemia" OR "smoking" OR "physical activity" OR "diet"] AND ["China"] AND ["incidence" OR "prevalence" OR "epidemiology" OR "population"]). Reference lists of review articles identified in the search process were also considered. Additionally, the annual National Reports on Cardiovascular Diseases in China (published by the National Center for Cardiovascular Diseases in China) were reviewed. After excluding duplicate articles, 2 reviewers (H.Q. and S.X.) independently screened all the remaining articles' titles and abstracts to determine whether the studies met the eligibility criteria. Discordant assessments were adjudicated by a third reviewer (E.B.), who made the final decision. After identifying eligible studies, the number of publications from each study was systematically searched on PubMed using the study names. We also supplemented our findings by searching 2 Chinese research databases (Wanfang and China National Knowledge Infrastructure). For each study, in order to expand studies' designs and outcomes for more accurate data



**FIGURE 1. Flow diagram of included studies**. Though 2 studies (the Kailuan Study and the 2010 China NCD [Non-communicable Disease Survey]) included slightly <100,000 people, they studied all 7 cardiovascular risk factors.

extraction, we searched both databases for any published papers and reviewed any such articles conducted on the Chinese population in China.

Our eligibility criteria included all studies that: (1) were conducted in mainland China; (2) reported prevalence/incidence of CVD or  $\geq 1$  cardiovascular risk factor (smoking, obesity, diet, physical activity, hypertension, diabetes, or dyslipidemia) in adults; (3) were population-based; and (4) had a total sample of  $\geq 100,000$  participants. Studies were excluded if they discussed the association between risk factors and CVD, biomedical mechanisms, or treatment responses in animal models. Interventional studies were not excluded. No restrictions were placed on studies' publication dates, eligibilities, or languages. In this study, we focused mainly on but were not limited to coronary heart disease and stroke.

#### Data extraction and analysis

For all included studies, we extracted the following information based on a modified version of the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) Checklist (Online Appendix 1): study name; name of the method paper (if available); first author; publication year; screening year; funding source; collaborating organizations; study aims/hypotheses; study design; eligibility criteria; sample size; population characteristics; sample selection method; sample source; diagnostic criteria; cardiovascular risk factors measured; method of measurement; data validation/quality assurance methods; and potential biases. We began each abstraction by reviewing the methods paper, then supplemented with details from other manuscripts of the same study. When the same study population was used in multiple articles, we selected the article with the most recent publication date or the longest follow-up. Three investigators (H.Q., S.X., E.G.) independently extracted the necessary information from all included studies. Disagreements were discussed and resolved to reach a consensus among all 3 investigators.

The characteristics of each study were summarized. Each study was assessed on the basis of study design, sampling strategies, number of cardiovascular risk factors studied, demographic characteristics, response rate, method of measurement, method of data validation, or quality assurance, as well as result information to analyze the methodological quality and transparency. To evaluate how successful these studies were in publishing their findings in high-profile journals, we selected articles published in journals of an impact factor (IF) >10 in the public health or cardiovascular realm (Online Appendix 2).

#### **RESULTS**

#### Study characteristics

In total, 17 studies satisfied our inclusion criteria (Figure 1). Two studies (the Kailuan Study and the 2010 China NCD [Non-Communicable Disease Surveillance]

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