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Cover Photo: COVID-19 vaccine administered at a campus in Beijing Municipality.

Preplanned Studies

Immunogenicity of 23-Valent Pneumococcal Polysaccharide Vaccine in Patients with Chronic Obstructive Pulmonary Disease — Hebei Province, China, September–December, 2019

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Summary

What is already known on this topic?

The global burden of chronic obstructive pulmonary disease (COPD) is serious. Pneumococcal infection is associated with acute exacerbations of COPD (AECOPD). The 23-valent pneumococcal polysaccharide vaccine (PPSV23) is recommended for COPD patients to decrease AECOPD due to pneumococcus, but evidence on the immunogenicity of PPSV23 in COPD patients is limited.

What is added by this report?

This study showed good immunogenicity of one dose of PPSV23 in COPD patients. Antibody levels against all 23 vaccine serotypes were assessed before and four weeks after vaccination of COPD patients with one dose of PPSV23. The percent of COPD patients who had two-fold increases in pneumococcal antibody levels following vaccination ranged from 65.2% (serotype 3) to 94.4% (serotype 2). There were statistically significant differences in immunogenicity by serotype.

What are the implications for public health practice?

This study supports current recommendations for PPSV23 vaccination of COPD patients in China to provide protection from pneumococcal diseases.

Although 23-valent pneumococcal polysaccharide vaccine (PPSV23) is recommended for patients with chronic obstructive pulmonary disease (COPD) to prevent acute exacerbations (AECOPD) from pneumococcal diseases (*1–2*), the immunogenicity of PPSV23 in COPD patients is not known for all 23 vaccine serotypes. COPD prevalence and immunosenescence both increase with age, making assessment of immunogenicity important to determine. An intervention cohort study was conducted to compare antibody geometric mean concentrations (GMCs) and 2-fold increases in antibody levels before and 4 weeks after administering a dose of PPSV23 to 89 COPD patients who were invited by respiratory physicians to the study and agreed to participate. We found that PPSV23 provided good immunogenicity, with 2-fold increases in antibody levels ranging from 65.2% to 94.4%, and significant increases in GMCs, but with little difference by age, presence of comorbidities, and COPD severity for most serotypes. Our findings support current recommendations to offer PPSV23 to COPD patients.

COPD represents an important public health challenge that is preventable and treatable. The disease burden of COPD is considered serious globally (*1*) and in China (*3*). Patients with COPD have frequent AECOPD that can lead to further decline in lung function, accelerating disease progression, increasing risk of death and family economic burden (*4*). Pneumococcus is 1 of the 3 most common bacterial antecedents to AECOPD (*4*). Vaccination with PPSV23 can prevent pneumococcal-related diseases.

This study was carried out in Tangshan City, Hebei Province, China between September and December 2019. Doctors from respiratory outpatient clinics of three hospitals (Majiagou, Linxi, and Kangfu) invited patients to participate in the study. Eligible patients had to have a ratio of post-bronchodilator one-second forced expiratory volume (FEV_1) to forced vital capacity (FVC) of less than 0.70 (*1*), be less than 80 years of age, and have stable COPD. Patients who received PPSV23 in the past 5 years or had a history of allergy to any vaccine component were excluded.

Subjects received a single intramuscular injection of 0.5 mL of PPSV23 that was produced by Merck Sharp & Dohme Corporation. Venous blood samples were obtained from each subject before and 4 weeks after vaccination. Enzyme-linked immunosorbent assay (ELISA) was used to measure antibody responses for the 23 serotypes in accordance with the WHO recommendation protocol (*5*) by National Institute for Food and Drug Control in China. An antibody-fold-increase was calculated by dividing the post-

vaccination antibody concentration by the pre-vaccination antibody concentration. GMCs and 2-fold increase rates were used as outcomes. One-half of the assay detection limit was assigned to results below the detection limit when calculating GMCs.

For the sample size calculation, the rate of 2-fold increases in antibody levels was assumed to be 70% (*6*) and that an acceptable 2-fold increase rate would be 50%; a one-sided significance test was used, α =0.05, and one-sided power=0.80 to determine the minimum sample size to be 73. The sample size was targeted to 88 to allow for a 20% loss of subjects to follow-up.

EpiData (version 3.1, EpiData Software, Epi Info V6, Denmark) and SAS (version 9.4, SAS Institute, Cary, NC, USA) were used for data entry and statistical analysis. Chi-squared or Fisher's exact probability testing was used to compare 2-fold-increase rates. Student's *t*-tests or analysis of variance was used to compare GMCs. $P<0.05$ was considered a statistically significant difference.

Overall, 95 subjects were enrolled and 89 subjects completed the study; 67 subjects (75.3%) were men; the median age was 64 years (range 47–77) and 46.1% were 65 years or older; 41 (46.1%) had co-morbid conditions (hypertension, diabetes, cardiovascular and cerebrovascular diseases, etc); 1 subject had received PPSV23 in the past. The distribution of COPD severity was 4 (4.5%) mild, 54 (60.7%) moderate, 30 (33.7%) severe, and 1 (1.1%) very severe.

The 2-fold increase rates ranged from 65.2% (serotype 3) to 94.4% (serotype 2). There were statistically significant differences in 2-fold increase rates among the 23 vaccine serotypes. Serotype 2 and 7F had the highest 2-fold increase rates (>90%); 2-fold increase rates for serotypes 1, 4, 5, 8, 9N, 9V, 10A, 12F, 15B, 17F, 18C, 19F, 20, 23F, and 33F were between 80% and 90%; 2-fold increase rates for serotype 11A, 19A, and 22F were between 70% and 80%; and 2-fold increase rates for serotypes 3, 6B, and 14 were less than 70%. The 2-fold increase rate for serotype 19F was higher among patients with mild or moderate-severity COPD (P=0.021) compared with patients with severe or very severe COPD. The 2-fold increase rates for 8, 10A, and 33F in patients with comorbidities were lower than for patients without comorbidities (P=0.005, P=0.016, P=0.01). There were no other statistically significant differences by age, COPD severity, or presence of comorbidities (Table 1, Figure 1).

GMCs ranged from 0.38 μg/mL (serotype 3) to 6.90 μg/mL (serotype 14) at baseline and from 1.03 μg/mL (serotype 3) to 30.36 μg/mL (serotype 14) after vaccination. There were statistically significant differences in baseline GMCs (P<0.0001) and post-vaccination GMCs (P<0.0001) among the 23 serotypes. Compared with subjects ≥65 years, younger subjects had lower baseline GMCs for serotype 9V (P=0.035) and higher post-vaccination GMC for serotype 10A (P=0.030). After vaccination, GMCs of serotype 6B and 19F among patients with mild or moderate COPD were higher than among patients with severe and very severe COPD (P=0.04, P=0.039). There were no other significant differences in GMCs by age, COPD severity, or presence of comorbidities (Figure 1, Supplementary Table S1, available in http://weekly.chinacdc.cn/).

DISCUSSION

This study found that immunogenicity provided by 1 dose of PPSV23 in COPD patients was good. Although immunogenicity varied by serotype, it varied little by age, presence of comorbidities, and severity of COPD for most of the vaccine serotypes. This is the first study to assess immunogenicity of all 23 serotypes from one dose of PPSV23 in COPD patients. The findings support current recommendations to offer PPSV23 to COPD patients in China to provide protection from pneumococcal disease and prevent or reduce the number of AECOPD.

There have been some evaluations of PPSV23 immunogenicity in COPD patients. A study conducted in Taiwan, China assessed the immunogenicity of 8 PPSV23 serotypes (4, 6B, 7F, 9V, 14, 18C, 19F, and 23F) in COPD patients (*6*). Two-fold increases for serotypes 6B and 14 and post-vaccination GMCs of the 8 corresponding serotypes in this study were lower than that in the study conducted in Taiwan, China. Differences between the two studies may be due to different blood collection intervals (4 weeks *vs.* 6 weeks) or different ELISA methods.

Two studies conducted in Japan among COPD patients showed lower 2-fold increases and post-vaccination GMCs for 6B, 14, 19F, and 23F than in this study (*7*–*8*). Differences between the studies may have been due to different pre-vaccination antibody concentrations or different characteristics of subjects. In this study, pre-vaccination GMCs for serotype 6B, 19F, and 23F were lower than that in the study conducted in Japan (*7*). The median age in this study was younger and fewer comorbid illnesses were considered to be other respiratory diseases than that in

TABLE 1. Two-fold increase rates (%) of 23 serotypes and 95% confidence intervals after PPSV23 vaccination in COPD patients in Tangshan City, Hebei Province, China during September to December 2019.

Serotype	Age group		COPD severity		Comorbidities		Total
	<65 years	≥65 years	Mild and moderate	Severe and very severe	Yes	No	
1	89.6 (77.3–96.5)	82.9 (67.9–92.9)	87.9 (76.7–95.0)	83.9 (66.3–94.6)	80.5 (65.1–91.2)	91.7 (80.0–97.7)	86.5 (77.6–92.8)
2	95.8 (85.8–99.5)	92.7 (80.1–98.5)	96.6 (88.1–99.6)	90.3 (74.3–98.0)	92.7 (80.1–98.5)	95.8 (85.8–99.5)	94.4 (87.4–98.2)
3	68.8 (53.8–81.3)	61.0 (44.5–75.8)	62.1 (48.4–74.5)	71.0 (52.0–85.8)	63.4 (46.9–77.9)	66.7 (51.6–79.6)	65.2 (54.3–75.0)
4	85.4 (72.2–93.9)	82.9 (67.9–92.9)	84.5 (72.6–92.7)	83.9 (66.3–94.6)	78.1 (62.4–89.4)	89.6 (77.3–96.5)	84.3 (75.0–91.1)
5	85.4 (72.2–93.9)	85.4 (70.8–94.4)	86.2 (74.6–93.9)	83.9 (66.3–94.6)	80.5 (65.1–91.2)	89.6 (77.3–96.5)	85.4 (76.3–92.0)
6B	66.7 (51.6–79.6)	68.3 (51.9–81.9)	72.4 (59.1–83.3)	58.1 (39.1–75.5)	68.3 (51.9–81.9)	66.7 (51.6–79.6)	67.4 (56.7–77.0)
7F	93.8 (82.8–98.7)	87.8 (73.8–95.9)	91.4 (81.0–97.1)	90.3 (74.3–98.0)	87.8 (73.8–95.9)	93.8 (82.8–98.7)	91.0 (83.1–96.0)
8	89.6 (77.3–96.5)	87.8 (73.8–95.9)	87.9 (76.7–95.0)	90.3 (74.3–98.0)	78.1 (62.4–89.4)	97.9 (88.9–99.9)	88.8 (80.3–94.5)
9N	95.8 (85.8–99.5)	82.9 (67.9–92.9)	89.7 (78.8–96.1)	90.3 (74.3–98.0)	85.4 (70.8–94.4)	93.8 (82.8–98.7)	89.9 (81.7–95.3)
9V	89.6 (77.3–96.5)	85.4 (70.8–94.4)	89.7 (78.8–96.1)	83.9 (66.3–94.6)	85.4 (70.8–94.4)	89.6 (77.3–96.5)	87.6 (79.0–93.7)
10A	91.7 (80.0–97.7)	78.1 (62.4–89.4)	86.2 (74.6–93.9)	83.9 (66.3–94.6)	75.6 (59.7–87.6)	93.8 (82.8–98.7)	85.4 (76.3–92.0)
11A	77.1 (62.7–88.0)	70.7 (54.5–83.9)	74.1 (61.0–84.7)	74.2 (55.4–88.1)	75.6 (59.7–87.6)	72.9 (58.2–84.7)	74.2 (63.8–82.9)
12F	91.7 (80.0–97.7)	87.8 (73.8–95.9)	93.1 (83.3–98.1)	83.9 (66.3–94.6)	87.8 (73.8–95.9)	91.7 (80.0–97.7)	89.9 (81.7–95.3)
14	70.8 (55.9–83.1)	65.9 (49.4–79.9)	72.4 (59.1–83.3)	61.3 (42.2–78.2)	75.6 (59.7–87.6)	62.5 (47.4–76.1)	68.5 (57.8–78.0)
15B	85.4 (72.2–93.9)	90.2 (76.9–97.3)	87.9 (76.7–95.0)	87.1 (70.2–96.4)	82.9 (67.9–92.9)	91.7 (80.0–97.7)	87.6 (79.0–93.7)
17F	89.6 (77.3–96.5)	87.8 (73.8–95.9)	91.4 (81.0–97.1)	83.9 (66.3–94.6)	85.4 (70.8–94.4)	91.7 (80.0–97.7)	88.8 (80.3–94.5)
18C	93.8 (82.8–98.7)	80.5 (65.1–91.2)	89.7 (78.8–96.1)	83.9 (66.3–94.6)	82.9 (67.9–92.9)	91.7 (80.0–97.7)	87.6 (79.0–93.7)
19A	79.2 (65.0–89.5)	75.6 (59.7–87.6)	79.3 (66.7–88.8)	74.2 (55.4–88.1)	73.2 (57.1–85.8)	81.3 (67.4–91.1)	77.5 (67.5–85.7)
19F	83.3 (69.8–92.5)	78.1 (62.4–89.4)	87.9 (76.7–95.0)	67.7 (48.6–83.3)	75.6 (59.7–87.6)	85.4 (72.2–93.9)	80.9 (71.2–88.5)
20	83.3 (69.8–92.5)	80.5 (65.1–91.2)	82.8 (70.6–91.4)	80.7 (62.5–92.6)	80.5 (65.1–91.2)	83.3 (69.8–92.5)	82.0 (72.5–89.4)
22F	77.1 (62.7–88.0)	68.3 (51.9–81.9)	77.6 (64.7–87.5)	64.5 (45.4–80.8)	68.3 (51.9–81.9)	77.1 (62.7–88.0)	73.0 (62.6–81.9)
23F	85.4 (72.2–93.9)	80.5 (65.1–91.2)	82.8 (70.6–91.4)	83.9 (66.3–94.6)	82.9 (67.9–92.9)	83.3 (69.8–92.5)	83.2 (73.7–90.3)
33F	93.8 (82.8–98.7)	85.4 (70.8–94.4)	91.4 (81.0–97.1)	87.1 (70.2–96.4)	80.5 (65.1–91.2)	97.9 (88.9–99.9)	89.9 (81.7–95.3)

Abbreviations: PPSV23=23-valent pneumococcal polysaccharide vaccine; COPD=chronic obstructive pulmonary disease.

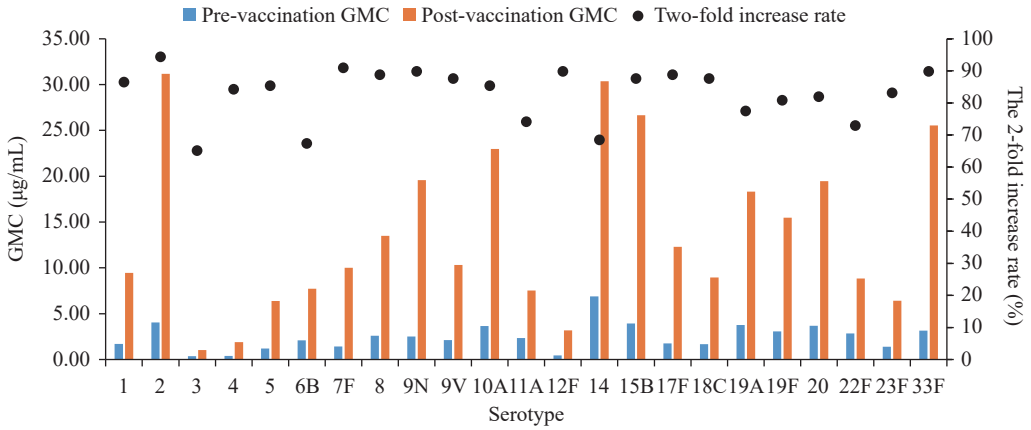

FIGURE 1. Geometric mean concentrations (GMCs) pre- and post-vaccination and 2-fold increase rates of 23 serotypes post 23-valent pneumococcal polysaccharide vaccination in patients with chronic obstructive pulmonary disease in Tangshan City, Hebei Province, China during September to December 2019.

the study conducted in Japan (*8*).

The immune response induced by PPSV23 in COPD patients appears to be comparable with those of age-matched healthy adults. One study assessed immunogenicity of PPSV23 in COPD patients and healthy controls and found that there were no statistically significant differences in the antibody GMCs between COPD patients and healthy controls (*9*). The 2-fold increase rates of 23 serotypes in this study were not lower than those in the Phase III licensure clinical trial of PPSV23 conducted in China (*10*).

This study was subject to at least four limitations. First, there were no healthy controls to assess differences in immune response between COPD patients and healthy adults. Other studies have shown comparable immunogenicity, however. Second, subjects were not selected randomly, which could affect representativeness. Third, the sample size was too small to assess immunogenicity among subgroups. Finally, the study was short term and did not provide evidence of persistence of immunity. There are several studies reporting 1–2 years of immune persistence following PPSV23 vaccination of COPD patients (*6*–*7*,*9*). Only one study reported long-term persistence (*8*). Following these subjects for an additional 4–5 years could provide additional evidence of persistence.

Antibody levels that correlate with protection from pneumococcal disease have not been clearly defined for adults. Thus, the relationship between immunogenicity and effectiveness is unclear. This important relationship merits additional research using experimental study designs to determine health and economic benefits of PPSV23 in COPD patients.

In conclusion, the immunogenicity of one dose of PPSV23 is good in COPD patients. PPSV23 vaccination should continue to be recommended for COPD patients in China.

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SUPPLEMENTARY TABLE S1. Geometric mean concentrations (μg/mL) and 95% confidence intervals before and after PPSV23 vaccination in COPD patients in Tangshan City, Hebei Province, China during September to December, 2019.

Serotype	Age group				Severity of COPD				Comorbidities				Total	
	<65 years		≥65 years		Mild and moderate		Severe and very severe		Yes		No			
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	1.61 (1.25−2.07)	9.93 (7.01−14.08)	1.83 (1.48−2.28)	8.91 (6.62−11.99)	1.69 (1.39−2.05)	10.02 (7.43−13.50)	1.75 (1.26−2.42)	8.47 (5.89−12.16)	1.81 (1.40−2.35)	8.49 (5.92−12.17)	1.63 (1.31−2.03)	10.35 (7.66−13.98)	1.71 (1.45−2.02)	9.45 (7.52−11.87)
2	3.56 (2.85−4.45)	29.46 (20.33−42.69)	4.74 (3.78−5.94)	33.30 (23.84−46.51)	3.96 (3.30−4.75)	34.76 (25.50−47.37)	4.25 (3.08−5.87)	25.43 (16.57−39.01)	4.30 (3.32−5.58)	30.95 (20.54−46.66)	3.86 (3.15−4.73)	31.36 (22.95−42.84)	4.06 (3.46−4.76)	31.17 (24.33−39.94)
3	0.34 (0.27−0.42)	1.14 (0.86−1.51)	0.42 (0.33−0.55)	0.93 (0.72−1.19)	0.38 (0.31−0.48)	0.98 (0.75−1.27)	0.36 (0.28−0.46)	1.15 (0.90−1.47)	0.43 (0.33−0.57)	1.01 (0.73−1.40)	0.33 (0.27−0.40)	1.06 (0.85−1.32)	0.38 (0.32−0.44)	1.03 (0.86−1.25)
4	0.40 (0.27−0.59)	1.99 (1.18−3.37)	0.38 (0.24−0.58)	1.78 (1.36−2.33)	0.42 (0.31−0.59)	1.90 (1.25−2.89)	0.34 (0.19−0.60)	1.88 (1.25−2.84)	0.35 (0.21−0.58)	1.39 (0.80−2.44)	0.43 (0.32−0.59)	2.46 (1.82−3.31)	0.39 (0.29−0.52)	1.89 (1.40−2.56)
5	1.20 (1.00−1.44)	5.71 (4.39−7.42)	1.21 (0.98−1.48)	7.32 (5.41−9.91)	1.25 (1.06−1.48)	7.28 (5.60−9.46)	1.11 (0.87−1.42)	5.03 (3.81−6.65)	1.21 (0.96−1.52)	6.12 (4.36−8.58)	1.20 (1.02−1.41)	6.66 (5.27−8.41)	1.20 (1.05−1.38)	6.40 (5.26−7.79)
6B	2.03 (1.63−2.53)	7.96 (5.42−11.69)	2.15 (1.71−2.71)	7.45 (5.62−9.87)	2.04 (1.71−2.44)	9.06 (6.52−12.60)	2.18 (1.59−2.98)	5.71 (4.22−7.73)	2.07 (1.59−2.71)	7.30 (5.04−10.58)	2.10 (1.73−2.54)	8.09 (5.85−11.20)	2.09 (1.78−2.44)	7.72 (6.07−9.81)
7F	1.28 (1.07−1.52)	10.01 (7.41−13.52)	1.62 (1.28−2.06)	10.00 (7.14−13.99)	1.49 (1.23−1.80)	10.39 (7.89−13.68)	1.32 (1.05−1.65)	9.32 (6.35−13.68)	1.59 (1.23−2.05)	11.09 (7.49−16.43)	1.30 (1.11−1.53)	9.16 (7.18−11.68)	1.43 (1.23−1.65)	10.00 (8.03−12.46)
8	2.50 (1.96−3.19)	15.09 (11.33−20.08)	2.72 (2.14−3.46)	11.85 (9.21−15.24)	2.41 (1.98−2.93)	13.12 (10.25−16.80)	3.00 (2.18−4.13)	14.23 (10.40−19.47)	3.07 (2.26−4.18)	12.74 (8.92−18.19)	2.26 (1.91−2.67)	14.18 (11.67−17.23)	2.60 (2.20−3.08)	13.50 (11.15−16.34)
9N	2.22 (1.77−2.78)	21.33 (15.25−29.83)	2.90 (2.20−3.82)	17.71 (13.76−22.79)	2.56 (2.05−3.18)	20.16 (15.21−26.72)	2.42 (1.79−3.29)	18.53 (13.39−25.64)	2.41 (1.83−3.18)	19.35 (13.49−27.75)	2.59 (2.06−3.27)	19.77 (15.29−25.57)	2.51 (2.11−2.99)	19.57 (15.84−24.20)
9V	1.78 (1.36−2.32)	9.35 (6.90−12.66)	2.59 (2.07−3.26)	11.60 (9.29−14.49)	2.16 (1.70−2.76)	11.02 (8.44−14.40)	2.03 (1.57−2.61)	9.13 (7.20−11.59)	2.18 (1.64−2.90)	10.71 (7.86−14.59)	2.06 (1.63−2.61)	10.00 (7.82−12.79)	2.12 (1.77−2.53)	10.32 (8.53−12.49)
10A	3.58 (2.93−4.37)	30.60 (20.47−45.75)	3.77 (3.02−4.72)	16.43 (11.11−24.31)	3.40 (2.81−4.11)	21.91 (15.37−31.21)	4.23 (3.36−5.33)	25.13 (15.20−41.57)	3.87 (3.04−4.93)	18.69 (12.39−28.18)	3.50 (2.92−4.21)	27.42 (18.38−40.90)	3.67 (3.17−4.25)	22.98 (17.29−30.53)
11A	2.17 (1.77−2.65)	7.17 (5.70−9.02)	2.59 (2.14−3.13)	7.95 (6.19−10.22)	2.34 (1.95−2.82)	7.88 (6.30−9.86)	2.37 (1.93−2.90)	6.89 (5.41−8.77)	2.38 (1.89−2.99)	7.73 (5.77−10.36)	2.33 (1.96−2.76)	7.35 (6.07−8.90)	2.35 (2.05−2.70)	7.52 (6.37−8.88)
12F	0.37 (0.26−0.52)	3.13 (2.09−4.67)	0.54 (0.44−0.66)	3.26 (2.27−4.69)	0.45 (0.34−0.60)	3.52 (2.46−5.04)	0.43 (0.33−0.54)	2.65 (1.79−3.93)	0.50 (0.34−0.73)	3.26 (2.09−5.07)	0.39 (0.32−0.48)	3.13 (2.23−4.40)	0.44 (0.36−0.54)	3.19 (2.44−4.17)
14	6.45 (5.26−7.91)	28.99 (20.25−41.52)	7.46 (5.88−9.47)	32.03 (22.18−46.27)	6.41 (5.33−7.71)	31.45 (23.27−42.50)	7.91 (5.98−10.46)	28.41 (17.58−45.92)	7.19 (5.52−9.36)	32.97 (22.42−48.49)	6.66 (5.56−7.98)	28.29 (20.05−39.92)	6.90 (5.92−8.04)	30.36 (23.58−39.07)
15B	3.75 (2.88−4.89)	27.07 (18.44−39.73)	4.17 (3.23−5.38)	26.17 (19.03−35.97)	3.85 (3.09−4.80)	25.71 (18.70−35.35)	4.10 (2.93−5.75)	28.49 (18.75−43.29)	4.27 (3.19−5.71)	23.15 (16.24−33.00)	3.68 (2.91−4.66)	30.05 (21.04−42.92)	3.94 (3.28−4.72)	26.65 (20.78−34.18)
17F	1.63 (1.36−1.95)	11.37 (8.35−15.49)	1.92 (1.49−2.48)	13.47 (10.45−17.36)	1.75 (1.47−2.08)	13.43 (10.39−17.35)	1.77 (1.31−2.39)	10.43 (7.51−14.48)	1.74 (1.36−2.23)	10.73 (7.84−14.68)	1.77 (1.46−2.14)	13.81 (10.61−17.98)	1.76 (1.51−2.04)	12.29 (10.06−15.02)
18C	1.49 (1.19−1.88)	8.54 (6.52−11.18)	1.92 (1.57−2.35)	9.49 (7.09−12.71)	1.62 (1.34−1.97)	9.13 (7.12−11.70)	1.78 (1.36−2.34)	8.67 (6.24−12.05)	1.68 (1.29−2.18)	9.89 (7.01−13.96)	1.68 (1.40−2.02)	8.25 (6.63−10.26)	1.68 (1.44−1.96)	8.97 (7.38−10.89)
19A	3.44 (2.74−4.32)	17.96 (12.62−25.56)	4.19 (3.29−5.32)	18.74 (13.75−25.54)	3.69 (3.06−4.46)	19.82 (14.73−26.66)	3.91 (2.82−5.41)	15.79 (10.66−23.39)	3.95 (3.02−5.17)	16.24 (11.55−22.82)	3.62 (2.94−4.44)	20.30 (14.61−28.20)	3.77 (3.20−4.44)	18.31 (14.50−23.13)
19F	2.75 (2.15−3.51)	15.02 (10.95−20.60)	3.52 (2.82−4.40)	16.05 (11.73−21.96)	2.85 (2.40−3.39)	18.28 (13.94−23.96)	3.55 (2.47−5.10)	11.35 (7.86−16.40)	3.18 (2.44−4.16)	13.97 (9.72−20.06)	3.00 (2.41−3.72)	16.91 (12.87−22.24)	3.08 (2.61−3.64)	15.49 (12.44−19.28)
20	3.19 (2.22−4.60)	19.14 (13.31−27.52)	4.33 (3.61−5.18)	19.84 (14.96−26.31)	3.50 (2.63−4.65)	17.82 (13.22−24.02)	4.02 (2.94−5.51)	22.93 (15.82−33.24)	3.17 (2.16−4.66)	17.88 (12.56−25.45)	4.16 (3.33−5.21)	20.91 (15.28−28.63)	3.67 (3.17−4.25)	19.46 (15.45−24.50)
22F	2.63 (2.19−3.16)	8.53 (6.49−11.20)	3.09 (2.58−3.70)	9.19 (7.23−11.69)	2.82 (2.43−3.27)	9.87 (7.87−12.36)	2.87 (2.24−3.67)	7.20 (5.32−9.75)	3.01 (2.48−3.66)	10.11 (7.65−13.36)	2.69 (2.26−3.20)	7.89 (6.21−10.02)	2.83 (2.50−3.22)	8.83 (7.37−10.57)
23F	1.28 (1.04−1.56)	6.11 (4.44−8.40)	1.55 (1.22−1.98)	6.79 (5.03−9.15)	1.39 (1.15−1.67)	6.63 (4.99−8.81)	1.41 (1.06−1.89)	6.01 (4.26−8.48)	1.47 (1.12−1.93)	6.33 (4.59−8.75)	1.34 (1.13−1.59)	6.48 (4.78−8.77)	1.40 (1.20−1.63)	6.41 (5.16−7.96)
33F	3.03 (2.45−3.76)	25.41 (17.99−35.87)	3.33 (2.69−4.11)	25.72 (19.66−33.64)	3.29 (2.75−3.94)	28.02 (21.02−37.35)	2.93 (2.22−3.87)	21.50 (15.31−30.20)	2.98 (2.36−3.76)	21.90 (15.35−31.24)	3.33 (2.73−4.06)	29.15 (22.09−38.45)	3.16 (2.73−3.67)	25.55 (20.52−31.81)

Abbreviations: PPSV23=23-valent pneumococcal polysaccharide vaccine; COPD=chronic obstructive pulmanary disease.

Preplanned Studies

Epidemiological Characteristics of Osteoarthritis in Yichang City — Hubei Province, China, 2017–2018

Yingying Zhang[1]; Jiajuan Yang[2]; Tanchun Yu[3]; Li Ma[1]; Yuewei Cheng[4]; Xudong Li[1,#]

Summary

What is already known about this topic?

OA has been listed as the fastest increasing major public health problem and ranked second as a cause of disability by World Health Organization (WHO). With population aging, osteoarthritis (OA) is causing an increased economic burden for individuals and society and is attracting an increasing amount of scientific attention.

What is added by this report?

This research used healthcare data to analyze the epidemiological characteristics of OA in Yichang City, Hubei Province, China. The exact number and distribution of patients were obtained, and a descriptive analysis of OA visits by age, gender, and season was performed. Knee joint disease among women was most common, followed by other joint diseases. Knee osteoarthritis was the most common OA diagnosis between 60 and 69 years of age.

What are the implications for public health practice?

In China, the prevalence of OA among middle-age and elderly people was high. With increases in the size of the elderly population, the burden of disease caused by OA may increase. It is necessary to strengthen publicity to improve people's awareness of self-health care of bone and joint. Interventions and preventive strategies targeting high-risk groups are urgently needed in order to improve healthy bones and healthy life quality among middle-age and elderly people.

World Health Organization (WHO) has identified osteoarthritis (OA) as the fastest growing major public health problem and the second leading cause of disability globally. OA is a disease that affects entire joints, leaving no tissues unaffected. The complete pathway that leads to destruction of joints is unknown (*1*). According to the Department of Bone and Joint Epidemiology of Peking University People's Hospital, the number of disability-adjusted life years lost in China per 100,000 caused by OA increased from 92.5 in 1990 to 98.8 in 2017 (*2*). The overall prevalence of OA among people over the age of 65 in China was 8.1% (*3*). OA causes huge economic burdens on patients, families, and society; it most commonly affects the hands, hips, knees, and spine, with knee joint involvement being the most common (*4*). For many years the seriousness of OA has been emphasized, but there are few large-sample-size epidemiological OA cohorts established in our country, as OA epidemiology is still in its infancy. Despite many investigations and studies having been repeated in a variety of areas, resulting data have not been well recognized internationally due to inconsistencies in testing methods and diagnostic standards (*5*). This study is based on the Big Data Information Platform of Health in Yichang City, which includes diagnostic and treatment information from OA-related visits by 817,700 permanent residents, over a 6-month period, in 5 administrative regions, 10 tertiary hospitals, and 26 community health service centers. The study could provide a basic description of Yichang's OA situation and help form the basis for public health risk assessments and policymaking.

Yichang Big Data Platform on Health serves 817,700 permanent residents and the outpatient records, inpatient records, prescription drug data, and physical examination records are all included. An one-person-one-card system is used to accurately track urban residents.

The research conducted a retrospective analysis of deidentified healthcare data from the Big Data platform. The study passed ethical review; unique identification codes were recoded. Patients diagnosed with OA who had records in the Big Data platform from January 1, 2017 to December 31, 2018 were selected. Patients with ICD codes M15-M19 who met imaging OA diagnostic criteria were included in the analytic data set. The OA cases in this analysis were redefined as at least one OA out-patient or in-patient visit, and those with multiple visits were classified as one OA patient and the earliest visit time was retained.

SAS software package (version 9.4, 100 SAS Campus Drive Cary, NC 27513, USA) was used for descriptive analyses by age, gender, and joint.

There were 16,745 patients who met inclusion criteria during the study period with a total of 23,460 visits, with an average of 1.40 visits. The mean age and standard deviation were 58.69±15.18 years; there were more females than males (Figure 1). The largest proportions of patients were among 60–69 years old, followed 50–59 years old and 70–79 years old (Figure 2). Outpatient and inpatient treatment rates were highest in the spring (Figure 3).

ICD-10 codes M15–M19 were polyarthropathy (M15), coxarthropathy (M16), knee OA (M17), arthrosis of first carpometacarpal joint (M18), and other joint diseases (M19) (Table 1). Knee OA was the most common diagnosis, with women more affected than men. Among 50–59 years old, M16, M18, and M19 were the most prevalent diagnostic codes. In 2017, the highest number of M15 OA patients were 50–59 years old; while in 2018, the highest number of M15 OA patients were 60–69 years old. In both 2017 and 2018, M17 OA patients, aged 60 to 69 years, represented the highest number of cases.

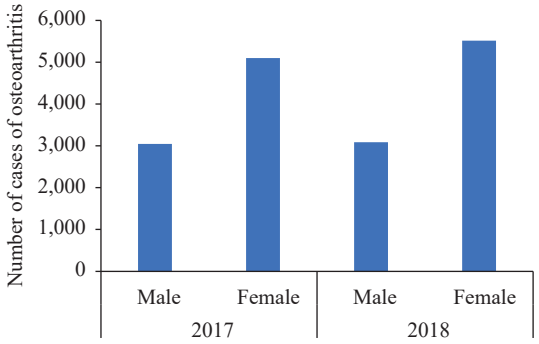

FIGURE 1. Distribution of osteoarthritis (OA) by gender and year from 2017 to 2018, Yichang City, Hubei province, China.

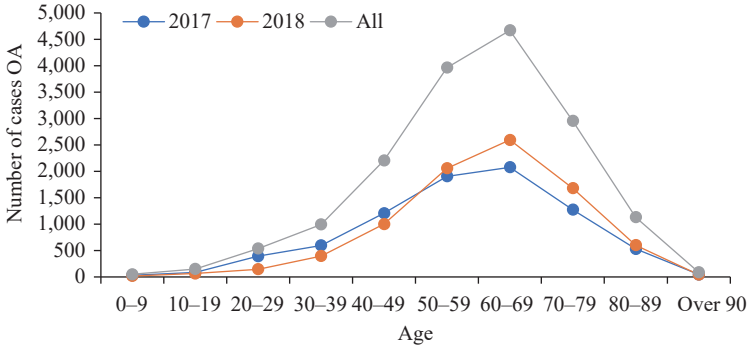

FIGURE 2. Distribution osteoarthritis (OA) in different age groups by study year from 2017 to 2018, Yichang City, Hubei Province, China.

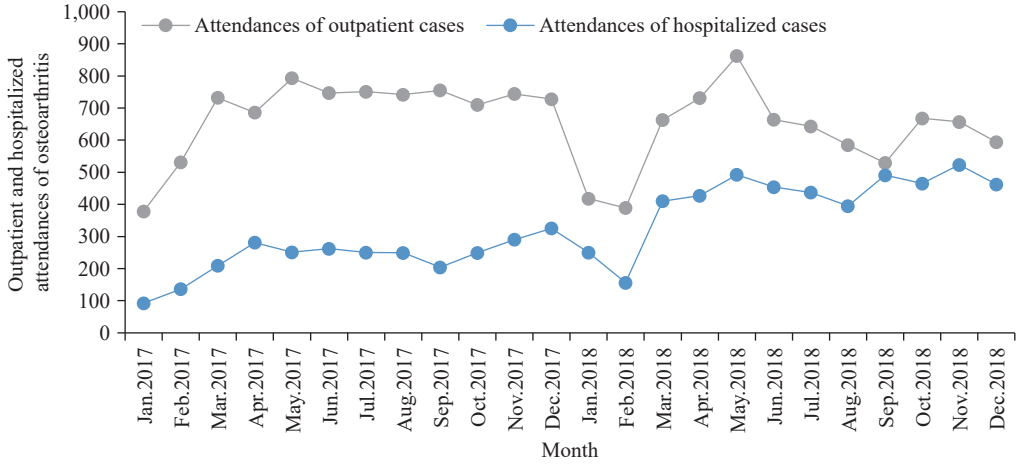

FIGURE 3. Outpatient and hospitalized attendance of osteoarthritis (OA) patients by month from 2017 to 2018, Yichang City, Hubei Province, China.

TABLE 1. Characteristics of different types of osteoarthritis in 2017–2018, Yichang City, Hubei Province, China.

Feature	2017						2018						All
	Male		Female		All		Male		Female		All		N
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	
Polyarthropathy (M15)													
0–29	12	2.38	19	3.76	31	6.14	8	0.89	8	0.89	16	1.78	47
30–39	8	1.58	16	3.17	24	4.75	12	1.33	26	2.89	38	4.22	62
40–49	21	4.16	39	7.72	60	11.88	31	3.44	72	7.99	103	11.43	163
50–59	48	9.50	82	16.24	130	25.74	64	7.10	184	20.42	248	27.52	378
60–69	48	9.50	71	14.06	119	23.56	77	8.55	178	19.76	255	28.30	374
Over 70	52	10.30	89	17.62	141	27.92	115	12.76	126	13.98	241	26.75	382
All	189	37.43	316	62.57	505	100.00	307	34.07	594	65.93	901	100.00	1,406
Coxarthropathy (M16)													
0–29	5	2.23	7	3.13	12	5.36	15	4.59	10	3.06	25	7.65	37
30–39	4	1.79	3	1.34	7	3.13	11	3.36	13	3.98	24	7.34	31
40–49	18	8.04	20	8.93	38	16.96	27	8.26	23	7.03	50	15.29	88
50–59	21	9.38	42	18.75	63	28.13	31	9.48	40	12.23	71	21.71	134
60–69	20	8.93	42	18.75	62	27.68	30	9.17	43	13.15	73	22.32	135
Over 70	19	8.48	23	10.27	42	18.75	32	9.79	52	15.90	84	25.69	126
All	87	38.84	137	61.16	224	100.00	146	44.65	181	55.35	327	100.00	551
Gonarthrosis (M17)													
0–29	72	1.81	81	2.04	153	3.85	66	1.16	63	1.11	129	2.27	282
30–39	88	2.21	109	2.74	197	4.95	111	1.95	115	2.02	226	3.98	423
40–49	204	5.13	284	7.14	488	12.27	238	4.19	376	6.62	614	10.81	1,102
50–59	282	7.09	627	15.77	909	22.86	423	7.45	865	15.23	1,288	22.68	2,197
60–69	363	9.13	869	21.85	1,232	30.98	518	9.12	1,322	23.27	1,840	32.39	3,072
Over 70	335	8.42	663	16.67	998	25.09	535	9.42	1,048	18.45	1,583	27.87	2,581
All	1,344	33.79	2,633	66.21	3,977	100.00	1,891	33.29	3,789	66.71	5,680	100.00	9,657
Arthrosis of first carpometacarpal joint (M18)													
0–29	1	5.56	0	0.00	1	5.56	1	4.00	0	0.00	1	4.00	2
30–39	1	5.56	4	22.22	5	27.78	3	12.00	5	20.00	8	32.00	13
40–49	3	16.67	0	0.00	3	16.67	1	4.00	1	4.00	2	8.00	5
50~59	1	5.56	4	22.22	5	27.78	3	12.00	5	20.00	8	32.00	13
60–69	1	5.56	1	5.56	2	11.11	2	8.00	5	20.00	7	28.00	9
Over 70	2	11.11	0	0.00	2	11.11	3	12.00	3	12.00	6	24.00	8
All	9	50.00	9	50.00	18	100.00	11	44.00	14	56.00	25	100.00	43
Other arthrosis (M19)													
0–29	127	3.71	185	5.41	312	9.12	29	1.74	27	1.62	56	3.36	368
30–39	172	5.03	192	5.61	364	10.64	61	3.66	46	2.76	107	6.42	471
40–49	235	6.87	383	11.19	618	18.06	97	5.82	134	8.04	231	13.87	849
50–59	266	7.77	534	15.60	800	23.38	187	11.22	256	15.37	443	26.59	1,243
60–69	268	7.83	395	11.54	663	19.37	176	10.56	243	14.59	419	25.15	1,082
Over 70	351	10.26	314	9.18	665	19.43	180	10.80	230	13.81	410	24.61	1,075
All	1,419	41.47	2,003	58.53	3,422	100.00	730	43.82	936	56.18	1,666	100.00	5,088

DISCUSSION

OA is a clinically common chronic degenerative disease and is the leading cause of impaired mobility and dysfunction in middle-aged and elderly people (*6*). Yichang is located in the southwest of Hubei Province. By 2020, the city had jurisdiction over 5 municipal districts, 3 county-level cities, 3 counties, and 2 autonomous counties, with a total area of 21,000 square kilometers, a permanent population of 4.1 million, and a registered population of 3.9 million. Its Big Data Platform for Health Management covers all 13 counties and urban districts of the city, as well as the 4.1 million permanent residents; it collects more than 1.8 million pieces of data every day, and stores more than 4 billion pieces of data. Interconnection maturity has reached Grade 4 A. Since its inception in 2014, data quality has been confirmed by published studies(*7*). Using the big data of Yichang, we analyzed the epidemiological characteristics of osteoarthritis by gender, age, and disease type to provide a foundation for overall management and clinical treatment of OA.

In 2017, China had 61.2 million OA patients, with an age-standardized prevalence of 3.1% (*2*). Based on number of the permanent residents in the Yichang urban area (817,700), we estimate that there are about 25,349 OA patients in the city in 2017. Among OA patients, 32.14% went to see a doctor, which reflects the low rate of doctor visits among patients with OA. This may be due to the fact that many patients are not fully aware of OA and consider it a normal phenomenon of aging and are ignored (*8*). As the population ages, so will the disease burden of OA. The proportion of OA patients in the study population was the highest between the ages of 60 and 69, with women higher than men, which is consistent with most epidemiological studies. The average age of onset for OA is around 20 years, and the majority of cases are asymptomatic. As people get older, the incidence rises; OA becomes most common after middle age (*9*), affecting women more than men (*10*). Although the effect of estrogen on OA has been extensively studied, its mechanism of action remains unknown (*11*).

The spring season has the highest number of OA hospitalizations. It is not clear if this is due to changing weather. People suffering from OA often believe that changes in the weather exacerbate pain (*12*). More research is needed to understand the relation between OA and climate change, if any. In our study, the proportion of patients with knee OA aged 60–69 years was higher in women than men from 2017 to 2018, followed by other joint diseases (M19), polyarthropathy (M15), coxarthropathy (M16), and arthrosis of first carpometacarpal joint (M18). According to Sun X et al., the prevalence of knee OA in middle-aged and elderly people in China was 21.51%; women are more likely to develop knee OA than men (*13*).

This study was subject to some limitations. First, we only analyzed OA patients who went to outpatient clinics or were hospitalized for diagnosis and treatment. The number of patients with OA was slightly underestimated due to exclusion of patients who did not seek medical attention. Second, because our study only covers the urban population of Yichang City, this exploratory research may have underestimated the number of OA patients. Data on the incidence and prevalence of OA in rural areas were not included. The incidence and prevalence of OA should be able to be analyzed in greater detail as the Big Data on Health Platform matures.

In China, the prevalence of OA among middle-age and elderly people was high. With increases in the size of the elderly population, the burden of disease caused by OA may increase. It is necessary to strengthen publicity to improve people's awareness of self-health care of bone and joint; advocate early detection, early diagnosis, and early treatment; and increase the rate of diagnosis of OA to reduce the burden of disease brought by OA. Interventions and preventive strategies targeting high-risk groups are urgently needed in order to improve healthy bones and healthy life quality among middle-age and elderly people.

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Conflicts of interest: The authors who have taken part in this study declared that they did not have any other potential conflicts of interest.

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Vital Surveillances

The Trend and Cause of Mortality Burden in Infancy — China, 1990–2019

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ABSTRACT

Introduction: China has made remarkable achievements in reducing infant deaths over the past 30 years. Meanwhile, the trend and cause composition of infant deaths have significantly changed, and the high-level years of life lost (YLLs) presents challenges to public health. This study analyzes the temporal trend and cause of infant mortality burden in China from 1990 to 2019.

Methods: Based on the updated estimates from the 2019 Global Burden of Disease Study, we used death and YLLs to describe the infant mortality burden. The percentage changes were applied to illustrate the temporal variation over the period 1990–2019.

Results: In 2019, the estimated infant deaths and YLLs in China were 101.9 (95% uncertainty interval: 88.6–116.4) thousand and 9.0 (7.9–10.3) million, respectively, which decreased by 89.9% compared with 1990. Most infant deaths occurred in the neonatal period, especially the first 7 days of life. China's infant mortality rates for all causes decreased from 1990 to 2019, whereas certain preventable causes such as preterm birth and congenital heart anomalies accounted for increasing proportions during this period.

Conclusion and Implications for Public Health Practice: The present study reveals the major preventable causes of infant deaths in China. Decreasing neonatal mortality and improving health status of children at early stage of life have great significance on public health. This is also a solution to achieve the goal of "ending preventable child deaths" of the 2030 Sustainable Development Agenda.

INTRODUCTION

Infant mortality rate (IMR) is one of the most critical indicators of social development; the reduction of IMR is proved to be the leading contributor to prolonged life expectancy (*1*–*2*). Over the past 30 years, China has made remarkable achievements in reducing the infant mortality and achieved the Millennium Development Goals ahead of schedule. Despite the gap in IMR between China and developed countries being progressively narrowed, regional disparities between rural counties of western China and urban areas in economically developed provincial-level administrative divisions remain high (*3*). Furthermore, premature mortality among infants causes a high level of years of life lost (YLL) in China, which presents challenges to population health.

A nationally comprehensive quantification of trends and leading causes of infant mortality burden (described by deaths and YLLs) can help the central authority identify national priorities for improving infant health. It can also provide important insights into achieving the Sustainable Development Goals in the new era.

In this study, we conducted a nationwide analysis with the most up-to-date data from the 2019 Global Burden of Disease (GBD) Study. Our findings can improve the evidence base for drivers that might hasten the pace of progress for infant survival.

METHODS

The GBD study used dynamic epidemiological models to ensure the results were comparable globally (*4*). Data on death causes and mortality were derived from China Disease Surveillance Points and Death Registration, China National Maternal and Child Health Surveillance System (MCHS), and relevant epidemiological studies. Cause of Death Ensemble model as the main standardized tool was applied to estimate mortality rates. The detailed methodology has been published previously (*4*–*5*). Causes of infant death in this study were defined as per the International Statistical Classification of Diseases (10th Revision). All data obtained were nationally representative.

IMR was defined as the number of infant (aged <1

year) deaths per 1,000 live births. YLLs were calculated by multiplying deaths at each age group by global age-specific standard life expectancy. For estimated absolute number of deaths and YLLs, corresponding 95% uncertainty intervals (UI) were calculated using the 2.5 percentile and 97.5 percentile estimates in a posterior simulation of 1,000 ordered draws, with the aim to examine uncertainty distributions deriving from random and systematic errors. This study presented the number of deaths and YLLs by age groups: early neonatal (0–6 days), late neonatal (7–28 days), and post neonatal (29–364 days). Percentage change was computed to characterize the temporal trend in mortality burden between 1990 and 2019.

Data obtained in this study were publicly available at the Institute for Health Metrics and Evaluation website and were accessed with open online tools (http://ghdx.healthdata.org/gbd-resultstool). SAS (version 9.4, SAS Institute Inc., Cary, NC, USA) and Microsoft Office Excel (version 2019, Microsoft, USA) were used to conduct all analyses.

RESULTS

Overall, the IMR of China underwent a notable decrease from 1990 to 2019, with variations in cause-specific IMRs and proportions of infant deaths being observed over the period.

Table 1 shows the numbers of infant deaths in 1990, 2000, 2010, and 2019, and percentage changes over the period 1990–2019. In 2019, a total of 101.9 (95% UI: 88.6–116.4) thousand deaths occurred in the infant period, which decreased by 89.9% from 1990 to 2019. China's IMR decreased by 84.3% from 43.2 deaths per 1,000 live births in 1990 to 6.8 deaths per 1,000 live births in 2019, with the rate in males being consistently higher than females. The IMR in China was considerably lower than the global level (Figure 1A).

YLLs caused by infant deaths decreased considerably from 89.8 (80.4–99.3) million in 1990 to 9.0 (7.9–10.3) million in 2019. Relative changes in YLLs and deaths in infants between 1990 and 2019 were homogeneous (Table 1).

In 2019, 55.4% of infant deaths occurred in the neonatal (early and late) period. The age composition of infant deaths has progressively changed during the past 30 years. In 1990, 36.4% (25.5% early-neonatal and 10.9% late-neonatal) of total infant deaths occurred during the neonatal period, and the proportion increased from 47.7% (37.2% early-

TABLE 1. Number of infant deaths and YLLs and percentage change (%) from 1990 to 2019, China.

Item	Deaths (thousand) (95% uncertainty intervals)					YLLs (thousand) (95% uncertainty intervals)				
	1990	2000	2010	2019	Percentage change (%), 1990–2019	1990	2000	2010	2019	Percentage change (%), 1990–2019
Early neonatal (0–6 days)	258.7 (231.1–287.0)	178.2 (162.4–194.0)	77.9 (70.9–85.2)	43.0 (37.4–49.0)	−83.4	22,988.8 (20,538.8–25,505.2)	15,831.6 (14,429.6–17,239.7)	6,919.8 (6,296.9–7571.2)	3,821.5 (3,325.5–4358.2)	−83.4
Late neonatal (7–28 days)	109.8 (98.3–121.6)	50.5 (46.0–55.0)	21.0 (19.2–22.9)	13.4 (11.7–15.3)	−87.8	9,755 (8,727.7–10,803.1)	4,489.1 (4,088.5–4,886.6)	1,868.4 (1,703.1–2,038.3)	1,193.9 (1,040.3–1,362.5)	−87.8
Post neonatal (29–364 days)	645.1 (579.2–713.5)	250.6 (228.4–273.4)	81.1 (74.0–88.7)	45.5 (39.6–51.9)	−92.9	57,029 (51,203.4–63,076.7)	22,152.4 (20,187.2–24,167.4)	7,169.1 (6,539.6,7844.0)	4,021.9 (3,497.3–4,583.8)	−92.9
<1 year	1,013.6 (908.0–1,121.6)	479.3 (436.7–522.3)	180.0 (164.2–196.7)	101.9 (88.6–116.4)	−89.9	89,772.8 (80,422.4–99,338.2)	42,473.0 (38,695.5–46,286.8)	15,957.2 (14,556.4,17437.6)	9,037.3 (7,857.3–10,322.3)	−89.9

Abbreviation: YLL=years of life lost.

neonatal and 10.5% late neonatal) in 2000 to 54.9% (43.3% early-neonatal and 11.6% late-neonatal) in 2010. By 2019, the age composition of infant deaths shifted to 42.2% for early-neonatal and 13.2% for late-neonatal. The trend of infant YLLs by age group was similar to that of deaths (Table 1).

Figure 1B focuses on IMRs for five main causes of infant death. In 2019, the 2 leading causes of deaths in infancy were preterm birth and congenital heart anomalies. Lower respiratory infection was the leading cause of infant death in both 1990 and 2000, whereas it fell in the fourth rank in 2019, with its IMR decreasing by 93.9% from 13.6 per 1,000 live births in 1990 to 0.8 per 1,000 live births in 2019. From 1990 to 2019, preterm birth, congenital heart anomalies, pulmonary aspiration and foreign body in airway, and syphilis accounted for increasing proportions of deaths, whereas the proportions in neural tube defects and some infectious diseases, such as lower respiratory infection and diarrheal disease, showed an opposite

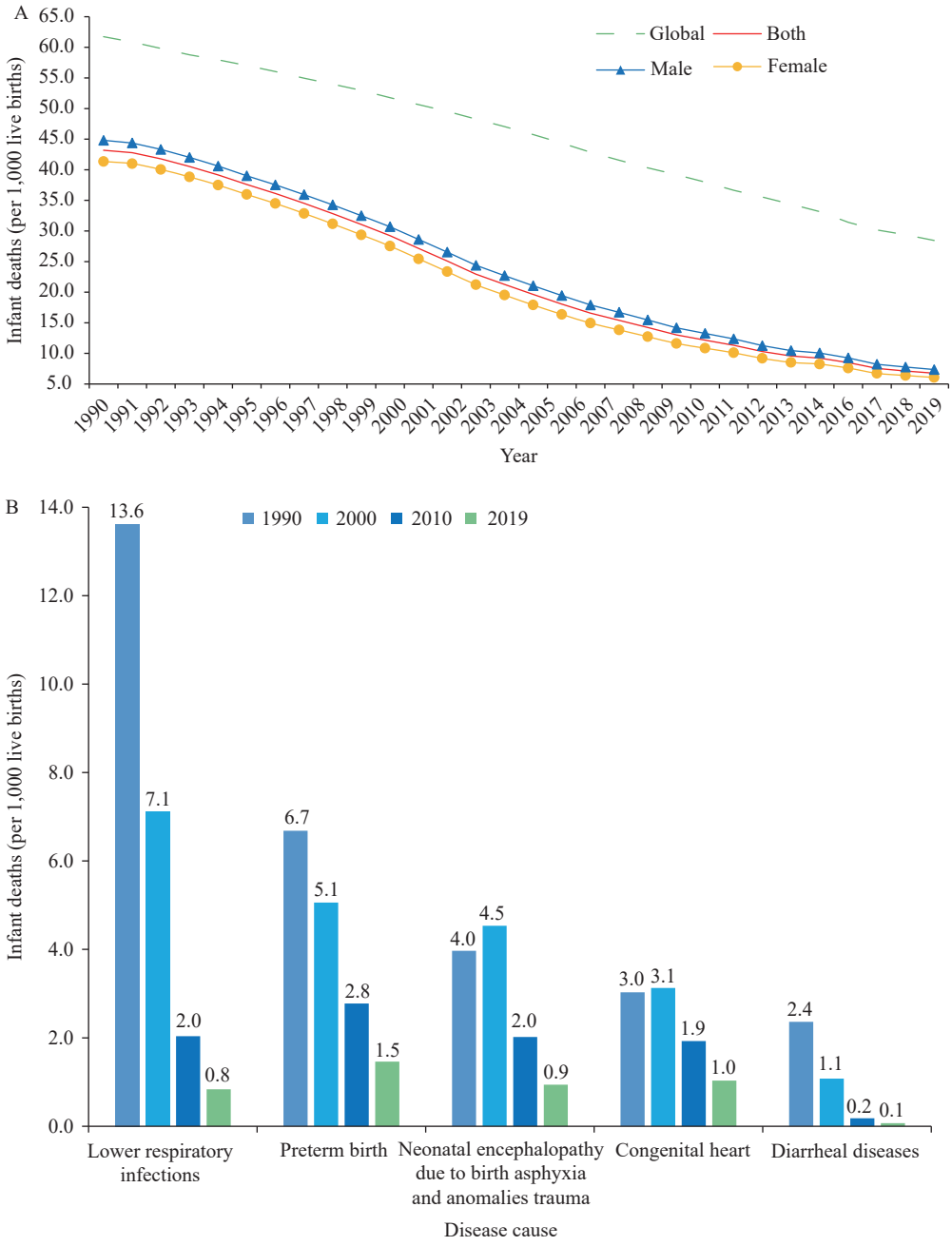

FIGURE 1. The trends of infant mortality rates by sex and cause in China, 1990–2019. (A) The trend of infant mortality rates by sex; (B) The trend of infant mortality rates by five main causes.

downward trend. A diverging trend in proportions of deaths due to neonatal encephalopathy birth asphyxia and trauma between 1990–2000 and 2010–2019 was observed (Figure 2).

DISCUSSION

Understanding the current condition of mortality burden among infants is of vital importance to prevent health loss, which is in concordance with the target "to promote and improve women and children's health" proposed in "the 14th Five-Year Health Development Plan" and "Healthy China 2030" (*6*).

Based on this study, we found that China had made tremendous progress in reducing national all-cause IMR and age-cause-specific IMRs since 1990. In 1994, the central authority introduced the *Law on Maternal and Infant Health Care* (*7*), which meant that improving maternal and infant health care as a policy priority was placed on the national development agenda. Furthermore, the implementation of health policies, as well as the improvements of income per

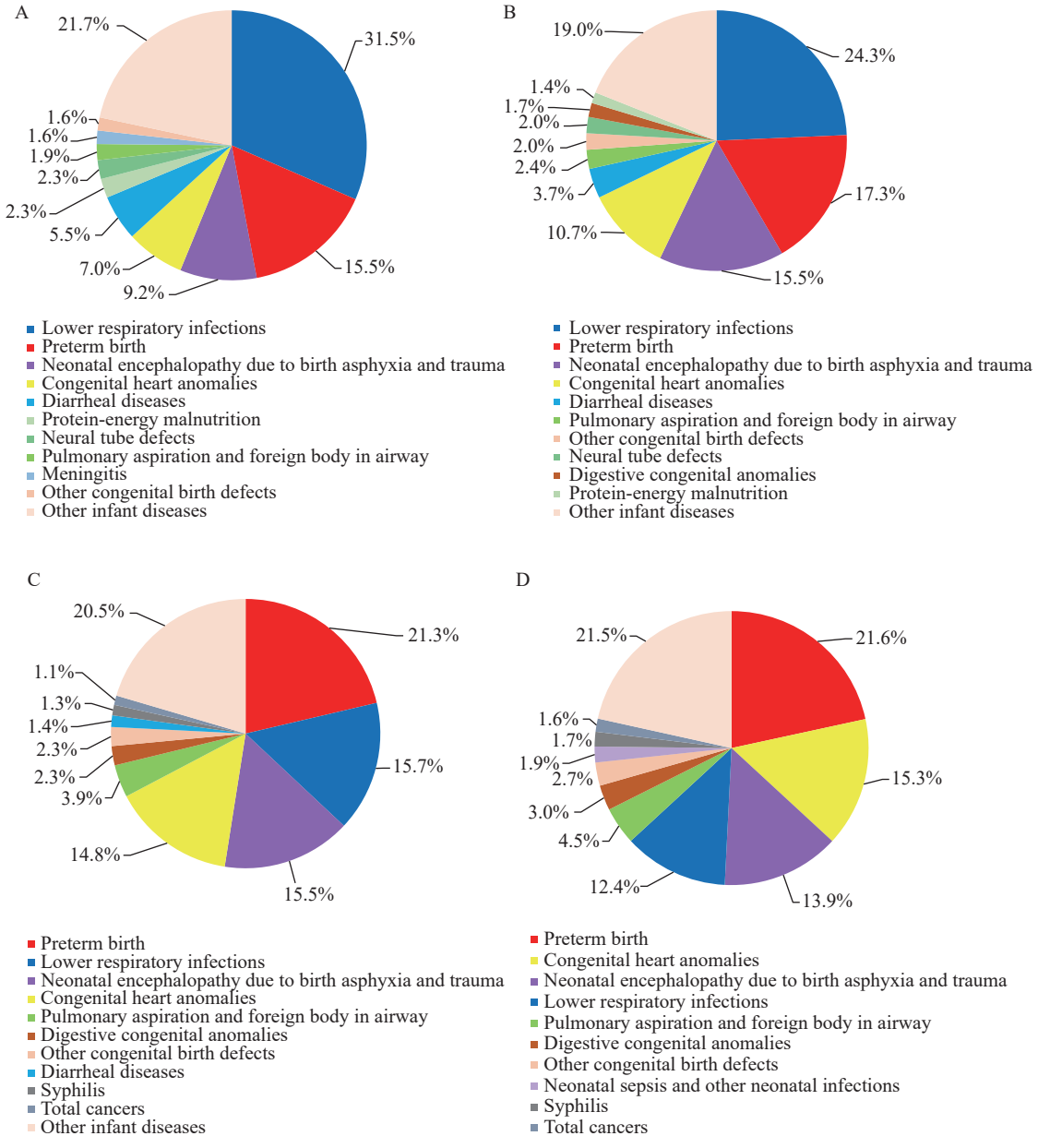

FIGURE 2. Proportion (%) of causes for infant deaths from 1990 to 2019, China. (A) in 1990; (B) in 2000; (C) in 2010; (D) in 2019.

capita, educational attainment, and medical technologies, made life-saving health interventions more available to local communities (*3*).

The cause composition of death has substantially changed over the past 30 years. For most causes including low respiratory infections, neural tube defects, and protein-energy malnutrition, the remarkable gains were closely related to the expansion of significant public health programs, such as "The Control and Prevention of Childhood Pneumonia," "The Expanded Program for Immunization," and "folic acid supplementation project," and the improvements of sanitation conditions, medical technologies, and maternal and child health services (*1*,*8*–*9*). Compared with 1990 to 2000, neonatal encephalopathy due to birth asphyxia and trauma accounted for a decreasing proportion of death from 2010 to 2019. In order to reduce the rates of mortality and disability for neonatal asphyxia, China implemented the Neonatal Resuscitation Program since 2004 (*10*). Evidence showed that the implementation of neonatal resuscitation was associated with decreased incidence and mortality rates for neonatal asphyxia (*11*). However, the increased proportions of death attributable to preterm birth, congenital heart anomalies, pulmonary aspiration and foreign body in airway, and syphilis underscore the needs of strengthening antenatal care, monitoring congenital anomalies, preventing unintentional infant injury, and intensifying the National Prevention of Mother-to-Child Transmission programme in future work (*9*).

By examining the age composition of infant mortality, we found that most infant deaths occurred in the neonatal period, especially the first seven days of life. In order to mitigate the mortality burden efficiently, interventions targeted to reduce preventable neonatal death should be implemented. The World Health Organization recommended intervention, Early Essential Newborn Care that contains a package of interventions to reduce neonatal mortality during childbirth and within the first few days after delivery, was such an attempt (*12*–*13*). National scale-up of similar practices is recommended to further promote infants' health.

This study was subject to some limitations. First, as we conducted this study at the national level, the gap in IMR between the national and sub-national levels underscores the need to undertake more specific assessments at the province/county and urban/rural levels in future studies. Second, with regard to the estimation of infant mortality, GBD used a unified methodology to ensure the results were comparable globally, which means data on mortality in this study may be slightly different from other data source such as MCHS. Nevertheless, this is the first study that provides the most up-to-date and comprehensive estimates of infants' mortality burden in China from 1990 to 2019. Our findings provide useful evidence for tailored strategies that consider highly vulnerable neonates and major causes of infant deaths and are expected to be adopted by the central and provincial health authorities.

Conflicts of interest: No conflicts of interest were reported.

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Healthy China

Interpretation of Healthy Diet Campaign in Healthy China Initiative 2019–2030

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Summary

With the continuous development of the economy and agricultural modernization in the past three decades, nutritional deficiency issues in the Chinese population have been gradually improving. However, new nutritional and health challenges have emerged. Overweight and obesity, diabetes, cardiovascular diseases, and other chronic diseases have increasingly become major disease burden. In view of the problems above, the State Council released the Healthy China Initiative 2019–2030 focusing on 15 special campaigns and the Healthy Diet Campaign (HDC) as the second campaign. This article intends to interpret HDC in details including the following four aspects: background, major indices, strategies, and features. Healthy diet is the foundation of human health, and the HDC needs to be carried out together with other campaigns to achieve the overall goal of Healthy China.

BACKGROUND

At present, one in every nine people in the world is hungry, and one in every three is overweight or obese. More and more countries experience the double burden of malnutrition, where undernutrition coexists with overweight, obesity, and other diet-related non-communicable diseases (NCDs) (*1*).

China also faces the similar problems that present serious challenges. Accompanying the acceleration of urbanization, industrialization, and population aging, people's lifestyles have changed dramatically. At the same time, there is still the issue of nutrition equity nationwide due to the vast territory, different eating habits, and uneven economic development in China.

It was reported that children aged below 6 years in the poor rural areas have the highest undernutrition prevalence resulting in 8.1% experiencing stunted, 2.5% experiencing being underweight, and 2.0% experiencing wasting in 2013. Although the anemia prevalence of children aged below 6 years was significantly decreased in comparison with 2002, 11.6% of children below 6 years still had anemia (*2*). On the other hand, the overweight and obesity prevalence of all age groups continued to rise. Overweight and obesity prevalence of children and adolescents aged 6–17 and the children aged below 6 years were 19.0% and 10.4%, respectively (*3*).

In terms of Chinese residents' diet, the intake of animal food increased, but the intake of milk and dairy products was insufficient, and the consumption of oil, salt, and sugar was excessive. The intake of fat and protein is increasing, the level of vitamin intake is decreasing, and the intake of calcium is seriously insufficient (*2*). Good nutrition is an important component of healthy living. "Healthy Diet and Balanced Nutrition" is not only important for physical health but also has a significant impact on mental health.

In October 2016, the China Central Committee and the State Council jointly released the Healthy China 2030 Blueprint, which clearly defined the objectives and action plans. As an important strategy for the Chinese government to implement the UN 2030 sustainable development goals, the Healthy China 2030 Blueprint has been updated to a new milestone in China (*4*). On July 15, 2019, the State Council issued Healthy China Initiative 2019–2030 (*5*). With a focus on disease prevention and health promotion, the initiative proposed 15 special campaigns covering 3 aspects of "intervention of health-related risk factors, protection of full-life-cycle health, and prevention and control of major diseases." The HDC, 1 of the 15 specific campaigns, plays a key role of diet in health promotion.

KEY CONTENT & TARGETS

HDC focuses on nutrition interventions for residents in poor areas, infants and young children, students, pregnant women, the elderly, and people with chronic diseases. The main places of nutrition

intervention are restaurants and canteens (cafeterias), families, food industries, schools, and communities.

HDC proposes four outcome indices including the growth rate of adult obesity, the awareness rate of nutrition and health knowledge of residents, the anemia prevalence of pregnant women, and the stunting prevalence of children under 5 years old. All of those are listed in Table 1. Seven advocacy indices were proposed by HDC, as listed in Table 2. In addition, HDC also sets index for governments. It requires one nutrition instructor (a person who could provide healthy diet and balanced nutrition guidance to the residents) per 10,000 people.

STRATEGIES

To implement this ambitious policy, we must unite people and their communities with healthcare professionals, scientists, industries, and policymakers. Therefore, the strategies were created for three levels: individual and household, societal, and governmental.

At the individual and household level, the strategies were set for different groups of people. For the general population, it is suggested to eat a variety of foods (more than 12 kinds per day and more than 25 kinds per week), limiting fatty meats, smoked and pickled meats, high-salt and fried foods, as well as the intake of added sugar. For overweight and obese adults, it is recommended to control the total energy intake, increase the intake of vegetables and fruits, moderate the intake of quality protein, and reduce consumption of greasy foods, snacks, and sugary foods. For anemia, wasting, or other undernutrition population, it is suggested to increase the intakes of lean meat, milk and eggs, soybean and bean products appropriately and maintain food diversity. It is better to increase the intake of iron-containing foods or take iron supplements under the guidance of your doctor. For pregnant and lactating women, it is recommended to learn and practice nutrition and health knowledge. Pregnant women should often eat foods which rich in iron, increase consumption of animal food products and seafood rich in high-quality protein and vitamin A, and choose iodized salt for adequate intake of iron, iodine, and folic acid during pregnancy. For the household, it is recommended to buy foods according to their needs; store the foods properly; choose fresh, hygienic, and seasonal food; adopt appropriate cooking methods; learn to read food labels; as well as dine at home.

There are five strategies at the societal level. First, the society as a whole should be encouraged to make joint efforts to promote the normalization of nutrition popularization and education activities. Second, nutrition and health practitioners should strengthen the guidance of nutrition label knowledge to food

TABLE 1. Outcome indices proposed by Healthy Diet Campaign (HDC) of Healthy China Initiative (2019–2030) in 2019.

Outcome indices	Base line	Target date	
		2022	2030
1. Growth rate of adult obesity (%)	From 2002 to 2012, the average annual growth rate was about 5.3%	Continuously slow down	
2. The awareness prevalence of nutrition and health knowledge of residents	–	10% more than in 2019	10% more than in 2022
3. The anemia prevalence of pregnant women	17.2% in 2013	<14%	<10%
4. The stunting prevalence of children under 5 years old	8.1% in 2013	<7%	<5%

TABLE 2. Advocacy indices proposed by Healthy Diet Campaign (HDC) of Healthy China Initiative (2019–2030) in 2019.

Advocacy indices	Base line	Target
1. Average daily salt intake per person (g)	10.5 in 2012	≤5
2. Average daily edible oil intake per person (g)	42.1 in 2012	25–30
3. Average daily added sugars intake per person (g)	30 in 2017	≤25
4. Average daily vegetables and fruits intake per person (g)	296 in 2012	≥500
5. Average daily types of food intake per person (g)	–	≥12
6. Adults maintain a healthy weight	In 2012, the proportion of BMI in the normal range (18.5≤BMI<24) was 52%	18.5≤BMI<24

Abbreviation: BMI=body mass index.

enterprises, guide consumers to correctly read nutrition labels, and improve the awareness rate on nutrition labels. Third, enterprises are encouraged to produce and sell low sodium salt and promote its use under the guidance of experts. Fourth, canteens and restaurants are encouraged to be equipped with full-time and part-time dietitians and regularly carry out relevant skills training and assessment for management and employees. Finally, collective meal units are required to formulate and implement nutrition operation specifications and carry out healthy canteen demonstration and healthy restaurant creation activities.

There are four strategies at the governmental level. First, relevant government departments should promote the implementation of the *National Nutrition Plan (2017–2030)* and provide nutrition and dietary guidance adjusted for local conditions, continually promote nutrition intervention in poor areas, and promote the Nutrition Improvement Program for Rural Compulsory Education Students. Second, the government should promote nutrition legislation and policy research, formulate and implement a dietitian system, strengthen clinical nutrition work, and standardize nutrition screening, evaluation, and treatment. Third, relevant departments should improve the food safety standard system, formulate nutrition and health standards based on food safety, and promote the construction of food nutrition standard system. The governments should promote the development of nutrition-oriented agriculture and food-processing industries, and promote the production and consumption of low-sugar or sugar-free foods. Fourth, it should speed up the revision of the general principles of nutrition labeling of prepackaged foods, increase the mandatory labeling of sugar such as sucrose to help consumers choose healthy foods quickly, explore the labeling of "sugar" in catering food, and study the packaging standards of oil, salt, and sugar.

FEATURES

First, HDC is a detailed dietary improvement guidance document covering the entire population for the full-life-cycle. Specific dietary guidelines and goals are given for overweight and obese people, malnourished people such as those with anemia and wasting, and pregnant women and infants. This fully reflects the precision medicine strategy. The establishment of outcome indices in stages is conducive to the gradual realization of healthy diet and the acceptance of residents.

Second, HDC advocates multilateral cooperation to promote nutritional health. Take "reducing salt, oil, and sugar" as an example. The government should formulate and implement relevant standards and stretch itself with the function of warning and marking. The social organization should strengthen the science popularization, education, and guidance to the society as a whole. It encourages and guides the nutritional transition of the food industry; the establishment and evaluation of healthy restaurants, healthy canteens, and nutrition in school; the formulation and implementation of nutritional operating norms for meals. In the household, it focusses on guiding the consumption behavior of families with low intakes of salt, sugar, and edible oil; appropriate cooking methods; and the use of salt-limiting spoons, oil-limiting pots, and other tools.

Third, HDC is closely linked to other health campaigns. HDC does not have independent effects on health status of residents. A balanced diet is the foundation of health and an important complement to the state of disease. For example, the implementation of the National Fitness Campaign requires adequate nutrition to provide the energy and nutrients needed. The prevention and treatment of chronic diseases also necessitates the adoption of different diets (including low-sodium diets, low-carbohydrate diets, etc.) according to different diseases (*6*). The occupational population in the Occupational Health Campaign needs special nutrient supplies as a special population (*7*).

CHALLENGES & PERSPECTIVE

In the past three decades, China has made considerable efforts and achieved great accomplishments in working out the problem of nutritional deficiencies, especially in the fields of maternal and child nutrition and nutrition in poor areas. However, nutrition is still facing great challenges. There has been a dramatic increase in the incidence of chronic diseases caused by nutritional excess. It is the right time to implement the HDC to fight for the rising risk of nutrition-related chronic diseases and low awareness of nutrition and health knowledge among residents in poor areas (*8*–*9*).

The Healthy China Initiative 2019–2030 is a long-term ambitious plan covering knowledge popularization, fitness, tobacco control, mental health,

and healthy environment promotion. HDC is the second major campaign aimed at comprehensive interventions for health-related nutritional risk factors. In addition, it is the basis for other campaigns to maintain health throughout the life cycle and to prevent and control major diseases. Although the current situation is still challenging, with the joint efforts of the individual and household, the society, and the government, the phased objectives and the ultimate goal of Healthy China will eventually be achieved.

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