Original Paper

Infectious Disease Diagnostic Capacity Across Hospital Tiers in China: National Cross-Sectional Survey

Ruyi Zhang[1,2], MSc; Yu Wu[3], PhD; Ziyang Ren[4], BSc; Lieyu Huang[2,5], MSc; Yihao Zhao[2], PhD; Xiaoying Zheng[2*], PhD; Jie Qian[2*], PhD; Yajie Wang[6*], PhD

[1]Beijing Ditan Hospital, Capital Medical University, Beijing, China

[2]School of Population Medicine and Public Health, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

[3]School of Management, Beijing University of Chinese Medicine, Beijing, China

[4]Department of Epidemiology and Biostatistics, School of Public Health, Peking University, Beijing, China

[5]Chinese Center for Disease Control and Prevention (Chinese Academy of Preventive Medicine), Beijing, China

[6]National Key Laboratory of Intelligent Tracking and Forecasting for Infectious Diseases, Beijing Key Laboratory of Viral Infectious Diseases, Department of Clinical Laboratory, Beijing Ditan Hospital, Capital Medical University, Beijing, China

[*]these authors contributed equally

Corresponding Author:
Xiaoying Zheng, PhD
School of Population Medicine and Public Health, Chinese Academy of Medical Sciences & Peking Union Medical College
No. 9 Dongdan Santiao, Dongcheng District
Beijing, 100730
China
Phone: 86 15001975603
Email: zhengxiaoying@sph.pumc.edu.cn

Abstract

Background: China's notifiable infectious disease surveillance relies on clinical recognition and diagnostic testing, but uneven hospital capacity may affect case ascertainment and interpretation of reported burden.

Objective: This study aims to assess infectious disease diagnostic capacity across hospital tiers in China, including alignment with notified disease burden, regional variation, diagnostic modalities, and implementation barriers.

Methods: We conducted a national cross-sectional web-based survey of hospitals in China in 2023. After centralized quality control and eligibility screening, 2689 hospitals were included: 124 (4.6%) primary, 1478 (55%) secondary, and 1087 (40.4%) tertiary hospitals. We assessed in-house and send-out testing availability; compared diagnostic availability with national notified incidence and mortality; and examined regional variation, selected diagnostic modalities, and reported barriers.

Results: Median in-house diagnostic coverage increased from 11.6% (IQR 9.3%-18.6%) in primary hospitals to 27.9% (IQR 18.6%-37.2%) in secondary hospitals and 39.5% (IQR 27.9%-48.8%) in tertiary hospitals; corresponding overall coverage, including send-out testing, was 14% (IQR 9.3%-23.3%), 32.6% (IQR 23.3%-44.2%), and 44.2% (IQR 30.2%-55.8%), respectively. Tier differences persisted in sensitivity analyses. Diagnostic availability was not consistently aligned with notified disease burden. In-house hepatitis B testing was available in 82.3% (102/124), 98% (1449/1478), and 99.3% (1079/1087) of primary, secondary, and tertiary hospitals, respectively. Pulmonary tuberculosis showed a pronounced tier gradient (26/124, 21% in primary vs 910/1087, 83.7% in tertiary hospitals). Hand, foot, and mouth disease and other infectious diarrheal diseases had limited availability even in tertiary hospitals (380/1087, 35% and 456/1087, 42%, respectively) despite high incidence. Some lower-incidence but high-consequence infections also had limited local capacity, including hemorrhagic fever with renal syndrome (151/1087, 13.9%) and rabies (43/1087, 4%) in tertiary hospitals. Geographic variation was partly consistent with known disease endemicity, with higher testing availability for hemorrhagic fever with renal syndrome in northeastern hospitals, although only 35.9% (55/153) of tertiary hospitals in this region offered in-house testing. Diagnostic depth also varied across tiers: hepatitis B virus (HBV) DNA testing increased from 8.1% (10/124) in primary hospitals to 61.1% (664/1087) in tertiary hospitals. For COVID-19, primary hospitals more frequently reported antigen than nucleic acid testing (57/124, 46% vs 27/124, 21.8%). Lower-tier hospitals more often reported workforce and infrastructure constraints, whereas tertiary hospitals more frequently cited reagent-licensing and fee-schedule barriers.

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Conclusions: Among surveyed hospitals, infectious disease diagnostic capacity differed substantially across hospital tiers, varied geographically, and was not consistently aligned with notified disease burden. These disparities extended beyond disease coverage to specific testing modalities and barriers to capacity expansion. These findings support tiered, regionally responsive diagnostic networks that provide essential testing closer to first-contact care while ensuring timely access to specialized diagnostics through reliable, quality-assured referral pathways.

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KEYWORDS

infectious diseases; diagnostic capacity; clinical laboratories; hospital tiers; disease surveillance; specimen referral; China

Introduction

Infectious diseases remain a major global health burden, contributing to substantial mortality and disability and placing considerable strain on health systems during outbreaks, epidemics, and pandemics [1]. Endemic infections, recurrent outbreaks, novel pathogens, and evolving epidemic threats continue to make infectious disease control a priority for both routine care and emergency preparedness [2-4].

Diagnostic capacity is essential to infectious disease control. Reliable testing supports clinical decision-making, antimicrobial and antiviral stewardship, outbreak detection, surveillance, and emergency response [2]. The COVID-19 pandemic highlighted the consequences of limited and uneven testing capacity, and recent global policy has increasingly positioned diagnostics as a foundation of universal health coverage, health security, and resilient service delivery [2,5]. International evidence shows that diagnostic capacity is strongly conditioned by service level [6,7] and that access is strongly shaped by laboratory network design [7,8]. Laboratory system frameworks therefore emphasize integrated diagnostic networks that combine local testing, specimen referral, transport systems, biosafety, quality assurance, and information systems [9].

China has a large tiered hospital system comprising primary, secondary, and tertiary hospitals, with hospital tiers reflecting institutional capacity for clinical care, medical education, and research [10]. In general, tertiary hospitals serve as referral hospitals providing specialist services; secondary hospitals provide comprehensive services at the city, county, or district level; and primary hospitals provide first-contact and preventive care for local populations. Hierarchical diagnosis and treatment reforms aim to organize service delivery through first contact in primary care, two-way referral, and vertical collaboration across hospital tiers [11]. However, these reforms and related evaluations have largely focused on general service delivery, resource allocation, referral behavior, and chronic disease management, whereas the cross-tier integration of infectious disease diagnostic networks has received less specific attention [12,13]. These structural differences may directly shape infectious disease diagnostic capacity, while geographic variation in infectious disease epidemiology means that national averages may obscure region-specific diagnostic needs.

China has established a national infectious disease reporting and surveillance system, with the National Notifiable Diseases Reporting System enabling direct online reporting of statutory infectious disease cases by medical and health institutions [14]. These systems provide essential population-level data for tracking incidence, mortality, and epidemic trends. However, publicly available surveillance outputs do not directly describe hospital-level diagnostic capacity. Access to individual-level surveillance and reporting data is also necessarily constrained by data security, authorization, and privacy protection requirements [15]. Previous studies in China have mainly examined public health laboratory systems; biosafety practice; laboratory equipment; emergency response capability; or selected disease-specific diagnostic fields, such as tuberculosis and fungal infections [16-18]. However, infectious disease diagnostics have rarely been evaluated as a distinct, disease-specific, and measurable hospital service capability across the national tiered hospital system [19,20]. Large-scale evidence also remains limited on how much testing can be performed locally, the extent to which send-out testing compensates for limited in-house capacity, whether diagnostic capacity is aligned with national disease burden, and how modality-specific testing capacity differs across hospital tiers. To address these gaps, we conducted a national cross-sectional survey to evaluate infectious disease diagnostic capacity across China's tiered hospital system, with particular attention to local testing availability, national disease burden alignment, regional variation, modality-specific testing capacity, and barriers to assay expansion. The findings provide system-level evidence to inform tier-specific strengthening of hospital diagnostic networks.

Methods

Study Design, Sampling, and Participants

We conducted a national cross-sectional, web-based survey of infectious disease diagnostic capacity in China in 2023. The broader survey targeted clinical laboratories in medical institutions and independent testing organizations. Network-based convenience sampling was used, with survey invitations and links disseminated through national professional networks in laboratory medicine, online professional platforms, academic meetings, and public websites. A total of 3462 questionnaire responses were initially received. All responses subsequently underwent centralized quality control and eligibility screening. During institutional deduplication, 489 (489/3462, 14.1%) duplicate submissions were removed, retaining 1 response per institution. Where multiple submissions from the same institution contained conflicting information, the laboratory director was contacted to verify the reported data. A further 195 (195/3462, 5.6%) responses were excluded because institutional information was ambiguous or internally

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inconsistent and could not be verified through follow-up. Additionally, 89 (89/3462, 2.6%) responses from independent testing organizations or other nonhospital institutions were excluded. The primary analysis sample comprised 2689 hospitals, with each hospital serving as the unit of analysis. For 1 sensitivity analysis, 242/2689 (242/2689, 9%) specialized infectious disease hospitals were excluded, leaving 2447 hospitals. The questionnaire screening and hospital selection process is illustrated in Figure S1 in Multimedia Appendix 1. The analysis was guided by previous facility readiness and diagnostic network assessment approaches [8,21]. Applied to China's statutory notifiable disease system, the framework jointly evaluated disease-specific in-house and send-out availability, hospital-tier differences, national burden alignment, regional variation, and modality-specific diagnostic depth.

Survey Instrument

The survey used a structured questionnaire developed by laboratory medicine specialists through expert interviews, 2 rounds of consultation, pilot testing, and 2 centralized reviews. It covered institutional characteristics, laboratory infrastructure, quality assurance and biosafety, disease-specific testing availability and location, diagnostic modalities, specimen referral pathways, and implementation barriers. The instrument instructed each institution to appoint a coordinator and involve the relevant laboratory specialties in completing a shared response. These procedures and reconciliation of discrepant duplicate responses supported internal consistency but did not independently validate every reported service. The present analysis used the modules relevant to assessing infectious disease diagnostic capacity in hospitals.

Disease Classification and Analytic Scope

Under the Law of the People's Republic of China on Prevention and Treatment of Infectious Diseases, statutory notifiable infectious diseases are classified into 3 categories according to their public health risks and corresponding control requirements. Class A diseases are subject to the most stringent control measures; class B diseases require specific surveillance, reporting, and control measures; and class C diseases are primarily subject to routine surveillance and prevention measures [22]. By the end of 2023, China had 41 statutory notifiable infectious diseases, comprising 2 class A, 28 class B, and 11 class C diseases. The present analysis followed the disease scope covered by the questionnaire, excluding 2 avian influenza categories (human infection with highly pathogenic avian influenza and human infection with avian influenza A[H7N9] virus) that were not separately assessed and disaggregating viral hepatitis into hepatitis A to E. Accordingly, the analytic framework comprised 43 disease-specific items: 2 class A, 30 class B, and 11 class C items. The questionnaire also included 17 preparedness-related categories of imported, emerging, or high-consequence infections of international concern. These were analyzed descriptively in Multimedia Appendix 1 but excluded from statutory disease coverage and burden-capacity analyses.

Definitions and Outcome Measures

For each disease, testing availability was classified as in-house, send-out, or unavailable. In-house availability indicated that at least 1 diagnostic modality was performed within the hospital, whereas send-out availability indicated access only through an external laboratory. Overall availability was defined as access through either pathway.

At the disease level, availability was summarized as the proportion of hospitals within each tier reporting each category; regional analyses used hospitals within each region-tier stratum as the denominator. At the hospital level, in-house diagnostic coverage was defined as the proportion of the 43 statutory notifiable infectious disease items for which in-house testing was reported. Overall diagnostic coverage was calculated similarly, counting diseases accessible through either in-house or send-out testing. Additional outcomes included modality-specific capacity for selected diseases and reported barriers to implementing assays not available in-house.

Burden-Capacity and Disease-Specific Analyses

National burden-capacity alignment was assessed by linking disease-level in-house testing availability with 2023 national incidence and mortality rates for statutory notifiable infectious diseases [23]. Priority diseases were defined as those in the highest quartile of incidence or mortality, using cutoffs of 4.9966 and 0.0005 per 100,000 population, respectively. We descriptively compared disease burden with in-house testing availability across hospital tiers. On the basis of the initial burden-capacity findings, 4 diseases were selected for further analysis, considering their public health importance, epidemiological characteristics, and observed variation in testing availability across hospital tiers and regions: hepatitis B; pulmonary tuberculosis; hand, foot, and mouth disease; and hemorrhagic fever with renal syndrome. Their specific diagnostic modalities were subsequently examined. COVID-19 was included in the hospital-level diagnostic coverage assessment but excluded from the burden-capacity comparison because comparable incidence and mortality data were not available in the official 2023 annual notifiable disease statistics. Its testing availability and diagnostic modalities were assessed separately across hospital tiers.

Statistical Analysis

Categorical variables were summarized as counts and percentages, and coverage measures as medians with IQRs. Differences in categorical variables were assessed using Pearson χ^2 tests or Fisher exact tests, as appropriate, and differences in coverage measures were assessed using Kruskal-Wallis tests. Trends across ordered hospital tiers (primary, secondary, and tertiary) were evaluated using Cochran–Armitage tests for binary indicators and Jonckheere–Terpstra tests for diagnostic coverage measures. Regional variation was examined as a secondary descriptive analysis. Hospitals were classified into 4 geographic regions (eastern, central, western, and northeastern China) according to their province-level location, following the official classification of the National Bureau of Statistics of China [24]. Within each hospital tier, we compared in-house and overall diagnostic coverage across regions and described regional

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variation in in-house testing availability for the 4 selected diseases. Hospital-tier distributions were compared with the corresponding 2023 national statistics reported in the *China Health Statistics Yearbook 2024* [25]. Two sensitivity analyses were conducted. First, hospital-level diagnostic coverage and disease-level burden-capacity analyses were repeated after excluding specialized infectious disease hospitals. Second, poststratification weights were applied to assess the influence of differences between the surveyed and national regional distributions within hospital tiers. Weights were calculated as the ratio of the national regional proportion to the corresponding sample regional proportion within each hospital tier (Table S1 in Multimedia Appendix 1). All tests were 2-sided, with $P<.05$ considered statistically significant. Analyses were conducted using Python (version 3.12; Python Software Foundation).

Ethical Considerations

This institution-level survey was determined to be exempt from ethics review by the Ethics Committee of Beijing Ditan Hospital, Capital Medical University. It collected information on hospital laboratory capacity and did not involve patient-level data, identifiable personal information, clinical interventions, or biological specimens. The requirement for informed consent was waived.

Results

Characteristics and Laboratory Readiness of Participating Hospitals

As shown in Table 1, among the 2689 hospitals included in the analysis, 124 (4.6%) were primary hospitals, 1478 (55%) were secondary hospitals, and 1087 (40.4%) were tertiary hospitals. Compared with the national distribution of graded hospitals in 2023, primary hospitals were substantially underrepresented (124/2689, 4.6% vs 13,252/29,053, 45.6%), whereas secondary (1478/2689, 55% vs 11,946/29,053, 41.1%) and tertiary hospitals (1087/2689, 40.4% vs 3855/29,053, 13.3%) were overrepresented (Table S1 in Multimedia Appendix 1). Hospital size differed markedly by tier: 92.7% (115/124) of primary hospitals had fewer than 500 beds, whereas 34.6% (376/1087) of tertiary hospitals had at least 1000 beds. Laboratory readiness also showed clear tier gradients. Across primary, secondary, and tertiary hospitals, respectively, participation in external quality assessment was reported by 53.2% (66/124), 89% (1316/1478), and 95.1% (1034/1087); biosafety level 2 (BSL-2) capacity by 30.6% (38/124), 89.9% (1329/1478), and 95.9% (1042/1087); and enhanced BSL-2 (P2+) or higher-level biosafety capacity by 6.5% (8/124), 10.1% (149/1478), and 22.7% (247/1087) (all $P<.001$ for trend across hospital tiers). ISO 15189 accreditation was most common in tertiary hospitals (166/1087, 15.3%), compared with 6.5% (8/124) in primary and 4.9% (73/1478) in secondary hospitals.

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Table 1. Characteristics and laboratory infrastructure of participating hospitals, by hospital tier[a].

Characteristic	Total sample (N=2689), n (%)	Primary hospitals (n=124), n (%)	Secondary hospitals (n=1478), n (%)	Tertiary hospitals (n=1087), n (%)	*P* value
Specialized infectious disease hospital	242 (9)	3 (2.4)	136 (9.2)	103 (9.5)	.03
Number of beds					<.001
<500	1491 (55.4)	115 (92.7)	1055 (71.4)	321 (29.5)	
500-999	739 (27.5)	4 (3.2)	345 (23.3)	390 (35.9)	
1000-1499	254 (9.4)	3 (2.4)	49 (3.3)	202 (18.6)	
≥1500	205 (7.6)	2 (1.6)	29 (2)	174 (16)	
Laboratory accreditation status					
ISO 15189	247 (9.2)	8 (6.5)	73 (4.9)	166 (15.3)	<.001
CAP[b]	28 (1)	3 (2.4)	15 (1)	10 (0.9)	.29
ISO 17025	25 (0.9)	2 (1.6)	15 (1)	8 (0.7)	.55
Others	59 (2.2)	1 (0.8)	37 (2.5)	21 (1.9)	.35
None	2358 (87.7)	115 (92.7)	1352 (91.5)	891 (82)	<.001
Average daily volume of preoperative 4- or 8-item infectious disease screening panels, cases/d					<.001
<20	918 (34.1)	82 (66.1)	667 (45.1)	169 (15.5)	
20-49	745 (27.7)	8 (6.5)	469 (31.7)	268 (24.7)	
50-99	505 (18.8)	2 (1.6)	223 (15.1)	280 (25.8)	
100-199	289 (10.7)	2 (1.6)	70 (4.7)	217 (20)	
≥200	158 (5.9)	2 (1.6)	21 (1.4)	135 (12.4)	
Not applicable	74 (2.8)	28 (22.6)	28 (1.9)	18 (1.7)	
Turnaround time for 4-item infectious disease screening in pregnant or postpartum women (min)					<.001
≤30	1108 (41.2)	56 (45.2)	655 (44.3)	397 (36.5)	
>30	1201 (44.7)	29 (23.4)	622 (42.1)	550 (50.6)	
Not applicable	380 (14.1)	39 (31.5)	201 (13.6)	140 (12.9)	
Handling of borderline or gray-zone results					
Report directly	76 (2.8)	6 (4.8)	38 (2.6)	32 (2.9)	.33
Report after review	2442 (90.8)	90 (72.6)	1355 (91.7)	997 (91.7)	<.001
Report with interpretive remarks	841 (31.3)	41 (33.1)	434 (29.4)	366 (33.7)	.06
Laboratory biosafety level					
BSL-1[c]	757 (28.2)	88 (71)	421 (28.5)	248 (22.8)	<.001
BSL-2[d]	2409 (89.6)	38 (30.6)	1329 (89.9)	1042 (95.9)	<.001
Enhanced BSL-2 (P2+[e]) or above	404 (15)	8 (6.5)	149 (10.1)	247 (22.7)	<.001
Participation in external quality assessment					<.001
Yes	2416 (89.8)	66 (53.2)	1316 (89)	1034 (95.1)	
No	248 (9.2)	47 (37.9)	155 (10.5)	46 (4.2)	
Not reported	25 (0.9)	11 (8.9)	7 (0.5)	7 (0.6)	

[a]Percentages were calculated using all hospitals within each column as the denominator. Multiple responses were allowed for laboratory accreditation status, handling of borderline or gray-zone results, and laboratory biosafety level. *P* values compare hospital tiers.

[b]CAP: College of American Pathologists.

[c]BSL1: biosafety level 1.

[d]BSL2: biosafety level 2.

[e]P2+: enhanced biosafety level 2.

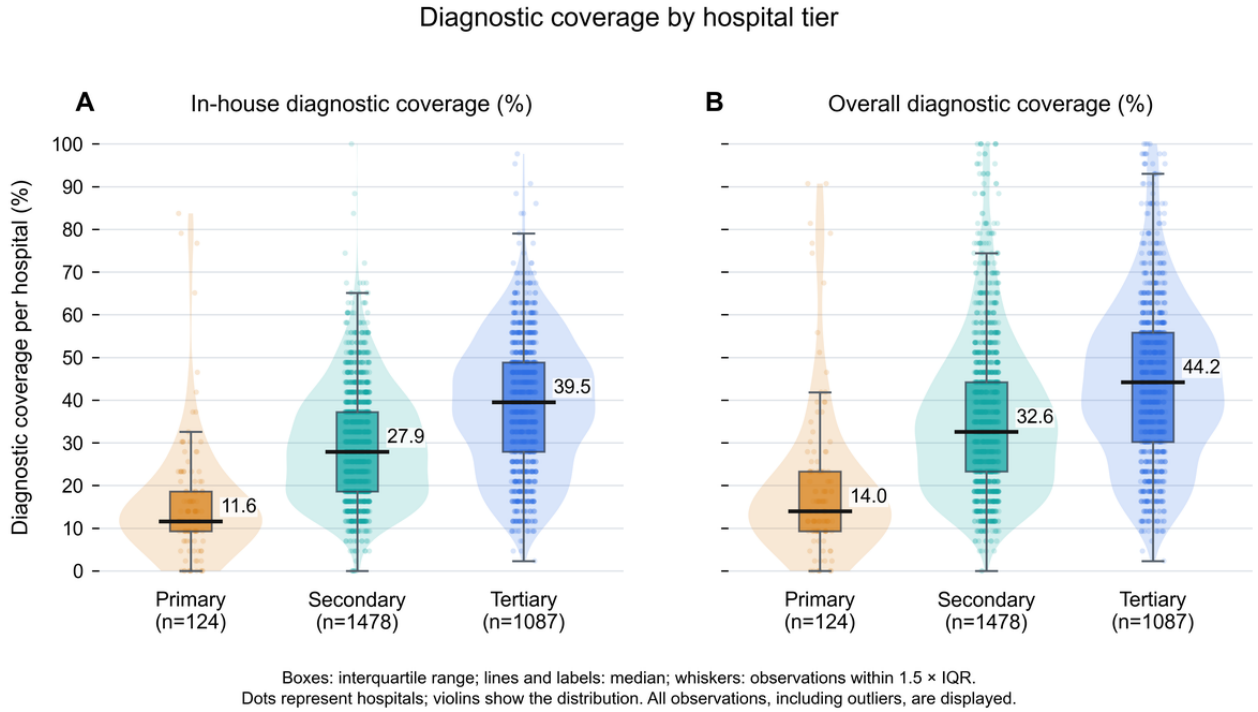
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Disease-Level Testing Availability and Statutory Disease Diagnostic Coverage

Disease-level testing availability was uneven and concentrated in a limited group of common or program-prioritized statutory diseases (Table S2 in Multimedia Appendix 1). In primary hospitals, in-house testing was mainly available for established screening or program-prioritized infections, including hepatitis B, AIDS, syphilis, and hepatitis C. In-house availability was broader in secondary and tertiary hospitals and exceeded 95% for all 4 infections in tertiary hospitals. By contrast, many rare, imported, or outbreak-prone infections had limited hospital-based testing availability, including mpox, poliomyelitis, rabies, Japanese encephalitis, and dengue. Some lower-volume or more specialized assays, such as hepatitis D testing, showed greater reliance on send-out testing.

Hospital-level diagnostic coverage was calculated only across the 43 surveyed statutory notifiable infectious disease items (Figure 1). Median in-house diagnostic coverage was 11.6% (IQR 9.3%-18.6%) in primary hospitals, 27.9% (IQR 18.6%-37.2%) in secondary hospitals, and 39.5% (IQR 27.9%-48.8%) in tertiary hospitals. Corresponding overall coverage, including send-out testing, was 14% (IQR 9.3%-23.3%), 32.6% (IQR 23.3%-44.2%), and 44.2% (IQR 30.2%-55.8%), respectively (both $P<.001$ for trend across hospital tiers). Thus, send-out testing modestly expanded availability but did not eliminate the substantial tier gradient in local diagnostic coverage. The hospital-tier gradient persisted in both sensitivity analyses (Table S3 in Multimedia Appendix 1). After excluding 242 specialized infectious disease hospitals, median in-house diagnostic coverage was 11.6% (IQR 9.3%-18.6%), 27.9% (IQR 18.6%-37.2%), and 37.2% (IQR 25.6%-48.8%) in primary, secondary, and tertiary hospitals, respectively; corresponding overall coverage was 14% (IQR 9.3%-23.3%), 32.6% (IQR 20.9%-44.2%), and 41.9% (IQR 30.2%-55.8%). Following poststratification to the national regional distribution within each hospital tier, median in-house coverage increased from 11.6% (IQR 9.3%-18.6%) to 14% (IQR 9.3%-20.9%) in primary hospitals, while overall coverage increased from 14% (IQR 9.3%-23.3%) to 16.3% (IQR 11.6%-23.3%). The corresponding medians in secondary and tertiary hospitals remained unchanged, and the graded differences across hospital tiers were maintained.

Figure 1. Distribution of in-house and overall diagnostic coverage by hospital tier. (A) In-house diagnostic coverage. (B) Overall diagnostic coverage. Diagnostic coverage was calculated across the 43 surveyed statutory notifiable infectious disease items. Violin plots show the distribution across hospitals; boxes indicate the IQR, and horizontal lines indicate the median. Overall diagnostic coverage was defined as availability through either in-house or send-out testing.



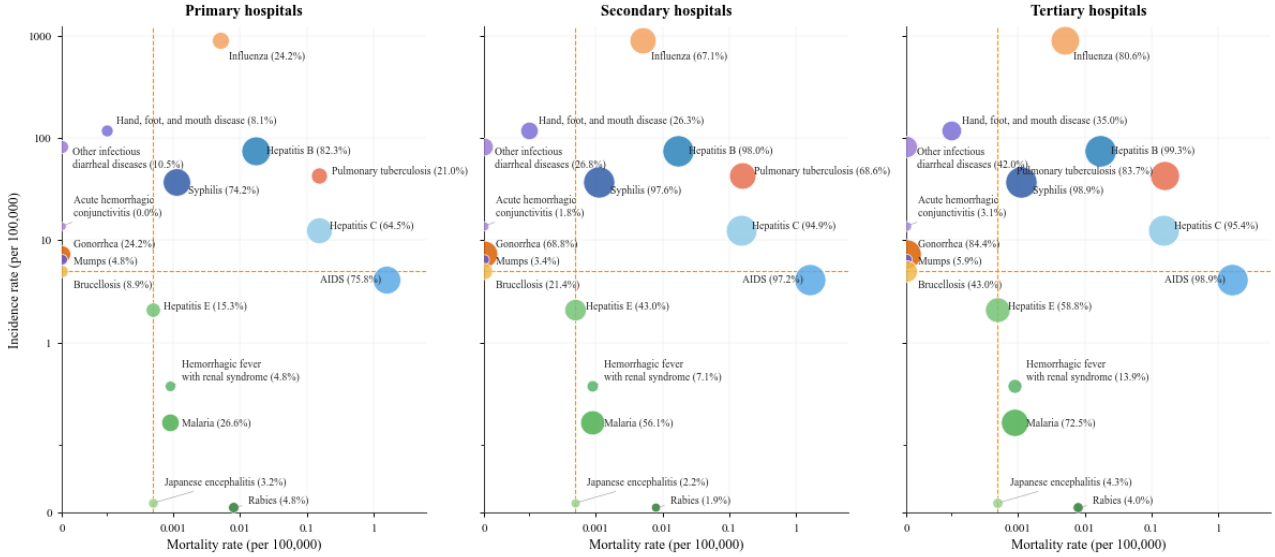
Diagnostic coverage varied across the 4 regions within each hospital tier (Table S4 in Multimedia Appendix 1). Median in-house coverage ranged from 9.3% (IQR 4.7%-14%) in eastern China to 16.3% (IQR 14%-23.3%) in central China among primary hospitals; among secondary hospitals, it was lowest in northeastern China (20.9%, IQR 14%-27.9%) and highest in central (30.2%, IQR 23.3%-39.5%) and western China (30.2%, IQR 18.6%-39.5%). Among tertiary hospitals, it ranged from 30.2% (IQR 18.6%-39.5%) in northeastern China to 44.2% (IQR 34.9%-51.2%) in eastern China. Differences in both in-house and overall diagnostic coverage across regions were statistically significant within each hospital tier (all $P\leq.001$). Including send-out testing increased overall coverage across regions but did not materially alter the broad regional patterns or the higher coverage observed in higher-tier hospitals within each region.

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Diagnostic Availability in Relation to Disease Burden and Geography

Among statutory notifiable diseases in the highest quartile of national notified incidence or mortality, in-house testing availability across hospital tiers is shown in Figure 2, with detailed estimates in Table S5 in Multimedia Appendix 1. Testing availability differed substantially in relation to disease burden. Hepatitis B, AIDS, syphilis, and hepatitis C showed high in-house availability, exceeding 94% in secondary and tertiary hospitals. Despite substantial notified incidence or mortality, pulmonary tuberculosis and influenza exhibited pronounced tier gradients, with availability increasing from 21% (26/124) to 83.7% (910/1087) and from 24.2% (30/124) to 80.6% (876/1087), respectively, between primary and tertiary hospitals (P<.001 for trend across hospital tiers). In contrast, hand, foot, and mouth disease and other infectious diarrheal diseases had high notified incidence (118.71 and 82.66 per 100,000 population, respectively) but limited availability even in tertiary hospitals (380/1087, 35% and 456/1087, 42%, respectively). Lower-incidence infections with mortality rates above the upper-quartile threshold, including hemorrhagic fever with renal syndrome and rabies, also showed limited availability in tertiary hospitals (151/1087, 13.9% and 43/1087, 4%, respectively). These findings remained broadly consistent after excluding specialized infectious disease hospitals (Table S6 in Multimedia Appendix 1).

Figure 2. National disease burden and in-house testing capacity for priority statutory infectious diseases across hospital tiers. The x-axis shows the national mortality rate per 100,000 population, and the y-axis shows the national incidence rate per 100,000 population; both use a modified logarithmic scale. Bubble size represents the proportion of hospitals reporting in-house testing. Dashed lines indicate the highest-quartile cutoffs used for disease selection: 4.9966 per 100,000 for incidence and 0.0005 per 100,000 for mortality. Burden measures are 2023 national notified rates.



We further examined regional variation in testing availability for 4 diseases with contrasting burden and diagnostic profiles: hepatitis B; pulmonary tuberculosis; hand, foot, and mouth disease; and hemorrhagic fever with renal syndrome. The results are presented in Table S7 in Multimedia Appendix 1. Hepatitis B testing was consistently high in secondary and tertiary hospitals across regions (165/174, 94.8% to 280/281, 99.6%). Pulmonary tuberculosis testing was more frequently reported in central and western primary and secondary hospitals, whereas eastern tertiary hospitals had the highest availability (253/268, 94.4%). Hand, foot, and mouth disease testing was highest in central China but remained limited even among tertiary hospitals (153/281, 54.4%). Hemorrhagic fever with renal syndrome showed marked regional variation, with in-house testing reported by 24.9% (49/197) of northeastern secondary hospitals and 35.9% (55/153) of northeastern tertiary hospitals.

Modality-Specific Testing Capacity

The availability of specific diagnostic modalities for the 4 selected diseases varied across hospital tiers (Table 2). For hepatitis B, in-house testing was primarily based on antigen or antibody assays. Hepatitis B virus (HBV) DNA testing increased from 8.1% (10/124) in primary hospitals to 61.1% (664/1087) in tertiary hospitals, whereas HBV RNA testing remained uncommon across all tiers. For pulmonary tuberculosis, availability increased across hospital tiers for both conventional and advanced modalities, including smear microscopy, culture, nucleic acid testing, interferon-gamma release assay, drug-resistance gene testing, and nontuberculous mycobacteria testing (all P<.001 for trend across hospital tiers). For hand, foot, and mouth disease, limited in-house availability was accompanied by limited method-specific capacity; even in tertiary hospitals, nucleic acid testing was reported by only 13.5% (147/1087), antigen testing by 7.7% (84/1087), and immunoglobulin M testing by 18.3% (199/1087). For hemorrhagic fever with renal syndrome, local serological capacity remained limited, with IgM testing reported by 4.8% (6/124) of primary hospitals and 13.1% (142/1087) of tertiary hospitals.

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Table 2. Modality-specific testing availability for selected infectious diseases, by hospital tier[a].

Disease and testing method	Primary hospitals (n=124), n (%)	Secondary hospitals (n=1478), n (%)	Tertiary hospitals (n=1087), n (%)	*P* value
Hepatitis B				
In-house testing	102 (82.3)	1449 (98)	1079 (99.3)	<.001
Send-out testing	7 (5.6)	20 (1.4)	3 (0.3)	<.001
Antigen or antibody testing	101 (81.5)	1443 (97.6)	1071 (98.5)	<.001
HBV[b] DNA testing	10 (8.1)	443 (30)	664 (61.1)	<.001
Quantitative HBV DNA testing	9 (7.3)	421 (28.5)	635 (58.4)	<.001
HBV RNA testing	1 (0.8)	32 (2.2)	33 (3)	.18
HBV resistance genotyping	11 (8.9)	84 (5.7)	138 (12.7)	<.001
Pulmonary tuberculosis				
In-house testing	26 (21)	1014 (68.6)	910 (83.7)	<.001
Send-out testing	7 (5.6)	95 (6.4)	39 (3.6)	.006
Smear microscopy	21 (16.9)	870 (58.9)	839 (77.2)	<.001
Culture	10 (8.1)	391 (26.5)	357 (32.8)	<.001
Nucleic acid testing	10 (8.1)	350 (23.7)	410 (37.7)	<.001
Interferon-gamma release assay	4 (3.2)	139 (9.4)	358 (32.9)	<.001
Drug-resistance gene testing	11 (8.9)	241 (16.3)	297 (27.3)	<.001
Nontuberculous mycobacteria testing	7 (5.6)	129 (8.7)	245 (22.5)	<.001
Hand, foot, and mouth disease				
In-house testing	10 (8.1)	389 (26.3)	380 (35)	<.001
Send-out testing	7 (5.6)	118 (8)	70 (6.4)	.26
Nucleic acid testing	3 (2.4)	60 (4.1)	147 (13.5)	<.001
Antigen testing	4 (3.2)	89 (6)	84 (7.7)	.07
IgM[c] testing	3 (2.4)	235 (15.9)	199 (18.3)	<.001
Hemorrhagic fever with renal syndrome				
In-house testing	6 (4.8)	105 (7.1)	151 (13.9)	<.001
Send-out testing	5 (4)	154 (10.4)	117 (10.8)	.06
IgM testing	6 (4.8)	96 (6.5)	142 (13.1)	<.001
IgG[d] testing	3 (2.4)	76 (5.1)	108 (9.9)	<.001
COVID-19				
In-house testing	70 (56.5)	1333 (90.2)	1041 (95.8)	<.001
Send-out testing	11 (8.9)	49 (3.3)	10 (0.9)	<.001
Nucleic acid testing	27 (21.8)	1181 (79.9)	1004 (92.4)	<.001
Fluorescence-based PCR[e]	25 (20.2)	1144 (77.4)	983 (90.4)	<.001
Antigen testing	57 (46)	988 (66.8)	756 (69.5)	<.001
Antibody testing	15 (12.1)	520 (35.2)	625 (57.5)	<.001

[a]Percentages were calculated using all hospitals within each tier as the denominator. *P* values compare hospital tiers using Pearson χ^2 tests or Fisher exact tests, as appropriate.

[b]HBV: hepatitis B virus.

[c]IgM: immunoglobulin M.

[d]IgG: immunoglobulin G.

[e]PCR: polymerase chain reaction.

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COVID-19 testing availability was additionally assessed across hospital tiers (Table 2). Overall testing availability reached 65.3% (81/124) in primary hospitals, with in-house availability exceeding 90% in secondary and tertiary hospitals (1333/1478, 90.2% and 1041/1087, 95.8%, respectively). In primary hospitals, antigen testing was more widely available than nucleic acid testing (57/124, 46% vs 27/124, 21.8%). In contrast, nucleic acid testing was widely available in secondary and tertiary hospitals (1181/1478, 79.9% and 1004/1087, 92.4%, respectively), predominantly through fluorescence-based polymerase chain reaction. Thus, relatively broad COVID-19 testing availability coexisted with pronounced hospital-tier differences in molecular testing.

Reported Barriers to Expanding In-House Testing Capacity

Reported barriers differed by hospital tier (Table 3). Insufficient personnel, laboratory space, and technical or laboratory capability became progressively less common from primary to tertiary hospitals (P=.004, P<.001, and P<.001, respectively, for trend across hospital tiers). Conversely, lack of licensed reagents and absence of an official fee schedule increased across tiers (both P<.001 for trend). These findings suggest that lower-tier hospitals were mainly constrained by infrastructure and operational capacity, whereas higher-tier hospitals were more often limited by regulatory and reimbursement conditions.

Table 3. Reported barriers to implementing infectious disease assays not available in-house, by hospital tier[a].

Reported barrier	Total sample (N=2689), n (%)	Primary hospitals (n=124), n (%)	Secondary hospitals (n=1478), n (%)	Tertiary hospitals (n=1087), n (%)	*P* value
Insufficient personnel	1163 (43.3)	64 (51.6)	660 (44.7)	439 (40.4)	.02
Lack of licensed reagents	389 (14.5)	6 (4.8)	117 (7.9)	266 (24.5)	<.001
No official fee schedule	985 (36.6)	14 (11.3)	429 (29)	542 (49.9)	<.001
Stringent biosafety requirements	747 (27.8)	60 (48.4)	392 (26.5)	295 (27.1)	<.001
Regulatory or policy restrictions	424 (15.8)	22 (17.7)	214 (14.5)	188 (17.3)	.13
Insufficient laboratory space	1202 (44.7)	92 (74.2)	682 (46.1)	428 (39.4)	<.001
Insufficient technical or laboratory capability	858 (31.9)	74 (59.7)	506 (34.2)	278 (25.6)	<.001
Other barriers	271 (10.1)	7 (5.6)	145 (9.8)	119 (10.9)	.16

[a]Multiple responses were allowed. Percentages were calculated using all hospitals within each tier as the denominator. *P* values in the table compare hospital tiers using Pearson χ^2 tests. *P* values for ordered trend reported in the text were calculated using Cochran-Armitage tests.

Discussion

Principal Findings

In this national cross-sectional survey of 2689 hospitals, infectious disease diagnostic capacity differed substantially across hospital tiers. Tertiary hospitals had broader diagnostic coverage, stronger laboratory readiness, and greater modality-specific capacity than secondary and primary hospitals. Send-out testing modestly expanded overall testing availability but did not eliminate disparities in in-house testing across hospital tiers. Importantly, diagnostic availability was not consistently aligned with national notified disease burden, as several diseases showed limited testing availability or pronounced hospital-tier disparities despite substantial notified incidence or mortality. Diagnostic breadth and disease-specific testing also varied geographically within tiers. Taken together, these findings indicate that disparities in hospital diagnostic capacity extend beyond disease coverage to differences in in-house testing availability, diagnostic modalities, geographic distribution, and reported barriers to capacity expansion.

Our findings are consistent with previous Chinese evidence showing that infectious disease surveillance and laboratory capacity vary across administrative levels, institutions, and regions. Studies of China's network-based notifiable disease reporting system have documented substantial improvements in reporting coverage and timeliness following the introduction of internet-based direct reporting, while also emphasizing the continuing need to strengthen data quality and system integration [14,26]. National surveys of public health laboratories have similarly identified uneven pathogen-detection capacity, biosafety practices, and equipment configuration [17,18]. Our study extends this evidence by examining routine, disease-specific diagnostic capacity within clinical hospitals, thereby complementing previous research focused on surveillance performance and general laboratory readiness.

The burden-capacity analysis revealed several notable differences in diagnostic availability across infectious diseases. First, hepatitis B, HIV, and syphilis showed relatively high testing availability across hospital tiers, consistent with China's reported disease burden [22,23,27] and potentially reflecting sustained screening demand and established national programs [28-30]. In contrast, many zoonotic infections with natural foci, vector-borne infections, and imported or outbreak-prone infections occur infrequently or are geographically clustered, making routine in-house testing difficult to sustain across all hospital tiers [31,32]. Second, pulmonary tuberculosis showed a pronounced hospital-tier gradient alongside geographic variation. Testing was more frequently available in western and central primary and secondary hospitals, consistent with the greater tuberculosis burden in western China [33], whereas the highest tertiary-hospital availability was observed in eastern

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China, suggesting that both epidemiological need and the geographic concentration of advanced hospital resources influenced capacity. Third, several common, high-incidence community-transmitted infections showed limited hospital-based diagnostic availability. For hand, foot, and mouth disease, despite its high incidence and concentration in southern and eastern China and in several central provinces [34,35], testing remained limited across regions, reaching only 54.4% (153/281) in central and 35.1% (94/268) in eastern tertiary hospitals. This suggests that high incidence alone does not necessarily translate into widespread hospital-based pathogen testing. Fourth, some lower-incidence but high-consequence infections showed geographically concentrated but generally limited capacity. Hemorrhagic fever with renal syndrome, for example, showed higher availability in northeastern hospitals, consistent with its long-standing geographic endemicity [36,37], although absolute availability remained low even in this high-risk region. Together, these observations suggest that notified burden alone does not determine hospital testing availability. Routine clinical demand, program design, geographic clustering, expected test volume, biosafety requirements, and the roles of designated hospitals and public health laboratories may also be relevant. These findings underscore the importance of considering regional epidemiology and hospital functions alongside national disease burden when assessing diagnostic needs.

Access through external laboratories cannot necessarily be equated with timely local diagnostic capacity. Effective referral testing depends on reliable specimen collection and transport; acceptable turnaround times; quality assurance; integrated reporting systems; and clear linkage with clinical care, surveillance, and public health laboratories [2,38]. Moreover, disease-level testing availability did not necessarily reflect diagnostic depth. In lower-tier hospitals, hepatitis B testing was largely limited to serological assays, whereas HBV DNA and other molecular methods were concentrated in higher-tier hospitals. Similar gradients were observed for tuberculosis culture, nucleic acid testing, drug-resistance testing, and mycobacterial identification, while method-specific capacity for hand, foot, and mouth disease and hemorrhagic fever with renal syndrome remained limited even in tertiary hospitals. COVID-19 provided a complementary example. Nationwide efforts to expand molecular testing capacity and introduce antigen testing in primary care during the pandemic may partly explain its relatively broad testing availability across hospital tiers [39,40]. Nevertheless, antigen testing was more widely available than nucleic acid testing in primary hospitals, whereas molecular testing was widely available in secondary and tertiary hospitals. These differences are consistent with international evidence that advanced assays require specialized platforms, trained personnel, biosafety infrastructure, validated workflows, quality systems, and sufficient testing volume [41-43]. The reported barriers further suggest why expansion strategies should differ by tier: lower-tier hospitals more frequently reported constraints involving personnel, laboratory space, technical capability, and biosafety infrastructure, whereas tertiary hospitals more frequently reported reagent-licensing and fee-schedule barriers. Policy responses should therefore combine investments in workforce and infrastructure at lower hospital tiers with regulatory and reimbursement reforms in settings where technical capacity is already established.

These findings support tiered strengthening of diagnostic capacity rather than uniform expansion: hospitals should provide tests appropriate to their functions, supported by referral pathways to public health or reference laboratories for specialized diagnostics [44]. Tier-specific minimum test packages should be guided by statutory responsibilities, national minimum requirements, regional epidemiological profiles, routine clinical demand, expected test volume, assay complexity, and referral networks [45], consistent with the World Health Organization Essential Diagnostics List [46]. Primary hospitals should provide reliable first-line testing for common, time-sensitive, and program-prioritized infections and safely refer cases requiring more complex testing; secondary hospitals should consolidate testing for common notifiable diseases and selected rapid or molecular assays; and tertiary hospitals should function as hubs for advanced diagnostics, confirmation, quality assurance, and training. For rare, imported, outbreak-prone, or specially managed infections, quality-assured send-out pathways linked to public health or reference laboratories may be more appropriate than universal on-site testing. Such pathways should include standardized specimen collection, packaging, and transport procedures; electronic specimen tracking; explicit fee and reimbursement arrangements; predefined turnaround-time targets; timely return of interpretable results; and clear linkage to surveillance, case management, and public health action [9,47].

This study has several strengths. Compared with previous facility readiness surveys based on a limited set of selected laboratory tests, we evaluated disease-specific diagnostic capacity across China's statutory notifiable disease framework in a large, geographically diverse sample of hospitals spanning all 3 tiers. By integrating in-house and send-out testing, national disease burden, regional variation, modality-specific diagnostic depth, and implementation barriers, we assessed diagnostic capacity in terms of coverage, local deliverability, burden alignment, geographic heterogeneity, technical complexity, and implementation constraints. Importantly, because routine surveillance counts depend on clinical recognition and diagnostic confirmation, this framework identifies potential structural sources of differential case ascertainment and provides an empirical basis for future studies seeking to calibrate surveillance data and estimate underlying disease burden.

Several limitations should be considered. First, hospitals were recruited through professional laboratory networks using convenience sampling, with primary hospitals substantially underrepresented relative to the national hospital distribution. Although poststratification accounted for differences in regional composition within hospital tiers, it could not eliminate potential selection bias within these strata. Hospitals with stronger laboratory capacity may have been more likely to participate, limiting the generalizability of our findings to hospitals nationwide, particularly primary hospitals. Second, diagnostic capacity was self-reported. To improve reporting consistency, institutions were asked to coordinate responses across relevant laboratory specialties, and discrepant duplicate submissions were checked with laboratory directors. However, reported

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testing availability was not independently verified through site inspections or operational records. Third, the study measured institutional capacity rather than patient-level diagnostic access, actual test use, turnaround time, affordability, diagnostic accuracy, or clinical outcomes. Finally, although the questionnaire identified whether hospitals reported a send-out testing pathway, it did not capture specimen transport frequency, result-return time, cost, digital integration, or whether results were clinically actionable. Therefore, send-out testing should be interpreted as a reported laboratory access pathway, not as equivalent to timely local diagnostic capacity.

Conclusions

Among participating hospitals in China, infectious disease diagnostic capacity differed substantially across hospital tiers, varied geographically, and was not consistently aligned with notified disease burden. The disparities extended disease coverage to in-house testing availability, modality-specific capacity, and barriers to expansion. The findings support a tiered and regionally responsive diagnostic strategy that strengthens essential testing near first-contact care while ensuring timely access to specialized diagnostics through reliable, quality-assured referral networks.

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Data Availability

The hospital-level data are not publicly available because they contain potentially sensitive institutional information. Access requests may be directed to the corresponding authors and will be considered subject to applicable data security, institutional authorization, and confidentiality requirements.

Generative AI Use

ChatGPT (GPT-5.5; OpenAI) was used during manuscript preparation to assist with English-language editing. All AI-generated suggestions were critically reviewed, fact-checked, and revised by the authors, who take full responsibility for the accuracy and integrity of the final manuscript.

Authors' Contributions

RZ led the conceptualization, data curation, visualization, and writing (original draft of the paper). Y Wu, ZR, LH, and YZ contributed to formal analysis and methodology. Y Wang supported the investigation and provided co-supervision with XZ and JQ. XZ, JQ, and Y Wang supported administration and revisions. All authors contributed to writing and reviewing the paper. XZ, JQ, and Y Wang are co-corresponding authors. Their correspondence information is as follows:

Xiaoying Zheng: School of Population Medicine and Public Health, Chinese Academy of Medical Sciences & Peking Union Medical College, No. 9 Dongdan Santiao, Dongcheng District, Beijing 100730, China. Email: zhengxiaoying@sph.pumc.edu.cn.
Jie Qian: School of Population Medicine and Public Health, Chinese Academy of Medical Sciences & Peking Union Medical College, No. 9 Dongdan Santiao, Dongcheng District, Beijing 100730, China. Email: qianjie@sph.pumc.edu.cn.
Yajie Wang: National Key Laboratory of Intelligent Tracking and Forecasting for Infectious Diseases, Beijing Key Laboratory of Viral Infectious Diseases, Department of Clinical Laboratory, Beijing Ditan Hospital, Capital Medical University, No. 8 Jingshun East Street, Chaoyang District, Beijing 100015, China. Email: wangyajie@ccmu.edu.cn.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Hospital distributions, disease-specific diagnostic testing availability, regional variations, burden-capacity comparisons, sensitivity analyses, and the questionnaire screening and hospital selection process.
[DOCX File , 103 KB-Multimedia Appendix 1]

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Abbreviations

HBV: hepatitis B virus
BSL-2: biosafety level 2

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