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Quality assurance in the HIV/AIDS laboratory network of China

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Background In 2009, there were 8273 local screening laboratories, 254 confirmatory laboratories, 35 provincial confirmatory central laboratories and 1 National AIDS Reference Laboratory (NARL) in China. These laboratories were located in Center for Disease Control and Prevention (CDC) facilities, hospitals, blood donation clinics, maternal and child health (MCH) hospitals and border health quarantine health-care facilities.

Methods The NARL and provincial laboratories provide quality assurance through technical, bio-safety and managerial training; periodic proficiency testing; on-site supervisory inspections; and commercial serologic kit evaluations.

Results From 2002 to 2009, more than 220 million HIV antibody tests were performed at screening laboratories, and all reactive and indeterminate samples were confirmed at confirmatory laboratories. The use of highly technically complex tests, including CD4 cell enumeration, viral load, dried blood spot (DBS)-based early infant diagnosis (EID), drug resistance (DR) genotyping, HIV-1 subtyping and incidence assays, have increased in recent years and their performance quality is closely monitored.

Conclusion China has made significant progress in establishing a well-coordinated HIV laboratory network and QA systems. However, the coverage and intensity of HIV testing and quality assurance programmes need to be strengthened so as to ensure that more infected persons are diagnosed and that they receive timely prevention and treatment services.

Keywords HIV/AIDS, laboratory network, quality control, quality assurance, proficiency testing

Introduction

The first reported HIV cases in China were found among foreign travellers in 1985 and the first indigenous infections were identified in 1989 among injection drug users (IDUs) in Yunnan province.[1] Subsequently, HIV infections spread to Henan province through contaminated plasma collection and to Xinjing Uygur Autonomous Region by IDUs. Recently, HIV transmission through sexual contact has

increased for both women and men who have sex with men.[1] In 2009, the national HIV prevalence was 0.057%, and the number of HIV-infected persons was estimated to be 740 000.[2] Since the late 1980s, a series of national strategic, managerial and technical plans have been set up to build a tiered laboratory system to accurately identify infected persons. Free HIV antibody screening has been provided to the general public since 2004 to increase testing coverage. Free CD4 cell enumeration, viral load (VL) determination and antibody confirmatory testing were provided in 2004, 2006 and 2008, respectively.[3] By the end of 2009, 8273 serologic screening laboratories were in place and more than 220 million cumulative screening tests had been performed nationwide since 2002.[4] To monitor trends in incidence, the efficacy of anti-retroviral treatments (ARTs) and vertical transmission, laboratory capacity was further expanded to include more sophisticated molecular methodologies. In this report, we describe the hierarchical structure, function, measures and challenges of the laboratory expansion process.

The Establishment of an HIV/AIDS Testing Laboratory Network

The establishment of the Chinese HIV laboratory network can be divided into three developmental stages. The initial stage, from 1985 to 1988, was a spontaneous reaction to the HIV epidemic outside of China. The laboratory capacity was inadequate to carry out timely testing and there was a general lack of scientific knowledge, technical skills and specialized equipment. Recognizing the need for an organized national response, China formulated a national HIV/AIDS prevention plan and additional HIV/AIDS surveillance regulations in 1987, focusing on serologic surveillance in most-at-risk populations and of blood products.

The second stage of laboratory development occurred from 1989 to 2002. Initially, the role of the national reference laboratory was played by the Institute of Virology at the Chinese Academy of Preventive Medicine. In 1998, the National AIDS Reference Laboratory (NARL) was established in the National Center for AIDS Prevention and Control of Chinese Center for Disease Control and Prevention (China CDC). By 2002, 44 confirmatory laboratories and 1870 screening laboratories were operational, which conducted more than 22 000 confirmatory and 12.3 million screening tests (Figure 1).

The third stage of laboratory development began in 2003 when China equipped its HIV network laboratories with contemporary instruments, and used standardized operating procedures to homogenize operations nationwide. Sophisticated molecular methodologies, optimized quality assurance programmes and an electronic data reporting system were developed. In 2004, China issued national HIV/AIDS management guidelines[5] to delineate the overall configuration and managerial structure of a tiered screening and confirmatory laboratory network (Table 1). The base of the network was comprised of screening laboratories located mostly in county-level public health facilities and hospitals. They primarily

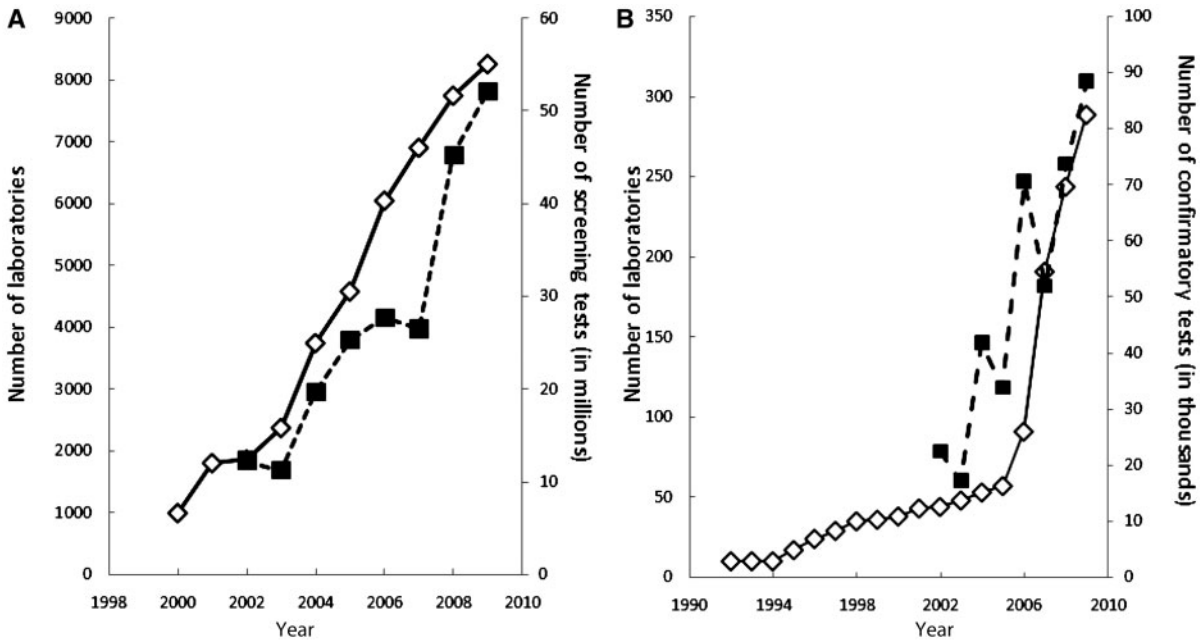

Figure 1 The yearly increase of screening (**A**) and confirmatory and confirmatory central laboratories (**B**) and the respective tests performed in China between 1992 and 2009. Diamonds: numbers of laboratories; squares: numbers of tests performed

Table 1 Distribution and major functions of each tier of the HIV testing facilities in China

Facilities	Number	Location	Major functions
NARL	1	China CDC in Beijing	Formulation of national testing guidelines, implementation and coordination of national testing projects, provision of quality assurance programmes, supervision, evaluation of novel technologies and reagent kits
Confirmatory central laboratories	35	One each in 31 provincial CDCs and four other special organizations[a]	Formulation of provincial policies and conducting in-province staff training, reagent kit evaluations, supervisory visits of lower tier laboratories and provincial serologic PT programmes
Confirmatory laboratories	254	Prefecture CDCs, large hospitals, Border Health Quarantine and other facilities	Conductance of confirmatory tests to verify all specimens screened reactive or indeterminate from the screening laboratories, provision of QA, training and supervision to screening laboratories
Screening laboratories	8273	County CDCs, hospitals, blood stations, MCH clinics, Border Health Quarantine and other facilities	Conductance of screening tests including ELISA and RTs

[a]Xinjiang Production and Construction Corps, Border Health Quarantine, Armed Forces and Military Police Bureau. MCH: maternal and child health; PT: proficiency testing; RTs: rapid tests.

performed serologic tests such as enzyme-linked immunosorbent assays (ELISA) and rapid tests (RTs). All reactive specimens were transported to confirmatory laboratories where western blot (WB) assays were used to confirm results before a positive report was issued.

The number of screening laboratories tripled from 2382 in 2003 to 8273 in 2009 (Figure 1). Screening laboratories used control specimens provided by reagent kits and external quality controls provided by commercial sources to perform run-to-run Levey–Jennings control charts[6] and ensure the test range was within the prescribed range. The total number of confirmatory central and confirmatory laboratories increased from 48 in 2003 to 289 in 2009. The number of screening and confirmatory tests performed in 2009 were 52 million and 88 498, respectively (Figure 1).

The screening laboratories were widely distributed in county CDCs, hospitals, blood banks, maternal and child health (MCH) clinics and border quarantine health-care facilities. Originally, these screening laboratories were located in CDC facilities; but by the end of 2009, 57% were in the hospital system. RTs were introduced into China in 1999 and their use followed the WHO recommendations of using a serial testing algorithm.[7] Initially, RTs were used primarily in prevention of mother-to-child transmission (PMTCT) programmes to quickly identify HIV-infected mothers. It is now widely used in voluntary counselling and testing (VCT) facilities, hospital surgery and out-patient departments and for hard-to-reach populations such as men who have sex with men (MSM) or female sex workers in prefecture and lower health-care facilities. Beginning in 2006, the NARL conducted a proficiency testing (PT) evaluation on confirmatory laboratories, and, by 2009, 269 of the 289 (93%) laboratories participated in the programme.

Provincial and confirmatory laboratories performed CD4 enumeration, HIV-1 incidence tests and molecular assays. In 2009, 84 of these laboratories conducted VL tests, 12 dried blood spot (DBS)-based polymerase chain reaction (PCR) for early infant diagnosis (EID), 6 drug resistances (DRs) and 15 BED-based incidences (Table 2). Because of the expansion of ART, the annual numbers of CD4 and VL tests performed increased by 52 and 90%, respectively, from 2008 to 2009. In 2009, nationally, 238 385 CD4 enumeration, 63 408 VL and 3946 DR tests were completed.

Laboratory and Staff Certification and Staff Training

HIV laboratory and staff certification systems have been in place since 1988. Laboratories have to be constructed according to the national HIV/AIDS management guidelines.[5] A serologic laboratory is required to have three operational areas: 'clean', 'semi-contaminated' and 'contaminated'. PCR-based tests (i.e. VL, EID, DR and subtyping) have to be conducted in a facility with three separate rooms for reagent preparation, blood sample processing and amplification. Laboratory staff are required to take specific biosafety and test-specific training and biannual refresher training in order to perform clinical testing. Provincial health authorities and technical HIV experts perform annual laboratory inspections and issue operational permits. Laboratories without

Table 2 The establishment and participants of various PT programmes organized and offered by the NARL

Categories	Tests	Programme initiation year	No. (coverage) of participating laboratories[a] in 2009 (%)	Frequency (No. per year)
Serologic tests	ELISA	2004	289 (100)	3
	WB	2004	289 (100)	3
	RT	2006	269 (93)	3
	Incidence (BED)	2006	15 (100)	2
Immunologic test	CD4	2004	234 (74)	2
Virologic tests	VL	2005	79 (94)	2
	DBS for EID	2006	12 (NA)	2
	DR	2006	6 (NA)	1
	Subtyping	2006	12 (NA)	2

[a]Serologic PT programmes were only offered to confirmatory central and confirmatory laboratories. Provincial confirmatory central laboratories were responsible for the serologic QA of their respective screening laboratories. The numbers of laboratories performing the tests of high complexity (i.e. CD4, VL, BED, DR and subtyping) are small. Some of these laboratories were sub-confirmatory laboratories in high-HIV-prevalent areas. NA: data not available in 2009.

operational permits or those that fail inspections are ordered to close until corrective remedies are instituted. If a laboratory is closed, the NARL and the provincial CDC provide onsite supervisory visits and training to raise the operational level of both staff and laboratory procedures.

With the input from domestic and international experts, the NARL formulated and established HIV-related technical guidelines.[8–10] The national HIV/AIDS testing technical guidelines[11] were published in 2004 and revised in 2009 to incorporate recent methodological changes and international recommendations. The NARL is responsible for the dissemination of the policies to laboratory staff through training workshops, electronic notifications and the semi-annual laboratory network newsletter[11] distributed to all screening facilities. Training is conducted in a top-down step-wise manner. The NARL trains staff from provincial and confirmatory laboratories. These trainees would in turn provide training to the staff at the lower level laboratories. The NARL is responsible for national training courses for sophisticated tests including BED, EID, DR and subtyping. Provincial laboratories are responsible for sub-provincial training on WB, RTs, ELISA and CD4. In 2009, the 229 technical staff from the 35 provincial laboratories received an average of 2.7 trainings per person. The 27 886 technical staff from the screening laboratories received 0.95 trainings per person. The training used to prepare the laboratory staff to obtain operational permits was conducted in laboratories with repetitious hands-on practice. In addition to the technical staff, ~10% of the trainees were non-laboratory staff responsible for general quality assurance and procurement service with classroom training. The inclusion of these staff in the training enhances co-ordination of operations so that reagent procurement and equipment maintenance would be carried out appropriately. The importance of laboratory-related biosafety and prevention of occupational exposure was recognized. Post-exposure prophylactic treatment for HIV was available. In 2009, 920 accidental exposures were reported by personnel working in HIV control and prevention programmes and laboratories.[5] Six hundred and eighty-four persons received ART prophylaxis, counselling and follow-up. No seroconversions were reported.

PT Programmes

To build and strengthen its own capacity, the NARL first participated in several international PT programmes. NARL staff were trained in HIV laboratories in western countries to learn to prepare PT materials. It also participated in the following programmes: (i) College of American Pathologists' HIV WB and p24 antigen tests; (ii) U.S. CDC's incidence assay,[12] and DBS-based EID detection[13]; (iii) Rush-Presbyterian-St Luke's Medical Center on VL and DR QA programmes[14]; (iv) Australia National Serology Reference Laboratory on antigen and antibody tests[15]; and (v) CD4 PT provided by United Kingdom's National External Quality Assessment Site programme[16] and Canadian National Immunology programme for the Quality Assessment and Standardization of Immunological Measures Relevant to HIV/AIDS.[17] The NARL began offering its own ELISA and WB PT programmes to domestic laboratories in 2004 (Table 2). In 2009, these programmes were expanded to cover RTs, BED, CD4, VL, DBS-based EID, DR and subtyping. The laboratory coverage in ELISA, WB, RTs, CD4 and viral load was 100% (289/289), 100% (289/289), 93% (269/289), 74% (234/317) and 94% (79/84), respectively. Provincial confirmatory central laboratories also offered PT

programmes on serologic tests (ELISA and RTs). In 2009, 97% (34/35) of confirmatory central laboratories provided this service to screening laboratories. The coverage of 29 provinces was 100%, but one province had a low coverage of 25% because of the lack of human resources and experience.

Serologic and virologic PT specimens were sent to participating laboratories using cold chain transport. CD4 PT specimens were sent at ambient temperature. Participating laboratories were required to report the results back to the NARL electronically. PT results were published anonymously in the Laboratory Network Newsletter.[11] However, NARL personnel provided feedback and discussed findings with laboratory staff. If a laboratory exhibited low performance, the NARL conducted on-site visits to resolve problems. Problems identified included transcriptional error or reporting specimens not pertaining to the PT programme (65%) and delay of reporting (35%). Technical managers of provincial laboratories participated in the quality monitoring process. With the exception of one confirmatory central laboratory in 2008 and another one in 2009, all others provided ELISA PT for their constituent screening laboratory, similar to the process used by the NARL.

Laboratory Supervisory Evaluations and Inspections

On-site laboratory evaluations are conducted annually, as stipulated by the National Management Regulation of HIV/AIDS Detection and the National Technical Guidelines for Detection of HIV/AIDS. The evaluation covers staff training, biosafety, documentation of standard operating procedures, record keeping equipment maintenance and laboratory performance. The NARL is responsible for the evaluation of provincial laboratories. They, in turn, evaluate lower level laboratories. All inspection results and resultant actions are reported to the NARL. In 2009, the NARL inspected 2963 WB-positive specimens nationwide and found the average turnaround time (TAT) for reporting was 5 working days (range: 1–21 days). The one with the longest TAT was 21 working days and occurred in a laboratory located in a region of low HIV prevalence where the number of specimens required to be confirmed was small and thus the test was not done until a larger number of specimens was collected. This laboratory was instructed to forward the specimens to other laboratory to complete the tests in a timely manner.

Evaluation of Diagnostic Reagent Kits

In 2002, the NARL and provincial CDCs adopted a multi-province evaluation to determine the sensitivity and specificity of commercial HIV antibody diagnostic kits in China (Table 3). In 2008, the NARL and five CDCs in high-HIV-prevalence areas (Anhui, Sichuan, Guangxi, Guangdong and Guizhou) jointly evaluated 16 ELISA and 12 RT kits[18] after they had received approval from China's State Food and Drug Administration (Table 3). Kits were purchased

Table 3 Evaluation of the performance of commercial HIV antibody diagnostic ELISA and RT kits (2002–08)

	ELISA			RT		
Year	Number of kits	Sensitivity (%) Average (range)	Specificity (%) Average (range)	Number of kits	Sensitivity (%) Average (range)	Specificity (%) Average (range)
2002	Domestic 10	99.10 (97.88–100)	98.41 (96.49–99.58)	–	–	–
	Foreign 1	99.65	99.40	–	–	–
2003	Domestic 11	99.75 (98.98–100)	96.72 (94.82–99.10)	4	94.37 (91.48–96.77)	97.72 (94.68–99.77)
	Foreign 2	99.61 (99.21–100)	98.41 (98.09–98.73)	3	98.31 (96.71–99.15)	98.10 (97.77–98.61)
2004	Domestic 15	99.47 (82.35–100)	91.87 (83.00–99.50)	6	89.48 (83.33–95.24)	98.33 (97.61–99.52)
	Foreign 3	99.61 (98.82–100)	97.50 (96.50–98.00)	4	92.26 (80.95–97.62)	97.85 (96.65–99.52)
2005	Domestic 13	99.29 (96.64–100)	94.16 (90.75–97.24)	7	97.81 (95.73–99.15)	97.82 (95.76–99.58)
	Foreign 3	99.44 (99.16–100)	98.68 (97.80–99.56)	5	98.44 (96.58–99.15)	98.45 (95.34–99.58)
2006	Domestic 14	99.65 (98.04–100)	97.91 (94.86–99.21)	8	99.23 (96.91–100)	97.99 (94.64–99.23)
	Foreign 3	99.67 (99.02–100)	98.41 (96.84–99.21)	5	98.76 (95.88–100)	98.71 (97.70–100)
2007	Domestic 11	99.91 (99.04–100)	99.38 (97.97–99.75)	11	94.83 (84.21–100)	99.09 (94.62–100)
	Foreign 3	100	98.90 (97.46–99.75)	3	98.31 (96.71–99.15)	98.10 (97.77–98.61)
2008	Domestic 13	99.53 (97.69–100)	98.72 (94.61–100)	9	98.09 (87.50–100)	99.51 (98.04–100)
	Foreign 3	100	98.20 (94.61–100)	3	100	99.51 (99.02–100)

randomly from the market and tested using standard panels previously confirmed by WB. The foreign RT kits evaluated had an average sensitivity of 100% and a specificity of 99.51% (range: 99.02–100%). The domestic RT kits had an average sensitivity of 98.09% (range: 87.5–100%) and specificity of 99.51% (range: 98.04–100%). One domestic kit performed especially poorly with a sensitivity of 87.5% and specificity of 100%. The finding of an RT kit with suboptimal performance strengthens the notion that frequent inspections of domestic products are important. The kit performance data were disclosed in the China CDC web site and published in the China AIDS Laboratory Network Newsletter.[18] Evaluations of this kind convey a message to domestic manufacturers to continue to improve their manufacturing technologies and enhance product quality.

Future Challenges and Conclusion

China has established a well-defined HIV laboratory network along with national and provincial QA systems to attain a high quality of testing. However, numerous challenges remain. The laboratory network follows a top-down hierarchical management approach. Because of the high testing volume and low number of staff, there is often insufficient human resources. With rapid technological advancements and guideline modifications, staff need constant training, particularly in the areas of CD4 and VL testing. Technical guidelines from the NARL are broad and thus may not be understood by staff at lower levels. Most instruments use English as the operating language, which presents problems for the technical staff at the confirmatory laboratory level. With the expected expansion of RT use, maintaining RT quality will become a challenge. The NARL and provincial CDCs will increase RT testing training and standardized record keeping in testing facilities as recently recommended by Parekh *et al*.[19]

Another challenge is the distribution of laboratory equipment. More than one brand of molecular testing instrument may be present in the same facility. This leads to low productivity and work quality. Many laboratories performing CD4 and VL do not participate in the PT programmes. These challenges will need to be resolved to guarantee sound development of the Chinese HIV/AIDS testing laboratory network and its QA system.

The developmental history of the Chinese HIV/AIDS testing laboratory network and QA system is reliant on strong financial support from central and local governments. The role of the NARL in laboratory network development, QA and new technology research is important and the effectiveness well documented. Technical research and method evaluations carried out by the NARL, such as HIV diagnosis technologies and strategies,[20] HIV-1 VL,[21] EID,[22] incidence assay[12,23–26] and DR testing,[27,28] have offered key scientific basis for the establishment of national technical guidelines and the application of new technologies. Provincial laboratories play an important role. These laboratories are pivotal in the training and dissemination of new technology, QA and site-directed technical support at the provincial level. They serve as the bridge linking the NARL with rural laboratories. In addition, frequent international cooperation and communications have produced constructive suggestions and ideas for the laboratory network and QA/QC development. The challenges China is facing are numerous. The majority of infected persons are still unaware of their infection status,[2] and testing CD4 or VL in patients who reside in hard-to-reach rural areas prior to and post-ART treatment is difficult. The low-cost point-of-care technologies such as CD4 measurement,[29] with easy instrument maintenance and simple QA procedures, may provide one of the solutions needed in many resource-constrained areas in China in the future.

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KEY MESSAGES

- A well-co-ordinated comprehensive HIV laboratory network and QA systems have been established in China.
- Coverage and intensity of HIV testing and quality assurance programmes remain to be strengthened.

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