Developing laboratory medicine and LAS in China

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This article sets out to provide an overview of the development of laboratory medicine in China, including present status and outlook. It is also designed to provide general information on upcoming advances and perspectives in clinical laboratory automation systems (LAS) in China, including the current status of LAS in China, considerations on the establishment and upgrading of LAS, examples of applications, problems and the future.

Modern laboratory medicine in China

First of all, I would like to summarise the current status of laboratory medicine in China.

The recent history of laboratory medicine in China has seen major changes. Before the 1990s most clinical tests were performed manually, until some procedures were automated (for example, sample and reagent collection or fraction). True automation of clinical laboratory work in China first began at the end of the 1990s, when the first autoanalyser (chemical analyses of urine) and haematological analyser were introduced. On the other hand, it cannot be denied that manual operation still plays an important role in our clinical laboratory. Moreover, there are significant differences in personnel structure in terms of education as a whole. It is well known that the quality of technical personnel in laboratories is one of the most important issues in the implementation of LAS in China. Quality of staff has improved greatly with the increasing proportion of researchers who have received higher education, such as medical doctors, taking the place of technicians graduating from technical secondary schools in the past.

Moreover, establishment and implement of standardisation and a quality assurance system is another trend. Communication with doctors and nurses has also been strengthened.

In conclusion, 'traditional medical laboratory examination' is tending towards 'modern laboratory medicine', with the major improvements characteristic of technology-intensive equipment and automation.

Current status of LAS in China

In recent years, LAS has been the focus of considerable attention in Chinese clinical laboratories. Since the first LAS was introduced by Zhejiang Medical College in 2001, seven hospitals have so far installed LAS, except for a haematological unit, and many Chinese hospitals plan to introduce LAS. Table 1 shows the list of hospitals with LAS in China, the year of installation and the manufacturers. Concurrently, various LAS such as A&T, Beckman-Coulter and Hitachi are currently being introduced in China. Table 2 shows the list of LAS manufacturers in the world. Accordingly, the effectiveness of each individual LAS differs greatly, and the cost-effectiveness of individual LAS is even greater.

To quote one example: An'zhen Hospital is a large institution specialising in cardiovascular diseases. Its capacity for serum samples is about 500 per day. As shown in figure 1 and figure 2, the whole lab is made up of an on-line section which covers specimen preparation, chemistry and immunology. The analysers of A&T, Abbott and Hitachi can be connected with an STS (specimen transportation system) and a

Table 1. Chronology of LAS in China.

No.	Name of institution	Year	Manufacture
1	Medical College of Zhejiang (1st)*	2001	Hitachi
2	Taida Hospital of cardiovascular diseases#	2003	Hitachi
3	Health Centre of Wenzhou*	2004	Beckman-Coulter
4	Medical College of Guangzhou#	2005	Beckman-Coulter
5	Central Hospital of Zhongshan*	2005	Beckman-Coulter
6	Central Hospital of Fuzhou Military Area#	2005	Dade Behring
7	An'zhen Hospital, Beijing#	2005	A&T

(Up to November 2005)
* Specimen Preparation Unit + automatic biochemical analysers
# Specimen Preparation Unit + automatic biochemical analysers + immunological analyzers

Table 2. Manufacturer list*.

Manufacturer	Country	Specimen racks			Chinese users
		1	5	10	
A&T	Japan	√	√	√	√
Abbott	US	product of Inpeco			×
ALOKA	Japan	×	√	√	×
Bayer	US	√	×	×	√
Beckmann-Coulter	US	product of IDS			√
Hitachi	Japan	×	√	×	√
IDS	Japan	√	×	×	
Inpeco	Italy	√	×	×	
Olympus	Japan	product of Inpeco			√
Roche	Switzerland	product of Hitachi			×
Dade Behring	US	product of Inpeco			√

* Up to November 2005

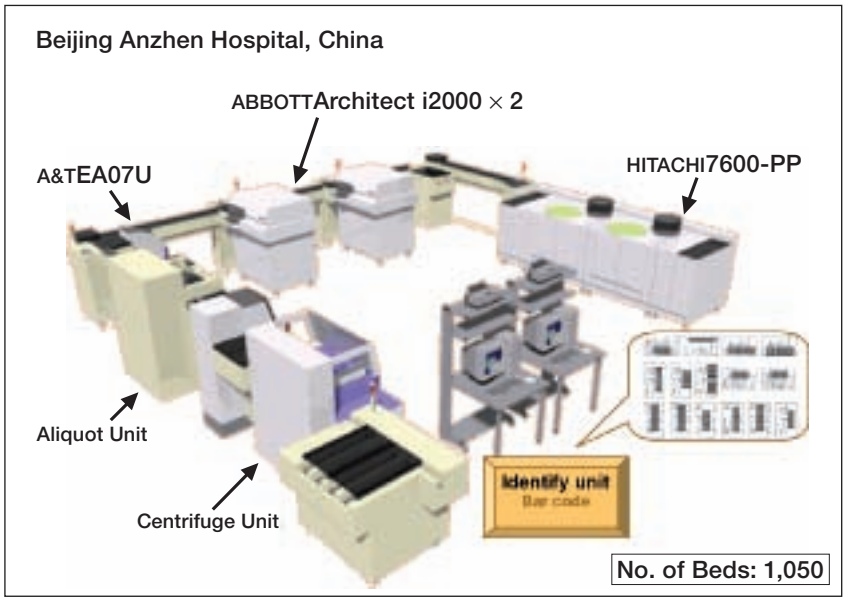

Figure 1
Sketch map of LAS in An'zhen Hospital, Beijing, China (Ver.A, A&T).

Figure 2
LAS demonstration of An'zhen Hospital, Beijing, China (Ver.A, A&T).

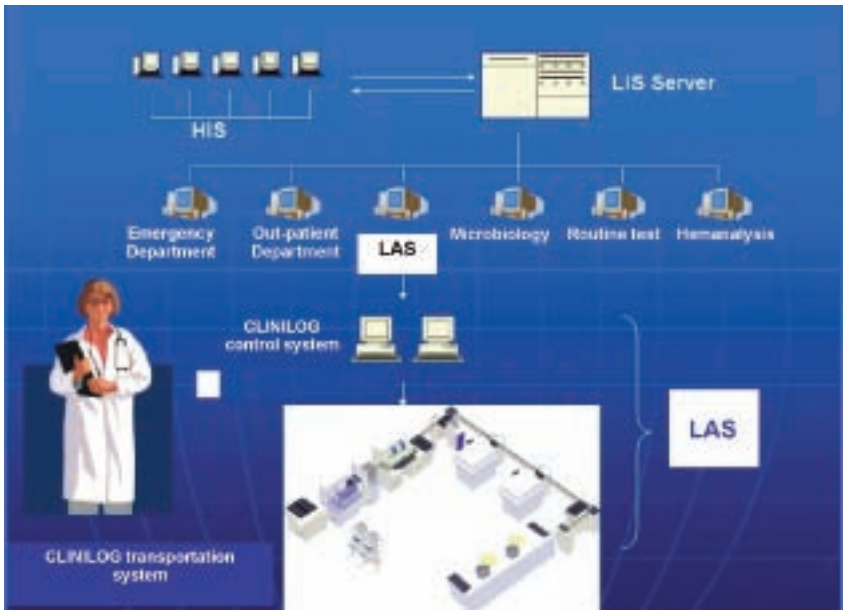

Figure 3
Laboratory configuration of An'zhen Hospital, Beijing, China (Ver.A, A&T).

specimen preparation unit including a specimen ID unit, aliquot unit and centrifuge unit. The characteristics of the system in An'zhen Hospital are as follows: 1. Multiple sample racks; 2. Intelligent STS with rack pass, rack buffering and sample jump functions; 3. On-site real-time rerun; 4. Automatic analysis and management. On the other hand, there are off-line sections, including the emergency department as shown in figure 3, the outpatient department, the microbiology, routine test, and haemanalysis units, which are all linked with LIS. And HIS receives information via LIS.

Pending problems

Next, I would like to dwell on some pending problems of current LAS.

The ultimate goal of clinical laboratories is to provide useful medical information to the patient care side. An individual test result is not valuable, and can only contribute to patient treatment after processing by laboratory inspection. However, the laboratory is in some cases not supported by a hospital information system. Even though an HIS is suitable for super-large laboratories, it is becoming obsolete in many hospitals where flexible information matching the needs of ever-changing clinical laboratory services must be delivered.

Standardisation is another problem. Standardisation is necessary in various areas for further LAS development. However, this is easier said than done. It is almost impossible to construct an LAS using analysers from only one manufacturer. Thus, it is indispensable to standardise all the components, including aspects of communication, electromechanical interface, specimen containers and racks, specimen ID, status indicator and troubleshooting. Recently, the NCCLS has begun standardisation. In addition, Chinese clinical laboratories have realised the importance of LAS standardisation and have planned for it by a thorough investigative process.

Last but no less important, the Chinese clinical laboratory is at present in a transition stage from a lab productivity type to an intelligence productivity type. In other words, some people will lose their jobs if LAS is introduced, and

how to allocate redundant staff members is a problem.

Some considerations before the introduction of LAS

It is perhaps too early yet to evaluate the success of some kinds of LAS in China, as they have been in place only for a short time. Many laboratories are planning to introduce LAS as a cost cutting move, and I would like to mention some important factors to be considered beforehand.

Firstly, reallocation and expansion of present equipment or systems must be considered. Secondly, establishment of LAS at an appropriate place. Thirdly, flexibility and capacity of analysers. Fourthly, the need to remodel the laboratory. Laboratory sections will need to be reclassified due to the highly integrated test items. And finally, as mentioned above, redistribution of laboratory technicians.

Prospects for LAS in China

Due to marked advances in medical technology and the continuous development of Chinese society, including the economy, the content and status of Chinese laboratory medicine have evolved favourably in recent years. In this connection the number of doctors per 1000 population can serve as a example, as shown in figure 4.

First, let us turn our attention for a moment to the constitution of Chinese health service institutions, including hospitals, as an aid in understanding the prospects for LAS in China. As shown in figure 5, Chinese health service institutions include hospitals, clinical laboratory centres, emergency centres, centres of disease control, women's and children's hygiene centres, and village health centres. Also, there are different types of hospital, as shown in table 3, comprising comprehensive hospitals, Chinese traditional medicine hospitals, ethnic medicine hospitals, and hospitals for special diseases. The focus of the future LAS market is hospitals of Grade 3 with more than 500 beds.

It is well known that there have been revolutionary improvements in transportation facilities, from the era of the bicycle to that of the automobile. In the next three to five years LAS will reach full development in China in the same way as motor transport. More and more LAS with transportation devices are being installed in China. In particular, ten to fifteen LAS will be introduced in China by 2006. Consequently, new analysers and transportation devices are under rapid development, and new instruments equipped with new technology are continuously introduced. By the 2010s the development of LAS will move into a stable growth stage.

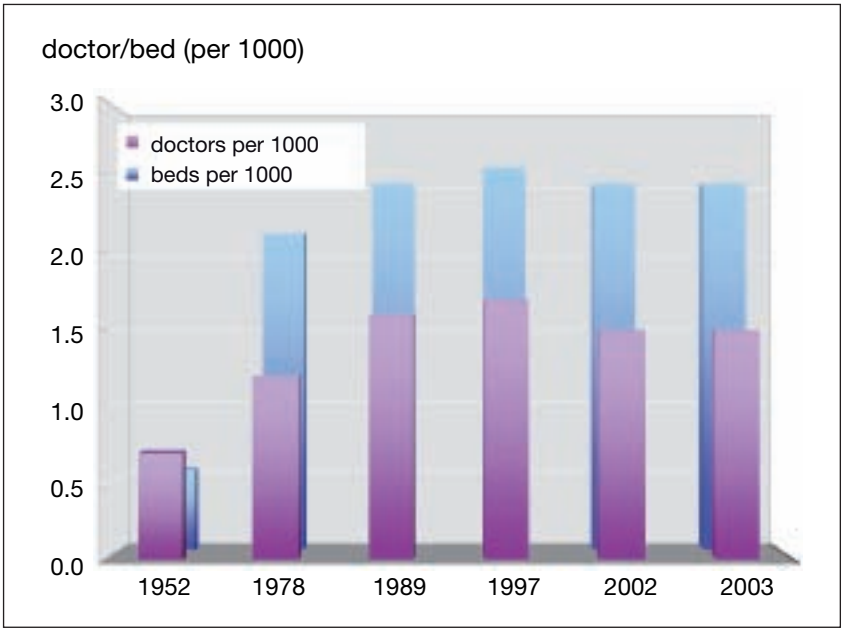

Figure 4
Number of doctors per bed and number of doctors per thousand in China.

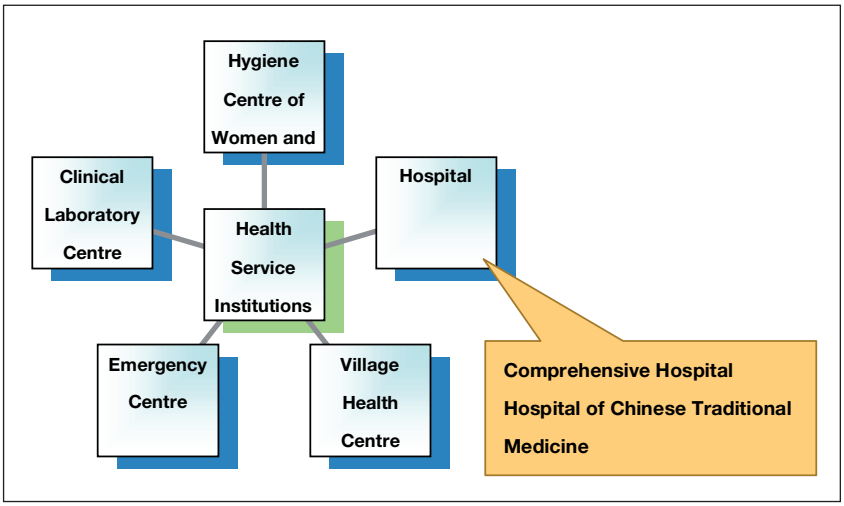

Figure 5
Overview of Health Service Institutions in China.

Extensibility of LAS in the future

In future laboratory tests will be increasingly integrated into on-line LAS. As for the extensibility of LAS in China, there will be increasing opportunities for automation of microbiology, molecular diagnostics and proteomics through microfabrication technologies. Also, automated analysers for molecular tests using DNA chips or protein chips will be developed and integrated into LAS. These tools will then enhance the possibility of improving service to patients.

Expectations for LAS, manufacturers and laboratory managements

I believe it is meaningless to attempt to compete with commercial laboratories with regard to test costs, although LAS

Table 3. Overview of Hospitals in China.

Grade Descriptions	Hospital of Grade 3 (>500 beds)	Hospital of Grade 2 (100~499 beds)	Hospital of Grade 3 (20~99 beds)
Department	Clinical Departments	Clinical Departments	Main Clinical Departments
	Laboratory Examination	Laboratory Examination	(e.g. internal medicine, surgery)
	Pharmacy	Pharmacy	Laboratory examination, Pharmacy
Staff	Doctor: 1.03+ per bed	Doctor: 0.88+ per bed	Doctor: 0.7+ per bed
	Nurses: 0.4+ per bed	Nurses: 0.4+ per bed	Nurses: 5+ per bed
Area (per bed)	Building 60 m^2+	Building 45 m^2+	Building 45 m^2+
	Ward 6 m^2+	Ward 5 m^2+	
	External 4 m^2+	External 3 m^2+	
Equipment	Basic	Basic	Basic
	Ward	Ward	Ward
	Special	Special	
Regulations	Integrated	Integrated	Basic
Funded institution	Local government	Local government	Local government

is a very economical tool. The economic result is just part of the final goal of LAS.

For hospital laboratories to survive while reducing costs they must provide extra services, such as pretreatment tests and urgent nighttime tests, assisting in data analyses and providing the latest laboratory information.

To achieve this goal, the manufacturers must be able to provide inexpensive, highly productive systems. System packaging, adapting standard specifications, low costs and integration with LIS are issues that must be addressed by manufacturers in producing the next generation of LAS.

For laboratory or hospital managements, the following considerations apply to the establishment and upgrading of LAS. Firstly, proper size means good operability, and a compatible system able to raise productivity will maximise profit. To some degree, whether LAS will be able to compete with high-performance players or not depends on the number of specimens in the laboratory. So for laboratory or hospital managements it is important to evaluate specimen capacity before taking action. However, it is very difficult to evaluate the real performance of LAS. Secondly, it is certain that LAS is a very economical tool, if users and manufacturers have a clear economic goal. The cause of overinvestment is not technology but the concepts and attitudes of users and manufacturers. Thirdly, in the near future, the level of automation in Chinese laboratories will be greatly improved. As a result, it will be important to build comprehensive clinical laboratories, achieving, almost simultaneously with the new generation of hospital information systems, a high level of performance that can easily meet the rapidly changing needs of today's and tomorrow's clinical laboratories.

Finally, I must emphasise again that while we must temporarily focus on the economic side, we must never forget the final goal of 'improvement of medical quality'. LAS needs comprehensive laboratory management. Chemicals, analysers, lab logistics and information are all integral elements which constitute the concept of comprehensive management.

The ultimate goal of laboratory tests is to produce results quickly and accurately and to reliably deliver the results to a client physician in order to aid clinical treatment of disease. Hence we cannot truly improve the efficiency of a clinical laboratory by simply improving the efficiency of laboratory operations in China. Rather, it is important to provide patients with high quality tests and contribute to patient-oriented medicine. All of these will change the paradigm of Chinese laboratory medicine.

Epilogue

In China dawn is now breaking in terms of LAS. As an LAS promoter, I hope from the bottom of my heart that the open environment will become a reality and that we shall be able to connect analysers to LAS at low cost. And I believe the sun will soon be shining in all its glory!

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