Development of Chinese POCT and hospital management status

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Faculty Disclosure

Laboratory Diagnosis Center, Beijing Tiantan Hospital

has no relevant financial relationship with commercial interests to disclose.
After this presentation, you will be able to:

1. Identify new trends of Chinese POCT industry development in the future.
2. Analyze the reasons of rapid development of POCT in China
Concept of POCT

- Point of care testing (POCT): Rapid detection carried out at the patient side in medical institutions by the laboratory or non-laboratory health care professionals, in clinical laboratory quality management system guidance.

--China 《POCT Management principal (draft)》
CPOCT Classification

- in hospital  Central Laboratory  Bedside

- Outside hospital  chronic disease management

- Disease surveillance and health assessment
  physical examination and Health Management detection

Exemption - security  equal to non-prescription drugs
Development of POCT in China

POCT industry in our country developed from the 1980s, after more than 20 years development, now it has a great industry scale.
A potential POCT market due to the big population
China's export growth is extremely rapid in recent years
POCT has a broad market, in point of the consumption, POCT products have a potential development.

Clinical application of domestic POCT broadly divided into two areas, one into the OTC retail pharmacy chain, the second into the primary hospital.
Prospects of POCT

1. Market Development

2. Technology Development
Trends of POCT

1. automation, miniaturization, diversification is the future of POCT test.
2. biochips and small-scale intelligent analysis system biochips, especially the protein chip for POCT, will play a great role.
3. non-invasive transcutaneous POCT detection may be an important direction of development.
4. small individual self detection has a certain significance for the establishment of family health center model, personalized medicine.
5. combined POCT data processing and network technology will play a very important role in building personal health records, analyzing sub-health state and disease prevention.
6. Development of third and fourth-generation POCT instrument is the only way

The first generation of qualitative detection (paper strips);

The second-generation semi-quantitative (color card reading colorimetric or semi-quantitative instruments); first and second generation of POCT products commonly used in non-professional family, personal health care.

Quantitative third generation systems (fewer manual operations);

The fourth-generation instrument (automated information intelligence) The third and fourth generations for quantitative detection will be used in hospital emergency and community care. In the future, third- and fourth-generation automated POCT instrument will become mainstream, solve the problem of people trapped on the quality of care, which is a new benchmark and milestone in POCT development.
Market prospect

Application in public health emergencies:

- Influenza (H1N1) virus prevention and control of State council
  - Second
    - Public places
    - Infrared Temperature
  - Minute
    - Rapid antigen detection
  - Hour
    - Virus genotyping
    - Nucleic acid detection
  - Day
    - Confirmatory test
The number of diabetic patients after India, the second in the world.

Prevention of chronic disease

Rural Diabetes Prevention Mode

Glucose meter manufacturer

Civil and health department

friendly family of Diabetic

Diabetic patient

Diabetic patient in rural area

Glucose meter manufacturer

County people’s hospital

Health clinics in towns

Community health center
Application of the new rural cooperative medical

Improve farmers' insurance rates

POC Application of the new rural cooperative medical examination

- Hepatitis B screening
- Glucose test
- Urine Detection
In the application of basic health units

County People's Hospital

Community Health Center

Township hospitals

Village health stations

First aid proposal
Myocardial infarction heart failure analyzer

Immune test
CRP
Gold standard chromatography qualitative detection reagents

Biochemical tests
Dry biochemical analyzer

Basic POCT

Basic test
Glucose meters
Urine analysis
Hemoglobin Analyzer
Export to international markets

Advantage of export overseas

- Easy to use operation, small service pressure
- Convenient storage and transportation
- Cost advantage

In the international market

- Europe: pregnancy (HCG / LH)
- Africa: Malaria (Malaria), HIV
- North America: drug testing
- Asia: infectious diseases (HBV, HIV, FluA / B), pregnancy (HCG / LH), drug testing
Prospects of technology

- Immunochromatographic qualitative detection technology
- Chromatographic quantitative detection technology
- Electrochemical detection technology
- Dry biochemical detection technology
- Biochip detection technology
Application of new technologies expand the future development space, exhibiting the advantages of POCT

- "Qualitative" and "quantitative" positioned on the POCT market has become increasingly clear.

- Multi-channel, high-throughput instrument to expand the new concept of POCT.

- Molecular POCT technology has matured and began to move toward commercialization.

- non-invasive blood glucose meter is a new area.
- the combination of POCT technology and communication technology
Three new trends of Chinese POCT industry development in the future:

- Localization:
  Chinese POCT market is mainly distributed in the medium and small hospital systems at all levels, even the smallest community hospitals, samples also significantly higher than the amount of foreign private clinics, especially after starting the new medical reform, the price of the product is very sensitive, and only quality and cheap products to adapt to circumstances.
Clinical

"Patient-centered" is the advanced concepts for the 21st century, is the “center of the specimen” as the laboratory model of a major breakthrough. Requires not only the experimental technician can interact with clinicians, but also require a direct dialogue with the patient, truly humane, personalized medical model.
Community

To completely change the "difficult and expensive" status, the state must start from the grassroots community health. POCT can play a role in many cases, not only in an emergency, first aid in a wide range of applications, even stay home to monitor the health status.
POCT has made rapid development in the domestic market over the past decade, mainly based on three aspects:

- Change of medical model:

  From a simple treatment to prevention, care, treatment and rehabilitation; expanded from hospital care to the community outside the hospital medical
Need of medical development

With the level of medical diagnosis and treatment of continuous improvement and the need for practical work, especially in the emergency department, intensive care unit, operating room, monitoring of environmental and food hygiene, forensic and military POCT testing needs to provide faster, more accurate and more convenient data, which led to the development of POCT.
Reform of health care system

Establishment of rural health service network, urban and rural public health service system, urban community health service system, medical security system, deepen the reform of public hospitals. These policies and measures required large medical centers to walk out of the hospital, for the community, for the rural areas, into the family, requiring a simple rapid diagnostic test system which is suitable for the needs of the grassroots, "adhere to prevention" is an important principle of the new health care reform.
Quality Management System of POCT
The preparatory committee for the first time of Chinese Hospital Association Clinical Laboratory Management Committee, POCT Sub-Committee meeting held on July 19th, 2006, determined the POCT management model of our country, “Grading, sub-projects, objective”.

![Image of the meeting](image-url)
POCT management

1. **Grading**
   Different hospital grade, different level of management and quality control, so the requirement is also different.

2. **Sub-projects**
   Different purpose, different requirement.

3. **Item**
   Different items, for emergency or conventional, different requirement levels.
Chinese Hospital Association Clinical Laboratory Management Committee POCT Sub-Committee was established in Beijing 2007

Experts on diagnostic field, scholars and representatives of manufacturers and sellers of POCT products were organized, and initially developed the "POCT inspection Checklist", "POCT Clinical Application Guide", "POCT implementation approach (draft)" and other related documents, which has made a preliminary consensus after repeated modification and research.
The draft of POCT management approach

第二章 草案
第一节 关于床旁检测的管理办法
（试行草案）
一、总则

床旁检测（POCT，Point of Care Testing）是利用便携式设备或和专用的试剂条、卡，在贴近受检者，短时间内得出检查结果的一种检验方式。该检验方式广泛适用于医院病房、重病监护、救护单位、医生诊所、家庭保健网络等领域，由非专业检验人员即可完成操作。这种快速的检验方式，可以满足人们对检验在时间上的要求，适应现代社会发展的需要。开展POCT的主要目的是方便病人，尽快而又准确地得到可靠的检验结果。但是,检验方式从临床实验室转移到床边检测后，是否仍然能够提供高质量、可信赖的检验结果，对POCT的管理就显得至关重要。

根据其他一些国家的管理经验，开设POCT要接受政府有关部门评审，从规章制度的建立、人员培训认可证书、仪器试剂的准入、质量控制措施落实、乃至和临床实验室的协调等一应俱全。在获准后，在规定期限内开展准许的POCT项目。并且必须参加政府指定的室间调查评价，随时接受政府有关部门的质量评
Knowledge of POCT was made popularized by Sub-Committee through professional website, professional continuing education magazine column, training courses and other forms.
Numbers of agencies opened three times of POCT detection progress classes, trained thousands of technicians and POCT Coordinator.
# 床旁检测协调员职责、技术人员规范操作学习班

## 讲座安排

<table>
<thead>
<tr>
<th>序号</th>
<th>讲座内容</th>
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<tr>
<td>1</td>
<td>床旁检测的发展现状和趋势及天坛医院床旁检测管理思路</td>
<td>康熙雄</td>
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<td>床旁检测相关规定、制度和要求</td>
<td>电子瑜</td>
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<td>3</td>
<td>操作技术在床旁检测的重要性</td>
<td>李智</td>
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<td>床旁检测的质量管理要点</td>
<td>王治国</td>
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<td>床旁检测的核查要求</td>
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<td>床旁检测产品的选择要求</td>
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<td>协调员在床旁检测中的重要作用</td>
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<td>8</td>
<td>浙江省床旁检测的体会</td>
<td>张伟民</td>
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<td>9</td>
<td>血糖仪检测的常见影响因素及其分析</td>
<td>张国军</td>
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<td>10</td>
<td>床旁检测技术对内分泌系统疾病诊断和病情监测的重要作用</td>
<td>纪立农</td>
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<td>床旁检测技术在心血管系统疾病诊断和病情监测过程中的重要作用</td>
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<td>快速检测技术对感染性疾病诊断和病情监测的重要作用</td>
<td>赵惊训 (山西省医学会)</td>
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<td>床旁及快速检测技术对急诊医学的影响</td>
<td>王申 (协和急诊科)</td>
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<td>14</td>
<td>床旁检测技术的快速发展对护理学的影响</td>
<td>孙红 (协和急诊科护士长)</td>
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Organizing POCT Forum
Essay collection
First National POCT qualified managers Seminar (2010-11-00-110 (country)) was held in order to establish manager team in May, 2010.

**Organizer:** Chinese Hospital Association Clinical Laboratory Management Committee POCT professional committee
local policy was also introduced in province following the proposed draft of POCT management promoting the POCT management in hospital
武汉市 POCT 质量管理办法（暂定）

根据卫生部 2006 年 73 号文件颁发的《医疗机构临床实验室管理办法》规定：开展病人身边检验的项目必须与临床实验室的常规方法进行 “比对”，以便保证检验结果的 “可靠性” 和 “可比性”。受武汉市卫生局的委托，特制定 “武汉地区 POCT 质量管理办法”（暂定）。

一、组织领导：

武汉市临床检验中心全面负责全市 POCT 质量管理工作

1. 对武汉地区各医疗单位开展 POCT 的情况（含组织领导，开展项目及操作者等）进行登记。

2. 举办 POCT 学习班，对有关 POCT 的管理人员进行培训，通
- POCT was included in the textbook 《Diagnosis》 the sixth edition for the first time, (Editor: Xi Xiong Kang)
POCT related publications
<table>
<thead>
<tr>
<th>status</th>
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<tbody>
<tr>
<td>Changes in the concept of health has prompted the development of POCT</td>
<td>Imperfect Quality control system</td>
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<td>POCT development needs of health care reform aid led to the development of POCT</td>
<td>Various level of operators</td>
</tr>
<tr>
<td>Advanced inspection technology promote the development of</td>
<td>Imperfect laws and regulations</td>
</tr>
<tr>
<td>To improve and solve problems</td>
<td>POCT results are reported in confusion</td>
</tr>
<tr>
<td>Based on clinical and fact need</td>
<td>Inadequate coordination</td>
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</table>
POCT quality management system established from the actual process, and the ability to achieve the ISO22870 quality management requirements

- POCT is based inspection characteristics, starting from the actual process, in accordance with the pre-analysis - Analysis - POCT quality management system established after the analysis.
- Establish and improve the quality of POCT control flow (all exempt and non-exempt POCT projects need to establish quality control rules and procedures)
- POCT periodic comprehensive personnel training assessment and recording capabilities.
- Uniform reporting format, standardized inspection reports of POCT.
- POCT network management software applications, multi-center POCT lab harmonization of quality management.
- And ultimately to establish a reasonable system of laws, regulations and norms, unified POCT ability and quality management.
### Management goals:

<table>
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<th>Category</th>
<th>Details</th>
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<tr>
<td>Assessment of new devices</td>
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<tr>
<td>Assessment of standard operation procedure</td>
<td></td>
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<tr>
<td>Purchased and installed equipment</td>
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<tr>
<td>Assessment of consumables and reagents</td>
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<tr>
<td>Training, Certification and Recertification for POCT operators</td>
<td></td>
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<tr>
<td>Quality Control and Assurance</td>
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</table>
Files international

- ISO/CD22870
- ISO15197
- ISO17593
- AST02-2
Relevant documents, regulations, research in 2006-2009 domestic

- Notice of the Ministry of Health-related emergency department management 《〔2009〕50》

- Notice of the General Office of the Ministry of Health to strengthen the clinical use of portable blood glucose testing meter management 《〔2009〕126》

- Clinical Laboratory Management Measures 〔2006〕73
Hospital management status of POCT in China

— POCT committee, Beijing Tiantan hospital, Capital medical university
First “hospital POCT Management Committee” was established in Beijing Tiantan hospital in 2009.
Management ideas and specific work procedures of POCT

- The Preparatory Committee—Explain the necessity and benefits of the committee
- Committee — clear responsibilities
- Training — determine training content, objects, and programs
- glucose meter calibration data file — quality control data, correction data and comparation data
- interference factor analysis——Clinical guidance
- Report to the Commission — training cases, blood glucose meter status (quality control, comparison, etc.)
Main contents

- Organization Management
- Portable blood glucose detector selection criteria
- Portable blood glucose detector operating specifications
- Operator training
Clinical background of Management Committee establishment

- Bedside glucose meters currently used widespread in clinical
- Many kind of meters in the market
- different brands and models of blood glucose meters even in one hospital
Organizational structure and responsibilities of the Management Committee

Committee Office

Coordinator
- Communication
- Policy advocacy
- Draw training plan

Technical Training
- SOP formulation
- Specimen collection and processing
- Notice

QC
- Internal QC
- External QA

Quality Manager
- Performance evaluation
- Precision
- Accuracy
Establishment of POCT Preparatory Commission Beijing Tiantan Hospital, Capital Medical University

- Nov. 24th, 2009
POCT Management Committee
Nov. 27th, 2009
Work content

1. hospital blood glucose meter usage survey, create a file
2. calibration, quality control results, analysis of common interfering factors, results comparison
3. training plan and content
## Survey of glucose meter, file created

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The distribution of Glucose meters in our hospital

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Training procedures for operating personnel

- **Purpose:** Operation standardization, quality assurance
- **Grading:**
  - Grade 1 training
  - Grade 2 training
  - Grade 3 training
- **Trainer:**
  - Grade 1 POCTC or Equipment manufacturers representative
  - Grade 2 POCTC and Equipment manufacturers representative
  - Grade 3 POCTC and Equipment manufacturers representative
Training certification: after training of each level, written and practical appraisal will be conducted by POCTC.

Training recording: Original notes, attendance book (lecturer needs to sign the attendance book), the issuance of a certificate of training after record.
Training procedures for POCT operating personnel

Grade 1 training included:

- Test purposes
- Test principles
- Specimen kind
- Requirement and preparation of patients
- Specimen collection and processing, the specimen container requirements, storage and rejection
- POCT device, reagents introduction:
- Each operation procedure
- Data recording
- Reference range
- Results out of range
- Critical value
- Restricts and mistakes (reference)
- Notice
- Waste deal
Grade 2 training included:

- The QC time and frequency
- Purpose and significance of POCT
- Choose of QC reagents
- Storage of control materials
- Specific operation of QC
- How to record the QC results
- How to recognize the results in or out of control
- How to deal with the QC result out of control
Grade 3 training included:

- Meanings of device failure error code
- Reasons of failure error codes
- Evaluation of care medical device performance after exclusion of the fault
- How to avoid the recurrence of failure
- Regular maintenance and repair equipment
- Contact care medical equipment manufacturers maintenance personnel
Training scenarios
The benefits of the establishment of the Commission

1. Strengthen the clinical use of blood glucose meters and other products for POCT
2. For clinical applications, making a clear understanding of the operation of the instrument specifications and precaution
3. Quality Supervisor (laboratory personnel commitments)
4. Quality manager (laboratory personnel commitments) to ensure that all aspects of the experimental performance of the product to meet clinical needs.
5. Coordinator can be more convenient to work
Problems to be solved:

POCT data Connectivity)

- Data connections are not simply delivering the result part of the whole POCT system, all members connected to the system: doctors, nurses, inspectors, patient...
- Connection different locations of POCT testing: hospitals, clinics, bedside patient's home, the scene...
- Help building a virtual laboratory (virtual lab) make it easier to use POCT devices connected to the system
- Connection Industry Association (connectivity industry consortium, CIC) was established in the year 2000
- The connection standard was established in 2001 (POCT1-A, point-of-care connectivity, approved standard) to ensure POCT device can connect with existing data management systems
- The second edition connection standard (POCT1-A2) published in 2006
Solving approaches

- The project developers and suppliers
  Understand the conditions, users, resources, applications background
- Funding agencies or donors:
  Funded projects with technology related events, Price of R & D projects, mechanisms
- Public health managers:
  Quality assurance, the results reported
  Case notices, results intervention
Professional management of POCT clinical information systems

- Enhance the quality control of clinical POCT devices; analysis of test results and so on
- Transfer work to streamline the reporting / data, to avoid the occurrence of errors
- Enhanced traceability of test data
- Improve the efficiency of clinical departments, reduce costs
Centralized control and distant management

Consumables

- patient
- specimen
- result

Alarm system / equipment alarms

QC range

Technical Review

LIS

Accepted manual

Accepted auto
Problems to be resolved

Standardization

- China In Vitro Diagnostic Product Certification System
  - GMP, "in vitro diagnostic reagents to review implementation details"
- EU certification system:
  - ISO13485, ISO9001
- U.S. certification system
  - 21CFR820 Quality System Regulation, FDA–site certification
Improve production automation, scale and intensive
Strengthen independent innovation

- Importance of intellectual property rights
- Increase R & D investment
- Construction of enterprises as the mainstay of the "research use" Innovation Alliance
Grasp the opportunity, the courage to open up

Development of foreign POCT industry very quickly, has become an inevitable trend in the development of laboratory medicine, we should cherish the initial stages of the development of POCT. The overall level gap with foreign countries is not very obvious development opportunity, must not be due to the presence of some of the issues currently POCT in the development process and produce POCT doubts, wait for improvement, so we will miss the opportunity, once awakened too late this is the R & D and testing colleagues worthy of attention!
Self –Assessment Questions
(multiple-choice only)

1. The main technologies applied in POCT include:
   a. Immunochromatographic qualitative detection technology
   b. Chromatographic quantitative detection technology
   c. Electrochemical detection technology
   d. Dry biochemical detection technology
   e. Biochip detection technology
Thanks!