



The Global Language of Business

# Zhou Hua

## Shanghai Shuguang Hospital, China

---

26 October 2016



---

# Full Traceability of External Supply Chain and Logistics within the Hospital by UDI Supports

Shuguang Hospital

Affiliated to Shanghai University of Traditional Chinese Medicine





# Outlines

---

- **Introduction of Shuguang Hospital**
- **Current situation of full traceable management**
- **The core link of UDI application in Shuguang**
- **Current situation of precision management of traditional Chinese medicine**
- **Conclusion**



# About Shuguang (1)



Cover area 126000m<sup>2</sup>  
West 19333 m<sup>2</sup>, East 106666 m<sup>2</sup>  
Construction area 136000 m<sup>2</sup>  
West 52000 m<sup>2</sup>, East 84000 m<sup>2</sup>  
  
No. of Beds 1320  
West 600 beds, east 720 beds  
  
Total Staff over 2000



National Key TCM Hospital  
Top 100 hospitals of National  
Health and Family Planning  
Commission  
Model TCM Hospital of State  
Administration of  
Traditional Chinese  
Medicine





# About Shuguang (2)



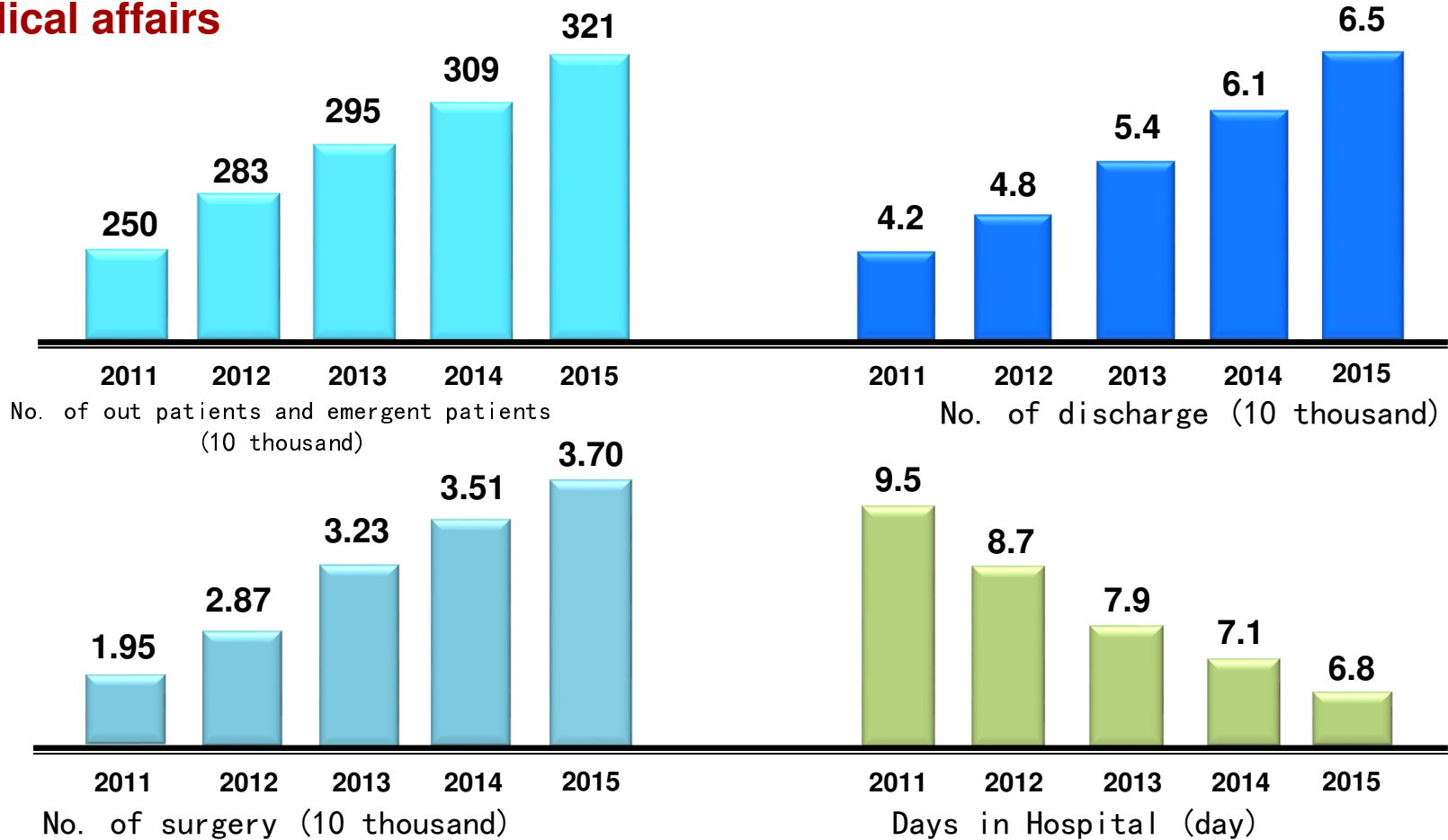
- First TCM hospital pass the ISO 9001 management system certification
- Passed ISO 15189 laboratory verification in Mar 2010
- Passed ISO 17025 laboratory verification in Apr 2010
- Passed FERCAP ethical clearance in Nov 2010
- Involved in the development of international standards such as ISO-TC249 and ICD 11
- National TCM Hospital Medical Quality Monitoring Center (since 1996)
- Shanghai Traditional Chinese Medicine Quality Control Center



# About Shuguang (3)

## Medical affairs

Longitudinal comparison







# About Shuguang (4)

## Differences between Chinese and Western Medical Management

	Medical Difference	Drug Difference	Advantage
<b>Western Medicine</b>	<ul style="list-style-type: none"><li>• Local view</li><li>• Inspection, palpation, percussion, and auscultation</li><li>• Medical device diagnostics</li><li>• Professional techniques and standardized treatment remedy</li></ul>	<ul style="list-style-type: none"><li>• Chemical preparation (pills, capsules, granules )</li><li>• Modern equipments</li></ul>	Emergent and server patients
<b>TCM</b>	<ul style="list-style-type: none"><li>• Concept of holism, the unity between human and nature</li><li>• Observation, questioning, smelling&amp;listening, pulse taking</li><li>• Syndrome differentiation and treatment</li><li>• Typical formula/empirical formula</li></ul>	<ul style="list-style-type: none"><li>• Herbal remedy</li><li>• Food remedy</li><li>• Acupuncture and Tui Na</li><li>• Plaster therapy</li><li>• Psychotherapy</li></ul>	Patients with incurable and chronic diseases



# Understanding of the application of UDI/GS1 standards in hospital



- Medical precision is the core element of hospital management
- Precise management requires the support of data environment
- Logistics informatization is the basis of precise management
- UDI is conducive to achieving precise management





# Application of global UDI traceable system in china



## 总局关于推动食品药品生产经营者完善追溯体系的意见

食药监科〔2016〕122号

2016年06月27日 发布

三、药品、医疗器械生产企业应当按照其生产质量管理规范（GMP）要求对各项活动进行记录。记录应当真实、准确、完整和可追溯。鼓励药品、医疗器械生产企业对产品最小销售单位赋以唯一性标识，以便经营者、消费者识别。植入性医疗器械应当标记生产企业名称或商标、批代码（批号）或序列号，以保证可追溯。

药品、医疗器械经营企业应当按照其经营质量管理规范（GSP）要求对各项活动进行记录。记录应当真实、准确、完整和可追溯，以保证药品、医疗器械购进、养护、出库、运输等环节可追溯，并按规定使用计算机信息管理系统进行有效管理。

药品、医疗器械使用单位应当按照《医疗机构药品监督管理办法（试行）》和《医疗器械使用质量监督管理办法》要求对药品和医疗器械的购进、验收、储存、使用等情况进行记录。

五、地方各级食品药品监管部门要按照《中华人民共和国食品安全法》《中华人民共和国药品管理法》《医疗器械监督管理条例》《化妆品卫生监督条例》等有关法律法规的规定，督促行政区域内相关生产经营者认真落实产品追溯主体责任，并对原料来源记录、生产过程记录、购销记录等追溯体系建设要求的落实情况进行督促检查和总结。对不履行追溯责任者依法及时查处。

六、鼓励生产经营者运用信息技术建立食品药品追溯体系。鼓励信息技术企业作为第三方，为生产经营者提供产品追溯专业服务。各级食品药品监管部门不得强制要求食品药品生产经营者接受指定的专业信息技术企业的追溯服务。

七、鼓励行业协会组织企业搭建追溯信息查询平台，为监管部门提供数据支持，为生产经营者提供数据共享，为公众提供信息查询。

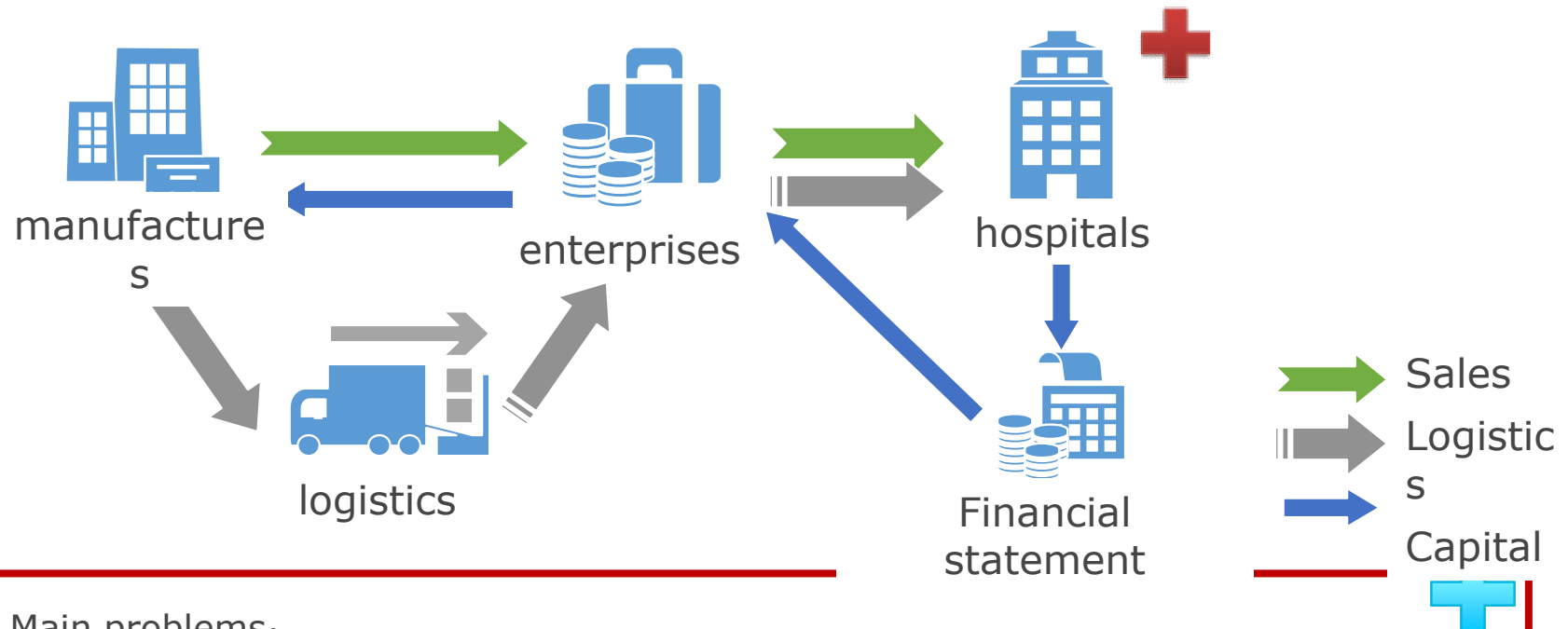
Encourage pharmaceuticals and medical device manufacturers to give the smallest product sales unit UDI, so that operators and consumers could identify the products. Implantable medical devices should be marked with the manufacturer's name or trademark, batch code or serial number to ensure traceability.

Encourage industry associations to organize enterprises to build a traceable information query platform to provide data support for the monitoring secretors, information sharing for producers and information query for the publicities.





# Current situation of full traceability management (1)



## Main problems:

- $UDI=DI+PI$ ; procurement DI, delivery DI, the hospitals requires DI+PI, the hospital may collecting PI upon recipient;
- Chinese drug electronic monitoring code haven't solve the problem of hospital PI collection for 10 years, the hospital is still unable to trace the source precisely.



# Current situation of full traceability management (2)



Medical instruments



Western Medicine



Chinese Herbal Medicine



GS1

HIB  
C



NDC

EAN-13



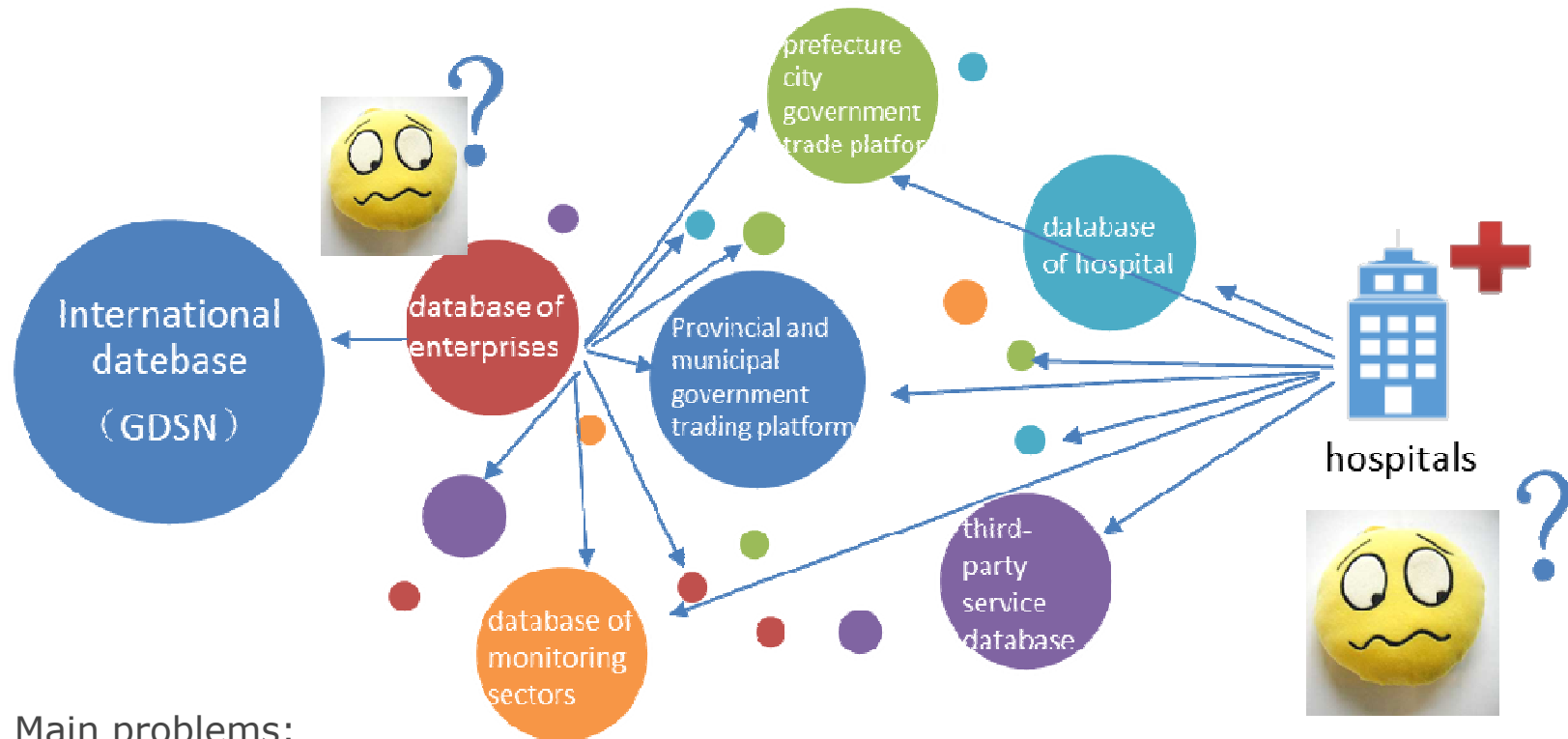
No national standards available, enterprises standards are currently adopted.

Main problems:

- The instrument UDI is not fully covered, China only covers category III implants and part of the category I and category II
- Western medicine and Chinese medicine coding standard is not uniformed, no automatic identification of the batch number information



# Current situation of full traceability management (3)



Main problems:

- Repeated construction of the database is astonishingly costly. The enterprises and hospitals are struggling to cope.
- The database can not be interconnected, the information island phenomenon is serious.



# Current situation of full traceability management (4)



Main achievements:

- implantable medical devices used in Shuguang are able to meet the UDI management requirements.
- Part of the category I and category II products are still without UDI, we suggest the enterprises to use the same GS1 standards.





# Core link of UDI application in hospital (1)

## Introduction of core link: Purchase and storage security management

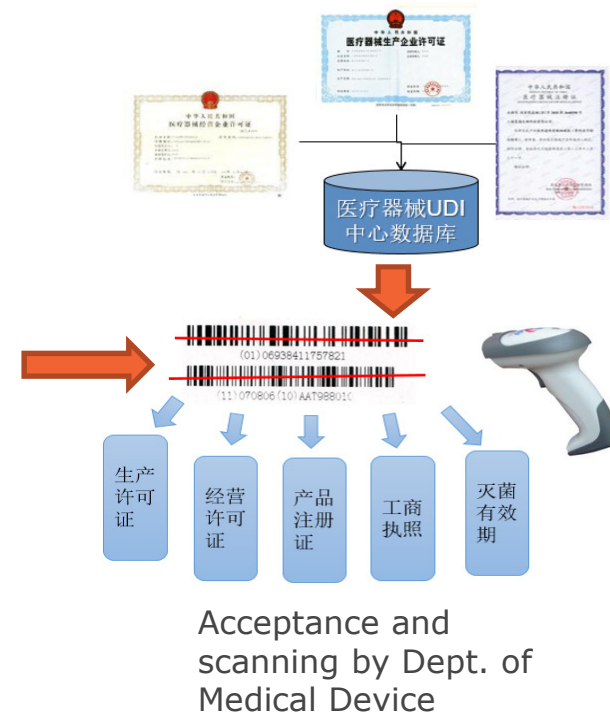
福建协和医院被罚千万的幕后故事  
2016-09-14 福建消费网



Due to poor acceptance of the use of undocumented products, the hospital was impose high penalties by the regulatory authorities



Supplier physical distribution to hospital



### Main achievements

- The hospital scan the UDI code on the package to collect the time information of PI and domestic approval information of DI by using the UDI database provided by third-party.
- Shanghai database was established in 2006. Now it owns 570,000 products DI data from 5000 medical device enterprises.







# Core link of UDI application in hospital (2)

## Introduction of core link: Postoperative UDI – Associated with patients



医疗器械实时监管医院系统

病人基本信息

单据号	37018100035	执行科室	外科住院	负责人	王勇-1001
患者住院号	1133016	住院状态	住院	年龄	70岁
病人姓名	陆程	性别	男	出生日期	1940年 9月 1日
证件类型	身份证	证件号		电话号	13482099548
地址		手机		备注	
病区名称		床号		消毒包号	

手术信息

手术名称: 腹腔镜微创前列腺切除术  
手术流水号: 2016年10月 7日  
手术医生: 王勇  
入院诊断: 前列腺增生  
手术时间: 2016年10月 7日  
手术部位: 手不穿

产品信息

序号	产品名称	UDI5特码	规格型号	生产日期	灭菌有效期	灭菌方式	注册证号	器械代码	发证日
4	金属固定	37422-44		2015-6-1		厂商灭菌	国械注进2	031002002	2015-4
4	金属固定	37422-42		2015-4-5		厂商灭菌	国械注进2	031002002	2015-4
3	金属缝合	37351-28		2014-5-22		厂商灭菌	国械注进2	031002002	2010-6
3	金属缝合	37351-30		2016-4-1		厂商灭菌	国械注进2	031002002	2013-6

使用登记表打印 科室领用清单打印 收费清单打印或预览 单据上报 单据作废

产品信息

条码信息: 11311 44 010012004301223 生产日期: 2015-6-1 数量: 2 收费单位: 件

产品名称: 腹腔镜微创前列腺切除术 规格: 国械 灭菌有效期: 2015-6-1 采购价格: 0000.00 (元)

规格型号: 37422-44腹腔镜多通道前列腺切除术 批号: 001 2013/191 收费价格: 0000.00 (元)

供应商名称: 国药控股嘉德医院管理服务有限公司(上海)有限公司 序列号: 030 截止日期: 2015-4-2

注册证号: 国械注进2015461133 发证日期: 2015-4-2

申请科室: 泌尿外科

申请日期: 2016-10-07

申请科室: 泌尿外科

植入性医疗器械使用登记表

单据号: 1133016 住院号: 1133016

病人姓名: 陆程 科室代码: 外科住院

手术名称: 腹腔镜微创前列腺切除术 手术时间: 2016-10-07

证件类型: 身份证 证件号: 1133016

联系方式: 13482099548

序号	器械代码	产品名称	规格型号	UDI5特码	生产日期	灭菌有效期	灭菌方式	注册证号	器械代码	发证日期
1	031002002	腹腔镜微创前列腺切除术	37422-44	37422-44	2015-6-1		厂商灭菌	国械注进2	031002002	2015-4
2	031002002	腹腔镜微创前列腺切除术	37422-42	37422-42	2015-4-5		厂商灭菌	国械注进2	031002002	2015-4
3	031002002	腹腔镜微创前列腺切除术	37351-28	37351-28	2014-5-22		厂商灭菌	国械注进2	031002002	2010-6
4	031002002	腹腔镜微创前列腺切除术	37351-30	37351-30	2016-4-1		厂商灭菌	国械注进2	031002002	2013-6

科室: 外科住院 负责人: 王勇-1001 手术医生: 王勇

手术部位: 手不穿

### Main achievements:

- Synchronizing the medical devices and patients' records by scanning the UDI in operation room
- UDI scanning has been used in the departments of orthopedics, ophthalmology, general surgery, brain surgery, cardiology, endoscopy, interventional medicine and cardiothoracic surgery
- The application of UDI will be expanded with the wider coverage of its products

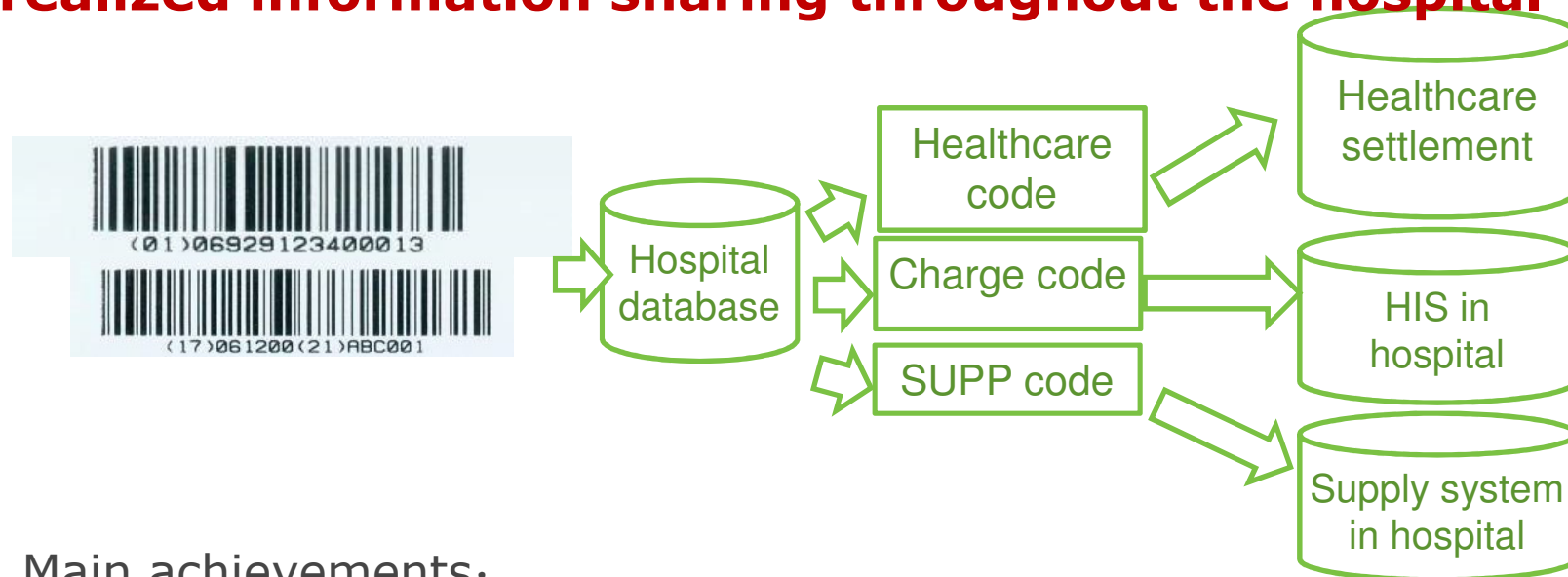






# Core link of UDI application in hospital (3)

## Introduction of core link: the application of UDI realized information sharing throughout the hospital



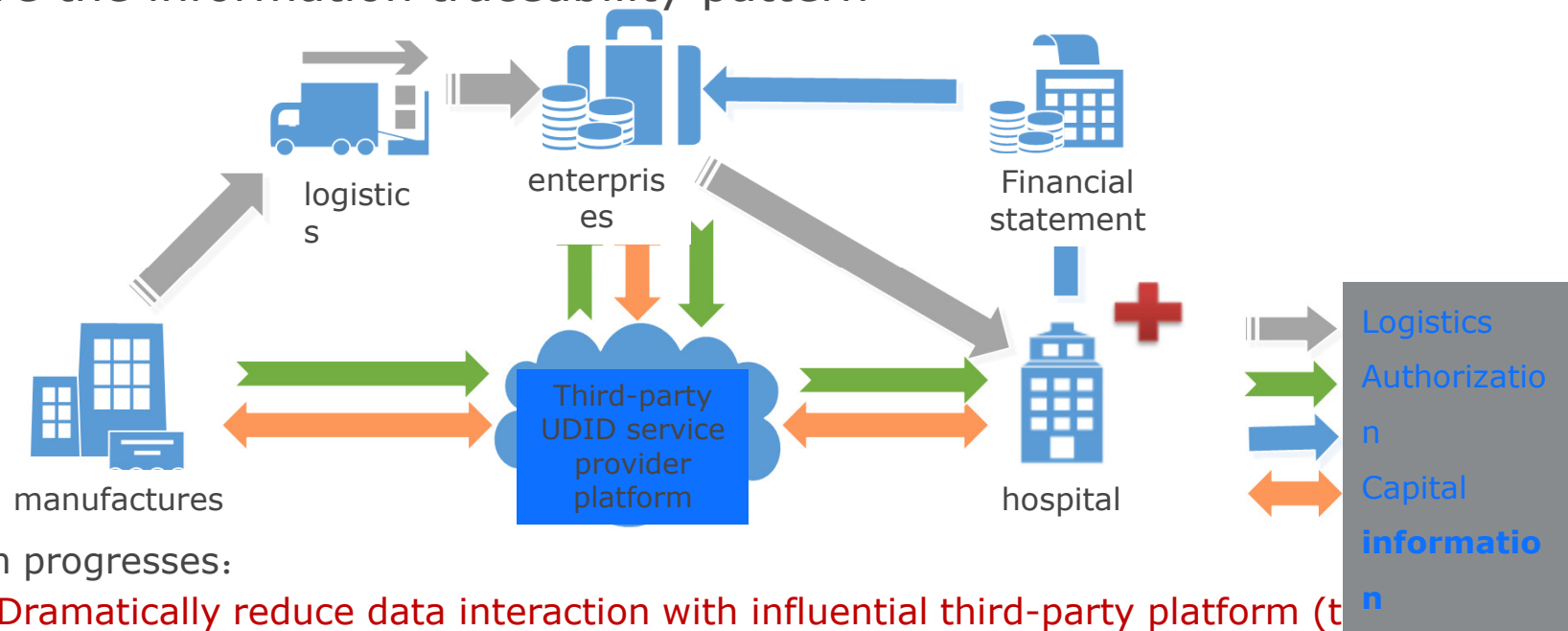
Main achievements:

- Connecting the information between the usage of medical devices and other records with the application of UDI in operation



# Core link of UDI application in hospital (4)

**Introduction of core line:** single node entry enables all parties to share the information traceability pattern



Main progresses:

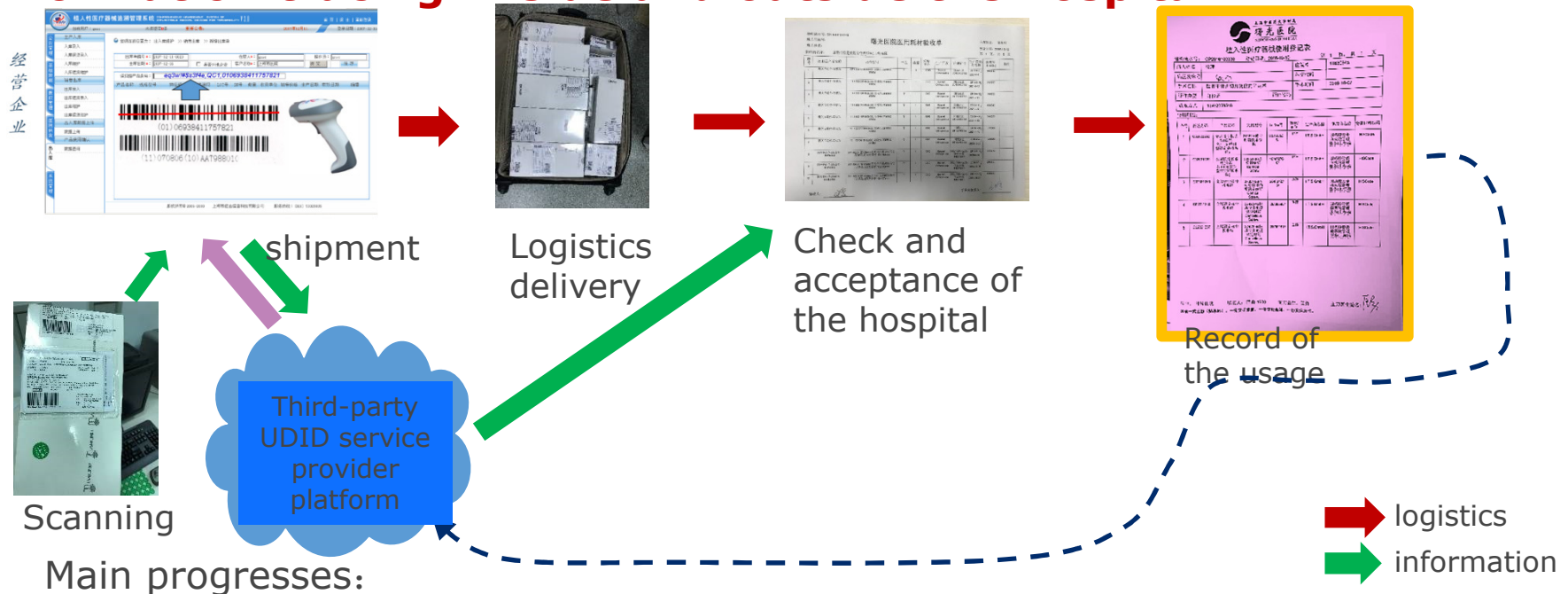
- Dramatically reduce data interaction with influential third-party platform (the platform contains more than 200 hospitals, over 4000 suppliers, 570000 products and 1200 manufactures)
- The interaction between hospitals and service providers in the supply chain greatly simplifies the construction of information system in the hospital, and facilitates safety management, patients tracing management and settlement management by information sharing.





# Core link of UDI application in hospital (5)

**Introduction of core link: realize the consistency of information tracing inside and outside the hospital**



Main progresses:

- Through the third-party platform service providers, suppliers and hospitals realize the closed-loop management
- **Realize the two-way check goods, data sharing reduces the data entry**





# Current situation of precise management of TCM (1)

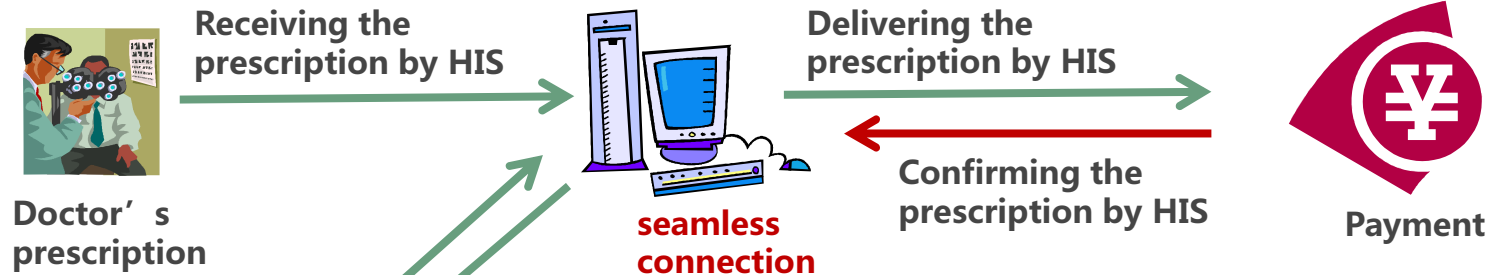


Main progress:

- automatic machines are used to deliver the TCM products with standardized package
- automatic identification tools are used for the TCM products without standardized package to avoid mistakes



# Current situation of precise management of TCM (2)



Drug management system in hospital

**Equipment management** real-time monitoring , operating log, device alarms

**Stock management** batch number and validity, early-in and early-out, slow moving reminder

**Drug distribution management** dispensary at the pharmacy, planning distribution, timeout reminder

**Replenish management** early warning of stock, Intelligent allocation, Automatic inventory

**Statement management** inventory analysis, routine adjustment, sales analysis

**Prescription early warning** drug incompatibility, multi-auditing , drug usage reference

**Drug monitoring** Drug consumption, variety categorized reports

**Performance appraisal** indicators for doctors and pharmacists



# Current situation of precise management of TCM (3)

	Goal	Current situation	Comparison
Capability of prescription	500/hour, 4000/day (in 8hours)	Maximum 2000/day	2 times
No. of drug delivery	4800 boxes/hour, 38400boxes/day (in 8hours)	Maximum 294 prescriptions/hour, delivering 1526 boxes of drugs	3 times
No. of drug kinds	2 Consis-D3 Automatic dispensing machine with the capacity of 1536 kinds	347 kinds	4.3 times
No. of drug stock	2 Consis-D3 Automatic dispensing machine with the capacity of 23040 boxes	9575 boxes	2.4 times
Processing speed	30-45s/prescription	8-10s/prescription	4 times
Time for taking drugs	5-10 mins	30s	5 times

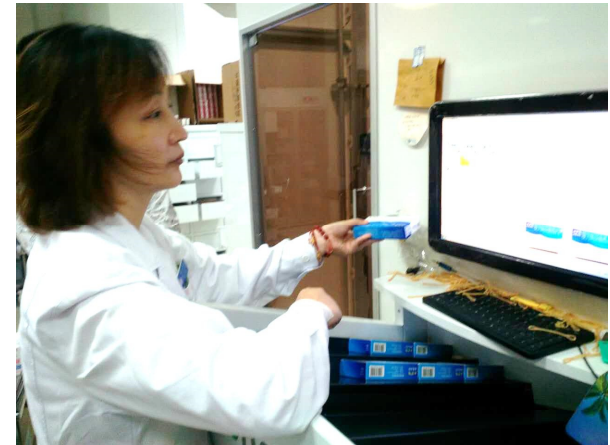
Main progress:

- Automated precision services greatly improving the service capability, increasing processing speed, and reducing mistakes while working





# Current situation of precise management of TCM (4)



- Automatic precision services dramatically increase service speed, but non-standard barcodes and untraceable information may fail the tracing of patients' usage.
- The empty of standard bar code in TCM making the traceability can only be carried out between hospitals and enterprises, can not form a full traceability chain.



# **Perception: NOT everyone can get coding!**

---



**Hospital precision management can not work alone without the standardization of logistics information. Information standardization should be proceed from a global perspective.**

**Thanks to GS1's efforts and contributions in this area, thanks to the experts in this field to contribute to the long-term unremitting efforts!**





---

# Thank you!

