



# Best Practices using Global Standards in Healthcare

rm/ficci-healthheal/080808

The global language of business

[www.gs1india.org](http://www.gs1india.org)



## GS1 India

GS1 India is a standards based not-for-profit body promoted by the **Ministry of Commerce**, Govt. of India and Indian Industry

Board members include representatives from:

- Ministry of Commerce
- BIS
- FICCI
- ASSOCHAM
- FIEO
- SPICES BOARD
- CII
- IMC
- IIP
- APEDA

Representations  
from  
all industries



890 indicates  
India as country  
of origin

Affiliated to **GS1**, based in Brussels, Belgium  
Example of true **Govt-Industry collaboration**



## **GS1:** Leading the design and implementation of global standards to improve the supply and demand chain



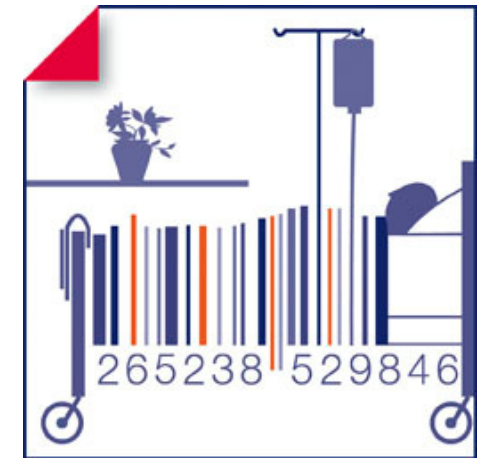
## GS1: A Broad Portfolio

GS1 offers **solutions**, each integrating a number of GS1 products.



**Traceability** is a robust solution for tracking and tracing items such as food or pharmaceuticals through the supply chain.

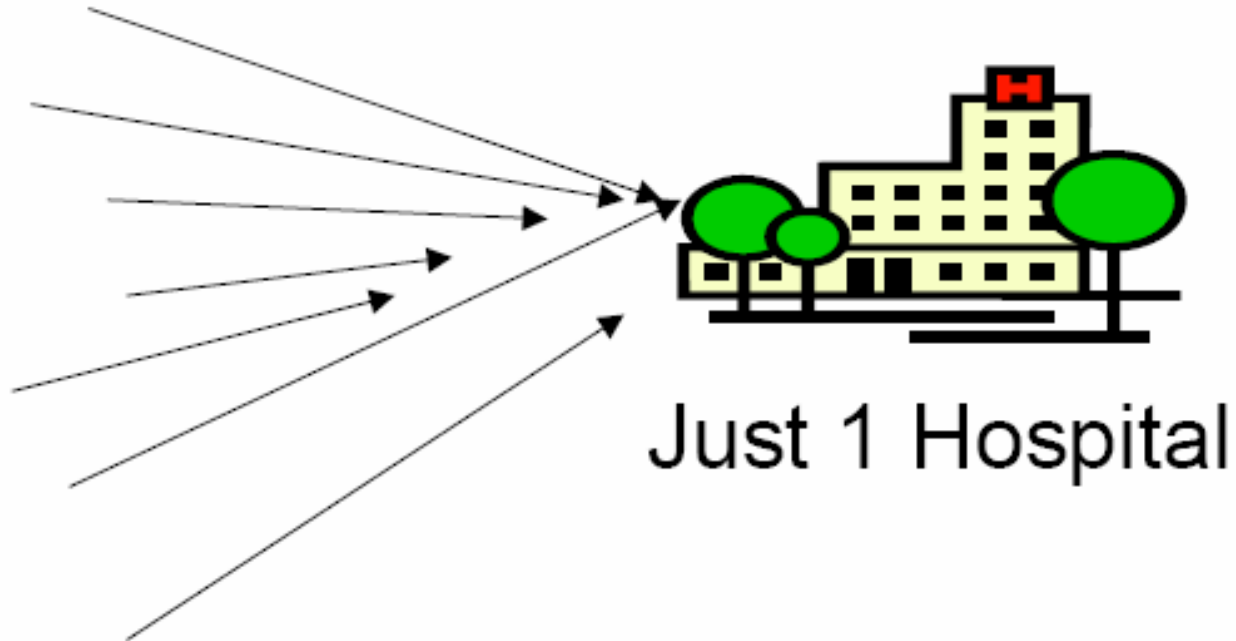
**Patient Safety** ensures the prevention of medical errors and counterfeiting through the healthcare supply chain.



**Healthcare:** In 56 countries worldwide, GS1 stds have been chosen to identify pharmaceutical products uniquely. Major regulatory bodies have endorsed them, including those in the US, Japan, Korea and the UK.

## Why global stds are important?

St. Michaels  
St Michaels  
St. Michael's  
Saint Michaels  
100084547  
JAOE  
CA2053  
50003000431  
Etc.



By Nancy Marsh  
Medical Reporter

A MENINGITIS patient died after hospital transfer when potentially life-saving drugs were given to another man with the same surname.

The relatives of 51-year-old Deepak Patel said yesterday that the error was a 'bad indictment of the NHS'.

Hospital bosses apologised for the mix-up but admitted that no-one would be disciplined.

Mr Patel was taken to Northwick Park Hospital in North West London with suspected gastro-enteritis.

The building maintenance worker who had recently become engaged was diagnosed with meningococcal septicaemia - a form of blood poisoning caused by meningococcal group antibodies.

But a senior registrar, Dr Stuart Dickson, had also been treating another patient named Mr Patel and mixed up the two patients giving the drugs to the wrong man.

An expert at Bartsay, North London, last Monday found that Mr Patel died of natural causes - ischaemic heart disease and meningococcal septicaemia - in April 2012.

A spokesman for the hospital said Dr Dickson had already seen the other Mr Patel so he thought it was the same person.

Deepak was not given the antibiotics and the other man was. Deepak was walking around and was taken average atypical case.

'In clinical and out care were just a high temperature and chills. It was only after when he died.'

She added: 'We are sorry we put it

# Patient died after drugs went to man with the same name



Deepak Patel: Fatal mistake

wrong. The Trust would like to extend its deepest sympathies to Deepak's family. Losing a son or brother is a devastating experience.

Mr Patel's relatives are understood to be considering legal action against the hospital and seeking an independent medical review of the case.

Mr Patel's brother Mark, a 28-year-old teacher, last night said his family had been torn apart by the blunder, and that his parents, who are sick with diabetes, were in a state of shock.

He added: 'We need to know just what his chances of survival would have been had he been given the proper drugs.'

The last time any parents were at his side he was awake and smiling and we thought he was going to pull through. It came as total shock.

My brother had his whole life ahead of him. He had just become engaged. I know doctors are not

guilt, but for such a thing to happen is disgraceful.

'I can only hope that my brother's death will not be in vain.'

'The hospital spokesman said Mr Patel's death had led to new safety measures being introduced. 'Since Mr Patel's death we have put in

place new procedures,' she added.

'This involves the verbal identification of the patient by hospital number or date of birth as well as their name.'

In addition, revised guidelines for the administration of antibiotics in cases of meningococcal disease have

been developed and implemented.'

The other Mr Patel, who had gone to the hospital, had a complete recovery.

Mr Patel's family may take legal action against the hospital and are seeking an independent medical review of the case.

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## Concerns for healthcare sector

- Patient safety and medication errors (*identification errors*)
- Traceability and fast & limited product recalls/ withdrawals
- Counterfeit detection (*unique and serialised product ID*)
- High costs of healthcare (incl. Supply Chain/distribution costs)
- Seamless, real-time and accurate information flow between stakeholders – hospitals, distributors, pharma cos., insurance, Regulators etc. (*Need for technology enabled information network*)

### Patient safety/Medication errors – Statistics

- Medication errors occur as a result of a lack of machine readable codes, which significantly increases the risk of human visual identification errors
- In US, studies shows that nearly 200.000 patient deaths each year due to medication errors (HealthGrade, 2003)
- In UK, the NHS has recently calculated that approx 60 patients die each day due to adverse drug errors. 50% of the estimated 72,000 deaths in the NHS are caused by medication errors. 34% of these errors are associated with drug administration. In addition to this, adverse reactions to medication cost approx £2 billion a year in additional hospital stays and the NHS pays out approx £400 million each year to settle clinical negligence claims.
- In NL a study of the Govt has shown that 90.000 admissions are due to medication errors, 300 millions € are recovery costs

## Counterfeiting

- WHO estimates - 10% of all drugs worldwide.
- Africa and **Asia** mainly concerned, but also well known drugs in the US have been faked.
- In Dec'04 a Counterfeit Medicines Report has been presented to the ad-hoc Committee on Counterfeit Medicines of the Council of Europe with recommendation to take action.
- ASSOCHAM estimates – 20 to 25% in Delhi alone (*TOI 12 Feb'08*)

## High costs of healthcare

- Channel inventory – 100 days. Potential decrease to 30 days
- Vendor expiry returns (2% of Rs.40,000 Crores)
- Medicine forecasting errors
- 20% of prescription drugs unavailable at pharmacies on average

## Improved patient safety



- ✓ The right medicine to the right person in the right dosage at the right time at the right route of the administration
- ✓ Traceability in the event of a recall or concern on origin of product



## What all is possible with global GS1 Stds

- Scan based customer billing with 100% accuracy
- Targeted product recalls at reduced cost
- Linkage with int'l hospitals for referral/medical tourism
- Facilitate compliance with stringent global Regulatory requirements
- Reduction in distribution of expired drugs
- Reduced healthcare costs thru reduced supply chain costs
- Counterfeit detection



## What all is possible with global GS1 Stds

- National repository of medical facilities, blood banks, doctors etc using global identification stds (GLN)
- E-medical national product catalogue (web based) as single referral data base for all stakeholders (Doctors, hospitals, Regulator, pharma cos, pharmacies)
- E-procurement by Govt/others (e-Com stds)
- Product authentication using serialised barcodes/RFID
- Asset tracking in hospitals
- Patient identification
- Faster insurance claim processing



## Global Healthcare User Group

Global Healthcare User Group is a global user community bringing together all healthcare stakeholders

- Pharmaceutical and medical devices manufacturer
- Wholesalers and distributors, group purchasing organisations
- Hospitals and pharmacy retailers
- Logistics providers
- Governmental and Regulatory bodies
- Associations





## Global healthcare user group

Abbott  
Alcon Laboratories, Inc.  
Amgen  
AngioDynamics Inc.  
Arthur Inc.  
Baxter  
**British Dental Trade Association**  
BD  
BMDi Pty Ltd  
BVmed  
**Cardinal Health**  
Celesio  
Cephalon  
Cofares  
Consorta

Edwards Lifescience  
EMD Serono Inc.  
**Food and Drug Administration (FDA)**  
Forsure Medical Products  
GE Healthcare – Clinical Systems  
Geodis  
**GIRP (The European Association of  
Pharmaceutical Wholesalers)**  
Health Technology (New South Wales Health)  
Institut Catala de la Salut  
**International Hospital Federation (IHF)**  
Ishan Herbotech International  
J&J Pharma  
Kimberly Clark Corp.  
Masikap Pharma  
Medtronic  
Michigan State University



## Use of GS1 stds in Healthcare Sector

*“Over 50 countries in the world including USA, Australia, New Zealand, Japan, Korea and European Union countries have adopted the GS1 system for identifying, tracking & tracing medical products”.*

- In UK, 70 NHS hospitals signed up to use GS1 stds to improve patient safety. The UK Deptt of Health have issued guidelines saying they support GS1 stds.
- Eucomed (European medical devices association) recommends the adoption of GS1 stds
- ISBT works with GS1 to improve patient safety
- HL7 works with GS1 to improve patient care

## Where and how do these stds impact NABH guidelines/stds?

### Access, Assessment and Continuity of Care (AAC)

- AAC.2 – a) developing standardised procedures for registration/admittance of patients (*patient identification, medical record identification to facilitate inter-hospital referrals, insurance claims etc*)
- AAC.3 – a) transfer of patients to other facilities (*std patient identification across hospitals*)
- AAC.7 – c) identification, handling and disposal of specimens (*stds for accurate identification without duplication*)
- AAC.10 – d) identification and safe transportation of patients (*identification stds*)
- AAC.9 & AAC.12 – handling disposal of radio active and hazardous materials (*universal and unique identification for audit by Regulatory authorities*)
- AAC.13 – e) patient record to authorise care providers to facilitate exchange of information (*unique patient medical record identification*)

## Where and how do these stds impact NABH guidelines/stds?

### Care of Patients (COP)

- COP.5 – rational use of blood and blood products (*unique and universal identification, collaboration with ISBT*)
- COP.12 – d) procedures to prevent adverse events like wrong site, wrong patient (*GLN, GSRN stds used globally*)

### Management of Medication (MOM)

Availability, correct storage, dispensing, administration of medications, expiry dates/stocks maintenance (by pharmacy),

- medication recalls (MOM.5.b)
- dosage/medication labeling/patient identification (MOM.6.b to g)
- narcotic drugs identification (MOM.9.a – *UN certified nomenclature using GS1 identification stds*)
- recording batch no./sr. no. of implantable prosthesis (MOM.12)
- replenishment of medical gases (MOM.13 – *returnable assets identification*)



## Where and how do these stds impact NABH guidelines/stds?

### Hospital Infection Control (HIC)

- HIC.8 – a) biomedical waste management (*identification of waste by different authorities*)

### Continuous Quality Improvement (CQI)

- CQI.2 – f) monitoring use of blood and blood products (*complete guidelines on blood management, blood products identification in collaboration with ISBT*)

### Facility Management and Safety (FMS)

- FMS.3 – c) equipment to be inventoried (*universal identification for maintenance etc as well*)
- FMS.7 – c) availability of medical supplies, equipment and materials during emergencies (*stocks management using barcodes and GS1 global stds endorsed by healthcare sector*)

### Information Management System (IMS)

To capture, transmit, store, analyse, utilise and retrieve information when require. Use of digital based system for improved efficiency (*barcodes for data capture, EDI stds etc*).

- IMS.3.a & d – unique identifier for medical records and author of entry (*GS1 global stds*)





## NABH guidelines/stds on quality assurance/quality improvement in hospitals

### *NABH key objectives – patient safety and quality of patient care*

- GS1 plays key role in meeting the above objectives thru creation of **user** (hospitals, mfgrs, Regulators) driven stds and technologies
- These stds are developed:
  - in response to sector needs to resolve existing/anticipated issues
  - with active collaboration of healthcare sector with domain knowledge provided by the sector stakeholders (business processes in hospitals, healthcare supply chain etc)
  - to facilitate compliance with growing Regulatory requirements worldwide and increasing demand for higher patient safety and care at affordable costs (USFDA laws on barcoding/ e-pedigree)
  - for higher efficiency/safety of healthcare sector (medication errors, logistics costs, delays etc)



### ***NABH key objectives – patient safety and quality of patient care***

- to handle national/global crises (recalls, fatalities, injuries, counterfeits, AIDS management etc)
- to help linkages with global hospitals, patient referrals, insurance claims handling (medical tourism, collaboration with int'l hospitals etc)
- To help Govts. and Int'l bodies (WHO/IHF/ISBT etc) monitor and run national/global healthcare programs (malaria control, nutrition mgmt, AIDS control etc) efficiently

#### ***Key point***

It is important to ***inform and guide*** the Industry on availability and acceptance of global stds and technologies to facilitate compliance/conformance with NABH guidelines/stds in a ***uniform, cost effective*** manner for convenience of all stake holders – accreditation agencies, regulatory bodies, hospitals, medical supplies distributors and mfgs, insurance agencies etc.

***Accreditation guidelines should provide this***

## Status in India

- Min. of Health & Family Welfare mandates use of GS1 barcodes for contraceptives. Same implemented.
- DGMS notified same for medicines used by CGHS etc.
- Emerging pharmacy chains (Fortis, CRS, Reliance etc), hospitals (Max, Wockhardt, Reliance etc) willing to adopt and implement GS1 barcodes on medicines, medical devices, hospital supplies.
- AIOCD has prepared aggressive plans for technology adoption (barcoding, EDI) and stds adoption (GS1 stds) to meet future healthcare requirements and measure up to emerging competition (pvt. Retail chains)
- OPPI & IDMA aligning their members to AIOCD plans and directing them to adopt and implement same.



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