Best Practices using Global Standards in Healthcare
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

Affiliated to GS1, based in Brussels, Belgium

Example of true Govt-Industry collaboration

890 indicates India as country of origin

Representations from all industries
GS1:
Leading the design and implementation of global standards to improve the supply and demand chain
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.

Just 1 Hospital
Why standardisation is important

Patient died after drugs went to man with the same name

By Nancy Warrin
Medical Reporter

A MENDOCINO patient died after hospital biladers went to a man with the same surname.

Nurse of 33-year-old Deepali Patel said that the error was a real and significant issue.

Hospital families apologised for the mistakes that occurred. Three staff members were disciplined.

Mr Patel was taken to Norwich Park Hospital in North London, where he died.

The hospital refused to comment on the case.

Mr Patel’s relatives stressed that the hospital refused to comment on the case.

Mr Patel’s family were taken to hospital and were asked to sign a death certificate.

Mr Patel’s brother, aged 39, who was in hospital, said: “We need to know what happens and get answers.”

Mr Patel’s family were taken to hospital and were asked to sign a death certificate.

The hospital replied that Mr Patel’s death had led to new safety measures being introduced. Since Mr Patel’s death, the hospital had put in place new procedures.

"I can only hope that my brother’s death will not happen again," she added.

The hospital has mounted an independent review of the case.

Mr Patel’s family have been given permission to open an independent review of the case.

The hospital’s medical director said: “We need to know what happens and get answers.”

Mr Patel’s family have been given permission to open an independent review of the case.

Mr Patel died of natural causes.

Mr Patel’s family have been given permission to open an independent review of the case.

Mr Patel’s family have been given permission to open an independent review of the case.

Mr Patel’s family have been given permission to open an independent review of the case.

Mr Patel’s family have been given permission to open an independent review of the case.

Mr Patel’s family have been given permission to open an independent review of the case.

Mr Patel’s family have been given permission to open an independent review of the case.

Mr Patel’s family have been given permission to open an independent review of the case.

Mr Patel’s family have been given permission to open an independent review of the case.

Mr Patel’s family have been given permission to open an independent review of the case.
Patient safety and medication errors \((\text{identification errors})\)

- Traceability and fast & limited product recalls/ withdrawals
- Counterfeit detection \((\text{unique and serialised product ID})\)
- 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. \((\text{Need for technology enabled information network})\)
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 show 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 Standards:

- National repository of medical facilities, blood banks, doctors etc using global identification standards (GLN)
- E-medical national product catalogue (web based) as single referral database 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 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
“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)
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/standards 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, mfrs, 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 guidelines/stds on quality assurance/quality improvement in hospitals

**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 stakeholders – accreditation agencies, regulatory bodies, hospitals, medical supplies distributors and mfgrs, 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.