Healthcare SW Safety & Verification

Prof. Il Kon Kim

Dept. of Computer Science & Engineering
College of IT
Kyungpook National University

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Health IT Standards for Safety - Publication

ISO/TS 25238:2007	Classification of safety risks from health software
ISO/TR 27809:2007	Measures for ensuring patient safety of health software
ISO/HL7 IS 27953-1:2011	Individual case safety reports (ICSRs) in pharmacovigilance -- Part 1: Framework for adverse event reporting
ISO/HL7 IS 27953-2:2011	Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR
ISO/TR 17791:2013	Guidance on standards for enabling safety in health software
IEC/IS 82304-1:2016	Health software -- Part 1: General requirements for product safety

Health IT Standards for Safety - Under Developement

Under Development	
ISO/TS 20405	Framework of event data and reporting definitions for the safety of health software
IEC/IS 62304	Software life cycle processes
ISO/IS 81001-1	Health software and health IT systems safety, effectiveness and security -- Part 1: Foundational principles, concepts, a nd terms

3 Healthcare Domains for Safety - Healthcare Services

- Info Button, Alert, Remind
- CDSS (Clinical Decision Support System)
  - ➢ Medical Logic Module
  - ➢ Deep Learning
- Testing/Certification for Hospital Information System, EMR/EHR)
  - ➢ Healthcare Provider: HIMSS Analytics
  - ➢ Vendors: ONC (Office of National Coordinator)
    - ✓ ISO 10781:2015 HL7 Electronic Health Records-System Functional Model, Release 2
- Value-based Care
  - ➢ Population Health

3 Healthcare Domains for Safety - Healthcare Services(2)

- **ISO/TR 17791:2013, Guidance on standards for enabling safety in health software**
- **ISO/IEC 82304-1:2016,** Health software -- Part 1: General requirements for product safety
- ISO/TS 20405 **Framework of event data and reporting definitions for the safety of health software**

3 Healthcare Domains for Safety - Medical Devices

- ISO/IEC 62304, Software life cycle processes
- **ISO/IEC 81001-1, Health software and health IT systems safety, effectiveness and security -- Part 1: Foundational principles, concepts, and terms**
- **IEC 80001-1:2010**, Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities

3 Healthcare Domains for Safety - Medication

- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 1: Framework for adverse event reporting
- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR
- ISO/DIS 11615 (under development) Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated medicinal product information
- ISO/DTS 20451 (under development) Identification of medicinal products – implementation guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

Safety Reports

- Individual Case Safety Reports (ICSRs) – the building block of safe ty assessment
- Report of an adverse event
  - May be drug-related
  - May not be drug-related
- Collect as much robust data as is possible and perform signal det ection
  - Increased/unexpected incidence of a particular type of event
- Need to identify e.g. the product, substance, dose, route of admin istration etc.
  - But not all information is available
    - "I felt sick after taking Paracetamol tablets"
    - "I felt sick after taking Panadol tablets"
    - "I felt sick after taking Panadol Extra Advance Tablets"
    - "I felt sick after taking Crocin tablets I bought whilst on holiday in India"

Ref.: Dr Andrew Marr, Managing Director, Marr Consultancy Ltd

Increasing quality

- Codification of substance and medicinal product information
- Assignment of an identifier for ‘all things similar’
- IDMP is born
  - Well, something is conceived but not yet ID MP

Ref.: Dr Andrew Marr, Managing Director, Marr Consultancy Ltd

ICH

- Regulators from USA, EU & Japan
- Industry from these regions
- Switzerland & Canada as observers

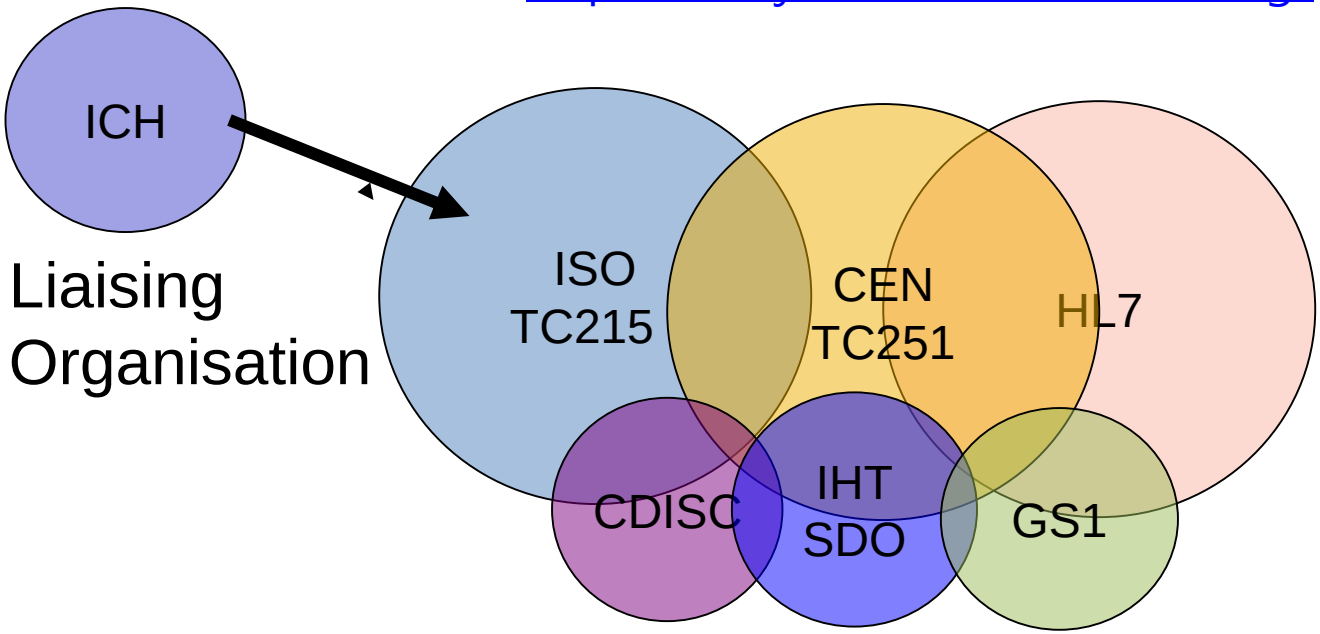
- Development of common guidances
  - 6 party agreement to progress a new piece of work
  - 3 regulators sign-off deliverables
  - Regions implement

- Now expanded to include other regulators

Ref.: Dr Andrew Marr, Managing Director, Marr Consultancy Ltd

Joint Initiative on Health Informatics

http://www.jointinitiativecouncil.org/



ISO = International Organization for Standardization
CEN = European Committee for Standardization
HL7 = Health Level 7
CDISC = Clinical Data Interchange Standards Consortium
IHTSDO = International Health Terminology SDO
GS1 = GS1

Joint recognition of standards

Ref.: Dr Andrew Marr, Managing Director, Marr Consultancy Ltd

Five Standards constituting IDMP

- ISO11615 - Health Informatics – Identification of medicinal products – Data elements and st ructures for the unique identification and exchange of regulated medicinal product informati on
  - New version of standard should be published mid-2017
  - ISO/TS 20443 : Implementation Guide for ISO11615 (to be published mid-2017)
- ISO11616 - Health informatics – Identification of medicinal products - Data elements and st ructures for the unique identification and exchange of regulated pharmaceutical product inf ormation
  - New version of standard should be published mid-2017
  - ISO/TS 20451 : Implementation Guide for ISO11616 (to be published mid-2017)
- ISO11238 - Health Informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substance s
  - New version of standard should be published early-2018
  - ISO/TS 19844 : Implementation Guide for ISO11238 – 2nd edition is current – 3rd edition to be published earl y-2018
- ISO11239 - Health Informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmace utical dose forms, units of presentation, routes of administration and packaging
  - ISO/TS 20450 : Implementation Guide for ISO11239 (published)
- ISO11240 - Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement

Ref.: Dr Andrew Marr, Managing Director, Marr Consultancy Ltd

IDMP

Identification of Medicinal Products

Data elements and structures
for the unique identification and exchange

EN ISO 11238

Substances

Regulated information on substances

Defines Substances by their main general characteristics and specified Substances (which are more granular, specific descriptions of a substance, e.g. including manufacturing information, purity, grade). Substances can have different roles in medicinal products (e.g. active, adjuvant, basis of strength, excipient). The standard also allows for the specification of multiple component substances ("Intermediate Products").

EN ISO 11239

Dose forms, etc.

Regulation on pharmaceutical dose presentation, form and packaging

Each of forms: suspension" term linked to these)

EN ISO 11615

MPID

Regulated medicinal product information

Defines, characterizes and uniquely identifies regulated medicinal products for human use during their entire life cycle (development, authorization, post-marketing and removal or withdrawal from the market) by describing the data elements and their structural relationships that uniquely identify a medicinal product.

EN ISO 11240

Units of measurement

Units of measurement

Specifies rules for the usage of measurement for IDMP; for traceability to metrology establishes reference provides structures between different unit language translations, linking systems, dictionaries and repos

EN ISO 11616

PhPID

Regulated pharmaceutical product information

Pharmaceutical Product uniquely identified represented at the subset

- Substance(s)
- Strength(s) - Strength of measurement and of presentation)
- Reference Strengths
- Administrable Dose Form

EN ISO Implementation guide

EN ISO Implementation guide

EN ISO Implementation guide

EN ISO Implementation guide

EN ISO 11238

EN ISO 11239

EN ISO 11240

ml

Pa

mg/l

[drp]

ppm] %

/min

EN ISO 11616

EN ISO 11615

Product

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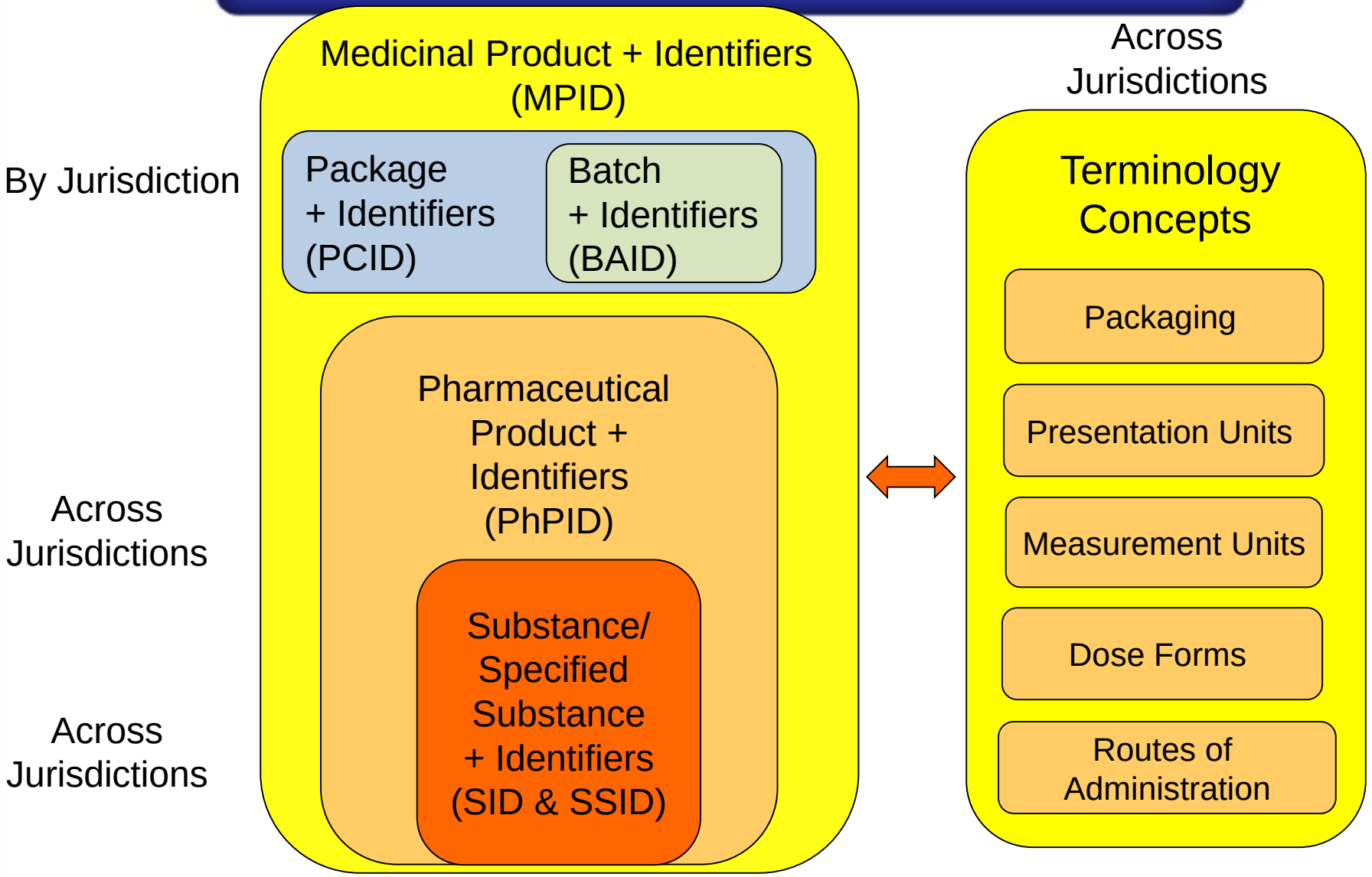
Identifiers and Terminologies



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Thank you

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Agency for Healthcare Research and Quality (AHRQ) Patient Safety

AHRQ Strategic Plan

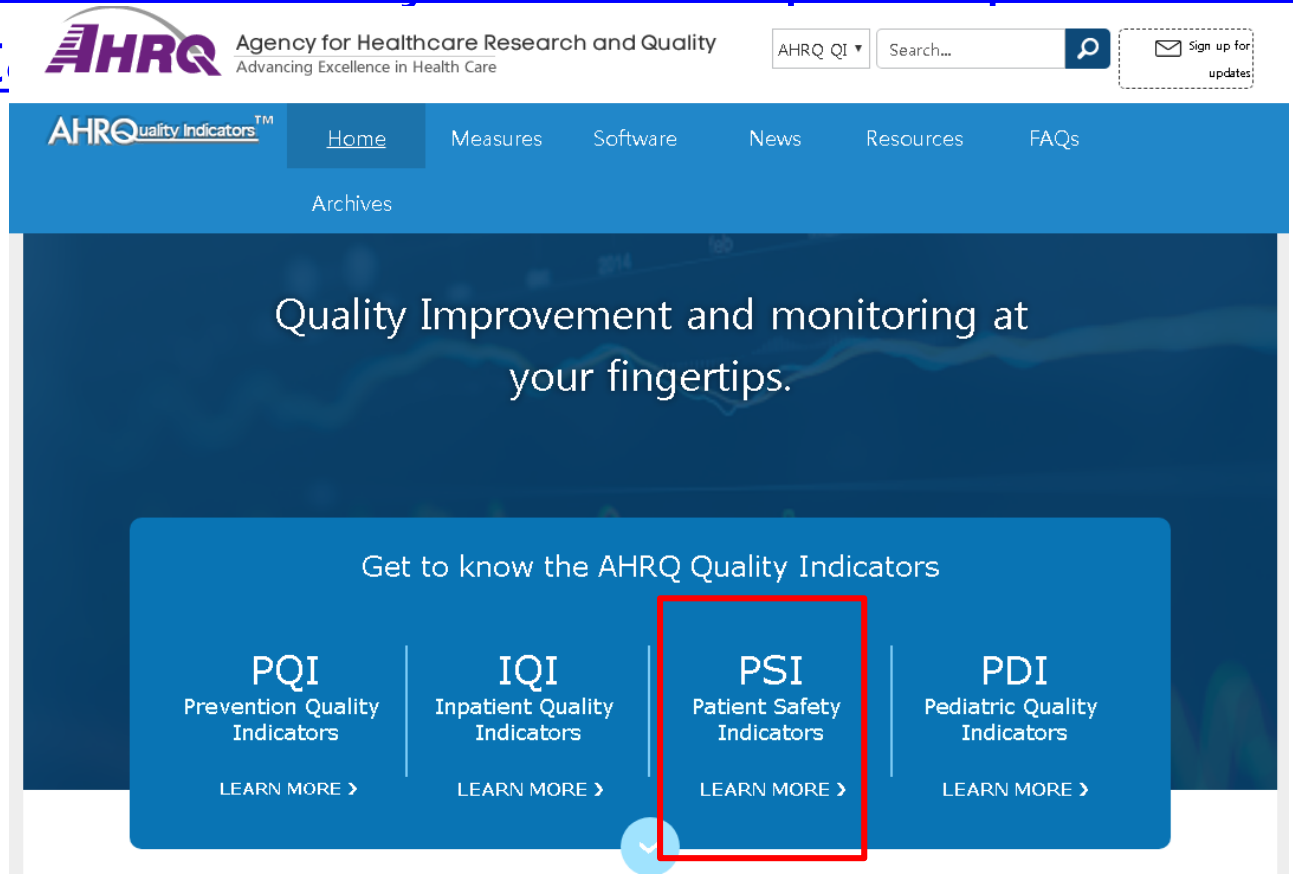
Information on the Agency's strategic plans.

As 1 of 12 agencies within the Department of Health and Human Services (HHS), the Agency for Healthcare Research and Quality (AHRQ) supports health services research initiatives that seek to improve the quality of health care in America. AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within HHS and with other partners to make sure that the evidence is understood and used.

AHRQ works to fulfill its mission by conducting and supporting health services research, both within AHRQ as well as in leading academic institutions, hospitals, physicians' offices, health care systems, and many other settings across the country. The Agency has a broad research portfolio that touches on nearly every aspect of health care.

AHRQ Quality Indicators

- Web site
  - http://www.qualityindicators.ahrq.gov/
  - https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/systems/hospital/qitoolkit/a2-boardst



Patient Safety Indicators

Patient Safety Indicators Overview

What are Patient Safety Indicators?

The Patient Safety Indicators (PSIs) are a set of indicators providing information on potential in hospital complications and adverse events following surgeries, procedures, and childbirth. The PSIs were developed after a comprehensive literature review, analysis of ICD-9-CM codes, review by a clinician panel, implementation of risk adjustment, and empirical analyses.

How are Patient Safety Indicators used?

The PSIs can be used to help hospitals identify potential adverse events that might need further study; provide the opportunity to assess the incidence of adverse events and in hospital complications using administrative data found in the typical discharge record; include indicators for complications occurring in hospital that may represent patient safety events; and, indicators also have area level analogs designed to detect patient safety events on a regional level.

For more information about the Patient Safety Indicators, download the Patient Safety Indicators Brochure.

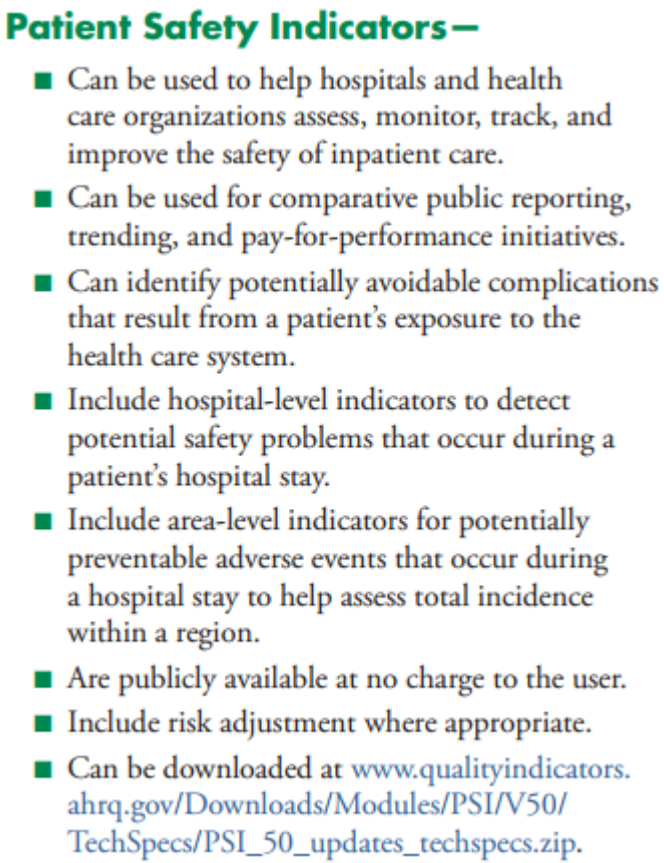
Patient Safety Indicators Resources

Technical Specifications

- Individual Measure Technical Specifications (v7.0 ICD-10-CM/PCS coding only)— Provides a breakdown of the calculations used to formulate each PSI; each technical specification document includes a brief description of the measure, numerator information, denominator information and details on cases that should be excluded from calculations. - *New!*
- Individual Measure Technical Specifications (v6.0 ICD-9-CM only version)— Provides a breakdown of the calculations used to formulate each PSI; each technical specification document includes a brief description of the measure, numerator information, denominator information and details on cases that should be excluded from calculations.
- Parameter Estimates for v6.0 ICD-9-CM* — Provides tables of PSI covariates and coefficients for risk adjustment logistic regression modelsProvides tables of PSI covariates and coefficients for risk adjustment logistic regression models.
- Benchmark Data Tables for v6.0 ICD-9-CM* — Provides tables of nationwide comparative rates for the PSI, including observed rate, numerator, and denominator data for each indicator overall and stratified by sex, age group, and insurance status.
- Log of Coding Updates and Revisions for the v7.0 ICD-10-CM/PCS and v6.0 ICD-9-CM versions.— Provides tables summarizing the revisions made to the PQI software, software documentation and the technical specification documents since the original release of these documents in November 2001. - *Updated September 2017*

PSI brochure

- download link
  - http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/PSI_Brochure.pdf



Patient Safety Indicators—

- Can be used to help hospitals and health care organizations assess, monitor, track, and improve the safety of inpatient care.
- Can be used for comparative public reporting, trending, and pay-for-performance initiatives.
- Can identify potentially avoidable complications that result from a patient's exposure to the health care system.
- Include hospital-level indicators to detect potential safety problems that occur during a patient's hospital stay.
- Include area-level indicators for potentially preventable adverse events that occur during a hospital stay to help assess total incidence within a region.
- Are publicly available at no charge to the user.
- Include risk adjustment where appropriate.
- Can be downloaded at www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/TechSpecs/PSI_50_updates_techspecs.zip.

PSI Technical Specification v7.0

Patient Safety Indicators Technical Specifications Updates - Version v7.0 (ICD 10), September 2017

- Updated Patient Safety Indicators Technical Specifications (PDF Format), Version 7.0 (Zip File)
  - PSI 02 Death Rate in Low-Mortality Diagnosis Related Groups (DRGs)
  - PSI 03 Pressure Ulcer Rate
  - PSI 04 Death Rate among Surgical Inpatients with Serious Treatable Conditions
  - PSI 05 Retained Surgical Item or Unretrieved Device Fragment Count
  - PSI 06 Iatrogenic Pneumothorax Rate
  - PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate
  - PSI 08 In Hospital Fall with Hip Fracture Rate
  - PSI 09 Perioperative Hemorrhage or Hematoma Rate
  - PSI 10 Postoperative Acute Kidney Injury Requiring Dialysis
  - PSI 11 Postoperative Respiratory Failure Rate
  - PSI 12 Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate
  - PSI 13 Postoperative Sepsis Rate
  - PSI 14 Postoperative Wound Dehiscence Rate
  - PSI 15 Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate
  - PSI 16 Transfusion Reaction Count
  - PSI 17 Birth Trauma Rate – Injury to Neonate
  - PSI 18 Obstetric Trauma Rate – Vaginal Delivery With Instrument
  - PSI 19 Obstetric Trauma Rate-Vaginal Delivery Without Instrument
  - PSI 90 Patient Safety for Selected Indicators
    Not currently available for ICD 10.
  - PSI Appendix A – Operating Room Procedure Codes
  - PSI Appendix C – Medical Discharge MS-DRGs
  - PSI Appendix E – Surgical Discharge MS-DRGs
  - PSI Appendix F – Infection Diagnosis Codes
  - PSI Appendix G – Trauma Diagnosis Codes
  - PSI Appendix H – Cancer Diagnosis Codes
  - PSI Appendix I – Immunocompromised State Diagnosis and Procedure Codes
  - PSI Appendix J – Admission Codes for Transfers
  - PSI Appendix K –Self-Inflicted Injury Diagnosis Codes
  - PSI Appendix M – Definitions of Neonate, Newborn, Normal Newborn, and Outborn

PSI 02 - Death Rate in Low-Mortality Diagnosis Related Groups (DRGs)

- Web site
  - http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V70/TechSpecs/PSI_02_Death_Rate_in_Low-Mortality_Diagnosis_Related_Groups_(DRGs).pdf

DESCRIPTION

In-hospital deaths per 1,000 discharges for low mortality (< 0.5%) Diagnosis Related Groups (DRGs) among patients ages 18 years and older or obstetric patients. Excludes cases with trauma, cases with cancer, cases with an immunocompromised state, and transfers to an acute care facility.

PSI 08 - In Hospital Fall with Hip Fracture Rate

- Web site
  - http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V70/TechSpecs/PSI_08_In_H

DESCRIPTION

In hospital fall with hip fracture (secondary diagnosis) per 1,000 discharges for patients ages 18 years and older. Excludes cases that were admitted because of conditions that make them susceptible to falling (seizure disorder, syncope, stroke, occlusion of arteries, coma, cardiac arrest, poisoning, trauma, delirium or other psychoses, anoxic brain injury), have conditions associated with fragile bone (metastatic cancer, lymphoid malignancy, bone malignancy), cases with a principal diagnosis of hip fracture, cases with a secondary diagnosis of hip fracture present on admission, and obstetric cases.

PSI 17 - Birth Trauma Rate

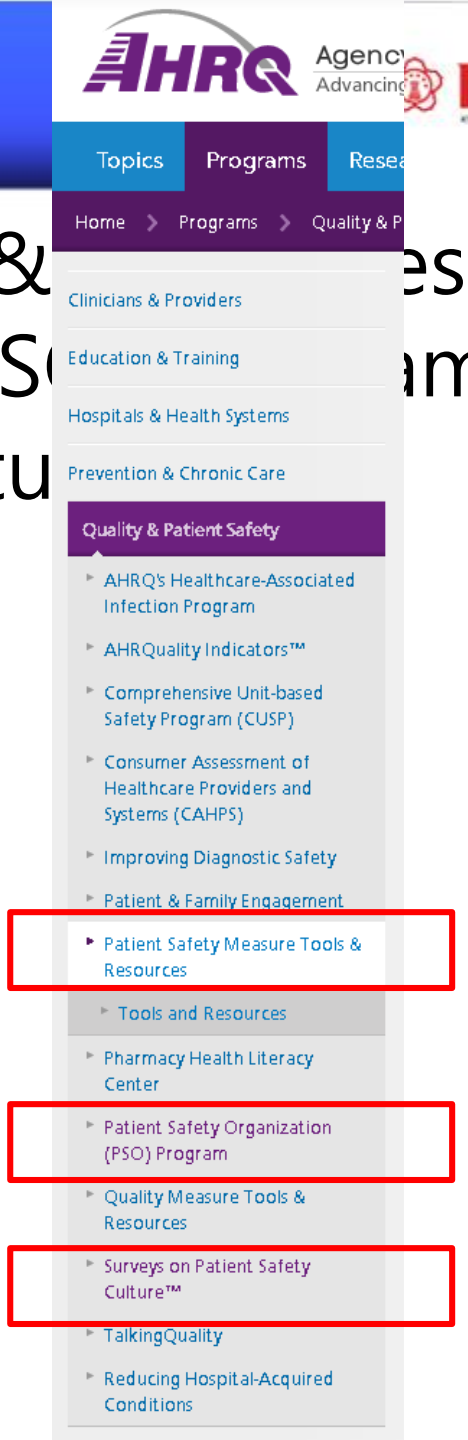
- Web site
  - http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V70/TechSpecs/PSI_17_Birth_Trauma_Rate-Injury_to_Neonate.pdf

DESCRIPTION

Birth trauma injuries per 1,000 newborns. Excludes preterm infants with a birth weight less than 2,000 grams, and cases with osteogenesis imperfecta.

Patient Safety - related topics

- Patient Safety Measure Tools &
- Patient Safety Organization (PS
- Surveys on Patient Safety Cultu

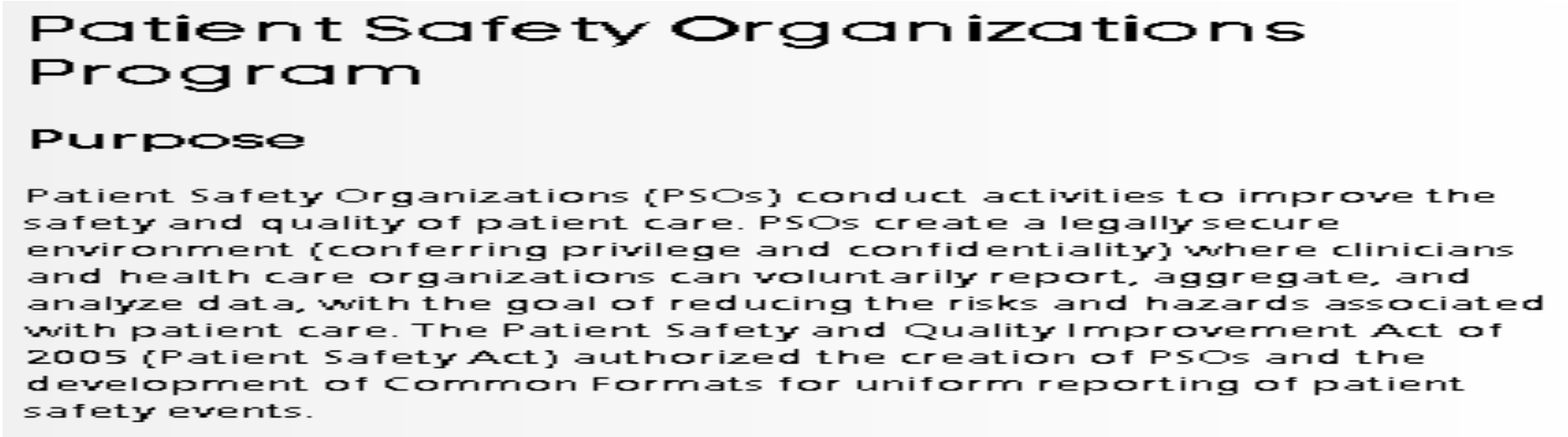


Patient Safety Measure Tools & Resources

- AHRQ Patient Safety Tools and Resources
  - https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/pstools/index.html

Patient Safety Organization (PSO) Program

- Web site
  - https://www.ahrq.gov/cpi/about/otherwebsites/pso.ahrq.gov/index.html
  - https://www.pso.ahrq.gov/sites/default/files/wysiwyg/ChoosingPSO_2016.pdf
- List of PSOs
  - https://www.pso.ahrq.gov/listed



Patient Safety Organizations Program

Purpose

Patient Safety Organizations (PSOs) conduct activities to improve the safety and quality of patient care. PSOs create a legally secure environment (conferring privilege and confidentiality) where clinicians and health care organizations can voluntarily report, aggregate, and analyze data, with the goal of reducing the risks and hazards associated with patient care. The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the creation of PSOs and the development of Common Formats for uniform reporting of patient safety events.

List of PSOs

There are 85 total PSOs listed by AHRQ.

Search for a PSO by Name:

- AABB Center for Patient Safety
- ABG Anesthesia Data Group, LLC
- AHS PSO, LLC
- Academic Medical Center (AMC) PSO
- Alliance for Patient Medication Safety
- American Data Network PSO
- American Medical Foundation Patient Safety Organization
- Anesthesia Quality Institute

Surveys on Patient Safety Culture

- Web site
  - https://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/index.html

Surveys on Patient Safety Culture

The AHRQ Surveys on Patient Safety Culture (SOPS™) program enables health care organizations to assess how their staff perceive various aspects of patient safety culture in the following settings:

- Hospital Survey on Patient Safety Culture.
- Medical Office Survey on Patient Safety Culture.
- Nursing Home Survey on Patient Safety Culture.
- Community Pharmacy Survey on Patient Safety Culture
- Ambulatory Surgery Center Survey on Patient Safety Culture

Health care organizations can use these survey assessment tools to:

- Raise staff awareness about patient safety.
- Diagnose and assess the current status of patient safety culture.
- Identify strengths and areas for patient safety culture improvement.
- Examine trends in patient safety culture change over time.
- Evaluate the cultural impact of patient safety initiatives and interventions.
- Conduct internal and external comparisons.

Hospital Survey on Patient Safety

Instructions

This survey asks for your opinions about patient safety issues, medical error, and event reporting in your hospital and will take about 10 to 15 minutes to complete.

If you do not wish to answer a question, or if a question does not apply to you, you may leave your answer blank.

- *An "**event**" is defined as any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm.*
- *"**Patient safety**" is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.*

SECTION A: Your Work Area/Unit

In this survey, think of your "unit" as the work area, department, or clinical area of the hospital where you spend *most* of your work time or provide *most* of your clinical services.

What is your primary work area or unit in this hospital? Select ONE answer.

- ☐ a. Many different hospital units/No specific unit
- ☐ b. Medicine (non-surgical)
- ☐ c. Surgery
- ☐ d. Obstetrics
- ☐ e. Pediatrics
- ☐ f. Emergency department
- ☐ g. Intensive care unit (any type)
- ☐ h. Psychiatry/mental health
- ☐ i. Rehabilitation
- ☐ j. Pharmacy
- ☐ k. Laboratory
- ☐ l. Radiology
- ☐ m. Anesthesiology
- ☐ n. Other, please specify: _____

Please indicate your agreement or disagreement with the following statements about your work area/unit.

Think about your hospital work area/unit…	**Strongly Disagree** ▼	**Disagree** ▼	**Neither** ▼	**Agree** ▼	**Strongly Agree** ▼
1. People support one another in this unit	☐1	☐2	☐3	☐4	☐5
2. We have enough staff to handle the workload	☐1	☐2	☐3	☐4	☐5
3. When a lot of work needs to be done quickly, we work together as a team to get the work done	☐1	☐2	☐3	☐4	☐5
4. In this unit, people treat each other with respect	☐1	☐2	☐3	☐4	☐5
5. Staff in this unit work longer hours than is best for patient care	☐1	☐2	☐3	☐4	☐5

Nursing Home Survey on Patient Safety

In this survey, **"resident safety"** means preventing resident injuries, incidents, and harm to residents in the nursing home.

This survey asks for your opinions about resident safety issues in your nursing home.
It will take about 15 minutes to complete.

To mark your answer, just put an X or a √ in the box: [x] or [√].

If a question does not apply to your job or you do not know the answer, please mark the box in the last column. If you do not wish to answer a question, you may leave your answer blank.

SECTION A: Working in This Nursing Home

How much do you agree or disagree with the following statements?	Strongly Disagree ▼	Disagree ▼	Neither Agree nor Disagree ▼	Agree ▼	Strongly Agree ▼	Does Not Apply or Don't Know ▼
1. Staff in this nursing home treat each other with respect	☐1	☐2	☐3	☐4	☐5	☐9
2. Staff support one another in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9
3. We have enough staff to handle the workload	☐1	☐2	☐3	☐4	☐5	☐9
4. Staff follow standard procedures to care for residents	☐1	☐2	☐3	☐4	☐5	☐9
5. Staff feel like they are part of a team	☐1	☐2	☐3	☐4	☐5	☐9
6. Staff use shortcuts to get their work done faster	☐1	☐2	☐3	☐4	☐5	☐9
7. Staff get the training they need in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9
8. Staff have to hurry because they have too much work to do	☐1	☐2	☐3	☐4	☐5	☐9
9. When someone gets really busy in this nursing home, other staff help out	☐1	☐2	☐3	☐4	☐5	☐9
10. Staff are blamed when a resident is harmed	☐1	☐2	☐3	☐4	☐5	☐9