Creating a Registry - Data Elements

Dr. Ali Khorshidi

Creating a Registry

- Planning
- Design
- Data Elements
- Data Sources
- Software
- Ethical and Legal Issues

Data Elements for Registries

Selection of data elements requires balancing competing considerations;

***importance** of data elements to integrity of registry,*

*their **reliability**,*

*their **necessity** for analysis of primary outcomes,*

*their **contribution** to the overall response burden,*

*the **incremental** costs associated with their collection*

Data Elements for Registries

Identifying Domains;

Registries generally include;

personal, exposure, and ***outcomes information***

Measuring ***potential confounding*** *factors should be taken into account*

Data Elements for Registries

Selecting data elements;

Each data element should *support purpose* of registry
Answer an explicit *scientific question*

The *most effective* way to select data elements;
start with the study *purpose* and *objective*,

decide what types of groupings, measurements, or calculations will be needed to *analyze objective*

Data Elements for Registries

Selecting data elements;

Use of established data standards

***Improve efficiency** in establishing registries;*

***promote more effective** sharing, combining, or linking of data sets from different sources*

*important to allow **comparisons** between studies*

Data Elements needed for specific types of Registries;

Registries ***examining safety*** for drugs, vaccines, procedures, devices;

History of exposure & Potential confounding factors;

Data on use (start & stop)

comorbidities, socioeconomic status, ethnicity, environmental and social factors

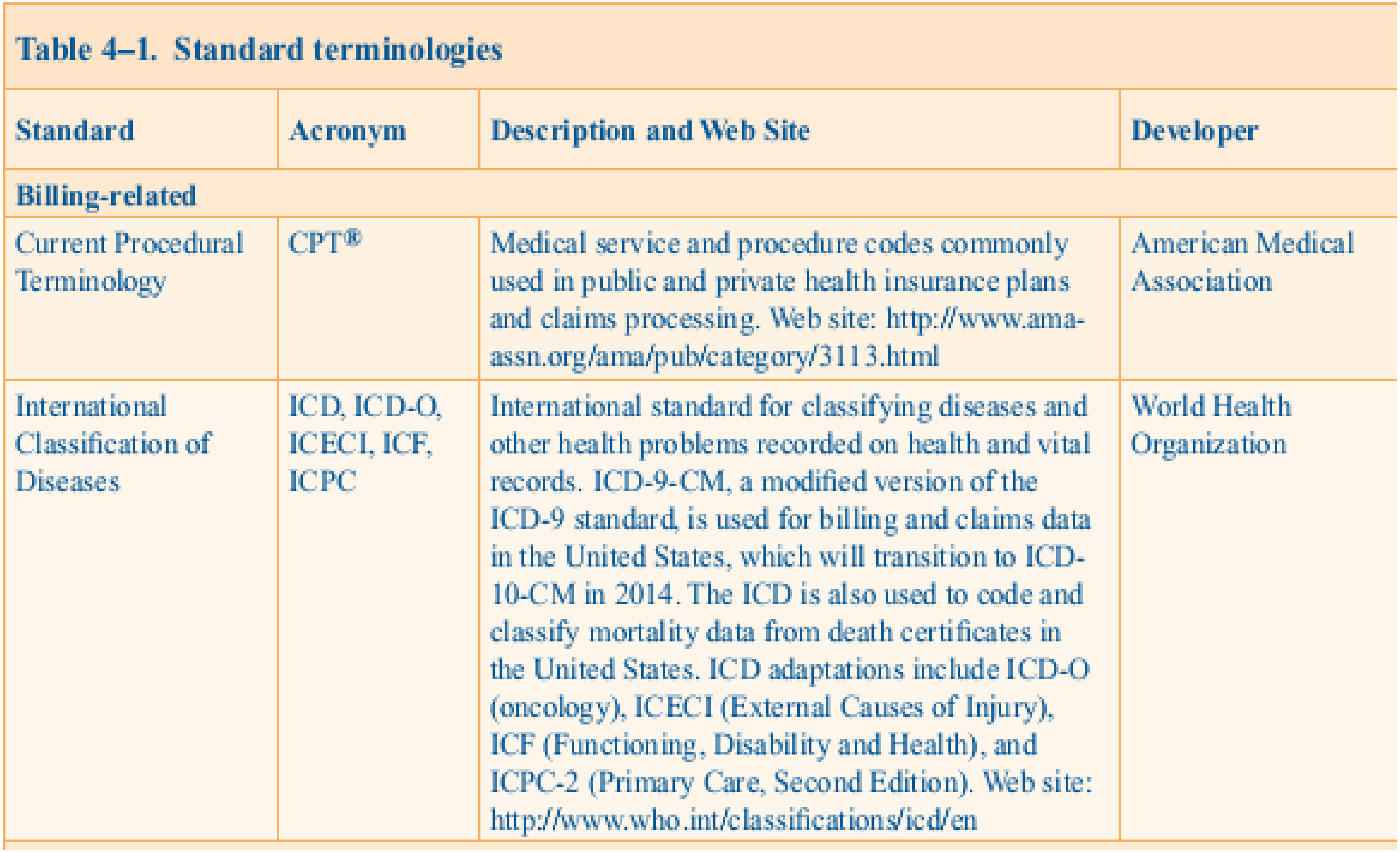

Table 4–1. Standard terminologies

Standard	Acronym	Description and Web Site	Developer
Billing-related			
Current Procedural Terminology	CPT®	Medical service and procedure codes commonly used in public and private health insurance plans and claims processing. Web site: http://www.ama-assn.org/ama/pub/category/3113.html	American Medical Association
International Classification of Diseases	ICD, ICD-O, ICECI, ICF, ICPC	International standard for classifying diseases and other health problems recorded on health and vital records. ICD-9-CM, a modified version of the ICD-9 standard, is used for billing and claims data in the United States, which will transition to ICD-10-CM in 2014. The ICD is also used to code and classify mortality data from death certificates in the United States. ICD adaptations include ICD-O (oncology), ICECI (External Causes of Injury), ICF (Functioning, Disability and Health), and ICPC-2 (Primary Care, Second Edition). Web site: http://www.who.int/classifications/icd/en	World Health Organization

Clinical			
Systemized Nomenclature of Medicine	SNOMED CT	Clinical health care terminology that maps clinical concepts with standard descriptive terms. Formerly SNOMED RT and SNOP. Web site: http://www.ihtsdo.org/snomed-ct	International Health Terminology Standards Development Organization
Unified Medical Language System	UMLS	Database of 100 medical terminologies with concept mapping tools.[19] Web site: http://www.nlm.nih.gov/research/umls/	National Library of Medicine
Classification of Interventions and Procedures	OPCS-4	Code for operations, surgical procedures, and interventions. Mandatory for use in National Health Service (England). Web site: http://www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/opcs_classification_of_interventions_and_procedures.asp	Office of Population, Censuses, and Surveys
Diagnostic and Statistical Manual	DSM	The standard classification of mental disorders used in the United States by a wide range of health and mental health professionals. The version currently in use is the DSM-IV. Web site: http://www.psych.org/MainMenu/Research/DSMIV.aspx	American Psychiatric Association
Drugs			
Medical Dictionary for Regulatory Activities	MedDRA	Terminology covering all phases of drug development, excluding animal toxicology. Also covers health effects and malfunctions of devices. Replaced COSTART (Coding Symbols for a Thesaurus of Adverse Reaction Terms). Web site: http://www.meddramsso.com	International Conference on Harmonisation (ICH)

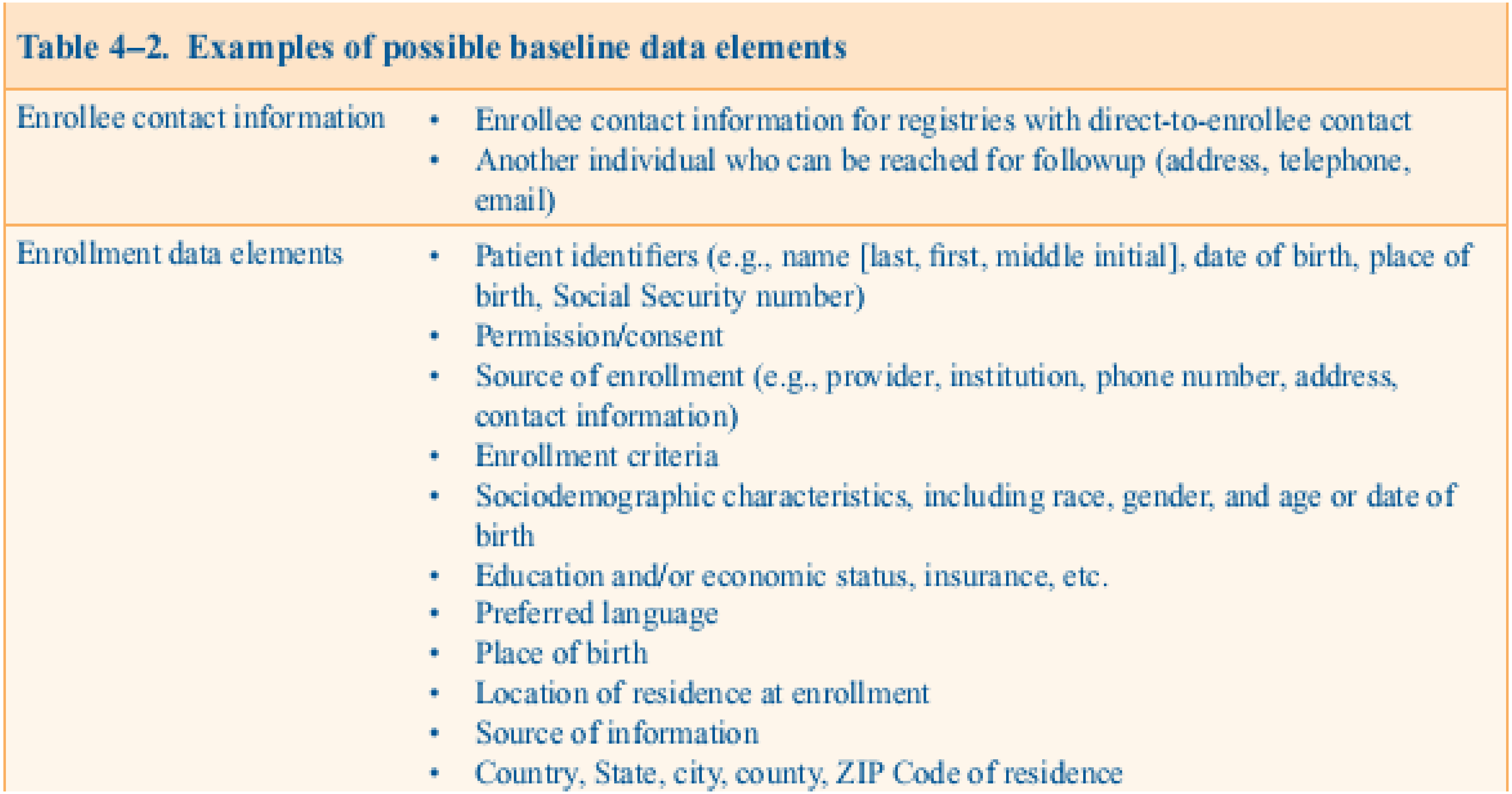

Table 4–2. Examples of possible baseline data elements

Enrollee contact information	• Enrollee contact information for registries with direct-to-enrollee contact • Another individual who can be reached for followup (address, telephone, email)
Enrollment data elements	• Patient identifiers (e.g., name [last, first, middle initial], date of birth, place of birth, Social Security number) • Permission/consent • Source of enrollment (e.g., provider, institution, phone number, address, contact information) • Enrollment criteria • Sociodemographic characteristics, including race, gender, and age or date of birth • Education and/or economic status, insurance, etc. • Preferred language • Place of birth • Location of residence at enrollment • Source of information • Country, State, city, county, ZIP Code of residence

Table 4–3. Examples of possible additional enrollee, provider, and environmental data elements

Pre-Enrollment History	
Medical history	• Morbidities/conditions • Onset/duration • Severity • Treatment history • Medications • Adherence • Health care resource utilization • Diagnostic tests and results • Procedures and outcomes • Emergency room visits, hospitalizations (including length of stay), long-term care, or stays in skilled nursing facilities • Genetic information • Comorbidities • Development (pediatric/adolescent)
Environmental exposures	• Places of residence

Patient characteristics	• Functional status (including ability to perform tasks related to daily living), quality of life, symptoms • Health behaviors (alcohol, tobacco use, physical activity, diet) • Social history • Marital status • Family history • Work history • Employment, industry, job category • Social support networks • Economic status, income, living situation • Sexual history • Foreign travel, citizenship • Legal characteristics (e.g., incarceration, legal status) • Reproductive history • Health literacy • Individual understanding of medical conditions and the risks and benefits of interventions • Social environment (e.g., community services) • Enrollment in clinical trials (if patients enrolled in clinical trials are eligible for the registry)
Provider/system characteristics	• Geographical coverage • Access barriers • Quality improvement programs • Disease management, case management • Compliance programs • Information technology use (e.g., computerized physician order entry, e-prescribing, electronic medical records)

Data Elements for Registries

Data Definitions

Explicit data definitions is essential to process of selecting data elements

Important to ensure ***internal validity***

History of exposure & Potential confounding factors;

Should include the ranges and acceptable values for each individual data element

Determine which data elements are ***required*** *or may be* ***optional***

Data Elements for Registries

Patient-Reported Outcomes

It is important to use patient-reported outcomes;

valid, reliable, responsive, interpretable, and translatable

Reflect patients' perceptions of their status

Data Elements for Registries

Pilot Testing

To determine time needed to complete the form and the resulting subject / abstractor burden

*Piloting may also **uncover problems** in registry logistics*

*Evaluation of **accuracy** and **completeness** of registry questions*

***Comprehensiveness** of both **instructional** materials and **training** in addressing these potential issues*

با تشکر و سپاس از توجه شما