بسم الله الرحمن الرحيم

Workshop for

Disease Registries

Mashhad University of Medical Sciences

(data collection)

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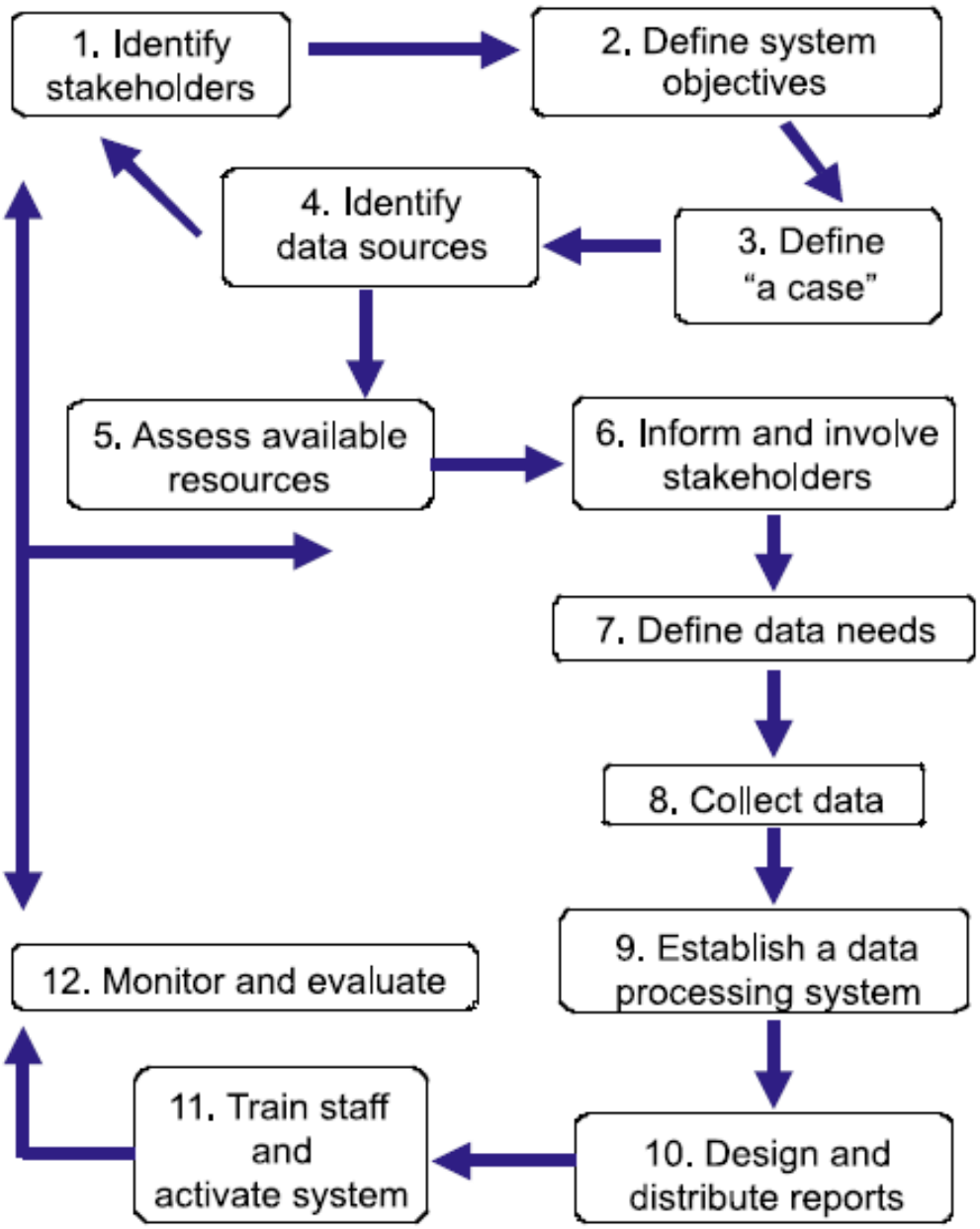
Design a system



Define "a case"

Define "a case" depends on the objectives of system.

* Incident case? Prevalent case? Each visit? Each person?
* to monitor the *burden of care* on a given service, a "case" will be any visit (first or repeat) to that service
* to monitor the *incidence*, a "case" will be one person for first time

Case finding criteria

* Covered health problem/ events?
* Referenced date ?
* Covered entities (settings; area)?
* Covered patients ? (in- or out-patient)

Define data needs (Data sets)

Data sets: the building blocks of a registry system

* minimum data sets (system purpose)
* Extra information

* Core data are the data a system collects on all types of events (MDS and optional)

* Supplementary data is additional data that a system may collect on specific types of event (traffic collisions; MDS, optional)

Data sources?

* Primary or secondary?
* Primary data sources incorporate data collected for direct purposes of the registry (primarily for the registry).
* Data of interest are not available elsewhere or, if available, are unlikely to be of sufficient accuracy and reliability
* Using common procedures and the same format across all registry sites

* Secondary data sources are comprised of data originally collected for purposes other than the registry under consideration

Identify data sources

Potential data sources

* Household (community) surveys
* Health records
* Family doctors' records
* Emergency Room records
* Ward admission records
* ICU admission records
* Death certificates

Potential data sources

* Other data bases /registries
* autopsy/pathology reports
* police reports
* insurance company records
* workplace records
* Patient
* Clinicians
* EHR/HIS
* etc.

Data collection

* Based on existent systems
* Revised forms
* Create forms

Data collection

* a similar range of data collection procedures may be acceptable, but only certain methodologies may be suitable for particular purposes of a registry.

* Certain end users of the data may require that data collection or validation be performed in accordance with their own guidelines or standards (FDA, MOH)

Data collection

* Type of data collected
* The types of authorization obtained
* Applicable governmental regulations
* Method of involvement
* Active vs. Passive?

* Define in advance

Case Report Forms

* Specific and consistent data definitions for collecting data elements in a uniform manner
* Patient-level variables
* CRF is a formatted listing of data elements
* paper or electronic formats

Paper CRFs

* Forms should be reviewed for completeness, accuracy, and validity
* Assessment of error rate (re-entering a sample of the data is sufficient for reporting purposes)
* Data validation checks on direct data entry

Electronic CRFs

* Allows clinician-reported data to be entered directly into the electronic system
* Web-based data entry forms
* Data validation checks or edits at the time of data entry

Sample CRF

Demographics/Patient Characteristics		
Center		⌊_⌊_⌊_
Patient ID		⌊_⌊_⌊_
Date of birth	ddmmyy	⌊_⌊_⌊_⌊_⌊_⌊_
Gender	0=male 1=female	⌊_
Hematologic response		
Date of hematologic response	ddmmyy	⌊_⌊_⌊_⌊_⌊_⌊_
WBC	x 10^9 /l	⌊_⌊_⌊_⌋.⌊_
Platelets	x 10^9 /l	⌊_⌊_⌊_⌊_⌊_
Immature cells in PB (blasts, promyelocytes, myelocytes, metamyelocytes)	0=no 1=yes	⌊_
Clinical symptoms and signs of disease including palpable splenomegaly	0=no 1=yes	⌊_
Hematologic response	1=complete 2=partial 5=no response 6=unknown	⌊_
Cytogenetic response		
Date of cytogenetic response	ddmmyy	⌊_⌊_⌊_⌊_⌊_⌊_
Number of evaluated metaphases		⌊_⌊_⌊_
Number of Ph-positive metaphases		⌊_⌊_⌊_
% of Ph-positive metaphases	%	⌊_⌊_⌊_
Cytogenetic response	1=complete 2=partial 3=minor 4=minimal 5=no response 6=unknown	⌊_
Molecular biology		
Date of molecular analysis	ddmmyy	⌊_⌊_⌊_⌊_⌊_⌊_
Source of material	1=PB 2=BM	⌊_
Volume	ml	⌊_⌊_⌊_
Ratio BCR-ABL/ABL	%	⌊_⌊_⌊_⌋.⌊_⌊_⌊_⌊_
Other control gene	Please specify	_____
Ratio BCR-ABL/other gene	%	⌊_⌊_⌊_⌋.⌊_⌊_⌊_⌊_
Nested PCR	1=positive 2=negative 4=not done	⌊_

Clinician-Reported Data

Benefits:

- Directly by the clinician
- From the medical record
- More specific data

* Clinicians are highly sensitive to burden.
* Who can collect? Abstractors?
* Data that must be collected directly by the clinician should be defined.

Patient-reported data

* Patient outcomes.
* Obtaining information on treatments not prescribed by clinicians (e.g., OTC drugs, herbal medications).
* Obtaining intended compliance information.

- Literacy, language, or other barriers that may lead to underenrollment of some subgroups.
- development of validated data collection instruments
- Loss to follow-up or refusal to participate
- Limited confidence in reporting clinical information and utilization information.

Medical records
Data Abstraction (limitation)

* Data collector other than the clinician extracts clinician-reported data
* Potential for comprehensive view of patient medical and clinical history
* Degrees of judgment and interpretation and even errors.
* Clarity of description and standardization
* Knowledgeable registry personnel as abstractors or a guide is needed.

Medical records
Data Abstraction (limitation)

* The underlying information is not collected in a systematic way.
* It is difficult to interpret missing data.
*
* Data abstraction is resource intensive.
* Complete medical and clinical history may not be available (e.g., new patient to clinic).

Chart abstraction guidelines

* Instructions to search for particular types of data
* Coding instructions (ICD, etc,)
* Data sources/forms
* Data definitions and their interpretation

* Training on the registry protocol and procedures, conditions

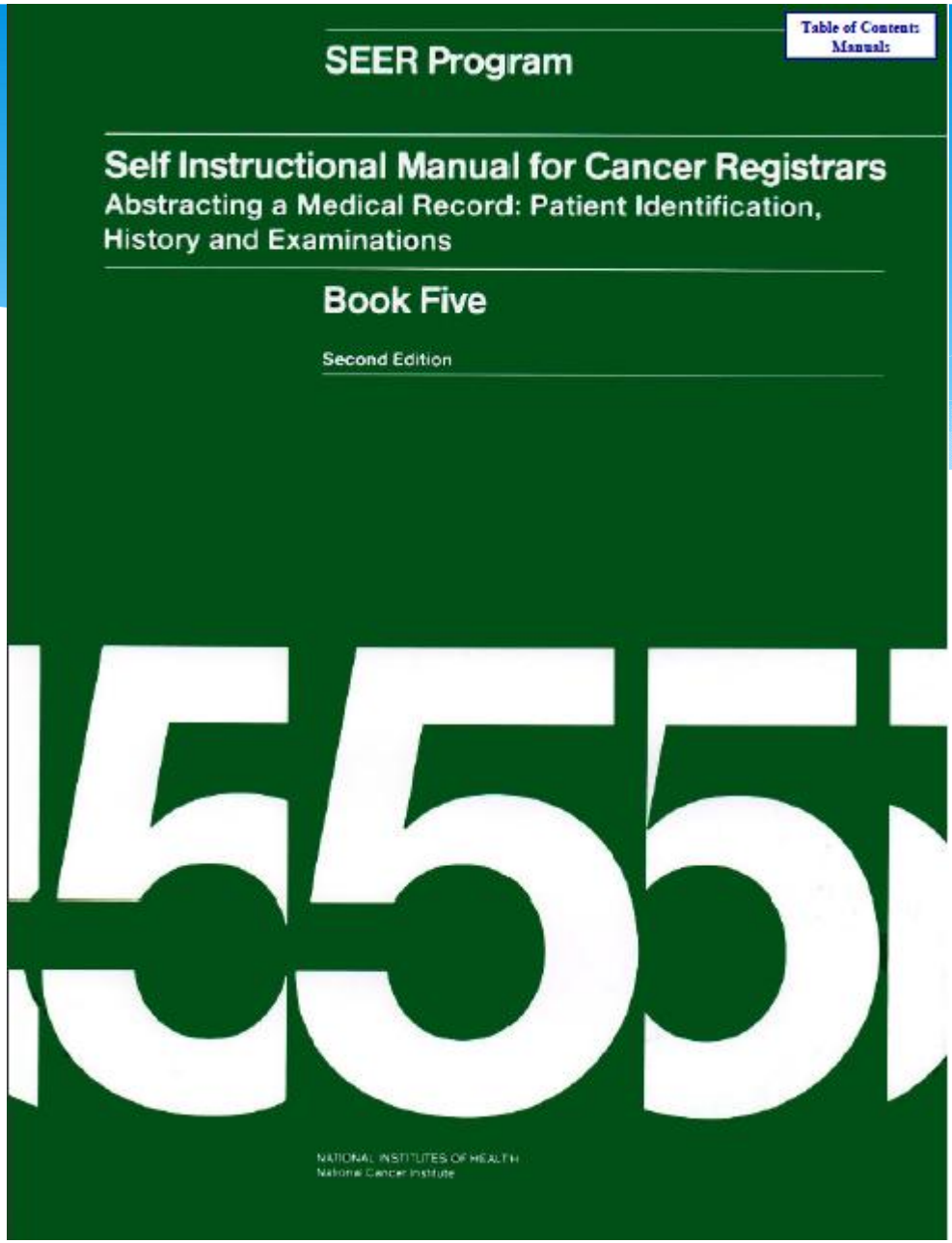


Table of Content: Manuals
SEER Program
Self Instructional Manual for Cancer Registrars
Abstracting a Medical Record: Patient Identification, History and Examinations
Book Five
Second Edition
NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Considerations for chart abstractions

* Standardized materials (e.g., definitions, instructions).
* Standardized training.
* Testing with standardized charts.
* Reporting of inter-rater reliability

Electronic Medical Record

* A source of clinical data for registries
* EMR may include patient demographics, diagnoses, procedures, progress notes, orders, flow sheets, medications, and allergies
* EMRs already serve as data sources in some registries

EMR benefits

* information on routine medical care and practice
* more clinical context than coded claims.
* Potential for comprehensive view of patient history.
* Efficient access to medical and clinical data.
* Use of data transfer and coding standards will increase the quality of data abstracted.

EMR challenges

* Underlying information from clinicians may not be collected.
* Consistency of data quality and breadth of data collected varies across sites.
* Difficult to handle information uploaded as text files into the EHRs (e.g., scanned clinician reports)
* Historical data capture may require manual chart abstraction (prior to EHR system)
* Complete medical and clinical history may not be available (e.g., new patient to clinic)
* EHR systems vary widely. If data come from multiple systems, the registry should plan to work with each system individually to understand the requirements of the transfer.

Existing registries

* To answer additional questions not considered in the original registry
* Specific data not generally collected in routine medical practice.
* Can provide historical comparison data.
* Reduces data collection burden for sites, thereby encouraging participation.
* understand the existing registry protocol to evaluate data collected for element definitions, timing, and format
* Other registry may change data elements
* Some sites may not participate in both.
* Must rely on the data quality of the other registry.

Considerations

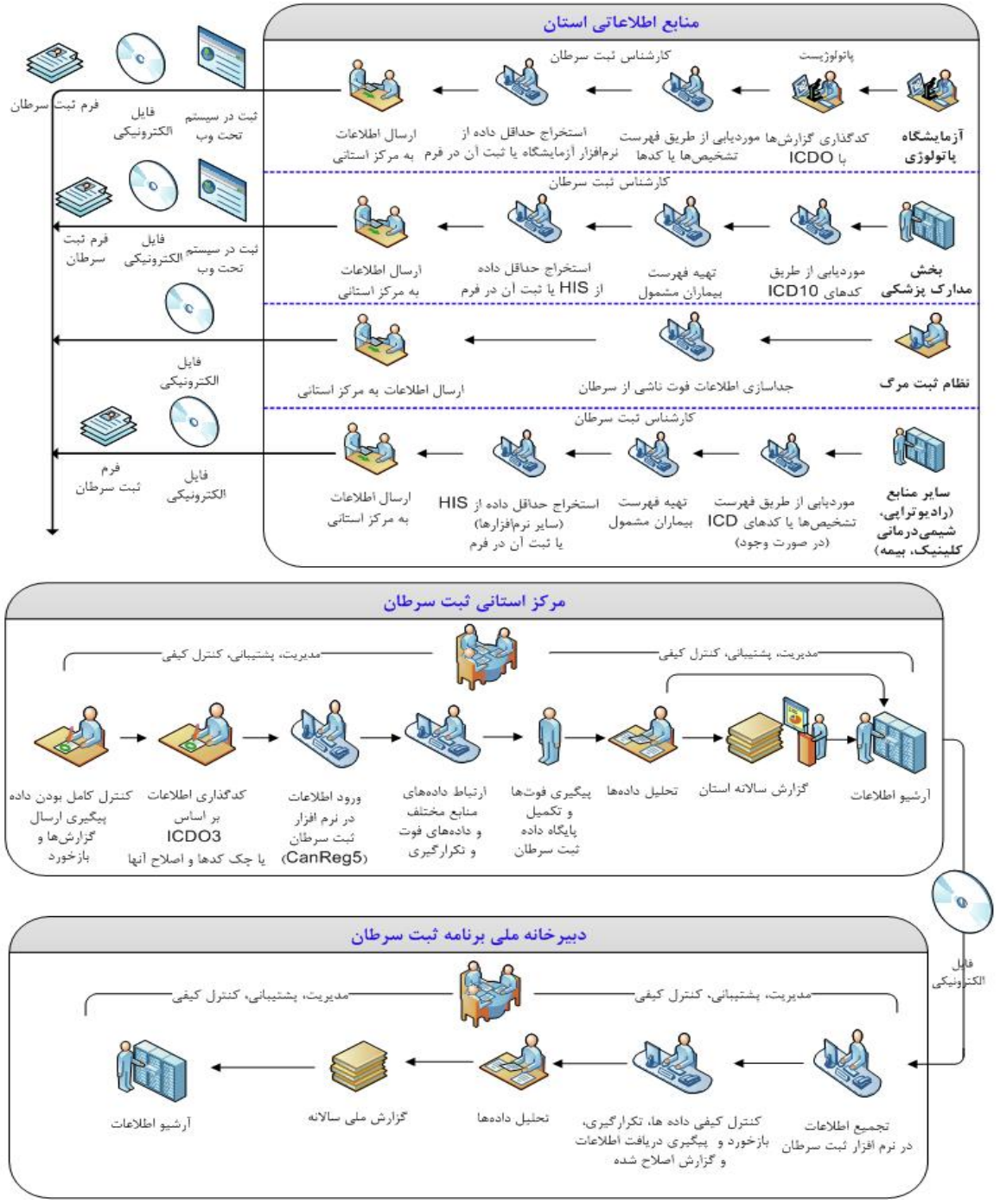
General Considerations:

* flexibility (the number of options available)
* data validity (whether all methods are equally able to produce clean data)
* Cost
* number of data elements
* number of sites
* Location
* registry duration
* followup frequency
* available resources

Procedures, Personnel, documentation

* **Workflow model** that can be integrated into the day to- day clinical practice of active physicians, nurses, pharmacists, and patients with **minimal disruption**.

منظور از نرم‌افزار، نرم‌افزاری است که در حال حاضر در حال استفاده است و حداقل داده‌های ثبت سرطان در قال فایل اکسل از آن قابل استخراج باشد



Documentation of Procedures

The data collection procedures for each registry should be clearly defined (Manual):

* protocols, policies, and procedures;
* the data collection instrument;
* a listing of all the data elements and their full definitions.
* If the registry has optional fields (i.e., fields that do not have to be completed on every patient), these should be clearly specified
* inclusion and exclusion criteria
* The methods of completing the report form and submitting it

SERIES III
PREPARING A POLICY AND PROCEDURE MANUAL

Edited by:
Registry Operations Committee
January 2001

Series IV: Cancer Case Ascertainment

Table of Contents

Personnel

* All personnel involved in data collection should be identified, and their job descriptions and respective roles in data collection should be described.

* The necessary documentation or qualification required for any role should be specified in the registry documentation.

Data Entry Systems

how data will be entered into the registry database

* paper CRFs → personnel, validation, feedbacks
* Direct data entry → online validation, offline checking
* Facsimile or scanning systems
* electronic CRFs
* EMR → standard coding, terms, import and export, coding errors (sensivity and specifity)

consideration for participation

* You need complete data (coverage)
* Participation is important
* Well-planned strategies for enrollment and retention are critical

* Registries that are not voluntary have different drivers for participation.

* Burden of participation should be kept as low as possible (focus on the main purpose)

* Rewards, particularly nonmonetary rewards, should be maximized.

* Building participation incentives into a registry should also be included in the planning phase.

* participation in a community of researchers,
* access to useful data or quality improvement benefits
* to continuing medical education,
* Public recognition or certification
* payments (payments should not exceed fair market)
* access to patients

* Research interest of a particular investigator or champion
* Ability of the hospital to achieve other goals through the registry (such as requirements for reimbursement, certification, or recognition, accreditation)
* The general interest of the particular institution in the disease area (e.g. specialty hospitals).

* Use stakeholder representatives to identify potentially interested hospitals/ physicians.
* Enroll hospitals through physicians who work there and are interested in the registry.
* Ask physician members of an advisory board (if applicable) to network with their colleagues in other hospitals.
* Reach out to physicians or hospital administrators through relevant professional societies or hospital associations.

* Ask leaders in the field to suggest interested colleagues.
* Partner with local and national medical societies or large physician hospital organizations.
* Use stakeholder representatives to identify interested physicians.
* Recruit and raise awareness at conferences.
* Advertise using email and the Web.

Thank you for your attention

Any comments and questions?