جمهوری اسلامی ایران
وزارت بهداشت، درمان و آموزش پزشکی
معاونت تحقیقات و فناوری

اولین کنگره بین المللی | مشهد مقدس
ثبت بیماری ها و پیامدهای سلامت | بهمن ماه ۱۳۹۵

Quality Control in Registry Program

February, 2017_Mashhad

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	Quality Assurance	Quality Control
Definition	QA is a set of activities for ensuring quality in the processes by which products are developed.	QC is a set of activities for ensuring quality in products. The activities focus on identifying defects in the actual products produced.
Focus on	QA aims to prevent defects with a focus on the process used to make the product. It is a proactive quality process.	QC aims to identify (and correct) defects in the finished product. Quality control, therefore, is a reactive process.
Goal	The goal of QA is to improve development and test processes so that defects do not arise when the product is being developed.	The goal of QC is to identify defects after a product is developed and before it's released.
How	Establish a good quality management system and the assessment of its adequacy. Periodic conformance audits of the operations of the system.	Finding & eliminating sources of quality problems through tools & equipment so that customer's requirements are continually met.
What	Prevention of quality problems through planned and systematic activities including documentation.	The activities or techniques used to achieve and maintain the product quality, process and service.
Responsibility	Everyone on the team involved in developing the product is responsible for quality assurance.	Quality control is usually the responsibility of a specific team that tests the product for defects.
Example	Verification is an example of QA	Validation/Software Testing is an example of QC
Statistical Techniques	Statistical Tools & Techniques can be applied in both QA & QC. When they are applied to processes (process inputs & operational parameters), they are called Statistical Process Control (SPC); & it becomes the part of QA.	When statistical tools & techniques are applied to finished products (process outputs), they are called as Statistical Quality Control (SQC) & comes under QC.

http://www.diffen.com/difference/Quality_Assurance_vs_Quality_Control

QA: Why

- Registers should be set up only to study important health problems, and the systems used should achieve their purpose efficiently.
- Registers are expensive to set up and maintain in terms of money and time. they also have substantial opportunity costs for professionals and for patients.

- The value of a register must be examined at intervals to ensure that the objectives still hold and are being met. If they are not, the objectives should be revised or the register closed.
- At a strategic level, it is important to allocate resources for registers in a balanced way. Funded registers should each be fulfilling a useful public health function, and duplication of effort should be avoided by co-ordinating the work of individual registries.
- The usefulness of registers is dependent on the quality of their design and of the data that they contain. Any public health system that relies on disease registers must ensure that the individual component registers are of adequate quality.

QA: What

1. Input
    - Objective
    - Organisatoinal chart
    - Staff
    - Guideline
    - Infrastrucure
    - Education
    - Funding
2. Process
    - Procedures
    - Feasibility,
    - Simplicity
    - Efficienccy
    - Cost-effectiveness
3. Output
    - Short term: results, data qulity, reports, publications, education meterials, etc.
    - Intemediate: maintenance,….
    - Long term

QA: Who

- Internal QC
    - Periodic QC
    - IT base QC
  - External Evaluation
    - Funder
    - Scientific groups
    - Patient advocates
    - Regulatory
    - Etc.

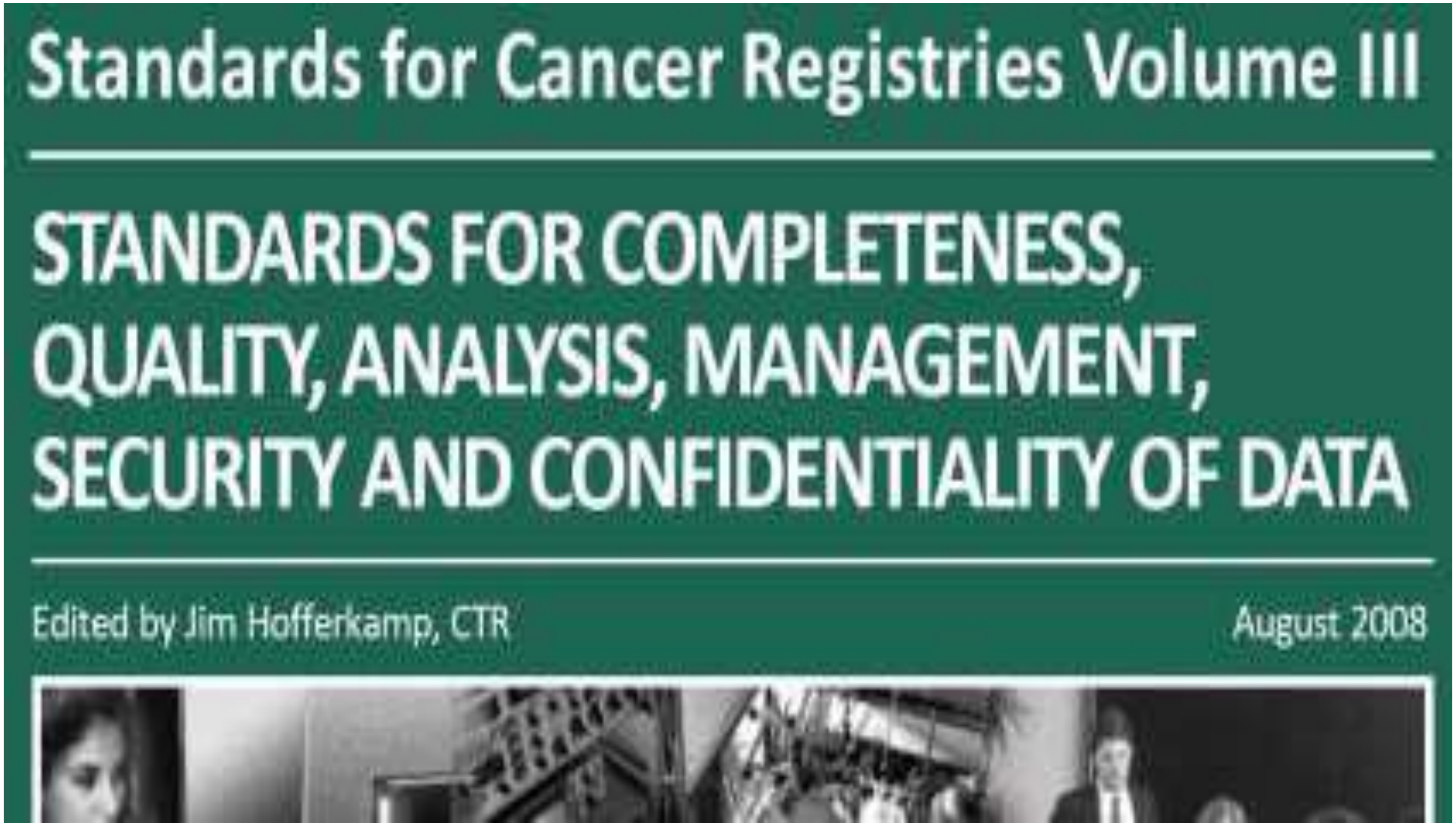
Be prepared for All types of QC in your registry

QA: When

- Before starting your registry (training, feasibility assessment)
- Regular evaluation
- Periodic evaluation
- After publication of the results (QC).

QA: How

- Planing and prevention measures
- Determine Quality indicators
  - Clear
  - Valid
  - Reliable
  - Feasible
- Methods
  - Monitoring
  - Statistical Methods
- Documentation (methods, results and interpretation)
- Planning and Intervention



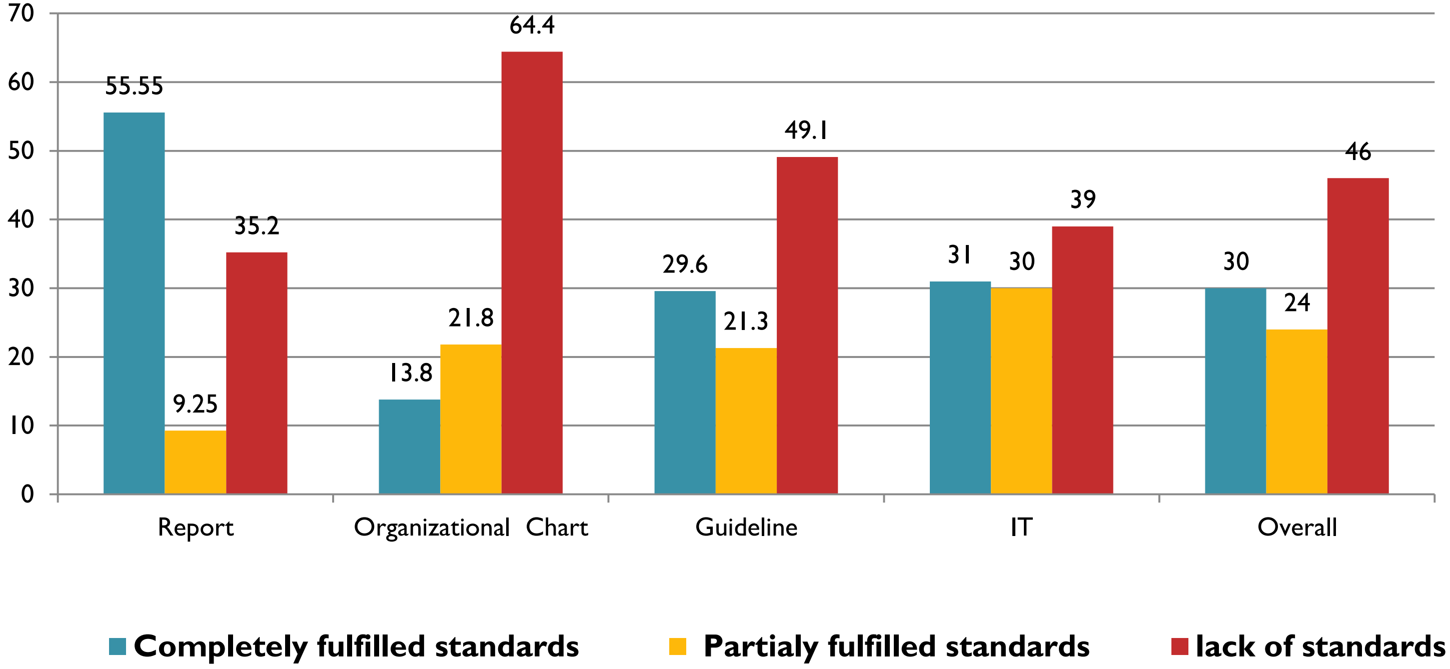
Standards for Cancer Registries Volume III

STANDARDS FOR COMPLETENESS, QUALITY, ANALYSIS, MANAGEMENT, SECURITY AND CONFIDENTIALITY OF DATA

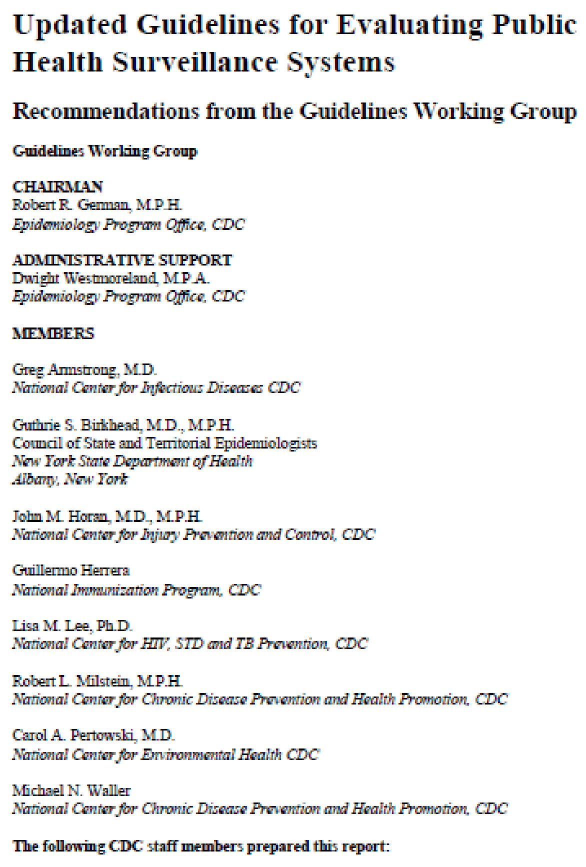
Edited by Jim Hofferkamp, CTR

August 2008

ارزيابي دستورالعمل، ساختار سازماني، گزرشها و فن آوري اطلاعات ثبت سرطان جمعيتي ايران بر اساس مستندات سال 1388



Evaluation of the Registry as a Public Health Surveillance System



Updated Guidelines for Evaluating Public Health Surveillance Systems

Recommendations from the Guidelines Working Group

Guidelines Working Group

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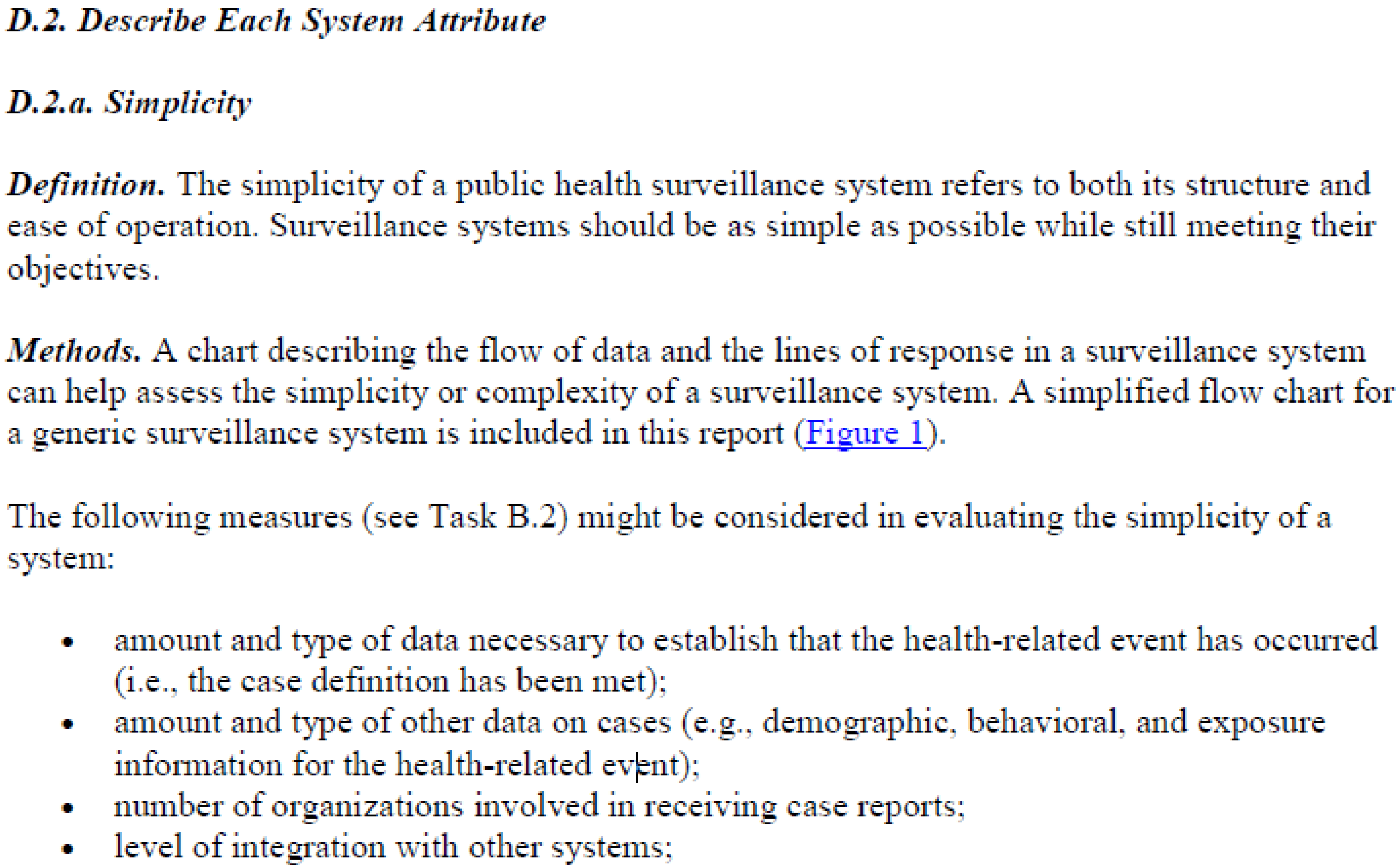
The following CDC staff members prepared this report:

System attributes:

- Simplicity
- Flexibility
- Data quality
- Acceptability
- Sensitivity
- Predictive value positive
- Representativeness
- Timeliness
- Stability



D.2. Describe Each System Attribute

D.2.a. Simplicity

Definition. The simplicity of a public health surveillance system refers to both its structure and ease of operation. Surveillance systems should be as simple as possible while still meeting their objectives.

Methods. A chart describing the flow of data and the lines of response in a surveillance system can help assess the simplicity or complexity of a surveillance system. A simplified flow chart for a generic surveillance system is included in this report (Figure 1).

The following measures (see Task B.2) might be considered in evaluating the simplicity of a system:

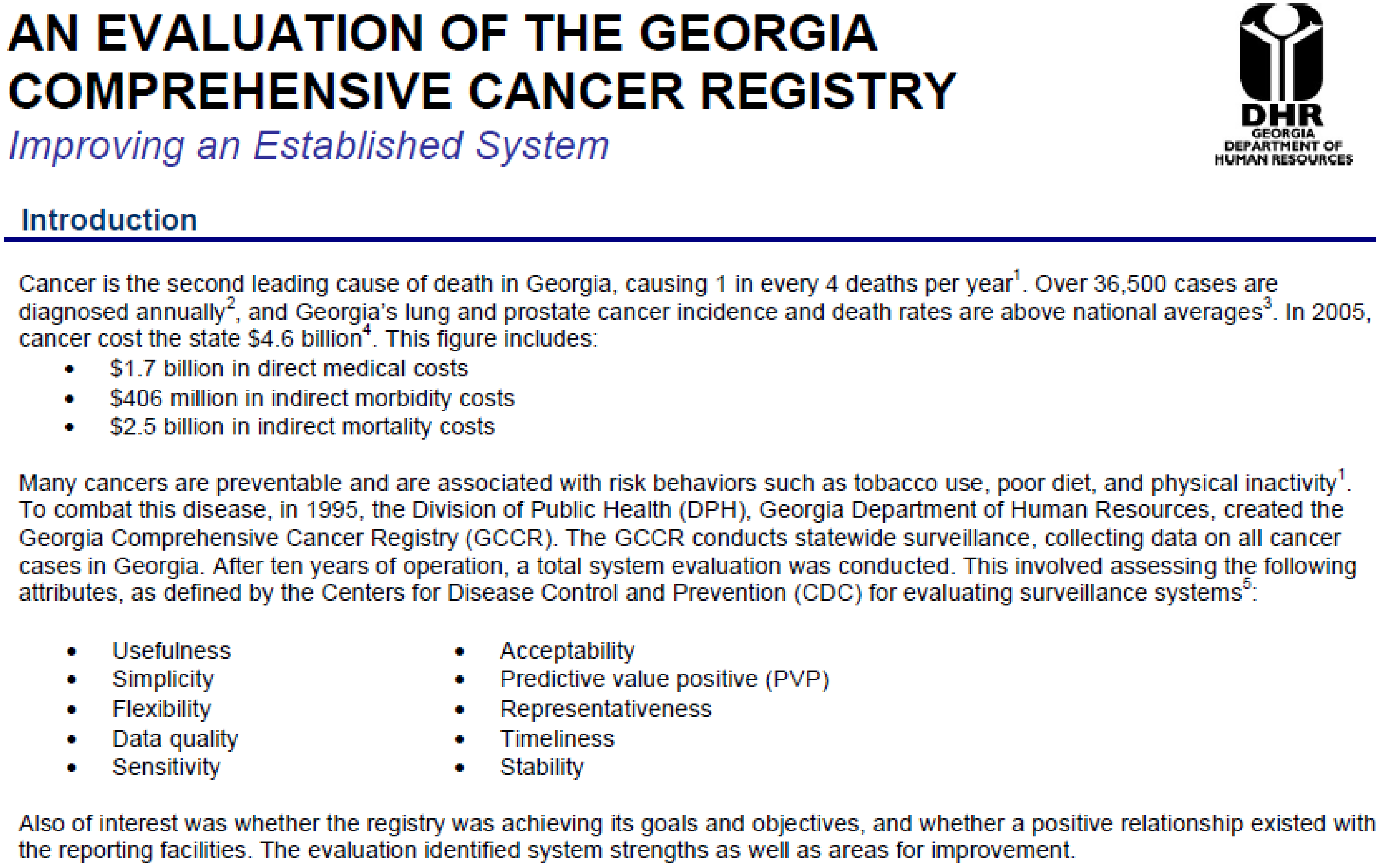
- amount and type of data necessary to establish that the health-related event has occurred (i.e., the case definition has been met);
- amount and type of other data on cases (e.g., demographic, behavioral, and exposure information for the health-related event);
- number of organizations involved in receiving case reports;
- level of integration with other systems;

- method of collecting the data, including number and types of reporting sources, and time spent on collecting data;
- amount of follow-up that is necessary to update data on the case;
- method of managing the data, including time spent on transferring, entering, editing, storing, and backing up data;
- methods for analyzing and disseminating the data, including time spent on preparing the data for dissemination;
- staff training requirements; and
- time spent on maintaining the system.

Discussion. Thinking of the simplicity of a public health surveillance system from the design perspective might be useful. An example of a system that is simple in design is one with a case definition that is easy to apply (i.e., the case is easily ascertained) and in which the person identifying the case will also be the one analyzing and using the information. A more complex system might involve some of the following:

- special or follow-up laboratory tests to confirm the case;
- investigation of the case, including telephone contact or a home visit by public health personnel to collect detailed information;
- multiple levels of reporting (e.g., with the National Notifiable Diseases Surveillance System, case reports might start with the health-care provider who makes the diagnosis and pass through county and state health departments before going to CDC [*29*]); and
- integration of related systems whereby special training is required to collect and/or interpret data.

Simplicity is closely related to acceptance and timeliness. Simplicity also affects the amount of resources required to operate the system.



AN EVALUATION OF THE GEORGIA COMPREHENSIVE CANCER REGISTRY

Improving an Established System

DHR
GEORGIA
DEPARTMENT OF
HUMAN RESOURCES

Introduction

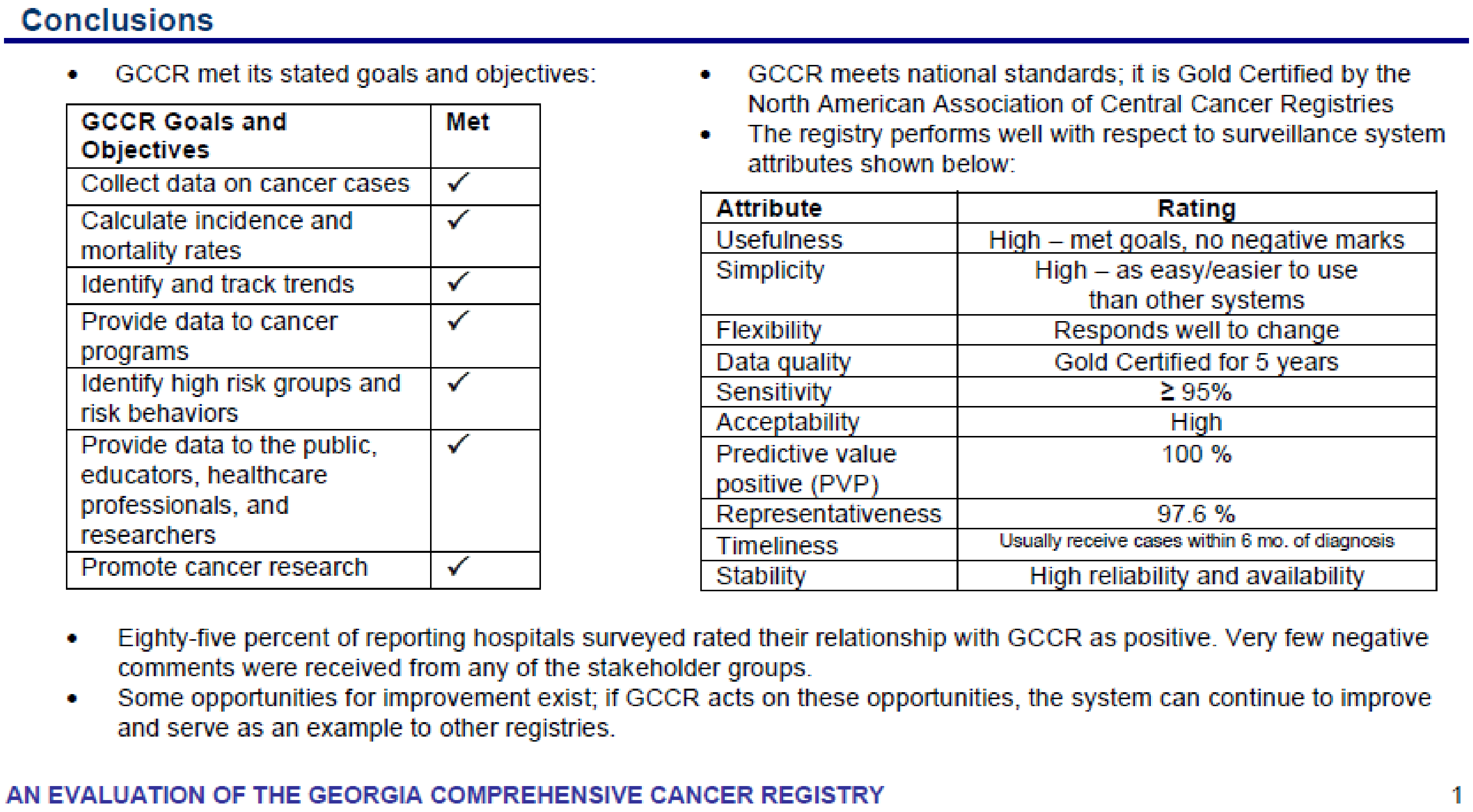
Cancer is the second leading cause of death in Georgia, causing 1 in every 4 deaths per year[1]. Over 36,500 cases are diagnosed annually[2], and Georgia's lung and prostate cancer incidence and death rates are above national averages[3]. In 2005, cancer cost the state $4.6 billion[4]. This figure includes:

- $1.7 billion in direct medical costs
- $406 million in indirect morbidity costs
- $2.5 billion in indirect mortality costs

Many cancers are preventable and are associated with risk behaviors such as tobacco use, poor diet, and physical inactivity[1]. To combat this disease, in 1995, the Division of Public Health (DPH), Georgia Department of Human Resources, created the Georgia Comprehensive Cancer Registry (GCCR). The GCCR conducts statewide surveillance, collecting data on all cancer cases in Georgia. After ten years of operation, a total system evaluation was conducted. This involved assessing the following attributes, as defined by the Centers for Disease Control and Prevention (CDC) for evaluating surveillance systems[5]:

- Usefulness
- Simplicity
- Flexibility
- Data quality
- Sensitivity
- Acceptability
- Predictive value positive (PVP)
- Representativeness
- Timeliness
- Stability

Also of interest was whether the registry was achieving its goals and objectives, and whether a positive relationship existed with the reporting facilities. The evaluation identified system strengths as well as areas for improvement.



Conclusions

- GCCR met its stated goals and objectives:

GCCR Goals and Objectives	**Met**
Collect data on cancer cases	✓
Calculate incidence and mortality rates	✓
Identify and track trends	✓
Provide data to cancer programs	✓
Identify high risk groups and risk behaviors	✓
Provide data to the public, educators, healthcare professionals, and researchers	✓
Promote cancer research	✓

- GCCR meets national standards; it is Gold Certified by the North American Association of Central Cancer Registries
- The registry performs well with respect to surveillance system attributes shown below:

Attribute	**Rating**
Usefulness	High – met goals, no negative marks
Simplicity	High – as easy/easier to use than other systems
Flexibility	Responds well to change
Data quality	Gold Certified for 5 years
Sensitivity	≥ 95%
Acceptability	High
Predictive value positive (PVP)	100 %
Representativeness	97.6 %
Timeliness	Usually receive cases within 6 mo. of diagnosis
Stability	High reliability and availability

- Eighty-five percent of reporting hospitals surveyed rated their relationship with GCCR as positive. Very few negative comments were received from any of the stakeholder groups.
- Some opportunities for improvement exist; if GCCR acts on these opportunities, the system can continue to improve and serve as an example to other registries.

Simplicity / Ease of Use

Strong reporting, dissemination methods
Group ratings:

Group	Excellent	Good
Internal staff	83 % (n=5)	17 % (n=1)
Data users	56 % (n=5)	33 % (n=3)
Reporting facilities	24 % (n=8)	49 % (n=16)

Internal staff:

- Improve funding, staffing, data submission discrepancies 33% (n=1)

Data users:

- Improve data collection rate 50% (n=1)
- Fewest high marks on integration with other systems 46% (n=5)

Reporting facilities:

- As easy/easier than other systems to use: 94% (n=17)
- Low marks from those with less training
    - Hard to use: 6% (n=1)
    - Too many requirements: 11% (n=4)
- Fewest high marks given for time spent collecting data

Simplicity: Reporters' Desired Changes

"Be able to track all cases submitted in one place, better productivity reporting, and easy access to all data requirements by diagnosis date"

"Better communication between GCCR and the hospital registry"

"Have list of all abstracts submitted rather than just the ones done with the last software update"

Simplicity: Training Received by Reporting Hospitals

Training Level	n	%
GCCR annual training	20	61%
Informal training by supervisor or colleague	16	49%
National training by Director of Emory's Georgia Center for Cancer Statistics	14	42%
Formal training by GCCR staff	13	39%
None received, will receive in future	1	3%
None received, none planned	1	3%

* For numbers reported in this format, n is the number of respondents that selected this answer choice or provided this answer, and % is the percentage that n represents, of all respondents for that question.

Flexibility

GCCR responds well to change

Reporting facilities:

- Policy & Procedures Manual update was:
  - Excellent: 26% (n=8)
  - Good: 55% (n=17)
- Georgia EDITS * update was:
  - Excellent: 52% (n=12)
  - Good: 35% (n=8)
- Somewhat quick response to change: 59% (n=19)

* EDITS is quality control software used by reporting facilities

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Acceptability

Internal staff:

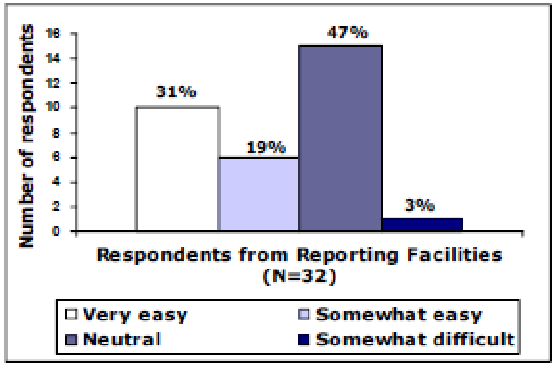
- Facilities are very willing to report: 50% (n=3)
- Facilities are willing to report: 50% (n=3)
- Usual completeness rate for facilities: 80%-90%
- Usual delay in reporting: 6-12 mo.

Reporting facilities perceived that:

- Their facility's completeness rate was between 90%-100% for the 2004 diagnosis year: 79% (n=26)
- Their completeness rate for 2004 was achieved within 6-12 mo. 60% (n=18)
- Their facility submits data in a timely manner: 94% (n=32)

Acceptability: Difficulty of Reporting

Reporting facilities' responses to the question, "How difficult is it for you or your facility to report cases?"



QC Indicators and Metods in Cancer Registry

- Comparability
- Completeness
- Validity or accuracy
- Timelines

QC: Definitions

- Comparability
  - standardization of practices concerning classification and coding of new cases, and consistency in basic definitions of incidence, such as rules for the recording and reporting of multiple primary cancers occurring in the same individual
- Completeness
- Validity or accuracy
- Timelines

QC: Definition

- Comparability
- Completeness

  All the incident cancers occurring in the population are included in the registry database. Incidence rates and survival proportions will be close to their true value if maximum completeness in case-finding procedures can be achieved
- Validity or accuracy
- Timelines

QC: Definitions

- Comparability
- Completeness
- Validity or accuracy
    - proportion of cases in the registry with a given characteristic that truly have that attribute, and depends on the precision of source documents and the level of expertise in abstracting, coding and recoding
- Timelines

QC: Definitions

- Comparability
- Completeness
- Validity or accuracy
- Timelines

Access to recent data is perceived as a priority by users, but, since registries are constantly updating their database as reports are received, and some notifications arrive long after the case was diagnosed, statistics for the recent periods will be incomplete, and will need future updates. There is, therefore, some conflict between the requirement for timely data, and other aspects of data quality, particularly completeness.

ارتقاء کیفی فعالیت‌های ثبت سرطان در ایران
بت‌های ثبت سرطان در کشور

و[۱]، دکتر آذین نحوی‌جو[۱]

میولوژی و آمار پزشکی، انستیتو کارولینسکا، سوئد
کز تحقیقات سرطان دانشگاه علوم پزشکی تهران، کد پستی: ۱۴۱۹۷۳۳۱۴۱
kzendeh@

پذیرش: ۸۸/۱۰/۲۲

، جزء مهم‌ترین الویت‌های بهداشتی در ایران می‌باشد. در دهه
ت ثبت سرطان صورت گرفته و گزارش‌های متعددی منتشر شده
رد ارزیابی قرار دادیم.

الی ۱۳۸۵ میزان‌های بروز استاندارد شده سنی سرطان (ASRs)
سپس نتایج ثبت پاتولوژی و ثبت جمعیتی مربوط به ۶ سرطان
ستان، و سمنان مورد مقایسه قرار دادیم.

ز ۱۳۸۳ الی۱۳۸۵ افزایش یافته است. البته بررسی استانی نشان
ان‌ها روند افزایشی مشاهده نشد. ثبت پاتولوژی در مردان ۶۳ –
در سرطان‌های کشنده مثل معده (۴۴٪ در مردان و ۴۸٪ در زنان)

طمینانی را ارایه نمی‌دهد و ASRs بسیار کمتر از میزان واقعی
اری و رفع نیازهای تحقیقاتی برنامه ملی ثبت سرطان نیاز به

یران

Basic & Clinical Cancer Research

ORIGINAL ARTICLE

Audit of a nationwide pathology-based cancer registry in Iran

Kazem Zendehde [1,2,*], Zahra Sedigh [1], Jaleh Hassanloo [1], Azin Nahvijou [1]

ABSTRACT

Background: Cancer registries are important infrastructure for cancer control programs. However most developing countries lack population based cancer registry. In Iran there cancer incidence is estimated based on pathology-based cancer registry. In this study we evaluated results of the nationwide pathology-based cancer registry in Iran.

Materials and Methods: We compared age-standardized incidence rate (ASRs) of all cancers combined among male and female from 2004 to 2006 for the entire country and stratified by 30 provinces. In addition, we compared ASRs of all cancer combined and six common cancers from pathology-based cancer registry with the results of population-based cancer registry conducted in five provinces including Tehran, Aradbil, Kerman, Golestan, and Semnan provinces. Ratio of pathology-based to population-based cancer registries in these provinces perceived as the completeness of pathology-based cancer registry.

Results: We found that ASRs among men and women increased from 2004 to 2006. However, the increasing trend was not consistent for all 30 provinces; ASRs increased, decreased on remained stable in different provinces. Completeness of pathology-based cancer registry was about 58% and 64% for men and women, respectively. Among the other, the completeness was extremely low for lung (26%) and esophageal (53%), and stomach (54%) cancers among male and for stomach (54%) and ovary (0.68%) among female.

Conclusion: Pathology-based cancer registry underestimates the cancer incidence and cannot be a reliable source for policy making and research. Inclusion of other sources such as death registry and establishment of population-based cancer registry is necessary. We suggest promoting regional population-based registries using standard methods in Iran and other developing countries.

Keywords: *cancer registry, pathology-based, population-based, Iran.*

1. Cancer Research Center, Tehran University of Medical Sciences, Iran.
2.Department of Medical Epidemiology and Biostatistics, Karolinska Institute, Sweden.

Completeness and underestimation of cancer mortality rate in I.R of Iran: a report from the Fars Province in southern Iran

Maryam Marzban[1], Ali-Akbar Haghdoost[2,3], Eshagh Dortaj[2,3], Abbas Bahrampour[2,3],Kazem Zendehdel

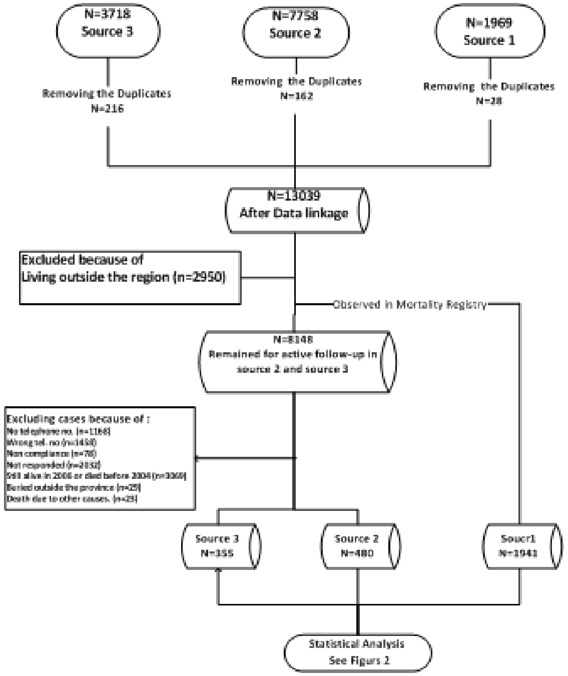


Figure1: Flowchart of the record linkage from the three data sources for using capture-recapture method and evaluate true mortality rate of cancer in Fars Province in the southern Iran in 2004-2006. **Source 1:** Mortality Registry. **Source 2:** Follow-up of Pathology Based Cancer Registry; **Source 3:** Follow-up of Hospital data

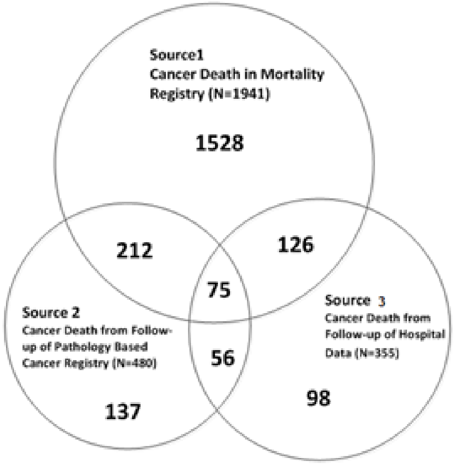
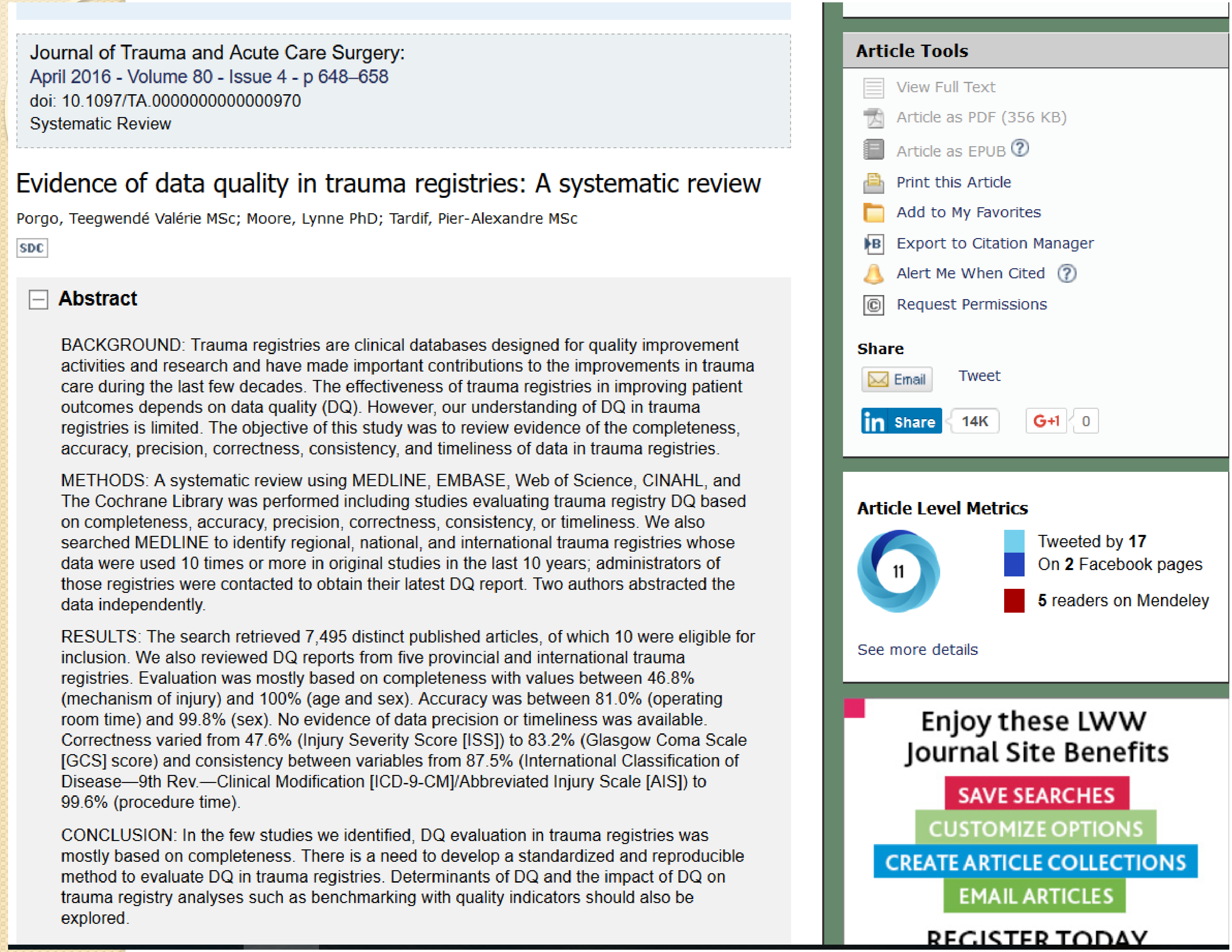


Figure2: Venn diagram, presenting number of cancer death observed in the three data sources independently and in common with the other in Fars Province in the southern Iran in 2004-2006.

کم شماری موارد مرگ ناشی از سرطان در ثبت مرگ استان فارس
در سالهای ۱۳۸۴ الی ۱۳۸۶ (مطالعه صید باز صید)

Cancer Type	**Underestimation rate (%)**
All Cancer	**42**
Bladder Cancer	**60**
Colon Cancer	**35**
Esophageal Cancer	**44**
Lung Cancer	**48**
Stomach Cancer	**30**
Ovarian Cancer**	**42**
Breast Cancer**	**27**
Endometrial Cancer**	**50**
Prostate Cancer**	**32**



Journal of Trauma and Acute Care Surgery:
April 2016 - Volume 80 - Issue 4 - p 648–658
doi: 10.1097/TA.0000000000000970
Systematic Review

Evidence of data quality in trauma registries: A systematic review

Porgo, Teegwendé Valérie MSc; Moore, Lynne PhD; Tardif, Pier-Alexandre MSc

Abstract

BACKGROUND: Trauma registries are clinical databases designed for quality improvement activities and research and have made important contributions to the improvements in trauma care during the last few decades. The effectiveness of trauma registries in improving patient outcomes depends on data quality (DQ). However, our understanding of DQ in trauma registries is limited. The objective of this study was to review evidence of the completeness, accuracy, precision, correctness, consistency, and timeliness of data in trauma registries.

METHODS: A systematic review using MEDLINE, EMBASE, Web of Science, CINAHL, and The Cochrane Library was performed including studies evaluating trauma registry DQ based on completeness, accuracy, precision, correctness, consistency, or timeliness. We also searched MEDLINE to identify regional, national, and international trauma registries whose data were used 10 times or more in original studies in the last 10 years; administrators of those registries were contacted to obtain their latest DQ report. Two authors abstracted the data independently.

RESULTS: The search retrieved 7,495 distinct published articles, of which 10 were eligible for inclusion. We also reviewed DQ reports from five provincial and international trauma registries. Evaluation was mostly based on completeness with values between 46.8% (mechanism of injury) and 100% (age and sex). Accuracy was between 81.0% (operating room time) and 99.8% (sex). No evidence of data precision or timeliness was available. Correctness varied from 47.6% (Injury Severity Score [ISS]) to 83.2% (Glasgow Coma Scale [GCS] score) and consistency between variables from 87.5% (International Classification of Disease—9th Rev.—Clinical Modification [ICD-9-CM]/Abbreviated Injury Scale [AIS]) to 99.6% (procedure time).

CONCLUSION: In the few studies we identified, DQ evaluation in trauma registries was mostly based on completeness. There is a need to develop a standardized and reproducible method to evaluate DQ in trauma registries. Determinants of DQ and the impact of DQ on trauma registry analyses such as benchmarking with quality indicators should also be explored.

Article Level Metrics

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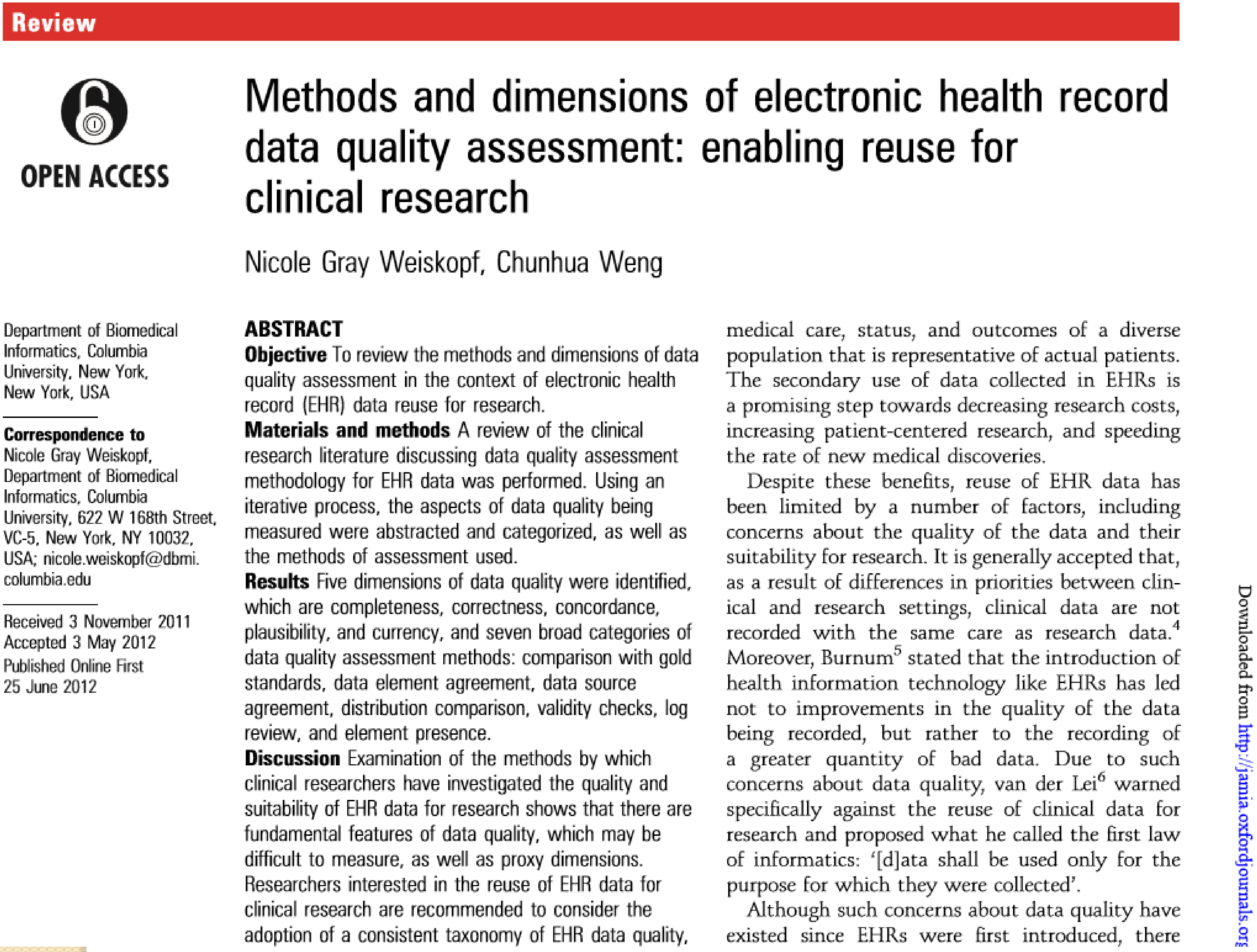

Review

OPEN ACCESS

Methods and dimensions of electronic health record data quality assessment: enabling reuse for clinical research

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Received 3 November 2011
Accepted 3 May 2012

ABSTRACT

Objective To review the methods and dimensions of data quality assessment in the context of electronic health record (EHR) data reuse for research.

Materials and methods A review of the clinical research literature discussing data quality assessment methodology for EHR data was performed. Using an iterative process, the aspects of data quality being measured were abstracted and categorized, as well as the methods of assessment used.

Results Five dimensions of data quality were identified, which are completeness, correctness, concordance, plausibility, and currency, and seven broad categories of data quality assessment methods: comparison with gold standards, data element agreement, data source agreement, distribution comparison, validity checks, log review, and element presence.

Discussion Examination of the methods by which clinical researchers have investigated the quality and suitability of EHR data for research shows that there are fundamental features of data quality, which may be difficult to measure, as well as proxy dimensions. Researchers interested in the reuse of EHR data for clinical research are recommended to consider the adoption of a consistent taxonomy of EHR data quality,

medical care, status, and outcomes of a diverse population that is representative of actual patients. The secondary use of data collected in EHRs is a promising step towards decreasing research costs, increasing patient-centered research, and speeding the rate of new medical discoveries.

Despite these benefits, reuse of EHR data has been limited by a number of factors, including concerns about the quality of the data and their suitability for research. It is generally accepted that, as a result of differences in priorities between clinical and research settings, clinical data are not recorded with the same care as research data.[4] Moreover, Burnum[5] stated that the introduction of health information technology like EHRs has led not to improvements in the quality of the data being recorded, but rather to the recording of a greater quantity of bad data. Due to such concerns about data quality, van der Lei[6] warned specifically against the reuse of clinical data for research and proposed what he called the first law of informatics: '[d]ata shall be used only for the purpose for which they were collected'.

Although such concerns about data quality have existed since EHRs were first introduced, there

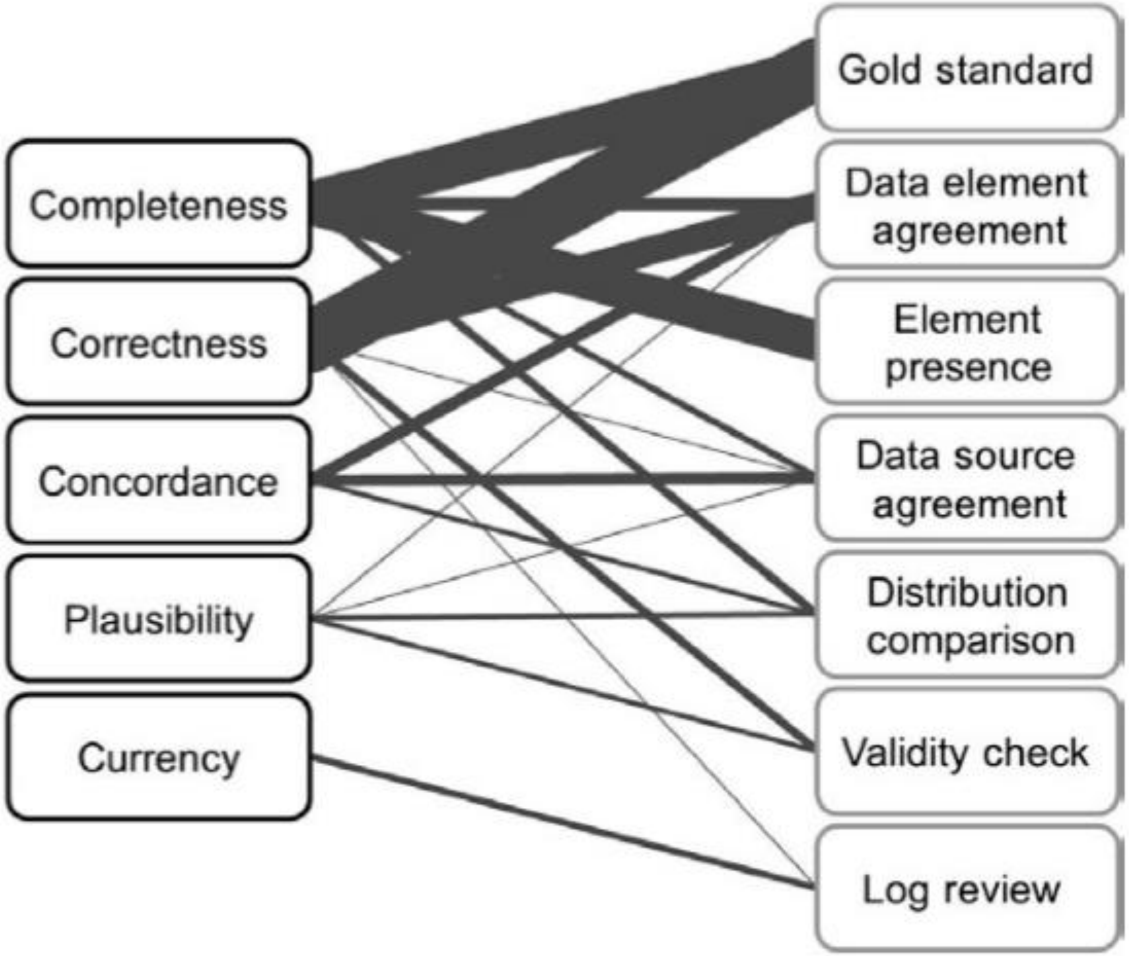

Figure 1 Mapping between dimensions of data quality and data quality assessment methods. Dimensions are listed on the left and methods of assessment on the right, both in decreasing order of frequency from top to bottom. The weight of the edge connecting a dimension and method indicates the relative frequency of that combination.

Suggested Reference

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