Advisory on
National Radiation Dose Registry for Patient Exposure
During Healthcare Procedures

EXECUTIVE SUMMARY

The advances in medical imaging, diagnosis and treatment have greatly improved patient health and longevity. The proposals to develop a National Radiation Dose Registry for Patient Exposure in the United States have far-reaching impacts that could adversely affect these improvements in medicine. The negative consequences for such a registry include the potential for (a) restricted access to medical imaging, resulting in grave patient outcomes; (b) unfounded confusion and fears among patients regarding the risks versus the benefits of diagnostic imaging, (c) misplaced trust of healthcare professional regarding the use of necessary medical imaging procedures. Currently there are a multitude of unanswered questions and concerns regarding a National Radiation Dose Registry for Patient Exposure, and the potential unintended consequences to patient care, patient education, population based risks vs benefits, and costs to the healthcare system that ultimately will be passed on to the patients or taxpayers.

Therefore the Texas Radiation Advisory Board [TRAB] strongly advocates full and continued clinically-indicated access to medical diagnostic imaging, without the unintended interference that a National Radiation Dose Registry for Patient Exposure could have on patient care. Furthermore, the TRAB supports ongoing monitoring of the impact of any such patient registry to monitor diagnostic imaging procedures and the potential positive and negative impacts on patient health of such a registry.

INTRODUCTION

The Texas Radiation Advisory Board [TRAB] consists of 18 expert advisors on radiation issues and members of the public appointed by the Governor. TRAB provides advice and recommendations to state regulatory agencies on radiation issues to ensure effective regulation for the public benefit regarding radiation safety, public health and protection of the environment. This TRAB advisory is written to review the proposed national registry metrics for exposure to ionizing radiation used within healthcare.

Decisions about the use of ionizing radiation in diagnostic imaging are now under great scrutiny. Medicine is attempting to find a balance between the need to assess the patient's clinical status, and the potential risks of radiation exposure in diagnostic imaging. The federally promulgated Image Wisely and Image Gently campaigns reaffirm the long-held ALARA ["as low as reasonably achievable"] principle of radiation protection. The expanded use of medical imaging in the United States has renewed the debate about its potential benefits and harms.

BACKGROUND INFORMATION

The potential harm of radiation in medical imaging has been extrapolated from atomic bomb survivors, and "empiric evidence" resulting in cancer risks from diagnostic imaging that "are at most very low" [3]. Data sources for the Biological Effects of Ionizing Radiation [BIER] reports are derived from more than six decades of following atomic bomb survivors [Radiation Effects Research Foundation; RERF], persons exposed to medical radiation, workers in radiation and nuclear industries, and populations exposed to environmental radiation including Chernobyl. Following 93,000 survivors, the RERF studies remain the
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major source regarding the known health consequences of radiation. The risk of radiation exposure at
doses greater than 100 mSv is clear. With exposures of less than 100 mSv, though, it is not statistically
possible to identify an increased risk for cancer compared with the normal incidence of cancer in the
exposed populations [2,4]. It is particularly difficult to extrapolate population-based health effects, as the
cancer incidence in Japan is very different from that in the United States [U.S.]. Furthermore, the cancer
rates of Japan today are also different from that in the 1940s. Most importantly, exposures from
intermittent medical imaging utilizing low energy x-rays and gamma rays cannot be directly compared to
high-energy gamma rays, neutrons and charged particles from a single whole-body exposure resulting
from an atomic bomb or nuclear accident.

The Science Committee of the International Organization for Medical Physics [IOMP] published a policy
statement that predictions of induced cancers and cancer deaths in a patient population exposed to <100
mSv of ionizing radiation during medical imaging are highly speculative. These predictions involve multiple
uncertainties including generalization of risk across different populations, in addition to dosimetric and
methodological uncertainties [5]. This IOMP policy statement is consistent with Paragraphs A86 and 151
of Report 103 of the International Commission on Radiological Protection [ICRP] that states,

"There is, however, general agreement that epidemiological methods used for the estimation of cancer risk do
not have the power to directly reveal cancer risks in the dose range up to around 100 mSv".

"The assessment and interpretation of effective dose from medical exposure of patients is very problematic
when organs and tissues receive only partial exposure or a very heterogeneous exposure"

Additionally, the United Nations Scientific Committee on the Effects of Atomic Radiation [UNSCEAR]
Report A-67-46, approved in May 2012, stated,

"UNSCEAR does not recommend multiplying very low doses by large numbers of individuals to estimate
numbers of radiation-induced health effects within a population exposed to incremental doses at levels
equivalent to or lower than natural background levels."

The IOMP, along with other internationally recognized scientific committees, emphasized that ionizing
radiation prevalent in nature, contributing an average annual effective dose of about 2 mSv/year/person,
and concluded that, "there is no reason to deter from any justified medical examination involving exposure
to ionizing radiation" [5].

Demographic data from the United States [U.S.], that includes the increasing utilization of diagnostic
imaging procedures, increasing cancer incidence, and increasing cancer mortality rates, does not reflect an
increased risk for cancer. In 1998, with a U.S. population of 276 million, 26 million CT scans were
performed. Ten years later, in 2008, this increased to 70 million CT scans with a U.S. population of 304
million. In the early 1980s, the total per capita radiation dose was 3.6 mSv, with 0.54 mSv contributed from
medical imaging and the remainder from background radiation [2]. In 2006, the total per capita radiation
dose was 6.2 mSv, with medical radiation accounting for 3 mSv of the total. Although the exposure nearly
doubled, it is still far less than the 100 mSv level where there is statistical uncertainty about the health
effects of radiation.
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Medical imaging has increased over the past three decades. There, however, has been no concomitant increase in cancer deaths; in fact, the age-adjusted cancer death rates have either declined dramatically or remained stable [6]. Between 1950 and 2010, advances in cancer diagnostic imaging and therapy have resulted in a 12.1% decline in U.S. cancer deaths and significant increases in overall life expectancy. After 1980, the most significant decline in cancer deaths coincided with the increase in diagnostic imaging [7-9]. This length of patient follow-up is also sufficient to account for the 5 to 20 year latency period that is identified in radiation-induced cancers.

The debate of radiation risk has raged for more than two decades with mammography. Multiple studies have demonstrated that the potential risk of a radiation induced breast cancer from yearly mammographic screening beginning at age 40 years was small compared to the expected reduction in mortality achieved with the early detection of breast cancer [10]. Of 7301 cases of invasive breast cancer diagnosed between 1990 and 1999 and followed through 2007, 609 patients died from breast cancer. Among the 609 confirmed deaths from breast cancer, 71% of the cases occurred in women whose last screening mammogram was more than two years prior to the cancer diagnosis and those who were never screened. Median age at diagnosis of fatal cancers was 49 years; in contrast, median age at diagnosis was 72 years in deaths not from breast cancer [11].

The Joint Commission issued Diagnostic Imaging Services Requirements in December 20, 2013. The standards, effective July 1, 2014, apply to every healthcare entity performing diagnostic imaging services. Under the Provision of Care, Treatment, and Services [PC], Elements of Performance for PC 01.02.15 [12]:

C.5 The organization documents in the patient's clinical record the radiation dose on every study produced during a computed tomography [CT] examination.

Note 1: This element of performance is only applicable for systems capable of calculating and displaying radiation doses.

Note 2: This element of performance does not apply to systems used for therapeutic radiation treatment planning or delivery, or for calculating attenuation coefficients for nuclear medicine studies.

C.6 The interpretive report of a diagnostic CT study includes the volume computed tomography dose index [CTDlvol] or dose-length product [DLP] radiation dose. The dose is either recorded in the patient's interpretive report or included on the protocol page.

Note 1: This element of performance is only applicable for systems capable of calculating and displaying radiation doses.

A.12 For organizations that provide diagnostic computed tomography [CT], magnetic resonance imaging [MRI], positron emission tomography [PET], or nuclear medicine [NM] services: The organization considers the patient's age, and recent imaging exams when deciding on the most appropriate type of imaging exam.

A 25. **Standard PC.01.03.01** The organization establishes imaging protocols based on current standards of practice, which address key criteria including clinical indication, contrast administration, age [to indicate whether the patient is pediatric or an adult], patient size and body habitus, and the expected radiation dose range.
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A6. **Standard PI.02.01.01** The organization compiles and analyzes data on patient CT radiation doses and compares it with external benchmarks, when such benchmarks are available.

Concurrent with the requirements from The Joint Commission are draft comments within Stage 3 of Meaningful Use documentation that is federally required of every healthcare provider. To summarize, Meaningful Use Stage 1, implemented between 2011-2013, involved data capture and patient access. Stage 2 of Meaningful Use, implemented between 2014-2015, involves information exchange and care coordination. Based on this foundation, the Stage 3 Draft Recommendations from the Meaningful Use Work Group, which will be implemented between 2016-2017, is intended to improve outcomes. Under the Imaging-118 Stage 3 Recommendation will mandate that the Certified Electronic Health Record Technology will display the radiation exposure associated with the imaging study. Proposed for a future stage of meaningful use will be standards that present imaging and radiation dosing information to the patient including the part of the body that was radiated.

A registry that collects all of the data of radiation exposure, both for the individual patient and the healthcare facility, will be required. The federal Agency for Healthcare Research and Quality [AHRQ] has provided additional guidance [2nd Edition] on creating "Registries for Evaluating Patient Outcomes" [13]. Within the 2nd Edition, the following topics were highlighted:

- The Use of Registries in Product Safety Assessment
- Linking Registry Data: Technical and Legal Considerations
- Interfacing Registries with Electronic Health Records

New examples of registries are Registries for Health Technology Assessment, and to Assess and Monitor Long-term Product Safety. Furthermore, initiatives exist to link a procedure-based registry with claims data to study long-term outcomes. However, Data Ownership and Privacy are recognized issues within registries. Recognized issues for registries designed for safety assessments include the following [13]:

- Size of the registry
- Enrolled population / Recruiting a meaningful patient population
- Duration of follow-up
- Evaluating the utility of a registry when the entire population at risk is not included
- Understanding the timing of treatments, treatment changes, multiple therapies, dose effects, delayed effects, and patient compliance
- Registries examining comparative effectiveness, the natural history of a disease, evidence in support of national coverage decisions, or quality improvement may gather and report adverse event data, but may not be able to reliably detect all events. In this case, the registry facilitates safety reporting rather than evaluating safety.

The Draft for Public Comment of the 3rd Edition on the use of registries to evaluate patient outcomes by AHRQ, addresses the protection of data from litigation [14]. This draft document proposes that the Integrating Healthcare Enterprise initiative develop the Radiation Exposure Monitoring [REM] profile. This profile would describe the way dose information should be transmitted to a registry in the form of a Radiation Dose Structured Report [RDSR]. Recognizing that only the most recent versions of CT scanners
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and software support RDSR, the registry software will need to convert data from older scanners into the RDSR format. All patient identifiers will be removed before data transfer to the registry. Secondly, the Radlex Playbook was used as the standard terminology to characterize CT exams. Currently, a data collection system, has been collecting direct transmission of CT information from CT scanners to the CT registry. This CT dose registry has collected CT radiation dose data from over 200 U.S. facilities for over 1 million CT exams. The goal is to compare this CT radiation dose data between facilities, and establish national benchmarks for CT dose indices.

These mandates enacted by The Joint Commission, proposed within Stage 3 of Meaningful Use, and the use of patient registries as proposed by AHRQ raise the following concerns:

1. How will patients and physicians, understand the radiation dose data that will be included within the patient's medical record?
   a. How will patients be educated about the relevance of this radiation data, especially with regard to their own medical condition?

   1. Since patient distress has been cited as a major component in changing screening recommendations for prostate and breast cancer, how will potential patient distress need to be handled to:
      a. Reassure patients that the imaging study is necessary. It is unclear how patient radiation fears and subsequent refusal to undergo imaging studies, will adversely impact patient outcomes.
      b. What level of informed consent will be needed for each imaging study? How will the risks and benefits of each study, relative to the clinical condition and patient age, be handled in healthcare facilities? How will such detailed informed consents provide beneficial information or add to further patient distress?

2. Who will be responsible, and legally liable, for providing the patient education regarding radiation risks relative to potential benefits of obtaining the study relative to the patient’s clinical presentation?
   a. How will access to care be impacted? How will this impact obtaining a head CT scan in the following clinical scenarios:
      • a 9 year old who is unconscious after a car accident,
      • a 9 year old who requires a follow-up CT scan after chemoradiation for a head and neck aggressive malignancy
      • a 45 year old lung cancer patient with new onset of seizures
      • a 45 year old lung cancer patient for re-evaluation after resection of a solitary brain metastasis
      • a 70 year old who presents with symptoms of a stroke

3. Will physicians of all specialties be required to receive specific training in radiological sciences / radiation safety if they are now legally liable for each imaging study ordered?
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a. What will be the liability for failure to order an imaging procedure and identify a medical problem? The implications range from the patient’s adverse outcome to public health concerns. For example:
   1. A delayed diagnosis of breast cancer which changes the prognosis from a curable to a fatal disease at presentation
   2. Failure to obtain a chest x-ray in a 20-year old with new respiratory symptoms after environmental exposure in an endemic area with tuberculosis

b. This also brings up the physician dilemma on how to limit radiation dose and be compliant with FDA recommendations for screening low dose chest CT for the diagnosis of lung cancer in certain high risk patients as mandated preventive services under the Affordable Care Act.

c. What impact will this have on medical malpractice?
   1. In Great Britain, the Ionising Radiations [Medical Exposure] Regulations that implement the European Directive 97/43/Euratom [the Medical Exposures Directive] require that all medical exposures to ionizing radiation be justified [15]. The principle that “no practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes [Justification of Practices Involving Ionising Radiation Regulations, 2004]."
      a. The question remains:
         • Who determines benefit versus risk?
         • How does the benefit to the individual relate to the benefit of society?

2. What will be done with the data?
   • Where will the data be sent, especially with regard to Meaningful Use Stage 3?
   • Who will review the data? How will the data be protected?
   • What will the data be used for?
   • Will some regulatory agency place lifetime limits on the number of diagnostic studies that can be performed for an individual? What will happen in an emergency if it is deemed that the patient needs imaging but is not allowed to have a procedure based on government regulations?

This is in light of the evidence that does not demonstrate any increase in cancer incidence, nor has there been an increase in cancer deaths due to radiation as the result of the increase in medical imaging. As indicated above, medical imaging has contributed in large part to the improvements to cancer survival rates.

• How will any governmental restrictions in the administration of medical imaging be indexed relative to the patient's clinical condition and age?
  o A cancer patient will usually require more frequent imaging to direct treatment and to
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determine response to surgery, chemotherapeutic and radiotherapy interventions
  o Given the known cancer latency period, patients over the age of 50 years have an extremely low risk of developing a radiation-induced cancer.

3. Who will pay for the radiation dose data collection and analysis?
   a. What will be the impact of these costs on the overall cost of healthcare that will be shifted to the consumer?
   b. Will these policies restrict the use of medical imaging thereby driving down healthcare costs?
   c. If the use of medical imaging declines, what agency will monitor health outcomes, such as increases in incidence of advanced stage cancer at diagnosis, and morbidity/mortality rates associated traumatic injury?

Some of these questions are already being answered. The Medicare Evidence Development & Coverage Advisory Committee [MEDCAC], that was held on April 30, 2014, evaluated "Lung Cancer Screening with Low Dose Computed Tomography" [16].

The MEDCAC charter, as renewed by Health & Human Services of Secretary Kathleen Sebelius on November 15, 2012, is to meet between 4 and 8 times per year, and has a maximum of 100 members who are selected by the Secretary of Health & Human Services, or designee, and may serve up to a total of 4 years, representing two 2-year terms [17]. Under the "Description of Duties" the MEDCAC, "reviews and evaluates medical literature, reviews technology assessments, public testimony, and examines data and information on the benefits, harms, and appropriateness of medical items and services that are covered under Medicare or that may be eligible for coverage under Medicare". Under the charter of renewal, the MEDCAC works from an agenda provided by the Designated Federal Official to determine the reasonable and necessary uses of medical services and technology. Additionally, the MEDCAC may be asked to develop recommendations about Medicare coverage, and/or review and comment upon proposed or existing Medicare coverage policies.

As of January 1, 2009, the Centers for Medicare & Medicaid Services [CMS] have been allowed to add coverage of "additional preventive services" if the requirements of all of the national coverage determinations [NCD] process are met:

1. Reasonable and necessary for prevention or early detection of an illness or disability;
2. Either an A or B grade recommendation from the United States Preventive Services Task Force [USPSTF]; and
3. Appropriate for individuals eligible for benefits under Medicare Part A or enrolled in Medicare Part B.

The USPSTF has given Lung Cancer Screening with Low Dose Computed Tomography [LC-LDCT] a grade B evaluation for certain persons at high risk for lung cancer based on age [55 to 80 years of age] and smoking history [30 pack-year smoking history and currently smoke, or have quit smoking within the past 15 years]. The USPSTF indicated that screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy.
Accepting two formal complete requests, CMS launched its evaluation of LC-LDCT, seeking evidence for the following issues that are of particular interest:

- Identification of patients eligible for lung cancer screening
- The appropriate frequency and duration of screening
- Facility and provider characteristics that predict benefit or harm
- Precise criteria for test positivity and the impact of false positive results
- Follow-up tests or treatments.
- CMS also solicited input on the influence of these factors on patient education and informed consent in Medicare beneficiaries, including the:
  - Elderly
  - Younger disabled populations
  - Persons receiving dialysis treatment for end stage renal disease
- Integration of smoking cessation interventions for current smokers

The MEDCAC questions and voted responses are listed within the Appendix. Although a medical physicist was present, no radiologists or any oncologic specialty or thoracic specialists were empaneled. The specialties of the other MEDCAC panel members included a cardiologist, outcomes researchers, statistician, health policy, nursing, and a health insurance representative. There were three questions that evaluated the [1] adequacy of evidence that the benefits outweigh the harms of lung cancer screening with an average effective radiation dose of 1.5 mSv, [2] that the harms of lung cancer screening will be minimized, and [3] that clinically significant evidence gaps remain for the Medicare population. The voting scale ranged from 1 - Low Confidence to 3 - Intermediate Confidence to 5 - High Confidence for all questions. A voting score of 2.5 or higher is required for further consideration. Regarding the adequacy of evidence that the benefits of LC-LDCT did not outweigh the potential harms including the risk of radiation exposure; the responses ranged from 1 to 4 with a voting member average score of 2.22. The score was only 2.33 among voting members regarding how effectively that the harms of LC-LDCT will be minimized in the Medicare population. The panel was very confident, with scores of 4.67, that clinically significant evidence gaps remain with the use of LC-LDCT in the Medicare population.

The MEDCAC scores, reflecting that the potential harms from LC-LDCT outweighed potential benefits and that significant gaps in clinical evidence existed, were surprising to the medical community given the multiple publications in high impact journals that documented improvements in overall survival with the early detection of lung cancer. Furthermore, given the approximate 20-year latency period between radiation exposure and potential development of solid tumors, the risk of radiation exposure to the Medicare population is extremely low.

The key study demonstrating a significant relative reduction in lung cancer deaths was published as the lead article in the New England Journal of Medicine in 2011 [18]. From August 2002 to April 2004, 53,454 persons at high risk for lung cancer at 33 U.S. medical centers were randomly assigned to undergo three annual screenings with either low-dose CT or single PA chest radiography. Data were collected on cases through December 31, 2009. The rate of adherence to the trial was more than 90%. The rate of positive screening tests was 24.2% with low-dose CT and 6.9% with radiography over all three rounds of screening.
False positive results totaled 96.4% in the CT group and 94.5% in the radiography group. There were 247 deaths from lung cancer per 100,000 person-years in the CT group compared to 309 lung cancer deaths per 100,000 person-years in the radiography group, representing a 20% relative reduction in mortality from lung cancer with low-dose CT screening. Importantly a 6.7% reduction in the rate of death from any cause was noted in the CT screening group.

Similar reductions in lung cancer deaths were also found with 6-years of follow-up in the Mayo Clinic helical CT screening study where a 37% relative increase in lung cancer detection was demonstrated. The relative reduction in cumulative lung cancer-specific mortality from five annual screening examinations was 28% at 6-years follow-up and 15% at 15 years follow-up [19]. The relative reduction in cumulative all-cause mortality was 4% at 6-year follow-up because of increased competing mortality risks associated with smoking.

One of the most significant concerns raised by the MEDCAC related to false positive evaluations. These concerns relate to the distress, the personal and societal economic costs, and potential morbidity of interventions that confirm a false positive finding. These are the same concerns that led to the USPSTF recommending against prostate-specific antigen [PSA] screening for prostate cancer [20]. However, the 2013 findings of the combined Pan-Canadian Early Detection of Lung Cancer Study [PanCan] and the British Columbia Cancer Agency Study [BCCA] reported that predictive tools allow the accurate diagnosis of lung nodules [21]. The study populations included 7008 nodules, of which 102 were malignant, among 1871 patients in the PanCan study, and 5021 nodules, of which 42 were malignant, in 1090 patients in the BCCA study. Even for nodules 10 mm or smaller, the accuracy was more than 90%.

The National Lung Screening Trial also stratified its findings according to risk quintile. The 60% of participants at highest-risk for lung cancer death [quintiles 3 through 5] accounted for 88% of those in whom death from lung cancer was prevented with CT screening; however, 64% of false positive studies were also in this group [22]. The 20% of participants having the lowest risk for lung cancer accounted for only 1% of the prevented lung cancer deaths. Additionally, further analysis of the National Lung Screening Trial and the lung cancer risk-prediction model from the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial was undertaken improving the predictive model and sensitivity without loss of specificity [23].

The more significant decline in lung cancer deaths achieved through CT screening was overshadowed by the also significant 5% decline in all cause mortality during the MEDCAC deliberation. Additionally, the MEDCAC focused on the utilization of societal healthcare resources and potential morbidity associated with the evaluation of false positive findings, and the radiation dose administered during CT screening of lung cancer.

SUMMARY

The advances in diagnostic imaging have greatly contributed to the improvements in morbidity and mortality rates in medicine. The proposals to develop a radiation dose registry for each patient in the United States have far-reaching impact that could adversely affect morbidity and mortality rates in medicine. Among these negative consequences include the restricted access to medical imaging resulting
in grave patient outcomes, and unfounded confusion and fears among patients and healthcare professional regarding the risks, relative to the benefits, of diagnostic imaging. Given the multitude of questions and concerns regarding the potential unintended consequences to patient care, patient education, population based outcomes, and costs to the healthcare system that ultimately will be passed on to the patient, the TRAB strongly advocates for continued clinically indicated access to diagnostic imaging, and ongoing monitoring of the impact of these efforts on diagnostic imaging procedures and their attendant impact on health outcomes.
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SUPPORTING DOCUMENTATION AND REPORTS
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Prepublication
Requirements

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Prepublication Requirements continued
December 20, 2013

delivered-CTD\(\text{vol}\) displayed on the CT console. The
dates, results, and verifications of these
verifications/measurements are documented.

Note 1: This element of performance is applicable only
applicable for systems capable of calculating and
displaying radiation doses in the form of CTD\(\text{vol}\).

* For the definition of “radiation dose” refer to section
116111(f) of the California Health and Safety Code.

Note 2: This element of performance does not apply to
dental cone beam CT radiographic imaging studies
performed for diagnosis of conditions affecting the
maxillofacial region or to obtain guidance for the
treatment of such conditions.

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Note: For pediatric brain-protooleach tested protocol is within 20
percent of the actual amount of radiation dose
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- Image uniformity for all radiofrequency (RF) coils used clinically
- Signal-to-noise ratio (SNR) for all coils used clinically
- Slice thickness accuracy
- Slice position accuracy
- Alignment light accuracy
- High-contrast resolution
- Low-contrast resolution (or contrast-to-noise ratio)
- Geometric or distance accuracy
- Magnetic field homogeneity
- Artifact evaluation
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#### Human Resources (HR)

**Standard HR.01.02.05**
The organization verifies staff qualifications.

**Elements of Performance for HR.01.02.05**

| C 19 | For organizations that provide computed tomography (CT) services: Starting July 1, 2015, the organization verifies and documents that a radiologic technologist who performs CT exams has the following qualifications:
| - | Registered and certified by the American Registry of Radiologic Technologists (ARRT), or certified by the Nuclear Medicine Technology Certification Board (NMTCB)
| - | Trained and experienced in the operation of CT equipment

**Note:** This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

| C 20 | For organizations that provide diagnostic computed tomography (CT) services: The organization verifies and documents that diagnostic medical physicists that support CT services have board certification in diagnostic radiologic physics or radiologic physics by the American Board of Radiology, or in Diagnostic Imaging Physics by the American Board of Medical Physics, or in Diagnostic Radiological Physics by the Canadian College of Physicists in Medicine, or meet all of the following requirements:
| - | A graduate degree in physics, medical physics, biophysics, radiologic physics, medical health physics, or a closely related science or engineering discipline from an accredited college or university
| - | Formal graduate-level coursework in the biological sciences with at least one course in biology or radiation biology and one course in anatomy

**Note:** This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

**Standard HR.01.05.03**
Staff participate in ongoing education and training.

**Elements of Performance for HR.01.05.03**

- Documented experience in a clinical CT environment conducting at least 10 CT performance evaluations under the direct supervision of a board-certified medical physicist

**Note:** This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

- MRI equipment emergency shutdown procedures
- Patient hearing protection

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- Management of patients with claustrophobia, anxiety, or emotional distress
  * Terminology for defining the safety of items in the magnetic resonance environment is provided in ASTM F2803 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (http://www.astm.org).

Medication Management (MM)

**Standard MM.06.01.01**
The organization safely administers medications.

**Element of Performance for MM.06.01.01**

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NM) services: The organization considers the patient's age and recent imaging exams when deciding
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on the most appropriate type of imaging exam.

Note 1: Knowledge of a patient’s recent imaging exams can help to prevent unnecessary duplication of these examinations.

Note 2: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

Standard PC.01.03.01
The organization plans the patient’s care.

Elements of Performance for PC.01.03.01
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Executive Summary

Defining Patient Registries
This user’s guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care.

Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure.

Planning a Registry
There are several key steps in planning a patient registry, including articulating its purpose, determining whether it is an appropriate means of addressing the research question, identifying stakeholders, defining the scope and target population, assessing feasibility, and securing funding. The registry team and advisors should be selected based on their expertise and experience.

The plan for registry governance and oversight should clearly address such issues as overall direction and operations, scientific content, ethics, safety, data access, publications, and change management. It is also helpful to plan for the entire lifespan of a registry, including how and when the registry will end and any plans for transition at that time.

Registry Design
A patient registry should be designed with respect to its major purpose, with the understanding that different levels of rigor may be required for registries designed to address focused analytical questions to support decisionmaking, in contrast to those intended primarily for descriptive purposes. The key points to consider in designing a registry include formulating a research question; choosing a study design; translating questions of clinical interest into measurable exposures and outcomes; choosing patients for study, including deciding whether a comparison group is needed; determining where data can be found; and deciding how many patients need to be studied and for how long. Once these key design issues have been settled, the registry design should be reviewed to evaluate potential sources of bias (systematic error); these should be addressed to the extent that is practical and achievable. The information value of a registry is enhanced by its ability to provide an assessment of the potential for bias and to quantify how this bias could affect the study results.
The specific research questions of interest will guide the registry’s design, including the choice of exposures and outcomes to be studied and the definition of the target population (the population to which the findings are meant to apply). The registry population should be designed to approximate the characteristics of the target population as much as possible. The number of study subjects to be recruited and the length of observation (followup) should be planned in accordance with the overall purpose of the registry. The desired study size (in terms of subjects or person-years of observation) is determined by specifying the magnitude of an expected, clinically meaningful effect or the desired precision of effect estimates. Study size determinants are also affected by practicality, cost, and whether or not the registry is intended to support regulatory decisionmaking. Depending on the purpose of the registry, internal, external, or historical comparison groups strengthen the understanding of whether the observed effects are indeed real and in fact different from what would have occurred under other circumstances.

Registry study designs often restrict eligibility for entry to individuals with certain characteristics (e.g., age) to ensure that the registry will have subgroups with sufficient numbers of patients for analysis. Or the registry may use some form of sampling—random selection, systematic sampling, or a haphazard, nonrandom approach—to achieve this end.

Data Elements
The selection of data elements requires balancing such factors as their importance for the integrity of the registry and for the analysis of primary outcomes, their reliability, their contribution to the overall burden for respondents, and the incremental costs associated with their collection. Selection begins with identifying relevant domains. Specific data elements are then selected with consideration for established clinical data standards, common data definitions, and whether patient identifiers will be used. It is important to determine which elements are absolutely necessary and which are desirable but not essential. In choosing measurement scales for the assessment of patient-reported outcomes, it is preferable to use scales that have been appropriately validated, when such tools exist. Once data elements have been selected, a data map should be created, and the data collection tools should be pilot tested. Testing allows assessment of respondent burden, the accuracy and completeness of questions, and potential areas of missing data. Inter-rater agreement for data collection instruments can also be assessed, especially in registries that rely on chart abstraction. Overall, the choice of data elements should be guided by parsimony, validity, and a focus on achieving the registry’s purpose.

Use of Patient Reported Outcomes in Registries
Patient reported outcomes (PROs) are reports of health status taken directly from patients without interpretation by clinicians. PROs can provide useful information for registries designed for many purposes, including natural history of disease, quality improvement, effectiveness, and comparative effectiveness. Using PROs raises such questions as when and how often to collect the data, which method or combination of methods should be used (e.g., paper-based, electronic), and which instrument(s) should be used. Many validated instruments and measures are available, such as general assessment scales (e.g., health-related quality of life), disease-specific scales, symptom-specific scales, evaluations of functioning across a variety of domains (e.g., physical, social, emotional), and scales assessing satisfaction with care received. When selecting instruments or measures, it is important to define (1) the population of interest, (2) the outcomes of interest, (3) the intended users of the registry, and (4) the purpose of the registry. Defining these factors will help determine which PROs are useful and appropriate for the study. The validity, reliability, and ability to detect change of the instrument should also be considered. Once PROs
have been selected, the registry should focus on consistency across patients and across sites in how the instruments are administered and how data are entered into the registry.

Data Sources
A single registry may integrate data from various sources. The form, structure, availability, and timeliness of the required data are important considerations. Data sources can be classified as primary or secondary. Primary data are collected by the registry for its direct purposes. Secondary data have been collected by a secondary source for purposes other than the registry, and may not be uniformly structured or validated with the same rigor as the registry’s primary data. Sufficient identifiers are necessary to guarantee an accurate match between data from secondary sources and registry patients. Furthermore, it is advisable to obtain a solid understanding of the original purpose of the secondary data, because the way those data were collected and verified or validated will help shape or limit their use in a registry. Common secondary sources of data linked to registries include medical records systems, institutional or organizational databases, administrative health insurance claims data, death and birth records, census databases, and related existing registry databases.

Ethics, Data Ownership, and Privacy
Critical ethical and legal considerations should guide the development and use of patient registries. The Common Rule is the uniform set of regulations on the ethical conduct of human subjects research issued by the Federal agencies that fund such research. Institutions that conduct research agree to comply with the Common Rule for federally funded research, and may opt to apply that rule to all human subjects activities conducted within their facilities or by their employees and agents, regardless of the source of funding. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations (collectively, the Privacy Rule) are the legal protections for the privacy of individually identifiable health information created and maintained by health care providers, health plans, and health care clearinghouses (called “covered entities”). The research purpose of a registry, the status of its developer, and the extent to which registry data are individually identifiable largely determine which regulatory requirements apply. Other important concerns include transparency of activities, oversight, and data ownership. This section focuses solely on U.S. law. Health information is also legally protected in European and some other countries by distinctly different rules.

Informed Consent for Registries
Informed consent for patient registries often raises different issues than informed consent for clinical trials. For example, registries may be used for public health or quality improvement activities, which may not constitute “human subjects research.” Registries also may integrate data from multiple electronic sources (e.g., claims data, electronic health records) and may be linked to biobanks. Institutional review boards may approve waivers or alterations of informed consent (e.g., electronic consent, oral consent) for some registries, depending on the purpose and risk to participants. Established registries that undergo a change in scope (e.g., changes in data sharing policies, changes to the protocol, extension of the follow-up period) may need to reconsent patients. When planning informed consent procedures, registry developers should consider several factors, including documentation and format, consent revisions and re-consent, the applicability of regulatory requirements, withdrawal of participants from the study, and the physical and electronic security of patient data and biological specimens.
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Protection of Registry Data from Litigation and Other Confidentiality Concerns for Providers, Manufacturers, and Health Plans
As patient registries are increasingly recognized as a valuable data source, questions about privacy and the confidentiality of the data arise, particularly when data are desired for litigation or other judicial or administrative proceedings. In addition to patient data, registries often include private, confidential, and/or proprietary information about providers, manufacturers, and health plans. While significant attention has been paid to protecting the privacy of identifiable patient information, there is no single comprehensive Federal law governing protection of registry data about providers, manufacturers, or health plans. Sources of protection for these data at the Federal level include the Patient Safety and Quality Improvement Act of 2005, the Health and Human Services Certificate of Confidentiality, the Agency for Healthcare Research and Quality Confidentiality Statute, the HIPAA Privacy Rule, the Privacy Act of 1974, the Federal Rules of Evidence and Civil Procedure, the Freedom of Information Act, Quality Improvement Organizations, the Federal Trade Secrets Act, and the Patient Protection and Affordable Care Act. Additional protections are available at the state level through safe harbor and peer review laws. Registry developers should consider this issue during the planning phase and clearly articulate the policies and procedures that the registry will follow in the case of a request for registry data (e.g., from litigation attorneys, regulatory authorities, the press, or members of the public).

Patient and Provider Recruitment and Management
Recruitment and retention of patients as registry participants and providers as registry sites are essential to the success of a registry. Recruitment typically occurs at several levels, including facilities (hospitals, physicians’ practices, and pharmacies), providers, and patients. The motivating factors for participation at each level and the factors necessary to achieve retention differ according to the registry. Factors that motivate participation include the perceived relevance, importance, or scientific credibility of the registry, as well as the risks and burdens of participation and any incentives for participation. Because patient and provider recruitment and retention can affect how well a registry represents the target population, well-planned strategies for enrollment and retention are critical. Goals for recruitment, retention, and followup should be explicitly laid out in the registry planning phase, and deviations during the conduct of the registry should be continuously evaluated for their risk of introducing bias.

Data Collection and Quality Assurance
The integrated system for collecting, cleaning, storing, monitoring, reviewing, and reporting on registry data determines the utility of those data for meeting the registry’s goals. A broad range of data collection procedures and systems are available. Some are more suitable than others for particular purposes. Critical factors in the ultimate quality of the data include how data elements are structured and defined, how personnel are trained, and how data problems are handled (e.g., missing, out-of-range, or logically inconsistent values). Registries may also be required to conform to guidelines or to the standards of specific end users of the data (e.g., 21 Code of Federal Regulations, Part 11). Quality assurance aims to affirm that the data were, in fact, collected in accordance with established procedures and that they meet the requisite standards of quality to accomplish the registry’s intended purposes and the intended use of the data.

Requirements for quality assurance should be defined during the registry’s inception and creation. Because certain requirements may have significant cost implications, a risk-based approach to developing
a quality assurance plan is recommended. It should be based on identifying the most important or likely sources of error or potential lapses in procedures that may affect the quality of the registry in the context of its intended purpose.

**Adverse Event Detection, Processing, and Reporting**
The U.S. Food and Drug Administration defines an adverse event (AE) as any untoward medical occurrence in a patient administered a pharmaceutical product, whether or not related to or considered to have a causal relationship with the treatment. AEs are categorized according to the seriousness and, for drugs, the expectedness of the event. Although AE reporting for all marketed products is dependent on the principle of “becoming aware,” collection of AE data falls into two categories: those events that are intentionally solicited (meaning data that are part of the uniform collection of information in the registry) and those that are unsolicited (meaning that the AE is volunteered or noted in an unsolicited manner). Determining whether the registry should use a case report form to collect AEs should be based on the scientific importance of the information for evaluating the specified outcomes of interest. Regardless of whether or not AEs constitute outcomes for the registry, it is important for any registry that has direct patient interaction to develop a plan for detecting, processing, and reporting AEs. If the registry receives sponsorship, in whole or in part, from a regulated industry (drugs or devices), the sponsor has mandated reporting requirements, the process for detecting and reporting AEs should be established, and registry personnel should receive training on how to identify AEs and to whom they should be reported. Sponsors of registries designed specifically to meet requirements for surveillance of drug or device safety are encouraged to hold discussions with health authorities about the most appropriate process for reporting serious AEs.

**Analysis, Interpretation, and Reporting of Registry Data**
Analysis and interpretation of registry data begin with answering a series of core questions: Who was studied, and how were they chosen for study? How were the data collected, edited, and verified, and how were missing data handled? How were the analyses performed? Four populations are of interest in describing who was studied: the target population, the accessible population, the intended population, and the population actually studied (the “actual population”). The representativeness of the actual population to the target population is referred to as generalizability.

Analysis of registry outcomes first requires an analysis of recruitment and retention, of the completeness of data collection, and of data quality. Considerations include an evaluation of losses to followup; completeness for most, if not all, important covariates; and an understanding of how missing data were handled and reported. Analysis of a registry should provide information on the characteristics of the patient population, the exposures of interest, and the endpoints. Descriptive registry studies focus on describing frequency and patterns of various elements in a patient population, whereas analytical studies concentrate on associations between patients or treatment characteristics and health outcomes of interest. A statistical analysis plan describes the analytical plans and statistical techniques that will be used to evaluate the primary and secondary objectives specified in the study plan. Interpretation of registry data should be provided so that the conclusions can be understood in the appropriate context and any lessons from the registry can be applied to the target population and used to improve patient care and outcomes.
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Modifying and Stopping Registries
Most, if not all registries, should undergo periodic critical evaluation by key stakeholders to ensure that the objectives are being met. When registry objectives are no longer being met or when clinical or other changes affect the registry (e.g., changes in treatment practices, the introduction of a new therapy), the registry may need to be adapted, or the registry may stop collecting new data. Many registries will undergo a modification or transition at some point in their lifecycle, and these changes will vary in scope and size. A major registry transition is a change in the purpose, stakeholders, and/or technology platform of the registry that has a substantive impact on the ongoing conduct of the registry. Considerations for the transition of a registry are similar to those for starting a registry, but transitions can also present some unique challenges. It is important to select a leadership team that will carefully plan and implement the transition and consider the impacts of the planned changes (e.g., legal and ethical issues, technology, and data analysis). The transition team should also be prepared to handle unplanned or exigent circumstances that may arise during the transition and modify the project plan accordingly. Open, ongoing communication between the project team, stakeholders, participants, and other resources is key to conducting a successful transition.

A registry may stop collecting new data because it has fulfilled its original purpose, is unable to fulfill its purpose, is no longer relevant, or is unable to maintain sufficient funding, staffing, or other support. If an open-ended registry is planned, reasonable goals should be set for data quality, study enrollment, and the amount of information needed to address specific endpoints of interest which will inform the decision if and when to end the registry.

Interfacing Registries and Electronic Health Records
Achieving interoperability between electronic health records (EHRs) and registries will be increasingly important as adoption of EHRs and the use of patient registries for many purposes both grow significantly. Such interoperability should be based on open standards that enable any willing provider to interface with any applicable registry without requiring customization or permission from the EHR vendor. Interoperability for health information systems requires accurate and consistent data exchange and use of the information that has been exchanged. Syntactic interoperability (the ability to exchange data) and semantic interoperability (the ability to understand the exchanged data) are the core constructs of interoperability and must be present in order for EHRs and registries to share data successfully. Full interoperability is unlikely to be achieved for some time. The successive development, testing, and adoption of open standard building blocks (e.g., the Healthcare Information Technology Standards Panel’s HITSP TP-50) is a pragmatic approach toward incrementally advancing interoperability while providing real benefits today. Care must be taken to ensure that integration efforts comply with legal and regulatory requirements for the protection of patient privacy.

Linking Registry Data with Other Data Sources to Support New Studies
Registry data may be linked to other data sources (e.g., administrative data sources, other registries) to examine questions that cannot be addressed using the registry data alone. Two equally weighted and important sets of questions must be addressed in the data linkage planning process: (1) What is a feasible technical approach to linking the data? (2) Is linkage legally feasible under the permissions, terms, and conditions that applied to the original compilations of each dataset? Many statistical techniques for linking records exist (e.g., deterministic matching, probabilistic matching); the choice of a technique should be guided by the types of data available. Linkage projects should include plans for managing
common issues (e.g., records that exist in only one database and variations in units of measure). In addition, it is important to understand that linkage of de-identified data may result in accidental re-identification. Risks of re-identification vary depending on the variables used, and should be managed with guidance from legal and statistical experts to minimize risk and ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Common Rule, and other legal and regulatory requirements.

Managing Patient Identity across Data Sources
As new technologies emerge to manage electronic health care data and create new opportunities for data linkage, patient identity management (PIM) strategies and standards grow increasingly important. If shared patient identifiers exist between two data sources, data can be linked using a unique patient identifier (UPI), such as a medical record number. The concept of a universal UPI has been the subject of debate for some time. Some view UPIs as a tool to reduce administrative workload and facilitate the exchange of electronic data, while others raise serious concerns about the privacy and protection of patient-identifiable information. These concerns have halted efforts to implement universal UPIs in the U.S. to date. As a result, common PIM practices in the U.S. include algorithms and other statistical methods to link and combine data when no shared patient identifiers are present. However, with no standardized PIM practices in place, methods can vary widely, making it difficult to ensure the accuracy and effectiveness of data linkage techniques.

Analysis of Linked Registry Datasets
Retrospective database studies are studies that use data collected for a primary purpose other than research (e.g., administrative databases) or collected for specific research objectives but used to support secondary studies focused on different objectives. These studies have yielded substantial information on the incidence, prevalence, and outcomes of many diseases and can be used to generate a rapid response to emerging research questions. However, these studies require special considerations related to conduct and interpretation because of the possibility of producing biased or invalid results. Challenges faced by retrospective database studies include inaccurate measurement of exposures, outcomes, and confounders and overweighting of results because of the large study population. To avoid these pitfalls, it is important to clearly define the study objective, patient population, and potential confounders and modifiers. Researchers must also understand the conditions under which the data were collected originally.

Use of Registries for Product Safety Assessment
Whether as part of a postmarketing requirement or out of a desire to supplement spontaneous reporting, prospective product and disease registries are also increasingly being considered as resources for examining unresolved safety issues and/or as tools for proactive risk assessment in the postapproval setting. Registries can be valuable tools for evaluating product safety, although they are only one of many approaches to safety assessments. When designing a registry for the purposes of safety, the size of the registry, the enrolled population, and the duration of followup are all critical characteristics to ensure validity of the inferences made based on the data collected. Consideration in the design phase must also be given to other recognized aspects of product use in the real world (e.g., switching therapies during followup, use of multiple products in combination or in sequence, dose effects, delayed effects, and patient compliance).
Registries designed for safety assessment purposes should also formulate a plan that ensures that appropriate information will reach the right stakeholders (through reporting either to the manufacturer or directly to the regulator) in a timely manner. Stakeholders include patients, clinicians, providers, product manufacturers and authorization holders, and payers such as private, State, and national insurers. Registries not designed specifically for safety assessment purposes should, at a minimum, ensure that standard reporting mechanisms for adverse event information are described in the registry’s standard operating procedures and are made clear to investigators.

**Rare Disease Registries**
A rare disease registry can be a valuable tool for increasing understanding of the disease and supporting the development of treatment protocols and therapies. Typical goals of a rare disease registry include generating knowledge around the natural history, evolution, risk, and outcomes of a specific disease; supporting research on genetic, molecular, and physiological basis of a disease; establishing a patient base for evaluating drug, medical devices, and orphan products; and connecting affected patients, families and clinicians. Many stakeholders often play an important role in rare disease registries. Stakeholders may include patient advocacy groups, regulatory, funding, and public health agencies, clinicians, scientists, industry, payers, and individuals and families. Because of the limited patient population, rare disease registries face unique planning and design challenges. For example, little information may be available on the disease to guide development of a research plan, and diagnostic criteria may be complex or evolving. Disease-specific patient reported outcome measures may not be available. Long-term (even lifelong) follow-up may be needed. Due to these challenges, rare disease registries may need to adapt and change over time as knowledge increases or treatments become available. Retention of patients and providers can also be difficult over the duration of the registry, and registry developers should monitor followup rates over time to identify potential issues. Clear policies for governance, data access, and publications should be developed, particularly if multiple stakeholders are involved.

**Pregnancy Registries**
A pregnancy exposure registry is an observational prospective cohort of women receiving a biopharmaceutical product(s) of interest as part of their routine clinical care who are enrolled voluntarily during gestation, before outcomes can be known. Participants are followed until the end of pregnancy or longer to systematically collect information on specific pregnancy outcomes and evaluate their frequency relative to a scientifically valid reference population(s). While pregnancy registries are an efficient method for evaluating the effects of medications used during pregnancy, they present unique challenges related to patient recruitment and retention, choosing reference or comparator groups, mitigating bias, and generalizability of registry results. Analysis and interpretation of data from pregnancy registries also requires careful consideration. Because specific birth defects are rare events, pregnancy registries usually do not have sufficient sample size/power to evaluate increased risks for specific defects unless the relative risks are quite large. Most registries compare the overall proportion of all major defects combined in the exposed group to the overall proportion in the reference group.

**Quality Improvement Registries**
Quality improvement (QI) registries use systematic data collection and other QI tools to improve the quality of care on the local, regional, or national level. In a QI registry, patients are either exposed to a particular health service (e.g., a procedure registry), or they have a disease/condition that is tracked over time through multiple health care providers and services. Most of the steps for planning a QI registry are...
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similar to the steps used for other types of registries, with two major differences. First, the identification of active, engaged participants, often called “champions” is critical for the early success of the registry. Second, the registry must collect actionable information that can be used to modify behaviors, processes, or systems of care. Actionable information is typically presented to providers in the form of process of care or quality measures. The selection of these measures requires balancing the goals of the registry with the desire to meet other needs for providers. In the design phase, QI registries can use the process of care or quality measures to drive the selection of data elements. Because many data elements collected in QI registries are often collected for other purposes (e.g., claims, medical records), integration with other data sources may be important for encouraging participation. Motivations for participation often differ from other types of registries, and incentives for participation focus on QI (e.g., recognition programs, QI tools, and benchmarking reports). Reporting information is also an important component of QI registries. Registries may report blinded or unblinded data at the individual patient, provider, or institution level. Lastly, QI registries must be able to adapt to new evidence and improvements in care over time, and they may face questions from institutional review boards that are less familiar with these types of registries.

Registries for Medical Devices
Medical device registries are an increasingly important tool for capturing patients’ experience with medical devices throughout the device lifecycle. Registries help to bridge the gap between device performance in clinical trial settings and in routine practice. However, the unique features of medical devices require special consideration when developing a registry. Regulations and approval guidelines for medical devices differ greatly from those for drugs. Compared to drugs, device technologies tend to see more rapid change over shorter amounts of time, and device registries must adapt to these changes. The current lack of unique device identifiers is also challenging, although efforts are underway to create unique device identifiers. In many cases, multiple devices are used, and devices may be used in combination with a drug component, further complicating efforts to examine safety and effectiveness. In addition, providers may have different levels of experience with the device, which may affect patient outcomes (especially with implantable devices). Medical device registries should attempt to classify all parts of a device with as much identifying information as possible, and many registries collect information on provider training and experience as well. An emerging trend is the ability for medical devices to transmit data directly to an electronic health record or registry. This new technology may reduce the burden of data entry for registries and increase the timeliness of registry data.

Public-Private Partnerships
A public-private partnership (PPP) refers to any partnership in which one entity is a public agency (e.g., a government entity) and the other entity is a private organization. The use of PPPs as a means to develop patient registries has increased in recent years, in part because of a growing interest from governments and payers in using registry data to make decisions about approval, coverage, and public health needs. Many models for PPPs exist. For example, a PPP may involve a partnership with Federal agencies and academia, health agencies from several countries and industry, or professional associations and public payers. During the planning phase of a PPP, it is important to define clear, transparent plans for governance, with documented roles for each stakeholder. Formal policies for analyses, publications, and data sharing are also critical, as are plans for managing conflicts of interest. During the operational phase, PPPs should focus on consistent communication with stakeholders to maintain interest. PPP registries are more likely to succeed if they have clear, agreed-upon goals; explicit roles and responsibilities for each
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stakeholder; strong leaders who are respected in the field; consistent data collection and analysis plans; and the flexibility to adapt to changing conditions.

Evaluating Registries
Although registries can provide useful information, there are levels of rigor that enhance validity and make the information from some registries more useful for guiding decisions than the information from others. The term “quality” can be applied to registries to describe the confidence that the design, conduct, and analysis of the registry can be shown to protect against bias and errors in inference—that is, erroneous conclusions drawn from a registry. Although there are limitations to any assessment of quality, a quality component analysis is used both to evaluate high-level factors that may affect results and to differentiate between research quality (which pertains to the scientific process) and evidence quality (which pertains to the data/findings emanating from the research process). Quality components are classified as either “basic elements of good practice,” which can be viewed as a checklist that should be considered for all patient registries, or as “potential enhancements to good practice,” which may strengthen the information value in particular circumstances. The results of such an evaluation should be considered in the context of the disease area(s), the type of registry, and the purpose of the registry, and should also take into account feasibility and affordability.
Electronic screening algorithms offer an efficient method of identifying potential AEs in large datasets in a timely manner. For such algorithms to be effective, the registry database must collect detailed information on the implants’ lots and catalog numbers, and must be updated frequently as new and modified products become available. In addition, when using medical codes, it is important to validate the results of the screening algorithm to ensure that coding errors have not affected the findings.

Case Example 57. Receiving Data from Medical Imaging Devices

Description
scanner models and software support RDSR. In order to accept dose information provided by older scanners, the registry developed software that could convert the data into the RDSR format. The software that collects dose information also removes patient identifiers before sending data to the registry.

The second hurdle in standardization was the development of a common nomenclature for CT exams. Different names are used for the same exam both within and among imaging facilities, and the registry needed a standard terminology for meaningful reporting. While it would have been possible to develop a new standard, the registry was aware of other lexicons under development, such as the Radlex Playbook. Conversations between the registry and the Radlex Playbook developers allowed the two groups to understand and meet each other’s needs, and the registry was able to adopt the Radlex Playbook as the standard terminology for exam names. For facilities that submit data using non-standard terminology, these terms are mapped to Radlex Playbook terminology using a mapping tool developed by the registry.

Results
To date, the data collection system has collected information related to CT radiation dose from over 200 facilities nationwide and has collected dose information from over 1,000,000 CT exams. In addition to allowing comparison of dose indices between facilities, data collected from the registry will also be used to establish national benchmarks for CT dose indices.

Key Point
While not a patient registry, this example demonstrates that registries that collect information from medical devices may be able to reduce data entry burden by incorporating data transmitted directly from the device. When considering this option, registries may benefit from communicating with industry to find solutions that are not manufacturer-specific and can be implemented within a reasonable timeframe. Registries may also benefit from working with existing standards to determine if they can be modified to fit the registry’s use case.

For More Information
http://nrdr.acr.org

Case Example 58. Combining Registry Data with EHR Data to Measure Real-World Outcomes of Implantable Devices

Description

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ease; and on the integration of smoking cessation interventions for current

helpful in minimizing harms?
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For the voting question, use the following scale identifying level of confidence with 1 being the lowest or no confidence and 6 representing a high level of confidence.

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<th>Question</th>
<th>Statutes</th>
<th>Rule</th>
<th>Procedure</th>
<th>Date</th>
<th>Health</th>
<th>Medical</th>
<th>Military</th>
<th>Mask</th>
<th>White</th>
<th>Man</th>
<th>Woman</th>
<th>Dose-Rate</th>
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<th>Silver</th>
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If you answer "Yes" to the question "Is there any evidence to demonstrate that the average effective dose of 3.5 mSv is a reasonable target for the mid-level population?"

- Low Confidence
- Moderate Confidence
- High Confidence

9. Are the average annual effective doses of 3.5 mSv, as measured in the mid-level population, reasonable?

10. Are the average annual effective doses of 3.5 mSv, as measured in the mid-level population, reasonable?

11. Are the average annual effective doses of 3.5 mSv, as measured in the mid-level population, reasonable?

For the voting question, use the following scale identifying level of confidence with 1 being the lowest or no confidence and 6 representing a high level of confidence.

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</tbody>
</table>

For the voting question, use the following scale identifying level of confidence with 1 being the lowest or no confidence and 6 representing a high level of confidence.

<table>
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<tr>
<th>Question</th>
<th>Statutes</th>
<th>Rule</th>
<th>Procedure</th>
<th>Date</th>
<th>Health</th>
<th>Medical</th>
<th>Military</th>
<th>Mask</th>
<th>White</th>
<th>Man</th>
<th>Woman</th>
<th>Dose-Rate</th>
<th>Gold</th>
<th>Silver</th>
<th>Wolf</th>
<th>Voting</th>
<th>Average</th>
<th>Overall</th>
<th>Average</th>
</tr>
</thead>
<tbody>
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<td>3</td>
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<td>3</td>
<td>4</td>
<td>5</td>
<td>High Confidence</td>
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