REPORT OF THE COUNCIL ON MEDICAL SERVICE

Subject: Clinical Data Registries

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Referred to: Reference Committee G
                (Craig A. Backs, MD, Chair)

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1   There is increasing interest in promoting the use of clinical data registries as a way to gather and
2   manage the information necessary to improve quality and lower costs in the health care system.
3   Clinical data registries have the potential to provide meaningful clinical information that facilitates
4   quality improvement and contributes to efforts to improve the value of health care. Thoughtful
5   consideration of ways to develop, maintain, and use the data collected by clinical registries can
6   help maximize their utility as a powerful, physician-led tool to help improve health care delivery.
7
8   This report, initiated by the Council, summarizes the scope and nature of clinical data registries;
9   describes the work of the National Quality Registry Network; highlights relevant American
10 Medical Association (AMA) policies and activities; and presents policy recommendations to
11 strengthen the relevance and impact of data registries.
12
13 BACKGROUND
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15 There are hundreds of health registries in the United States, operated by a wide variety of
16 stakeholders, including medical specialty societies, medical practices, hospitals, integrated delivery
17 systems, health plans, consumer groups, government entities and non-profit health organizations.
18 Most registries track information about patient demographics, medical condition(s) and treatments.
19 More advanced systems, particularly registries that are regional or national in scope, can be
20 designed or customized to store and analyze data related to patient outcomes, comparative
21 effectiveness, individual clinician information, costs, and other information that can be used to
22 inform system-wide quality improvement efforts. The specific data elements included in a registry
23 design depend on the intended use of the registry data. Common uses include managing the care of
24 individual patients, tracking clinical effectiveness of a particular treatment, reporting to fulfill a
25 coverage with evidence development (CED) requirement, monitoring for adverse effects, public
26 health reporting, documenting disease progression, assessing cost effectiveness, and measuring
27 outcomes and the quality of care.
28
29 Several national medical specialty societies sponsor clinical data registries designed to promote
30 quality improvement and enhance patient safety. The American College of Cardiology is one of the
31 leaders in registry development and operation, and established the National Cardiovascular Data
32 Registry (NCDR) in 1997 as part of an effort to collect and organize clinical data to help improve
33 cardiovascular care. The NCDR consists of seven separate registries that target different clinical
34 interests but use standard data elements and definitions so that the information can be compared
35 across the data sets. The information is used by hospitals and physician practices to support
36 performance measurement and quality improvement efforts, and is widely recognized as a valuable
37 source of clinical data related to cardiovascular care. More information is available at ncdr.com.

1 Similarly, the Society of Thoracic Surgeons (STS) developed a registry in 1989 to promote quality
2 improvement and patient safety within the cardiothoracic surgical community. The STS database
3 includes three components that focus on different areas of cardiothoracic surgery. STS' registry
4 supports quality improvement and clinical research activities, and continues to evolve based on
5 emerging needs. Information about the STS registry is available at sts.org/national-database.
6
7 THE NATIONAL QUALITY REGISTRY NETWORK
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9 The potential of a data registry to provide meaningful information depends on several factors
10 including but not limited to the intended use of the registry; the planning and design of the registry;
11 the level of physician participation; the ability of the registry to provide useful, actionable data to
12 clinicians; and the ability of the registry to adapt to changing clinical and data needs. Because
13 registries serve multiple purposes and stakeholders, it is unrealistic to expect that all registries will
14 reflect the same level of complexity or sophistication. While it is not necessary that all registries
15 have the same data tracking and reporting capabilities, efforts are underway to advance a
16 coordinated approach to registry development across a wide range of stakeholders in order to
17 facilitate and accelerate efforts to improve health care delivery in the United States.
18
19 In 2011, the AMA-convened Physician Consortium for Performance Improvement® (PCPI®)
20 proposed the creation of the National Quality Registry Network (NQRN™), a voluntary network of
21 registry stewards and others interested in advancing the development and use of registries to
22 measure and improve patient outcomes. The NQRN is led by a steering committee representing
23 multiple stakeholders including national medical specialty societies, health insurers, consumer
24 advocates, the federal government, and other organizations that support or are planning registries.
25 Funding and staff support have been provided by the AMA.
26
27 With hundreds of registries operating in the United States alone, the NQRN was created to engage
28 multiple stakeholders in a coordinated effort to promote the "triple aim" (i.e., better health care,
29 improved population health, at lower cost) through the expanded use of clinical registries. The
30 NQRN's work is focusing on:
31
32 • Establishing and disseminating leading practices for registries;
33 • Identifying gaps where clinical registries could support national priorities;
34 • Advocating for and supporting a learning network to accelerate national registry development,
35   maturation and use;
36 • Facilitating linkages among registries; and
37 • Addressing the needs of multiple stakeholders, including end-users of registry data.
38
39 The NQRN has done significant research into the current state of patient registries, particularly
40 those operated by medical societies and disease-related organizations. The NQRN identified 45
41 such organizations that support a total of 74 registries, and conducted a survey of 32 registry
42 stewards who operate patient registries based on disease or medical condition. Among the findings,
43 half of the respondents operate more than one registry; more than three-quarters of the registries
44 collect national-level data related to a specific disease or medical condition; and most registries
45 capture data on patient demographics, treatments, co-morbidities and treatment outcomes. The
46 most common uses of registry data include performance improvement, comparative effectiveness
47 research, and fulfillment of the quality improvement component of Maintenance of Certification
48 requirements (i.e., Part IV). Additional information about the NQRN's "Environmental Landscape
49 of Clinical Registries" is available at ama-assn.org/resources/doc/cqi/pcpi-112013-us-clinical-data-
50 registries-faq.pdf.

1 AMA STRATEGIC FOCUS, POLICY AND ADVOCACY
2
3 The AMA strategic plan includes a focus on improving health outcomes and on shaping delivery
4 and payment systems to enhance physician satisfaction and practice sustainability. The issue of the
5 optimal development and use of clinical data registries is relevant to both of these focus areas. As
6 noted, clinical data registries hold great promise for helping to generate information that can be
7 used to improve population health and improve patient outcomes. With respect to physician
8 satisfaction, well designed and managed clinical data registries can provide physicians with critical
9 information to help them provide quality care to their individual patients, a key factor in enhancing
10 physician satisfaction.
11
12 The AMA has been actively engaged in efforts to advance the use of clinical data registries, and
13 was instrumental in shaping the language in the American Taxpayer Relief Act (ATRA) of 2012
14 that outlined basic requirements for an entity to be considered as a qualified clinical data registry
15 for the purpose of meeting federal quality reporting requirements (e.g., under the Physician Quality
16 Reporting Program [PQRS]). Specifically, ATRA requires entities to be transparent regarding data
17 elements and specifications, risk models and measures; requires the submission of data on patients
18 from multiple payers; provides timely performance reports to participants at the individual clinician
19 level; and supports quality improvement initiatives for physicians.
20
21 The 2014 Physician Fee Schedule rule further defines Centers for Medicare & Medicaid Services
22 (CMS) criteria for qualifying clinical data registries, and outlines the process by which eligible
23 professionals can use qualified clinical data registry participation to meet the reporting
24 requirements under the PQRS and the Value-Based Payment Modifier programs. The AMA is
25 concerned that CMS' requirements are too stringent, and has encouraged CMS to phase in the
26 requirements to enable all registries—advanced, newly developed, and those in the early stages of
27 development—the opportunity to develop an infrastructure that is capable of satisfying the registry
28 option and aligning with the CMS quality programs.
29
30 Existing AMA policy supports the use of clinical data registries. Policy H-450.941, which is related
31 to pay-for-performance systems, calls for the AMA to work with other medical and specialty
32 associations to develop effective means of maintaining high quality medical care, such as the use of
33 specialty-based clinical data registries. Policy H-160.919, "Principles of the Patient-Centered
34 Medical Home," identifies registries as a mechanism to help ensure that patients receive
35 appropriate care at the appropriate time.
36
37 Policy H-406.998, "Role of Physicians and Physician Organizations in Efforts to Collect
38 Physician-Specific Health Care Data," supports physicians taking a leadership role in developing
39 and participating in data collection systems designed to improve the quality of care, and encourages
40 active involvement of physician organizations and practicing physicians in all aspects of health
41 care data collection and interpretation.
42
43 The AMA also has two policies that support specific types of registries: Policy H-440.899
44 encourages physicians to participate in the development of immunization registries in their
45 communities and use them in their practices, and Policy H-460.923 encourages the development of
46 a melanoma registry to capture data from inpatient and outpatient settings.
47
48 DISCUSSION
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50 There is general agreement that the health care system should support quality improvement efforts
51 that promote the triple aim of better health care, improved population health and lower costs.

1 Unfortunately, the mechanisms for achieving these goals are at times misguided and ineffective,
2 creating complex and burdensome requirements for physicians that yield limited value for patients.
3 In contrast, the majority of clinical data and health registries that currently exist were developed to
4 meet data collection and performance improvement needs that were identified by physicians and
5 patients. CMS' willingness to accept participation in qualified clinical data registries as an
6 alternative pathway for federal quality reporting requirements creates a unique opportunity to
7 promote and expand the use of registries as a physician-led alternative to data collection and
8 quality reporting mechanisms developed by government regulators.
9
10 Through the efforts of hundreds of individual registry stewards, clinical data registries are already
11 providing valuable information that supports improved patient care. However, in order to increase
12 the impact of data registries, it will be necessary to move toward increased coordination of registry
13 efforts. As noted, the NQRN has done extensive work to enhance the understanding of the current
14 state of clinical data registries, and has articulated clear goals related to the advancement of clinical
15 data registries as a tool to promote quality improvement. NQRN's leadership includes members
16 who represent the diverse needs of patients, clinicians, payers, business, regulators, and others who
17 have a direct interest in the development and use of robust, high-quality clinical data registries.
18 This structure allows groups to work collaboratively to identify and pursue common goals that will
19 have the greatest impact on the health care system. The Council believes that such multi-
20 stakeholder efforts are critical to maximizing the potential value and clinical relevance of data
21 registries.
22
23 The use of clinical data registries continues to evolve, and it is critical that policymakers, payers
24 and others allow flexibility in the development and implementation of clinical data registries.
25 However, the Council believes that registries should strive to follow certain guidelines in order to
26 maximize their value. In particular, practicing physicians must be actively involved in decisions
27 related to the development, maintenance and use of clinical data registries and registry data. This
28 helps ensure that the registry is designed and used in a way that enhances patient care and the
29 patient-physician relationship. Registry stewards must also have mechanisms in place to maximize
30 the accuracy and utility of clinical registry data, both the data inputs and the analyses and reports
31 generated from the data. In order to promote stakeholder trust in registry data, data elements and
32 specifications, risk-adjustment models and measures used in the registry should be fully
33 transparent. In order to streamline administrative burdens and facilitate information sharing,
34 registries and electronic health records should be interoperable, and should be capable of sharing
35 and integrating information across systems.
36
37 Registries should provide information that enhances clinical decision-making, facilitates process
38 improvements and supports research that improves patient outcomes and increases the efficiency of
39 health care delivery. In order to ensure the relevance of registry data, registries should provide
40 timely, actionable feedback reports to individual physicians or entities reporting at the
41 organizational level. Registries must also be capable of evolving and adapting in order to leverage
42 advances in technology and accommodate changing information needs. Registry stewards should
43 establish a formal process to facilitate the modification, expansion, or dissolution of the registry in
44 order to ensure continued utility of the registry.
45
46 Widespread participation in clinical data registries is critical to their success and relevance.
47 Physicians should be encouraged to participate in clinical data registries, and efforts should be
48 made to help physicians identify existing registries that are suitable for and of benefit to their
49 patient populations. As registries continue to develop and advance, there are likely to be increased
50 opportunities for collaboration among stakeholders that will maximize the utility of registry
51 platforms and reduce the resources necessary to build or maintain stand-alone systems. The AMA

1 should continue to advocate for and support initiatives that minimize the financial burden to
2 physician practices of participating in clinical data registries.
3
4 Finally, it is likely that the use of clinical registry data to meet third-party quality reporting
5 requirements will become more widespread. The Council believes that continued physician
6 leadership in the development and operation of clinical data registries provides an important
7 safeguard against the misuse of clinical registry data. However, the Council believes it is important
8 that our AMA articulate specific safeguards with respect to the use of physician-specific clinical
9 registry data. Consistent with other AMA policies related to the collection and use of physician
10 data, the Council believes clinical registry data should be used to improve the quality of patient
11 care and the efficient use of resources; cost of care data must be evaluated and reported in
12 conjunction with quality of care data; safeguards must be established to ensure the accuracy of the
13 data; case-matched, risk-adjusted quality measure and resource use data should be provided to
14 physicians to assist them in determining their relative utilization of resources; and when data are
15 collected and analyzed for the purpose of quality reporting requirements, the methodologies are
16 developed in conjunction with relevant physician organizations and practicing physicians, and are
17 disclosed in sufficient detail to allow each physician or medical group to re-analyze the validity of
18 the reported results prior to more general disclosure.
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20 RECOMMENDATIONS
21
22 The Council recommends that the following be adopted, and that the remainder of the report filed:
23
24   1. That our American Medical Association (AMA) encourage multi-stakeholder efforts to
25   develop and fund clinical data registries for the purpose of facilitating quality
26   improvements and research that result in better health care, improved population health,
27   and lower costs. (New HOD Policy)
28
29   2. That our AMA encourage national medical specialty societies, state medical associations,
30   and other physician groups to join the National Quality Registry Network and to participate
31   in efforts to advance the development and use of clinical data registries. (New HOD
32   Policy)
33
34   3. That our AMA support flexibility in the development and implementation of clinical data
35   registries. The following guidelines can help maximize opportunities for clinical data
36   registries to enhance the quality of care provided to patients:
37   a) Practicing physicians must be actively involved in decisions related to the
38   development, maintenance and use of clinical data registries and registry data.
39   b) Data elements, risk-adjustment models and measures used in the registry should be
40   fully transparent.
41   c) Registries should provide timely, actionable feedback reports to individual
42   physicians or entities reporting at the organizational level.
43   d) Registries and electronic health records should be interoperable, and should be
44   capable of sharing and integrating information across registries and with other data
45   sources in a HIPAA-compliant and confidential manner.
46   e) Registry stewards should establish a formal process to facilitate the modification,
47   expansion, or dissolution of the registry in order to accommodate advances in
48   technology and changing clinical data needs to ensure continued utility of their
49   registry. (New HOD Policy)

4. That our AMA encourage physicians to participate in clinical data registries, and will encourage efforts that help physicians identify existing registries suitable for and of benefit to their patient populations and their practices. (New HOD Policy)

5. That our AMA will continue to advocate for and support initiatives that minimize the costs and maximize the benefits of physician practice participation in clinical data registries. (New HOD Policy)

6. That our AMA support that, with the consent of the participating physician, physician-specific clinical registry data may be used to meet third-party quality reporting requirements, in accordance with the following principles:
   a) Data should be used to improve the quality of patient care and the efficient use of resources in the delivery of health care services.
   b) Data related to resource use and cost of care must be evaluated and reported in conjunction with quality of care information.
   c) Effective safeguards must be established to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data.
   d) Case-matched, risk-adjusted quality measure and resource use data are provided to physicians to assist them in determining their relative utilization of resources in providing care to their patients.
   e) When data are collected and analyzed for the purpose of meeting quality reporting requirements, the methodologies used to create the profiles and report the results are developed in conjunction with relevant physician organizations and practicing physicians, and are disclosed in sufficient detail to allow each physician or medical group to re-analyze the validity of the reported results prior to more general disclosure. (New HOD Policy)

Fiscal Note: Less than $500