Policy Forum Perspective

AJKD

The Role of Big Data in the Development and Evaluation of US Dialysis Care

Kevin F. Erickson, Samaya Qureshi, and Wolfgang C. Winkelmayer

Rapid growth in electronic communications and digitalization, combined with advances in data management, analysis, and storage, have led to an era of "Big Data." The Social Security Amendments of 1972 turned end-stage renal disease (ESRD) care into a single-payer system for most patients requiring dialysis in the United States. As a result, there are few areas of medicine that have been as influenced by Big Data as dialysis care, for which Medicare's large administrative data sets have had a central role in the evaluation and development of public policy for several decades. In the 1970/1980s, Medicare data helped identify concerning trends in costs, access to dialysis care, and quality of care delivered. As the research community and policymakers made Medicare's administrative data increasingly accessible for investigation, analyses of Medicare claims have had a large role in facilitating policy synthesis and refinement. Efforts to address the skyrocketing cost of injectable drugs in the 1990s and 2000s exemplify this expanded role of Big Data. Although there are opportunities for large government and nongovernmental administrative data sets to continue serving a critical role in the evaluation and development of ESRD policies, it is important to understand challenges and limitations associated with their use.

Introduction

Rapid growth in electronic communications and digitization, combined with advances in data management, analysis, and storage, have led to the era of "Big Data." There are ongoing efforts to transform large data resources into advancements in nearly every area of science,[1] including health care delivery and policy.[2-4] As technology advances, the term Big Data is used to describe increasingly large data resources. We use this term to describe analyses of large health care data resources, while recognizing that data sets that were once considered to be large may be small relative to data currently available or that might become available in the future.

Few areas of medicine have been as influenced by Big Data as dialysis care, for which Medicare's large administrative data sets have had a central role in the evaluation and development of public policy for decades. The ways that large data sets have been used to guide past policies in dialysis care indicate where they have the greatest potential to inform future policies and where newer data may also have a valuable role in policy evaluation and development.

Large Data Sets and Early Dialysis Policy

In 1972, an amendment to the Social Security Act made almost all patients in the United States with end-stage renal disease (ESRD) eligible for Medicare coverage, regardless of age.[5] Because the federal government became

the primary payer for most dialysis care, the Health Care Financing Administration (HCFA), established in 1977 and later renamed the Centers for Medicare & Medicaid Services (CMS), was able to collect administrative data for most individuals receiving dialysis in the United States.[6]

In the first 2 decades of the ESRD program, researchers and government agencies used Medicare's data to identify and respond to concerning trends regarding cost, access to dialysis care, and, in some instances, quality of care. Between 1979 and 1982, HCFA generated annual reports to Congress demonstrating rapid growth in both the number of patients with ESRD and program cost.[7-9] In some respects, these trends were encouraging because many patients who previously would have died from kidney failure had access to dialysis care. However, these trends also indicated that costs associated with ESRD would likely continue to increase.

Reflecting the central role of the federal government in financing ESRD care, policymakers have maintained an interest in monitoring for and addressing concerning trends involving patients with ESRD. The Omnibus Budget Reconciliation Act of 1981 established the composite rate system for dialysis reimbursement in an effort to rein in federal costs of ESRD care, setting the payment per dialysis treatment at a fixed level of ∼$130. This did not increase over time with inflation or health care costs, leading to several decades of inflation-adjusted declines in reimbursement for dialysis care.[10]

This composite rate system led to concerns that the quality of dialysis care would suffer as a consequence of reduced reimbursement. Analyses of HCFA's administrative data from the 1970s demonstrated a proliferation of free-standing proprietary dialysis facilities that appeared better able to provide dialysis at a lower cost than not-for-profit hospital-based facilities.[11] Some welcomed this trend, noting the potential for private enterprise to advance efficiency in medical care.[12] Others were concerned that profit motives in the setting of decreasing dialysis reimbursement would lead to industry consolidation and subsequently would compromise the quality of care and access to home dialysis and transplantation and shift provider focus away from patient preferences and the greater public good.[13-17]

Initially, only a limited number of researchers and institutions had both access to Medicare's administrative dialysis data and the technical capacity to analyze it. However, they demonstrated how Medicare data could address concerns about the quality of dialysis care. Analyses of Medicare claims data from the late 1970s and early 1980s provided reassurance that survival for patients receiving dialysis improved over time[8] and that there was no significant difference in survival among patients dialyzed at for-profit versus not-for-profit facilities. Meanwhile, several analyses supported fears that declining reimbursement was influencing the composition of dialysis providers and might adversely affect quality of care.[10,18]

Concerns about the quality of ESRD care, supported by analyses of Medicare data, led Congress to ask for the

Institute of Medicine (IOM) to report on the ESRD program. The IOM report, released in 1991, combined expert opinion with findings from studies based on Medicare data and other sources. It included recommendations to: (1) closely monitor the quality implications of changing dialysis provider mix, (2) develop ESRD-specific quality assessment and quality assurance systems, (3) update dialysis reimbursement annually, and (4) develop data systems that more easily link epidemiologic and reimbursement data to address quality of care, epidemiologic trends, and cost-effectiveness[19] (Fig 1).

Expanding the Role of Big Data in Policy Analysis

The IOM's recommendation to enhance data collection reflected broader acknowledgement that Medicare's administrative data could advance dialysis care. The Omnibus Budget Reconciliation Act of 1986 directed the Secretary of Health and Human Services to establish a "National ESRD Registry" that would study, among other things, the economic impact and cost-effectiveness of alternative dialysis modalities, epidemiologic trends, and resource allocation.[20] Meanwhile, the value of ESRD registries in other countries led to calls from the kidney research community for development of a US ESRD registry.[21] This culminated in development of the US Renal Data System (USRDS) registry in 1988, jointly funded by HCFA and the National Institutes of Health (NIH).[6] The USRDS database made Medicare's ESRD data accessible to
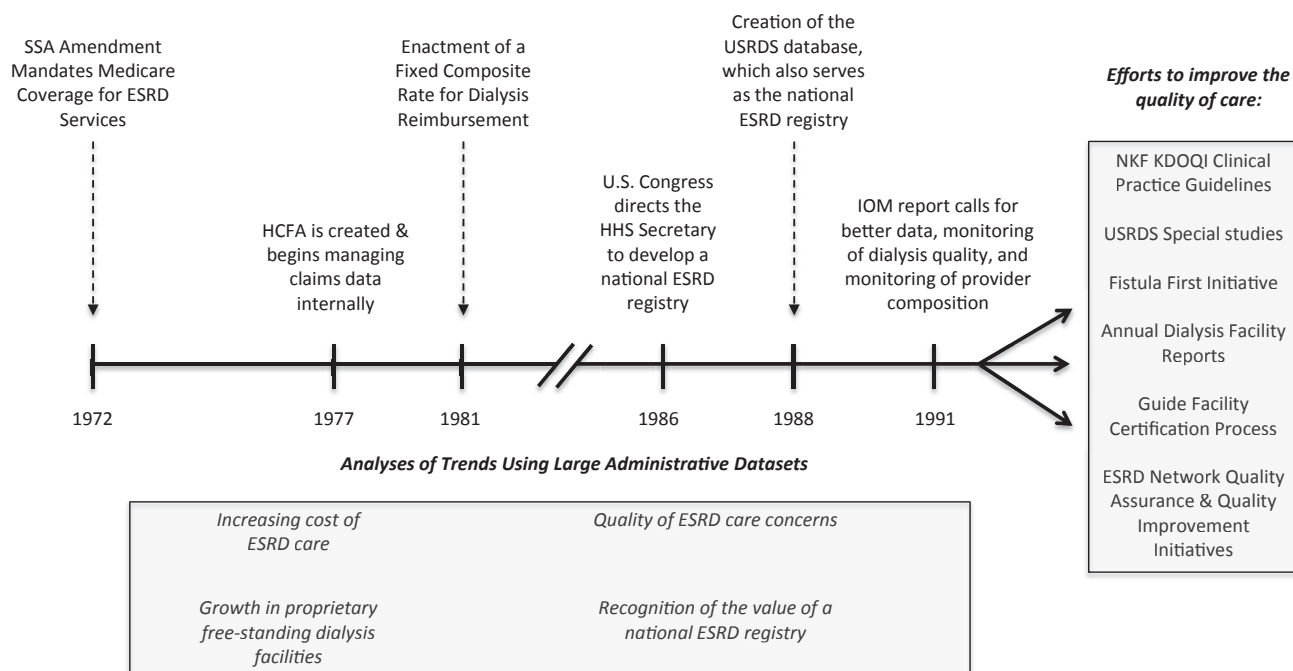
Figure 1. The influence of large administrative data sets in early end-stage renal disease (ESRD) policy evaluation and development. Abbreviations: HCFA, Healthcare Financing Administration; HHS, Health and Human Services; IOM, Institute of Medicine; NKF KDOQI, National Kidney Foundation Kidney Disease Outcomes Quality Initiative; SSA, Social Security Act; USRDS, US Renal Data System.