CMS 2728: What Good Is It?

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Layton et al. (1) have an interesting assessment of the accuracy of glomerular disease as a reported cause of ESRD in the US Renal Data System (USRDS) database. In short, their conclusions are fairly damning. For patients with glomerular diseases (GN), there is only 14.8% agreement between what is reported on the Centers for Medicare and Medicaid Services (CMS) 2728 form and biopsy results.

Of the potential reasons listed by the authors, the most plausible is that attending physicians had no access to patients’ medical histories. Not mentioned by the authors is the likelihood that the form was filled out by an administrative assistant with little or no medical expertise or knowledge of the patient. Even more discouraging, cause of renal failure was missing in 57% of cases. Cause of renal failure is missing in only approximately 1% of cases in the USRDS in general (2). Whether the high rate of “missing” in this study is a local phenomenon or is more common when the underlying disease is GN is unknown.

However, the incidence of GN as the reported cause of ESRD has remained steady at between 8000 and 9000 cases per year since 1994. Because there are only approximately 500 cases of “missing” cause each year, it does not seem that the GN cases would be found there.

We can thank Otto Von Bismarck for the oft-quoted maxim, “Laws are like sausages, it is better not to see them being made.” The same can be applied to many aspects of large-scale registries such as the USRDS. Those of us who work with the data tend to get used to vagaries of the data collection enterprise and try to be up front in our strengths and weaknesses sections of manuscripts. Conversely, studies like Layton’s are a useful reminder that the data can be pushed only so far.

The 2728 form has been around since the initiation of the program in 1973. It was and is a necessary method of determining Medicare eligibility for those who do not otherwise qualify for Medicare on the basis of age or disability. Many aspects of the form are legally required. For example, the physician attestation is there to prevent a backdoor entry into Medicare for patients who would not otherwise qualify. Similarly, the transplant data and the ESRD self-dialysis training are required for patients to qualify for Medicare in less than the 90-day waiting period designated by law. And of course, patient identification (e.g., name, Social Security Number) are needed to enroll the patient.

Most of the other elements on the form are more or less optional. CMS 2728 has been revised at least three times, in 1987, 1995, and 2005. Each time, the revision was initiated by staff from CMS and underwent a fairly rigorous vetting by representatives of the renal community. In addition, it must be approved by the Office of Management and Budget. It is at this point that each item has to be justified for inclusion by weighing the benefits of data collection against the burden of filling out the form.

The USRDS itself is a Congressionally mandated entity (Omnibus Reconciliation Act of 1986, PL 99-509). Among the requirements of the legislation are that the USRDS (1) characterize the ESRD population; (2) describe the prevalence and incidence rates of kidney disease that lead to ESRD; and (3) investigate the relationship among the modalities, diseases, and patient groups. These requirements are used to justify the clinical variables on the CMS 2728 form.

The USRDS is a compilation of many databases that go far beyond the contents of CMS 2728. More than 2 million patients are included in the ESRD portion of the USRDS. CMS 2728 data are supplemented with Medicare enrollment and coverage data, Social Security mortality data (more than 1.5 million deaths), more than 340,000 transplant records from the Organ Procurement and Transplant Network, 750,000 Medicare hospital payment records per year, and more than 100 million Medicare physician/supplier records per year. Each year, the USRDS adds 110,000 patients to the registry, with the accompanying administrative, transplant, death, and billing data. With that volume of data, it is hardly surprising that it does not meet the same standard of precision as biopsy data.

But is it any good at all? I would say yes. It certainly gives a broad picture of ESRD in the United States. Ascertainment of ESRD is virtually 100% complete, as are mortality and transplantation. Cause of renal failure and the much maligned comorbidity data do pick up some clinical “signals.” Mortality, hospitalization, and cost tabulations reported in the Annual Data Report and in the renal literature by users of the data are consistent with the burden of disease one would expect of, say, diabetes, as compared with GN.

ESRD Network personnel and the USRDS staff do a fair

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amount of data cleaning and oversight. In addition, we make
the USRDS available to researchers on a fairly regular basis.
Approximately 30 to 40 data requests are approved each year.
Having independent research studies such as these help to
ensure that "fresh" eyes are continually examining the data.
Also, in the past few years, we have expanded the data
availability for linkages with outside databases. These include
large-scale epidemiologic databases such as ARIC, REGARDS,
and PICARD; administrative/clinical databases such as North-
ern California Kaiser, FMC, Davita, and DCI; and clinical trial
databases such as the MDRD and ALLHAT trials. It is these
outside linkages where the strengths of local data collection can
be combined with the breadth of USRDS cost and outcome
ascertainment to conduct more powerful analyses.
The USRDS is a valuable national resource and may be the
finest national disease-specific registry in the world. It does not
(and cannot) attain the specificity of small clinical databases but
will be an important adjunct to both clinical and trial study
efforts as long we do not expect it to replace clinical informa-
tion.

Disclosures
None.

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See related article, “Discrepancy between Medical Evidence Form 2728 and Renal Biopsy for Glomerular Diseases,” on
pages 2046–2052.