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REFERENCES


A Modest Proposal to Spur Innovation in Chronic Dialysis Care

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The kidney care community bemoans the lack of innovation not only in treatment of CKD but also, in the therapy of chronic kidney failure by dialysis. To be sure, chronic kidney failure care is better today than at the inception of its modern era, which I take to be the federal Medicare legislation of 1972. Accurate volume control of ultrafiltration, erythropoiesis stimulating agents, and therapies for bone disease are a few notable advances over that nearly half century, but there have been few such advances over the last two decades; especially lacking are ones that could be considered patient centered. Thoughtful analyses targeted at improving dialysis research have been recently published.1 Money to

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support research would, of course, be critical.

I am proposing that for-profit dialysis providers pay a research contribution of $3.00 dollars for each dialysis treatment paid for by commercial insurance and $0.50 for those treatments paid by Medicare. This differential stems from the fact that commercial insurance provides the large share of profits for dialysis providers, whereas Medicare payments are said to be almost equal to the costs of dialysis.\(^3\) Such a graduated set of fees should also guard against Medicare-dominant clinics being closed as money losers. I estimate that this would yield slightly \(>\$58\) million/yr. This represents a tiny fraction of the $4 + billion of the annual profits of the two major dialysis providers. Precedent exists for such a payment. The ESRD Networks are supported by a similar payment system (50 cents per treatment).\(^3\) Like the support of the renal networks, a congressional authorization might be required for the Medicare contribution.\(^3\) Indeed, if this proposal is to have traction, support from multiple entities both governmental and nongovernmental will be needed. Although the details of how the money would be disbursed are important, one model to consider is that used for the Patient-Centered Outcomes Research Institute (PCORI). That organization, a facet of the Affordable Care Act of 2010, receives several streams of funding, but a major one is a fee assessed on private insurance and self-insured health plans. Research proposals to the PCORI are reviewed by a panel that includes patients and their advocates, experienced researchers, clinical experts, and relevant commercial entities such as insurers and pharma (J.P. Briggs, Interim Executive Director of the PCORI, February 4, 2020; personal communication).\(^4\) Furthermore, dialysis providers themselves might propose and conduct trials under such a program. Other grant-funding mechanisms, notably the National Institute of Diabetes and Digestive and Kidney Diseases, would also be a natural choice as a funder with the research targeted on chronic kidney failure are with patients and providers as well as researchers participating in funding decisions.

Of the over $58 million deriving from the proposed fees, probably 10%–15% would be needed to support the administrative costs of such a granting agency, leaving about $50 million for research work. The PCORI 10% maximum for overhead seems reasonable. This would be a major increment to current funding. A Government Accounting Office report in 2016 noted that the National Institutes of Health (NIH) supported $564 million of kidney-related research in 2015.\(^5\) The fraction of this support directed at improving dialysis is unclear, but surely, it is a small minority because many aspects of kidney disease and function, not just dialysis, are rightly within the NIH’s purview.\(^6\) For example, not only are kidney physiology and the usual nephrologic diseases included but so are urologic and kidney cancer research. This proposal would almost surely more than double the current research funding for chronic kidney failure care.

Why has chronic dialysis related research been so slow? One answer is that many of the problems are hard ones and not readily solved, but the research expenditures of the funding agencies and the minimal ones of major dialysis providers must also be noted. The two largest dialysis providers had combined profits of over $4 billion in 2018, but their annual reports hardly note research expenditures.\(^7,8\) The providers clearly have researchers on their staffs, but this research seems to be dominantly directed at improving practice efficiency and commercial outcomes or remunerative testing of products from other commercial entities such as pharma. By contrast, one major pharmaceutical company spent a bit over $9 billion on research and development in 2019.\(^9\) Thus, $58 million seems a trivial amount compared with the dialysis industry’s profits, but as noted, it would be a real boost to current funding in this area.

Dialysis provider charitable activities are typically directed at maintaining goodwill for affiliated physicians and patients with little or no application to research that could improve care and quality of life for those patients or all patients with chronic kidney failure. To be sure, there are a few notable examples in which for-profit dialysis provider companies have contributed to research by working with the NIH, such as in the Frequent Hemodialysis Network and the Time Trial. They have also permitted research initiated at local levels in their centers but usually charge for it.

At various times, certain portions of the dialysis industry have supported investigator-initiated research. As examples, in the past Baxter and Satellite Health Care solicited such proposals, but they no longer seek unrestricted applications. Some providers (e.g., DCI, Northwest Kidney Centers, and RRI) have also provided support but usually to individuals or groups in their systems, and none have issued grants in the magnitude that this proposal envisions.

Why might the dialysis providers be so unsupportive of research? Providing the dialysis care to hundreds of thousands of people is in itself costly and difficult. For this scale of care, the providers are to be congratulated. One reason for the paucity of industry-sponsored research may be that some potential important findings might not be patentable, unlike the research and development usually performed by pharma, and therefore not in the interest of stockholders. For example, discovering a better dialysate bath composition likely would not yield a proprietary formula. However, to offset this problem, the providers themselves might apply for and receive support to fund important trials that would not yield a patent. Probably, yet other barriers exist. Currently, dialysis care in centers is virtually industrialized; if certain bath compositions benefited certain patients, then individualizing them would confound the smooth running of such units. Indeed, dialysis care must be one of the least “personalized” sectors of current health care. Other problems, such as the safety of ultrafiltration, have not received sufficient attention. For example, one blood volume monitoring device, Crit-Line, is
proprietary and inadequately tested on a convincing scale. Assessment of appropriate fluid volumes is a notoriously fraught business in nephrology, but application of resources to this problem has been in our view meager. Cramping and itching are major problems for patients, and very little is known about their causes; therefore, therapies are almost nonexistent. Most nephrologists doubt that urea itself is very toxic. Rather the many disabilities suffered by patients with chronic kidney failure are likely the result of other solutes that may not be removed as readily as urea. Discovering those more relevant toxins (and devising means of lowering them) would not be easy, but without substantial research support, it will never occur. It is likely the case that the dialysis providers are content with a urea removal–based operation proceeding with business as usual, whereas more advanced or personalized care would just be a hindrance to the smooth running of typical dialysis centers.

A very modest fee collected on the basis of dialysis treatments could provide a major stimulus to chronic kidney failure research. The PCORI-type mechanisms for grant review could be adapted to the chronic kidney failure setting. We should stop bemoaning our fates and more importantly, those of our patients and advocate some means of raising the resources. Without money, there will be no innovation.

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