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Influenza Vaccination in a High-risk Population:
An Evidence-Based Approach to Public Health Practice

By

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Doctor of Philosophy

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Abstract

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By T. Christopher Bond

The vaccination of high-risk patients against influenza and other vaccine-preventable diseases is a public health priority. Evidence-based guidelines about how best to increase vaccination rates among high-risk patients are currently lacking or inconclusive. This dissertation reports the results of a multiyear plan to increase influenza immunization rates among patients with end-stage renal disease (ESRD) in 3 dialysis Networks (65,000 patients in 14 states).

The first study determined that the adoption of a controversially broad policy for vaccination ordering (facility-wide standing orders) may not be necessary. Instead, a provider survey and multivariable analysis of vaccination data showed that two policy options (chart orders and facility-wide orders) were equivalent in their associations with immunization against three vaccine-preventable diseases. Based on these data the Networks could work with a minority of centers to adopt one of two policies.

As part of a direct effort to increase influenza vaccination rates at poorly-performing centers, we developed a protocol for a multifaceted intensive intervention within a group-randomized evaluation. This design of this second project allowed us to isolate the marginal benefit that the "intensive" elements provided over standard intervention and controlled for the very high year-to-year variability among these underperforming centers. The results showed that the effect of the intensive intervention was significant (+8.9%), but not nearly as powerful as had been previously estimated.

A third study provided an estimate of the increased mortality risk associated with failure to receive influenza vaccination among ESRD patients. Using newly available data on recent patient health status, we were able to provide an adjusted odds ratio for all-cause mortality by vaccination status using data from the ESRD Networks. The odds ratio for 1-year all-cause mortality was 0.83 (95% CI: 0.76, 0.91) for vaccinated versus unvaccinated patients. This study also highlighted changes that could be made to ESRD data collection to ensure a self-sufficient dataset for future evaluations.

As a whole, these three studies applied evidence-based public health methods to discourage a difficult policy change that would have had little benefit, re-evaluate the impact of intensive (and resource-intensive) intervention, and estimate the impact of vaccination increases on patient outcomes.

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CHAPTER 1: INTRODUCTION

The public health project outlined in this dissertation was conducted as part of a multiyear program by the Safe and Timely Immunization Coalition (STIC) to increase immunization rates at dialysis facilities across three End-Stage Renal Disease (ESRD) Networks in 14 states. Adding efficient data collection tools and making small changes to the usual quality improvement (QI) practices in these three Networks allowed for evidence-based program evaluation.

I was involved in all aspects of the STIC program—including the development of an immunization resource guide for dialysis centers, the publication of new vaccination guidelines for patients with end-stage renal disease and chronic kidney disease,[1] and the design and implementation of an intensive intervention program to increase influenza immunization rates at poorly-performing dialysis centers. My contributions to the STIC program that are outlined in this dissertation include:

- A survey of dialysis center practices, beliefs, and attitudes which, when analyzed in light of vaccination rates for influenza, hepatitis B, and pneumococcal disease, provided key information about potential interventions to increase vaccination rates.

- A group-randomized assessment of the relative impact of a new intensive intervention program versus a standard intervention program to increase influenza vaccination rates at poorly-performing centers.

- The compilation of patient data from various sources in a multilevel analysis that produced a more complete picture of the association between influenza vaccination and mortality risk.

As a whole, the project applied evidence-based methods to a complete cycle of continuous quality improvement: assessment of practices, beliefs, and attitudes, collection of baseline data, preliminary analysis of that data, the implementation of an intervention, an evidence-based evaluation of that intervention, and a way to estimate the impact of the measured improvement on patient outcomes.

STIC began as a special project in 2005, organized in response to a Centers for Medicaid and Medicare Service (CMS) mandate to address low immunization rates among ESRD patients. The coalition was organized by 3 multistate ESRD Networks: Network 6 (North Carolina, South Carolina, Georgia), Network 11 (Michigan, Minnesota, North Dakota, South Dakota, and Wisconsin) and Network 15 (Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming). These Networks combined their administrative resources and invited participation from representatives of the Centers for Disease Control and Prevention (CDC), the American Association of Kidney Patients (AAKP), the American Nephrology Nurses' Association (ANNA), large dialysis providers, state survey agencies, quality improvement organizations, and Emory University. The goal of STIC is to achieve 90% vaccination rates for influenza, hepatitis B, and pneumococcal disease, in correspondence with healthy people 2010 goals.[2] This was considered feasible given various characteristics of this population. In comparison to other at-risk patient populations, ESRD patients have frequent encounters with the healthcare system: most receive dialysis treatments 3 times per week at a hemodialysis facility. Also, the costs of

care for ESRD patients, including vaccination, are covered under Medicare or a combination of Medicare and Medicaid.

The ESRD Network system was founded in 1978. Each Medicare-certified dialysis facility in the U.S. participates in one of these 18 regional Networks (**Figure 1-1**), which are in turn under contract to CMS. The Networks are responsible for assuring appropriate care for patients through quality monitoring and improvement of the care ESRD patients receive, collecting data to administer the national Medicare ESRD program, providing technical assistance to patients who have ESRD and providers, and addressing patient grievances.

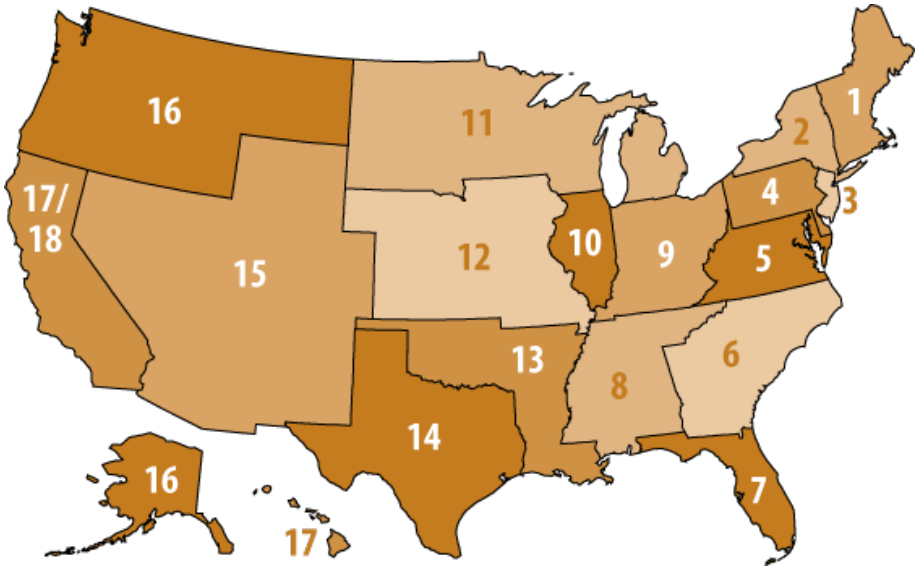

Figure 1-1. Map of the 18 ESRD Networks.

The ESRD Networks collect information about patient characteristics and outcomes and store such data in the Standard Information Management System (SIMS). SIMS data is part of the U.S. Renal Data System (USRDS). See **Figure 1-2**.

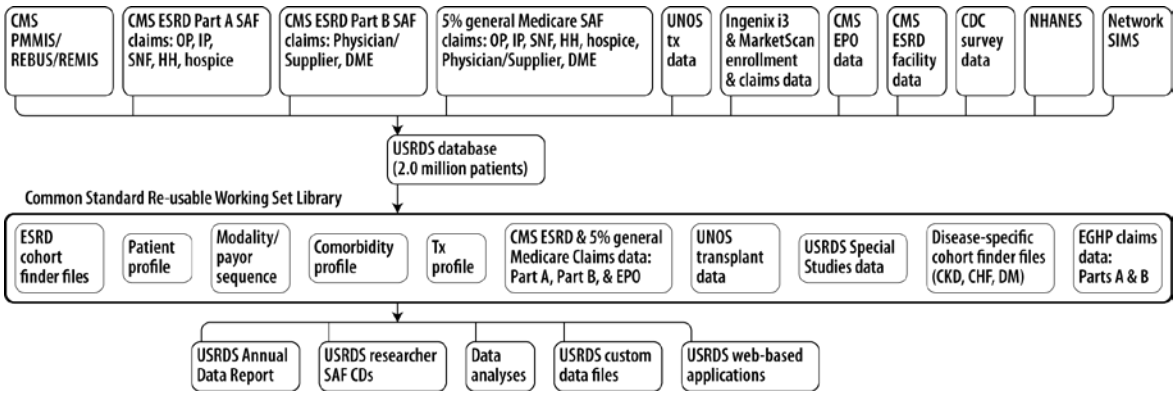

Figure 1-2. Structure of the U.S. Renal Data System.

The VPBA Survey: Association of Standing Order Policies with Vaccination Rates in Dialysis Clinics

The Vaccination Practices, Beliefs, and Attitudes (VPBA) survey collected data about how patient vaccinations against influenza, hepatitis B and pneumococcal disease are ordered within each center (from individual physician orders for each vaccination to a facility-wide policy that all patients receive vaccination without any explicit orders). It also ascertained potential barriers to implementation of facility-wide standing order programs for vaccination, a center's likeliness to change its policy (and the roles involved in such a decision), and the existence of standing order policies for procedures or processes other than immunization. Center administrators were asked about specific vaccination practices such as the use of tracking systems or documentation, reminder mechanisms, performance assessment programs, and provider feedback, and about the level of patient and staff education they provide. They were also asked about their attitudes, opinions and beliefs with regard to the severity of these three vaccine-preventable diseases, the risk/benefit of immunization, and the level of responsibility the dialysis center bears to ensure patients receive vaccinations.

Manuscript 1 details the conclusions of the survey and the associations found between existing policies and practices and vaccination rates for hepatitis B, pneumococcal disease, and the influenza season that corresponds to the survey period.

Assessment of an Intensive Intervention to Increase Influenza Immunization Rates

The program outlined in **Manuscript 2** was designed and conducted as a group-randomized evaluation in which two equivalent sets of poorly-performing dialysis clinics were given different interventions (standard or intensive). Though much effort was given to designing the intensive intervention program according to the best evidence available, the randomized, controlled assessment of the program was the primary contribution of this element of the project. Previously the Networks had given an "intensive" intervention to the poorest performing centers and compared the mean change in vaccination rates for these centers to the change in rates for all centers. This critically flawed method does not account for the high year-to-year variability in rates among poorly-performing centers. Our goal was to provide a more accurate picture of the effectiveness of a well-documented intensive program and show how much of the change seen in the past may have been due to regression to the mean for the poorest-performing centers. The program itself was designed to be part of a pragmatic evaluation—intensive intervention centers followed a set protocol for building and reporting their action plans, but were given a range of options with regard to the specific interventions they chose.

The standard intervention included the resources available to all centers throughout the Networks. These included a resource guide of educational materials on hepatitis B, influenza, and pneumococcal immunizations and guidelines for the vaccination of kidney

dialysis patients and patients with chronic kidney disease.[1] Both of these were produced by STIC. All centers also received a feedback report summarizing their vaccination rates from the previous year and how their rates compared to those of their state, their Network, and across all 3 STIC Networks. The report also reiterated the 90% goal for vaccination of dialysis patients.

Multilevel Analysis of Influenza Vaccination and Mortality

In order to assess the impact of increasing influenza immunization, we wanted to determine whether prevalent ESRD patients (receiving dialysis for at least 1 year) who received an influenza vaccination had a lower all-cause mortality risk in the 12 months following the start of flu season than those who did not. The availability of both individual and center-level data on patient characteristics (demographics and comorbidities) and vaccination allowed us to adjust for interactions between center and patient characteristics as well as for unmeasured confounding by center. Ignoring such group-level variables in the presence of individual-level data has been shown to have potentially large effects on parameter estimation.[3] We also were able to add data about recent health status (lab data) to the models for effect estimation. The ability of the Networks to account for outcomes within their own data system (SIMS) is essential to their ability to evaluate the effectiveness of their programs. The strengths and weakness of the data in this area have implications for the system as a whole and must be explored.

In addition to providing an adjusted estimate of the association between mortality and influenza immunization (**Manuscript 3**), this element of the project also included two additional assessments. A sensitivity analysis explored the variation in mortality rates

within vaccination categories (eg, vaccinated at center versus vaccinated elsewhere, or refused versus not offered vaccination) and the impact of missing vaccination data. An assessment of the utility of individual-level versus facility-level vaccination data was also conducted. If facility-level data (vaccination rate and mortality ratio) proved to be as useful as individual-level data (vaccination and death), resources might be saved with a simpler annual data collection.

CHAPTER 2: LITERATURE REVIEW

In this dissertation, the general principles of evidence-based public health were applied to influenza vaccination in a population of dialysis patients, each of whom receives treatment at a specific dialysis center. The following sections review what has been reported about this health issue in this population (and similar patient populations) and where gaps in this knowledge necessitated these further studies.

Evidence-Based Public Health

Evidence-based public health uses a combination of *population-based data* and *data on intervention programs* to allow decision makers in health systems to make rational, well-founded decisions about public health programs.[4] It is concerned with what the National Institutes of Health (NIH) calls Type II translation: the adoption and institutionalization of effective practices in the community.[5]

Population-based data in this context includes the health status of members of the population, their risks, and the potential outcomes of health issues (such as morbidity, mortality, economic impact). It also includes the attitudes and beliefs of population members and healthcare providers regarding the specific health issue.[4]

In addition to providing useful data about general attitudes and beliefs, analysis of attitudes and beliefs within a system can reveal variations in care that cut along institutional lines (eg, the number of patients at a dialysis facility or its profit status) or individual characteristics (eg, the race, age, or socioeconomic status of patients). Geographic and treatment center variations in care in this patient population have been

described in detail for adequacy of dialysis,[6, 7] pre-ESRD care,[8] and kidney transplant waiting lists.[9] Guidelines for standardizing clinical performance measures to evaluate discrepancies in ESRD patient care were published in 2003.[10]

Detailed data regarding interventions are essential to assess their success or failure and their generalizability to other populations. An evidence basis for a program or policy can be found externally in systematic reviews of the peer-reviewed literature. The largest and best-known source of such reviews is the Cochrane Collaboration, which has provided systematic reviews (and updates) about healthcare interventions since 1993. The U.S. Preventative Services Task Force (USPSTF), operating as part of the Agency for Healthcare Research and Quality (AHRQ), provides evidence-based information on healthcare outcomes, quality, cost, use, and access in the form of an annual *Guide to Clinical Preventive Services*[11] and other publications. AHRQ itself also conducts research that adds to this information base.

Evidence-based practice guidelines issued by authoritative institutions, when available, are considered the gold standard for general recommendations about process. (For example, National Kidney Foundation-Dialysis Outcomes Quality Initiative (K/DOQI) clinical practice guidelines have been issued on a variety of topics since 1997.[12-14]) However, reviews by the Cochrane Effective Practice and Organization of Care group in 1998 and 2004 found that passive dissemination of guidelines (via publication) is "generally ineffective" and that specific strategies are needed to ensure uptake.[15, 16] Systematic reviews of evidence-based strategies for implementing guidelines have been attempted in some specialties (in, for example, obstetrics[17] and psychiatry[18]). However,

the variable reporting methods and poor general quality of studies usually cannot support definitive conclusions about how to ensure the adoption of guidelines.[16]

Communication and dissemination issues aside, an evidence-base founded in externally-produced reviews, expert panels, or guidelines cannot serve all the needs of a system. Even if a concept for a new policy or program has been validated externally and appears to be applicable to the population at hand, it must go through a recursive process of revision and testing internally to suit the population and system in question.[19, 20] To be fully engaged with evidence-based public health practices, a healthcare system must conduct data collection and analysis of its own activities. These activities allow for modification and refinement of the program as part of a continuous cycle of quality improvement. To the extent they are generalizable, these observations can also contribute to the general evidence base in the scientific literature. This has been referred to as evidence-based implementation of evidence-based care.[21, 22] This cycle has been described in detail by McClellan et al. in the case of improving dialysis adequacy in ESRD Network 6.[6, 7]

Assessing Health Status and Risk

End-stage renal disease (ESRD), also known as kidney failure or stage 5 chronic kidney disease (CKD), is a condition in which a patient requires renal replacement therapy (dialysis) or transplantation. In most cases, ESRD is caused by long-term damage to the kidneys due to diabetes (43.8%) or hypertension (26.8%).[23] Kidney damage can also cause hypertension or worsen existing hypertension.

Between 2000 and 2007, the prevalent dialysis population (patients on dialysis for 1 year or more) in the U.S. increased 20%—to 370,000. The vast majority (92.8%) of these patients received hemodialysis at dialysis centers and are the patient population for this project. Hemodialysis patients receive dialysis approximately 3 times per week at a dialysis facility—a process of filtering the blood which takes 4-5 hours. The remaining patients received various types of peritoneal dialysis—which include varying degrees of contact with dialysis providers.[23]

The growing prevalent population in this period where incidence rates for ESRD have stabilized indicated longer survival for ESRD patients. However, people with ESRD have significantly higher adjusted rates than the average population for mortality (192.8 per 1000 patient years), all-cause hospitalization (1.94 per patient-year) and infection-related hospitalization (0.45 per patient-year).[23] For this reason they are considered high-risk patients and prioritized for immunization against influenza and other vaccine-preventable diseases.[1, 24]

Demographic data and heath status at initiation of dialysis as well as dialysis center characteristics are readily available for this population through the Standard Information Management System (SIMS) database. (See **Methods, Data Sources**.) Information about demographic data and center characteristics is crucial to the analysis at hand due to known associations with vaccination likelihood and probability of mortality. Black patients are less likely to receive influenza vaccination[25] and also have lower mortality rates than whites according to the U.S. Renal Data System (USRDS).[23]

A preliminary analysis of previous data from Network 6 showed that vaccination rates increased with the age of patients and were slightly higher among men.[26] The number of patients treated at a facility and its profit status have also been discussed as correlates of quality of care and outcomes in this and other high-risk populations, with inconclusive results.[27-30] An analysis of previous data from Network 6 did find that vaccination rate was inversely associated with size of center and that vaccination rates at for-profit centers were lower.[26]

The adequacy of the immune response to influenza vaccination among ESRD patients has been established in several studies. In two separate studies, Antonen et al found that dialysis patients had lower antibody increases but reached a protective antibody level at an comparable proportion in comparison to cardiac patients with normal renal function[31, 32] and that the cross-reactivity of vaccination-induced antibodies in dialysis patients was as good as that in young healthy males.[32] Other studies also found adequate immune response in patients with ESRD and similarly recommend vaccination against influenza in dialysis patients.[33, 34] This conclusion about an impaired-but-sufficient immune response countered small pharmacokinetic studies in the 1970s and 1980s,[35-37] which had generally been interpreted as evidence against the vaccine's efficacy in this population and continue to be cited.[38]

The Centers for Disease Control and Prevention (CDC) conducted national surveillance of immunization of dialysis patients (among other measures of care) and found that the influenza vaccination rate among dialysis patients was 65% in 2001-02.[39, 40] Previously, Gilbertson, et al had used Medicare billing data to determine that the influenza vaccination rate of dialysis patients was under 50% in the 1997-98 and 1998-99 influenza

seasons.[41] However, this rate was lower than that reported from surveillance data collected by Network 15 during this time period.[42]

At the beginning of this project in 2005, the Advisory Committee on Immunization Practices (ACIP) vaccination guidelines regarding influenza had been published for the general population and included specific statements for some high-risk populations (children, adults aged ≥ 65 years, residents of nursing homes, women pregnant during the influenza season, and immunosuppressed persons). Though these guidelines also mention a variety of patients with system/organ compromise, they do so in a general way that includes up to 73% of the population (when caregivers are also considered).[43-45] This leap from high-risk populations to other individuals left an essential gap in the guidelines for patients such as those with CKD or ESRD. Previously-issued ACIP vaccination guidelines for dialysis patients (children and adults) had discussed influenza vaccination briefly, but in the context of reduced antibody response.[46] The work of the coalition involved in this project included writing and publishing new guidelines specifically for vaccination of patients with CKD or ESRD.[1]

Assessing Attitudes and Beliefs (Manuscript 1)

Several issues regarding attitudes and beliefs are relevant to influenza immunization of dialysis patients: those of patients to the risks of influenza and the safety and efficacy of the vaccination, those of healthcare providers to the risks of influenza and the safety and efficacy of the vaccination, and those of healthcare providers to vaccination guidelines and policies.

Surveys of community-dwelling elderly in the U.S. found that patient education regarding the vaccine[47] and perceptions of physician and other healthcare provider attitudes to vaccination[47, 48] were associated with their current vaccination status. Studies of influenza vaccination disparities found assess barriers, cost barriers, underestimation of personal risk and misunderstanding of vaccination risk, and mistrust of the healthcare system.[49, 50] Misunderstanding of vaccination risk and mistrust of the healthcare system were particularly strong among black patients.[49, 51, 52] No studies of vaccination attitudes and beliefs among dialysis patients were found. The particulars of dialysis care and reimbursement remove barriers to assess and cost.

Strong guidelines for the vaccination of healthcare professionals against influenza were issued in 2006.[53] Subsequent studies have shown significant lag in uptake of these recommendations, with convenience and cost burden to the healthcare provider as the most strongly indicated barriers among U.S. healthcare providers, particularly nurses and allied health professionals.[54, 55] However, the level of basic knowledge about influenza has been also shown to be associated with vaccination in U.S. nurses[56] and some studies of U.S. nurses cite reasons for non-vaccination such as perceived lack of susceptibility, doubts about vaccine efficacy, and concerns about side effects.[57] These concerns were much more prevalent (or more readily expressed) in nursing surveys from other countries.[58-62] Free programs and policies under which healthcare providers must sign declination forms have been shown to increase rates among U.S. healthcare providers.[54, 63]

Studies which have looked at associations healthcare provider attitudes and beliefs and their own vaccination status have also found that these attitudes and beliefs impact their

recommendations to patients.[64] A study of 1182 nurses in British Columbia found that those who reported previously suffering from severe influenza effects were much likely to be vaccinated and recommend vaccination to others.[55]

Documented barriers to ACIP patient vaccination guideline adoption by healthcare providers include lack of education regarding guidelines,[54, 64, 65] patient refusals,[66] and the unprofitability of vaccination programs.[67] The lack of knowledge can be striking. For example, one study of pediatricians in Chicago detailed the lack of knowledge about the severity and complications of influenza infection in young children, contraindications to receiving vaccination, and the use of 2 doses for some patients.[65]

As will be discussed below, standing order programs have been employed as a method of increasing guideline adoption and have been cited as a best practice. However the adoption of a policy option that removes permissions barriers and makes patient vaccination a part of routine patient care brings its own set of issues related to institutional attitudes and beliefs. Barriers to standing orders documented in long-term care facilities include primary legal concerns (liability, lack of authority)[68] but no data were available about such barriers in dialysis centers.

In order to assess dialysis provider attitudes and beliefs about vaccination, we developed a survey of standing order policies in dialysis clinics. This survey was based in part on a survey of long-term care facilities previously used by the CDC and the Centers for Medicaid and Medicare Services (CMS).[27] Additions and changes to the survey were based on two well-established theories of individual-level health behavior models: the health belief model and the transtheoretical model.

The core of the health belief model is based on value expectancy theory: perceptions of risk, severity, benefits, and barriers.[4, 69, 70] In the case of influenza vaccination and dialysis providers such considerations would include: the risk of the patient contracting influenza, the potential severity of that outcome, the efficacy versus safety of vaccination, and the practical obstacles to vaccination (procedural, risk of refusal, etc.). Other elements of the model have been added in recent years to emphasize the mutability of health beliefs. These include modifying variables (such as personal experience with influenza), cues to action (initiatives that may change behavior), and self-efficacy (perceived active role in influenza prevention).[69] This model fits well with the reviewed literature about patient and healthcare provider explanations for failure to receive vaccination. The relationship between various components of the health belief model and influenza vaccination receipt has been validated in a post-vaccination survey of nurses in Israel[71] and pre-and-post surveys of healthy clerical and service workers in the U.S.[72] and the elderly in Denmark.[73]

The transtheoretical model is based on stages of change from one health behavior to another—either on an individual or an organizational level.[74] In this case the model applies to transition from one policy to another (the adoption of facility-wide standing orders). In the survey, center administrators were asked about their willingness to change policies, with responses roughly corresponding to the stages of change: precontemplation, contemplation, preparation, action, or maintenance (for those with the policy in place). This model has been discussed specifically in relation to guideline dissemination.[75] However, the transtheoretical model is—as its name states—an amalgam of other behavioral theories. “Readiness to change” has become such an ingrained concept that it

is rarely cited explicitly. The analysis of barriers in the health belief model was also applied to the issue of potential policy change.

Evidence Basis for Vaccination Policies and Practices

Standing order policies—which reduce the permissions burden for vaccination allowing vaccination without a signed physician's order—have been advocated as a best practice in recent years in various contexts. A 2002 CMS policy change removed the federal requirement for an individual physician-signed order for pneumococcal and influenza vaccination in CMS-participating institutions.[76] One previous and multiple subsequent guidelines advocated the adoption of these policies for vaccination of high-risk patients.[43, 77-79] Some evidence for the positive association between new standing order policies (as a part of multicomponent interventions) and vaccination rates has been shown in long-term care facilities[28, 80-82] and in a 10-year study at a Veterans Administration (VA) hospital.[83, 84] In the VA study, influenza vaccination rates for high-risk patients increased from 58% during the 1987-88 vaccination season to 84% in 1996-97 ($p < 0.001$). At the University of Pittsburgh Medical Center-Presbyterian, pneumococcal vaccination rates for inpatients improved after initiation of a standing order program: from 15% in 2003 to 69% in 2005.[85] However, other studies have detailed failed attempts to institutes such a system.[86, 87] The use of standing orders for vaccinations in dialysis centers has not previously been described.

Other practices have been found to be related to higher vaccination rates when introduced into the clinical setting. Practices that have been shown to increase various vaccination rates among high-risk groups include the following elements, usually employed in some combination: assessment and feedback, provider education, patient education, physician reminder/recall systems, patient reminder/recall systems.[27, 28, 68, 88-92] Evidence for the efficacy of single component interventions from this list have been published for physician reminder/recall systems,[89] centralized tracking of immunization,[90] and patient reminder/recall systems.[91, 92] One report found immunization rates less subject to modification than other measures of quality care for pediatric patients.[93] The efficacy of provider education alone—in the more general context of guideline implementation—was disputed by Cochrane Effective Practice and Organization of Care group in 1998, but they reversed this position in 2004.[15, 16]

Based on these and other data, the *Community Guide to Preventive Services*, produced by the CDC's National Center for Health Marketing, published a chart of recommended interventions to increase immunization rates for influenza, hepatitis B, and pneumococcal disease in high-risk populations (**Figure 2-1**), not including dialysis patients.[89, 94, 95] The use of multiple interventions to increase vaccination coverage had itself been previously recommend by *The Community Guide*.[78] This paradigm starts with access and cost, which are not elements that translate for current dialysis patients. ESRD patients have very frequent encounters with healthcare providers and all of their costs, including the cost of immunization, are covered under Medicare and/or Medicaid.

Recommended intervention combinations to increase targeted vaccination coverage		Examples or descriptions of interventions
ONE OR BOTH of these **interventions to enhance access to vaccination services:**	- Expanded access in healthcare settings	Increase availability of vaccinations by adding locations or increasing hours, or by removing administrative barriers
	- Reducing client out-of-pocket costs	Pay for vaccinations or administration, provide insurance coverage or reduce co-payments for vaccinations
PLUS		
One or more of these **provider- or system-based interventions:**	- Standing orders	Allow professionals who are not physicians (e.g., nurses or pharmacists) to give vaccinations without direct physician involvement at the time of the vaccination
AND/OR	- Provider reminder systems	Let providers or other appropriate staff know when individual clients are due for vaccinations, through notations, stickers, or other prompts in clients' charts or computer databases or registries
	- Provider assessment & feedback	Assess the provider's performance in delivering one or more vaccinations to clients and provide assessment results to the provider
One or both of these **interventions to increase client demand for vaccination services:**	- Client reminder systems	Provide information or advice directly to individual clients at increased risk to encourage them to obtain appropriate vaccinations
	- Client education	Provide information on vaccinations to clients while they are being served in a medical or public health clinic setting

Figure 2-1. Recommendation chart on increasing vaccination coverage in high risk patients from the *Community Guide to Preventive Services*.

Interventions found to increase immunization rates specifically among ESRD facilities included new tracking systems for influenza vaccination,[28, 90] and provider and patient education for hepatitis B vaccination.[96, 97]

Existing programs and policies, as opposed to new programs and policies introduced as part of an intervention, get very little coverage in the literature. A survey of nursing homes conducted by the CDC and CMS has documented the policies and standing order programs present in long-term care facilities.[27] However, no comprehensive survey of dialysis centers had been published that documented current practices and their association with vaccination rates.

Evaluating Public Health Interventions (Manuscript 2)

As this project progressed, evaluating an intensive intervention program to increase influenza immunization rates at poorly-performing centers emerged as a goal for STIC and the participating Networks. A review of the approach to evaluating Network interventions found it to be flawed. The centers with the lowest rates had been selected for intervention and a comparison of pre- and post-intervention rates was posited to be the effect of the program. However, this uncontrolled evaluation was unadjusted for the considerable year-to-year variability in center rates, especially among poorly-performing centers (see **Methods** for further discussion).

This problem was hardly unique to this setting. Even when programs are constructed based on best practices and published data, proper evaluation by evidence-based means has not been done well.[21, 22, 98, 99] For example, a study on an intervention to increase influenza vaccination in pregnant women included “brief educational sessions” and the placement of "Think Flu Vaccine" notes in active obstetric charts. The researchers claim a one-year increase at family practices from 3.2% to 44.9% due to the intervention.[100] However, no control group was included and no adjustment is made for the selection of poorly-performing practices or the introduction of the tracking system employed as part of data collection.

Previous interventions across the 3 participating Networks used a mixture of approaches but generally focused on center-specific action plans for quality improvement. Reviews of evidence-based public health interventions have identified several key components to a successful action plan: clearly stated aims and objectives, clearly identified roles and responsibilities, mechanisms of accountability, the use of multiple intervention tactics, mechanisms for evaluation, and a basis in evidence for all components.[4, 78, 101] These principles were applied to the action plans for the intensive intervention conducted here.

As discussed above, studies of the efficacy of intervention tactics to increase vaccination rates have significant variation in the type and number of components included within each intervention program. Thus, in addition to the problem of differing patient populations and time periods, few intervention programs are directly comparable. As described in detail by Weingarten et al, this situation makes meta-analysis extremely difficult and suggests the need for controlled evaluation studies of specific combinations of tactics.[102] However, another approach to this issue is through the use of a pragmatic "trial."

A CONSORT extension statement regarding pragmatic trials was published in 2008—after the beginning of the intervention outlined here—but the concept of a pragmatic trial goes back several decades.[103] In contemporary terms, a pragmatic trial is "a randomized controlled trial whose purpose is to inform decisions about practice."[104] In terms of intervention assessment, pragmatic trials tend toward the use of "usual practice" rather than an highly explicit protocol.[104, 105] Such an approach favors external applicability over internal validity. The 2008 CONSORT guidelines specify that reports should:[104]

- Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardize the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites.

- Describe the comparator in similar detail to the intervention.

The evaluation of the intensive intervention program (**Manuscript 2**) was set up along these lines. Random allocation was employed and centers were assigned to standard intervention (a well-defined set of usual practices) or intensive intervention. A protocol provided a selection of intervention tactics for intensive intervention centers and sought to document the choices centers made rather than proscribing them. This broadened the question from one about specific intervention tactics to one about a program to increase vaccination rates by guiding centers through the composition of their own thoroughly-constructed multicomponent action plans.

Measuring Impact of Implementation on Patients (**Manuscript 3**)

The potential outcomes of the health issue is the final piece of evidence needed to assess this program to increase vaccination rates. Immunization against influenza has been found to associated with decreased morbidity and mortality in the general population[43, 106] and the high burden of infection-related complications in this population has been documented.[23, 107, 108]

Gilbertson et al found that among hemodialysis patients, influenza vaccination was associated with an adjusted all-cause mortality odds ratio of 0.75 (95% CI: 0.71, 0.80) in

1997-98 and 0.77 (95% CI: 0.73, 0.81) in 1998-99. Adjustments their analysis included variables for age, gender, race, ethnicity, ESRD network, a comorbidity index, and a severity of disease measure.

Though valid and compelling, the data by Gilbertson et al was collected at a time of much lower influenza vaccination rates and in a dialysis population that had poorer standards of care, lower overall survival, and a difference mix of causes for hospitalization and death.[23] They also note the discrepancy between the vaccination rates they found through review of Medicare data and the reported rates in ESRD Network 15 for 1998-99.[42] Issues raised by this discrepancy include that of how to account for vaccinations received outside the dialysis setting.

CHAPTER 3: METHODS

Three activities relevant to this dissertation were completed by the STIC program in 2005-06: a survey of all centers about vaccination practices, beliefs and attitudes (VPBA), the construction of a resource guide of educational materials on the 3 immunizations (to be distributed to all dialysis centers), and the publication of vaccination guidelines for dialysis patients and patients with chronic kidney disease (CKD).[1] Promulgation of the resource guide and guidelines ensured that all dialysis centers had useful, clear, and up-to-date information about vaccination. The survey was the first step toward developing a plan to increase rates. An evaluable intervention program and a multilevel analysis of mortality impact would follow later as the second and third parts of the program outlined in this thesis.

Manuscript 1 details the conclusions of the VPBA survey (**Appendix D**) and the associations found between existing policies and practices and vaccination rates for the influenza season that corresponds to the survey period. Survey development began with a review of recent literature pertinent to institutional vaccination programs for influenza, hepatitis B, and pneumococcal disease. We sought to identify characteristics of interventions that successfully increased immunization rates among dialysis patients and high-risk populations, such as the elderly and other immunocompromised persons. We concluded that previously documented interventions which improved immunization rates for at least one vaccination type were targeted to both providers and patients, were multi-component, and were conducted in various locations including communities, hospitals, long-term care facilities, and dialysis facilities. Specific interventions that had been shown to increase vaccination rates among high-risk groups included one or more of the

following: assessment and feedback, patient education, reminder/recall systems, provider education or standing orders, written protocols, and minimal consent requirements.[27, 28, 68, 89, 90, 96, 97] Interventions found to increase immunization rates among ESRD facilities included tracking systems,[28, 90] and provider and patient education (in the case of hepatitis B vaccination).[96, 97] Based on the these findings we included questions to ascertain the degree to which these components were present in ESRD treatment centers in Networks 6, 11, and 15.

The STIC survey committee decided that the main purpose of the VPBA survey would be to assess the presence of facility-wide standing order programs—programs in which no written or verbal communication with a physician is needed in order to administer vaccinations against influenza, hepatitis B, or pneumococcal disease. As the system with the most minimal consent requirement, facility-wide programs were considered desirable for increased vaccination coverage. A survey of standing order policies in long-term care facilities previously used by the CDC and the Centers for Medicaid and Medicare Services (CMS).[27] was adapted and extended to serve as a questionnaire for dialysis center administrators. At the recommendation of the CDC and Emory, the exposure variable used in CDC-CMS Nursing Home Survey was changed from a yes/no question (facility-wide orders versus all other order policies) to an analysis across 4 given policy options (facility-wide, chart-based, physician-specific, and individual orders).

The survey collected data about the current immunization order programs which were in place, potential barriers to implementation of a facility-wide immunization program, an assessment of a center's likeliness to change its policy (and roles involved in such a decision), the existence of standing order policies for procedures/processes other than

immunization, the use of tracking systems/documentation, reminder mechanisms, performance assessment programs, and provider feedback, the level of patient and staff education, and attitudes, opinions and beliefs with regard to severity of infections and risk/benefit of immunization.

Because centers are the decision-making entities with regard to policy, they were used as the unit of analysis. ANOVA tests and t-tests were employed to test the significance of the difference in crude vaccination rate among centers with different characteristics and order policies. Center vaccination rates were not weighted by size, but no center with under 20 patients was included in the analysis of rates.

Linear regression analysis was chosen as the most direct evaluation of associations at the center level. In addition to center characteristics, individual factors which may be related to vaccination likelihood were considered as aggregate effects for the center. These included mean age, racial composition, and prevalence of diabetic comorbidity.

Multivariate linear regression was used to determine the correlation between standing order policy and vaccination rate. Center-level characteristics found to be associated with vaccination rate (racial composition, size, and profit status) were incorporated into multivariate linear models that included terms representing the standing order policies. Size and racial composition (percent black) were classified into quintiles and used as interval variables. Profit status was included as a dichotomous variable. All 2-way interactions among these terms were included in the models. In this manner, the impact of policy, adjusted for center characteristics, could be determined. Backward elimination

was employed on the full model to remove non-significant variables ($p \geq 0.05$) one by one to achieve a final reduced model.

Additional multivariate analysis incorporated all of the factors above, plus regression terms for other survey questions described above. Correlation between policies and practices was expected to preclude quantification of the impact of every element due to multicolinearity.

Based on the results of the VPBA survey and analysis, discussions with health leaders, and literature review, STIC proposed a multifactorial initiative to improve influenza immunization rates. The initiative, coupled with a method of evaluating the effectiveness of the program, was approved by the Emory University institutional review board as well as by the medical review boards of the 3 participating Networks.

Approval of the evaluation program (**Manuscript 2**) proved to be a challenging task. STIC was asking for a change in the usual practice: instead of the lowest 45 dialysis centers across these 14 states receiving the intensive intervention, we were proposing that half of the bottom 90 receive the intensive intervention. This meant that some very poorly-performing centers would not receive the intensive intervention. We were able to convince all reviewers that the evaluation was necessary to determine the effectiveness of the program. We were also able to demonstrate, via historical data, that the differences among the bottom 90 centers were relatively small in comparison to the year-to-year variability in rates (**Figure 3-1**). However, after approval and before random allocation, one Network withdrew its 10 lowest centers (those with under 40% immunization) from the evaluation—choosing to provide intensive intervention for all of them.

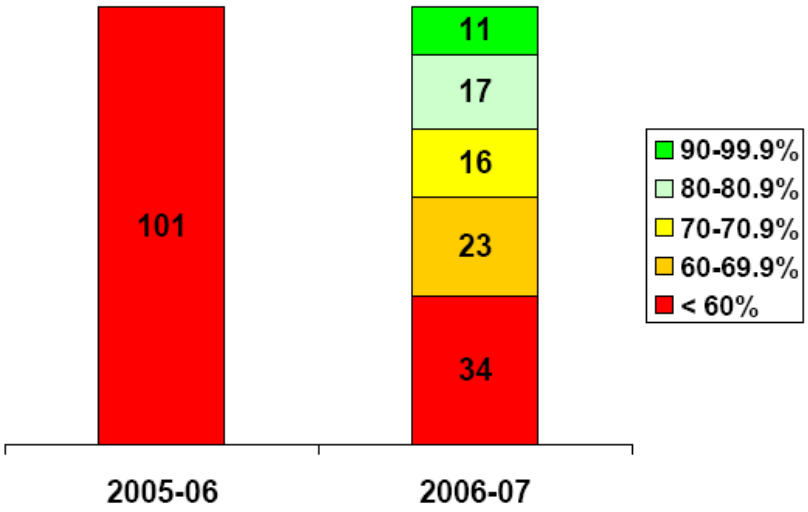

Figure 3-1. Reported influenza vaccination rates in 2005-06 and 2006-07 for the 101 centers in networks 6, 11, and 15 below 60% in 2005-06 and which reported rates in both years.

A controlled evaluation was essential for reasons beyond the year-to-year variability in rates. The inclusion of a standard intervention group allowed us to account for temporal trends (changes in overall vaccination rate due to a variety of outside factors such as public awareness level and vaccine availability) and the changing patient population.

Centers were selected if they met the following criteria: 1) responded to the survey for the 2006-07 influenza season; 2) had ≥ 30 patients on their treatment roster; and 3) either reported an influenza immunization rate lower than 75% in 2005-06 or failed to report any rate for 2005-06. The third criteria was employed in order to ensure a group of consistently underperforming centers.

To further account for year-to-year variability in the selected centers, centers were stratified into three groups: no 2005-06 rate reported, 2005-06 rate within one standard deviation of 2006-07 rate (+/-18%), and 2005-06 rate more than one standard deviation

different than 2006-07 rate. Within these rate strata, centers were further stratified by size (above or at the median versus below the median for the Network as a whole) to ensure balanced selection. Thus a total of 18 strata were defined: 3 Networks * 3 variability groups * 2 size categories.

Centers were randomly assigned in a 1:1 ratio to intensive intervention or standard intervention within Networks and within blocks for each Network. The intensive intervention group included 38 centers, with 39 in the standard intervention group.

We chose a coordinated multicomponent approach to intensive intervention based on previous assessments of such programs,[102, 109] including in this patient population.[6, 90, 110] The intervention and evaluation program conducted by McClellan et al in Network 6 to increase facility-specific mean urea reduction ratio was a direct precursor to the STIC activities outlined here.[6] Selected intervention components included some elements previously used by the Networks (such as the resource guide described earlier, the construction of facility-specific action plans, and direct contact between the staff of the dialysis facilities and the QI staff of the Networks). However additional elements were added—based on the VPBA survey results—including a 3-part communication program to inform centers about influenza immunization basics, designing and implementing a center-specific plan, and overcoming barriers (such as order policies and refusals).

Center action plans were required to meet certain criteria associated with successful approaches: clear aims and objectives, details regarding specific roles in the plan including names of staff responsible for those roles, and the selection of multiple intervention tactics which had a basis in the scientific literature, and a mechanism for

feedback and evaluation.[4] (See **Appendix G** for instructions issues to selected centers.) To assure confidentiality (between center staff and their Network administration), a data extraction form was used by Network staff to document whether roles and responsibilities were defined (**Appendix H**). Data were also collected about the target vaccination rate each center chose as their aim, the topics each center chose to address in their plan, and the center's participation in the approval process and monthly monitoring and reporting.

"Standard intervention" is used as a label for the baseline practice of these 3 Networks with regard to influenza vaccination. It includes a feedback report and educational materials developed for past influenza vaccination campaigns. All centers also have access to Network staff and can request additional assistance.

The center-specific quality of care feedback reports summarized the findings from the 2006-07 immunization survey and provided comparative data about immunization rates at their clinic and of other treatment centers within the three Networks. Thus poorly-performing centers were made aware of their status and—as participants in their ESRD Network—the potential for additional action.

All centers were provided with educational materials previously developed for both staff and patients by the STIC coalition: the CDC/STIC *Guidelines for Vaccinating Kidney Dialysis Patients and Patients with Chronic Kidney Disease* (2006)[111], along with videos, booklets, and brochures related to established guidelines and the importance of immunization.

Analyses of the pre- to post-intervention change used center-specific values based on reported immunization rates from the influenza seasons before and after the intervention

period: 2006-07 (baseline) and 2007-08 (post-intervention). The change from baseline in influenza immunization rate was calculated for each center as the numerical difference between these values. Thus the absolute change was considered, irrespective of baseline value. The primary analysis was not weighted by center size because the outcome of interest was the effectiveness of the intervention program on each center. However, a secondary weighted analysis was also conducted in order to assess the sensitivity of the unweighted analysis.

Due to the stratified randomization employed, we assessed the change in vaccination rate through a linear model that included the intervention type (standard or intensive) and 16 variables representing strata , one fewer than the 17 populated strata (1 of the 18 strata was unpopulated). All significance testing was evaluated using a p-value of < 0.05. This analysis proceeded under intention to treat assumptions. Data for all centers were included regardless of their level of participation in any intervention programs. Additional secondary analyses of data from the intensive intervention centers were planned for differences in mean change by participation in elements of the intervention and by topics indentified in the action plans of centers.

Analyses of data regarding patient mortality and influenza vaccination (**Manuscript 3**) were initially conducted as simple measures of the potential effect of increased vaccination (see **Data Sources and Collection** below). The first presentation of these data to the Network 6 medical review board in early 2009 included an estimated odds ratio for mortality of 0.65 (vaccinated versus unvaccinated patients), with adjustment for patient demographics (age, race, time on dialysis, gender) and comorbidities at dialysis initiation. High estimates for the effect of influenza immunization on mortality—a 50%

reduction in some populations including community-dwelling elderly—have been discussed in the literature in terms of a "healthy vaccine recipient bias."[112, 113] When the preliminary data from this population showed a similarly strong effect the medical review board of Network 6 questioned it and encouraged the use of additional data to adjust for possible reporting biases. The subsequent inclusion of monthly laboratory data for albumin, hemoglobin and KT/V for the 3-month vaccination period, including indications of missed dialysis sessions, allowed for a potentially more accurate assessment.

In the final assessment we employed a multilevel model with measures of current health status as well as demographic factors (patient- and center-based), baseline comorbidities, center characteristics (such as size and profit status), and coefficients to account for the effect of treatment center on mortality.

Patient characteristics by vaccination status were compared via chi-square tests and t-tests. The likelihood of mortality was assessed via multivariable logistic regression controlling for patient age, race, gender, time on dialysis (vintage), diabetes as primary cause of ESRD (yes or no), comorbidities at dialysis initiation (congestive heart failure, cerebrovascular disease [CVD], peripheral vascular disease [PVD], history of hypertension, chronic obstructive pulmonary disease [COPD], and malignant neoplasm), mean monthly patient lab values for albumin, hemoglobin and KT/V during the 3-month vaccination period. Pneumococcal vaccination status was included in the model and interaction (effect modification) with influenza vaccination was assessed. All possible interaction terms for patient demographics—age, race, gender, time on dialysis (vintage), and diabetes as cause of ESRD—were included in the multivariable models.

We controlled for effect for center in two separate analyses: by including fixed effect terms for center in a maximum likelihood model and by including a random effect for center in a penalized quasi-likelihood model. A center code was included for all patients at centers with a patient population of 20 or more. Other patients were assigned a "missing" value for center code.

Survival curves, adjusted for age and vintage and stratified by race, were produced to examine the association of mortality with vaccination over the course of the year.

This analysis was also conducted at the center level to determine if a relationship between a center's vaccination rate and its mortality rate was observable. To obtain a standardized mortality rate (SMR) for each center, patient-specific predicted probabilities of mortality were calculated based on all non-vaccination data (demographics, baseline comorbidities, and lab values), and summed for each center. The observed number of deaths at a center was then divided by this predicted number of deaths. These SMRs were compared to center-level vaccination rates via Spearman correlation to determine whether centers with higher vaccination rates are more likely to have lower SMRs (ie, fewer deaths than were predicted by a model which did not include influenza vaccination data).

Data Sources And Collection

The data sources and collection methods for this program are outlined in the following section. Full forms for 8 of these sources are available in **Appendices A-H**.

SIMS

Most data for ESRD patients is stored in a Standard Information Management System (SIMS), developed under CMS contract by ESRD Network 6—a STIC coalition member. SIMS is used to maintain facility demographic and patient-specific information and has been in use since 2000. The data for all national ESRD patients are stored at a central repository, housed in Baltimore, MD, that is accessible through electronic retrieval.

SIMS data used in this project are from the following sources:

- **CMS-2728: ESRD Medical Evidence Report/Medicare Entitlement and/or Patient Registration**

  Registration form completed after the patient is diagnosed as having ESRD and within 45 days of the first dialysis treatment. This form contains information about current health conditions, the cause of renal failure, current insurance status, current and past employment status, the modality of dialysis (peritoneal dialysis or hemodialysis) and information about pre-dialysis care. The 2728 form serves two purposes: it provides medical evidence of an end-stage renal condition for Medicare entitlement, and registers a patient in the United States Renal Data System (USRDS). See **Appendix A**.

- **CMS-2746: ESRD Death Notification**

  Death report completed by the designated center for that patient and due with 30 days of the date of death. Includes the date, place, and cause of death. See **Appendix B**.

- **CMS-2744: ESRD Annual Facility Survey**

  Form completed annually by all Medicare approved renal providers. Includes the address of the facility, modalities offered, number of patients at beginning and end of the year, and number and type of staff. See **Appendix C**.

The Elab Project

Laboratory data for ESRD patients has been collected by Network 11—another STIC member—since 1998. These data are submitted electronically—directly from the clinical laboratory to Network 11—and used to generate facility-specific profiles and comparative data at the state and Network level that can be used for QI purposes. Data from patients in Networks 6, 11, and 15 were used in the analysis of the association between influenza immunization and mortality.

Vaccination Practices, Beliefs, and Attitudes Survey

The VPBA survey was produced by the STIC coalition. Each center in networks 6, 11, and 15 received this 7-page survey on various immunization policies, including standing orders for 3 vaccinations (influenza, hepatitis B, pneumococcal disease). Completed surveys were mailed to a single ESRD Network where all of the data were entered.

Centers were asked about standing order policies, as well as other policies and procedures for vaccine administration. Respondents were given 4 options with regard to standing orders for each of 3 vaccinations: influenza, hepatitis B and pneumococcal disease. The wording of the options was adapted from a previous study of vaccination in nursing homes[28] and included extensive descriptions. The survey also included questions

regarding the consistency of charting methods, centralization of record storage, documentation of patient vaccination refusals, vaccination of patients with unknown vaccination status, use of reminder systems and performance evaluations, and beliefs and attitudes toward immunizations. These data were collected in order provide a more complete picture of potential correlates with standing order policies and vaccination rates. See **Appendix D**.

STIC Immunization Data Collection Tool

Data collection form provided by STIC and pre-populated with each center's patient roster as of December 31. This form was filled out by the nursing staff under the direction of the clinic director or nursing director. Influenza vaccination was recorded for the 2005-06 influenza season. Hepatitis B vaccination series was recorded as fully completed (complete series), partly completed (≥ 1 dose received), or no doses received. Pneumococcal vaccination was assessed based on whether the patient had ever received 1 dose. Vaccination was considered to have been received if administration took place at the dialysis center or was reported (by the patient) as having been given at another location. Patients with documented "unknown" status were considered as non-vaccinated. Other non-vaccinated categories were "not offered," "refused," "allergic," and "not time (for dose in hepatitis B series)."

This form was used for all centers in Networks 6, 11, and 15 for the 2005-06 data collection period and by Networks 6 and 15 in the 2007-08 data collection period. See **Appendix E**.

STIC Influenza Immunization Worksheet

This simplified data collection form coved only influenza vaccination and asked for only 3 data points: the total number of patients on the center's roster, the total number of these patients that received the influenza vaccination, and the total number of these patients that did not receive the shot or had an unknown vaccination status.

This form was used for all centers in Networks 6, 11, and 15 for the 2006-07 data collection period and by Network 11 in the 2007-08 data collection period. See **Appendix F**.

Action Plan Instruction Sheet and Data Collection Form

The action plans designed by centers assigned to the intensive intervention group in the 2007-08 influenza season were not accessible outside of the Networks due to confidentiality issues (eg, the names of individuals responsible for improvements). Network staff used this form—based on the initial action plan development instruction sheet (**Appendix G**)—to document key aspects of the action plan for each center. These included whether or not the following were accomplished: a vaccination goal given, root causes of poor performance identified, action steps outlined, responsible individuals named, an evaluation method and timeframe established, required topics addressed, and proper approvals and reviews completed. See **Appendix H**.

SPECIFIC AIMS AND DATA SOURCES USED

Manuscript 1

Association of Standing Order Policies with Vaccination Rates in Dialysis Clinics

AIM: Determine whether patients at dialysis centers with facility-wide standing order policies are more likely to receive influenza vaccination than patients at centers with other policies.

DATA: Vaccination Practices, Beliefs, and Attitudes Survey; STIC Immunization Data Collection Tool; CMS-2744; CMS-2728

Manuscript 2

Improving Influenza Immunization Rates Among ESRD Clinics: a Group-Randomized Evaluation of a Quality Improvement Intervention

AIM: Use a group-randomized evaluation to determine whether an "intensive" intervention program to improve influenza immunization rates at poorly-performing dialysis centers is associated with an additional benefit beyond "standard" intervention.

DATA: STIC Immunization Data Collection Tool (2005-06 and 2007-08); STIC Influenza Immunization Worksheet (2006-07 and 2007-08); CMS-2728; CMS-2744; Action Plan Data Collection Form

Manuscript 3

Influenza Vaccination Status and Mortality in End-Stage Renal Disease Patients

AIM: Determine whether prevalent ESRD patients (receiving dialysis for at least 1 year) who received an influenza vaccination have a lower all-cause mortality risk in the 12 months following the start of influenza season than those who did not.

DATA: CMS-2728; CMS-2744; CMS-2746; Elabs; STIC Immunization Data Collection Tool

CHAPTER 4: MANUSCRIPT 1

Association of Standing Order Policies with Vaccination Rates in Dialysis Clinics: A U.S.-Based Cross-Sectional Study

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ABSTRACT

Background: Patients with end-stage renal disease (ESRD) are at increased risk for morbidity and mortality due to infection. Quality improvement efforts for this patient population include assessment of institutional policies and practices that may increase vaccination rates against influenza, hepatitis B, and pneumococcal disease.

Study Design: A survey of vaccination, practices, beliefs, and attitudes was sent to all dialysis centers in ESRD Networks 6, 11, and 15.

Setting & Participants: Of the 1052 dialysis facilities considered, 683 returned the survey, reported vaccination rates for 2005-06, and had $n \geq 20$.

Predictor or Factor: Standing order policy of dialysis facility, categorized as facility-wide orders, pre-printed admission orders for each patients (chart orders), physician-specific orders and individual orders.

Outcomes: Vaccination rates for influenza, hepatitis B (full or partial series), hepatitis B (full series only) and pneumococcal disease.

Measurements: Patient vaccination, given at center or outside center.

Results: Overall vaccination rates (%, SD) were 76 (18) for influenza, 73 (22) for hepatitis B (full or partial series), 62 (25) for hepatitis B (full series) and 44 (34) for pneumococcal disease. Compared to individual orders, facility-wide standing orders and chart orders were not associated with higher (%, CI) vaccination rates for influenza [0.4 (-4, 5) and 1.27 (-3, 5), respectively), but were associated with higher vaccination rates

for hepatitis B full or partial series [9 (3, 15) and 11 (5, 17), respectively], hepatitis B full series [11 (4, 17) and 13 (7, 19), respectively], and pneumococcal disease [21 (14, 29) and 20 (13, 27), respectively].

Limitations: Data are cross-sectional and vaccinations outside the center were self-reported.

Conclusions: Existing facility-wide or chart-based order programs may be more effective in promoting vaccination against hepatitis B and pneumococcal disease.

BACKGROUND

Immunization against influenza and hepatitis B reduces morbidity and mortality in the general population.[43, 106] Among end-stage renal disease (ESRD) patients, influenza and hepatitis B immunization reduces infection rates,[31, 34, 114, 115] hospitalization, and mortality.[41, 115] Additionally, prevention of pneumonia via the pneumococcal polysaccharide vaccine is recommended for patients at increased risk of pneumococcal disease and its complications, including patients with kidney failure.[116] Despite these benefits, substantial under-vaccination has been reported among ESRD patients.[40, 39]

In comparison to other at-risk patient populations, ESRD patients have frequent encounters with the healthcare system: most receive dialysis treatments 3 times per week at a hemodialysis facility. ESRD patients are fully covered under Medicare and each dialysis facility participates in one of 18 regional ESRD Networks under contract to the Centers for Medicare and Medicaid Services (CMS). Network responsibilities include oversight of care and the collection and feedback of performance measure data.

Since 2005, the immunization quality improvement efforts of Networks 6, 11, and 15 have been coordinated with academic, professional, public health and patient groups in the Safe and Timely Immunization Coalition (STIC). STIC activities focus on achieving the Healthy People 2010 objectives for immunization against vaccine-preventable diseases in persons with ESRD: 90% coverage for influenza, hepatitis B, and pneumococcal disease.

Standing order policies have been advocated as a best practice in recent years in various contexts. A 2002 CMS policy change allows for,[76] and recent guidelines advocate,[43, 77-79]

the institution of these policies for vaccination of high-risk patients. Facility-wide standing orders authorize nurses or other non-physicians to administer vaccinations under an institution- or physician-approved protocol without direct physician involvement at the time of vaccination. Some evidence for the positive association between standing order policies and vaccination rates has been demonstrated in long-term care facilities[28, 80-82, 85] and in a 10-year study at a Veterans Administration hospital.[83] Other studies have shown the difficulties of implementing such a system.[86, 87] However, the use of standing orders for vaccinations in dialysis centers has not previously been described.

The goals within this analysis of this STIC-facilitated project were: 1) to document vaccination policies and practices at dialysis centers across the 14 states of these 3 Networks ; 2) to report any association between treatment center policies and reported vaccination rates; and 3) to analyze this association after adjustment for facility characteristics which may be associated with vaccination rates.

METHODS

Target population

Dialysis facilities from ESRD Networks 6 (North Carolina, South Carolina, Georgia), 11 (Michigan, Minnesota, North Dakota, South Dakota, and Wisconsin) and 15 (Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming) were included. These are the 3 Networks which chose to participate in STIC.

Measurements and data collection

Three sources of data were merged to produce a dataset for analysis: 1) a 2006 STIC Vaccination Practices, Beliefs, and Attitudes (VPBA) survey of all of the centers in the 3 Networks to ascertain their standing order policies for the 3 immunizations considered, 2) 2005-06 influenza, hepatitis B, and pneumococcal vaccination status by patient, collected by the 3 Networks, and 3) center-level characteristics and demographics based on facility surveys (CMS 2744) and baseline patient information forms (CMS 2728).

For this analysis, a center was included only if the VPBA survey was returned, immunization data was reported, and the center had 20 or more patients. Information from the Vaccination Practices, Beliefs, and Attitudes (VPBA) survey was available from 886 (84.2%) of these 1052 centers. Vaccination information was available for a total of 54,749 patients from 873 (83.0%) of 1052 centers across ESRD Networks 6, 11, and 15. Of these centers, 776 had 20 or more patients. A total of 683 centers met all inclusion criteria (**Figure 4-1**).

2006 Vaccination Practices, Beliefs, and Attitudes Survey

Each center in the 3 Networks received a Vaccination Practices, Beliefs, and Attitudes (VPBA) survey on various immunization policies, including standing orders for 3 vaccinations (influenza, hepatitis B, pneumococcal disease). Completed surveys were mailed to a single ESRD Network where all of the data were entered.

Centers were asked about standing order policies, as well as other policies and procedures for vaccine administration. Respondents were given 4 options with regard to standing

orders for each of 3 vaccinations: influenza, hepatitis B and pneumococcal disease. The wording of the options was adapted from a previous study of vaccination in nursing homes and included extensive descriptions.[28]

- Treatment centers responding that a "Facility-wide standing order (no written or verbal communication with physician needed)" was used were classified as having facility-wide standing orders.

- Treatment centers responding that they used a "Preprinted admission order for each patient signed by physician (may or may not need periodic renewal)," were classified as having chart orders.

- Treatment centers responding that they had "No facility-wide standing order, but physician-specific standing orders employed" were classified as having physician-specific orders.

- Treatment centers responding that they had an "Individual order needed for every vaccine" were classified as having individual orders.

The 7-page survey included multiple option questions regarding the consistency of charting methods, centralization of record storage, documentation of patient vaccination refusals, vaccination of patients with unknown vaccination status, use of reminder systems and performance evaluations, and beliefs and attitudes toward immunizations. These data were collected in order provide a more complete picture of potential correlates with standing order policies and vaccination rates.

In most cases, the survey was completed by a clinic manager/director (n= 277), a facility administrator (n=161), a nurse manager/director (n=110), or a nurse in another administrative role. Individuals completing the survey reported a median of 4.0 years at their facility and a median of 5.0 years total career experience in their current role.

Network administration made follow-up calls to centers to determine that the survey had been received and to solicit questions. Standing order information was collected on the first page of the survey. All data were collected without regard to individual state policies and laws regarding medical procedures. Centers that did not respond to the survey were not significantly different from responders with regard to size, racial composition, or profit status.

2005-06 immunization status

2005-06 vaccination status was reported to each Network by its centers on a standard form provided by STIC and pre-populated with the center's patient roster as of 1/1/2006. All patients were included regardless of when they had started dialysis. This form was filled out by the nursing staff under the direction of the clinic director or nursing director. Influenza vaccination was recorded for the 2005-06 influenza season. Hepatitis B vaccination series was recorded as fully completed (complete series), partly completed ($\geq$ 1 dose received), or no doses received. Vaccination against pneumococcal disease was assessed based on whether the patient had ever received 1 dose.

Vaccination was considered to have been received if administration took place at the dialysis center or was reported (by the patient) as having been given at another location. Patients with documented "unknown" status were considered as non-vaccinated. Other

non-vaccinated categories were “not offered,” “refused,” “allergic,” and “not time (for dose in hepatitis B series).”

Statistical methods

Centers are the decision-making entities with regard to policy and thus were used as the unit of analysis. ANOVA tests and t-tests were employed to test the significance of the difference in crude vaccination rate among centers with different characteristics and order policies. Center vaccination rates were not weighted by size, but no center with under 20 patients was included in the analysis of rates.

Linear regression analysis was chosen as the most direct evaluation of associations at the center level. In addition to center characteristics, individual factors which may be related to vaccination likelihood were considered as aggregate effects for the center. These included mean age, racial composition, and prevalence of diabetic comorbidity. Of these, only racial composition showed a wide range of values.

Multivariate linear regression was used to determine the correlation between standing order policy and vaccination rate. Center-level characteristics found to be associated with vaccination rate (racial composition, size, and profit status) were incorporated into multivariate linear models that included terms representing the standing order policies. Size and racial composition (percent black) were classified into quintiles and used as interval variables. Profit status was included as a dichotomous variable. All 2-way interactions among these terms were included in the models. In this manner, the impact of policy, adjusted for center characteristics, could be determined. Backward elimination

was employed on the full model to remove non-significant variables ($p \geq 0.05$) one by one to achieve a final reduced model.

Additional multivariate analysis incorporated all of the factors above, plus regression terms for other survey questions described above. Correlation between policies and practices was expected to preclude quantification of the impact of every element due to multicolinearity.

RESULTS

Vaccination Practices, Beliefs, and Attitudes (VPBA) Survey

Standing order usage by facilities varied with vaccination type. Among the 683 centers who met all inclusion criteria, facility-wide standing orders for influenza vaccination were reported by 36.7%, 44.5% used chart orders and 6.9% used physician-specific orders (**Table 4-1a)**. For hepatitis B vaccination, 35.6% had facility-wide standing orders, 49.2% used chart orders, and 5.0% used physician-specific orders (**Table 4-1b**). Pneumococcal vaccination was given by facility-wide standing order in 27.8% of centers, 38.9% had chart-specific orders, 8.8% used physician-specific orders (**Table 4-1c**). Overall 278 (40.7%) of the centers reported using facility-wide standing orders for 1 or more immunizations and 179 (26.2%) had such policies for all 3 vaccinations. There were no significant geographic differences in the prevalence of facility-wide standing order policy among the 14 states considered here.

For-profit centers were significantly more likely that non-profit/government centers to have facility-wide standing orders for pneumococcal immunization (30.8% versus 19.1%,

p = 0.004) (**Table 4-1c**) and hepatitis B immunization (38.0% versus 28.3%, p = 0.02) (**Table 4-1b**). Percentages were more similar for influenza (38.4% versus 31.2%, p = 0.2) (**Table 4-1a**). None of the order policy options for the 3 vaccinations were associated with racial composition or size of center.

Centers with chart orders or facility-wide standing order policies were more likely than centers with other policies to have systems to support their immunization efforts. Consistent charting methods were more commonly employed at such centers for all 3 vaccinations (influenza: 91.4 vs 80.5, hepatitis B: 95.2 vs 82.6, pneumococcal: 83.8 vs 64.9; all $p < 0.001$). Centers with chart or facility-wide orders for influenza were also more likely to have centralized records (83.1 vs 71.2, p = 0.003). Those with chart or facility-wide orders for pneumococcal vaccination were more likely to have centralized records (78.5% vs 58.8%, $p < 0.001$), performance evaluation systems (45.6% vs 24.2%, $p < 0.001$) and a policy to offer vaccination to patients with unknown status (85.8% vs 60.0%, $p < 0.001$).

The survey also found that 62 (8.8%) of the 683 centers did not offer pneumococcal vaccine on site. In comparison, 10 (1.5%) centers did not offer influenza vaccination and 12 (1.8%) did not offer hepatitis B vaccination. (However, patient charts at all centers include records of patient vaccinations received elsewhere.)

In general there was little variability in attitudes and beliefs about influenza and hepatitis B vaccination. For each of these vaccinations, the vast majority of respondents (≥ 95%) reported that they "agree" or "agree strongly" that they are important and safe; 86.8% agree or agree strongly that the influenza vaccine is effective and 87.2% report the same for hepatitis B vaccination. Attitudes and beliefs regarding pneumococcal vaccination were more diverse with substantial proportions of respondents reporting they "neither agree nor disagree" that pneumococcal vaccination is effective (28.2%) or safe (16.5%). Only 69.9% strongly agreed or agreed that the pneumococcal vaccine is effective; 83.0% that it was safe; 88.4% that it was important for their patients. On the point of immunization in general, 94.0% agree or strongly agree that the dialysis facility bears responsibility to ensure that its patients are vaccinated.

Centers that did not respond to the survey were not significantly different from those that did respond with regard to size (68.8 versus 69.7, p=0.53) , racial composition (48.5% versus 47.6%, p=0.70), or profit status (70.4% versus 74.5%, p=0.15).

Vaccination for influenza, hepatitis B, and pneumococcal disease across ESRD Networks 6, 11, and 15

In total, vaccination data were available for 54,749 patients from 873 centers. The mean unweighted center-level vaccination rates across centers with more than 20 patients (n=776) were: 75.9% for influenza, 72.7% for at least partial hepatitis B series, 62.1% for a full hepatitis B series, and 44.3% for pneumococcal vaccination. The unweighted mean rates for the 683 of these centers that responded to the survey were similar (76.2%, 73.1%, 62.3%, and 44.2%). Detailed data from all 776 centers is reported in **Table 4-2** for the convenience of other researchers.

Vaccination rates varied significantly by racial composition and size of the center. For example, the 174 centers with 80% or more black patients had rates of 70.7% (influenza), 70.1% (hepatitis B any), 59.2% (hepatitis B full), and 33.0% (pneumococcal). The 241 centers with under 20% black patients had corresponding rates of 80.3%, 75.6%, 67.1%, and 53.5% respectively. Differences by racial composition appeared to be stepwise for influenza and pneumococcal vaccination. Differences in hepatitis vaccination occurred between 0-19.9% and 20-39.9%.

For all 3 vaccinations, non-profit/government centers had higher mean rates than for-profit centers. The relationships found here support adjustment of the primary analysis for center characteristics.

Correspondence of standing order policy with vaccination rates

The unadjusted rates for the 683 centers which met all inclusion criteria **(Table 4-3)** were very similar to those found for all reporting centers with ≥ 20 patients (**Table 4-2**).

Influenza vaccination rates were not significantly different across the 4 vaccination policies considered. This was true before **(Table 4-3)** and after **(Table 4-4)** adjustment for racial composition, size, and profit status. In the full linear model, racial composition and size were related to influenza vaccination rate. The proportion of patients vaccinated declined with increasing size and increasing proportion of black patients.

Both hepatitis B and pneumococcal vaccination standing order policies were associated with the proportion of dialysis patients vaccinated in unadjusted **(Table 4-3)** and adjusted **(Table 4-4)** analyses. Presence of a facility-wide hepatitis B standing order policy was

associated with an +8.9% absolute difference (adjusted for racial composition, size, and profit status) in the proportion of patients vaccinated with ≥ 1 dose of a hepatitis B series, and a +11.0% adjusted absolute difference in the proportion who completed a full series. Chart orders were associated with an adjusted +11.0% absolute difference in the partial series proportion and an adjusted +13.0% absolute difference for the full series. Vaccination rates were lower with increasing size of center, but this relationship was not statistically significant. No relationship was seen with racial composition. For-profit centers had lower adjusted rates (-4.8% for ≥ 1 dose and -9.8% for a complete series).

The presence of a facility-wide pneumococcal vaccination standing order policy was associated with an adjusted +21.3% absolute difference in the proportion of patients who were ever vaccinated against pneumococcal disease. Chart orders were associated with an adjusted +20.1% absolute difference. Vaccination rate was negatively associated with proportion of black patients and size of center.

These linear models were also employed after eliminating data from patients who self-reported being vaccinated outside the center from both the numerator and the denominator. In this way, the patients "available" for the center to immunize were isolated and potential reporting bias reduced. The impact of facility-wide standing orders and chart orders were not notably different from those described above.

Other reported practices, attitudes, and beliefs and vaccination rates

In order to more fully explore the associations of policies and practices with immunization rates, all of these multivariable analyses were also run including other facility practices potentially associated with vaccination rate. These were consistent

charting methods, centralized record storage, documentation of patient vaccination refusals, vaccination of patients with unknown vaccination status, use of reminder systems, and provider performance evaluations.

For influenza vaccination only a performance evaluation program was associated with higher rates (+3.7%, adjusted as above). No additional facility policy or practice improved the predictive value of standing order policy for hepatitis B vaccination rates. Colinearity precluded an evaluation of models for pneumococcal vaccination rates that included standing orders plus other policies. A model using only other policies (not standing orders) showed positive correlation between rates and consistent charting (+13.8%, $p < 0.001$) performance evaluation (+7.5%, $p = 0.003$) and offering vaccination to patients with unknown vaccination status (+19.6%, $p < 0.001$).

DISCUSSION

The overall vaccination rates reported here are higher than those seen in a CDC analysis of United States Renal Data System (USRDS) data from 2001 and 2002.[39] Though not complete national data, these results cover patients in 3 Networks across 14 states with considerable geographical diversity. Also, these data are compiled from patient-specific data, which may provide more accurate reporting than the facility-level summaries used in previous studies.

This cross-sectional comparison suggests that existing standing order programs—facility-wide and chart-based—are associated with higher pneumococcal and hepatitis B vaccination rates, but not with higher influenza coverage. We were surprised to find no substantial differences in vaccination rates between centers with facility-wide policies

and those with chart-based systems. This novel finding regarding the relative efficacy of chart-based orders may provide an alternative approach for facilities which do not or cannot implement facility-wide standing order programs.

The associations found here remained strong after adjustment for racial composition, size, and profit status. There were significant correlations between these facility-level characteristics and rates for each of the 3 vaccinations considered. The rate for all vaccinations declined with increasing proportion of black patients and increasing size (number of patients on roster). Rates at for-profit centers were lower on average than those at non-profit/government centers. Adjusting for racial composition and size in the multivariate model helps explain why for-profit centers (which tend to be larger and have a higher proportion of black patients) have more facility-wide standing orders but lower overall vaccination rates. Racial disparities in vaccination coverage for high-risk patients have been reported elsewhere.[25] The size of a facility and its profit status have been discussed as correlates of quality of care and outcomes in this and other high-risk populations, with inconclusive results.[27-30]

The results presented here have specific limitations. Cross-sectional data does not allow for causal conclusions regarding the effect of policies. The VPBA survey was issued by STIC and mentioned its affiliation with CMS. Such a clear connection may have produced reporting bias. Reported standing order policies were not independently verified and their implementation was not monitored. The validity of each report relies on the individual completing the form. However, in most cases, the survey was completed by a clinic manager/director, a facility administrator, or a nurse manager/director with a median of 4 years at their facility and 5 years of career experience in their current role.

The analysis covers *documented* vaccination and categorizes patients with missing data as unvaccinated. This may include patients who started dialysis late in the year and thus may not have been active at the center at the time the majority of patients were vaccinated. Verification was not required for patients who stated they had received vaccinations elsewhere. Thus it is a measure of facility records rather than patient coverage. Also, 14% of eligible centers with 20 or more patients on their roster did not respond to the survey. However, centers that did not respond to the survey were not significantly different from those that did respond with regard to size, racial composition, or profit status.

This analysis contributes to the body of information regarding institutional policies and vaccination rates in this high-risk patient population. Although cross-sectional in nature, it suggests that facility-wide or chart-based order programs may be effective in promoting vaccination against hepatitis B and pneumococcal disease.

A 1999-2002 CMS-CDC intervention to increase the use of facility-wide standing orders in long-term care facilities across 14 states documented a 10 percentage point or higher increase in influenza immunization for 20% of facilities and in pneumococcal coverage for 28%.[28] We would need to conduct a similar intervention study in ESRD centers to draw more definitive conclusions about whether changing order policies would lead to changes in vaccination coverage.

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Table 4-1a. Standing order policies with breakdown of influenza by center characteristics

	Centers	Chart orders (%)	Facility-wide orders (%)	Physician-specific orders (%)	Individual orders (%)	Not given at facility (%)
Influenza	**683**	**44.5**	**36.7**	**6.9**	**10.4**	**1.5**
Percentage black						
80% to 100%	157	42.7	35.7	4.5	14.0	3.2
60%to 79.9%	139	44.6	33.1	6.5	15.1	0.7
40%to 59.9%	85	41.2	38.8	7.1	11.8	1.2
20% to 39.9%	94	41.5	39.4	11.7	7.4	0.0
0% to 19.9%	208	48.6	38.0	6.7	5.3	1.4
Size						
100+	119	45.4	35.3	9.2	8.4	1.7
70-99	152	45.4	38.8	5.9	7.9	2.0
50-69	144	49.3	30.6	9.0	9.7	1.4
35-49	125	40.0	41.6	5.6	11.2	1.6
20-34	143	42.0	37.8	4.9	14.7	0.7
Profit status						
Profit	510	43.7	38.4	7.1	9.8	1.0
Nonprofit/gov't	173	46.8	31.8	6.4	12.1	2.9

Table 4-1b. Standing order policies with breakdown of hepatitis B by center characteristics

	Centers	Chart orders (%)	Facility-wide orders (%)	Physician-specific orders (%)	Individual orders (%)	Not given at facility (%)
Hepatitis B	**683**	**49.2**	**35.6**	**5.0**	**8.5**	**1.8**
Percentage black						
80% to 100%	157	44.6	38.9	4.5	9.6	2.5
60% to 79.9%	139	49.6	31.7	4.3	12.9	1.4
40% to 59.9%	85	43.5	37.7	7.1	9.4	2.4
20% to 39.9%	94	44.7	41.5	5.3	6.4	2.1
0% to 19.9%	208	56.7	32.2	4.8	5.3	1.0
Size						
100+	119	47.9	35.3	7.6	6.7	2.5
70-99	152	46.7	38.8	3.3	8.6	2.6
50-69	144	52.1	32.6	4.9	8.3	2.1
35-49	125	47.2	36.0	6.4	8.8	1.6
20-34	143	51.7	35.0	3.5	9.8	0.0
Profit status						
Profit	510	48.0	38.0	5.5	7.3	1.2
Nonprofit/gov't	173	52.6	28.3	3.5	12.1	3.5

Table 4-1c. Standing order policies with breakdown of pneumococcal by center characteristics

	Centers	Chart orders (%)	Facility-wide orders (%)	Physician-specific orders (%)	Individual orders (%)	Not given at facility (%)
Pneumococcal	**683**	**38.9**	**27.8**	**8.8**	**15.4**	**8.8**
Percentage black						
80% to 100%	157	35.7	28.0	7.6	19.1	9.6
60% to 79.9%	139	38.1	28.1	7.9	20.1	5.8
40% to 59.9%	85	41.2	32.9	9.4	12.9	3.5
20% to 39.9%	94	29.8	33.0	11.7	16.0	9.6
0% to 19.9%	208	45.2	23.1	8.7	10.1	13.0
Size						
100+	119	38.7	28.6	10.9	14.3	7.6
70-99	152	38.2	29.0	8.6	13.1	11.2
50-69	144	41.0	25.7	10.4	16.0	6.9
35-49	125	36.8	28.8	8.8	16.0	9.6
20-34	143	39.9	27.3	5.6	17.5	9.8
Profit status						
Profit	510	37.7	30.8	9.2	14.1	8.2
Nonprofit/gov't	173	42.8	19.1	7.5	19.1	11.6

Table 4-2. Immunization rates by center characteristics (centers with 20 or more patients)

	Centers	Mean influenza vaccination % (SD)	Mean hepatitis B vaccination (partial or full series) % (SD)	Mean hepatitis B vaccination (full series) % (SD)	Mean p. pneumonia vaccination % (SD)
All centers	**776**	**75.9 (17.6)**	**72.7 (22.1)**	**62.1 (24.8)**	**44.3 (34.3)**
Percentage black patients					
80% to 100%	174	70.7 (19.5)	70.1 (23.0)	59.2 (25.5)	33.0 (34.2)
60% to 79.9%	160	73.7 (19.2)	72.4 (22.1)	60.4 (24.6)	39.6 (32.5)
40% to 59.9%	91	76.2 (17.7)	72.8 (20.3)	60.2 (24.4)	48.0 (31.4)
20% to 39.9%	110	76.5 (17.4)	70.7 (22.1)	59.9 (23.9)	45.8 (34.8)
0% to 19.9%	241	80.8 (13.4)	75.6 (22.0)	67.1 (24.6)	53.5 (33.6)
ANOVA p-value		**<0.001**	**0.1**	**0.007**	**<0.001**
Size					
100+	135	69.8 (15.1)	71.2 (20.4)	58.8 (22.2)	39.7 (31.7)
70-99	177	73.8 (17.1)	68.7 (22.4)	57.5 (24.7)	41.1 (31.9)
50-69	156	75.8 (17.0)	75.6 (18.3)	63.1 (23.7)	40.5 (35.1)
35-49	144	77.2 (19.8)	70.7 (24.7)	60.9 (27.0)	44.3 (35.7)
20-34	164	82.2 (16.4)	77.3 (23.0)	69.9 (24.6)	55.1 (34.9)
ANOVA p-value		**<0.001**	**0.002**	**<0.001**	**<0.001**
Profit status					
Profit	577	74.8 (18.1)	71.5 (21.3)	59.9 (24.2)	42.5 (34.0)
Nonprofit/government	199	79.0 (15.8)	76.2 (24.1)	68.4 (25.6)	49.4 (34.6)
t-test p-value		**0.003**	**0.01**	**<0.001**	**0.02**

Table 4-3. Association of standing order policies for influenza, hepatitis B, and pneumococcal disease with vaccination rates (per center)*

	Influenza		Hepatitis B			Pneumococcal disease	
	Centers (%)	Mean vaccination (%)	Centers (%)	Mean vaccination partial + full (%)	Mean vaccination full (%)	Centers (%)	Mean vaccination (%)
All centers	683	76.2	683	73.1	62.3	683	44.2
Chart orders	304 (44.5)	77.0	336 (49.2)	75.9	65.3	266 (38.9)	51.3
Facility-wide orders	251 (36.7)	76.4	243 (35.6)	73.5	62.6	190 (27.8)	52.3
Physician-specific orders	47 (6.9)	73.6	34 (5.0)	61.8	53.1	60 (8.8)	41.3
Individual orders	71 (10.4)	75.0	58 (8.5)	64.1	52.0	105 (15.4)	30.0
ANOVA p-value		**0.5**		**<0.001**	**<0.001**		**<0.001**
Not given at facility	10 (1.5)	69.6	12 (1.8)	61.7	51.5	62 (8.8)	21.7

* Unadjusted rates.

Table 4-4. Linear model of vaccination rates (per center) by of standing order policies, adjusted for racial composition, size, and profit status

	Influenza		**Hepatitis B partial + full**		**Hepatitis B full**		**Pneumococcal disease**	
	Absolute change (%), CI	p-value	Absolute change (%), CI	p-value	Absolute change (%), CI	p-value	Absolute change (%), CI	p-value
Intercept	**84.08** (79.69, 88.47)	<0.001	**68.48** (62.94, 74.02)	<0.001	**59.38** (53.12, 65.64)	<0.001	**43.51** (36.29, 50.73)	<0.001
Order policy								
Chart orders	1.27 (-2.91, 5.45)	0.5	**11.01** (5.46, 16.56)	<0.001	**12.98** (6.70, 19.25)	<0.001	**20.05** (13.11, 26.99)	<0.001
Facility-wide orders	0.42 (-3.84, 4.68)	0.8	**8.93** (3.18, 14.68)	0.002	**10.95** (4.45, 17.45)	<0.001	**21.35** (14.04, 28.65)	<0.001
Physician-specific orders	-1.91 (-7.99, 4.18)	0.5	-2.65 (-11.43, 6.12)	0.5	1.76 (-8.12, 11.68)	0.7	**10.72** (0.88, 20.57)	0.03
Individual orders	reference group		reference group		reference group		reference group	
Not given at facility	-39.22 (-62.72, -15.73)	0.001	-63.26 (-93.13, -33.39)	<0.001	-51.74 (-85.51, -17.98)	0.003	**-18.16** (-28.31, -8.00)	0.001
Other factors (if significant)								
Size (quintile, 0=low, 4=high)	**-2.56** (-3.48, -1.64)	<0.001					**-2.41** (-4.12, -0.69)	0.002
Black % (quintile, 0=low 4=high)	**-1.73** (-2.56, -0.91)	<0.001					**-4.06** (-5.59, -2.52)	0.006
Profit (yes)			**-4.84** (-8.63, -1.06	0.01	**-9.84** (-14.09, -5.59)	<0.001		

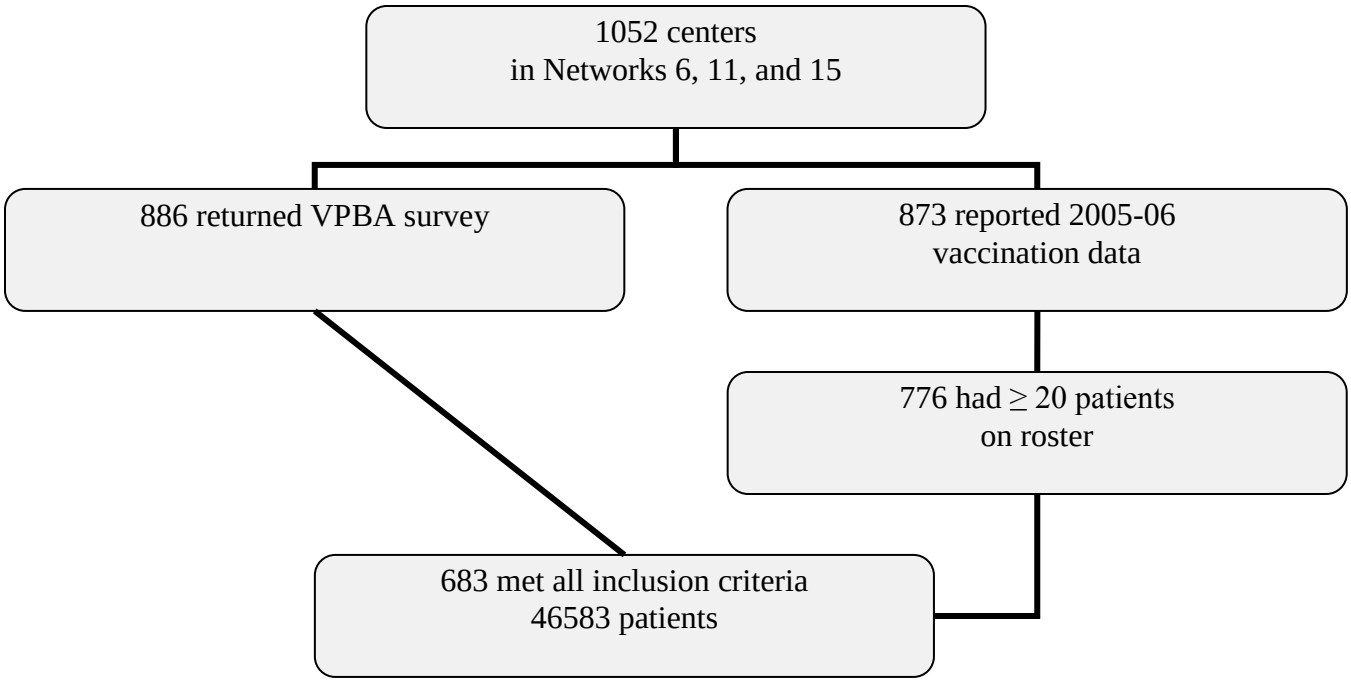

Figure 4-1. Survey study flow

CHAPTER 5: MANUSCRIPT 2

Improving Influenza Immunization Rates Among ESRD Clinics: a Group-Randomized Evaluation of a Quality Improvement Intervention

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ABSTRACT

Background: Patients with end-stage renal disease (ESRD) are at high risk for complications from influenza, but many dialysis centers report < 50% influenza immunization coverage.

Study Design: A group-randomized evaluation of a multicomponent intervention to increase influenza vaccination rates in poorly performing dialysis centers in ESRD Networks 6, 11, and 15.

Setting & Participants: Facilities with the lowest immunization percentages in 2006-07 were selected from each Network and randomly-assigned to a "standard intervention" (n=39) or "intensive intervention" (n=38). Standard intervention included a feedback report with comparison to other centers in their Network and educational materials for staff and patients. Intensive intervention centers also received 3 educational seminars, assistance with and review of center-specific action plans, and monthly monitoring of vaccination plan and rates.

Results: There was an 8.9% (p=0.041) mean absolute difference in improvement between intervention centers (+28.2%) and standard intervention centers (+19.2%).

Limitations: Some vaccinations were self-reported by patients. The vaccination data form does not have option for patient data unavailable, which may have caused patients without data to be coded as unvaccinated.

Conclusions: Poorly-performing centers receiving multicomponent intervention had a mean change in rate that was 8.9% higher than center that had a standard intervention.

This is a measure of the efficacy of the intensive program. Influenza vaccination reduces mortality among ESRD patients who have been on dialysis for more than 1 year.

BACKGROUND

Influenza vaccination is important for end-stage renal disease (ESRD) patients as influenza complications in this group are considerably worse than in the general population.[107] Influenza vaccination in patients on dialysis provides adequate protection with standard dosing regimens.[114] Available data suggest that influenza vaccination is associated with a lower risk for hospitalization and death.[41] The Healthy People 2010 goal for ESRD patients is that 90% should be vaccinated annually against influenza. Despite the clear benefits of influenza vaccination and accessibility of this patient population, reported coverage among ESRD populations (average vaccination rate: 59-76%) is suboptimal and varies substantially by age, and geographic region.[39, 40, 42, 117]

Coordinated multicomponent quality improvement (QI) interventions have been shown to improve the care of ESRD patients.[6, 110] For example, Zgibor et al[90] have reported that a multicomponent intervention using an immunization toolbox and documentation system was associated with increases in reported influenza vaccination rates from approximately 60% to approximately 80% in two states.

This evaluation method employed here can serve as a model for other efforts to determine the effectiveness of policies or treatment protocols via experimental means. Applying evidence-based methods of evaluation can more fully assess the impact of QI interventions, isolating the effect of the intervention from other factors (eg, change in policies/programs, new mandates or guidelines, vaccine supply issues, etc.).[99, 102, 109] Here we present one approach to this analytical issue: a group randomized evaluation of a multicomponent intervention to increase influenza vaccination rates in poorly performing

dialysis centers in three ESRD Networks. The inclusion of a “standard intervention” group and an “intensive intervention” group allowed us to formally evaluate the benefits of the enhanced QI program above and beyond existing efforts while accounting for unknown factors.

MATERIAL AND METHODS

The clinical setting for our quality improvement intervention was outpatient hemodialysis centers in ESRD quality improvement Networks 6 (North Carolina, South Carolina, Georgia), 11 (Michigan, Minnesota, North Dakota, South Dakota, and Wisconsin) and 15 (Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming). These three Networks served over 65,000 patients in 1050 dialysis facilities at the time of the intervention. Networks 6, 11, and 15 are all members of an ad hoc working group, the Safe and Timely Immunization Coalition (STIC), which was convened to coordinate efforts to increase immunization rates.

Median influenza vaccination rates in 2006-07 were 78.9% in Network 6, 81.7% in Network 11, and 81.2% in network 15. The overall median across Networks was 80.0%. For the purposes of this evaluation, 45 intensive intervention centers were to be randomly selected among the 90 centers in each Network with the lowest reported rates, allowing for an equivalent comparison group. The nonselected centers would receive the standard intervention (see below).

In Network 15, the medical review board determined that all centers with 2006-07 rates under 40% should receive the intensive intervention. These 10 centers—not subject to random assignment—were not included in this evaluation. The network allowed 8 additional intensive interventions to be assigned among the next-lowest performing centers. Due to a tie, 17 eligible centers were identified. Thus the final list of eligible centers included 77 centers: 30 from Network 6, 30 from Network 11, and 17 from Network 15.

Treatment Center Selection

Each Network had conducted surveys of patient influenza immunization rates for all centers during the previous 2 influenza seasons: 2005-06 and 2006-07. These outcomes were used to select centers for this 2007-08 intervention program. Centers were selected if they met the following criteria: 1) responded to the survey for the 2006-07 influenza season; 2) had $\geq$ 30 patients on their treatment roster; and 3) either reported an influenza immunization rate lower than 75% in 2005-06 or failed to report any rate for 2005-06. The third criteria was employed in order to ensure a group of consistently underperforming centers.

To further account for year-to-year variability in the selected centers, centers were stratified into three groups: no 2005-06 rate reported, 2005-06 rate within one standard deviation of 2006-07 rate (+/-18%), and 2005-06 rate more than one standard deviation different than 2006-07 rate. Within these rate strata, centers were further stratified by size (above or at the median versus below the median for the Network as a whole) to ensure

balanced selection. Thus a total of 18 strata were defined: 3 Networks * 3 variability groups * 2 size categories.

Centers were randomly assigned in a 1:1 ratio to intensive intervention or standard intervention within Networks and within blocks for each Network. Centers were identified only by Network, ID number, size, and vaccination rates and assignment was performed centrally. The intensive intervention group included 38 centers, with 39 in the standard intervention group.

Standard Intervention

"Standard intervention" is used as a label for the baseline practice of these 3 Networks with regard to influenza vaccination. It includes a feedback report and educational materials developed for past influenza vaccination campaigns. All centers also have access to Network staff and can request additional assistance.

All treatment centers received a center-specific quality of care feedback report that summarized the findings from the 2006-07 immunization survey. These feedback reports provided comparative data about immunization rates at their clinic and of other treatment centers within the three Networks. Thus poorly-performing centers were made aware of their status and—as participants in their ESRD Network—the potential for additional action.

All centers were provided with educational materials previously developed for both staff and patients by the STIC coalition: the CDC/STIC *Guidelines for Vaccinating Kidney*

Dialysis Patients and Patients with Chronic Kidney Disease (2006)[111], along with videos, booklets, and brochures related to established guidelines and the importance of immunization.

Intensive Intervention

In addition to the standard intervention, centers allocated to the intensive intervention group received a multifaceted intervention that included: 1) educational seminars; 2) assistance with and review of center-specific action plans for improving immunization coverage; and 3) monthly calls between the Networks and the centers in order to monitor plan implementation and proportion of patients vaccinated.

Educational seminars. During the period of October-December 2007, three 30-45 minute internet educational seminars were conducted (WebEx Communications, Inc., Santa Clara, CA). Printed materials were sent to the Medical Director, Center Administrator, and Director of Nursing. The seminars covered: 1) influenza immunization basics (influenza, its health burden in ESRD population, the efficacy and safety of immunization, Centers for Disease Control and Prevention (CDC) guidelines for ESRD)[111], 2) how QI methods could be used to identify, design, and implement a center-specific plan to overcome barriers to immunization, and 3) overcoming barriers (potential barriers to immunization, information about successful programs, and details from 2006 survey regarding concerns versus experiences with standing order policies). These seminars were developed collaboratively by Network staff, the CDC, and Emory University. They were posted online and available to clinical staff from all centers. A

planned live check-in system malfunctioned. However, centers selected for the intensive intervention were called by Network staff to confirm that staff had attended the seminar and/or reviewed the materials.

QI assistance and review. Assistance with and review of center-specific action plans was provided by each Network's staff. These plans, composed by center staff, were tailored to the process and outcome indicators for their treatment center. A template with written instructions and details about the elements of a QI plan was distributed to the participating centers, including adapted materials about root cause analysis and generating a list of potential barriers. All plans were to include an immunization goal for the 2007-08 influenza season, problem statements defining each problem or underlying cause that had prevented this goal from being met in the past, and action plan steps for addressing each problem or underlying cause (including the team members responsible for completing the task and an estimated time frame). Although the action plans were composed wholly by center staff (i.e., not on a prescribed, standardized form), they were asked to address the following topics in some manner: 1) review of immunization order procedures; 2) education process for staff regarding efficacy, safety, and administration of immunizations; 3) education process for patients; and 4) plan to address patient refusal of immunization. The QI plan was to be submitted by the center and reviewed by the Network staff in consultation with its own medical review board. Plans were approved or returned with feedback and then resubmitted until approved by the Network.

Monthly monitoring. Monitoring of a center's implementation of their action plan and influenza vaccination rate was conducted by its Network's quality improvement coordinator between October 2007 and May 2008. Verbal reports were to address: 1) progress toward immunization goal; 2) progress toward implementation of action plan; 3) changes to immunization order procedures; 4) number of staff receiving educational programs and/or materials; 5) number of patients receiving counseling or information regarding influenza immunization; and 6) information about patients who refused vaccination (number of patients, additional education provided to such patients, and number (if any) who Action plan content for each intensive intervention center was summarized via a data collection form by Network staff. Details about the completeness of a plan, its approval process, the topics it addressed, as well as the center's participation in monthly monitoring and topics discussed during that monitoring were available. were subsequently vaccinated. If necessary, Network staff or a designated member of the Network's medical review board provided phone consultation to treatment centers that had difficulty implementing their action plan or demonstrating improvement in immunization coverage.

Data Collection

The 2006-07 immunization survey of all Network centers (used as pre-intervention data) included the number of patients at the center and the number who were vaccinated. These data were provided by each center and based on the center's own immunization recordkeeping practices (e.g. a centralized system, chart review).

The 2007-08 (post-intervention) survey of standard and intensive intervention centers listed each patient and requested individual information about vaccination status. These data were collected between May and July of 2008. In two Networks, this patient-specific data collection form was sent to all centers (regardless of participation in this intervention). In Network 11, patient-specific data were collected only from centers within the intensive intervention group.

Statistical Analyses

All analyses used center-specific values based on reported immunization rates from the influenza seasons before and after the intervention period: 2006-07 (baseline) and 2007-08 (post-intervention). The change from baseline in influenza immunization rate was calculated for each center as the numerical difference between these values. Thus the absolute change was considered, irrespective of baseline value: a change from 30% to 50% was considered equivalent to a change from 50% to 70%.

Mean differences between intervention groups were compared though a linear model that included the intervention group and dummy variables to account for the strata established during the process of random assignment, 16 variable for the 17 populated strata (1 of the 18 strata was unpopulated). All significance testing was evaluated using a p-value of < 0.05. This analysis proceeded under intention to treat assumptions. Data for all centers were included regardless of their level of participation in any intervention programs.

Additional secondary analyses of data from the intensive intervention centers were planned for differences in mean change by participation in elements of the intervention and by topics indentified in the action plans of centers.

RESULTS

Of the 77 centers selected for inclusion, 68 (88.3%) reported vaccination data for 2007-08, including 33 (84.6%) of 39 standard intervention centers and 35 (92.1%) of 38 intensive intervention centers. There were no significant differences between standard and intensive intervention centers with regard to mean baseline (2006-07) influenza immunization rate, size, percentage of black patients, profit status, mean age of patients, and gender distribution (**Table 5-1)**.

As assessed via the linear model, there was an 8.9% (95% CI: 0.36, 17.37; p=0.041) greater increase in influenza immunization rate in centers which had the intensive intervention. The crude difference was 8.4% (+30.4% in intensive intervention centers versus +22.0% in standard intervention centers. Breakdown by Network showed a pre- to post-intervention difference between 1.6% and 18.1% in the three Networks (**Table 5-2**).

Participation for intensive intervention centers was assessed by self-reported attendance at / review of educational seminars, submission of a QI plan, approval of that plan by the Network, participation in monthly monitoring of plan and rate, and reporting a rate for 2007-08 (**Table 5-3**).

Of the 38 centers selected for the intensive intervention, 35 (92.1%) submitted and obtained approval for a QI plan and 32 (84.2%) submitted a plan and reported a vaccination rate for 2007-08. There were 3 centers that participated in the QI plan process but did not report a rate and 2 intensive intervention centers that reported a rate but did not submit a plan or participate in any other aspect of the intervention. One of these 2 centers, in Network 6, reported a very low 2007-08 vaccination rate (14.63%) but was included in this intention-to-treat analysis. The other center, in Network 11, reported a rate of 68.95%. Of the 39 centers which received the standard intervention, 33 (86.8%) reported a 2007-08 rate. Among the 35 centers that submitted a plan, 32 (91.4%) participated in at least 4 months of monitoring.

All but 1 of the 35 intensive intervention centers that submitted a plan set a vaccination goal as requested: 11 set a goal of higher than 90%, 18 of 90%; 5 lower than 90%. One center set a goal of 100% and did not develop their plan further, stating that all patients had been vaccinated as of October 31, 2007. All of the 34 other plans were completely developed and reviewed. Of these, 32 were approved upon submission and 2 were sent back for revision. One of these plans was subsequently approved (it had lacked only signatures); the other was not resubmitted. No Network judged any plan to need further review by its medical review board. Submitted plans were generally complete. All 34 plans identified specific problems to address and outlined action steps to address all or most of these identified causes; 32 identified specific team members responsible; 33 included a time frame; and 32 stated an evaluation method.

Three topics were address by at least 1/3 of the 34 submitted action plans:

- New patient education programs (28 centers) were most likely to focus on general topics such as barriers and misconceptions (23/28). Seven centers incorporated an "immunization day" event; 5 of these also had another educational component.

- Patient refusal of immunization (25 centers) was most frequently addressed via a dedicated "level 2" staff member (e.g., nurse supervisor) (20/25).

- Alteration of immunization procedures (12 centers) included revision of tracking and documentation systems (5), changing the timing or scheduling of the vaccination program (3), focusing on vaccinating new patients (3), establishing a new standing order programs for influenza vaccination (2), and reviewing consent forms (1). Monthly monitoring reports to Network staff found that at least 5 additional centers also addressed procedures.

The mean change in vaccination rate from 2006-07 to 2007-08 did not differ significantly by inclusion of any specific topic (**Table 5-4**). The total number of topics addressed by a center was also unrelated to change in rate.

High participation in all elements of the intensive intervention precluded analysis of differences in rate change by participation in specific elements (seminars, plans, and monitoring).

DISCUSSION

The aim of this evaluation was to determine whether an intensive intervention program to improve influenza immunization rates adds an additional benefit beyond a "standard intervention" (here defined as comparative feedback reports, educational materials, and

access to usual QI Network resources). The additional benefit was statistically significant on a per-patient basis at the poorly-performing centers studied. Overall, this evaluation provides evidence-based data regarding the extent to which a multicomponent intervention can impact vaccination rates at poorly performing dialysis centers. The evaluation of a differential effect such as that seen here (8.9%) must be assessed in light of the priorities of an institution/system, the resources it has available, and its patient population. For example, this intensive intervention program may be most appropriate for centers that have had consistently low rates, within networks with strong central administration, and for which other novel interventions (eg, patient incentives, signed declination forms) have failed or have been judged to be inappropriate.

Differences between the intervention groups varied across 3 ESRD Networks. Two Networks showed substantial differences in mean change between the standard and intensive intervention groups (+10.6% and +18.1%) and one Network did not (+1.6%). Because this study was conducted as an observation of 3 independently-operating Networks, variation may be expected. The Network with the lowest net change was different from the others in potentially important ways. These included lower participation in the intensive intervention components (**Table 5-3**) and data collection on the patient level for intensive intervention centers, but only as an overall number for the standard intervention centers. However, the impact of these differences cannot be determined and other unmeasured differences exist among all Networks.

These results are comparable to those of a group-randomized evaluation of coordinated multi-component intervention to increase dialysis adequacy in these same Networks.[6] The previous evaluation showed that an intensive intervention (feedback, seminars,

educational materials, clinical practice guidelines, technical assistance, and continued monitoring) was more effective than feedback alone. The mean center urea reduction ratio (URR) increased nearly 3% among intensive intervention centers but only 0.9% among the feedback-only centers.[6]

Strengths of this evaluation include the random allocation of centers, which allows for the evaluation of intensive intervention versus a comparable group of centers receiving standard support. The increase above standard intervention can thus be isolated from the raw increase. This is a truer representation of the effectiveness of an intervention and should be considered during resource allocation. Such an evaluation also accounts for changed conditions (eg, other initiatives, reimbursement procedures, regulations) and secular trends that may have contributed to the variation. It also addresses the problem of regression to the mean—particularly important in the case of poorly performing centers.

Some issues complicated this intention-to-treat analysis. The increases seen here are from a pre-intervention year (2006-07) for which only overall center figures were collected to a post-intervention year (2007-08). that patient-specific data were collected (except for standard intervention centers in one Network). These two contexts may produce different reported immunization rates. For example, patients with missing immunization data would appear on a patient-specific data collection form (as used in 2007-08) as unvaccinated. Patients with missing data may be more likely to be erroneously excluded altogether from an overall center tally (as in 2006-07)—producing an artificially higher rate. The precision with which immunization data are obtained also may differ between the two collection methods.

Centers were not eligible for inclusion in the study if they did not report a rate for 2006-07. Thus some centers that would have qualified for the intervention may have been missed. Otherwise eligible centers were also missed in Network 15, where centers that had a rate of lower than 40% were excluded from the random assignment—and thus the evaluation. (These centers improved by a mean of 48.8%: from 28.8% to 77.6%.) No data were collected on strategies in the standard intervention centers. These factors and the differing sizes of the Networks, make a precise comprehensive definition of the target facilities difficult. This intervention also took place in the context of a larger, multi-year program to increase vaccination rates.

The pragmatic nature of this evaluation (ie, not tightly controlled) demonstrates a possible model for the evaluation of policies and treatment protocols via experimental means. Pragmatic aspects of the program included the center-specific formulation of QI plans and the lack of blinding during the observation. Centers were asked to formulate their own plans, assert their own vaccination goal, and identify the root causes of past problems and the action steps, personnel, time frame, and evaluation steps to address those problems. This flexible framework allows for an assessment of a QI process that can be applied to a variety of situations, rather than a narrowly-defined plan that is designed for dialysis centers in specific geographical areas.

The framework of this intervention did not allow analysis of individual intervention elements because a large majority of centers chose the same options (education program and addressing refusals). A future evaluation may provide additional insight is educational programs are excluded from the intervention program or made mandatory for all centers (eg, not counting as one of the selected element).

Centers in both groups were not blinded to the evaluation process and frequent communication occurs among centers in the context of Network activities and, in some cases, being part of a larger multi-state for-profit dialysis provider group. No centers which were randomly allocated to the standard intervention group requested elements of the intensive intervention, but knowing of the intervention may have affected their behavior. Cross-talk—which potentially spurs additional action—complicates the interpretation of this study, but may benefit patients. Potential multiyear effects should also be considered: intensive intervention centers may be more likely than standard intervention centers to sustain their improved patient coverage.

Overall, this evaluation provides evidence-based data regarding the extent to which a multicomponent intervention can impact vaccination rates at poorly performing dialysis centers. The evaluation of a differential effect such as that seen here (8.9%) must be assessed in light of the priorities of an institution/system, the resources it has available, and its patient population. For example, this intensive intervention program may be most appropriate for centers that have had consistently low rates, within networks with strong central administration, and for which other novel interventions (eg, patient incentives, signed declination forms) have failed or have been judged to be inappropriate.

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Table 5-1. Characteristics of dialysis centers in the QI program evaluation

	All Networks			Network 6		Network 11		Network 15	
	Standard	Intensive	p-value	Standard	Intensive	Standard	Intensive	Standard	Intensive
Centers	33	35		13	15	11	12	9	8
2006-07 (baseline) rate (mean, SD)	45.58 (12.91)	43.19 (13.09)	0.4529	34.07 (7.74)	32.73 (9.65)	51.87 (10.57)	51.00 (10.81)	54.51 (8.79)	51.11 (7.13)
Mean number of patients	95.0 (62.4)	90.2 (46.3)	0.7187	69.2 (27.6)	73.9 (25.9)	122.0 (77.7)	108.4 (61.8)	99.3 (69.1)	93.5 (43.5)
Mean percent black	51.4 (27.0)	59.2 (34.2)	0.3264	75.1 (15.7)	81.8 (16.0)	50.8 (20.7)	55.8 (37.2)	23.3 (14.6)	25.9 (23.4)
Percentage of centers for profit	87.9	88.6	0.8875	100.0	100.0	72.7	83.3	88.9	75.0
Mean age of patients	60.5	59.9	0.8970	57.9	56.9	60.7	61.0	62.7	61.5
% Female	47.6	46.7	0.5151	51.6	46.2	46.8	46.7	45.0	47.4

Table 5-2. Changes in vaccination rate

	Intensive intervention			Standard intervention			Comparison		
	n	**2007-08 % (mean)**	**Change from 2006-07 %| (mean, 95% CI)**	**n**	**2007-08 % (mean)**	**Change from 2006-07 %| (mean, 95% CI)**	**Crude difference in mean change % (mean, 95% CI)**	**Adjusted difference in mean change % (mean, 95% CI)**	**p-value**
All	35	73.56	**30.37** (24.65, 36.08)	33	67.57	**21.99** (15.25, 28.73)	**8.38** (-2.98, 17.05)	**8.86** (0.36, 17.37)	p=0.041
Network 6	15	68.72	**35.99**	13	59.65	**25.59**	**10.40**	**10.64**	
Network 11	12	73.38	**22.38**	11	73.20	**21.32**	**1.05**	**1.59**	
Network 15	8	82.92	**31.81**	9	72.12	**17.61**	**14.20**	**18.06**	

Table 5-3. Participation among centers assigned to the intensive intervention

	Selected	Plan submitted	Plan approved	Participated in ≥ 4 monthly monitoring periods	2007-08 rate reported*	Plan submitted and 2007-08 rate reported
All	38	35 (92.1%)	34 (89.5%)	32 (84.2%)	35 (92.1%)	33 (86.8%)
Network 6	15	14 (93.3%)	14 (93.3%)	13 (86.7%)	15 (100%)	14 (93.3%)
Network 11	15	13 (86.6%)	12 (80.0%)	11 (73.3%)	12 (80.0%)	11 (73.3%)
Network 15	8	8 (100%)	8 (100%)	8 (100%)	8 (100%)	8 (100%)

* Group used for analysis.

Table 5-4. Reported change in vaccination rate by topics addressed in the intervention plan among intensive intervention facilities*

	Yes			No			p-value
	N total	N with reported rate	% change	N total	N with reported rate	% change	
Patient education	28	27	31.82	6	5	28.97	0.7083
Address refusals	25	23	29.56	9	9	36.02	0.2906
Change order procedures	12	11	28.20	22	21	33.04	0.4037
Staff vaccination incentives	5	5	25.61	29	27	32.45	0.3667
Patient reminder system	4	4	23.35	30	28	32.53	0.2681
Provider assessment and feedback	2	1	28.81	32	31	31.46	0.8675
Patient incentives	2	2	45.97	32	30	30.41	0.1671

* Centers were asked to address multiple topics. Combinations of topics were not assessed.

CHAPTER 6: MANUSCRIPT 3

Influenza Vaccination Status and Mortality in End-Stage Renal Disease Patients

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ABSTRACT

Background: Patients with end-stage renal disease (ESRD) are at increased risk for morbidity and mortality due to infection. The association between influenza vaccination and all-cause mortality in this population is not known.

Study Design: Retrospective analysis of health status at dialysis initiation, vaccination data for influenza and pneumococcal disease, laboratory results, and mortality data for all patients in ESRD Networks 6, 11, and 15.

Setting & Participants: Of the 1033 dialysis facilities considered, 903 centers with a total patient population of 54734 reported vaccination data. A total of 36966 of these patients had initiated dialysis treatment 1 year or more before the mortality period under consideration.

Results: When the effect of dialysis center was taken into consideration, the estimated adjusted OR for mortality (vaccinated versus unvaccinated patients) was 0.74 (95% CI: 0.68, 0.80). When patients with “UNKNOWN, not known by patient” status were excluded, the measured effect was reduced but remained significant: OR=0.83 (95% CI: 0.76, 0.91).

Limitations: Some vaccinations were self-reported by patients. Data form does not have option for patient data unavailable, which may have caused patients without data to be coded as unvaccinated.

Conclusions: Influenza vaccination reduces mortality among ESRD patients who have been on dialysis for more than 1 year.

BACKGROUND

People with ESRD have a significantly higher adjusted mortality rate than the average population, 192.8 per 1000 patient years for this population with a mean age of approximately 60 years.[23] For this reason they are considered high-risk patients and prioritized for influenza immunization.[1, 24] However, unlike other community-dwelling patient populations, ESRD patients receive dialysis approximately three days per week. Among their many responsibilities, dialysis centers treating these patients are charged with ensuring the administration of the seasonal influenza vaccine and thus ESRD patients have repeated opportunities to receive vaccination so long as they continue dialysis treatment. The aim of this study was to determine whether prevalent ESRD patients on dialysis for at least 1 year who received an influenza vaccination have a lower all-cause mortality risk in the 12 months following the start of influenza season than those who did not.

METHODS

The patient population for this study includes patients in ESRD Network 6 (North Carolina, South Carolina, Georgia), Network 11 (Michigan, Minnesota, North Dakota, South Dakota, and Wisconsin) and Network 15 (Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming). These three Networks serve over 65,000 patients in 1050 dialysis facilities. The Networks collected the data used here as part of an ad hoc working group, the Safe and Timely Immunization Coalition (STIC). STIC, a consortium of Network administrators and representatives of large dialysis providers, nursing groups, quality improvement organizations, patients groups, and Emory University, was convened to coordinate efforts to increase immunization rates.

Patients were eligible for inclusion in this assessment if they had been receiving dialysis for at least one year as of January 1, 2005 (**Figure 6-1**). Individual patient baseline data were available through each patient's ESRD initiation form (CMS 2728). The ESRD facility survey (CMS 2744) was used to specify facility characteristics. Death and cause of death information through December 31, 2006 was collected through the ESRD death notification form (CMS 2746). Patients with missing vaccination data were excluded from the analysis.

Monthly laboratory data for albumin, hemoglobin and KT/V (a urea-based measure of dialysis adequacy) for the 3-month vaccination period (October-December) came from records at each center. All tests were conducted at the centers as part of routine patient care. Mean values for each test were calculated over the 3 months, so long as at least one value was available for a given test. Patients will all data missing for a given month were documented as "missing" for that month and an integral variable was included in the each model for number of months with missing lab values.

Vaccination data for each patient from the 2005-06 influenza season between September 2005 and March 2006, were collected from each center by a survey conducted by the participating ESRD Networks. Both influenza vaccination (received yearly vaccination) and vaccination against pneumococcal disease (ever vaccinated) were available. Patients were considered vaccinated if they were recorded as having been vaccinated within the treatment center "received at this facility" or reported that they have received a prior vaccination "received at another location." Otherwise patients were considered unvaccinated.

Patient characteristics by vaccination status were compared via chi-square tests and t-tests. The likelihood of mortality was assessed via multivariable logistic regression controlling for patient age, race, gender, time on dialysis (vintage), diabetes primary cause of ESRD (yes or no), comorbidities at dialysis initiation (congestive heart failure, cerebrovascular disease [CVD], peripheral vascular disease [PVD], history of hypertension, chronic obstructive pulmonary disease [COPD], and malignant neoplasm), mean monthly patient lab values for albumin, hemoglobin and KT/V during the 3-month vaccination period, and pneumococcal vaccination status. All possible interaction terms for patient demographics—age, race, gender, time on dialysis (vintage), and diabetes as cause of ESRD—were included in the multivariable models.

We controlled for effect for center (to account for confounding due to unmeasured dialysis facility characteristics) in two separate analyses: by including a fixed effect term for center in a maximum likelihood model (SAS 9.2) and by including a random effect for center in a penalized quasi-likelihood (PQL) model (HLM 6.08). A center code was included for all patients at centers with a patient population of 20 or more. Other patients were assigned a “missing” value for center code.

Survival curves, adjusted for age and vintage and stratified by race, were produced to examine the association of mortality with vaccination over the course of the year. Survival analyses were run in PROC PHREG (SAS 9.2).

This analysis was also conducted at the center level to determine if a relationship between a center’s vaccination rate and its mortality rate was observable. To obtain an standardized mortality rate (SMR) for each center, patient-specific predicted probabilities

of mortality were calculated based on all non-vaccination data (demographics, baseline comorbidities, and lab values), and summed for each center. The observed number of deaths at a center was then divided by this predicted number of deaths. These SMRs were compared to center-level vaccination rates via Spearman correlation to determine whether centers with higher vaccination rates are more likely to have lower SMRs (ie, fewer deaths than were predicted by a model which did not include influenza vaccination data).

RESULTS

Among patients who had been receiving dialysis for more than 1 year, 80.3% were vaccinated against influenza during the 2005-06 season. Vaccine recipients had a lower proportion of black patients (43.3% versus 55.7%, $p < 0.0001$) and were older on average (61.5% versus 58.1%, $p < 0.0001$) (**Table 6-1**). They also had generally worse baseline health status as evidenced by small but significant differences in rates of comorbid conditions at the time of dialysis initiation: congestive heart failure, CVD, PVD, history of hypertension, diabetes, COPD, and malignant neoplasm. Patients who received vaccination had better lab values for 3-month mean albumin, hemoglobin, and KT/V. They were also less likely to miss blood draws for their lab tests (a possible indicator of dialysis receipt and/or overall health).

Of all patients who met the inclusion criteria, 6311 (20.59%) of 36933 died (**Table 6-2**).Mortality rates differed across reported vaccination status and included substantial variability within groups (vaccinated and unvaccinated). For example, patients who were documented as receiving influenza vaccination at their center had a 1-year mortality rate

of 15.23% and those who self-reported vaccination elsewhere had a rate of 21.45%. Patients who refused vaccination had a mortality rate of 15.63% but those who were listed as “NO, other reason” had a rate of 26.09% and those considered unvaccinated because they did not know their status had a rate of 26.67%.

The OR (95% CI) for mortality, adjusting for all individual patient characteristics, for pneumococcal vaccination and significant interaction terms (age*race, age*sex, and age*vintage), was 0.75 (95% CI: 0.70, 0.81) for individuals receiving the influenza vaccination. When center was employed as a fixed effect, accounting for correlation within center, OR (95% CI) was 0.74 (95% CI: 0.68, 0.80) (**Table 6-3**). When “UNKNOWN” patients were eliminated from consideration, the effect remains significant: 0.83 (95% CI: 0.76, 0.91) (see **Conclusions**).

When the adjusted OR was calculated with center as a random effect in a PQL model, the estimated effect of influenza vaccination was very similar: OR=0.73 (95% CI: 0.67, 0.81) including patients with “UNKNOWN” status and 0.82 (95% CI: 0.75, 0.92) without these patients. The significance of the random effect was $p < 0.0001$.

The effect of vaccination against pneumococcal disease was as strong as that of influenza vaccination and the effects of the two vaccinations were independent of one another in the main logistic analysis. When patients of “UNKNOWN” were excluded and the comparison group limited to patients who received neither vaccination, those who received only influenza vaccination had a mortality OR=0.83 (95% CI: 0.75, 0.93), those with only pneumococcal vaccination had an OR=0.87 (95% CI: 0.67, 1.12), and those who received both vaccination had an OR=0.70 (95% CI: 0.62, 0.80).

The OR estimate for the protective effect of influenza vaccination varied by the overall vaccination rate of the center, indicating a possible attenuation of individual benefit at centers with high vaccination rates (perhaps due to secondary protection provided to unvaccinated patients). However, the association between vaccination and mortality remained strong throughout all strata and significant in all strata below 90% (**Table 6-4**). Herd immunity thresholds for influenza vaccination among adults only have not been established, but thresholds for other vaccine-preventable diseases are generally estimated at 80% or higher.[118, 119]

Due to significant interaction between race and other covariates (but not influenza vaccination), two survival curves were required to visually summarize deaths over the course of the year: one for black patients and one for white and other patients (**Figures 6-2 and 6-3**). In both cases, the relationship between vaccination and mortality—when adjusted for previously considered factors—was more pronounced in the first half of the year versus the second half of the year. The hazard ration (HR) for vaccinated versus unvaccinated black patients was 0.64 in the first half of the year and 0.88 in the second half. The HR for vaccinated versus unvaccinated white and other patients was 0.67 in the first half of the year and 1.05 in the second half. The differences between the two halves of the year were statistically significant for both groups.

Of the 6311 deaths, a total of 237 patients (3.8%) had “Pulmonary infection (pneumonia, influenza)” listed as the primary (n=126) or secondary (n=111) cause of death. Of these patients, 197 were vaccinated and 40 were unvaccinated. The incidence densities for the two groups (7.26 and 6.22 deaths/1000 pt-yrs, respectively) were not significantly different (p=0.2093). There were no significant differences in vaccination rate across

groups when the patient deaths were classified by primary cause into infection (779 deaths, 75.22% vaccinated), cardiac (2641 deaths, 77.55% vaccinated), and other (2889 deaths, 77.02% vaccinated).

An unadjusted analysis of one-year mortality and influenza vaccination percentage showed no significant negative correlation among centers with at least a 40% vaccination rate (**Figure 6-4**). When SMRs were calculated for each center based on summed patient-specific predicted probabilities of mortality, the resulting Spearman correlation between SMR and vaccination rate among centers with ≥ 20 patients and a vaccination rate of ≥ 40% was not statistically significant (-0.034, p=0.3869) (**Figure 6-5**). However, the estimated correlation is inconsistent across the range of vaccination rates.

CONCLUSIONS

The reportedly high estimated effect of influenza immunization on mortality—as high as a 50% reduction in some populations—has been a recent topic of methodological debate.[112, 113] A study in a community-dwelling elderly population found a nonsignificant effect of immunization on mortality (8% reduction) when a manual chart review of underlying health conditions was conducted along with a specific endpoint (mortality in X-ray confirmed pneumonia hospitalizations).[120] Two major issues have been indentified in these analyses: 1) selection bias (eg, healthy community-dwelling elderly are more likely to receive a vaccination than their less healthy counterparts who may be confined to their homes or more concerned about other health issues); and 2) measurement bias (determination of influenza-related death). The current study, conducted in a population

of patients with end-stage renal disease (ESRD), addresses some of the methodological concerns related to selection bias.

The adequacy of the immune response to influenza vaccination among ESRD patients has been established,[31-34, 41] as has the high burden of infection-related complications in this population.[107, 108] ESRD patients—especially hemodialysis patients—are more likely than other patients to be hospitalized for bacteremia or septicemia (102.0 admissions per 1000 pt-years) and pneumonia (73.4 per 1000 pt-years) and once hospitalized these patients have lower 6-month survival rates.[23, 38] The issue of influenza and mortality in this population extends beyond the assignment of a primary cause of death. ESRD patients admitted with an infection have a 10-fold mortality risk versus ESRD patients admitted with no infection.[38] Overall hospital admissions rates for hemodialysis patients were down 0.6% in the 1993-2005 period, but up 37.5% for infection-related causes (not including infection related to dialysis access).[23]

Gilbertson et al had found that among hemodialysis patients, influenza vaccination was associated with an adjusted all-cause mortality odds ratio of 0.75 (95% CI: 0.71, 0.80) in 1997-98 and 0.77 (95% CI: 0.73, 0.81) in 1998-99.[41] Adjustments their analysis included variables for age, gender, race, ethnicity, ESRD network, a comorbidity index, and a severity of disease measure. These data add to theirs and provide additional value.

The data by Gilbertson et al was collected at a time of much lower influenza vaccination rates and in a dialysis population that had poorer standards of care, lower overall survival, and a difference mix of causes for hospitalization and death.[23] Also, Gilbertson et al also note the discrepancy between the vaccination rates they found through review of

Medicare data and the reported rates in ESRD Network 15 for 1998-99.[42] Aside from that study, the specific association between influenza vaccination and mortality has not been investigated in this population for several decades.[121]

This population—patients with ESRD—carries advantages over other at-risk populations in this context. Unlike community-dwelling elderly, or any other non-institutionalized population, patients with ESRD are seen by heath care professionals on a very frequent basis. Evaluation of the association between influenza vaccination and mortality may thus be less affected by any "healthy vaccine recipient" measurement bias. If a patient is healthy enough not to be hospitalized, he or she will have multiple opportunities to be vaccinated. In fact, dialysis patients in worse overall health should be prime candidates for vaccination at their center.

In all patient-level analyses a significant association was found between influenza vaccination and mortality in the subsequent 12 months. Survival curves suggest that this effect was most pronounced in the first 6 months following the start of influenza season. Patients at centers with higher vaccination rates received less apparent benefit from vaccination, as would be expected in a community with high immunization.

Among pulmonary infection-related deaths, a crude associated between vaccination and mortality was not found. Similarly, crude vaccination rates did not vary significantly across broad death categories (infection, cardiac, and other). Cause of death information is difficult to assess in ESRD patients,[122] particularly for patients who discontinue dialysis.[123, 124] Of all deaths in these data, 28.4% were classified as "unknown" (12.4%), "due to dialysis withdrawal" (10.9%), or "other" (5.2%). However, the conclusions of

this study would be stronger if a more pronounced association had been found between infection-related deaths and vaccination against influenza.

A second analysis asked the question “What would we find if we had only center-level vaccination data and ignored the available patient-level data?” The lack of crude association between a center’s mortality rate and its vaccination rate was not surprising. Dialysis centers vary considerably with respect to factors associated with both vaccination and mortality. The adjusted center-level analyses (SMR versus vaccination rate) proved to be very sensitive to decisions about a minimum size and range of influenza vaccination rates for centers and was significantly affected by outliers. The centers in these 3 Networks may be too similar in their overall rates (half are above 80%) to detect a difference. The instability of the center-level analysis (even with up to 600 centers included) and its apparent contradiction of the individual-level analysis supports the need for the collection of patient-specific data.

Several key limitations should be noted for this study. Most are related to the issue of measurement bias with respect to vaccination.

Current practices in the Network vaccination reporting in the system count patients as vaccinated if they received the vaccination at the dialysis clinic or report receiving the vaccination elsewhere. The self-reported vaccinations are not confirmed via medical records—indeed it may be very difficult to do so. However, mortality data by vaccination status show that patients vaccinated at the center (n=26346) had a mortality rate of 15.73% and patients who self-reported being vaccinated elsewhere (n=3329) had a

mortality rate of 21.45%. Incorrect self-reports of receiving vaccination would bias the results of this analysis toward the null.

As outlined previously, patients with missing data were excluded from this analysis. Death rates among patients with missing data varied substantially by the percent of missing patients at a center and the patients with missing data who died in 2006 did so earlier in the year compared to other 2006 deaths.

A total of 1542 patients had missing vaccination data. Of these, 189 patients were at centers that sent in a blanks for all patients for influenza vaccination, 339 were from centers which returned influenza vaccination data for less than 50% of their patients, and 1014 from centered that returned data for 50% or more of their patients.

All of these patients were on the patient roster for their respective center on 12/31/2005, but may have died or transferred to another care situation by the time the form was completed in the Spring of 2006. The data collection form did not provide an additional option for patients no longer on dialysis at that center. Data were intended to be collected regardless of any events prior to 1/1/2006.

The mortality rate for patients with missing data from centers with a reporting rate $\geq$ 50% was high (35.6%) and the average date of death was early (week 14) (**Table 6-5**). These observations suggest that patients with missing vaccination data were more likely to have discontinued dialysis or died in the period between 12/31/2005 and when their centers completed the vaccination survey.

Patients whose vaccination status is recorded as “UNKNOWN, not known by patient” were considered to be unvaccinated. (Individual centers have varying policies on whether or not to vaccinate patients whose status is unknown.) This may be a reasonable assumption, but this category also may provide a default option for patients whose vaccination status is in fact unknown *by the center* (because the patient was never asked or the records for a patient who left the facility between 12/31/2005 and the time the survey was completed were not consulted). The mortality rate for this group (n=1350) was 28.67%. When these patients are excluded from the analysis, the OR for mortality in the model with a fixed effect for center was 0.83 (95% CI: 0.76, 0.91) rather than 0.74 (95% CI: 0.68, 0.80).

According to the survey instructions, vaccination data should have been recorded for all patients, regardless of their current status. However, it is reasonable to assume that centers were more likely to enter “UNKNOWN” or fail to record the vaccination status of patients who had stopped dialysis at the center and/or died in early 2006. Based on these observation, future data collection forms may be more effective if an option is added for “UNKNOWN, patient records unavailable.” Alternatively, instructions should emphasize the need to gather information on all patients regardless of their current status.

It should be noted that patient comorbidities were determined at the initiation of dialysis—an average of more than 4 years prior to observation year. Current health status of patients was measured by lab values for last three months of 2005, however patient records were not reviewed for additional information. Staff vaccination records were not available.

In summary, the association between influenza vaccination and 12-month mortality among ESRD patients is significant, strong and independent of association between vaccination against pneumococcal disease and mortality. When the effect of center was taken into consideration, the estimated adjusted OR was 0.74 (95% CI: 0.68, 0.80). In a sensitivity analysis—when “UNKNOWN” patients were eliminated from consideration, the measured effect was reduced but remained significant: OR=0.83 (95% CI: 0.76, 0.91).

Data collection forms

- **Dialysis provider vaccination report**: A center-specific listing of all patients receiving dialysis at that center as of 12/31/2005. Data column included a code for each of 3 vaccinations (influenza, hepatitis B, and pneumococcal disease). The codes were:
  1. YES, received at this facility
  2. YES, received at another location
  3. NO, not received, pt refused
  4. NO, not received, pt allergic
  5. NO, not offered to pt
  6. NO, not time for dose (valid for hepatitis B only)
  7. NO, other reason
  8. UNKNOWN, not known by patient

- **CMS 2728**: Form which is completed for all newly-diagnosed ESRD patients. This form contains information about current health conditions, the cause of renal failure, current insurance status, current and past employment status, the modality of dialysis (peritoneal dialysis or hemodialysis) and information about pre-dialysis care. The 2728 form serves two purposes: it provides medical evidence of an end-stage renal condition for Medicare entitlement, and registers a patient in the United States Renal Data System (USRDS).

- **CMS 2744**: Form completed annually by all Medicare approved renal providers. Includes the address of the facility, modalities offered, number of patients at beginning and end of the year, and number and type of staff.

- **CMS 2746**: Death report completed by the designated center for that patient and due with 30 days of the date of death. Includes the date, place, and cause of death.

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Table 6-1a. Patient characteristics by exposure (influenza vaccination status)

Vaccination status		Vaccination status		95% CI for difference	p value
		+	-		
All patients	N %	29675 80.28	7291 19.72		
Male	%	53.12	50.39	+2.73 (1.45, 4.01)	<0.0001
Black	%	43.36	55.67	-12.31 (-13.58, -11.04)	<0.0001
Age (years)	mean	61.54	58.11	+3.43 (-3.82, -3.04)	<0.0001
Vintage (years)	mean	4.46	4.84	-0.38 (-0.28, -0.47)	<0.0001
Diabetes as cause of ESRD	%	44.86	38.71	+6.15 (4.88, 7.42)	<0.0001
Congestive heart failure	%	23.56	21.97	+1.59 (0.50, 2.67)	0.0041
CVD	%	7.26	6.15	+1.11 (0.49, 1.74)	0.0009
PVD	%	9.80	8.02	+1.78 (1.03, 2.53)	<0.0001
History of hypertension	%	80.87	78.21	+2.66 (1.61, 3.71)	<0.0001
Diabetes (insulin-dependent)	%	24.60	21.11	+3.49 (2.40, 4.58)	<0.0001
COPD	%	4.89	3.68	+1.22 (0.72, 1.71)	<0.0001
Malignant neoplasm	%	3.81	3.06	+0.75 (0.27, 1.23)	0.0022
Current smoker at dialysis initiation	%	5.85	6.82	-0.96 (-1.57, -0.35)	0.002
Alcohol dependence	%	1.65	1.96	-0.31 (-0.65, 0.02)	0.0643
Abnormal mean albumin	%	65.27	66.70	-1.43 (-2.68, -0.18)	0.0246
Abnormal mean hemoglobin	%	44.27	48.67	-4.40 (-5.70, -3.10)	<0.0001
Abnormal mean KT/V	%	8.69	14.42	-5.73 (-6.56, -4.89)	<0.0001
Missed labs (0-3)	mean	0.12	0.23	-0.11 (-0.13, -0.10)	<0.0001
Missing all 3 months	%	2.94	4.79	-1.85 (-2.31, -1.39)	<0.0001
Private insurance prior to ESRD	%	49.10	42.35	+6.74 (5.48, 8.02)	<0.0001
Previously employed (not vs full-time)	%	16.93	18.08		
Previously employed (part-time vs full-time)	%	3.12	3.25		
Employed at dialysis initiation (not vs full-time)	%	8.74	9.44		
Employed at dialysis initiation (part-time vs full-time)	%	2.24	2.19		

Table 6-1b. Influenza vaccination status by patient characteristics

		%
Sex	Male	81.10
	Female	79.37
Race (black/white or other)	Black	76.03
	White/other	83.88
Age	< 65	77.99
	≥ 65	83.39
Congestive heart failure	+	81.36
	-	79.95
CVD	+	82.78
	-	80.09
PVD	+	83.26
	-	79.97
History of hypertension	+	80.80
	-	78.13
Diabetes (insulin-dependent)	+	82.59
	-	79.55
COPD	+	84.42
	-	80.07
Malignant neoplasm	+	83.53
	-	80.15
Current smoker at dialysis initiation	+	77.75
	-	80.44
Alcohol dependence	+	77.37
	-	80.33
Abnormal mean albumin	+	80.27
	-	81.26
Abnormal mean hemoglobin	+	79.08
	-	81.85
Abnormal mean KT/V	+	71.74
	-	81.80
Missed labs (0,1,2,3)	0	81.27
	1	63.84
	2	47.64
	3	71.39
Private insurance prior to ESRD	+	82.51
	-	78.23

Previously employed (not, part, full)	Not	80.53
	Part-time	79.62
	Full-time	79.22
Employed at dialysis initiation (not, part, full)	Not	80.39
	Part-time	80.58
	Full-time	79.03

Table 6-2. Mortality by recorded vaccination status

Recorded vaccination status	Group	n	% of total	mortality
YES, received at this facility	YES	26346	71.27	15.73
YES, received at another location	YES	3329	9.01	21.45
NO, not received, pt refused	NO	4390	11.88	15.63
NO, not received, pt allergic	NO	113	0.31	16.81
NO, not offered to pt	NO	217	0.59	18.43
NO, not time for dose (valid for hepatitis B only)	NO	6	0.02	16.67
NO, other reason	NO	1215	3.29	26.09
UNKNOWN, not known by patient	NO	1350	3.65	28.67
Total		**36966**	**100.00**	**20.59**

Table 6-3. Odds ratios for influenza vaccination, patient-specific covariates, and a fixed effect for center

Effect	OR	Lower CL	Upper CL
Influenza vaccination	0.74	0.68	0.80
Pneumococcal \ vaccination	0.73	0.67	0.79
Diabetes as cause of ESRD	1.24	1.16	1.32
Congestive heart failure	1.33	1.24	1.42
CVD	1.28	1.16	1.43
PVD	1.25	1.13	1.37
History of hypertension	0.95	0.87	1.04
COPD	1.19	1.04	1.35
Malignant neoplasm	1.24	1.08	1.43
Current smoker at dialysis initiation	1.32	1.16	1.50
Alcohol dependence	1.21	0.96	1.54
Abnormal mean albumin	2.09	1.93	2.25
Abnormal mean hemoglobin	1.38	1.30	1.47
Abnormal mean KT/V	1.56	1.40	1.74
Missed labs (0-3)	1.36	1.20	1.54
Private insurance prior to ESRD	0.94	0.88	1.01
Previously employed (not vs full-time)	1.24	1.09	1.42
Previously employed (part-time vs full-time)	1.02	0.78	1.34
Employed at dialysis initiation (not vs full-time)	1.19	1.00	1.41
Employed at dialysis initiation (part-time vs full-time)	1.33	0.96	1.85
Provnum . vs 032501	1.96	0.97	3.98
Provnum 030022 vs 032501	0.92	0.26	3.24
Provnum 03013F vs 032501	0.85	0.20	3.58
Provnum 032502 vs 032501	1.66	0.71	3.89
Provnum 032503 vs 032501	1.67	0.62	4.49
Provnum 032504 vs 032501	2.36	0.68	8.12
Provnum 032506 vs 032501	0.35	0.09	1.37
Provnum	. . . . .	. . . . .	. . . . .

Table 6-4. Odds ratios for influenza vaccination stratified by vaccination rate at center—no center-level effects

Vaccination rate	Number of patients	OR	Lower CL	Upper CL
< 60%	5476	0.71	0.59	0.84
60% to < 80%	10440	0.70	0.61	0.79
80% to < 90%	13425	0.77	0.68	0.88
90% to 100%	7625	0.84	0.65	1.08

Table 6-5. Mortality rates for patients with missing vaccination data by percent of patients with missing data at center

Influenza vaccination status	n	Deaths	Mortality	Median date of death
Missing, center reporting rate ≥ 50%	1014	361	35.60%	Week 14.0
Missing, center reporting rate >0% but < 50%	339	70	20.65%	Week 24.5
Missing, center reporting rate = 0%	189	24	12.70%	Week 20.0
	1542	455	29.51%	

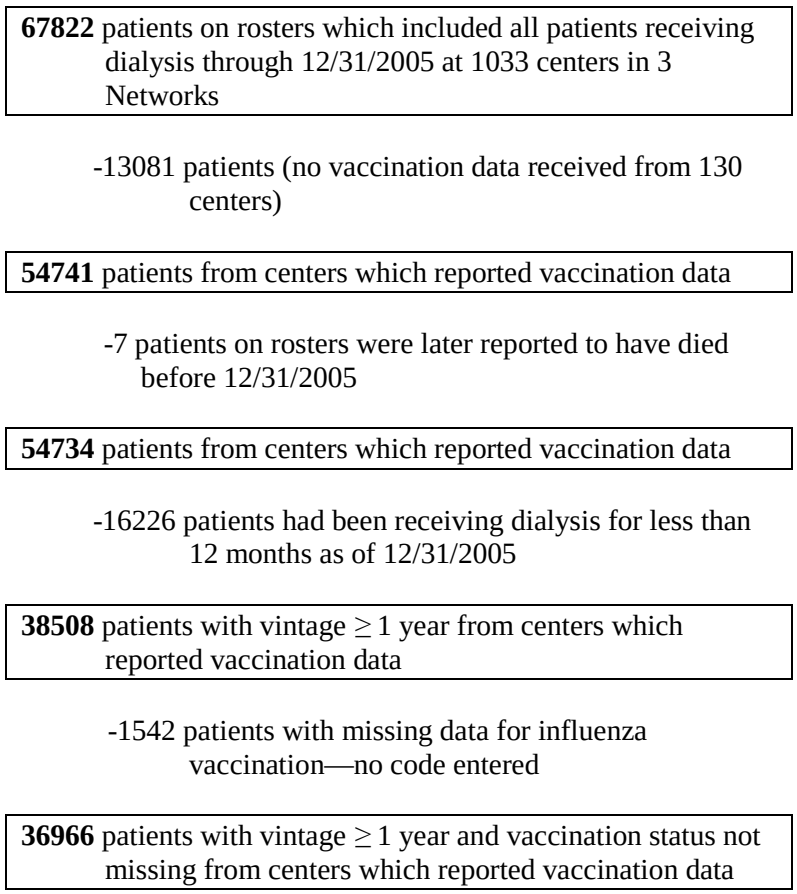

Figure 6-1. Mortality study flow: patient inclusion and exclusion.

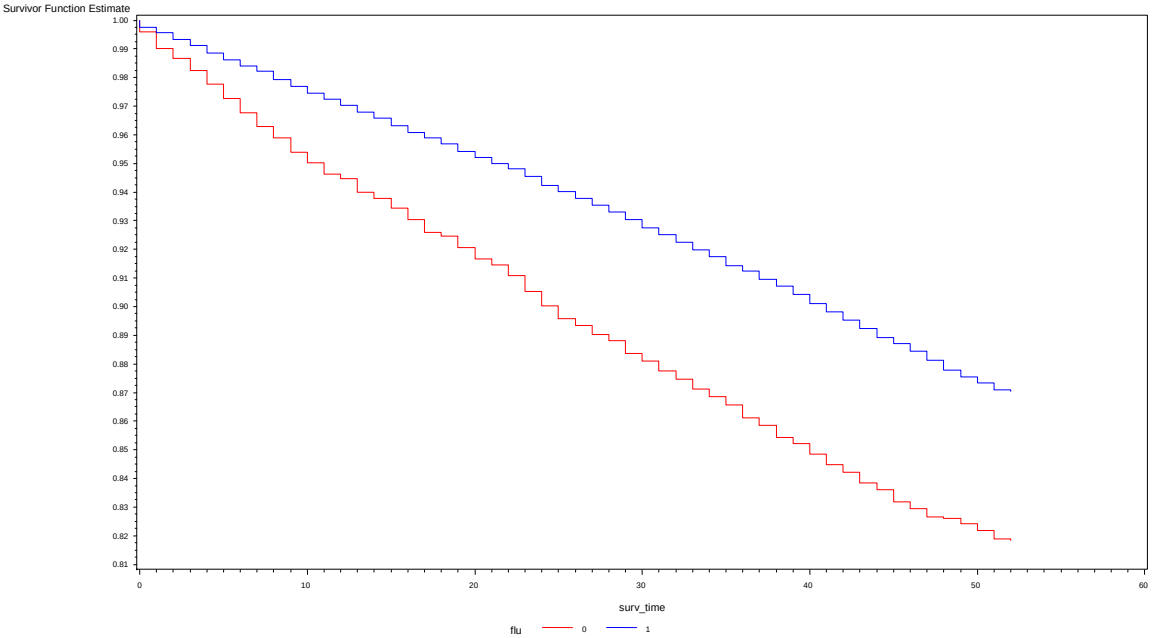

Figure 6-2. Survival curve for black patients: adjusted mortality by vaccination status.

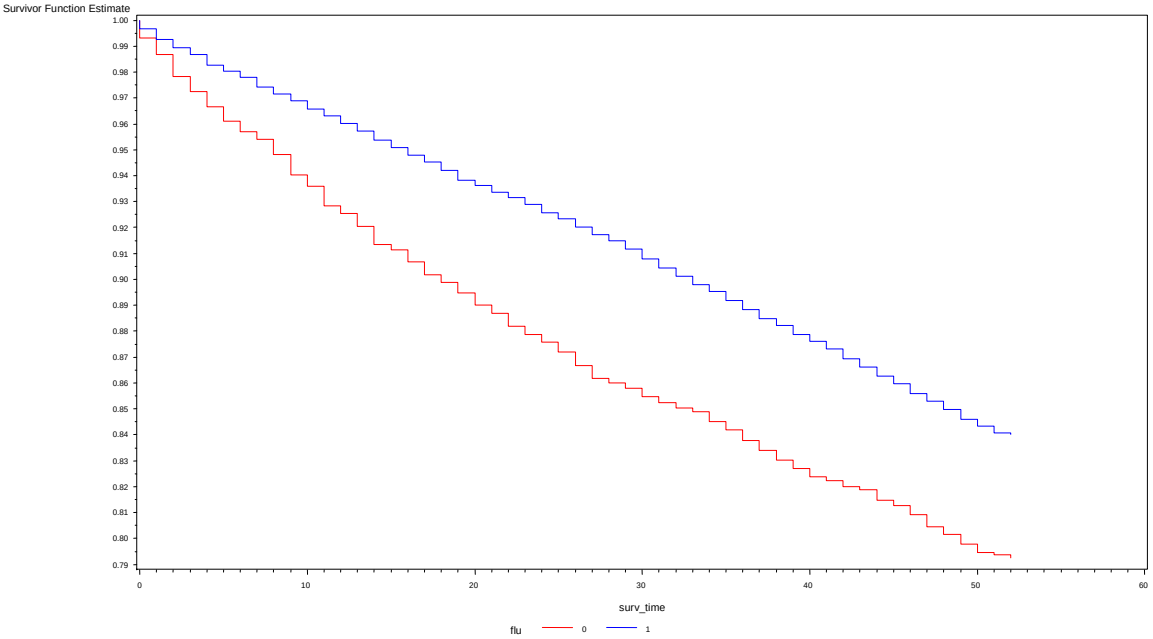

Figure 6-3. Survival curve for white and other race patients: adjusted mortality by vaccination status.

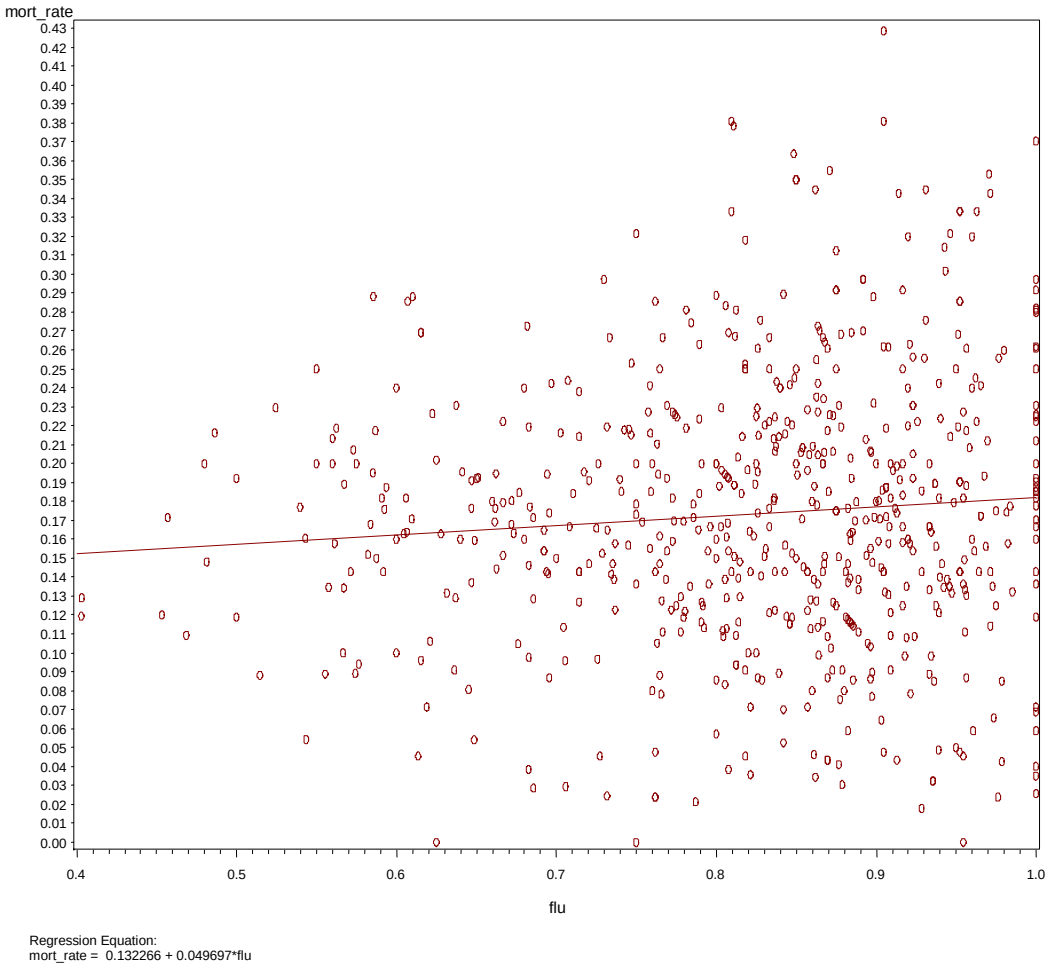

Figure 6-4. Crude mortality rate by influenza vaccination percentage.

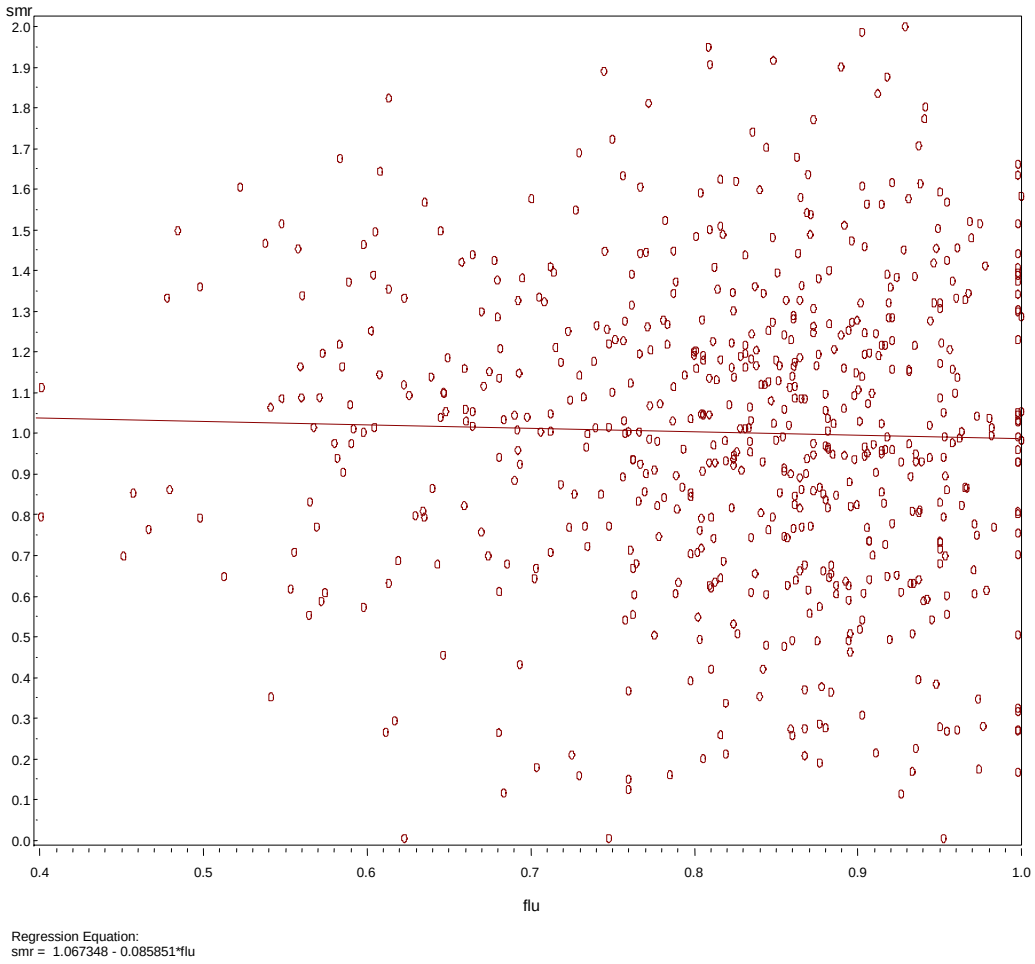

Figure 6-5. Standardized mortality rate by influenza vaccination percentage.

CHAPTER 7: CONCLUSIONS

The quality improvement program discussed here—conducted within 3 ESRD Networks under the mandate of a CMS-funded coalition—provided useful data and several key considerations for future work.

The VBPA Survey: Association of Standing Order Policies with Vaccination Rates in Dialysis Clinics

The Vaccination Practices, Beliefs, and Attitudes (VPBA) survey provided a snapshot of center-specific conditions and allowed for an assessment of the place of standing order programs in the overall quality improvement (QI) strategies of these Networks. The Networks had been operating under the assumption that promoting facility-wide standing order programs—the least restrictive permissions system—would lead to increases vaccination rates. However the results of a cross-sectional analysis of vaccination rates and order policies showed that: 1) chart-based orders and facility-side orders were equally associated with higher rates for vaccination against hepatitis B and pneumococcal disease, and 2) influenza vaccination rates did not vary significantly by policy. Both of these findings were unexpected and could potentially change the approach of these Networks to permissions policies.

If chart-based order programs—in which a patients have permissions for vaccination pre-recorded in their charts—are as effective as facility-wide orders in promoting vaccination against hepatitis B and pneumococcal disease, then centers need not be pushed to adopt facility-wide orders. The VPBA survey showed that centers with facility-wide orders were unlikely to experience many of the problems that centers without such orders anticipated when they were asked to contemplate adopting such a policy. However, chart

orders may be an effective alternative for centers with strong barriers (perceived or real) to facility-wide policies. Chart orders were the most popular option for all vaccination types among these centers and the majority of centers throughout the Networks had either chart orders or facility wide orders in place for influenza (81.2%), hepatitis B (84.8%) and pneumococcal disease (66.7%). Thus, rather than attempting to persuade a majority of centers to adopt a new facility-wide policy for vaccination, the Networks could choose to work with a minority of centers to adopt one of two possible new policies.

The lack of significant association between policies and influenza rates may be a result of the higher mean rate for influenza vaccination (76.2%) versus a full hepatitis B series (62.1%) and vaccination against pneumococcal disease (44.2%). This may be an indication of the limits of the association between policy and vaccination, or a result of the differences in vaccination schedules (annual versus 3-shot series versus one-time administration), or simply a chance occurrence. However, it suggests that efforts to increase vaccination rates via policy change may be more effective for the other two vaccinations.

Though not complete national data, these results cover patients in 3 Networks across 14 states with considerable geographical diversity. Also, the data discussed here are compiled from patient-specific data, which may provide more accurate reporting than the facility-level summaries used in previous studies.[39, 40] These observations are based on cross-sectional data. Though such data do not allow for causal conclusions regarding the effect of policies, this assessment relies on the temporality of the relationship between current policy and rate. Some data are available regarding rate change based on a new facility-wide policy.[28] However, in the evaluation context, the relationship with an

existing policy may be more informative that the change from one year to the next after the implementation of a policy. In that context, an increase may be more indicative of a renewed emphasis on vaccination than the effect of the policy.

The relationship between STIC and the VPBA survey must be considered in interpreting these results. The survey was clearly labeled as issued by "The Safe and Timely Immunization Coalition" and mentioned its affiliation with CMS. Such a clear connection may have produced reporting bias with regard to beliefs (efficacy and safety of vaccination) and even practices in place (ie, existence of a "centralized" record-keeping system).

Standing order policies were very clearly defined and should be less affected by such problems. However, reported standing order policies were not independently verified and their implementation was not monitored. The validity of each report relies on the individual completing the form. Fortunately, in most cases, the survey was completed by a clinic manager/director, a facility administrator, or a nurse manager/director with a median of 4 years at their facility and 5 years of career experience in their current role. Although 14% of eligible centers with 20 or more patients on their roster did not respond to the survey, nonresponding centers were not significantly different from those that did respond with regard to size, racial composition, or profit status.

Assessment of an Intensive Intervention to Increase Influenza Immunization Rates

As outlined in **Manuscript 2**, a multicomponent intensive intervention to improve influenza immunization rates in poorly-performing centers was compared to a standard intervention approach via a group-randomized evaluation. The additional benefit showed

a statistically significant difference on a per-patient basis at poorly-performing centers (8.9%).

This evaluation was important because it established the mean increase in rate above the standard intervention—rather than the mean raw increase—as the measure of the effectiveness of the intensive intervention. The intensive intervention itself was well-defined. Generally, it included elements that had been used by the Networks in the past, standardized their application, and added an educational component. Overall the program—a multicomponent program with active and educational aspects, goals, responsibilities, and a clear timeframe—followed best practices for interventions.[102, 109]

The evaluation of the intensive intervention and the reporting of the results were designed along the principles of the CONSORT statement on parallel-group randomized trials.[125, 126] However, as an evaluation program, some differences from a "trial" design were necessary for pragmatic reasons. The assignment of groups was random, but blinding was not feasible. Though the design of the evaluation (standard versus intensive intervention) was not discussed with the participating centers, crosstalk allowed discussion of the program to take place. However, it should be noted that this was not a pilot study or test program. The number of centers involved in the intensive intervention was the maximum allowed under the existing QI programs. These are the conditions under which intensive interventions normally take place within the Networks.

The real innovation produced by this evaluation was in providing an equivalent comparison group. Some effort was required to convince Network administration and their medical review boards to allow for a randomized evaluation in which more centers

than usual would be considered for, but only half would be randomly allocated to, the intensive quality improvement program. Without this allowance, the evaluation would not have been possible because the added effect of intensive intervention would not have be estimable.

The pragmatic nature of this evaluation (ie, not tightly controlled) demonstrates a possible model for the evaluation of policies and treatment protocols via experimental means. The flexible framework used here allows for an assessment process that can be applied to a variety of situations, rather than a concrete plan that is designed for dialysis centers in specific geographical areas. Centers were asked to formulate their own plans, assert their own vaccination goal, and identify the root causes of past problems and the action steps, personnel, time frame, and evaluation steps to address those problems.

These result found here are comparable to those of a group-randomized evaluation of coordinated multi-component intervention to increase dialysis adequacy in these same Networks.[6] The previous evaluation showed that an intensive intervention (feedback, seminars, educational materials, clinical practice guidelines, technical assistance, and continued monitoring) was more effective than feedback alone. The mean center urea reduction ratio (URR) increased nearly 3% among intensive intervention centers but only 0.9% among the feedback-only centers.[6]

The power of the evaluation program was somewhat weakened by a development just before random allocation was finalized. Eligible centers that had a rate of lower than 40% were excluded from the random assignment—and thus the evaluation—in Network 15. These centers improved by a mean of 48.8% (28.8% to 77.6%).

The ability to measure the difference between the interventions groups also may have been hindered by data collection methods in Network 11. Network 11 collected data on the patient level for intensive intervention centers, but only as an overall rate for the standard intervention centers. The differing data collection methods make direct comparison difficult. This Network was the only one which did not show a substantial difference in mean change between the intensive and standard intervention groups. The Network 11 difference (+1.59%) was far lower than those seen in Network 6 (+10.64%) and Network 15 (+18.06%).

The framework of this intervention did not allow analysis of individual intervention elements because a large majority of centers chose the same options (education program and addressing refusals). A future evaluation may provide additional insight is educational programs are excluded from the intervention program or made mandatory for all centers (eg, not counting as one of the selected element).

Overall, this evaluation provides new evidence-based data regarding the extent to which a multicomponent intervention can impact vaccination rates at poorly performing dialysis centers. The evaluation of a differential effect such as that seen here must be assessed in light of the priorities of an institution/system, the resources it has available, and its patient population. For example, this intensive intervention program may be most appropriate for centers that have had consistently low rates, within networks with strong central administration, and for which other novel interventions (eg, patient incentives, signed declination forms) have failed or have been judged to be inappropriate. But regardless of the interpretation of the results, the evaluation establishes solid data from which to work.

Multilevel Analysis of Influenza Vaccination and Mortality

Analysis of the relationship between 12-month mortality and vaccination status among prevalent dialysis patients allows for the translation of this QI program in terms of patient outcomes. In addition to providing an estimate of the mortality risk for unvaccinated versus vaccinated patients, this part of the project also highlighted some important limitations to the vaccination data collected by these Networks.

The mortality analysis outlined in **Manuscript 3** uses patient demographic data, comorbidities at dialysis initiation, insurance and employment status at dialysis initiation, vaccination status for pneumococcal disease as well as influenza, and recent lab data on dialysis adequacy and anemia. A thorough review of each patient's medical records—with particular attention to recent health status—would provide valuable additional information in this context. However, the data used here are the most complete set used in this population and provide the best information possible short of chart review.

The limitations of patient vaccination data found here apply to all parts of this project. Accounting for the 4.0% patients with missing vaccination data (blank on the STIC Immunization Data Collection Tool) was problematic in the mortality analysis. Ideally, no patient data should be missing. Even if a patient transferred to another center or died early in the following year (ie, before the survey was completed), their vaccination records from the previous should be available to the dialysis center. Thus there is no "records unavailable'' option on the data collection form. However, a strong association was found between missing vaccination data and mortality likelihood. Also, on average,

patients with missing data who died during the 12-month follow-up period did so earlier in the year compared to other deaths.

Due to the associations found with mortality, patients with missing data were excluded from the analysis (**Manuscript 3**). However, they were included as unvaccinated in the other two parts of the project. The standing order policy analysis (**Manuscript 1**) was concerned with recorded vaccination status and there was no clear reason to conclude that the association between policy and rate would be affected by differences in the percentage of missing data among centers. In the evaluation of an intensive intervention (**Manuscript 2**) the missing rates were not significantly different between the groups (2.9% in intensive intervention versus 4.1% in standard intervention; p=0.5).

Patients whose vaccination status is recorded as "UNKNOWN, not known by patient" were considered to be unvaccinated. However, the 28.7% mortality rate of patients in this vaccination category (3.5% of all patients) suggests that this category may provide a default option for "missing" data. In a sensitivity analysis of the mortality data—when "UNKNOWN" patients were eliminated from consideration, the measured association between vaccination status and mortality was reduced from 0.74 (95% CI: 0.68, 0.80) to 0.83 (95% CI: 0.76, 0.91). For reasons similar to those outlined above, such considerations were not made in the other two parts of the project: no clear association with policy (**Manuscript 1**) and no significant between-group difference (**Manuscript 2**).

Possible differences among patients recorded as vaccinated were also found in the course of the mortality analysis. Current vaccination reporting in these 3 ESRD Networks count

patients as vaccinated if they received the vaccination at the dialysis clinic or report receiving the vaccination elsewhere. These self-reported vaccinations are not confirmed via medical records. Mortality data by vaccination status show that patients vaccinated at the center had a mortality rate of 15.73% versus 21.45% for patients who self-reported being vaccinated elsewhere. This may indicate that there are meaningful health differences among patients who receive care outside the center, or that self-reporting is not accurate. In the mortality analysis, counting self-reported patients as vaccinated may have biased the estimated association toward the null. Again, adjustments were not made in the other two parts of the project due to no clear association with policy (**Manuscript 1**) and no significant between-group difference (**Manuscript 2**).

Recommendations

As a whole, the results of this project lead to several clear recommendations for this continuous QI program.

<u>Data from Manuscript 1 suggest that:</u>

1. The adoption of facility-wide standing order programs for hepatitis B and pneumococcal vaccination may not be necessary at centers that have chart-based orders. Both policies are associated with equivalently higher vaccination rates versus individual or physician-specific orders.

2. Changes in order policies are unlikely to affect influenza vaccination rates. Such efforts should be limited to vaccination programs against hepatitis B and pneumococcal disease.

Data from Manuscript 2 show that:

1. The estimated effectiveness of the multicomponent intensive intervention program used by these Networks to increase influenza vaccination rates at poorly-performing center is +8.9% above standard intervention. This difference—which is statistically significant difference on a per-patient basis—should be used for planning and resource allocation purposes.

Data from Manuscript 3 indicate that:

1. Among dialysis patients, vaccination against influenza is associated with decreased all-cause mortality in the subsequent 12 months, with an OR estimate of 0.83 (95% CI: 0.76, 0.91). This estimate should be used for when considering the potential impact of QI programs to increase influenza vaccination rates.

2. Collection of vaccination data in this system should be changed to account for patients whose status is unknown by their center. Either an option should be added for "UNKNOWN, patient records unavailable" or instructions should emphasize the need to gather information on all patients regardless of their current status.

Future Considerations

Patient refusal of influenza vaccination was the most pressing need identified through this project. If the participating Networks are to achieve their goal of 90%, refusal rates must be lowered dramatically. Overall, 11.2% of patients refused vaccination for influenza. Of the patients who did not receive vaccination in 2005-06, over half (60.2%) were listed as

refusing vaccination. The intervention evaluation listed “address patient refusal of immunization” as a possible topic for center-specific action plans and 25 of 34 centers chose this option as an area to address. Of these 25 centers, 20 chose to assign a “level 2” person (eg, a supervisor) to counsel patients about the importance of vaccination. Follow-up data collection asked for details about how many patients who initially refused vaccination were later vaccinated, but reports were incomplete. The mean refusal rate in 2007-08 for intensive intervention centers was not significantly different from standard intervention centers (16.5% versus 19.7%, p=0.3). Of those patients who were not vaccinated, the percentage refused was also similar to the baseline year (62.4% in intensive intervention centers and 60.7% in standard intervention centers).

Before a specific plan is put into place, more data should be collected about refusals. Patients who did not receive influenza vaccination may be listed as unvaccinated because they refused, were allergic, were not offered the vaccination, for an unspecified “other reason,” or due to unknown vaccination status. The definitions of “offered” and “refused” should be clarified and additional information should be noted. How many times was the patient offered vaccination? Was the patient directly offered the vaccination or were vaccinations simply available for patients upon request? Due to the high proportion of refusals among the unvaccinated, we should ensure that this is not simply a default category for patients who did not get vaccinated at centers that offered it.

In addition to addressing the issue of missing data, outlined above, a study to validate self-report of vaccination may be helpful. The lower mortality rate of patients who were vaccinated at the center versus those who report being vaccinated elsewhere shows that these groups of patients are not truly equivalent. Centers could follow-up with a portion

of the 3300 patients who self-report vaccination and asked them for additional details. Do the patients know where and approximately when they were vaccinated? How sure are they that they received the vaccination this season?

The group-randomized evaluation of the intensive intervention program provided an estimate of the overall difference, but did not find significant differences among the various approaches chosen to increase vaccination rates. The choice of initiatives for each center is an important part of the process, so it would be against the spirit of the program to randomly assign approaches. However, additional data could be collected about the most common choices and descriptive accounts could be provided. Due to privacy concerns, the action plans were not directly accessible to anyone outside the Network administration. A different structure for the action plan composition process (eg, separate private and public information) could be helpful. However, based on the documented experience this could be a sensitive issue for Network administration and medical review boards.

The mortality estimates given here could be made more accurate and precise with the addition of patient data regarding recent health issues. Chart review would be very difficult in this population, but Medicare claims could allow for additional adjustment and would be the most reasonable supplement to this analysis.

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APPENDIX A: ESRD MEDICAL EVIDENCE REPORT: MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION (CMS-2728)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0046

END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

A. COMPLETE FOR ALL ESRD PATIENTS

Check one: ☐ Initial ☐ Re-entitlement ☐ Supplemental

1. Name *(Last, First, Middle Initial)*

2. Medicare Claim Number

3. Social Security Number

4. Date of Birth ____/____/____ MM DD YYYY

5. Patient Mailing Address *(Include City, State and Zip)*

6. Phone Number ( )

7. Sex ☐ Male ☐ Female

8. Ethnicity ☐ Not Hispanic or Latino ☐ Hispanic or Latino (Complete Item 9)

9. Country/Area of Origin or Ancestry

10. Race *(Check all that apply)*
☐ White ☐ Asian
☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander*
☐ American Indian/Alaska Native
Print Name of Enrolled/Principal Tribe _____ *complete Item 9

11. Is patient applying for ESRD Medicare coverage?
☐ Yes ☐ No

12. Current Medical Coverage *(Check all that apply)*
☐ Medicaid ☐ Medicare ☐ Employer Group Health Insurance
☐ DVA ☐ Medicare Advantage ☐ Other ☐ None

13. Height
INCHES _____ OR
CENTIMETERS _____

14. Dry Weight
POUNDS _____ OR
KILOGRAMS _____

15. Primary Cause of Renal Failure *(Use code from back of form)*

16. Employment Status *(6 mos prior and current status)*

Prior	Current	
☐	☐	Unemployed
☐	☐	Employed Full Time
☐	☐	Employed Part Time
☐	☐	Homemaker
☐	☐	Retired due to Age/Preference
☐	☐	Retired (Disability)
☐	☐	Medical Leave of Absence
☐	☐	Student

17. Co-Morbid Conditions *(Check all that apply currently and/or during last 10 years)* *See instructions

a. ☐ Congestive heart failure
b. ☐ Atherosclerotic heart disease ASHD
c. ☐ Other cardiac disease
d. ☐ Cerebrovascular disease, CVA, TIA*
e. ☐ Peripheral vascular disease*
f. ☐ History of hypertension
g. ☐ Amputation
h. ☐ Diabetes, currently on insulin
i. ☐ Diabetes, on oral medications
j. ☐ Diabetes, without medications
k. ☐ Diabetic retinopathy
l. ☐ Chronic obstructive pulmonary disease
m. ☐ Tobacco use (current smoker)
n. ☐ Malignant neoplasm, Cancer
o. ☐ Toxic nephropathy
p. ☐ Alcohol dependence
q. ☐ Drug dependence*
r. ☐ Inability to ambulate
s. ☐ Inability to transfer
t. ☐ Needs assistance with daily activities
u. ☐ Institutionalized
☐ 1. Assisted Living
☐ 2. Nursing Home
☐ 3. Other Institution
v. ☐ Non-renal congenital abnormality
w. ☐ None

18. Prior to ESRD therapy:

a. Did patient receive exogenous erythropoetin or equivalent?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
b. Was patient under care of a nephrologist?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
c. Was patient under care of kidney dietitian?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
d. What access was used on first outpatient dialysis:	☐ AVF	☐ Graft	☐ Catheter	☐ Other		
If not AVF, then: Is maturing AVF present?	☐ Yes	☐ No				
Is maturing graft present?	☐ Yes	☐ No				

19. Laboratory Values Within **45** Days Prior to the Most Recent ESRD Episode. (Lipid Profile within 1 Year of Most Recent ESRD Episode).

LABORATORY TEST	VALUE	DATE	LABORATORY TEST	VALUE	DATE
a.1. Serum Albumin (g/dl)	___ . ___		d. HbA1c	___ ___ . ___ %	
a.2. Serum Albumin Lower Limit	___ . ___		e. Lipid Profile TC	___ ___ ___	
a.3. Lab Method Used (BCG or BCP)			LDL	___ ___ ___	
b. Serum Creatinine (mg/dl)	___ ___ . ___		HDL	___ ___	
c. Hemoglobin (g/dl)	___ ___ . ___		TG	___ ___ ___ ___	

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

20. Name of Dialysis Facility

21. Medicare Provider Number *(for item 20)*

22. Primary Dialysis Setting
☐ Home ☐ Dialysis Facility/Center ☐ SNF/Long Term Care Facility

23. Primary Type of Dialysis
☐ Hemodialysis (Sessions per week____/hours per session____)
☐ CAPD ☐ CCPD ☐ Other

24. Date Regular Chronic Dialysis Began ____/____/____ MM DD YYYY

25. Date Patient Started Chronic Dialysis at Current Facility ____/____/____ MM DD YYYY

26. Has patient been informed of kidney transplant options?
☐ Yes ☐ No

27. If patient NOT informed of transplant options, please check all that apply:
☐ Medically unfit ☐ Patient declines information
☐ Unsuitable due to age ☐ Patient has not been assessed
☐ Psychologically unfit ☐ Other

C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

28. Date of Transplant (MM / DD / YYYY)	29. Name of Transplant Hospital	30. Medicare Provider Number for Item 29

Date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of actual transplantation.

31. Enter Date (MM / DD / YYYY)	32. Name of Preparation Hospital	33. Medicare Provider number for Item 32

34. Current Status of Transplant *(if functioning, skip items 36 and 37)*	35. Type of Donor:
☐ Functioning ☐ Non-Functioning	☐ Deceased ☐ Living Related ☐ Living Unrelated
36. If Non-Functioning, Date of Return to Regular Dialysis (MM / DD / YYYY)	37. Current Dialysis Treatment Site ☐ Home ☐ Dialysis Facility/Center ☐ SNF/Long Term Care Facility

D. COMPLETE FOR ALL ESRD SELF-DIALYSIS TRAINING PATIENTS (MEDICARE APPLICANTS ONLY)

38. Name of Training Provider	39. Medicare Provider Number of Training Provider (for Item 38)
40. Date Training Began (MM / DD / YYYY)	41. Type of Training ☐ Hemodialysis a. ☐ Home b. ☐ In Center ☐ CAPD ☐ CCPD ☐ Other
42. This Patient is Expected to Complete *(or has completed)* Training and will Self-dialyze on a Regular Basis. ☐ Yes ☐ No	43. Date When Patient Completed, or is Expected to Complete, Training (MM / DD / YYYY)

I certify that the above self-dialysis training information is correct and is based on consideration of all pertinent medical, psychological, and sociological factors as reflected in records kept by this training facility.

44. Printed Name and Signature of Physician personally familiar with the patient's training	45. UPIN of Physician in Item 44
a.) Printed Name b.) Signature c.) Date (MM / DD / YYYY)	

E. PHYSICIAN IDENTIFICATION

46. Attending Physician *(Print)*	47. Physician's Phone No. ( )	48. UPIN of Physician in Item 46

PHYSICIAN ATTESTATION

I certify, under penalty of perjury, that the information on this form is correct to the best of my knowledge and belief. Based on diagnostic tests and laboratory findings, I further certify that this patient has reached the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. I understand that this information is intended for use in establishing the patient's entitlement to Medicare benefits and that any falsification, misrepresentation, or concealment of essential information may subject me to fine, imprisonment, civil penalty, or other civil sanctions under applicable Federal laws.

49. Attending Physician's Signature of Attestation *(Same as Item 46)*	50. Date (MM / DD / YYYY)
51. Physician Recertification Signature	52. Date (MM / DD / YYYY)

53. Remarks

F. OBTAIN SIGNATURE FROM PATIENT

I hereby authorize any physician, hospital, agency, or other organization to disclose any medical records or other information about my medical condition to the Department of Health and Human Services for purposes of reviewing my application for Medicare entitlement under the Social Security Act and/or for scientific research.

54. Signature of Patient *(Signature by mark must be witnessed.)*	55. Date (MM / DD / YYYY)

G. PRIVACY STATEMENT

The collection of this information is authorized by Section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Federal Register, Vol. 67, No. 116, June 17, 2002, pages 41244-41250 or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the *Federal Register* notice cited above. You should be aware that P.L.100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

Item 15. Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-9-CM code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary. **Code effective as of September 2003**.

ICD-9	NARRATIVE
DIABETES	
25040	Diabetes with renal manifestations Type 2
25041	Diabetes with renal manifestations Type 1
GLOMERULONEPHRITIS	
5829	Glomerulonephritis (GN) (histologically not examined)
5821	Focal glomerulosclerosis, focal sclerosing GN
5831	Membranous nephropathy
58321	Membranoproliferative GN type 1, diffuse MPGN
58322	Dense deposit disease, MPGN type 2
58381	IgA nephropathy, Berger's disease (proven by immunofluorescence)
58382	IgM nephropathy (proven by immunofluorescence)
5834	With lesion of rapidly progressive GN
5800	Post infectious GN, SBE
5820	Other proliferative GN
SECONDARY GN/VASCULITIS	
7100	Lupus erythematosus, (SLE nephritis)
2870	Henoch-Schonlein syndrome
7101	Scleroderma
28311	Hemolytic uremic syndrome
4460	Polyarteritis
4464	Wegener's granulomatosis
58392	Nephropathy due to heroin abuse and related drugs
44620	Other Vasculitis and its derivatives
44621	Goodpasture's syndrome
58391	Secondary GN, other
INTERSTITIAL NEPHRITIS/PYELONEPHRITIS	
9659	Analgesic abuse
5830	Radiation nephritis
9849	Lead nephropathy
5909	Nephropathy caused by other agents
27410	Gouty nephropathy
5920	Nephrolithiasis
5996	Acquired obstructive uropathy
5900	Chronic pyelonephritis, reflux nephropathy
58389	Chronic interstitial nephritis
58089	Acute interstitial nephritis
5929	Urolithiasis
27549	Other disorders of calcium metabolism
HYPERTENSION/LARGE VESSEL DISEASE	
40391	Unspecified with renal failure
4401	Renal artery stenosis
59381	Renal artery occlusion
59383	Cholesterol emboli, renal emboli

ICD-9	NARRATIVE
CYSTIC/HEREDITARY/CONGENITAL DISEASES	
75313	Polycystic kidneys, adult type (dominant)
75314	Polycystic, infantile (recessive)
75316	Medullary cystic disease, including nephronophthisis
7595	Tuberous sclerosis
7598	Hereditary nephritis, Alport's syndrome
2700	Cystinosis
2718	Primary oxalosis
2727	Fabry's disease
7533	Congenital nephrotic syndrome
5839	Drash syndrome, mesangial sclerosis
75321	Congenital obstruction of ureterpelvic junction
75322	Congenital obstruction of uretrovesical junction
75329	Other Congenital obstructive uropathy
7530	Renal hypoplasia, dysplasia, oligonephronia
75671	Prune belly syndrome
75989	Other (congenital malformation syndromes)
NEOPLASMS/TUMORS	
1890	Renal tumor (malignant)
1899	Urinary tract tumor (malignant)
2230	Renal tumor (benign)
2239	Urinary tract tumor (benign)
23951	Renal tumor (unspecified)
23952	Urinary tract tumor (unspecified)
20280	Lymphoma of kidneys
20300	Multiple myeloma
20308	Other immuno proliferative neoplasms (including light chain nephropathy)
2773	Amyloidosis
99680	Complications of transplanted organ unspecified
99681	Complications of transplanted kidney
99682	Complications of transplanted liver
99683	Complications of transplanted heart
99684	Complications of transplanted lung
99685	Complications of transplanted bone marrow
99686	Complications of transplanted pancreas
99687	Complications of transplanted intestine
99689	Complications of other specified transplanted organ
MISCELLANEOUS CONDITIONS	
28260	Sickle cell disease/anemia
28269	Sickle cell trait and other sickle cell (HbS/Hb other)
64620	Post partum renal failure
042	AIDS nephropathy
8660	Traumatic or surgical loss of kidney(s)
5724	Hepatorenal syndrome
5836	Tubular necrosis (no recovery)
59389	Other renal disorders
7999	Etiology uncertain

INSTRUCTIONS FOR COMPLETION OF END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

For whom should this form be completed:

This form **SHOULD NOT** be completed for those patients who are in acute renal failure. Acute renal failure is a condition in which kidney function can be expected to recover after a short period of dialysis, i.e., several weeks or months.

This form **MUST BE** completed within 45 days for **ALL** patients beginning any of the following:

Check the appropriate block that identifies the reason for submission of this form.

Initial

For all patients who initially receive a kidney transplant instead of a course of dialysis.

For patients for whom a regular course of dialysis has been prescribed by a physician because they have reached that stage of renal impairment that a kidney transplant or regular course of dialysis is necessary to maintain life. The first date of a regular course of dialysis is the date this prescription is implemented whether as an inpatient of a hospital, an outpatient in a dialysis center or facility, or a home patient. The form should be completed for all patients in this category even if the patient dies within this time period.

Re-entitlement

For beneficiaries who have already been entitled to ESRD Medicare benefits and those benefits were terminated because their coverage stopped 3 years post transplant but now are again applying for Medicare ESRD benefits because they returned to dialysis or received another kidney transplant.

For beneficiaries who stopped dialysis for more than 12 months, have had their Medicare ESRD benefits terminated and now returned to dialysis or received a kidney transplant. These patients will be reapplying for Medicare ESRD benefits.

Supplemental

Patient has received a transplant or trained for self-care dialysis within the first 3 months of the first date of dialysis and initial form was submitted.

All items except as follows: To be completed by the attending physician, head nurse, or social worker involved in this patient's treatment of renal disease.

Items 15, 17-18, 26-27, 49-50: To be completed by the attending physician.
Item 44: To be signed by the attending physician or the physician familiar with the patient's self-care dialysis training.
Items 54 and 55: To be signed and dated by the patient.

1. Enter the patient's legal name (Last, first, middle initial). Name should appear exactly the same as it appears on patient's social security or Medicare card.
2. If the patient is covered by Medicare, enter his/her Medicare claim number as it appears on his/her Medicare card.
3. Enter the patient's own social security number. This number can be verified from his/her social security card.
4. Enter patient's date of birth (2-digit Month, Day, and 4-digit Year). Example 07/25/1950.
5. Enter the patient's mailing address (number and street or post office box number, city, state, and ZIP code.)
6. Enter the patient's home area code and telephone number.
7. Check the appropriate block to identify sex.
8. Check the appropriate block to identify ethnicity. Definitions of the ethnicity categories for Federal statistics are as follows:

   Not Hispanic or Latino—A person of culture or origin not described below, regardless of race.

   Hispanic or Latino—A person of Cuban, Puerto Rican, or Mexican culture or origin regardless of race. Please complete Item 9 and provide the country, area of origin, or ancestry to which the patient claims to belong.
9. Country/Area of origin or ancestry—Complete if information is available or if directed to do so in question 8.
10. Check the appropriate block(s) to identify race. Definitions of the racial categories for Federal statistics are as follows:

    White—A person having origins in any of the original white peoples of Europe, the Middle East or North Africa.

    Black or African American—A person having origins in any of the black racial groups of Africa. This includes native-born Black Americans, Africans, Haitians and residents of non-Spanish speaking Caribbean Islands of African descent.

    American Indian/Alaska Native—A person having origins in any of the original peoples of North America and South America (including Central America) and who maintains tribal affiliation or community attachment. Print the name of the enrolled or principal tribe to which the patient claims to be a member.

    Asian—A person having origins in any of the original peoples of the Far East, Southeast Asia or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.

    Native Hawaiian or Other Pacific Islander—A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. Please complete Item 9 and provide the country, area of origin, or ancestry to which the patient claims to belong.

DISTRIBUTION OF COPIES:

- Forward the first part (blue) of this form to the Social Security office servicing the claim.
- Forward the second part (green) of this form to the ESRD Network Organizations.
- Retain the last part (white) in the patient's medical records file.

11. Check the appropriate yes or no block to indicate if patient is applying for ESRD Medicare. **Note: Even though a person may already be entitled to general Medicare coverage, he/she should reapply for ESRD Medicare coverage.**

12. Check **all** the blocks that apply to this patient's current medical insurance status.

    Medicaid—Patient is currently receiving State Medicaid benefits.

    Medicare—Patient is currently entitled to Federal Medicare benefits.

    Employer Group Health Insurance—Patient receives medical benefits through an employee health plan that covers employees, former employees, or the families of employees or former employees.

    DVA—Patient is receiving medical care from a Department of Veterans Affairs facility.

    Medicare Advantage—Patient is receiving medical benefits under a Medicare Advantage organization.

    Other Medical Insurance—Patient is receiving medical benefits under a health insurance plan that is not Medicare, Medicaid, Department of Veterans Affairs, HMO/M+C organization, nor an employer group health insurance plan. Examples of other medical insurance are Railroad Retirement and CHAMPUS beneficiaries.

    None—Patient has no medical insurance plan.

13. Enter the patient's most recent recorded height in inches **OR** centimeters at time form is being completed. If entering height in centimeters, round to the nearest centimeter. Estimate or use last known height for those unable to be measured. (Example of inches - 62. DO NOT PUT 5'2") NOTE: For amputee patients, enter height prior to amputation.

14. Enter the patient's most recent recorded dry weight in pounds **OR** kilograms at time form is being completed. If entering weight in kilograms, round to the nearest kilogram.

NOTE: For amputee patients, enter actual dry weight.

15. **To be completed by the attending physician**. Enter the ICD-9-CM from back of form to indicate the primary cause of end stage renal disease. These are the only acceptable causes of end stage renal disease.

16. Check the first box to indicate employment status 6 months prior to renal failure and the second box to indicate current employment status. **Check only one box for each time period**. If patient is under 6 years of age, leave blank.

17. **To be completed by the attending physician**. Check all co-morbid conditions that apply.

    ***Cerebrovascular Disease** includes history of stroke/ cerebrovascular accident (CVA) and transient ischemic attack (TIA).

    ***Peripheral Vascular Disease** includes absent foot pulses, prior typical claudication, amputations for vascular disease, gangrene and aortic aneurysm.

    ***Drug dependence** means dependent on illicit drugs.

18. Prior to ESRD therapy, check the appropriate box to indicate whether the patient received Exogenous erythropoetin (EPO) or equivalent, was under the care of a nephrologist and/or was under the care of a kidney dietitian. Provide vascular access information as to the type of access used (Arterio-Venous Fistula (AVF), graft, catheter (including port device) or other type of access) when the patient first received outpatient dialysis. If an AVF access was not used, was a maturing AVF or graft present?

NOTE: For those patients re-entering the Medicare program after benefits were terminated, Items 19a thru 19c should contain initial laboratory values within 45 days prior to the most recent ESRD episode. Lipid profiles and HbA1c should be within 1 year of the most recent ESRD episode. Some tests may not be required for patients under 21 years of age.

19a1. Enter the serum albumin value (g/dl) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or kidney transplant.

19a2. Enter the lower limit of the normal range for serum albumin from the laboratory which performed the serum albumin test entered in 19a1.

19a3. Enter the serum albumin lab method used (BCG or BCP).

19b. Enter the serum creatinine value (mg/dl) and date test was taken. **THIS FIELD MUST BE COMPLETED.** Value must be within 45 days prior to first dialysis treatment or kidney transplant.

19c. Enter the hemoglobin value (g/dl) and date test was taken. This value and date must be within 45 days prior to the first dialysis treatment or kidney transplant.

19d. Enter the HbA1c value and the date the test was taken. The date must be within 1 year prior to the first dialysis treatment or kidney transplant.

19e. Enter the Lipid Profile values and date test was taken. These values: TC–Total Cholesterol; LDL–LDL Cholesterol; HDL–HDL Cholesterol; TG–Triglycerides, and date must be within 1 year prior to the first dialysis treatment or kidney transplant.

20. Enter the name of the dialysis facility where patient is currently receiving care and who is completing this form for patient.

21. Enter the 6-digit Medicare identification code of the dialysis facility in item 20.

22. If the person is receiving a regular course of dialysis treatment, check the appropriate **anticipated long-term treatment setting** at the time this form is being completed.

23. If the patient is, or was, on regular dialysis, **check the anticipated long-term primary type of dialysis**: Hemodialysis, (enter the number of sessions prescribed per week and the hours that were prescribed for each session), CAPD (Continuous Ambulatory Peritoneal Dialysis) and CCPD (Continuous Cycling Peritoneal Dialysis), or Other. **Check only one block**. NOTE: Other has been placed on this form to be used only to report IPD (Intermittent Peritoneal Dialysis) and any new method of dialysis that may be developed prior to the renewal of this form by Office of Management and Budget.

24. Enter the date (month, day, year) that a "regular course of chronic dialysis" began. The beginning of the course of dialysis is counted from the beginning of regularly scheduled dialysis necessary for the treatment of end stage renal disease (ESRD) regardless of the dialysis setting. The date of the first dialysis treatment after the physician has determined that this patient has ESRD and has written a prescription for a "regular course of dialysis" is the "Date Regular Chronic Dialysis Began" regardless of whether this prescription was implemented in a hospital/ inpatient, outpatient, or home setting and regardless of any acute treatments received prior to the implementation of the prescription.

NOTE: For these purposes, end stage renal disease means irreversible damage to a person's kidneys so severely affecting his/her ability to remove or adjust blood wastes that in order to maintain life he or she must have either a course of dialysis or a kidney transplant to maintain life.

If re-entering the Medicare program, enter beginning date of the current ESRD episode. Note in Remarks, Item 53, that patient is restarting dialysis.

25. Enter date patient started chronic dialysis at current facility of dialysis services. In cases where patient transferred to current dialysis facility, this date will be after the date in Item 24.

26. Enter whether the patient has been informed of their options for receiving a kidney transplant.

27. If the patient has not been informed of their options (answered "no" to Item 26), then enter all reasons why a kidney transplant was not an option for this patient at this time.

28. Enter the date(s) of the patient's kidney transplant(s). If reentering the Medicare program, enter current transplant date.

29. Enter the name of the hospital where the patient received a kidney transplant on the date in Item 28.

30. Enter the 6-digit Medicare identification code of the hospital in Item 29 where the patient received a kidney transplant on the date entered in Item 28.

31. Enter date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of the actual transplantation. This includes hospitalization for transplant workup in order to place the patient on a transplant waiting list.

32. Enter the name of the hospital where patient was admitted as an inpatient in preparation for, or anticipation of, a kidney transplant prior to the date of the actual transplantation.

33. Enter the 6-digit Medicare identification number for hospital in Item 32.

34. Check the appropriate functioning or non-functioning block.

35. Enter the type of kidney transplant organ donor, Deceased, Living Related or Living Unrelated, that was provided to the patient.

36. If transplant is nonfunctioning, enter date patient returned to a regular course of dialysis. If patient did not stop dialysis post transplant, enter transplant date.

37. If applicable, check where patient is receiving dialysis treatment following transplant rejection. A nursing home or skilled nursing facility is considered as home setting.

Self-dialysis Training Patients (Medicare Applicants Only)

Normally, Medicare entitlement begins with the third month after the month a patient begins a regular course of dialysis treatment. This 3-month qualifying period may be waived if a patient begins a self-dialysis training program in a **Medicare approved training facility** and is expected to self-dialyze after the completion of the training program. Please complete items 38-43 if the patient has entered into a self-dialysis training program. Items 38-43 must be completed if the patient is applying for a Medicare waiver of the 3-month qualifying period for dialysis benefits based on participation in a self-care dialysis training program.

38. Enter the name of the provider furnishing self-care dialysis training.

39. Enter the 6-digit Medicare identification number for the training provider in Item 38.

40. Enter the date self-dialysis training began.

41. Check the appropriate block which describes the type of self-care dialysis training the patient began. If the patient trained for hemodialysis, enter whether the training was to perform dialysis in the home setting or in the facility (in center). If the patient trained for IPD (Intermittent Peritoneal Dialysis), report as Other.

42. Check the appropriate block as to whether or not the physician certifies that the patient is expected to complete the training successfully and self-dialyze on a regular basis.

43. Enter date patient completed or is expected to complete self-dialysis training.

44. Enter printed name and signature of the attending physician or the physician familiar with the patient's self-care dialysis training.

45. Enter the Unique Physician Identification Number (UPIN) of physician in Item 44. (See Item 48 for explanation of UPIN.)

46. Enter the name of the physician who is supervising the patient's renal treatment at the time this form is completed.

47. Enter the area code and telephone number of the physician who is supervising the patient's renal treatment at the time this form is completed.

48. Enter the physician's UPIN assigned by CMS.

    A system of physician identifiers is mandated by Section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985. It requires a unique identifier for each physician who provides services for which Medicare payment is made. An identifier is assigned to each physician regardless of his or her practice configuration. The UPIN is established in a national Registry of Medicare Physician Identification and Eligibility Records (MPIER). Transamerica Occidental Life Insurance Company is the Registry Carrier that establishes and maintains the national registry of physicians receiving Part B Medicare payment. Its address is: UPIN Registry, Transamerica Occidental Life, P.O. Box 2575, Los Angeles, CA 90051-0575.

49. To be signed by the physician supervising the patient's kidney treatment. Signature of physician identified in Item 46. A stamped signature is unacceptable.

50. Enter date physician signed this form.

51. To be signed by the physician who is currently following the patient. If the patient had decided initially not to file an application for Medicare, the physician will be re-certifying that the patient is end stage renal, based on the same medical evidence, by signing the copy of the CMS-2728 that was originally submitted and returned to the provider. If you do not have a copy of the original CMS-2728 on file, complete a new form.

52. The date physician re-certified and signed the form.

53. This remarks section may be used for any necessary comments by either the physician, patient, ESRD Network or social security field office.

54. The patient's signature authorizing the release of information to the Department of Health and Human Services must be secured here. **If the patient is unable to sign the form, it should be signed by a relative, a person assuming responsibility for the patient or by a survivor**.

55. The date patient signed form.

NOTICE

This form is to be completed for all End Stage Renal Disease patients beginning June 01, 2005 regardless of when the patient started dialysis or received a kidney transplant. Prior blank versions of this form should be destroyed. Old versions of the CMS-2728 will not be accepted by the Social Security Administration or the ESRD Network Organizations after May 31, 2005.

APPENDIX B: ESRD DEATH NOTIFICATION (CMS-2746)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0448

ESRD DEATH NOTIFICATION

END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

1. Patient's Last Name	First	MI	2. Medicare Claim Number

3. Patient's Sex	4. Date of Birth	5. Social Security Number
a. ☐ Male b. ☐ Female	__ __ / __ __ / __ __ __ __ (Month / Day / Year)	

6. Patient's State of Residence	7. Place of Death	8. Date of Death
	a. ☐ Hospital c. ☐ Home e. ☐ Other b. ☐ Dialysis Unit d. ☐ Nursing Home	__ __ / __ __ / __ __ __ __ (Month / Day / Year)

9. Modality at Time of Death

a. ☐ Incenter Hemodialysis b. ☐ Home Hemodialysis c. ☐ CAPD d. ☐ CCPD e. ☐ Transplant f. ☐ Other

10. Provider Name and Address (Street)	11. Provider Number

Provider Address (City/State)

12. Causes of Death (enter codes from list on back of form)

a. Primary Cause _ _ _

b. Were there secondary causes?

☐ No

☐ Yes, specify: _ _ _ _ _ _ _ _ _ _ _ _

C. If cause is other (98) please specify:_____

13. Renal replacement therapy discontinued prior to death: ☐ Yes ☐ No

If yes, check one of the following:

a. ☐ Following HD and/or PD access failure
b. ☐ Following transplant failure
c. ☐ Following chronic failure to thrive
d. ☐ Following acute medical complication
e. ☐ Other
f. Date of last dialysis treatment __ __ / __ __ / __ __ __ __ (Month / Day / Year)

14. Was discontinuation of renal replacement therapy after patient/family request to stop dialysis?

☐ Yes ☐ No

☐ Unknown ☐ Not Applicable

15. If deceased ever received a transplant:

a. Date of most recent transplant __ __ / __ __ / __ __ __ __ (Month / Day / Year) ☐ Unknown

b. Type of transplant received
☐ Living Related ☐ Living Unrelated ☐ Deceased ☐ Unknown

c. Was graft functioning (patient not on dialysis) at time of death?
☐ Yes ☐ No ☐ Unknown

d. Did transplant patient resume chronic maintenance dialysis prior to death?
☐ Yes ☐ No ☐ Unknown

16. Was patient receiving Hospice care prior to death?

☐ Yes ☐ No

☐ Unknown

17. Name of Physician (Please print complete name)	18. Signature of Person Completing This Form	Date

This report is required by law (42, U.S.C. 426; 20 CFR 405, Section 2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 U.S.C. 5520; 45 CFR Part 5a).

ESRD DEATH NOTIFICATION FORM
LIST OF CAUSES

CARDIAC
- 23 Myocardial infarction, acute
- 25 Pericarditis, incl. Cardiac tamponade
- 26 Atherosclerotic heart disease
- 27 Cardiomyopathy
- 28 Cardiac arrhythmia
- 29 Cardiac arrest, cause unknown
- 30 Valvular heart disease
- 31 Pulmonary edema due to exogenous fluid
- 32 Congestive Heart Failure

VASCULAR
- 35 Pulmonary embolus
- 36 Cerebrovascular accident including intracranial hemorrhage
- 37 Ischemic brain damage/Anoxic encephalopathy
- 38 Hemorrhage from transplant site
- 39 Hemorrhage from vascular access
- 40 Hemorrhage from dialysis circuit
- 41 Hemorrhage from ruptured vascular aneurysm
- 42 Hemorrhage from surgery (not 38, 39, or 41)
- 43 Other hemorrhage (not 38-42, 72)
- 44 Mesenteric infarction/ischemic bowel

INFECTION
- 33 Septicemia due to internal vascular access
- 34 Septicemia due to vascular access catheter
- 45 Peritoneal access infectious complication, bacterial
- 46 Peritoneal access infectious complication, fungal
- 47 Peritonitis (complication of peritoneal dialysis)
- 48 Central nervous system infection (brain abscess, meningitis, encephalitis, etc.)
- 51 Septicemia due to peripheral vascular disease, gangrene
- 52 Septicemia, other
- 61 Cardiac infection (endocarditis)
- 62 Pulmonary infection (pneumonia, influenza)
- 63 Abdominal infection (peritonitis (not comp of PD), perforated bowel, diverticular disease, gallbladder)
- 70 Genito-urinary infection (urinary tract infection, pyelonephritis, renal abscess)

LIVER DISEASE
- 64 Hepatitis B
- 71 Hepatitis C
- 65 Other viral hepatitis
- 66 Liver-drug toxicity
- 67 Cirrhosis
- 68 Polycystic liver disease
- 69 Liver failure, cause unknown or other

GASTRO-INTESTINAL
- 72 Gastro-intestinal hemorrhage
- 73 Pancreatitis
- 75 Perforation of peptic ulcer
- 76 Perforation of bowel (not 75)

METABOLIC
- 24 Hyperkalemia
- 77 Hypokalemia
- 78 Hypernatremia
- 79 Hyponatremia
- 100 Hypoglycemia
- 101 Hyperglycemia
- 102 Diabetic coma
- 95 Acidosis

ENDOCRINE
- 96 Adrenal insufficiency
- 97 Hypothyroidism
- 103 Hyperthyroidism

OTHER
- 80 Bone marrow depression
- 81 Cachexia/failure to thrive
- 82 Malignant disease, patient ever on Immunosuppressive therapy
- 83 Malignant disease (not 82)
- 84 Dementia, incl. dialysis dementia, Alzheimer's
- 85 Seizures
- 87 Chronic obstructive lung disease (COPD)
- 88 Complications of surgery
- 89 Air embolism
- 104 Withdrawal from dialysis/uremia
- 90 Accident related to treatment
- 91 Accident unrelated to treatment
- 92 Suicide
- 93 Drug overdose (street drugs)
- 94 Drug overdose (not 92 or 93)
- 98 Other cause of death
- 99 Unknown

INSTRUCTIONS FOR COMPLETING OF ESRD DEATH NOTIFICATION
CMS-2746-U2 (10/04)

ITEM **PROCEDURES**

1. **Patient's Last Name, First, and Middle Initial**
   Enter the patient's last name, first name, and middle initial as it appears on the Medicare Card or other official SSA notification.

2. **Medicare Claim Number**
   Enter the patient's Medicare number as it appears on the Medicare Card or other official SSA notification.

3. **Patient's Sex**
   Check the box that indicates the patient's sex.

4. **Date of Birth**
   Enter the date in month, day, and year order, using an 8-digit number; e.g., 07/24/2000 for July 24, 2000.

5. **Social Security Number**
   Enter the patient's own social security number.

6. **Patient's State of Residence**
   Enter the two-letter United States Postal Service abbreviation for State in the space provided; e.g., MD for Maryland, NY for New York.

7. **Place of Death**
   Check the one block which indicates the location of the patient at time of death. In-transit deaths or dead on arrival (DOA) cases are to be identified by checking "Other."

8. **Date of Death**
   Enter the date in month, day, and year order, using an 8-digit number.

9. **Modality at Time of Death**
   Check the one block, which indicates the patient's modality at time of death. "Other" has been placed on the form to be used only to report IPD (Intermittent Peritoneal Dialysis) and any new method of dialysis that may be developed prior to the renewal of this form by the Office of Management and Budget.

10. **Provider Name and Address (City and State)**
    Enter the complete name of the provider submitting the form and the city and State in which the provider is located.

11. **Provider Number**
    Enter the provider number (6-digit Medicare identification code) assigned by the Centers for Medicare & Medicaid Services.

12. **Causes of Death**
    a. Primary Cause
       Enter the numeric code from the list on the form, which represents the patient's primary cause of death. Do not report the same cause of death for primary and secondary causes.
    b. Were there secondary causes?
       Check the one block, which indicates whether or not there were secondary cause(s) of death. If yes, enter the code from the list on the form, which represents the secondary cause(s) of death.
    c. If cause is "Other" (98) please specify.

NOTES:
1. Code 82, "Malignant disease, patient ever on immunosuppressive therapy" means immunosuppressive therapy prior to the diagnosis of malignant disease.

2. Code 104, "Withdrew from dialysis" may not be reported as a cause of death (e.g., Code 98; "Other") and specify.

13. **Renal Replacement Therapy Discontinued Prior to Death Indicate Yes / No**
Check the one block, which indicates whether or not the patient voluntarily discontinued renal replacement therapy prior to death.

If YES, check one of the following:

Check the one box, which best describes the condition under which the patient discontinued renal replacement therapy.

a. Following HD and/or PD access failure

b. Following transplant failure

c. Following chronic failure to thrive

d. Following acute medical complication

e. Other

f. Enter date of last dialysis treatment using an 8-digit number

14. **Was Discontinuation of Renal Replacement Therapy after Patient/Family Request to Stop Dialysis**
Check the appropriate box that applies. Yes / No / Unknown / or Not Applicable

15. **If Deceased Ever Received a Transplant**
If the patient had ever received a transplant, complete items a through d.

a. Date of most recent transplant

Enter the date of the most recent transplant in month, day, and year order using an 8-digit number. If unknown, check box for unknown.

b. Type of transplant received
Check the block that indicates type of transplant received.

c. Was graft functioning at time of death?
Check appropriate block Yes / No or Unknown.

d. Did transplant patient resume chronic maintenance dialysis prior to death? Check appropriate block Yes / No or Unknown.

16. **Was Patient Receiving Hospice Care Prior to Death?**
Check appropriate block Yes / No or Unknown.

17. **Name of Physician**
Enter the name of the physician supplying the information for this form.

18. **Signature of Person Completing This Form**
The person completing the form should sign this space. The date should be entered.

Distribution of Copies:
Complete the ESRD Death Notification, CMS-2746, within 2 weeks of the date of death. If the patient was a dialysis patient, the dialysis facility last responsible for the patient's maintenance dialysis (or home dialysis) must complete this form. If the patient was a transplant patient, the transplant center is responsible for completing this form.

Mail the original (GREEN) copy to the ESRD network.

Retain the facility (WHITE) copy at your facility.

The form CMS-2746 can be obtained from your ESRD Network office.

APPENDIX C: ESRD FACILITY SURVEY (CMS-2744A)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0447

END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM
ESRD FACILITY SURVEY (DIALYSIS UNITS ONLY)

FOR THE PERIOD

Facility Physical Address _____
(If different than mailing address) *Suite/Room* *Street* *City* *State/Zip Code*

Number of Dialysis Stations: _____ **Facility Telephone: (** **)** _____

Facility Ownership Type: ☐ **Profit** ☐ **Non-Profit**

Facility Local/National Affiliation/Chain Information _____
(i.e. Gambro, etc.)

Types of dialysis services offered:
☐ Incenter Hemodialysis ☐ Peritoneal Dialysis ☐ Home Hemodialysis Training

Does your facility offer a dialysis shift that starts at 5:00 p.m. or later?
☐ Yes ☐ No

DIALYSIS PATIENTS AND TREATMENTS

DIALYSIS PATIENTS

Patients Receiving Care Beginning of Survey Period		
Incenter	Home	Total Fields 01 thru 02
01	02	03

	Additions During Survey Period			
	Started for first time ever	Restarted	Transferred from other dialysis unit	Returned after transplantation
Incenter				
Home				
	04A 04B	05A 05B	06A 06B	07A 07B

Losses During Survey Period					
Deaths	Recovered kidney function	Received transplant	Transferred to other dialysis unit	Discontinued dialysis	Other (LTFU)
08A 08B	09A 09B	10A 10B	11A 11B	12A 12B	13A 13B

Patients Receiving Care at End of Survey Period											
Incenter Dialysis		Self-Dialysis Training				Total Incenter Dialysis	Home Dialysis				Total Home Dialysis
Hemo-Dialysis	Other	Hemo-Dialysis	CAPD	CCPD	Other	Fields 14 thru 19	Hemo-Dialysis	CAPD	CCPD	Other	Fields 21 thru 24
14	15	16	17	18	19	20	21	22	23	24	25

Total Patients
Fields 20 and 25
26

Patient Eligibility Status End of Survey Period		
Currently enrolled in Medicare	Medicare application pending	Non-Medicare
27	28	29

Hemodialysis Patients Dialyzing More Than 4 Times Per Week		
Setting	Day	Nocturnal
Incenter		
Home		
	30A 30B	31A 31B

Vocational Rehabilitation			
Patients aged 18 through 54	Patients receiving services from Voc Rehab	Patients Employed full-time or part-time	Patients attending school full-time or part-time
32	33	34	35

TREATMENT AND STAFFING

Incenter Dialysis Treatments (Include Training Treatments)	
Hemodialysis	Other
36	37

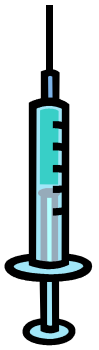
Staffing				
	Number of Staff		Number of Open Pos.	
Position	Full Time	Part Time	Full Time	Part Time
a. RNs				
b. LPN/LVNs				
c. PCTs				
d. APNs				
e. Dietitians				
f. Social Workers				
	38	39	40	41

COMPLETED BY (Name)	DATE	TITLE	TELEPHONE NO.

REMARKS REGARDING INFORMATION PROVIDED ON THIS SURVEY SHOULD BE ENTERED ON THE LAST PAGE OF THE SURVEY

This report is required by law (42 USC 426; 42 CFR 405.2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 USC 5520; 45 CFR, Part 5a).

APPENDIX D: STIC DIALYSIS FACILITY PROVIDER IMMUNIZATION SURVEY: PRACTICES, BELIEFS, AND ATTITUDES



Safe &
Timely
Immunizations
Coalition

STIC Dialysis Facility Provider Immunization Survey: Practices, Beliefs, and Attitudes

Name _____ Credential(s) _____
(i.e., R.N., M.D.)

Job Title _____

Facility Name _____

Facility Provider Number _____

Years at this Facility _____ Total Years of Experience in Current Role _____

Date _____

Time Estimated to Complete This Survey: 10-15 minutes

Facility Provider Number _____

1. Which Immunization Program Option (A, B, C, or D) *best* describes this facility's current program to ensure that all consenting patients without medical contraindications are immunized against influenza?
   □ A □ B □ C □ D
   □ Other (Please describe):
   _____
   _____

2. Which Immunization Program Option (A, B, C, or D) *best* describes this facility's current program to ensure that all consenting patients without medical contraindications are immunized against pneumococcal disease?
   □ A □ B □ C □ D
   □ Other (Please describe):
   _____
   _____

3. Which Immunization Program Option (A, B, C, or D) *best* describes this facility's current program to ensure that all consenting patients without medical contraindications are immunized against hepatitis B?
   □ A □ B □ C □ D
   □ Other (Please describe):
   _____
   _____

Immunization Program Options

Option A.	**Each patient's physician signs the facility's preprinted admission order before administration of the vaccine to the patient. The preprinted order may address the patient's current vaccination needs as well as those in the future (e.g., annual vaccination against influenza). This order may have to be renewed periodically.**
Option B.	**A facility policy authorizes appropriate nursing staff to immunize patients by facility- or medical director-approved protocol without the need for a written or verbal order from the patient's physician.**
Option C.	**Although there is no facility-wide policy, individual physicians have the option to sign an order authorizing appropriate nursing staff to immunize their patients without the need for specific written or verbal consultation between the physician and the patient**
Option D.	**Each patient's physician must sign an individual order for every vaccine before its administration to the patient. The facility has no preprinted admission orders (Option A) or facility policy as in Option B for influenza, pneumococcal, or hepatitis B vaccines.**

4. If this facility were to implement Immunization Program Option B (description is repeated below in italics), please indicate if the following items *would be* potential problems in its implementation—within *your* facility—for influenza, pneumococcal, and hepatitis B vaccines.

   OR

   If this facility has already implemented Immunization Program Option B for influenza, pneumococcal, or hepatitis B vaccines, please indicate if the following items *have been* problems in its implementation.

Immunization Program Option B: *A facility policy authorizes appropriate nursing staff to immunize patients by facility- or medical director-approved protocol without the need for a written or verbal order from the patient's physician.*

Please circle one best response for each row in EACH column I, II, III
(Y = Yes, N = No, DK = Don't Know)

PROBLEMS with OPTION B implementation for:	**I. Influenza Vaccine?**			**II. Pneumococcal Vaccine?**			**III. Hepatitis B Vaccine?**		
Inappropriate or unnecessary immunization of patients	Y	N	DK	Y	N	DK	Y	N	DK
Staff may lack legal authority to immunize without an order from the patient's physician	Y	N	DK	Y	N	DK	Y	N	DK
Lack of support by facility leadership	Y	N	DK	Y	N	DK	Y	N	DK
No advantage over current immunization program	Y	N	DK	Y	N	DK	Y	N	DK
Need to educate patient's physicians regarding Option B	Y	N	DK	Y	N	DK	Y	N	DK
Cost of program (e.g., retraining staff, administrative time)	Y	N	DK	Y	N	DK	Y	N	DK
Low reimbursement for vaccine administration	Y	N	DK	Y	N	DK	Y	N	DK
Other priorities for staff time	Y	N	DK	Y	N	DK	Y	N	DK
Nursing staff turnover	Y	N	DK	Y	N	DK	Y	N	DK
Medical liability for the facility	Y	N	DK	Y	N	DK	Y	N	DK
Other – describe: _____ _____ _____ _____	Y	N	DK	Y	N	DK	Y	N	DK

5. A. In the next year, how likely is your facility to review and consider changes to the current immunization program option?
   - ☐ Very likely
   - ☐ Likely
   - ☐ Neither likely or unlikely
   - ☐ Unlikely
   - ☐ Very unlikely

   B. Who must approve immunization policies that determine the major features of this facility's immunization programs? (Check all that apply.)
   - ☐ Administrator
   - ☐ Corporate Officer
   - ☐ Medical Director
   - ☐ Director of Nursing
   - ☐ Infection Control Officer
   - ☐ Other quality improvement personnel
   - ☐ Other _____ (list as many as appropriate – do not list specific names only title)
     _____

6. Does your facility have standing orders which give non-physician staff authority to initiate the following procedures and processes:

   a. Screening for prevention of renal osteodystrophy in order to make recommendations to physician and/or dietician

      ☐ Yes ☐ No ☐ In some cases ☐ Don't know

   b. Anemia treatment to maintain a specific Hgb/Hct level

      ☐ Yes ☐ No ☐ In some cases ☐ Don't know

   c. Surveillance of AV grafts for hemodynamically significant stenosis / referral for venography

      ☐ Yes ☐ No ☐ In some cases ☐ Don't know

Questions 7-10 refer to Patient Immunizations

7. A. Does this facility currently have a **consistent way (e.g., immunization record)** of tracking patients' vaccination status in patient charts?

Influenza	☐ Yes	☐ No	☐ Don't know
Pneumococcal	☐ Yes	☐ No	☐ Don't know
Hepatitis B	☐ Yes	☐ No	☐ Don't know

B. Does this facility currently have a **centralized location (e.g., computer tracking system or log book)** to track vaccination status for all patients?

Influenza	☐ Yes	☐ No	☐ Don't know
Pneumococcal	☐ Yes	☐ No	☐ Don't know
Hepatitis B	☐ Yes	☐ No	☐ Don't know

C. Are patient refusals of vaccines documented?

☐ Yes ☐ No ☐ Don't know

8. Are vaccinations for the following offered to patients whose vaccine histories are unknown?

Influenza	☐ Yes	☐ No	☐ Don't know
Pneumococcal	☐ Yes	☐ No	☐ Don't know
Hepatitis B	☐ Yes	☐ No	☐ Don't know

9. What kinds of educational materials are provided to **patients** regarding the following immunizations? (Check all that apply.)

Influenza
- ☐ Leaflet/pamphlet
- ☐ Video
- ☐ Verbal counseling (≥2 min)
- ☐ Immunization record/wallet card
- ☐ Other _____
- ☐ None

Pneumococcal
- ☐ Leaflet/pamphlet
- ☐ Video
- ☐ Verbal counseling (≥2 min)
- ☐ Immunization record/wallet card
- ☐ Other _____
- ☐ None

Hepatitis B
- ☐ Leaflet/pamphlet
- ☐ Video
- ☐ Verbal counseling (≥2 min)
- ☐ Immunization record/wallet card
- ☐ Other _____
- ☐ None

10. Consider the amount of information provided to **patients** by the facility about issues such as diet and nutrition. Is the amount of information provided about immunization:
- ☐ Significantly more
- ☐ More
- ☐ About the same
- ☐ Less
- ☐ Significantly less

Questions 11-13 refer to Staff Immunizations

11. Which of the following describes the facility's practice for immunizing **staff** against influenza?
    - ☐ Immunization required as a condition of employment
    - ☐ Immunizations offered to all staff, but not required
    - ☐ Immunizations are encouraged, but not offered
    - ☐ Immunizations neither offered nor encouraged

12. A. If influenza immunizations are required or offered, are they available to **staff** on-site?
    - ☐ Yes
    - ☐ No
    - ☐ Not applicable (not required or offered)

    B. If influenza immunizations are required or offered, at what cost to **staff** are they provided?
    - ☐ No cost
    - ☐ Low Cost (≤ $15)
    - ☐ Other: $_____
    - ☐ Not applicable (not required or offered)

13. Does this facility currently have a **centralized location (e.g., computer tracking system or log book)** to track vaccination status for all **staff**?

Influenza	☐ Yes	☐ No	☐ Don't know
Pneumococcal	☐ Yes	☐ No	☐ Don't know
Hepatitis B	☐ Yes	☐ No	☐ Don't know

14. How much education does the **staff** receive regarding the importance of immunizing patients against influenza, pneumococcal disease, and hepatitis B? (Circle one response in **EACH** row.)

INFLUENZA	**Extensive** (e.g., dedicated annual session)	**Limited** (e.g., during usual staff meeting or via print materials only)	**Little or none**
PNEUMOCOCCAL	**Extensive** (e.g., dedicated annual session)	**Limited** (e.g., during usual staff meeting or via print materials only)	**Little or none**
HEPATITIS B	**Extensive** (e.g., dedicated annual session)	**Limited** (e.g., during usual staff meeting or via print materials only)	**Little or none**

15. To implement or improve an influenza, pneumococcal, and hepatitis B immunization program, would this facility benefit from **staff training sessions** OR **educational materials** on these topics OR BOTH?

Please circle one best response for each row in <u>BOTH</u> columns I and II.
(Y = Yes, N = No, DK = Don't Know)

Training Topics needed	**I. Staff training sessions needed?**			**II. Educational materials for staff needed?**		
Model policy to vaccinate on admission	Y	N	DK	Y	N	DK
Administration of vaccines	Y	N	DK	Y	N	DK
Information about influenza vaccine	Y	N	DK	Y	N	DK
Information about pneumococcal vaccine	Y	N	DK	Y	N	DK
Information about hepatitis B vaccine	Y	N	DK	Y	N	DK
Specific information about these infections	Y	N	DK	Y	N	DK
Vaccination storage	Y	N	DK	Y	N	DK
Billing procedures	Y	N	DK	Y	N	DK
Process or software for tracking immunization rates	Y	N	DK	Y	N	DK
Other – describe: _____ _____ _____	Y	N	DK	Y	N	DK

16. How are **physicians** reminded about the immunization status of their patients? (Check all that apply.)
- ☐ Letters/postcards
- ☐ Phone calls
- ☐ Chart stickers
- ☐ Staff verbally remind physicians
- ☐ Pre-printed orders in patient charts
- ☐ Other _____
- ☐ No reminder system

17. Is your facility's performance in delivering any of the following vaccinations **to your patient population** assessed annually and feedback provided on your performance:

Influenza	☐ Yes (☐and feedback provided)	☐ No	☐ Don't know
Pneumococcal	☐ Yes (☐and feedback provided)	☐ No	☐ Don't know
Hepatitis B	☐ Yes (☐and feedback provided)	☐ No	☐ Don't know

18. Please indicate your opinions about the following statements:

Statement	Agree strongly	Agree	Neither agree nor disagree	Disagree	Disagree strongly
1. Our facility is responsible to ensure that each of our patients is vaccinated appropriately.					
2. Our facility is responsible to ensure that staff involved in patient care are vaccinated appropriately.					
3. Influenza is a serious medical concern for our patients.					
4. The influenza vaccine is generally effective in our patients.					
5. The influenza vaccine is generally safe.					
6. Pneumococcal disease is a serious medical concern for our patients.					
7. The pneumococcal vaccine is generally effective in our patients.					
8. The pneumococcal vaccine is generally safe.					
9. Hepatitis B is a serious medical concern for our patients.					
10. The hepatitis B vaccine is generally effective in our patients.					
11. The hepatitis B vaccine is generally safe.					

APPENDIX E: STIC IMMUNIZATION DATA COLLECTION TOOL

Facility Name	Provider number
Contact Name	**Phone Number**

Safe and Timely Immunizations Coalition
Immunization Data Collection Tool

Safe & Timely Immunizations Coalition

Instructions: Under the specific immunization column, indicate with the appropriate number (1 or 2) if the immunization was given. If the immunization was NOT given, indicate with the appropriate number (3,4,5,6,7). If unknown, indicate with the appropriate number (8). See codes for clarification.

Immunization Codes:
1. YES, received at this facility
2. YES, received at another location
3. NO, not received, pt refused
4. NO, not received, pt allergic
5. NO, not offered to pt
6. NO, not time for dose (Hep B only)
7. NO, other reason
8. UKNOWN, not known by patient

Note Regarding Hepatitis B: If the patient received part of the series at another facility but completed the series in your facility, use Immunization Code #1. **Please only answer one of the options (that best describes patient's current status)** and indicate code in appropriate column. *We need to know about the initial 3 or 4 dose series only.*

Note Regarding Dates: If the year is known but not the month or day, just write the year in the appropriate box.

Immunization →	Influenza	Pneumonia				Hepatitis B								
			Most recent dose				Date completed				Date of most recent dose			
Patient Name	During 2005-06 season 10/05-3/06 (enter code)	Ever Received dose (enter code)	MM	DD	YYYY	Patient has received complete series (enter code 1 or 2)	MM	DD	YYYY	Patient has completed partial series (enter code 1 or 2)	MM	DD	YYYY	Patient has not received any doses (enter code 4-8)

Total Patient Census														
0														
Yes, given at this facility (#)	0	0				0				0				0
Yes, given at this facility (%)	#DIV/0!	#DIV/0!				#DIV/0!				#DIV/0!				#DIV/0!
Yes, given at another location (#)	0	0				0				0				0
Yes, given at another location (%)	#DIV/0!	#DIV/0!				#DIV/0!				#DIV/0!				#DIV/0!
Total Patients Receiving Vaccine (#)	0	0				0				0				0
Total Patients Receiving Vaccine (%)	#DIV/0!	#DIV/0!				#DIV/0!				#DIV/0!				#DIV/0!
No, patient refused (#)	0	0				0				0				0
No, patient refused (%)	#DIV/0!	#DIV/0!				#DIV/0!				#DIV/0!				#DIV/0!
No, patient allergic (#)	0	0				0				0				0
No, patient allergic (%)	#DIV/0!	#DIV/0!				#DIV/0!				#DIV/0!				#DIV/0!
No, not offered to patient (#)	0	0				0				0				0
No, not offered to patient (%)	#DIV/0!	#DIV/0!				#DIV/0!				#DIV/0!				#DIV/0!
No, not time for dose (Hep B only) (#)	0	0				0				0				0
No, not time for dose (Hep B only) (%)	#DIV/0!	#DIV/0!				#DIV/0!				#DIV/0!				#DIV/0!
No, other reason (#)	0	0				0				0				0
No, other reason (%)	#DIV/0!	#DIV/0!				#DIV/0!				#DIV/0!				#DIV/0!
Total Patients NOT Receiving Vaccine (#)	0	0				0				0				0
Total Patients NOT Receiving Vaccine (%)	#DIV/0!	#DIV/0!				#DIV/0!				#DIV/0!				#DIV/0!

APPENDIX F: STIC 2006-07 INFLUENZA IMMUNIZATION WORKSHEET

Complete and return this form to the Network office by **August 31, 2007**

Safe & Timely Immunizations Coalition

FAX #: 919-855-0753

2006-07 Influenza Immunization Worksheet

PROVIDER NUMBER: **«Provider_»**

PROVIDER NAME: **«Provider_Name»**

1. Complete the following steps to calculate the Influenza Immunization rate for your facility. If you have hemodialysis and peritoneal patients, please calculate the rates together to produce a **FACILITY** rate. **Return this worksheet only by August 31, 2007.**

   Step 1: Using your patient list, count the number of patients for fields A, B, C and enter them here.

A. Total number of patients (hemodialysis and peritoneal) on roster	
B. Total number of patients on roster that received the flu shot during the 2006-07 Season (September 1, 2006 to February 28, 2007) (**REMEMBER THIS IS REGARDLESS OF WHERE IT WAS GIVEN)**.	
C. Total number of patients on roster that did not receive the flu shot or were in unknown status	

   Step 2: Check your math. Does **B+C=A? If not check your figures.**

   Step 3: Calculate your Influenza Immunization Rate

_____ divided by _____ x100= **%**

Field B Field A

Your 2006-07 Influenza Immunization Rate

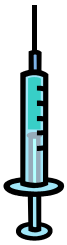
Individual Completing Form (**Please Print**)

First Name_____ Last Name_____ Title_____

Phone Number_____ Fax Number_____

Return to: **Maura McCann**
Southeastern Kidney Council
1000 St. Albans Drive, Suite 270
Raleigh, NC 27609
(919) 855-0882 ext45
(919) 855-0753 (fax)

APPENDIX G: STIC IMMUNIZATIONS QUALITY IMPROVEMENT PLAN DEVELOPMENT



Safe & Timely Immunizations Coalition

Immunizations
Quality Improvement Plan Development

Your facility has been asked to complete a quality improvement plan because your Influenza Immunization Rate is below acceptable standards. Completing *and* implementing an effective quality improvement plan is one way to drive sustained improvement. These plans are successful when they include each component of the quality improvement process and also incorporate ongoing participation from the entire multidisciplinary team. Please use the following strategies as you develop a quality improvement plan for your facility:

- **Goal:** Define the desired outcome area currently not being met. **Example: 100% of eligible patients will receive the Influenza Immunization during the 2007-08 season**

- **Problem Statement:** Define the problem that has prevented goal from being met, remembering that your facility could have multiple problem statements for one outcome area. **Example: Patients are refusing the Influenza Immunization**

- **Multidisciplinary Team:** Determine the team members necessary to improve the outcome identified in the problem statement. **Example: Medical Director, Nurse Manager, Renal Social Worker, Renal Dietitian, Attending Nephrologists, Dialysis Nurses, Patient Care Technicians**

- **Root Causes:** Determine the underlying causes that have led to the problem. **Example: Lack of patient education regarding the importance of the Influenza Immunization**

- **Action Plan Implementation Steps:** Determine what steps need to be taken to address the problem and its root causes. For each step, determine what team member(s) are primarily responsible for completing the task, what date the task should begin, and an estimated date for completing the task.
  Example: Step 1. Address barriers and misconceptions related to the Influenza Immunization
  Responsible team member(s): Lucy Luck RN and Joe Smile PCT
  Start Date: October 1, 2007
  Estimated Completed Date: October 5, 2007 and incorporate into monthly care conferences

- **Evaluation:** Determine a timeframe and structure for how each action plan step will be evaluated. During task evaluation, tasks may need to be revised or changed to facilitate further improvement. **Example: Bring list of current patients that have not received the Influenza Immunization to CQI meeting monthly for team to review; report changes in immunization status at CQI meeting. Give positive feedback to patients when they receive the Influenza Immunization.**

Safe & Timely Immunizations Coalition

Immunizations
Quality Improvement Plan Development – Required Elements

When you formulate your Quality Improvement Plan include at least one activity that targets you (the provider) and one activity that targets the patient. Under systems-based approach, identify at least one activity to explore with your CQI team to work toward:

I. Provider-oriented approach
   a. Provider education
      i. Address barriers & misconceptions
   b. Provider incentives/recognition
   c. Assessment and performance feedback for providers

II. Patient-oriented approach
   a. Patient education
      i. Address barriers & misconceptions
      ii. Immunization Education Day at the facility for each shift of patients
         1. Posters in waiting area
         2. Distribute flyers related to immunizations
         3. Offer immunization at that time
   b. Patient reminder system
      i. Mail or hand deliver
   c. Patient incentives
   d. Immunization counseling
      i. Have a dedicated “level 2” person talk to patients who refuse immunizations
   e. Patient-level immunization tracking
      i. Encourage use of patient immunization cards

III. System-based approach
   a. Standing orders
   b. Physician reminder system
   c. Check-box for immunization incorporated into admission & annual order sheets

Additional Recommended/Encouraged Elements:

IV. Staff vaccination initiative
   a. Monitor staff vaccination rates
   b. Offer vaccines free to all staff
   c. Require staff vaccination or singed declination form (sample attached)
   d. Provide incentives

V. Surveillance/monitoring
   a. Maintain centralized tracking system for patient immunizations and calculate facility vaccination rates
   b. Incorporate record of all patient immunizations on separate sheet in patient’s medical chart

Problem Statement: _____% Currently meeting goal (update monthly)	Facility Name:
Goal for Improvement:	Person completing report:
Data Required-Needed Resources:	Date:
Root Causes-Barriers:	
Actions Already in Place:	

Action Plan Implementation Steps	Team Members (Note responsible member)	Start Date	Estimated Completion Date	Checkpoint Dates	Date Completed	Comments (Status, outcomes, disposition, etc)

APPENDIX H: STIC QUALITY IMPROVEMENT PLAN DATA COLLECTION FORM

Network ____

Center ID _____

1. Were the following elements included in the center's quality improvement (QI) plan?

   ☐ An immunization goal for this flu season

   → **If yes, center goal was ____ %**

   ☐ Statements defining problems or underlying causes that have prevented this goal from being met in the past

   → **If yes, number of statements included: ____**

   Action plan steps for addressing problems/causes were provided for . . .

   ☐ All problems/causes
   ☐ Most problems/causes
   ☐ Some problems/causes
   ☐ No problems/causes

   Team member(s) responsible for action plan steps were indicated for . . .

   ☐ All problems/causes
   ☐ Most problems/causes
   ☐ Some problems/causes
   ☐ No problems/causes

   Time to complete each action plan step was estimated for . . .

   ☐ All problems/causes
   ☐ Most problems/causes
   ☐ Some problems/causes
   ☐ No problems/causes

   A method and timeframe to evaluate each action plan step was provided for . . .

   ☐ All problems/causes
   ☐ Most problems/causes
   ☐ Some problems/causes
   ☐ No problems/causes

2. Were the following topics addressed in the action plan?
   - ☐ Assessment and performance feedback for providers
   - ☐ Proposed changes to immunization procedures (eg, standing orders)
     - **YES NO** Facility-wide standing order program implemented
     - **YES NO** Limited standing order program implemented
     - **YES NO** Specific changes to ordering/storing vaccine implemented
     - **YES NO** Specific changes to vaccination timing/scheduling implemented
   - ☐ Provider reminder system
   - ☐ Education process for patients regarding influenza immunization
     - **YES NO** Program to address barriers and misconceptions
     - **YES NO** "Immunization Day" program (event, flyers/posters)
   - ☐ Immunization counseling plan to address patient **refusal** of immunization
     - **YES NO** Use of "level 2" person to talk to patients (eg, nurse supervisor)
   - ☐ Patient reminder system
     - **YES NO** Mailed to patients
     - **YES NO** Delivered by hand to patients
   - ☐ Patient incentives
   - ☐ Staff vaccination initiative

     NOTE: should be NEW programs, not pre-existing policies
     - **YES NO** Staff rates monitored
     - **YES NO** Staff education
     - **YES NO** Free immunization of staff
     - **YES NO** Required staff vaccination or declination form
     - **YES NO** Incentives provided

3. With regard to this plan, did the Network . . .

   ☐ Review submitted plan for completeness

   ☐ Consult with MRB

   ☐ Provide feedback for revisions to quality improvement coordinator

   ☐ Request revisions

   ☐ Approve plan

   Date plan approved _____

4. Monitoring—please indicate **number of months** each of the following was ascertained for this center:

   ____ Progress toward center's immunization goal

   ____ Progress toward implementation of action plan

   ____ Evaluation of completed action plan steps

   If monitoring was ended early, please provide date and reason: _____

   _____

5. Monitoring—please indicate whether information was exchanged between the Network and this center **during monthly monitoring** regarding:

   ☐ Changes to immunization procedures (ie, permissions, ordering, scheduling)

   Describe changes made: _____

   _____

   ☐ Staff educational programs

   YES NO Specific materials and details were discussed

   _____ Number of staff receiving education (if reported)

   ☐ Patient educational programs

   YES NO Specific materials and details were discussed

   ____ Number of patients receiving education (if reported)

   ☐ Patient refusals

   YES NO Specific materials and details were discussed

   ____ Total number of refusals (if reported)

   ____ Number of these patients provided with additional information

   ____ Number of these patients who did and did not receive immunization