2009

Vaccination Toolkit

Developed by the Forum of ESRD Networks' Medical Advisory Council (MAC)

The Forum MAC has developed a series of QAPI toolkits to assist dialysis facilities in meeting the requirements of the Conditions for Coverage.

Forum Medical Advisory Council (MAC)
The Forum of ESRD Networks
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The National FORUM of ESRD NETWORKS
Improving Care Through Collaboration

This toolkit was developed by members of the Forum of ESRD Networks' Medical Advisory Council (MAC). The Council members who participated in this project are listed below.

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Note: Some tools contained in this toolkit were originally created by the ESRD Networks. Several resources were provided by the Safe & Timely Immunizations Coalition (STIC).

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INCREASING IMMUNIZATION RATES AMONG DIALYSIS PATIENTS AS A QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI) PROJECT

INTRODUCTION

The goal of this toolkit is to suggest quality improvement approaches that a facility can use to ensure care coordination for patients.

As you are aware, the recently revised Conditions of Coverage for dialysis facilities mandates ongoing QAPI projects within each facility, and places responsibility for the direction of these projects upon the Medical Director. The purpose of the attached documents is to provide a ready-made toolkit for the initiation and documentation of QAPI projects, with the goal of increasing immunization rates for influenza, pneumococcal disease, and hepatitis B among dialysis patients.

These vaccines have been chosen in accordance with the recommendations of the Centers for Disease Control, as summarized in the attached document "Guidelines for Vaccinating Kidney Dialysis Patients and Patients with Chronic Kidney Disease". In particular, please note that the CDC recommends the use of inactivated influenza vaccine, rather than the live attenuated intranasal vaccine, for dialysis patients. The forms for initiating the project and tracking performance improvement have been adapted from those used successfully for the past several years by the Safe and Timely Immunization Coalition, a project initiated by ESRD Network 6, with the participation of Networks 11 and 15 and the support of CMS.

Separate projects are suggested for the three vaccines, since prior documentation requirements, vaccine schedules, and goals of therapy differ considerably among them. We suggest using the attached Quality Assurance and Performance Improvement Plan Development template prior to embarking upon each vaccine plan you intend to implement. Adherence to the template will result in a project design that should fulfill the requirements for QAPI as outlined in the Conditions of Coverage, as well as provide documentation of Medical Director leadership and multidisciplinary involvement that may be helpful during state agency inspections. Individual data collection and tracking forms are provided for each vaccine.

The first documents are general instructions for generating QAPI project templates that the facility can review and revise to meet its own needs for any QAPI activity. Since individuals have different ways of viewing problems and organizing their approaches, these are essentially "how to" documents to help guide the QAPI process. We provide brief examples of root causes/barriers and potential interventions that address those barriers, as they might apply to influenza vaccination in a dialysis facility.

Potential interventions can be listed to address the barriers, and can likewise be ranked in terms of feasibility and whether they are likely to lead to the desired outcome. We included a formatted grid that can be used to summarize specific goals, timelines, and responsible personnel. We suggest the creation of individual grids for influenza, pneumococcal, and

hepatitis B vaccination projects if the intention is to undertake QAPI activities in more than one of these areas.

We have also provided an Excel spreadsheet as an example of a central resource to record and update information on individual patient vaccination status and eligibility. We suggest running the spreadsheet as a live electronic document and periodically saving updates, rather than printing it out and recording data by hand. Monthly updates on vaccination progress, suitable for unit quality assurance meetings, may be generated with the included tracking tool.

We provided a link to the PDF document "Guidelines for Vaccinating Kidney Dialysis Patients and Patients with Chronic Kidney Disease", which resulted from a collaboration between the Safe and Timely Immunization Coalition (STIC, a special project supported by CMS and implemented by ESRD Networks 6, 11 and 15) and the Centers for Disease Control, published in 2006. The other materials in the toolkit were also adapted from materials generated as part of the STIC project by ESRD Network 6 personnel. Also included are links to other vaccination resources on Network websites.

HOW TO USE THIS TOOLKIT

The enclosed Toolkit will assist the facility to design a QAPI (Quality Assessment and Performance Improvement) project (also known as CQI, or Continuous Quality Improvement) with the goal of improving care for ESRD patients. QAPI is a major focus of responsibility for the dialysis unit and the unit's Medical Director as outlined in the Conditions for Coverage of October 2008. According to the new ESRD Conditions for Coverage (494.110) "The dialysis facility must develop, implement, maintain and evaluate an effective, data driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team (IDT). The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS".

It is recognized that there are many different practice patterns, resources and non-facility factors that contribute to the complexity of any process of care in the dialysis facility. This Toolkit can help the facility understand and improve its own particular processes. It is not meant to provide formulas for a facility to adopt; each facility will need to determine its own goals, challenges and solutions.

We start with a generic description of QAPI, then provide narrowly focused examples along with background information, flowsheets, references, etc.; facilities should feel free to redefine and expand the scope of their projects as they identify additional opportunities for improvement. We also included reference materials that outline the duties of the major facility personnel. Note that the Medical Director is charged with the leadership role in quality improvement, and that all personnel have important roles and responsibilities.

Any materials can be downloaded, revised, printed and distributed without restriction to meet the needs of the facility.

QUALITY IMPROVEMENT

There is no one right way to do quality improvement; the important thing is to identify and describe the problem(s), analyze the causes, determine what resources are available, brainstorm and prioritize solutions, implement a plan, then determine whether improvement occurred, quantitate it, and analyze the findings. There are numerous templates that can be utilized. So called "rapid cycle change" seeks to simplify and accelerate the process, and asks three questions: What are we trying to accomplish, what changes will bring about an improvement, and how will we know a change is an improvement? It forgoes complex flow charts and step by step instructions in favor of small scale changes that can be tested, revised and staged.

We have outlined the basic processes of a QAPI project below in narrative form. The facility should use its internal, interdisciplinary resources to "fill in the blanks" to design its own project. Importantly, the facility should feel free to start with a small piece of the identified problem, work through the QAPI process, then use the information and experience gained to tackle the next project.

Problem: Define the problem that needs to be addressed. It could be an outcome or a process.

Goal: State what you would like to see instead. Important: You can do this in stages. You do not have to address all aspects of the problem or even all patients in the first project.

GET STARTED

First, decide what data you need from patient charts, facility logs, etc.

Next, decide which persons at your facility should be included in the team effort. The team should be interdisciplinary, tailored to the problem.

To get started, consider what the root causes and barriers prevent your facility from performing optimally. These may be personnel factors, patient factors, equipment or physical plant issues, lack of processes or faulty processes, language barriers, financial or reimbursement problems, etc.

Decide on an "AIM" Statement; what are you trying to accomplish? Establish goals. For example, you may aim for 90% success in reaching an identified clinical goal, or may want to see a particular clinical process performed the same way 100% of the time.

How will you measure improvement? This may require chart audits, review of logs, observation of practices in the facility, questionnaires or other means of assessing improvement.

Measurement: decide on a numerator and an appropriate denominator.

Brainstorm potential solutions based on barriers / root cause prioritized by your QI team. You can prioritize the root causes as well as the solutions. Prioritization will help you determine which root causes are most critical and significant. Potential solutions can be prioritized by how "doable" they are, as well as by their anticipated impact. Not all root causes or solutions need to be addressed in every QAPI project.

PLAN: Plan a specific intervention(s). Keep it simple and focused; do not over-reach. Your initial project may be quite limited; you may learn more than you think. You can use what you learn to determine what the next project should be.

Designate personnel and resources for each intervention.

Consider whether to target a specific subgroup for initial intervention.

Determine a timeline; when and how will you collect your follow-up information?

DO: Implement your intervention. Each intervention should have a timeframe and designated personnel.

Collect your follow-up data at the agreed-upon timeline.

Tabulate and/or graph your data, using numerators and denominators where appropriate. Calculate percent changes. **Document.**

STUDY: Examine your results and re-evaluate with your team. Is the process working? If not, why not? What is working well? If necessary, re-evaluate the root causes/barriers as well as your interventions.

Document your progress and findings and revisions in goals and interventions as appropriate.

ACT: If you have not met your goals, begin again with your new plan. If you met your goals, consider whether to expand to another aspect of the problem.

DO NOT HESITATE TO INVOLVE YOUR ESRD NETWORK AND MEDICAL REVIEW BOARD QI RESOURCES. The outline above is intentionally simplified. Your Network Quality Improvement Director will have expertise as well as additional resources and references for you. The Forum of ESRD Networks will soon have a toolkit available that will explain in greater detail the theory and techniques of QAPI (Quality Assessment and Performance Improvement). But you don't need to wait for this to get started on your own projects!

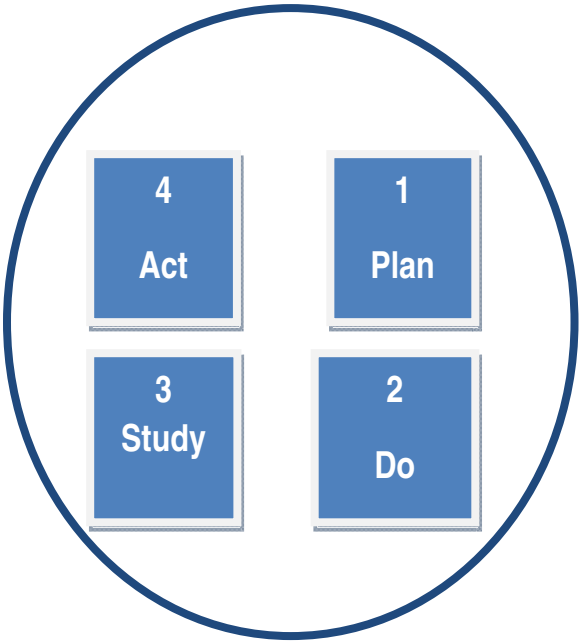
PDSA CYCLE

4-*ACT

-Adopt the change *or*

-Abandon it *or*

-Run through the cycle again, possibly under different environmental conditions



1-Plan a change or a test aimed at improvement

3- Study the results

What did we learn?

2-Carry it out

(Preferably on a small scale)

Begin a new PDSA Cycle!

QI PROJECT PHASES	ACTIVITIES	KEEP IN MIND
Plan	Make a plan for the change, collect baseline data, plan to carry out the cycle (who, what, where, when)	Brainstorming, motivating
Do	Carry out the plan, document problems and unexpected observations, continue to monitor data	Flowchart, run chart
Study	Complete the analysis of the data, compare data to predictions, summarize what was learned	Fishbone diagram, Pareto chart, control chart, histogram
Act	What changes are to be made? Develop ongoing evaluation/monitoring, next cycle?	Flowchart, brainstorming

Immunizations
Quality Assessment & Performance
Improvement Plan Development

Completing *and* implementing an effective data driven 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 interdisciplinary 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 2009-10 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, 2009
  Estimated Completed Date: October 5, 2009, 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.**

IMMUNIZATIONS
QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT PLAN DEVELOPMENT

Required Elements: When you formulate your Quality Assessment & Performance Improvement (QAPI) Plan include **at least one** activity that targets you (provider/system based approach) and **at least one** activity that targets the patient (patient-oriented approach).

I. Provider/System Based approach
- a. Assessment and performance feedback for providers
- b. Standing orders
- c. Provider reminder system

II. Patient-oriented approach
- a. Patient education (chose one of the following)
  - i. 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 on education day
  - ii. Immunization counseling
    1. Have a dedicated "level 2" person talk to patients who refuse immunizations (i.e. Nurse Supervisor, Physician, Nurse Practitioner, Physicians Assistant)
  - iii. Other
    1. Your action plan must be specific
- b. Patient reminder system
  - i. Mail or hand deliver

Additional Recommended/Encouraged Elements:

III. Staff vaccination initiative (for influenza)
- a. Monitor staff vaccination rates
- b. Staff education
- c. Offer vaccines free to all staff
- d. Provide incentives

IV. Patient vaccination initiative
- a. Patient incentives
- b. Consider communicating vaccination rates to patients, and fostering competition (e.g. between shifts) for highest vaccination rate

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
- c. Encourage use of patient immunization cards

VI. Other
- a. Check-box for immunization incorporated into admission & annual order Sheets

Problem Statement: ____% Currently meeting goal (update monthly) Goal for Improvement: Data Required-Needed Resources: Root Causes-Barriers: Actions Already in Place:	Facility Name: Facility Provider Number: Person completing report: Date: I have reviewed this action plan _____ Medical Director Signature _____ Administrator

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

VACCINATION CQI ACTION PLAN

SAMPLE - This SAMPLE is not a complete ACTION PLAN

Problem Statement:
Only 45% of the patients in the facility received the influenza immunization in 2008. The Healthy People 2010 goal is 90%.

Goal for Improvement:
Increase the percentage of patients receiving the influenza immunization by 45 percentage points in the 2009-2010 influenza season; rate will be equal to or greater than 90%.

Data Required/Needed Resources:
Number of patients receiving influenza immunization, tracking mechanism, personnel time and commitment to the project, patient education resources regarding the need for immunization, physician orders for immunization

Root Causes-Barriers:
Lack of patient/staff education regarding the importance of vaccination of kidney patients, lack of documentation of immunizations including those given outside of the dialysis facility, refusal of vaccine by patients who do not want to receive the immunization.

Actions Already In Place:
The facility does not currently have an immunization program. Patients are encouraged to seek immunization outside the dialysis facility.

Facility Name: XYZ Dialysis
Facility Provider Number: 098765

Name of Person Completing Report:
Janie Doe

Date: May 1, 2009

I have reviewed this Action Plan:

_____
Medical Director

_____
Administrator

ACTION PLAN IMPLEMENTATION STEPS	RESPONSIBLE TEAM MEMBER	START DATE	ESTIMATED COMPLETION DATE	CHECKPOINT DATE	DATE COMPLETED	COMMENTS (STATUS, OUTCOMES, EVALUATION, ETC.)
Enlist the support of the Medical Director and the other facility Nephrologists for an influenza immunization program.	Facility Administrator	May 2, 2009	May 5, 2009	May 4, 2009	May 4, 2009	Medical Director and attending Nephrologists approve of an influenza immunization program within the facility. The MDs have agreed to participate on the QI team and are interested in discussing standing orders for immunization of their patients.
Establish current immunization status for all patients-did they receive the influenza immunization in the past year?	Facility RNs	May 10, 2009	May 30, 2009	May 20, 2009	May 28, 2009	Immunization status verified for all patients. The 45% rate thought to be accurate in the problem statement was found to be inaccurate. The actual immunization rate is 40%.
Develop an education program for patients and staff regarding influenza immunization-secure education materials, schedule learning sessions, and document all education efforts for both patients and staff. Determine when vaccine can be ordered and storage requirements. Confirm standing orders and consent requirements. Research documentation/tracking.	Facility Nurse Manager / Educator	May 30, 2009	Jun 30, 2009	Jun 25, 2009	Jun 30, 2009	Resources gathered for patient and staff education. Educational materials reviewed by the QI team. Staff education in-services scheduled to impress upon staff the importance of patient and staff immunization. Patient "Education Days" scheduled. Nurse Manager is looking into when vaccine can be ordered for the upcoming flu season and will confirm storage requirements. MDs contacted regarding standing orders. The Administrator is in the process of researching a documentation/tracking tool for all immunizations.

DATA TOOLS

Facility Name	Number of patients
Contact Name	**Phone Number**

Immunization Data Collection Tool

Instructions: Use the codes at right to indicate immunization status for influenza, pneumococcal pneumonia, and hepatitis B. Codes 4, 6, and 9 (and 3/N for Hep B) indicate opportunities to improve individual patient immunization status.

Immunization Codes:
1. YES, received at this facility
2. YES, received at another location
3. YES, but surface antibody negative (Hep B only)
4. NO, not received, pt refused
5. NO, not received, pt allergic
6. NO, not offered or other reason
7. NO, series started, not complete (Hep B only)
8. NO, surface antigen positive (Hep B only)
9. Unknown

Note Regarding Hepatitis B: In the right column, indicate immune status ((I =immune, N=not immune, P=persistent anti-HBs negative after 2 vaccine series). If the patient has already received a vaccine series, but is antibody negative and another series is started, enter code 3 AND 7 in left column and N in right column, and use the middle columns to track the revaccination series. If the patient subsequently becomes antibody positive, change the codes to 1 and I, respectively. If revaccination is unsuccessful, change left column code to 3 and right column code

Immunization	Influenza	Pneumonia				Hepatitis B								
			Most recent dose				Date completed					Date of most recent dose			
Patient Name	During 2008-09 season 10/08-3/09 (enter code 1,2, 4-6, or 9)	Received 23-valent vaccine in last 5 years (enter code 1,2,4,6, or 9)	MM	DD	YYYY	Patient has received complete series (enter code 1 to 9)	MM	DD	YYYY	Patient has received partial series (enter 1 or 2 doses)	MM	DD	YYYY	Hep B immune status
Number of entered patients	3													
Patients vaccinated (codes 1,2) (#)														
Percentage vaccinated (%)	0%	0%				0%								0%
Vaccine candidates (codes 3N,4,6,9)	0	0				0								0

Percent vaccine eligible	0%	0%				0%								0%
Vaccination in progress (code 7)										0				
Percent in progress										0%				
Vaccination not indicated (5,8, or 3P)	0					0								0
Percent not indicated	0%					0%								0%
DATE COMPLETED														

IMMUNIZATION
MONTHLY INTERVENTION TRACKING TOOL

Facility Name:
Provider Number:
Month:
Due Date:

Date Action Plan Submitted: _____
Action Plan Accepted: ❑ Yes ❑No
If no, date action plan will be resubmitted: _____

Action Plan Progress

Action Plan Influenza Immunization Goal: _____%

A. Number of patients on facility census as of (date): _____

B. Of the patients on the facility census, number that were vaccinated for influenza this season (regardless of where the vaccine was given): _____

Remember to include patients who received their influenza vaccine somewhere other than this facility!

C. Percent of patients vaccinated (B divided by A x 100): _____ %

1. Outline the progress your facility has made toward implementation of each action plan step (be specific):
   _____
   _____
   _____
   _____
2. Has your facility made any changes to its immunization policies/procedures as a result of this initiative?
   ❑ Yes ❑No

   If yes, what are the changes?

_____
_____

3. Has your facility instituted a program to educate staff about influenza immunization?

❑ Yes ❑No

4. Has your facility instituted a program to educate patients about influenza immunization?

❑ Yes ❑No

5. For patients who refuse the immunization (not based on medical contraindications) are you providing additional information/education related to the influenza immunization?

❑ Yes ❑No

If yes, did any of these patients decided to be vaccinated?

❑ Yes ❑No

6. Has your facility reached the Influenza Immunization Goal you set in your action plan? ❑ Yes ❑No

If no, what actions are planned to achieve the Immunization goal?

_____
_____
_____
_____
_____
_____

7. Does your facility have any additional issues or questions that you would like the Network to address regarding immunizations?

❑ Yes ❑No

If yes, please be specific.

_____
_____
_____

Facility Number	
Facility Name	
Contact Name	
Clinic Manager	

IMMUNIZATION DATA COLLECTION WORKSHEET

Immunization	Influenza Vaccine

Instructions:
Under the specific column, enter the correct Immunization Code

IMMUNIZATION CODES
1 = YES, received at this facility
2 = YES, received at another location
3 = NO, not received, patient refused
4 = NO, not received, patient allergic
5 = NO, not offered to patient
6 = NO, other reason
7 = UNKNOWN, not known by patient

Provider Number	Facility Name	Patient Names	INFLUENZA VACCINE Current Influenza season Immunization Code

Facility Number	
Facility Name	
Contact Name	
Clinic Manager	

IMMUNIZATION DATA COLLECTION WORKSHEET

Immunization	Pneumovax Vaccine

Instructions:
Under the specific column, enter the correct Immunization Code

IMMUNIZATION CODES
1 = YES, received at this facility
2 = YES, received at another location
3 = NO, not received, patient refused
4 = NO, not received, patient allergic
5 = NO, not offered to patient
6 = NO, other reason
7 = UNKNOWN, not known by patient

Provider Number	Facility Name	Patient Names	PNEUMOVAX VACCINE	
			Immunization Code	Year of last dose (YYYY)

Facility Number	
Facility Name	
Contact Name	
Clinic Manager	

IMMUNIZATION DATA COLLECTION WORKSHEET

Immunization	Hepatitis B Vaccine

Instructions:
Under the specific column, enter the correct Immunization Code

IMMUNIZATION CODES
1 = YES, received at this facility
2 = YES, received at another location
3 = NO, not received, patient refused
4 = NO, not received, patient allergic
5 = NO, not offered to patient
6 = NO, not time for dose
7 = NO, other reason
8 = UNKNOWN, not known by patient

If the patient received part of the Hepatitis series at another facility, but completed the series in your facility, use Immunization Code #1. Please answer only one of the options (Completed, Partial, or Not Received) that best describes patient's current status and indicate code in appropriate column. A complete series includes only the initial 3 or 4 immunizations -- which ever number of immunizations is used by your facility as an initial complete series. If the year is known, but not the month, then use 06/30/YYYY; if the month and year are known, but not the date, then use the first date of the month MM/01/YYYY.

			Hepatitis B Vaccine				
			Patient has received complete series	Patient has received partial series			Patient has not received any doses
Provider Number	Facility Name	Patient Names	Immunization Code	Date completed (MM/DD/YYYY)	Number of administrations that comprise a complete series (3 or 4)	Immunization Code	Date of most recent dose (MM/DD/YYYY)	Immunization Code

IMMUNIZATION DATA COLLECTION WORKSHEET

Facility Number	
Facility Name	
Contact Name	
Clinic Manager	

PATIENT NAME	

Immunization	**Complete this Column**

Hepatitis B Vaccine

Patient has received complete series (enter Immunization Code)	
Date completed (MM/DD/YYYY)	
Number of administrations that comprise a complete series (3 or 4)	

Patient has received partial series (enter Immunization Code)	
Date of most recent dose (MM/DD/YYYY)	

Patient has not received any doses (enter Immunization Code)	

If the patient received part of the Hepatitis series at another facility, but completed the series in your facility, use Immunization Code #1. Please answer only one of the options (Completed, Partial, or Not Received) that best describes patient's current status and indicate code in appropriate column. A complete series includes only the initial 3 or 4 immunizations -- which ever number of immunizations is used by your facility as an initial complete series. If the year is known, but not the month, then use 06/30/YYYY; if the month and year are known, but not the date, then use the first date of the month MM/01/YYYY.

HEPATITIS IMMUNIZATION CODES

1 = YES, received at this facility
2 = YES, received at another location
3 = NO, not received, patient refused
4 = NO, not received, patient allergic
5 = NO, not offered to patient
6 = NO, not time for dose
7 = NO, other reason
8 = UNKNOWN, not known by patient

Pneumovax Vaccine

Pneumovax Immunization Code	
Year of last dose (YYYY)	

PNEUMOVAX IMMUNIZATION CODES
1 = YES, received at this facility
2 = YES, received at another location
3 = NO, not received, patient refused
4 = NO, not received, patient allergic

5 = NO, not offered to patient
6 = NO, other reason

Influenza Vaccine	Influenza Immunization Code (Current Influenza season)	

Influenza IMMUNIZATION CODES
1 = YES, received at this facility
2 = YES, received at another location
3 = NO, not received, patient refused
4 = NO, not received, patient allergic
5 = NO, not offered to patient
6 = NO, other reason

RESOURCES AND REFERENCES

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI) FOR ESRD MEDICAL DIRECTORS

Medical Directors set the course for their dialysis center. Patients and staff members rely on the Medical Director to lead effectively. The Conditions for Coverage released on 4/15/08 by the Centers for Medicare & Medicaid Services (CMS) has updated the responsibilities of ESRD facility Medical Directors. As Pay for Performance (P4P) becomes a reality, it is increasingly important for facilities to achieve and sustain clinical performance targets in order to receive reimbursement. Medical Directors are encouraged to read carefully and become very familiar with the new Conditions.

The Medical Director has operational responsibility for the QAPI program and ensures that program data is used to develop actions to improve quality of care and must ensure that the facility's QAPI program is effectively developed, implemented, maintained, and periodically evaluated. The dialysis facility must maintain and demonstrate evidence of its QAPI program for review by the Centers for Medicare & Medicaid Services (CMS).

This portion of the toolkit contains references that may help with the details of setting up a QAPI project; it is not intended to be complete or authoritative.

The table below contains a breakdown of some Medical Director QAPI and responsibilities.

Patient Clinical Outcomes	**Reuse & Water Treatment**	**Patient Safety & Satisfaction**	**Staff Training**	**Involuntary Discharge of Patients**	**Oversight of Attending Physicians**	**Biohazard & Infection Control**	**Facility Policies & Procedures**
Adequacy of dialysis Nutritional status Mineral metabolism Anemia management Vascular access	Reuse program Deviations from AAMI standards (corrective action plan) Water treatment equipment Pt did not reach target weight	Medical injuries Medical errors Patient satisfaction Grievances	Ensure that staff receive appropriate education and training to competently perform job	Written and signed order from both Med. Dir. and attending physician prior to discharge (Note: The new *discharge/transfer process is very lengthy, specific, and progressive.)	Inform medical staff of facility P&P including QAPI Written and signed order from both Med. Dir. and attending physician prior to pt discharge Assure the attending physicians adhere to P&P	Adverse events Infection control issues	Participate in developing P&P Assure the attending physicians & other staff adhere to P&P

The QAPI team includes all interdisciplinary members and physicians.

Work together to:

- Track
- Trend
- Analyze data
- Formulate strategies
- Intervene
- Set goals
- Set timelines
- Document your efforts

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QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI)
TEAM MEMBER RESPONSIBILITIES & ROLES

The ESRD Conditions for Coverage that were released by the Centers for Medicare & Medicaid Services (CMS) on April 15, 2008, require that dialysis facilities establish a written Quality Assessment and Performance Improvement (QAPI) Program. The program is led by the Medical Director of the facility and designed to assist the facility in achieving clinical performance excellence. Below is a listing of possible QAPI team members and examples of their various responsibilities and roles. Facilities are encouraged to utilize this resource as they develop the written facility QAPI program.

Team Member	Responsibilities related to QAPI	Role in QAPI
Patients	*Patients are responsible to adhere to the physician ordered plan of care and dialysis treatment prescription to the best of his/her ability. Patients are encouraged to ask questions of the dialysis care team when clarification is necessary. Patients are encouraged to work cooperatively with the team to ensure that he/she receives the highest quality of renal care.*	
Medical Director _____ Name	The Medical Director (MD) has operational responsibility for the Quality Assessment and Performance Improvement (QAPI) program and ensures that program data is used to develop actions to improve quality of care. The Medical Director ensures that the facility's QAPI program is effectively developed, implemented, maintained, and periodically evaluated. The Medical Director ensures that the facility achieves clinical outcomes that include but are not limited to: adequacy of dialysis, nutritional status, anemia management, vascular access, medical injuries, and medical errors identification, hemodialysis reuse program, patient satisfaction and grievance. The Medical Director is in charge of oversight of attending physicians. The Medical Director controls the involuntary patient discharge/transfer process. The Medical Director The Medical Director ensures that the facility participates in ESRD Network activities and pursues Network goals.	*Meet monthly with the QAPI team* *Review aggregate patient data and formulate an overall facility plan for improvement, including a timeline* Adjust individual patient care plans (with attending physicians if applicable) to facilitate the meeting of clinical care goals for that patient. *Make recommendations to the team on how to improve the quality of care delivered to the patients* *Control the involuntary patient discharge/transfer process for the facility* *Ensure that the facility participates in ESRD Network activities and pursues Network goals.* *Receive and act upon recommendations from the ESRD Network.* Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Nephrologist _____ Name _____ Name _____ Name _____ Name	The Nephrologist is responsible to assist the Medical Director in the coordination of the Quality Assessment and Performance Improvement (QAPI) program. He/she agrees to adhere to and enforce facility policies and procedures. The nephrologist agrees not to dismiss or transfer a patient involuntarily without first discussing it with the Medical Director. The nephrologist will utilize clinical data to develop action plans to improve quality of care. The nephrologist will adjust individual patient care plans to facilitate achievement of clinical goals. The nephrologist agrees to promote participation in ESRD Network activities and the pursuit of Network goals.	*Meet monthly with the QAPI team* *Review patient data and formulate patient specific plans for improvement, including a timeline* Adjust individual patient care plans to facilitate the meeting of clinical care goals for that patient. Make recommendations to the team on how to improve the quality of care delivered to the patients *Ensure that the facility participates in ESRD Network activities and pursues Network goals.* *Receive and acts upon recommendations from the ESRD Network.* Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Advanced Practice Nurse _____ Name _____ Name	The Advanced Practice Nurse (APN) is to practice under the authority of the Medical Director and Nephrologist. He/she is responsible to assist the Medical Director and Nephrologist in the coordination of the Quality Assessment and Performance Improvement (QAPI) program. To adhere to and enforce the facility policies and procedures. The APN agrees not to dismiss or transfer a patient involuntarily without first discussing it with the Medical Director. The APN utilizes data to develop actions to improve the patients' quality of care. The APN adjusts individual patient care plans to facilitate achievement of clinical goals. The APN promotes participation in ESRD Network activities and the pursuit of Network goals.	*Meet monthly with the QAPI team* *Assist the team with tracking, trending, and analysis of the clinical data.* *Make recommendations to the team on how to improve the quality of care delivered to the patients* *Review patient data and formulate patient specific plans for improvement, including a timeline* Adjust individual patient care plans to facilitate the meeting of clinical care goals for that patient. *Ensure that the facility participates in ESRD Network activities and pursues Network goals.* *Receive and acts upon recommendations from the ESRD Network.* Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Unit Administrator _____ Name	To assist the Medical Director (MD) in the coordination of the Quality Assessment and Performance Improvement (QAPI) program. The MD monitors facility management and patient care staff actions to assure that patient safety is a top priority and that the desired clinical outcomes are being achieved. The MD supports facility participation in ESRD Network activities and pursuit of Network goals.	*Meet monthly with the QAPI team* *Educate the patient care staff regarding QAPI requirements* *Assist the team with tracking, trending, and analysis of the clinical data.* *Suggest changes in policies and procedures that would facilitate achievement of clinical performance goals, promote patient safety, and/or improve patient satisfaction.* *Track and trend medical injuries, medical errors, hemodialysis reuse program, patient satisfaction, and grievances* *Work with the physicians and patient care staff to identify patient safety or grievance issues* *Monitor and track patient satisfaction, grievances, patient safety, and other issues* Ensure that physicians' orders are carried out. *Ensure that the facility participates in ESRD Network activities and pursues Network goals.* *Receive and acts upon recommendations from the ESRD Network.* Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Registered Nurse _____ Name	The registered nurse is responsible for assisting the Unit Administrator in helping the patient care staff to adhere to and deliver the patients prescribed plan of care and the dialysis prescription.	*Meet monthly with the QAPI team* *Educate the patient care staff regarding QAPI requirements* *Maintain written minutes and notes from the QAPI meetings and distribute them as directed by the Unit Administrator* Under the direction of the Unit Administrator, assigns staff members to coordinate the following performance measures: Adequacy of dialysis, nutritional status, and anemia management *Work with the Unit Administrator and patient care staff to identify patient safety or grievance issues* Ensure that physicians' orders are carried out. *Ensure that the facility participates in ESRD Network activities and pursues Network goals.* *Receive and acts upon recommendations from the ESRD Network.* Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Vascular Access Coordinator _____ Name	The vascular access coordinator is responsible for monitoring adherence to the patients prescribed plan of vascular access care and dialysis prescription and coordinating education and care related to the selection, creation, and maintenance of the vascular access.	*Meet monthly with the QAPI team* *Educate the patient care staff regarding QAPI requirements* *Track and trend catheter usage, arteriovenous fistula, and arteriovenous grafts.* *Track and trend vascular access infections* *Work with the Unit Administrator and patient care staff to identify vascular access issues and/or the need for interventions* *Coordinate vascular access care (surgical referrals, etc.)* Ensure that physicians' orders are carried out. *Ensure that the facility participates in ESRD Network activities and pursues Network goals.* *Receive and acts upon recommendations from the ESRD Network.* Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Registered Dietitian _____ Name	The registered dietitian is responsible for counseling patients on management of protein, sodium, potassium, phosphorus, and fluid controlled diets, translating the chemistry of these limits into meals for patients; monitoring vitamin and mineral supplementation including iron levels and their effect on erythropoietin; managing glycemic control of diabetic patients by manipulation of diet; and assessing nutritional status by using clinical and biochemical measures.	*Meet monthly with the QAPI team* *Work with the care team to identify patient dietary issues and/or the need for interventions* *Make recommendations for interventions* *Implement interventions as directed by the team* *Perform follow up to assess improvements* Ensure that physicians' orders are carried out. *Ensure that the facility participates in ESRD Network activities and pursues Network goals.* *Receive and acts upon recommendations from the ESRD Network.* Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Social Worker _____ Name	The Social Worker is responsible to assist patients to achieve and sustain an effective level of vocational, emotional and social wellbeing. The social worker evaluates and addresses challenging or disruptive behavior as well.	*Meet monthly with the QAPI team* *Work with the care team to identify patient issues and/or the need for interventions* *Make recommendations for interventions* *Implement interventions as directed by the team* *Perform follow up to assess improvements* Ensure that physicians' orders are carried out. *Ensure that the facility participates in ESRD Network activities and pursues Network goals.* *Receive and acts upon recommendations from the ESRD Network.* Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Additional Team Members _____ Name _____ Name _____ Name	The team members assist the QAPI team to improve the quality of care provided to the patients. Team members perform specific duties as assigned by the Unit Administrator and/or Medical Director.	*Meet monthly with the QAPI team* *Work with the care team to identify patient issues and/or the need for interventions* *Make recommendations for interventions* *Implement interventions as directed by the team* *Perform follow up to assess improvements* *Ensure that physicians' orders are carried out.* *Support other team members as directed by the Unit Administrator and/or Medical Director* *Ensure that the facility participates in ESRD Network activities and pursues Network goals.* *Receive and acts upon recommendations from the ESRD Network.* *Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work*

IMMUNIZATION RESOURCES AVAILABLE ON THE INTERNET

Numerous resources related to immunizations and immunization processes are available on the Internet from the ESRD Networks as well as the Centers for Disease Control (CDC), the National Immunization Action Coalition and the Centers for Medicare & Medicaid Services (CMS).

ESRD NETWORK WEBSITES:

Network 1:	http://www.networkofnewengland.org/
Network 2:	http://esrd.ipro.org/
Network 3:	http://www.tarcweb.org/
Network 4:	http://www.esrdnetwork4.org/
Network 5:	http://www.esrdnet5.org/
Network 6:	http://www.esrdnetwork6.org/
Network 7:	http://www.fmqai.com/ESRD.aspx
Network 8:	http://www.esrdnetwork8.org/
Network 9/10:	http://www.therenalnetwork.org/
Network 11:	http://www.esrdnet11.org/
Network 12:	http://www.heartlandkidney.org/
Network 13:	http://www.network13.org/
Network 14:	http://www.esrdnetwork.org/
Network 15:	http://www.esrdnet15.org/
Network 16:	http://www.nwrenalnetwork.org/
Network 17:	http://www.esrdnet17.org/
Network 18:	http://www.esrdnetwork18.org/

OTHER RESOURCES AVAILABLE:

Adult Immunizations (http://www.cms.hhs.gov/AdultImmunizations/) - information on the CMS website for both providers/caretakers and patients.

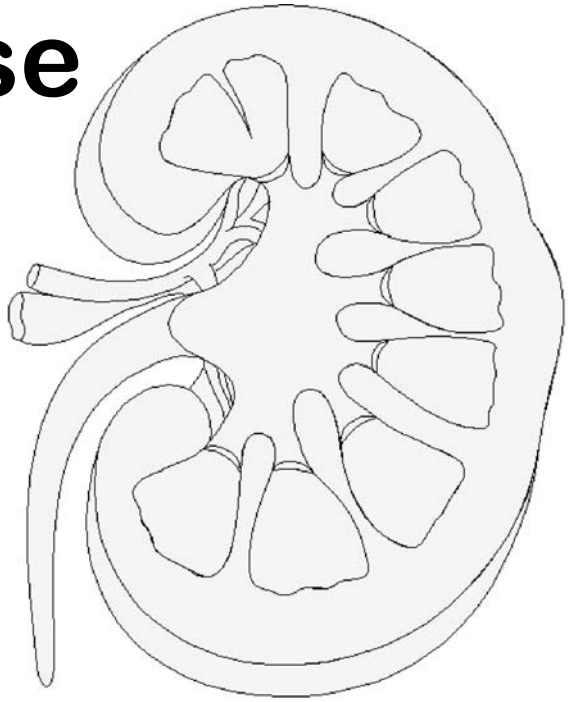
National Immunization Program (http://www.cdc.gov/vaccines/) - this is a portion of the CDC Web site that is specifically geared to healthcare professionals and has a plethora of immunization resources.

Immunization Action Coalition (http://www.immunize.org) - vaccination information for healthcare professionals including a directory of available resources across the Internet. This site contains the ability to subscribe for immunization alerts and new practice recommendations.

Under CMS contract # HHSM-500-2006-NW015C, ESRD Network #15 created a spreadsheet-based immunization tracking form, the Multiple Immunization Monitoring Instrument (MIMI). This resource is available on the Intermountain ESRD Network, Inc. (ESRD Network #15) website at: http://www.esrdnet15.org/QI.htm#mimi .

Guidelines for Vaccinating

Kidney Dialysis Patients and Patients with Chronic Kidney Disease



summarized from
Recommendations of the Advisory Committee on Immunization Practices (ACIP)

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC
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June 2006

This summary is not meant to apply to kidney patients who are recently post-transplant. These patients are considered more significantly immunosuppressed than those who have only chronic kidney disease, with or without dialysis.

Vaccination of Renal Dialysis Patients and Patients with Chronic Renal Disease

"Patients with renal failure have an increased risk of infection with a variety of pathogens, particularly pneumococcus and hepatitis B. The efficacy of pneumococcal vaccination for some of these patients, including those on dialysis, may be considerably lower than for immunocompetent patients, their antibody levels may be lower, and they may require repeat vaccination or an increased dose of vaccine. Because secondary antibody responses are less affected than primary antibody responses, immunization strategies should be formulated early in the course of progressive renal disease. This approach is particularly important if transplantation and chronic immunosuppressive therapy are being considered. Nephrotic syndrome is the renal disease most clearly associated with an increased risk for pneumococcal infection."[1]

Vaccine	Recommended	May Use if Otherwise Indicated	Contraindicated
Anthrax		X*	
DTaP/Tdap/Td		X*	
Hib		X*	
Hepatitis A		X*	
Hepatitis B	X (see p. 2)		
Influenza (TIV)	X (see p. 3)		
Influenza (LAIV)			X (see p. 4)
Japanese Encephalitis		X*	
MMR		X*	
Meningococcal		X*	
Pneumococcal	X (see p. 4)		
Polio (IPV)		X*	
Rabies		X*	
Rotavirus		X†	
Smallpox		X*	
Typhoid		X*	
Varicella		X*	
Yellow Fever		X*	

*No specific ACIP recommendation for this vaccine exists for renal dialysis patients and patients with chronic renal disease.

†Children with primary immunodeficiency disorders and both children and adults who have received hematopoietic, hepatic, or renal transplants are at risk for severe or prolonged rotavirus gastroenteritis and can shed rotavirus for prolonged periods. ["Prevention of Rotavirus Gastroenteritis Among Infants and Children: Recommendations of the Advisory Committee on Immunization Practices" Unpublished]

NOTES

Hepatitis B Vaccine

"Hepatitis B vaccination is recommended for all susceptible chronic hemodialysis patients . . . Vaccination is recommended for pre-end-stage renal disease patients before they become dialysis dependent and for peritoneal and home dialysis patients because they might require in-center hemodialysis.

"Patients with uremia who were vaccinated before they required dialysis have been shown to have higher seroconversion rates and antibody titers. The response may also be better in children."[2]

Dosage and Schedule

"For patients undergoing hemodialysis and for other immunosuppressed patients, higher vaccine doses or increased number of doses are required. A special formulation of one vaccine is now available for such persons (Recombivax HB, 40 µg/mL)".[3]

Doses and Schedules: Hepatitis B Vaccines for Hemodialysis Patients

Group	Recombivax HB			Engerix B		
	Dose	Volume	Schedule	Dose	Volume	Schedule
≥20 years of age: Predialysis*	10 µg	1.0 mL	3 doses at 0, 1, & 6 months	20 µg	1.0 mL	3 doses at 0, 1, & 6 months
≥20 years of age: Dialysis-dependent	40 µg	1.0 mL†	3 doses at 0, 1, & 6 months	40 µg	Two 1.0 mL doses at one site	4 doses at 0, 1, 2, & 6 months
<20 years of age¶	5 µg	0.5 mL	3 doses at 0, 1, & 6 months	10 µg	0.5 mL	3 doses at 0, 1, & 6 months

* Immunogenicity might depend on degree of renal insufficiency.
† Special formulation.
¶ Doses for all persons aged <20 years approved by the U.S. Food and Drug Administration. For hemodialysis patients, higher doses might be more immunogenic.

NOTE: All doses should be administered in the deltoid by the intramuscular route.

Adapted from CDC. Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients. *MMWR* 2001;50 (No. RR-5):Table 3

"If an adult patient begins the vaccine series with a standard dose before beginning hemodialysis treatment, then moves to hemodialysis treatment before completing the series, complete the series using the higher dose recommended for hemodialysis patients. No specific recommendations have been made for higher doses for pediatric hemodialysis patients. If a lower than recommended vaccine dose is administered to either adults or children, the dose should be repeated."[4]

continued . . .

Hepatitis B Vaccine, continued

Immunogenicity and Duration of Immunity

"Although data concerning the response of pediatric hemodialysis patients to vaccination with standard pediatric doses are lacking, protective levels of antibody occur in 75% -97% of those who receive higher dosages (20-μg) on either the 3- or the 4-dose schedule."[5]

"Limited data are available on the duration of immune memory after hepatitis B vaccination in . . . dialysis patients. No clinically important HBV infections have been documented among immunocompromised persons who maintain protective levels of anti-HBs. . . .However, among hemodialysis patients who respond to the vaccine, clinically significant HBV infection has been documented in persons who have not maintained anti-HBs concentrations of ≥10 mIU/mL."[6]

Serologic Testing

Testing after vaccination is recommended for persons (including hemodialysis patients) whose subsequent clinical management depends on knowledge of their immune status. "Testing should be performed 1-2 months after administration of the last dose of the vaccine series by using a method that allows determination of a protective level of anti-HBs (≥10 mIU/mL)."

"Persons found to have anti-HBs levels of <10 mIU/mL after the primary vaccine series should be revaccinated. Administration of three doses on an appropriate schedule . . ., followed by anti-HBs testing 1-2 months after the third dose, is usually more practical than serologic testing after one or more doses of vaccine."

"Persons who do not respond to revaccination should be tested for HBsAg. If the HBsAg test result is positive, the persons should receive appropriate management . . . and any household, sexual, or needle-sharing contacts should be identified and vaccinated. Persons who test negative for HBsAg should be considered susceptible to HBV infection and should be counseled about precautions to prevent HBV infection and the need to obtain HBIG postexposure prophylaxis for any known or likely parenteral exposure to HBsAg-positive blood."[7]

Booster Doses

"For hemodialysis patients, the need for booster doses should be assessed by annual antibody to hepatitis B surface antigen (anti-HBs) testing. A booster dose should be administered when anti-HBs levels decline to <10 mIU/mL."[8]

Influenza Vaccine

Inactivated Influenza Vaccine (TIV)

"The following groups are recommended to receive annual influenza vaccination . . . Persons at Increased Risk for Complications . . . adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV])."[9]

continued . . .

Influenza Vaccine, continued

Live, Attenuated Influenza Vaccine (LAIV) CONTRAINDICATED

"Persons Who Should Not Be Vaccinated with LAIV . . . persons with . . . other underlying medical conditions, including such metabolic diseases as diabetes, renal dysfunction, and hemoglobinopathies . . ." "These persons should receive inactivated influenza vaccine."[10]

Use of influenza antivirals for persons with impaired renal function[11]

Zanamivir. Limited data are available regarding the safety and efficacy of zanamivir for patients with impaired renal function. Among patients with renal failure who were administered a single intravenous dose of zanamivir, decreases in renal clearance, increases in half-life, and increased systemic exposure to zanamivir were observed. However, a limited number of healthy volunteers who were adminisistered high doses of intravenous zanamivir tolerated systemic levels lf zanamivir that were substantially higher than those resulting from administration of zanamivir by oral inhalation at the recommended dose. On the basis of these considerations, the manufacturer recommends no dose adjustment for inhaled zanamivir for a 5-day course of treatment patients with either mild-to-moderate or severe impairment in renal function.

Oseltamivir. Serum concentrations of oseltamivir carboxylate (GS4071), the active metabolite of oseltamivir, increase with declining renal function. For patients with creatinine clearance of 10-30 mL/min, a reduction of the treatment dosage of oseltamivir to 75 mg once daily and in the chemoprophylaxis dosage to 75 mg every other day is recommended. No treatment or chemoprophylaxis dosing recommendations are avialable for patients undergoing routine renal dialysis treatment.

Pneumococcal Vaccine

PPV23

"Vaccination is . . . recommended for immunocompromised adults at increased risk of pneumococcal disease or its complications (e.g., persons with splenic dysfunction or anatomic asplenia, Hodgkin's disease, leukemia, lymphoma, multiple myeloma, chronic renal failure, nephrotic syndrome, or conditions such as organ transplantation associated with immunosuppression)."[12]

Revaccination

". . . revaccination once is recommended for persons aged ≥2 years who are at highest risk for serious pneumococcal infection and those who are likely to have a rapid decline in pneumococcal antibody levels, provided that 5 years have elapsed since receipt of the first dose of pneumococcal vaccine. Revaccination 3 years after the previous dose may be considered for children at highest risk for severe pneumococcal infection who would be aged ≤10 years at the time of revaccination.

Persons at highest risk and those most likely to have rapid declines in antibody levels include persons with . . . chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression (e.g., organ or bone marrow transplantation) . . ."[13]

continued . . .

Pneumococcal Vaccine (PPV23): continued

Recommendations for use of PPV23 Among Children Previously Vaccinated with PCV7

"Children who have completed the PCV7 vaccination series before age 2 years and who are among risk groups for which PPV23 is already recommended should receive one dose of PPV23 at age 2 years (≥2 months after the last dose of PCV7). These groups at high risk include children with SCD, children with functional or anatomic asplenia, children who are HIV-infected, and children who have immunocompromising or chronic diseases. Although data regarding safety of PPV23 administered after PCV7 are limited, the opportunity to provide additional serotype coverage among these children at very high risk justifies use of the vaccines sequentially." [14]

PCV7

(These recommendations apply to children 24-59 months of age. All children 6 months through 23 months of age should get PCV7 regardless of their health status as part of the routine childhood immunization schedule.)

"Children aged 24-59 months should receive PCV7 vaccination if they are at high risk for pneumococcal infection caused by an underlying medical condition. This recommendation applies to the following groups: . . .
- children with immunocompromising conditions, including . . . chronic renal failure or nephrotic syndrome."

"For children aged 24-59 months with underlying medical conditions . . ., ACIP recommends two doses of PCV7, administered 2 months apart, followed by one dose of PPV23 administered ≥2 months after the second dose of PCV7."[15]

Recommendations for Use of PCV7 Among Children Previously Vaccinated with PPV23

"Children aged 24-59 months who are at high risk for pneumococcal disease and who have already received PPV23 (i.e., children with [Sickle Cell Disease], HIV infection, or who have other immunocompromising illnesses or chronic diseases) could benefit from the immunologic priming and T-cell-dependent immune system response induced by PCV7. Thus, among children in these groups at high risk sequential use of the two pneumococcal vaccines can provide additional protection. Health-care providers should vaccinate children aged 24-59 months at high risk who have not previously received PCV7 but who have already received PPV23 with two doses of PCV7 administered ≥2 months apart. Vaccination with PCV7 should be initiated ≥2 months after vaccination with PPV23. Providers should be aware that minimal safety data are available regarding this vaccine sequence."[14]

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