Prenatal Tdap Vaccination Toolkit

This toolkit was created to assist prenatal care providers to improve pertussis vaccination rates in their practices. Implementation of this toolkit may also help meet requirements for specialty board maintenance of certification (MOC).

POPULATION HEALTH DIVISION
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

SF HEALTH NETWORK
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

Developed by:

The San Francisco Department of Public Health, Population Health Division, Communicable Disease Control and Prevention Section

San Francisco Health Network, Maternal, Child, and Adolescent Health Division

Members of the San Francisco Perinatal and Newborn Pertussis and Flu Collaborative

Monica Kaitz, MD, MPH, Preventive Medicine Resident
Sona Aggarwal, MD, MPH, Preventive Medicine Resident

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Introduction

Goal of this toolkit:

To guide prenatal care providers through a Quality Improvement (QI) Project tailored to their practices leading to increased Tdap (tetanus, diphtheria, and acellular pertussis) immunization rates for pregnant patients in weeks 27 through 36. The American Board of Obstetricians and Gynecologists (ABOG) requires QI activities for maintenance of certification, and this project may meet the ABOG requirements.

- According to CDC and American College of Obstetricians and Gynecologists (ACOG) recommendations, Tdap should be given to all pregnant women between weeks 27 through 36 for maximal transfer of passive immunity. Tdap should be administered in each pregnancy, even if pregnancies are closely spaced and regardless of prior immunization status.[1]

- Pertussis (whooping cough) is a highly contagious bacterial infection that is preventable with vaccination. Childhood immunization begins at 6 weeks of life, but full protection against pertussis is only achieved after 4 doses of vaccine.

- Newborns and infants too young to be fully immunized are most vulnerable to suffering serious complications or death due to pertussis. The person most likely to transmit pertussis to an infant is the mother.

- 11,203 pertussis cases in California in 2014 led to 456 hospitalizations and 3 deaths; 278 hospitalizations were in infants <4 months old and all deaths were in infants < 5 weeks old.[2]

- Immunity induced by pertussis vaccine wanes over time, sometimes in as little as two years after vaccination. [3]

- Following a pertussis outbreak, the U.K. implemented nation-wide Tdap vaccination of pregnant women. Follow up studies show that the vaccine was 92% effective in preventing pertussis infections in infants[4] and is safe (no adverse events in 23,000 mothers).[5]

1] For a more detailed discussion of these points, please refer to the ACOG Committee Opinion, June 2013, Update on Immunization and Pregnancy: Tetanus, Diptheria, and Pertussis Vaccination and CDC Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) in Pregnant Women — Advisory Committee on Immunization Practices (ACIP), 2012.

2] For detailed pertussis surveillance information for California, please see California Department of Public Health's Pertussis Summary Reports.

3] Cherry JD. Editorial Commentary: Tetanus-Diphtheria-Pertussis Immunization in Pregnant Women and the Prevention of Pertussis in Young Infants, Clinical Infectious Diseases (2015) 60(3):338-340. doi: 10.1093/cid/ciu823

4] Amirthalingam G, Andrews N, Campbell H, et al. Effectiveness of maternal pertussis vaccination in England: an observational study, The Lancet (2014) 384(9953):1521-8.

5] Munoz FM, Bond NH, Maccato M, et al. Safety and immunogenicity of tetanus diphtheria and acellular pertussis (tdap) immunization during pregnancy in mothers and infants: A randomized clinical trial, JAMA (2014) 311(17):1760-9.

PREGNANCY TDAP VACCINATION = STANDARD OF CARE

This toolkit can be used by prenatal care providers in a range of clinical settings and practice sizes. It includes instructions and templates to plan and carry out a QI project. The appendices contain practical tools and examples.

For more information on Tdap vaccination, including a discussion of the evidence behind vaccinating pregnant women in the 3rd trimester (weeks 27 through 36 of pregnancy), a physician script for patient discussions, and billing codes, you may refer to the ACOG immunization toolkit, ACOG prenatal Tdap webinar, and ACIP recommendations.

Unimmunized close contacts to newborns should also get a dose of Tdap per CDC/ACOG recommendations. This practice is called cocooning. This toolkit focuses on maternal immunization as the most achievable immunization-related QI goal in prenatal practices, although immunization of close contacts/cocooning could be added as a secondary outcome.

The Quality Improvement Process

Assemble your multidisciplinary team

This is a comprehensive list of potential roles for you to draw from; however, you do not need to include all of the people on this list to complete a successful QI project.[6] A team can be made up of only three people: for example, a Clinician or Nurse Manager, RN or Medical Assistant and a Clerical Staff Member. Responsibilities may be distributed in a manner appropriate for your practice setting. It is helpful if the QI team includes the staff members who have the most knowledge about the practice's current Tdap immunization process. Below are examples of possible members of the QI Team and their responsibilities. The team should have a team leader to provide oversight and an administrator with dedicated time to keeping the QI project on the priority list and keeping to the time line of the action plan.

Meetings should be short and frequent (30 min every 1-2 weeks) to keep momentum. Use an agenda and keep minutes with action items, dates and responsible parties noted. You can use the action plan template (Appendix I) for meeting minutes.

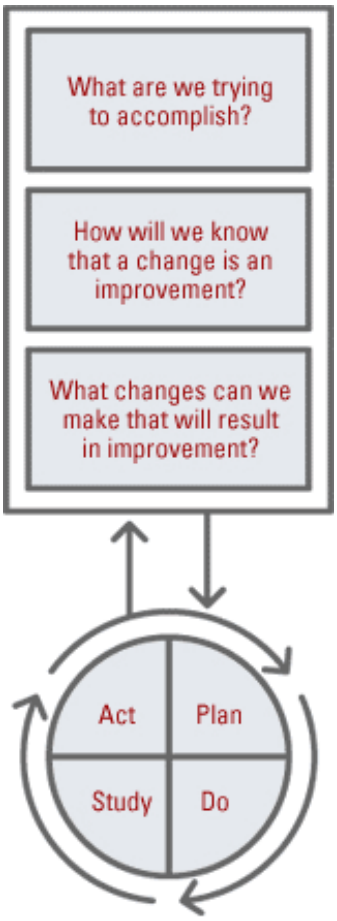
Roles	Responsibilities related to quality improvement
Team Leader	• Operational Oversight of development, implementation, maintenance, and evaluation of QI project • Ensure achievement of desired clinical outcome • Oversight of other staff
Administrator	• Assist Team Leader in coordination of QI action plan. • Oversee implementation of the QI action plan • Maintain written minutes and notes from QI meetings and distribute them as directed by unit administrator.
Clinician Champion: OB/GYN, Family Medicine, Midwife providers	• May assist the Team Leader, or may also be the Team Leader • Implement action plan • Educate and rally other clinicians, adhere to and enforce QI policies/procedures
Nurse Manager	• Coordinate and educate nursing staff to perform action plan activities. • Educate staff to assure patient safety is top priority, action plan is being implemented, and clinical outcomes are being achieved
Registered Nurse/ Licensed Vocational Nurse/ Medical Asst.	• Vaccine administration and documentation • Educate patients about risks and benefits of vaccination • Pre and post visit planning and follow-up • Vaccine storage and handling
Social Worker/ Health Educator/ Health Worker/ Case Manager	• Vaccine administration and documentation • Educate patients about risks and benefits of vaccination • Pre and post visit planning and follow-up
Pharmacist	• Provide consultation and technical assistance regarding immunization procedures and vaccine supply • Supply and dispense Tdap

6] Adapted from Vaccination Toolkit, ESRD Networks' Medical Advisory Council, 2009 (accessed at: http://esrdnetworks.org/groups/MAC/mac-toolkits-071509/Vaccination Toolkit 061609.docx/view)

Roles	Responsibilities related to quality improvement
Data, IT, or QI Analyst	• Obtain data from EHR • Maintain runcharts and tables • Create summary data reports and charts for team and practice to review
Patient	• Provide patient perspective on barriers to vaccination
All Team Members	• Meet monthly • Map the current process • Suggest changes in policies or procedures that would facilitate achievement of clinical performance goals, promote patient safety, and/or improve patient satisfaction • Identify barriers and solutions to contribute to planning sessions. • Inform Team Leader if any problems in data or action plan

USE THE "MODEL FOR IMPROVEMENT" TO ORGANIZE YOUR QUALITY IMPROVEMENT PROJECT[7]

This diagram illustrates a framework commonly used to plan quality improvement interventions. Answer the three questions in the diagram before embarking on any change. More on the PDSA process is found below the diagram and in Appendix F.



Setting Aims

Improvement requires setting aims. The aim should be time-specific and measurable; it should also define the specific population of patients or other system that will be affected.

Establishing Measures

Teams use quantitative measures to determine if a specific change actually leads to an improvement.

Selecting Potential Changes

Quality Improvement begins with understanding the current process and identifying potential changes. Ideas may come from the insights of those who work in the system, from change concepts or other creative thinking techniques, or by borrowing from the experience of others who have successfully improved.

Testing Changes

The Plan-Do-Study-Act (PDSA) cycle is shorthand for testing a change in the real work setting on a small scale— by planning it, trying it, observing the results and making changes based on what is learned. This is the scientific method adapted for action-oriented learning.

Implementing Changes

After testing a change on a small scale, learning from each test, and refining the change through several PDSA cycles, the team may implement the change on a broader scale — for example, for an entire pilot population.

7] Adapted from: Institute for Healthcare Improvement Model for Improvement and Langley GL, Moen R, Nolan KM, Nolan TW, Norman CL, Provost LP. The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (2nd edition). San Francisco: Jossey-Bass Publishers; 2009. Related resources at: http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx

SETTING AIMS: CREATE AN AIM STATEMENT

The statement should summarize the goal of the project. Use the SMART goal framework. Good goal –setting is critical to the success of the project. The goal should be **S**pecific, **M**easurable, **A**chievable, **R**esults-focused and **T**ime-bound.

Specific: Goals should be simplistically written and clearly define what you are going to do.

Measurable: Goals should be measurable so that you have tangible evidence that you have accomplished the goal. Usually, the entire goal statement is a measure for the project, but there are often several short-term or smaller measurements built into the goal. Measurable means that data exists and is easily accessible.

Achievable: Goals should be achievable; they should stretch you slightly so you feel challenged, but realistic enough so that you can achieve them. Initial successes encourage ongoing QI work. You must possess the appropriate knowledge, skills, and abilities needed to achieve the goal.

Results-focused: Goals are measured by data. The best goals measure outcomes, but sometimes one can only measure activities.

Time-bound: Goals should be linked to a time frame that creates a practical sense of urgency, (i.e. shorter time intervals can be better to keep momentum and motivation or results in tension between the current reality and the vision of the goal.) Without such tension, the goal is unlikely to produce a relevant outcome.[8]

A sample aim:

"We will increase Tdap vaccination rates during gestational weeks 27 through 36 by 10% from a baseline of 50% to a goal of 60% by January 1, 2016."

8] Adapted from: http://www.hr.virginia.edu/uploads/documents/media/Writing_SMART_Goals.pdf

Establishing Measures: Get your baseline data

When available, Electronic Health Records and registries are the most efficient way to obtain baseline data. When EHR data is not available, prospective and retrospective chart review is the most accurate means of assessing vaccine eligibility and immunization status.

In the case of Tdap vaccination, the EHR or chart review data would have to capture gestational age and date of vaccination at a minimum. Other relevant data would be information such as reason for refusal or contraindication. A practice can work with its information technology (IT) team or EHR vendor to set up immunization tracking or a more comprehensive data pull.

Additional sources of data may help you track your QI progress. These include:

1. Billing records for vaccine administration

2. California Immunization Registry (CAIR) – www.cairweb.org

First step: calculate rough baseline vaccination rate by reviewing 30 charts

This calculation will give you a general idea of what proportion of your patient population is currently getting vaccinated. Knowing your baseline vaccination rate will help you to choose an appropriate QI goal.

Chart Review:

- Exclude patients who were NOT seen in the practice at least once during weeks 27-36 of gestation.
- Exclude patients with a contraindication to vaccination (Appendix A)
- Review charts after completion of 36 weeks gestation in order to accurately assess vaccination status, as multiple visits may occur during the 27-to-36-week time window.
- One may need to review a larger number of charts to have 30 data points after exclusions.

For this, you have two options:

Prospective approach: review charts for the next 30 patients (meeting the criteria above) consecutively seen in your practice. This should be performed before any process changes or provider education is implemented to avoid falsely elevating the baseline rate.

Retrospective approach: review charts for the last patients consecutively seen in your practice until you obtain 30 that meet the criteria

Calculate an estimated vaccination rate:

$$\text{Vaccination rate*} = \left(\frac{\text{Number of pregnant women vaccinated during weeks 27 through 36 weeks of pregnancy}}{\text{Total number of patients seen during weeks 27 through 36 of pregnancy who do not have a contraindication to}} \right) \times 100$$

*Only include patients that meet the criteria noted under Chart Review above.

Sample calculation:

Number of records reviewed	32
Number patients seen during weeks 27 to 36 of pregnancy who do not have a contraindication to vaccination	30
Of those, number vaccinated during weeks 27 through 36 of pregnancy*	15
Calculation	15/30 x 100
Estimated baseline vaccination rate	50%

* Patients vaccinated outside of the 27 to 36 week window will be included in the denominator but will not be included in the numerator

Second step: determine the appropriate sample size for your QI project

After you have determined a rough baseline, you then can use the following power calculation table to determine the number of patient observations/patient charts required to detect a 10% improvement at a 95% confidence level.[9] It is important to take statistical power into account to ensure that any change in vaccination rate that you detect is unlikely to be due to chance or random variation. If you would like to detect instead a 5% improvement or a 20% improvement, please refer to the tables in Appendix B. Keep in mind that more charts will need to be reviewed if you wish to detect a smaller percent improvement.

Table for Effect Size: 10 % vaccination rate improvement

Current Estimated Baseline Vaccination Rate	Desired Vaccination Rate	# of Patient Charts Needed
20%	30%	137
30%	40%	172
40%	50%	191
50%	60%	194
60%	70%	182
70%	80%	153
80%	90%	108

An interpretation of the result in the table above is: *"Given a 50% current estimated vaccination rate, a total of 194 patients must be included in both the pre-and post-intervention groups to detect a difference of 10% between pre and post-intervention groups."* (Because the vast majority of third-trimester patients are expected to be eligible for vaccination, the number of charts needed is expected to be approximately equivalent to the number of eligible patients, not more.)

9] 80% power at a 0.05 alpha significance level using Pearson's two-tailed χ 2 test; STATA13 sampsi function

You will need to estimate what time interval would be required to see the number of patients needed as specified by the table. Throughout your QI project, vaccination rate change will be repeatedly assessed at this time interval (also known as the "monitoring interval"). The overall length of the QI project, called the study period, may consist of several monitoring intervals.

Practical Hints:

- If you do not want to perform the sample method of looking at the last 30 charts to estimate baseline vaccination rate, you can skip that step and assume that you would need 200 patients to detect a 10% difference. This conservative estimate is the maximum number of patients needed from the table above. However, it is not recommended to skip the baseline calculation.

- One way to easily figure out how many vaccine-eligible patients are seen in the practice during a certain time period is to calculate the number of patients in the practice who deliver during that time period. This should roughly correspond to the number of patients in the practice who begin their third trimester each month. The vast majority of third trimester patients are expected to be eligible for vaccination.

- In determining a feasible sample size, take into consideration the proportion of charts that may be ineligible to get the vaccine. If you did a baseline vaccine rate calculation then you already know that you need to review 10 charts to get 8 vaccine-eligible patients, for example.

Selecting Potential Changes

Understand the current process

The team should understand and document how the process is currently taking place. A "process map" or flowchart can be a helpful tool for this step. You can find additional resources on process mapping at http://www.ihi.org/resources/pages/tools/flowchart.aspx.

Identify barriers and solutions

Based on the current process, brainstorm with your QI Team a list of potential barriers to immunization, their root causes and associated solutions. Consider eliciting feedback from other clinic members including but not limited to clinicians, nurses or medical assistants, support staff. We are providing a list of examples in Appendix C that may or may not apply to your practice. The root causes of these barriers will likely also vary by practice. More discussion on root cause analysis at http://www.ihi.org/resources/Pages/Tools/CauseandEffectDiagram.aspx.

Determine the measure of success

Measurement is a critical part of quality improvement. Measurement over time tells the team whether or not the changes really lead to an improvement. Choose changes that can be measured or tracked in some fashion. Examples of measures are given in Appendix C.

Select a change to test

Often, there are many problems to fix or many potential interventions to try. There are several tools that help choose which problem or intervention should be prioritized. A simple way to choose is by using a prioritization grid. The team scores each problem or intervention on two scales such as effort and impact. Low effort, high impact activities may be prioritized for early attention while high effort, low impact activities might be postponed or dropped from consideration. See Appendix K for an example and more information.

Testing Changes: PDSA Cycles

Use PDSA cycles to try out solutions to the barriers the team identified. This approach allows the QI team to work out problems and perfect the solution before asking the entire practice to implement a change. It is psychologically and practically easier and faster for the team to implement small-scale rapid cycles.

To test ideas for change, try them out on a few patients, on one provider team or for one day rather than committing to a broad-scale change from the outset. Use the PDSA worksheet (Appendix F) to plan and evaluate each test. Once a potential solution has been tested a few times and changes no longer need to be made, it can be spread to the rest of the patients and/or care teams.

Implementing Changes: Your Action Plan

Once your team has tested solutions to the identified barriers, the administrator or another designated individual should draft the action plan for implementation.

The action plan (see Appendix I for a sample Action Plan and a blank Action Plan template) will detail the steps necessary for implementing the chosen solutions to the barriers this QI project will address. The action plan should include: estimated start and completion times for tasks, assigned individuals for tasks, and a section of task results, notes, and follow up. The team should be actively involved in subsequent edits of the action plan.

Track, Document and Report Your Results

You will need a system of documentation to track immunizations during implementation of your action plan and intervention. You will then need to have that data in a format that can be analyzed. If you have an electronic medical record system (EMR), you may be able to use the EMR to track immunizations. However, you may find it more convenient to collect the data in one document or spreadsheet for easy analysis. The easiest method of tracking is an Excel spreadsheet (Appendix H) which you can adapt to your practice. You can enter data in real-time or print out the Excel sheet for staff to record data by hand and subsequently enter the data into the spreadsheet.

At regular intervals, summary calculations should be performed and reported to the QI team and to the practice as a whole. Reports should include comparison to previous rates and intended goal. They can also include comparison to other providers in the practice. See Appendix J for a sample report.

Appendices

Appendix A: Contraindications to Tdap Vaccine

ABSOLUTE CONTRAINDICATIONS:

a. History of severe allergic reaction (anaphylaxis) after previous Tdap or Td or vaccine component. For information on these components, go to manufacturer's insert (www.immunize.org/packageinserts).

b. Coma or history of encephalopathy within 7 days following a dose of DTP, DTaP, or Tdap not attributable to another cause.

RELATIVE CONTRAINDICATIONS (TALK TO A PROVIDER FIRST FOR THE FOLLOWING PATIENTS):

a. History of Guillain-Barre syndrome within 6 weeks of previous dose of tetanus toxoid containing vaccine.

b. History of an arthus-type reaction following a previous dose of tetanus or diphtheria containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-containing vaccine.

c. Moderate or severe acute illness with or without fever.

d. Progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy; until a treatment regimen has been established and the condition has stabilized.

Appendix B: Power Calculation Tables

Table for Effect Size: 20% vaccination rate difference. This means that if you have a <20% difference, you will not know if the difference is a statistically significant improvement or a difference of chance variation.

Current Estimated Background Vaccination Rate	Desired Vaccination Rate	# of Patient Charts Needed to Detect a 20% Difference in Vaccination Rates
20%	40%	36
30%	50%	44
40%	60%	48
50%	70%	47
60%	80%	43
70%	90%	34

Table for Effect Size: 5 % vaccination rate difference (note that the high number of charts required makes a 5% effect size a less promising selection)

Current Estimated Background Vaccination Rate	Desired Vaccination Rate	# of Patient Charts Needed to Detect a 5% Difference in Vaccination Rates
20%	25%	1134
30%	35%	1416
40%	45%	1573
50%	55%	1605
60%	65%	1511
70%	75%	1291
80%	85%	995
90%	95%	474

Appendix C: Examples of Barriers, Root Causes, & Potential Solutions

Barrier	Root Cause
Tdap vaccination not offered to patient or not offered at the correct visit.	Lack of time during busy clinic visits, lack of appropriate reminder cues for providers and staff.

Potential Solutions:

1. Add Tdap education/referral, and/or administration to the standard workflow for the 28 week clinic visit.
2. Implement standing orders[1] that allow nursing staff to discuss and administer vaccine without MD involvement. See example, Appendix G.
3. Electronic Medical Record (EMR) provider reminders[2] – automatically calculates date based on delivery date; flag/popup if past due.
4. Paper chart provider reminders.
5. Performance feedback for individual providers/clinical teams.
6. Refer to an outside pharmacy for vaccination.

Measure of Success: # offered vaccine/# seen

Barrier	Root Cause
Vaccine offered, accepted but not administered.	Patient left as wait time for administration was too long, patient unable to find vaccination area/clinic location.

Potential Solutions:

1. Expanding access – increase hours of operation.
2. Administration in waiting room or in exam room before patient visit.
3. Reduce administrative barriers (i.e. drop in clinic, MA can administer).
4. Follow-up phone call to direct patient to outside vaccination resources.

Measure of Success: # administered/# offered vaccine

1] Standing orders are an effective and evidence-based way of increasing adult immunization rates. See Use of Standing Orders Programs to Increase Adult Vaccination Rates: Recommendations of the Advisory Committee on Immunization Practices, 2009

2] Provider reminders for vaccinations are recommended by the Community Preventive Services Task Force.

Barrier	Root Cause
Tdap vaccination not offered to patient or not offered at the correct visit.	Providers may not understand the need to track whether patients have received the vaccine.

Providers may not have a built-in designated location for documenting vaccination administration in either EMR or patient's paper chart. Alternatively, this location for documentation may exist, but providers are not educated and aware of it nor using it for this purpose.

Potential Solutions:

1. Print out a referral (see Appendix E) for the patient to give to the pharmacist who will fax patient's provider with confirmation of vaccine administration.
2. Obtain vaccination status from the California Immunization Registry (CAIR) at cairweb.org.
3. Institute chart prompts to request documentation.

Measure of Success: # for whom vaccination history reviewed/# seen

Barrier	Root Cause
Patients are being referred but are not following through with off-site vaccination.	Vaccine too expensive for patient, did not remember to do task, transport to pharmacy, time constraints.

Potential Solutions:

1. Provide printed referral for patient to take with them (see Appendix E).
2. Mail/telephone /email/text reminders to patients, automatically generated if possible.
3. Social Worker/MA to discuss resources, transportation, and finances with patient.
4. Prompts and follow-up at next visit or at reminder call for next visit.

Measure of Success: # #obtained off-site vaccination/# referred

Appendices

Barrier	Root Cause
Vaccines are not being administered at the prenatal care facility.	Cost, storage/handling difficulties, staff availability and training.

Potential Solutions:

1. Immunization Action Coalition – advice on dose, route, site, needle size and vaccine storage. www.immunize.org/handouts.
2. For individualized help with obtaining equipment and handling questions, the San Francisco Department of Health can provide technical assistance concerning vaccine storage/handling. Call (415) 554-2955.
3. For comprehensive guidance on proper storing and handling of vaccines, review CDPH's Vaccine Storage and Handling Resources

Measure of Success: completion/tracking of steps taken towards administering vaccine at your facility

Barrier	Root Cause
Patients are refusing Tdap.	Lack of patient education or agreement regarding importance of Tdap immunization.

Potential Solutions:

1. Patient survey to understand reasons for refusal.
2. Cheat-sheet of talking points for staff (see Appendix D).
3. Provider script for discussion with patients on ACOG website.
4. Group counseling/discussion sessions led biweekly by RN/MA/NP/CNM
5. Patient education materials – fliers and posters in waiting area.
6. Staff education/training (MA, PA, RN) so that any staff can provide education, administer vaccine (with standing order), and bill for it.

Measure of Success: # refusals/# seen

Appendix D: Pertussis Facts for Discussion with Patients

- Pertussis and flu can cause serious disease and death to newborns.
- The most vulnerable population is newborns < 2 months as they cannot yet be vaccinated and do not yet have their own antibodies.
- Antibodies are a part of your immune system. When you receive a vaccine, your body produces antibodies to the disease you were vaccinated against.
- To protect your baby the most, get the vaccine during weeks 27 through 36 of pregnancy. It takes about two weeks for the mother's body to develop the antibodies that will be passed to baby at delivery. This is why it is important to receive the vaccine during weeks 27 through 36, before your baby is born.
- All adults and adolescents in contact with the baby need to get the Tdap (and flu) vaccines, including partners, fathers, grandparents, caregivers and siblings.
- If you did not receive the Tdap (and flu) vaccines during your pregnancy, you can still get them post-partum – it is safe during breastfeeding.
- It is safe and encouraged to administer both vaccines at the same time.
- If you are getting your Tdap vaccine outside of your provider's office, let your provider know the date you got it.

Appendix E: Patient Referral to Pharmacy for TDAP

From the Office of: _____

Patient Name: _____ Date: _____

Check if Recommended By Provider:	Check if Administered By Pharmacy:
☐ Tdap (tetanus, diphtheria, pertussis) during following date range: _____ (dates correspond to week 27 through 36 of pregnancy)	☐
☐ Other vaccine: _____	☐

Pharmacist: Please fax this document back to the provider upon vaccine administration at the following fax number: _____

CONFIDENTIAL

To order free, printed prescription pads for this purpose, visit www.sfcdcp.org/request_materials.

APPENDIX F: PDSA WORKSHEET[1]

Change to be tested: _____

Plan

List the tasks needed to set up this test of change	Person responsible	When to be done	Where to be done

Predict what will happen when the test is carried out	Measures to determine if prediction succeeds

Do Describe what actually happened when you ran the test

Study Describe the measured results and how they compared to the predictions

Act Based on what you learned, describe what modifications to the plan will be made for the next cycle.

1] Adapted from the Institute for Healthcare Improvement. http://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx

APPENDIX G: STANDING ORDERS

Standing Orders for Administering Tdap to Pregnant Women[1]

Policy

Under this standing order and in compliance with California state law, healthcare professionals including nurses, pharmacists, medical assistants, and physician assistants may vaccinate people who meet the criteria below (and are 18 years or older).

Procedure

1. Identify pregnant women of all ages who lack prior Tdap vaccination within the current pregnancy irrespective of prior Tdap administration or women with newborns < 2 months who did not receive a Tdap vaccination during their pregnancy. The optimal time of administration is during 27 to 36 weeks' gestation, although vaccination may occur at any time during the pregnancy.

2. Screen for contraindications to Tdap vaccine:

   ABSOLUTE CONTRAINDICATIONS (DO NOT give vaccine):

   - History of severe allergic reaction (anaphylaxis) after previous Tdap or Td or vaccine component. For information on these components, go to manufacturer's insert (www.immunize.org/packageinserts)
   - Coma or history of encephalopathy within 7 days following a dose of DTP, DTaP, or Tdap not attributable to another cause.

   RELATIVE CONTRAINDICATIONS (talk to a provider first for the following patients):

   - History of Guillain-Barre syndrome within 6 weeks of previous dose of tetanus toxoid containing vaccine.
   - History of an arthus-type reaction following a previous dose of tetanus or diphtheria containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-containing vaccine.
   - Moderate or severe acute illness with or without fever.
   - Progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy; until a treatment regimen has been established and the condition has stabilized.

1] Adapted from Immunization Action Coalition (accessed at: http://www.immunize.org/catg.d/p3078B.pdf) and adapted from San Francisco Health Plan (accessed at: http://www.sfhp.org/files/Standing_Order_for_Adult_Td_and_TDap_Vaccine.pdf)

3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS) prior to administration of the vaccine. Found at http://www.imunize.org/vis.

4. Document publication date of VIS and date given to patient. Provide non-English speaking women VIS in their language. The most current VISs can be found in multiple languages here: http://www.immunize.org/vis/.

5. Administer 0.5mL Tdap vaccine intramuscularly (22-25 G, 1-1 1/2" needle) in the deltoid muscle or, alternatively, the anterolateral thigh. Note: a 5/8" needle may be used for people weighing less than 130 lbs. (60kg) for injection in the deltoid muscle only if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle.)

6. Document vaccination administration including date of administration, manufacturer and lot number, site and route, and name and title of the person administering the vaccine in the patient's chart.

7. Document vaccination administration in the patient's personal immunization card, CAIR registry, and facility tracking log.

8. Be prepared for management of a medical emergency related to the administration of the vaccine by having a written emergency medical protocol available, as well as equipment and medications. To prevent syncope, vaccinate patients while they are seated or lying down.

9. Report all adverse reactions to the Tdap vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/index or (800) 822-7967.

This policy and procedure shall remain in effect for all patients of the (name of practice or clinic) until rescinded or until (date): _____

Medical Director's Signature: _____

Effective Date: _____

APPENDIX H: TRACKING LOG

Immunization Data Collection Tool

Facility Name: Women's Health Center

Number of Patients: 8

Contact Name: Suzanne Smith, MA

Contact Phone Number: 555-555-1234

Data Tracking Period if applicable (ex: 1/1/2014 – 1/1/2015): _____

					Reasons for lack of vaccination				
Patient Name	Medical Record Number	Date Tdap received xx/xx/xx	Week of Pregnancy Tdap received	Tdap received at other location	Tdap ordered but not received	Patient refused Tdap	Contraindication to Tdap	Tdap not offered	Tdap not administered for other reason
M	xxx	3/31/15	32	x					
N	xxx	2/2/15	35	x					
O	xxx	0							x
P	xxx	0				x			
Q	xxx	0					x		
R	xxx	0						x	
S	xxx	3/12/15	37	x					
T	xxx	0						x	

Summary Calculations

	Calculation	Result
Total patients	Count	8
Patients without contraindication to vaccination	Count	7
Total patients vaccinated	Count	3
Patients vaccinated during weeks 27-36	Count	2
Percentage total patients vaccinated	(3/7)*100	43%
Percentage vaccinated during weeks 27-36	(2/7)*100	29%

TRACKING LOG (EMPTY TEMPLATE)

Immunization Data Collection Tool

Facility Name: _____

Number of Patients: _____

Contact Name: _____

Contact Phone Number: _____

Data Tracking Period if applicable (ex: 1/1/2014 – 1/1/2015): _____

Instructions: Yes = 1, No = 0 if using excel provided spreadsheet to aid in summation calculations. If printing out this table, can check boxes as appropriate.

This excel spreadsheet has built in analysis capabilities including calculations of vaccination rates and sums. You may also print out sheets for staff to fill in then input the data into the excel file later.

					Reasons for lack of vaccination				
Patient Name	Medical Record Number	Date Tdap received xx/xx/xx	Week of Pregnancy Tdap received	Tdap received at other location	Tdap ordered but not received	Patient refused Tdap	Contraindication to Tdap	Tdap not offered	Tdap not administered for other reason

Summary Calculations

	Calculation	Result
Total patients		
Patients without contraindication to vaccination		
Total patients vaccinated		
Patients vaccinated during weeks 27-36		
Percentage total patients vaccinated		
Percentage vaccinated during weeks 27-36		

Links to customizable templates from the appendices can be found at www.sfcdcp.org/tdaptoolkit.

Appendix I: Action Plan

EXAMPLE

Facility: Women's Health Center

Author: Suzanne Smith, MA

Date: 8/1/15

Team Members who have reviewed action plan: Nurse Roberts, Dr Ruiz, Pharmacist Chin, MA Smith, MA Reynolds

Problem Statement: Estimated only 50% of eligible patients in this prenatal care practice received Tdap during the monitoring interval based on baseline calculation from review of 30 charts.

Goal for Improvement: We will increase Tdap vaccination rates during gestational weeks 27 through 36 by 10% from a baseline of 50% to a goal of 60% by January 1, 2016.

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

Root Causes/Barriers: lack of staff education regarding need to vaccinate, lack of patient knowledge about benefits of vaccination.

Actions Already in Place: Standing orders

Action Plan Implementation Steps	Responsible Team Member	Start Date	Target Date	Date Completed	Comments (status, outcomes, evaluation...)
Develop educational program for patient and staff regarding patient discussions of Tdap	Facility Nurse Manager/ Educator	4/2	5/1	4/28	Resources gathered for patient and staff education. Materials reviewed by QI team – includes "cheat-sheet" adapted to this practice. In-service at staff meeting on 4/15/15.
Implement biweekly MA-led, group vaccination discussion for patients.	MA	5/5	6/10	6/10	First discussion held. Patient satisfaction, feedback, and concerns solicited. Plans implemented to continue further regularly held group sessions on an ongoing basis.
Vaccination Rate Tracking and practice feedback	Administrator	5/13	6/30	6/25	New vaccination rate calculated for monitoring period May 20 – June 20 is 56%. Results presented at monthly QI Team meeting.
Brainstorming Session for changes to Action Plan at QI monthly meeting	Medical Director	7/1	7/13	7/13	Brainstorming session at monthly QI meeting held – facilitated by Medical Director with prepared materials. Decision to implement second intervention: vaccine administration in waiting room. Second action plan filled out.

ACTION PLAN EMPTY TEMPLATE

Facility:

Author:

Date:

Team Members who have reviewed action plan:

Problem Statement:

Goal for Improvement:

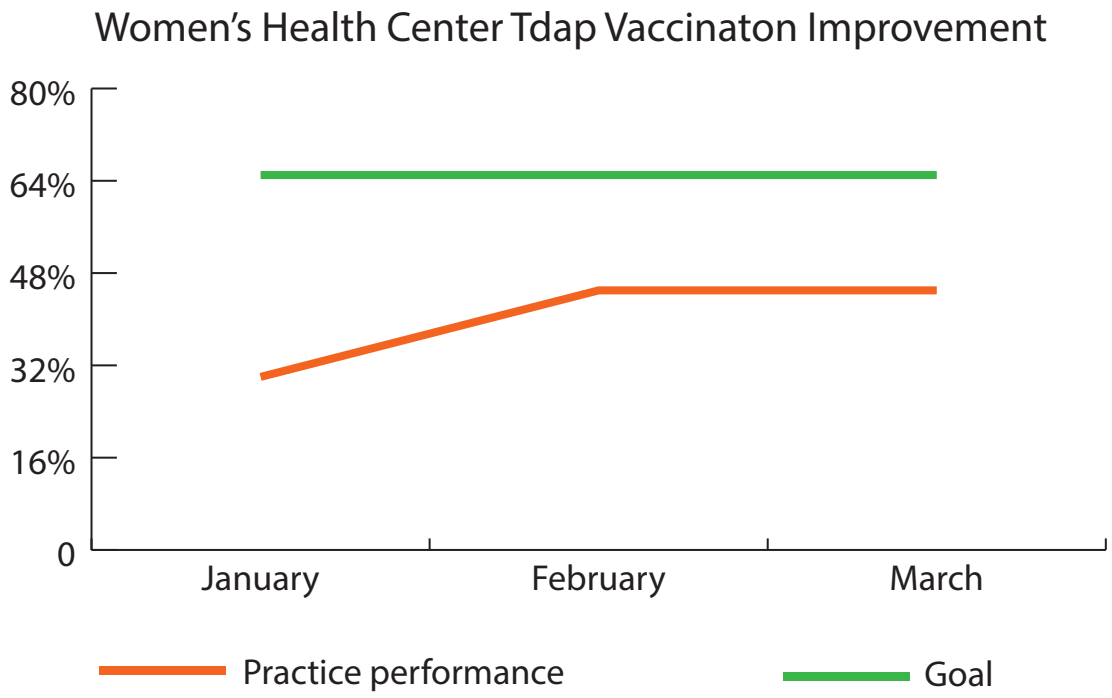
Data/Resources Required:

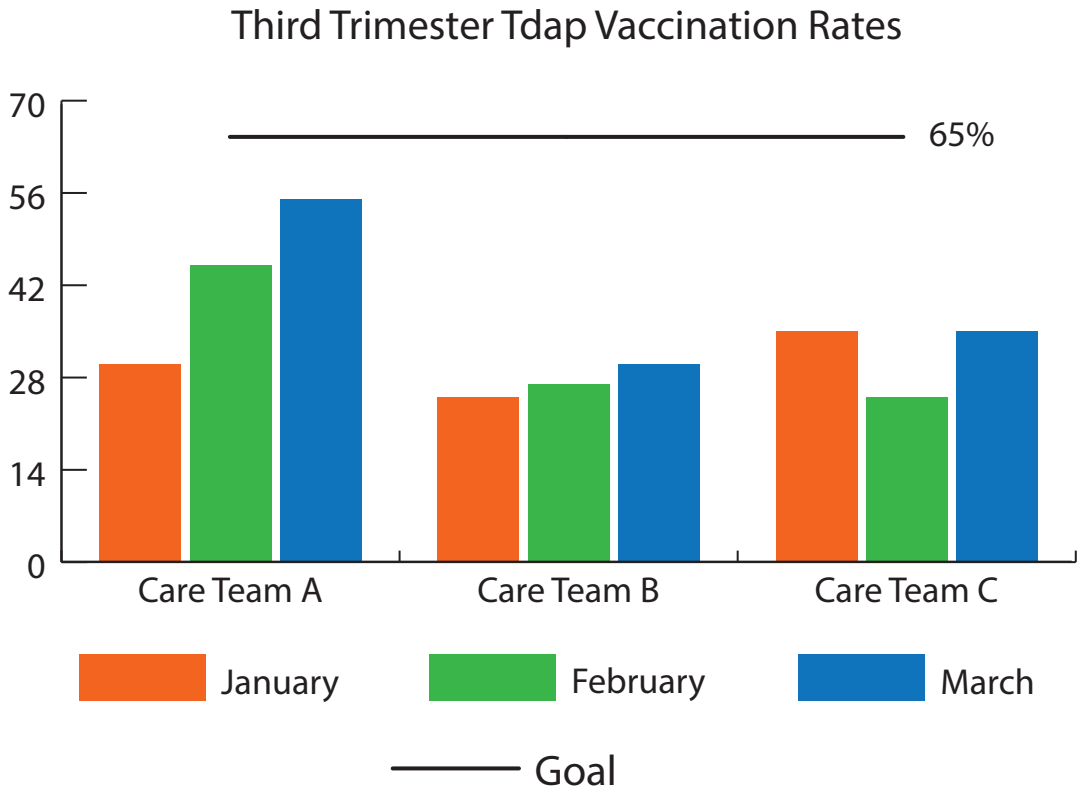
Root Causes/Barriers:

Actions Already in Place:

Action Plan Implementation Steps	Responsible Team Member	Start Date	Target Date	Date Completed	Comments (status, outcomes, evaluation...)

APPENDIX J: QI PRACTICE REPORT





Consider including information that allows viewers to compare the care teams e.g. panel size.

APPENDIX K: PRIORITIZATION GRID[1]

Example: Potential solutions to the problem: Providers do not offer patients Tdap

Standing orders *Do now*	EHR Reminders Performance feedback to providers In-house vaccine clinic *Do soon*
Paper chart reminders Refer to outside vaccination site Educational flyer to providers *Likely not worth the effort*	Phone call reminders to patients to ask for vaccination during visit *Maybe/ Maybe not*

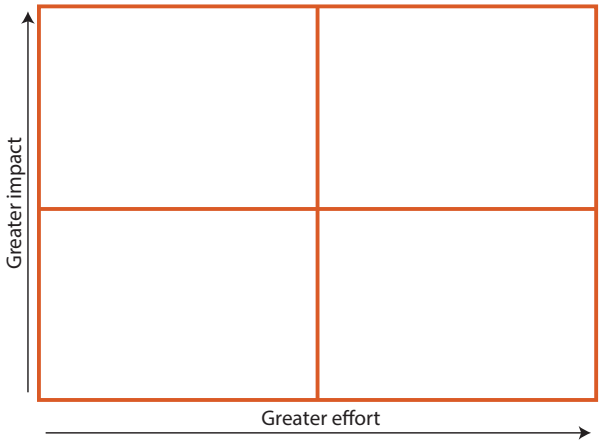
Greater impact

Greater effort

Possible Scales:

Impact
Effort
Feasibility of the intervention/solution
Frequency of the problem
Importance
Cost

Template



Available online at www.sfcdcp.org/tdaptoolkit

1] For more in-depth analysis: "Prioritization Matrix" http://www.health.state.mn.us/divs/opi/qi/toolbox/print/prioritizationmatrix.pdf and "Pareto Charts" http://asq.org/learn-about-quality/cause-analysis-tools/overview/pareto.html

APPENDIX L: QI COCOONING FLYER

Protect Your Baby from Whooping Cough (Pertussis) & Flu!

Family Members Need Tdap & Flu Vaccines

Pertussis (Whooping Cough) and influenza (flu) infections can cause serious and sometimes life-threatening health problems in babies, especially in their first 6 months of life.

- About half of infants diagnosed with whooping cough become hospitalized.
- Four out of five babies with whooping cough were infected by someone at home.

How to protect your baby before 6 months of age?

Newborns are too young to receive the Tdap (Tetanus, diphtheria, and pertussis) and Flu vaccine. So, it is very important for the mother and household members to get the vaccine before having contact with the baby.

- **Pregnant women** need to get the **flu** vaccine anytime during pregnancy and **Tdap** vaccine (best between 27- 36 weeks) **with every pregnancy**.
- **All adults and adolescents in contact with the baby** need to get the **flu and Tdap vaccines.** This includes: partners, fathers, grandparents, caregivers, and siblings. The flu vaccine is recommended **every year**. Unless you are pregnant, the current Tdap recommendation is **once during adulthood** (after 19 years old). Adults should be immunized before caring for a baby. If you are not sure when you last received the Tdap vaccine you should get the vaccine again right after the baby is born.

Where to get Tdap (whooping cough) and Flu Vaccines?

The best place to get these vaccines is at your health provider's office. They are included at no extra cost if you have health insurance. If you do not have health insurance you can go to the health department or pharmacies listed below.

Locations	Cost*	Schedule
Name of site Address Phone Website	Flu: $ Tdap: $	Day of the week Hours of operation
Name of site Address Phone Website	Flu: $ Tdap: $	Day of the week Hours of operation
Name of site Address Phone Website	Flu: $ Tdap: $	Day of the week Hours of operation
Name of site Address Phone Website	Flu: $ Tdap: $	Day of the week Hours of operation
Name of site Address Phone Website	Flu: $ Tdap: $	Day of the week Hours of operation

*Prices are subject to change, please check website or call location.

San Francisco Department of Public Health. January 2016

Versions in Chinese and Spanish also available.

APPENDIX M: STORAGE AND HANDLING FLYER

Could you do your job well if your office was too hot or too cold?

Vaccines Need to Be Stored at the Right Temperature to Do Their Job!

Vaccines lose some or all of their strength when exposed to excessive heat and cold, and the damage may be permanent. You can't tell by looking at a vaccine whether it's been damaged or not.

Keeping your vaccines within the right temperature range protects your vaccines -- and your patients.

In the event that vaccines are exposed to out-of-range temperatures, immediately restore proper conditions or move vaccines to a temperature-stable storage unit. Never assume vaccines have been ruined. Instead, keep vaccines at the proper temperature, and contact the manufacturers to verify whether the vaccines can still be used or need to be discarded.

Vaccine Storage & Handling Guidelines

1. **Use the Right Equipment.**
   Avoid using under the counter combination freezer/refrigerator units. These "dormitory style" refrigerators don't maintain stable temperatures.

2. **Maintain Correct Temperatures:**
   35°F - 46°F in Refrigerators
   -58°F to +5°F in Freezers

3. **Monitor and Record Temperatures 2x Daily.**
   Use two digital thermometers, one as your primary and one as a back-up. Make sure they each have a glycol probe and an alarm that lets you know if temperatures go out of range.

4. **Always Contact Vaccine Manufacturers if Your Storage Temperatures Go Out of Range.**
   Vaccine manufacturers can let you know whether your vaccines are still viable.

For a complete list of storage and handling recommendations:

Visit http://sfcdcp.org/izmedicalproviders.html and Review CDC's Storage and Handling Toolkit: www.cdc.gov/vaccines/recs/storage/toolkit/

San Francisco Department of Public Health, Communicable Disease Prevention Unit
Website: www.sfcdcp.org Phone: (415) 554-2955 Fax: (415) 554-2854 Email: immunization@sfdph.org

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Prenatal Tdap Vaccination Toolkit