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Program Evaluation for Tdap Immunization Standing Orders in a Birthing Hospital

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Running Head: STANDING ORDERS FOR TDAP IMMUNIZATION

Program Evaluation for Tdap Immunization

Standing Orders in a Birthing Hospital

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Capstone Project

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Abstract

Newborn infants are vulnerable to pertussis infections. Although the Advisory Committee on Immunization Practices (ACIP) recommends that babies begin their diphtheria, tetanus and acellular pertussis (DTaP) immunization series at two months of age, the minimum age for administration of the vaccine is six weeks of age (Centers for Disease Control [CDC], 2008). Young infants are at risk for whooping cough infection transmitted from parents, siblings and care-givers during the pre-vaccination period in the first two months of life, particularly pertussis transmitted from their mothers. Since the licensure of adult/adolescent formulations of tetanus, diphtheria and acellular pertussis (Tdap) vaccine in 2005, healthcare providers have been encouraged to use Tdap vaccine in the family and caregivers of susceptible infants. Vaccinating the family and close contacts of the baby helps to establish a 'protective cocoon' of immunization against pertussis around the child (CDC, 2008). The ACIP guideline on the prevention of pertussis in post-partum women promotes the use of Tdap vaccine in the period immediately following delivery in the hospital setting for susceptible mothers (CDC, 2008).

The purpose of this project was to conduct a program evaluation of current immunization practices, and to assess the feasibility of instituting standing orders for Tdap immunization, in a birthing hospital. The evaluation was conducted with members of the medical and nursing obstetrical service in a tertiary care medical center of 783 beds in Western Massachusetts during the winter of 2009-2010. The project was carried out utilizing program evaluation guidelines published by the Centers for Disease Control (CDC, 2007). The program evaluation found that the project hospital met standards for providing immunization in a non-traditional setting and the evaluation culminated with a recommendation for instituting Tdap immunization on the birthing

unit. The Capstone experience concluded that the birthing hospital is an apt setting for immunization standing orders and an ideal partner in addressing the public health issue of increasing pertussis incidence.

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Introduction

This project centered on a program evaluation of a hospital's current practices regarding pertussis immunization and to assess the feasibility of developing a standing order for Tdap immunization in the maternity unit of the medical center under study. This paper presents the mechanisms of transmission of pertussis infection, current immunization recommendations for pertussis, and the use of standing orders for Tdap immunization among newborn mothers in a birthing facility. The ultimate goal of the project was to increase the protection of newborn infants in the battle against this vaccine preventable disease.

Young infants are particularly susceptible to whooping cough infection transmitted from parents, siblings and caregivers during the period prior to initiation of their vaccination series, from birth through the first few months of life. The 2005 licensure of Boostrix® and Adacel® vaccines was hailed as a way to counter waning immunity among adolescent and adult populations which represents a reservoir of infection and a potential transmission threat to infants. Health care providers have been encouraged to use Tdap vaccine for immediate and extended families, as well as caregivers of newborns. This use of Tdap provides an indirect means of protecting vulnerable infants from pertussis infection, helping to establish a 'protective cocoon' of immunization against pertussis around the baby (CDC, 2008a).

A prospective area of application for improving Tdap immunization rates includes establishing standing orders for Tdap immunization of newborn mothers in birth hospitals. This program evaluation will seek to determine the feasibility, facilitating factors, and barriers to implementing standing orders for Tdap immunization in the birth setting. Although various members of the project site expressed a desire to implement a Tdap program, they also expressed the difficulty in "pulling a program together". The program evaluation was seen as a way of

preparing for a Tdap program by identifying current practice, formalizing the process, bringing together the required parties, documenting a need, exploring the situation and using the report to actualize a proposal into a bona fide program.

Project Rationale

The implementation of Tdap standing orders in the birth hospital represents a window of opportunity to immunize the mother of the newborn. The ACIP guideline relates the evidence and rationale for administering Tdap vaccine to post-partum women (CDC, 2008). Tdap is not recommended for use in expectant women in any country as the safety and efficacy of Tdap vaccine has not been demonstrated in pregnant women (CDC, 2008). There is also concern that Tdap-induced transplacental maternal antibody might have a negative effect on the infant's ability to develop a protective immune response from routine DTaP vaccine administered at the recommended time (CDC, 2008). Developing a program to administer Tdap vaccine in the immediate post-partum period represents an advantageous moment in time, not only to protect susceptible mothers, but also to extend protection to newborn babies.

Standing orders for immunization “enable non-physician personnel such as nurses to administer vaccinations using an approved protocol without the direct involvement of a physician”, (Philadelphia Immunization Best Practices, 2009). Evidence shows that standing orders are an effective means of increasing immunization rates (Briss, 2000). Standing orders as a preventive tool are “recommended” by the United States Preventive Services Task Force (USPSTF) in their Guide to Community Preventive Services (Zaza, 2005). The Task Force found that “Standing orders, when used alone, were effective in increasing vaccine coverage in adults by approximately fifty-one (51) percentage points” (Zaza, 2005). The Community Guide evaluated twelve studies that USPSTF utilized to determine the strength of evidence for standing

orders. One study found that improvements in immunization coverage rates associated with the use of standing orders continued over a span of five years although most of the studies averaged about a year.

Intent of Program Evaluation

The intent of this program evaluation was to assess the feasibility of developing a standing order for Tdap immunization in the maternity unit of the medical center under study. This was undertaken by evaluating current immunization activities and then evaluating the possibility of adopting a standing order system for Tdap. The aims of program evaluation, “stimulating improvements, improving outcomes and translating findings into practice” (CDC, 1999) were put into application using the Framework for Program Evaluation in Public Health Practice. The Framework is a tool that promotes a systematic method “to improve and account for public health actions involving procedures that are useful, feasible, ethical, and accurate” (CDC, 1999). CDC has an on-going program to assist in developing evaluation programs as an overall focus on health improvement but specifically in developing strong partnerships that “allow partners to achieve common goals” (CDC, 1999). This project explored aspects of partnership of a community hospital and the state health department. CDC has stated that program evaluation is necessary for guiding public health interventions which include science as a basis for decision-making, expanding the quest for social equity, performing effectively as a service agency, making efforts outcome oriented, and being accountable” (CDC, 1999). The intent of this project sought to address improving access to immunization services and increasing immunization coverage in a specific cohort.

Theoretical Foundation

The theoretical basis for implementing Tdap immunization standing orders in a birthing facility comports with Lewin's Theory of the stages of change (Dale & Sorenson, 1975). Hospitals, for the most part, operate under the premise of medical orders written specifically for individual patients. Institution of standing orders would require an 'unfreezing' (the first stage of change) of the traditional medical model. The second stage – 'changing', an area ripe for nursing leadership, would entail composing standing orders, having them reviewed and accepted by the policy making committees of the facility and establishing the capability to administer vaccine in the maternity unit. Under Lewin's theory, 'restraining forces' would include a reluctance by physicians to institute standing orders for immunization by nursing staff or the non-recognition by providers of the extent of pertussis morbidity. Lewin's concept of the third stage of change – 'refreezing', would take place when the standing order for Tdap becomes widely accepted as the new standard of practice within maternity units.

Change Theory applied to public health practice

A study evaluating inpatient standing orders for influenza immunization found that the main barrier to immunization in the hospital was the requirement for an individual order; "most of the medical staff did not view vaccination as a priority or were concerned that vaccination might 'complicate' the patient's course in hospital" (Lawson, Baker, Au, & McElhaney, 2000). Standing orders can decrease restraining forces by facilitating the process for nurses to administer vaccine, alleviating the need for individual orders by attendant physicians.

A University of Pittsburgh Medical Center study found that inpatient pneumococcal (PPV23) immunization rates ranged from 15 – 30% prior to the development of a hospital-based standing orders program. "The primary reason for lower than expected immunization rates was the failure of physicians to sign pre-printed orders on the chart" (Sokos, et al, 2007). A multi-

disciplinary workgroup in which nurses and pharmacists played key roles, created a successful Standing Order Protocol (SOP) for PPV23 immunization. Dramatic increases were seen in PPV23 immunization after the institution of an SOP, ranging from 65 – 87% (Sokos, et al, 2007). The Pittsburgh facility subsequently set up a similar SOP for in-patient influenza vaccination.

Another aspect of the change required for Tdap SOP's to be successful is for nursing personnel to feel empowered in assessing patients for immunization through screening and to use the SOP to act independently in vaccinating new mothers before discharge. Computer assisted nursing standing orders improved immunization rates more than physician reminders in a study comparing the two options (Dexter, Perkins, Maharry, Jones & McDonald, 2004). The 'need to attend to more pressing medical issues' and 'physician oversight' in generating vaccination orders were cited as reasons for low in-patient pneumococcal vaccination in another study on this topic (Nowalk, et al, 2003).

Rubenstein & Pugh (2006) also reference the tenets of change theory in promoting organizational change. They state that there is a quality chasm between what is known from research to be best practice, and the implementation of those findings. They relate that implementation science "consists of a body of knowledge on methods to promote the systematic uptake of new or underused findings into the usual activities of healthcare organizations" (Rubenstein & Pugh, 2006). In order for organizational change to occur, such as adopting standing orders in a birthing facility, a culture change may also need to occur. Vaccination was traditionally viewed as "clinic medicine"; over time, wider availability of vaccination has been realized through the advent of immunization clinics held in pharmacies and grocery stores; through 'vote and vaccinate' campaigns and even in 'drive-through' immunization campaigns. The culture change inherent in these efforts lessens the mystique of immunization and

demonstrates both the ability to reach larger cohorts and the ability for nurses to be the agents of change, and promotes the overall safety of immunization in “ordinary” settings.

The last stage of change, ‘refreezing’ represents the adaptation of involved parties to adopt the new condition – the standing order for immunization in a hospital setting. Refreezing has occurred for inpatient standing order protocols for influenza and pneumonia vaccines with the assistance of oversight agencies. The Center for Medicare and Medicaid Services (CMS) changed its Conditions of Participation in 2002 to remove requirements for individual patient orders for both influenza and pneumococcal immunization in provider’s offices, long term care facilities, and home health agencies (Nowalk, et al, 2003). CMS continues to encourage immunization by annually increasing reimbursement rates for immunization administration.

A study was designed that based the implementation of an inpatient standing order program for pneumococcal immunization program on registered nurses in assessing and administering vaccine to patients. In the ninety days after implementation, the hospital program was successful in raising pneumococcal immunization rates from 13% to 26% (Eckrode, Church, & English, 2006). In 2005, a New Jersey review found that the prevalence and trend for hospital-based standing order protocols was increasing over time (Pentakota & Halperin, 2007). Referring to influenza and pneumococcal protocols, Pentakota and Halperin concluded that given the morbidity and mortality associated with those diseases and the issues of impediments to vaccination for adults, the role of standing order protocols deserved substantially more attention (Pentakota & Halperin, 2007).

It is important to take advantage of every healthcare encounter to ensure adults are up-to-date with their recommended vaccinations. Hospitals are generally thought of in terms of providing acute and sometimes chronic patient care and are not usually considered to be public

health agencies. In contrast, ‘immunization’ is frequently proclaimed the quintessential example of preventive care. The core functions of public health are assessment, policy development and assurance. One of the facets of assurance is linking people to needed personal health care services (Aday, 2005). Using the hospital setting for immunization links mothers and infants with protection against pertussis through in-hospital Tdap immunization of the new mother. In this sense, the hospital is defined as a public health resource in decreasing susceptibility to whooping cough in mothers thereby extending protection to their babies. A 2008 article describing the provision of Tdap vaccine to parents of high-risk infants in a neonatal intensive care unit found the program to be an effective means of increasing immunization rates in parents of NICU patients. Importantly, the study concluded that using the hospital setting as an opportunity for immunization had the potential to mitigate a public health problem (Dylag, & Shah, 2008).

Change theory aptly applies to the problem of creating a protective cocoon of pertussis immunization to surround young infants. Perceptions of the disease burden and severity of illness on the part of obstetrical providers may require a change in knowledge, developing an expectation for immunization in all health care settings – including birthing hospitals - requires a change in attitude and instituting standing orders rather than individual provider orders in the hospital setting requires a change in practice.

Review of the Literature

Study Significance

Pertussis, commonly known as whooping cough, is an acute infectious disease caused by the *Bordetella pertussis* bacterium. The organism was isolated in 1906 and the first pertussis

vaccine was made available in the early 1940's (CDC, 2009). Prior to the licensure of a vaccine, approximately 270,000 cases were reported annually with some 10,000 deaths (Plotkin, Orenstein, & Offit, 2008). Cases declined precipitously after the introduction of a vaccine, especially after the inclusion of pertussis-containing vaccine to school entry requirements in many states. The lowest point recorded for pertussis incidence occurred in 1976 when only about 1,000 cases were reported through state and national surveillance systems (Plotkin, Orenstein, & Offit, 2008). Since that time, unlike other vaccine-preventable diseases, pertussis cases have continued to increase, particularly among adolescents and adults. Over 25,000 cases were identified in 2004, the highest number reported since 1959 (Plotkin, Orenstein, & Offit, 2008). Recent reports demonstrate the threat that circulating pertussis poses to infants too young to have received the first three doses of pertussis-containing vaccine. Between 2000 and 2004, an average of almost 2,500 cases annually were reported among infants less than a year of age, with 63% requiring hospitalization (Plotkin, Orenstein, & Offit, 2008). In 2005-2006, the incidence of pertussis in infants less than six months of age was 111 cases per 100,000 population; for infants six to eleven months of age, the incidence declined to 19 cases per 100,000 (CDC, 2008a). The majority of infant deaths have occurred among unvaccinated infants. There were 40 pertussis-related deaths in 2005 and 16 in 2006. Of these deaths, 39 (98%) occurred in infants during 2005 and 14 (88%) in 2006 (CDC, 2008a). At increased risk for pertussis mortality are Latino infants, infants born at less than 37 weeks gestation and babies who are born at low birth weights (CDC, 2008a). The development and maturity of the infants' respiratory system in premature and low birth weight babies has an obvious impact on their ability to cope with an insult to the lungs, such as in whooping cough, however the reason for greater risk among Latino infants remains unclear.

Evidence shows that infants are at greatest risk for infection from family members and close contacts. Household members, relatives living in the infants' home and care givers who are susceptible to pertussis may become infected and potentially transmit infection to the child (Gerbie & Tan, 2009). The most frequent source of pertussis infection in infants was found to be the baby's mother, with transmission likely due to the close and prolonged contact between mother and child, especially during feeding times (Wendelboe, et al. 2007).

Pertussis disease remains a major health problem, primarily due to waning immunity in those previously vaccinated, the lack of a safe and efficacious vaccine for adults – prior to 2005, missed diagnosis of cases by providers, and the prolonged length of time for uptake of new vaccine biologics to become widely dispersed in communities. Professional organizations have developed recommendations for a “cocooning strategy” for pertussis immunization, figuratively wrapping the infant within a protective cushion of immunization. The strategy counsels that Tdap vaccine should be administered to parents, siblings, grandparents, care-givers, and health care workers in contact with newborn babies. The Advisory Committee on Immunization Practices (ACIP) and the American Congress of Obstetricians and Gynecologists (ACOG) are endorsing Tdap immunization of new mothers in the birthing facility as the Standard of Care (Appendix A).

Standing Orders

In 2000, ACIP published recommendations for standing order programs as a method of increasing immunization rates among adults (Centers for Disease Control, 2000). The Committee encouraged the introduction of standing orders in non-traditional areas such as outpatient and inpatient hospital settings, managed-care organizations, assisted living facilities, correctional facilities, pharmacies, adult workplaces, and home-health care agencies (CDC,

2000). ACIP also recommends that Tdap vaccine be administered to adolescents and adults who have contact with young children and to women of child bearing age during routine pre-conception health care visits or during the immediate post-partum period (CDC, 2008). Thus nurses caring for patients in birthing facilities are uniquely positioned to provide expanded access to pertussis protection via the implementation of standing orders for Tdap immunization in the post-partum hospital setting.

In Massachusetts, the Board of Registration in Nursing (BORN), under the Executive Office of Health and Human Services (EOHHS) regulates the use of “Standing Order Protocols” (SOPs) for administration of vaccines as an aspect of nursing practice. In 1998, the BORN issued a regulatory interpretation advising that licensed nursing professionals in the Commonwealth may administer immunizing agents under standing order protocols (Appendix

B). Under the provisions of standing orders the nurse must undertake the following steps:

- verify that the standing orders are signed by a duly authorized prescriber;
- be educated in proper storage and handling of vaccine biologics, administration; contraindications, adverse event reporting, and documentation.
- comply with federal and state laws in regard to record keeping;
- provide client education on the risks and benefits of accepting or refusing the immunizing agent;
- document a process of informed consent, reflective of the required educational materials;
- complete an assessment of the client’s condition in relation to history of allergies prior to immunization;
- be knowledgeable about access to emergency services, devices and techniques in the event of adverse reactions and;

- obtain parental consent in the case of vaccine administration to minors, in compliance with federal, state and local statutes.

Current clinical problem

Issel points out that when data are collected at the aggregate level, for example, in a pre-intervention environment, this helps to establish baseline data (Issel, 2009). The National Immunization Survey (NIS), the Behavioral Risk Factor Surveillance Survey (BRFSS), and the National Health Interview Survey (NHIS) have added Tdap coverage to their surveillance assessments of immunization status. Since Tdap vaccine for adults was only recently licensed (i.e. 2005), many facilities, including most birthing facilities, are not yet in the habit of gathering Tdap immunization information.

MDPH will conduct the second portion of a statewide CDC birth hospital survey this spring, including audits of birth records from 2008 deliveries. The first part of the birth hospital survey was conducted last year that consisted of policy reviews within the 48 birth hospitals and 2 free-standing birthing facilities. The initial survey in 2009 was designed to elicit information regarding the implementation of ACIP recommendations for the birth dose of hepatitis B vaccine and post-exposure prophylaxis for babies born to HBsAg+ mothers. It also queried facilities on the use of standing orders for influenza and Tdap immunization. Of the fifty birthing facilities in the Commonwealth, eleven of those sites report having a policy for Tdap immunization in place (Mary Conant, MDPH Deputy Immunization Program manager, personal communication, August 3, 2009). The current record review will in part assess which facilities are routinely screening for and documenting Tdap immunization status of women presenting for delivery in the hospital setting providing baseline data for the state immunization program.

Barriers to Immunization

A recent review of adolescent and adult immunization issues in Massachusetts found significant obstacles to vaccination in these populations. In adolescents, several factors, primarily financial in nature, were found to present barriers to immunization. Limited availability of state supplied (“free”) vaccines and lack of comprehensive insurance coverage for immunization were common problems. In many instances where coverage was available, inadequate reimbursement to the provider for the cost of administering vaccines and a lack of reimbursement for vaccines administered outside of the primary medical home were disincentives to immunization. A lack of measurement of adolescent vaccination coverage at the provider level, and the current lack of K-12 school requirements for Tdap were cited as challenges to increasing immunization in this age group (Lazorik, Hoffman, & Fuchs, 2009). For adults, misconceptions among providers about the burden of pertussis disease, hesitancy related to vaccine safety on the part of patients and providers, and a lack of comprehensive coverage for immunization are all factors adversely affecting the provision of Tdap (and other) vaccines. Missed opportunities to assess immunization status and administer immunizations in all health care settings were found to be problematic in both adolescent and adult cohorts (Lazorik, Hoffman, & Fuchs, 2009). This is exacerbated in the some areas of the state which are federally designated medically underserved areas (MUA), further limiting opportunities for adults to receive medical care and preventive services.

Access to Immunization

A clinical review of pertussis infection in the United States concluded that Tdap immunization could have a substantial positive impact on pertussis morbidity and mortality, if vaccination was widely administered (Brooks, & Clover, 2006). A systematic review of population-based interventions to improve vaccination coverage found that the positive effects of

immunization standing orders had been demonstrated in a range of settings including private practices, community hospitals, and academic clinical organizations (Shefer, et al, 1999). Studies have demonstrated increased vaccination rates for influenza and pneumococcal disease through the use of standing order programs (Dexter, Perkins, Maharry, Jones, & McDonald, 2004); one study also found that the increases in immunization rates were sustainable over a ten-year period (Nichols, 1998).

Even prior to the licensure of Tdap vaccine, it had been suggested that a possible approach to expanding access to adult immunizations was to increase the number of sites where patients could obtain needed vaccines (Bergus, Ernst, & Sorofman, 2001). Subsequent to the introduction of Tdap vaccine, in a monograph on the implementation of immunization best practices for special populations, a case study summarized that initiatives for in-patient standing orders for post-partum immunization of newborn mothers had the potential to significantly benefit both mothers and infants by reducing the incidence of pertussis infection (Steele, 2008).

Using birthing facilities as a location to implement standing orders for Tdap vaccine would improve access to the immunization for new mothers. Immunizing post-partum women will also raise awareness of the need for immunization within the family. This may lead to wider uptake of the vaccine which would help to build community or herd immunity. This would ultimately lead to a favorable impact on the prevalence of pertussis morbidity.

Vaccination is increasingly becoming a regular component of services in the hospital setting as evidenced by the more recent implementation of systems to assess for influenza and pneumococcal vaccination during acute care stays. Traditionally, new mothers have been assessed for rubella immunity, with MMR vaccine being routinely administered to susceptible women. Universal Hepatitis B immunization of newborns has also been in place for nearly two

decades. Assessing and immunizing against pertussis at the hospitals birthing unit may be modeled after protocols for influenza, pneumococcal, hepatitis and MMR vaccines. Making Tdap vaccine available in the birthing facilities would level the playing field of access to immunization for all new mothers including those who have adequate prenatal care and those who do not.

Vaccination of Adults

The nation has a long history of providing immunizations to its children including some of the first legislative efforts to make vaccine available dating back to the provision of polio vaccine in the 1950's. As recounted in *Poor People's Medicine* (Engel, 2006) health legislation, including that for immunization, evolved over time into a hodgepodge of laws and regulations, often starting with "deserving" groups such as children and later expanding to provide benefits to other "at risk" populations. In more recent times, legislation has funded the federal Vaccines for Children (VFC) entitlement program; there is no such corresponding program to fund vaccines for adults. Funding for adult vaccines such as Tdap is subject to the adoption of a new vaccine for coverage by the individual state Medicaid system or by third-party payers. Since there is no national policy for adult immunization or corresponding legislation, the availability and provision of vaccines to adults has also resulted in a mixture of funding coverage and services as evidenced by our corresponding survey of Tdap coverage by Massachusetts health insurance plans. Some insurers provide full coverage for immunizations, some afford partial coverage (resulting in a cohort of 'under-insured' adults) and some provide no coverage for vaccines. As a consequence, some adult providers do not make vaccination services available in their offices; this is often a problem with newer vaccines such as Tdap.

Financial Impact

The economic burden of pertussis infection is estimated to be substantial with direct costs including the need for hospitalization to treat pertussis-related complications. One study found that costs for hospitalization in children under 24 months of age were projected to be approximately \$3,000 per case escalating to about \$6,000 for treatment of pertussis related encephalopathy (Greenberg & Caro, 2005). Societal costs of morbidity for adults (≥ 18 years of age) with confirmed pertussis were found to be \$773 with a mean of \$326 for medical costs and an additional \$447 for non-medical costs (Lee, et al, 2004). Medical costs in that study included physician visits, chest radiography, laboratory tests such as culture, serology and PCR, and the cost of antibiotics to treat the infection. Non-medical expenses included the costs of associated child-care, transportation, and OTC preparations (Lee, et al, 2004). Since pertussis cough symptoms may present similarly to other cough and respiratory illnesses, patients may make up to two or three trips to a clinician for an accurate diagnosis (DeSerres, et al., 2000). In Lee's study, non-medical costs represented 58% of the total cost burden in adults. If the cost of antibiotics to treat contacts were included, the societal cost could run as much as \$1952 per case, given an average of 4.3 contacts per case (Lee, et al, 2004).

In a paper describing the cost of nosocomial pertussis in an outbreak amongst health care workers in a tertiary health care facility, the total measured cost was \$81,382 associated with exposure to one confirmed case of pertussis in an infant (Calugar, Ortega-Sanchez, & Tiwari, et al, 2005). Seventeen symptomatic cases among health care workers and some 307 contacts of those HCWs required antibiotic prophylaxis. The contacts included other patients, household members, and students. The largest direct cost was for laboratory testing and surveillance activities designed to contain the outbreak. The largest indirect costs resulted from furloughs of infected workers (Calugar, Ortega-Sanchez, & Tiwari, et al, 2005).

The Program Evaluation

The Centers for Disease Control and Prevention has provided a number of documents to guide program evaluations. This capstone experience utilized the Framework for Program Evaluation in Public Health (CDC, 1999) and adapted elements of the Guide to Immunization Program Evaluation for Grantees (CDC, 2007). Both the Framework and the Grantee guide begin by outlining the steps of program evaluation listed in Table 1 and the progression of evaluation steps as depicted in Appendix D.

Program evaluation is a systematic method of evaluation. It is a tool that can assist in promoting change when adjustments or modifications to programs are necessary or to support the introduction of a new course of action. Program evaluation summarizes the essential elements of the program, provides structure to the assessment, and incorporates the use of standards for appraisal. The steps of change - unfreezing, changing and refreezing – may be thought to mesh with the steps of program evaluation. For example, unfreezing may acquaint with engaging stakeholders and program description, changing may be aligned with gathering the evidence and justifying conclusions during the evaluation and refreezing may be seen to happen when lessons from the program evaluation are shared and used.

Table 1. *CDC’s Framework for Program Evaluation Steps.*

Step	Actions
1	Engaging stakeholders
2	Describing the program
3	Focusing the evaluation design
4	Gathering credible evidence

5	Justifying conclusions
6	Ensuring use and share lessons learned

The Program Evaluation Site

The program evaluation site is best described as an academic, research, and teaching hospital serving as a campus for a large medical school. It is a Level 1 trauma center and is designated as a Magnet hospital for nursing excellence by the American Nurses Credentialing Center (ANCC). The medical center houses 659 beds in the flagship facility with some 57 bassinets. It provided for approximately 46,000 patient stays and welcomed about 4500 new infants last year. It is employer to almost 10,000 employees. The hospital was chosen for the size of its birthing center, its national reputation as one of the Top 100 Hospitals in the Nation, and its promotion of quality of care and recognition of the importance of nursing in the healthcare arena.

Engaging stakeholders/ Unfreezing

The initial process, engaging stakeholders at the study site began with identifying key participants for the Tdap immunization project. These individuals included the Director of Maternal-Fetal Medicine, the Clinical Coordinator of Labor, Delivery, Recovery and Post-partum units, the Nursing Director of Women’s and Infant’s Services, and the Assistant Director of Pharmacy. These team members satisfied the tenets of the framework seeking to involve those who would be critical to program operations and the primary users of the evaluation. At the initial meetings, the role of each person in the evaluation process was identified in Table 2.

Table 2. *Evaluation Team Roles and Responsibilities.*

Role	Responsibility
Director of Maternal-Fetal Medicine	Oversee the program evaluation
Clinical Coordinator of LDRP	Main contact for technical aspects of the program evaluation.
Nursing Director of Women and Infants Services	Identify and coordinate interviews with additional personnel
Assistant Director of Pharmacy	Coordinate aspects relate to product provision

Although the Medical Director represented the ultimate decision maker for the implementation of Tdap standing orders, these participants identified other relevant stakeholders to the process -implementers, physician participants, and partners - for developing an immunization program.

Describing the Program/ Unfreezing

The second step in the program evaluation is to describe the project. The overall goal of the project was to determine the feasibility of implementing a post-partum Tdap immunization order within the birthing unit of the Medical Center under study; the primary goal and objectives for implementing Tdap immunization orders are shown in Table 3.

Table 3. *Describing the aims of the project.*

Goal	Provide Tdap vaccine in the maternity unit
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Objectives	<ol style="list-style-type: none"> 1. Institute assessment of Tdap coverage for pregnant women as part of prenatal screening. 2. Develop a program for Tdap immunization before discharge. 3. Undertake educational programs for: obstetricians, OB residents, nurse midwives, nursing staff, mothers & families
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CDC’s Evaluation Framework suggests that a program description include: the need, expected effects, activities, resources and stage of development, and context of the program, concluding with a summary of the elements into a logic model. The hospital's mission is “to improve the health of the people in communities every day, with quality and compassion”. In keeping with that mission, implementing standing orders for Tdap vaccine utilizes the window of opportunity to immunize women while they are in the birth setting. It levels the playing field of access, utilizes protocols already in place for influenza, rubella, and hepatitis vaccinations, and occurs as medical centers across the nation begin to implement the protocol as the standard of care promoted by nationally recognized authorities. The logic model, in Appendix E, developed over the course of the evaluation lists inputs to the program, activities, measurable outputs, and short term, intermediate and long term outcomes. Inputs to the logic model are the elements of staff and materials that would be necessary to undertake the program, activities include the actions taken in preparation and the behaviors of the program, the term output denotes the measurable ‘harvest’ of the activities, short term outcomes indicate the immediate product, intermediate outcomes are the further results of the program, long term outcomes are the ultimate goals of the project.

Table 4 displays the issues related to administration of Tdap vaccine that were identified by the program evaluation questions. The questions developed during the initial stage of meetings, helped to center specific aspects of the issue that will be weighed and hopefully help to concentrate the findings into a consensus of recommendations. The answers to the program evaluation questions were elicited during interviews with maternity nurses, infection control staff, pharmacy personnel, nurse midwives, and from experts consulted for the external review panel.

Table 4. *Guiding the focus of the program evaluation.*

What problem does this program component address?	lack of pertussis immunization
What causes the problem?	myriad issues: lack of immunization service from adult providers, lack of adult primary care providers, misunderstanding of the burden of disease
What are the consequences of the problem?	reservoir of pertussis infection, propensity for transmission to newborn infants
What is the magnitude of the problem?	increased morbidity and severity among infants
What changes or trends have occurred?	increasing pertussis incidence over the last two decades

There is a gap in uptake of pertussis-containing vaccine in adult cohorts and some adolescents, especially among women of child-bearing age. Multiple issues have been identified as problems in adult vaccination programs, such as 1) limited availability of state supplied (“free”) vaccines; 2) lack of comprehensive insurance coverage for immunization; 3) inadequate reimbursement to the provider for the cost of administering vaccines; 4) misconceptions among providers about the burden of pertussis disease; 5) hesitancy related to vaccine safety on the part of patients and providers; 6) missed opportunities to administer immunizations in all health care settings (Lazorik, Hoffman, & Fuchs, 2009).. These issues were found to be problematic in both adolescent and adult cohorts (Lazorik, Hoffman, & Fuchs, 2009). The consequence of low pertussis-containing vaccine coverage is the pool of infection existing in the community permitting transmission to susceptible infants. The magnitude of the problem is demonstrated by the impact of morbidity and mortality on newborns with the trend for pertussis increasing over the past three decades. Other issues related to this population were identified during the evaluation process. For example, many women of child –bearing age are considered to be in the prime of health and thus do not seek out regular health care visits with health care providers. Once a woman becomes pregnant, it is has been stated that the obstetrician becomes the defacto primary health care provider. Another issue pertinent to areas that are considered to be “medically-underserved areas” (MUA), is that there is a lack of primary providers. The local community health centers (CHCs) report that patients may encounter waits of up to several months for routine health care visits, and often have little choice of providers who are ‘accepting’ new patients. These factors coupled with an infectious disease on the rise, creates a “perfect storm” that threatens the health of newborn infants.

Focusing the evaluation design

“Program evaluation remains more an art than a science”, (Burns & Grove, 2005). There are two basic designs of program evaluation, those seeking to answer process questions and those seeking to define outcomes. Thus, this program evaluation sought to examine in-hospital immunization and the feasibility of making Tdap vaccine available in the women’s unit. The CDC guide presented suggested standards for focusing the program evaluation: utility and feasibility. In term of utility, Table 5 served as a worksheet identifying who will use the evaluation findings; how they will be used; and what they need to learn from the evaluation, (CDC, 2007). With regard to feasibility, the evaluation solicited information regarding identification of the resources necessary to carry out the program; What new educational materials might be needed?; What community partners (e.g. outpatient clinic staff, vaccine representatives) would be necessary to engage?; Will additional staff training be necessary?; Will it be necessary to write additional policies?; and What outreach efforts will be needed?

Table 5. *Focusing the Evaluation Worksheet.*

Who will use the findings?	What do they need to learn from the evaluation?	How will the findings be used?
Obstetrical staff	Does the program staff have the requisite knowledge to implement the program?	Justify the need for such a program?
OB Residents		Identify a timeline for program activities
Nurse Midwives		Identify midcourse alterations to the program.
Nursing staff	What are the funding issues related to the program?	Modify/identify additional program needs (e.g. future
Pre-natal clinic staff	What barriers exist to implementing the program?	
	How will the program measure	

	<p>performance? What outreach/educational efforts will be required to implement the program?</p>	<p>educational needs) Advocate/promote the program component in the community</p>
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The program evaluation design consisted of individual interviews, group dialogues, attendance at regularly schedule meetings, review of documents and policies, and the use of an expert review panel. The project began with an initial identification of participants, but was an iterative process in that as the project progressed, additional participants and pertinent meetings were identified. During each meeting and interview, roles of the participants were identified. At the end of each meeting tasks were identified and responsibilities assigned to members. The course of the in-hospital program evaluation included clinical nurse managers from maternity and neonatal units, medical and nursing administration from obstetrics, obstetrical nursing informatics liaison, hospital infection preventionists, quality improvement staff, pediatric infectious disease physicians, the pharmacy department, the emergency department director, financial managers, and ethics committee members.

The purpose of the interviews and meetings was to gain insight into the perspective for an identified need, the abilities of each individual member or group of members, and the necessities for a Tdap order to be implemented. At each step barriers and facilitating factors were brought up and discussion included measuring the fundamental effect of the program. Discussion also included the aspect of practice change necessary to incorporate a new standard of care to refine services already in place.

The interviews found that there were three main areas of concern for implementing a new treatment: education, logistics of Tdap immunization, and cost. Educational needs were identified for the various stakeholders to the program: the obstetricians, the OB resident staff, nurse mid-wives, the nursing staff and ultimately the patients. Logistical concerns included questions over contraindications for Tdap vaccine, the issue of simultaneous administration with other products such as Rhogam®, informed consent to vaccination and documenting the immunization in the EMR. The issue of cost was of great concern. Discussion centered on potential reimbursement for vaccination from third party payers and the availability of funding for vaccination in the hospital setting.

Gathering credible evidence/ Changing

Evidence in this program evaluation took many forms. Standards for conducting adult immunization programs in non-traditional settings, listed in Appendix F, were utilized both for the program evaluation and to determine if any gap existed (CDC, 2000). National and state statistics for Tdap vaccine coverage were collected, as was data on the number of births at the site, the reported reimbursement coverage for Tdap immunization by Massachusetts health care plans and the availability of state supplied (“free”) vaccine.

The Centers for Disease Control requires the all vaccinees be provided information on the risks and benefits of vaccination. To facilitate and standardize the informational process, CDC develops educational material in the form of Vaccine Information Statements (VIS forms) that are made electronically available at the CDC website (<http://www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm>) and the Immunization Action Coalition website (www.immunize.org). The VIS forms satisfy federal and state (Commonwealth of Massachusetts) educational requirements under “Duty to Warn” provisions. There are no federal or state “informed consent” or signature

requirements for vaccine administration. The development of VIS forms by the CDC ensures that information in current, the Tdap VIS in Appendix G was most recently updated in November of 2008, and that they are culturally and linguistically appropriate. VIS forms are available in multiple languages and are formatted for a fifth grade reading level. VIS formats are also available in an audio format for ease of technology use. The implementation of this standard was already familiar to the nursing staff at the facility due to the long standing universal provision of hepatitis B vaccine to newborns, the provision of MMR vaccine to rubella-susceptible women, and the more recent hospital protocols making influenza and pneumococcal vaccines available to hospitalized patients. In the study hospital, Maternity nurses are well versed in obtaining current VIS forms and forms in various foreign languages and the provisions for educating patients by reviewing VIS form information. This is most commonly done for the birth dose of hepatitis B vaccine for newborns but was also carried out with regularity for H1N1 influenza vaccination in recent months.

At the facility, the maintenance of biologic supplies is overseen by the Pharmacy Department. The vaccine platform in this hospital is held by the GlaxoSmithKline (GSK) vaccine manufacturer. During the program evaluation, discussions were facilitated between the pharmacy department and the local GlaxoSmithKline (GSK) vaccine representative. Plans for a prospective Tdap initiative at the site were conveyed to the two national distribution centers McKesson and Cardinal, via the GSK representative, (John Crowley, personal communication, February 11, 2010). The effect of the notification is that the medical center is now able to order additional doses of Tdap vaccine as needed without potential delays within the ‘just-in-time’ supply chain.

The Pharmacy department has policies in place for maintaining the proper storage environment for vaccine biologics to maintain their potency and effectiveness; for inactivated vaccines, this generally means refrigerated storage between 2 – 8 ° C. The hospital currently maintains supplies of a number of vaccines – hepatitis B, varicella, influenza vaccine, pneumococcal, MMR, Td and Tdap. To ensure that the cold chain is maintained, the study hospital requires nursing units that provide vaccines record temperatures twice a day as per federal guidelines for compliance with vaccine storage practices and the various manufacturer provisions listed in the individual package inserts of vaccine products. The proper handling of Tdap vaccine, while a new addition to the biologics offered within the nursing unit, mimics the storage provisions of other inactivated vaccines such influenza and pneumococcal vaccine, requiring refrigerated storage (as opposed to frozen storage) which were utilized throughout the flu season and the on-going provisions for hepatitis B and MMR vaccines.

Standards require obtaining an immunization history from the client prior to immunization. The ideal situation would be one where every client was fully aware of their immunization status and in possession of immunization records. This is often not the case with adults in general and not in the study hospital. Many are unaware of their own vaccination status and fewer carry adult immunization records. One perceived barrier identified during this program evaluation is the fact the state of Massachusetts does not have an immunization registry. Legislation is pending within the legislature of the Commonwealth that addresses funding of an immunization registry (see discussion under Health Plan Survey). ACIP recommendations state Td vaccine boosters are usually recommended every ten years and that a shorter interval of five years is utilized for wound prophylaxis (CDC, 2008). ACIP also recommends that with respect to pertussis protection, intervals of five years from the last tetanus booster, lessens the potential

for localized reactions such as redness or swelling after vaccine administration. Importantly, ACIP states that for post-partum mothers or others having contact with young infants, an interval of two years or less since the last Td booster, be considered. Educational efforts with all cohorts at this facility, obstetrical residents, nurse-midwives and nurses included discussion of the timeframe of licensure of Tdap vaccine (i.e. 2005) and the interval since a patient's last Td immunization. It is hoped that when discussing whooping cough immunization in a relatively young relatively healthy population, that clients may have some awareness of whether or not they received a vaccination against tetanus within the last five years. In particular, if a client expresses that they had a tetanus booster seven years ago, for example, the provider can feel somewhat certain that the vaccine was the pre-licensure Td product. More questions would arise if the client stated that they had been vaccinated in the most recent five year period. Ultimately, ACIP advises that in the absence of documentation, the benefit of pertussis protection outweighs the smaller risk of vaccine side effects (CDC, 2008 & 2000) and that vaccine is recommended. Recommendations for best practice would include promoting awareness of adult immunization through the provision of adult immunization cards documenting vaccine administration dates similar to the "Blue Book" of infant immunization. This hospital does not routinely provide for documentation of adult immunizations provided in the facility. Instituting this practice would improve communication between the acute care setting and the medical home.

In general, assessment of the vaccinee recipient is conducted by the health care provider who will administer the vaccine, with the criteria for immunization set by the provider. In order to implement Tdap immunization in the birthing unit of this facility, a nursing policy for administration of the vaccine would need to be developed. Nursing policies typically set out the criteria for immunization which would include the true contraindications and precautions

pertinent to the vaccine. While there is no policy specifically for Tdap currently in the study hospital, there are policies for rubella and varicella administration and one of those could be easily adapted for Tdap vaccine administration. The educational effort for the nurses would need to include identifying misconceptions to vaccine administration and mistaken beliefs about Tdap vaccine which would provide strength to the nursing assessment prior to immunization

All immunizations in the study hospital are documented in the patient's electronic medical record (EMR). One difficulty was identified within this system. The Obstetrical unit utilizes a separate electronic medical record, PeriBirth (formerly E & C), from the EMR utilized throughout the rest of the medical center, CIS. This is due to the features available in PeriBirth that are useful in documenting the course of pre-natal, delivery and post-partum care. The PeriBirth and CIS systems do not have a direct interface, a common problem in the realm of healthcare informatics. Although the data from PeriBirth and CIS are accessible to personnel all through the hospital, they must be accessed separately. The practical implication is that a post-partum Tdap immunization would need to be entered into each database. Both systems are in keeping with the federal guidelines for compliance capturing the date the dose was administered, the person and credentials of the vaccine administrator, the lot number and expiration date of the vaccine, the dosage, site and route of administration, the date the Vaccine Information Statement (VIS) was provided and the publication date of the VIS. The electronic systems have an on-line history at the facility of about three years; formerly the hospital kept paper records which are maintained for a period of at least thirty years, as mandated by law. Thus if a patient recently received a Tdap immunization in the emergency room at this site, the documentation would have been recorded and accessible to staff of the Women's Unit (Dr. John Santoro personal communication, February 1, 2010).

Standards also delineate the qualifications for vaccine administration. This is perhaps the easiest to abide by within the hospital setting as only registered nurses (RNs) or licensed practical nurses (LPNs) may administer medications. Unlike the office setting where medical assistants may administer under a physician's license, only professional personnel act in this capacity within the acute care setting. In this hospital, certain vaccines are maintained on the nursing unit as stock for administration, such as influenza vaccine. Other vaccines that are used less frequently are maintained in the pharmacy and delivered to the nursing unit within about 2 hours of ordering the biologic. Nursing and pharmacy staffs at this facility agree that with respect to Tdap administration, it would be appropriate to stock the vaccine on the maternity nursing units .

The need for treatment of potential adverse events is also facilitated by the hospital environment due to the proximity to multiple personnel and equipment that may not be available in non-hospital sites. In the project hospital, as in most hospitals, each patient unit is equipped with a "crash cart" with resuscitation equipment and medications to treat anaphylaxis; nursing personnel are trained in CPR and there are a multitude of disciplines providing for rapid response to emergency events ('codes'): respiratory therapists, anesthesiologists, IV therapists, lab personnel as well as nursing and resident physicians. The study site meets all of the standards relating to providing immunizations in non-traditional settings (i.e. hospitals). This represents a major facilitating factor to implementing Tdap standing order in this medical center.

National and State statistics

Data collection for this program evaluation included reviewing published national and state statistics for Tdap immunization coverage from the National Immunization Survey (NIS), the Behavioral Risk Factor Surveillance Survey (BRFSS), MDPH Immunization Program

Summary of Immunization Level (i.e. schools and colleges) Surveys, National Health Interview Survey (NHIS), and Massachusetts birth hospital survey findings.

Data identified from both the National Immunization Survey and the Behavioral Risk Factor Survey has demonstrated disparities in uptake or coverage of the Tdap vaccine.

Adolescent uptake has increased over time and continues to improve across the Commonwealth.

The proportion of teens, aged 13 to 17, immunized with one dose of Tdap vaccine increased from 30.4% to 40.8% from 2007 to 2008 (CDC, 2008b). The Massachusetts Department of Public Health found that of the 81% of eligible children receiving a tetanus booster required for entry into 7th grade, 60% of adolescents Tdap vaccine (unpublished summary of school immunization survey levels, 2008-2009 school year). Within the college-aged population, coverage is much lower as evidenced in Table 7.

Table 7. MDPH Annual School and College Immunization Survey 2008-2009.

Level	Td	Tdap
All College age students	82.55%	6.48%
Undergraduate	82.82%	7.01%
Health Science students	87.46%	8.73%
Health Science Graduate	79.08%	2.96%

National Immunization Survey (NIS) data from 2007 reveals that uptake of the new Tdap vaccines among all adults in the two years since licensure was slow, only 2.1% in all groups (CDC, 2008b). At the current time, the gap in vaccine uptake appears to be greatest within older adolescent and adult cohorts.

In the study hospital, currently there is no system in place to assess Tdap coverage. One of the program recommendations is for the hospital and its' associated women's clinic to begin routine assessment and documentation of Tdap immunization of all women.

Financial Considerations

The study hospital reports approximately 4,000 – 4,300 births annually over the last few years as shown in Table 6.

Table 6. *Annual births reported at the Project Hospital.*

Year	Deliveries
2007	4,323
2008	4,180
2009	4,253

The area sees a high percentage of births in the adolescent age group. Springfield has been reported to have the second highest teen birth rate in the Commonwealth according to a MDPH report on Massachusetts births 2007 at 84.3/1,000 (MDPH, 2009). This figure is close to four times the state rate of 22/1,000 births. Teen births account for roughly one-third of the overall number of deliveries at the study site (Molly Gray RN MSN, personal communication, February 19, 2010) and as previously mentioned, waning pertussis immunity represents a potential threat for transmission to infants.

Massachusetts surveillance data has found the incidence rate of pertussis per 100,000 persons was highest in the age group less than one year of age. In 2007, the incidence rate was 103.8 and in 2008 it was 66.7. The overall incidence for all age groups in those two years was 18.8 and 12.1, respectively (N. Corcoros, personal communication, January 12, 2010). Since the

beginning of the evaluation project, two infant cases of pertussis were identified in children who were born in the hospital under study.

Eleven sites responding to DPH during the course of a recent policy analysis had a procedure in place for post-partum Tdap administration. Each of these sites was contacted for an interview to ascertain whether the facility had developed a written policy for vaccine administration and the format of the protocol - either a generalized standing order or a physician directed order. Six sites truly had a procedure in place, although none had yet developed a written policy for administration. The other five sites were actually still in the process of developing Tdap orders.

When queried about the issue of financial reimbursement with the facilities already promoting Tdap vaccine, each of the hospitals indicated that there have been no financial repercussions following the implementation of the new policy. Several organizations mentioned that promoting a Tdap policy was in keeping with the mission of the hospital to provide the best care for the mother. One maternity unit nurse manager remarked to me, "It is essentially the right thing to do".

One potential cost of an indeterminate nature is that of possible litigation if a facility was to be found negligent in not providing the standard of care. During the course of the program evaluation, two babies born at the study hospital were identified as having contracted pertussis. While the aspect of potential liability was raised, it was not a main focus of the financial considerations.

The provision of vaccine by the Massachusetts Department of Public Health to providers who serve adolescent populations will have a financial impact on the Tdap program at the project hospital. There currently is no corresponding program providing vaccine comprehensively to

adults as does the federal entitlement Vaccines for Children (VFC) funding. MDPH's Childhood Vaccine Availability Table (effective November 1, 2009, attached) affirms that Tdap vaccine is provided for all children through eighteen years of age, regardless of insurance status, particularly:

- Adolescents at 7th grade entry (11 - 12 years of age).
- Catch-up immunization of all 13 - 18 year olds.
- Children 10 - 18 years of age who have been exposed to pertussis or in an outbreak setting.

Catch up immunization of all thirteen to eighteen year olds would include young women falling into that age category who present for delivery at the hospital under study. Provision of state supplied ("free") Tdap vaccine doses to mothers who are under nineteen years of age would effectively reduce the overall number of doses that would need to be purchased in order to implement Tdap immunization in the birthing unit by approximately one third.

Health Plan survey

In an unpublished survey of some of the major third party payers for healthcare in Massachusetts, approximately fifteen major carriers provided feedback on Tdap coverage. All insurance carriers indicated that their plans provided for reimbursement for the cost of Tdap vaccine as well as administration costs associated with vaccination to their participants. Information on the specific amount of reimbursement provided by each company was considered proprietary between carriers and their contracted providers. The attached chart in Appendix H shows a compilation of responses to questions regarding reimbursement settings. All of the respondents indicated that Tdap immunization would be covered in the birth setting. There appeared to be some conflict in responses to whether the plan included reimbursement for Tdap

as part of the global reimbursement fee for delivery and its coverage in the birth setting. Further follow up was necessary to determine the specifics of coverage. Eight health plans indicated that it is not currently included; six indicated that it is included and one responded “maybe” (indicating that Tdap is included for payment by that carrier, if the particular birth hospital is a contracted provider with that company).

What does this mean in financial terms for instituting a Tdap immunization program at this hospital site? There are two potential implications. The first is related to providers who do not include Tdap as part of the reimbursement. The Managed Care Accounts department could undertake discussions negotiating remuneration with those carriers originating from institution of an added service - Tdap vaccination. This added service would be based upon Standard of Care recommendations published by recognized authorities and professional organizations (i.e. Advisory Committee on Immunization Practices, American Congress of Obstetricians and Gynecologists, formerly American *College*). The second implication relates to providers who do currently include Tdap as part of the global delivery fee. Similarly, remuneration would have to be re-negotiated with each carrier based upon the establishment of a new service to the spectrum of care normally provided during delivery thereby increasing the cost per delivery. Some carriers who responded to whether Tdap vaccine would be covered in the birth setting as “no” Tdap was not included as part of the reimbursement schedule for delivery were contacted for clarification of their answers. Several carriers indicated that Tdap would be a covered expense; however it would have to be billed separately.

There is also pending legislation that would greatly aid in implementing the standard of care for Tdap immunization in the birth setting. Two Senate bills, S859 and S470, and one House bill, H3453 would provide for “first dollar coverage” of vaccine purchases and 100% of

the reasonable and customary charges for associated with administration of vaccines in all health care setting and provide funding for a statewide immunization registry. Senate bill 859, drafted by Senator Richard Moore was referred to the Joint Committee on Public Health in January of '09, the House concurred and a hearing was held in September of 2009. Ms. Fargo's Senate bill 470 was referred out of the Senate, with the House concurring, to the Joint Committee on Financial Services. The bill presented by Alice Wolf in January of 2009, House 3453, was referred to the Joint Committee on Health Care Financing, with the Senate concurring. I met with State Representative John Scibak in mid-February and learned that these three bills were recently reported favorably and redrafted into Senate bill 2195 which is now in the Senate Ways and Means Committee (John Scibak, personal communication, February 15, 2009). This legislation would alleviate the financial burden on hospitals in implementing the Tdap standard of care at birth. State employees are prohibited from lobbying on behalf of legislation; however the information about these proposals was made available to the team at the medical center so that their appropriate professional organizations (and/or individuals) could assist with legislative efforts by advocating for favorable consideration of anticipated laws.

Overall, the cost of instituting Tdap immunization in the post-partum setting was perhaps the most difficult one to ascertain and would essentially require lengthy and on-going financial analysis by the institution. It was challenging to try to obtain precise information for the program evaluation in terms of cost analysis. Conducting the health plan survey dealt with generalizable answers rather than specific responses related to patients for this hospital. The medical center also did not afford access to explicit details in terms of the numbers of patients covered by various third party payers delivering within their facility. Ultimately, final recommendations to

the organization incorporated a suggestion for the Pharmacy Department to work closely with Managed Care Accounts to delineate the incremental impact on operations.

External Reaction Panel

The use of an External Reaction Panel was a unique feature of the program evaluation. This feature was utilized by the AACN Task Force charged with examining the clinical doctorate or practice doctorate program. The strategy was embraced and applied to this capstone project, interviewing professionals outside of project facility inviting comments, perspectives, soliciting resources and insights, especially as my project related to an evaluation to determine feasibility for a new program. My panel consisted of 10 individuals with varying areas of expertise listed in Appendix J, representing a wide array of perspectives and disciplines. The dialogues with expert panel members afforded valuable perspectives.

In the consultation with the public health physician, she emphasized the fact that providing Tdap vaccine to susceptible women in the post-partum period is a standard of care as much as providing hepatitis B post-exposure prophylaxis to high risk infants born to HBsAg+ women. The maternity unit nurse manager of a competing hospital facility was able to outline the rationale for their institution to begin offering Tdap to new mothers and also to demonstrate the ordering system and the manner in which vaccine is provided to the maternity unit for ready access and ease of administration at a time prior to discharge. The nurse recounted that through the educational efforts of nurses throughout the family life center, an estimated 85% of patients availed themselves of the opportunity to become immunized. She also related the cultural issues involved for a number of their foreign born clients. Patients who immigrated to the United States from Russia, Somalia and some other locales are distrustful of immunization and eschew vaccination if it is not “required” by the government.

Two nurses provided practical perspectives related to the project. The first, a nurse educator in the National Immunization Program at CDC was able to provide contacts with hospitals in other states who have undertaken Tdap vaccine programs. Upon contacting those programs, it was noted that a number of them were grant funded from institutions like the Robert Wood Johnson Foundation. The funding issues were essentially the same as here in the Commonwealth, adult immunization programs lack a comprehensive source of funding similar to childhood programs and as a result must rely on a mixture of funding sources. Another insight gleaned from the out-of-state contacts is that most programs instituted vaccination programs first and wrote policies secondarily – if at all. Seemingly, “form followed function”. The second nurse, a clinical practice manager who was relatively new to office practice but with a long history of acute care experience was disturbed by what she saw as a lack of standardization among providers in office settings and among organizationally related office practices. Approximately two years ago, she set about to institute standard practices by developing an immunization manual for all project hospital-related offices which integrated immunization standing orders for all vaccines, including Tdap for adults. The response by providers has been overwhelmingly favorable.

Two interviews were conducted to gain perspectives on changing practice; both recounted the difficulties encountered in health care when practice changes are identified as being necessary. The nurse educator recounted stories about student projects involving examples of change in practice, change in knowledge and change in theory. She related her absolute belief in the power of nursing to connect with community needs and the value of nursing leadership in guiding and influencing change. She stated that linking actions to theory, operationalizing guidelines in a creative and assertive manner are keys to addressing gaps in practice and to multi-

disciplinary collaboration. A colleague in the DNP program described those same aspects of change required in her oral health Capstone project. Her project incorporated changes required in knowledge, addressed changes in the attitude of providers and the public, and necessitated changes in practice. She recommended an interesting book entitled the Policy Paradox (Stone, 2002) that highlights the issues of equity, efficiency, liberty, and security when advocating policy change. The topics of equity and efficiency were especially pertinent to this program evaluation.

I attended two presentations by colleagues at the Department of Public Health on initiatives for decreasing Hospital Acquired Infections (HAIs) and Serious Reportable Events (SREs). The focus on HAIs originated all the way back to the 1960s as a result of a staphylococcus aureus pandemic in the 1950s. It was interesting to note how often public health initiatives only result from profound events that are perceived to be serious enough to demand change in practice. Her presentation provided documentation of the decreasing crude death rate from infectious disease and the effects of changes in 21st century technology. The technology issue is especially pertinent to the topic of pertussis. Through laboratory analysis, research has been able to document the prevalence of waning immunity in previously immunized populations. Breakthroughs in vaccine manufacturing have capitalized on new technologies in the production of biologics to produce an acellular formulation of pertussis vaccine, one that is safe and effective for adults and produces minimal side effects. The second presentation highlighted the definition by the National Quality Forum (NQF) of hospital-associated adverse medical events divided into six major categories: surgical related events, product or device related events, environmental events, criminal events, and patient protection related events and care management related events. These last two categories are conceivably where hospital Tdap

initiatives might fall. The talk also stressed the importance of the topic within the scope of the national health care reform debate vis a vis reporting requirements enacted by individual states and federal and state regulations for reimbursement by health insurance carriers. Both presentations reaffirmed the shifting vantage point with respect to preventable medical problems and the national scope to raise awareness, promote transparency and motivate healthcare facilities to prioritize infection prevention. All of these factors could be linked to protection of infants through the promotion of pertussis protection of the mother.

Perhaps the most interesting discussion I had was with Commander Linder, USAF in talking about Cockpit Resource Management (CRM) initiative. Commander Linder who is a 27 year pilot recounted the atmosphere in flying 25 years ago where the Captain was akin to a God (perhaps similar to the era where the physician was like a God). Over the course of time, changes have occurred that created an environment which allowed for respectful communication among flight operations personnel that permitted to introduction of new or better information upon which to base changes in practice. This very successful model of leadership has been widely explored in recent years and touted as a methodology of improving performance in other sectors.

The external reaction panel served as a focus group to give me feedback and new direction to the program evaluation. It was a valuable learning tool and extremely informative during the program evaluation.

Justifying conclusions/ Changing

Standards reflect the value held by stakeholders (CDC, 1999). As previously cited, the hospital's mission is to improve the health of the people in communities every day, with quality and compassion. The consensus of the program evaluation was that instituting an immunization order for Tdap "is the right thing to do". The analysis and synthesis of information collected

demonstrated that the medical center may incur some costs especially at the beginning of the program. The values held by the participants assisted in deciding for immunization in keeping with the standard of care for which the hospital strives and would serve as a method of collaboration with other agencies in the larger public health fight against pertussis. Interpretation of the health plan survey showed itself as a forum for negotiating reimbursement for Tdap vaccine from plans not currently providing coverage and potential for re-negotiating increased reimbursement from plans already providing coverage for the immunization. Participants felt the worth of a Tdap immunization program to be almost immeasurable in terms of the immediate post-partum delivery period presenting a window of opportunity and the optimal time to immunize susceptible women and representing a significant chance for impacting the health of newborn infants.

The recommendation for implementing Tdap orders post-delivery also demonstrates a commitment to social equity in that all women would be afforded a chance to become immunized and protect their babies, not just the ones who have primary care physicians that choose to stock and administer adult vaccines. As of April 1st, an electronic prompt appeared in the electronic medical record (EMR) once a mother is identified as having delivered. The prompt reminds the provider about ordering Tdap vaccine for the newly delivered woman. The plan is to estimate the impact of the electronic reminder after a pilot period of two weeks before implementing a full standing order in the care set for post-partum women.

Ensuring use and sharing lessons learned/ Refreezing

Interviews with facility personnel identified educational needs for providers, residents, nursing staff, and for patients. While many of the obstetrical staff members were in favor of the idea of standing orders for pertussis, a few felt that pertussis was not a pressing enough issue to

warrant the effort or expense during a hectic hospital stay for the new mom and a demanding schedule for the nurses. Some providers were unaware of the requirements for documentation relating to vaccine administration, specifically the need for a signature of the patient or provisions for informed consent. It was suggested that a Grand Rounds presentation for providers in the obstetrical and pediatric units could help to address these concerns. An educational presentation was made in February for nurse midwives and another session is scheduled in April for Obstetrical Residents. These seminars review the epidemiology of pertussis, national guidelines for the standard of care relating to Tdap immunization, federal and state requirement for the ‘duty to warn’, documentation and the impact of a provider orders. Presentations will be made to the nursing staff to review the licensure properties of Tdap, administration recommendations, documentation and MA Board of Registration in nursing provisions and to the Women’s clinic staff emphasizing the need for promoting pre-conception immunization and documenting immunization coverage prior to delivery. All groups will be advised on the paramount importance of assessing Tdap coverage in all settings and the tremendous impact that professional advocacy for Tdap vaccination will contribute to the success of the initiative.

Program Evaluation Recommendations

Specific recommendations for project site

It was recommended that the medical center consider the application of “Sutton’s Law” to the issue of instituting Tdap standing orders for new mothers in the birth setting. The famous bank robber, Willie Sutton, when asked why he robbed banks, was purported to have answered, “Because that's where the money is”. In Massachusetts, it is documented that 97% of all births take place in a birthing facility. In terms of assessing the optimal point of impact for Tdap

immunization of new mothers, the obvious answer is the birthing unit, “because that’s where the mothers are!”

The formal recommendations to the hospital were to:

- Institute assessment for Tdap coverage for pregnant women as part of prenatal screening, recommending post-partum immunization for susceptible women along with recommending immunization to the father of the baby, siblings, grandparents and care givers in order to deploy the ‘cocooning’ strategy.
- Develop a program for Tdap immunization before discharge via standing orders as provided for by BORN ruling or a care set for individual providers to choose Tdap vaccine from a list of prescribed orders.
- Develop documents for screening patients before immunization for nursing staff to undertake proper assessment of indications and contraindications for vaccination utilizing the Tdap VIS form.
- Undertake educational programs for stakeholders: obstetricians and pediatricians, residents, nurse midwives, nursing staff, mothers and families.

The hospital was encouraged to utilize the resources available to them from the Department of Public Health in the form of state-supplied (free vaccine) supported with federal VFC funds. Strong collaborations were developed between DPH and the birthing facilities throughout the pandemic response in the fall, the Tdap initiative could capitalize on those partnerships.

A recommendation was also made for personnel from the Pharmacy and Therapeutics Committee and the Managed Care Accounting Department to further investigate the issue of

third party payer reimbursement for a more representative cost analysis than the generic health plan survey was able to offer.

In term of assessing the effects of an electronic reminder prompt, a physician directed order or an institutional standing order, measurements should be made after a pilot period of two weeks to ascertain any ‘glitches’ in the system. After that initial period, measurements should be taken after the first month (to assess whether a mid-course correction or alteration is required), quarterly and after the first year. Table 7 shows a potential chart for collection of data.

Table 7. *Tdap immunization data collection.*

	Pilot Period	1st month	1st quarter	2nd quarter	3rd quarter	4th quarter
Number of overall deliveries						
Number of susceptibles (minus women previously immunized with Tdap vaccine)						
Number of ineligible (medical contraindications, religious or philosophical declinations, refusals)						
Number of women immunized						

These recommendations would enhance services already in place at the facility to improve the health of patients across the region. Accordingly, this medical center has previously been recognized by a myriad of organizations such as the National Benchmarks for Success’

recognition as one of the Top Ten Teaching Hospitals in the Nation, the 2006 Premier Award for Quality, the recent affirmation of Magnet Hospital for Nursing designation, and the Foster McGraw Prize for Excellence in Community Service. Among the lobby display of awards is one from the American Hospital Association awarded for “leadership in meeting health care needs of the community and commitment to mutual goal of increasing quality health care and health services for all people”. Implementing Tdap immunization for new mothers in the birthing unit furthers the mission of the center to improve the health of the people in the communities of the area.

One of the three legs of public health practice (assessment, policy development, and assurance) is demonstrated through the proposed amendments to the school entry regulations. In the fall of 2011, seventh grade and college students will be required to have a dose of Tdap vaccine. This regulation will update the requirement for Td boosters in preference of a pertussis-containing vaccine. Although it will take many years, over time, as more class cohorts fall under the requirement and as Tdap vaccine enjoys further distribution and a wider uptake, the overall financial impact of providing Tdap vaccine to susceptible women in the hospital setting will lessen as the gap in vaccine coverage shrinks.

The Strengths and Weaknesses of the Evaluation

The strengths and weaknesses of program evaluation were reflected against the Standards for Evaluation in Appendix I. Establishing a hospital-based Tdap immunization program would provide peace of mind to the new mother until the infant reaches the recommended age for DTaP immunization as well as providing immunity to susceptible women. This evaluation ultimately recommended that the obstetrical management of the project hospital expand immunization

services, to include Tetanus- Diphtheria- and acellular Pertussis (Tdap) vaccines – in the birth setting.

First, the collaborative effort in this evaluation was paramount. The program evaluation benefited from the use of resources of the Department of Public Health and networking that was invaluable to moving the process along. Several individuals and organizations not affiliated with the institution were solicited for advice, comments, and feedback. Members of the project team remarked that there had been a long standing desire “to do something about Tdap”; unfortunately none of the hospital personnel had the time to devote to the project, so it was advantageous to have one person dedicated to the topic. It was a team effort and the commitment of certain employees of the facility was evident. Initially there were a couple of stakeholders who expressed opinions of “There are *so many* vaccines now!” and “Why should I be worried about pertussis?” These two people were in the minority however as the sentiment for the project was overwhelmingly in favor of the idea.

Weaknesses involved in the evaluation also arose from not being an employee of the institution. Not being intimately familiar with the organizational hierarchy and the “politics” that permeates every organization was a disadvantage. Positioned as an ‘outsider’ also affected access to information and affected the timeline in that as a guest of the facility, it took somewhat longer to arrange interviews and meetings than had I been working within the facility, although as an employee, perhaps I, too, would not have had the time to commit to the undertaking. It was difficult to go into a nationally recognized facility and make observations that resulted in recommendations for change. An important facet of the evaluation was how others would react to the findings. The wording and delivery of recommendations had to be made respectfully and without judgmental overtones. It was essential that the stakeholders feel an integral part in the

evaluation process and that the resulting outcome was a positive experience, seen as one that would move the organization forward in implementing a new standard of care for mothers. It was also necessary from the outset that all parties understand that the task was a student Capstone project rather than a formal requirement by the State Health Department.

One issue that was difficult to ascertain was that of the actual incidence of infant pertussis cases related to the overall number of births at this site. The MDPH policy is to report infectious disease data in the aggregate. Confidentiality prohibits release of data for community populations of less than 50,000 people if cell sizes contain numbers of five or fewer cases. Therefore, we were unable to obtain data on pertussis cases that may have been born in the facility but actually resided in the multitude of communities in the surrounding area with populations less than the reporting threshold. Additionally, the facility itself would be unaware of pertussis cases associated with births in the medical center. Pediatric providers or family practitioners are required to report communicable disease findings to the state not to the birthing facility.

Another issue pertinent to program evaluation in general and this project in particular is the time factor involved. An ambitious timeline was set out that was ultimately affected by history – events outside the program affecting the project and those involved. The advent of the first influenza pandemic in more than forty years had both beneficial and detrimental effects. Surveillance data demonstrating that transmission of the novel virus strain was highest in younger populations and that complications were inordinately affecting pregnant women lead to ACIP recommendations for pregnant and post-partum women to be included in the first priority group for immunization once H1N1 vaccine became available. All other activities in public health agencies and acute care facilities seemed to take a back seat to the urgent need to

immunize the population against the new virus, thus the timeline for the program evaluation became prolonged. The pandemic produced a favorable though perhaps unintended outcome. Precisely because pregnant women were affected by influenza morbidity and mortality, new attention was focused on the safety of immunizing women during the perinatal period; this will help to raise the awareness of both the need to assess risk factors in this cohort and the ability to use the opportunity to immunize susceptible women. This may have a favorable effect on Tdap immunization programs in the future.

The issue of maturation will ultimately lessen the overall need for the program. At the present time, the lack of school requirements for Tdap and deficiencies in vaccination services for adults point to post-partum immunization as a way to address a gap in vaccine delivery systems. Over time, the implementation of school regulations at the 7th grade and college levels as well as requirements for Tdap vaccination among health care students will result in higher population coverage with the vaccine. High immunization rates will decrease the urgency for in-hospital Tdap immunization similar to the history of rubella vaccination. The need for assessing and immunizing post-partum women will never disappear entirely however due to varying school regulations among the fifty states and the number of women giving birth who hail from countries other than the United States where vaccination services are not readily available.

While most personnel agreed theoretically that the pertussis is an awful disease and one worthy of prevention in all age groups, especially infants, the project outcome essentially meant more work for the nurses. This is where utilizing change theory became important to the educational process, especially in promoting the ethics of the change and the climate for evidenced based practice – essentially the public health nursing leadership required to improve the standard of care for all delivering mothers.

The elements of program evaluation were carried out in a professional and ethical manner on the basis of dialogue, observation and reflection. Clear and accurate documentation of the program under evaluation was attempted with sufficient detail to provide context and possible influences on the program. Sources of information provided sound statistics for valid and reliable conclusions. One drawback that was encountered was the lack of access to proprietary information. The evaluator was not privy to contractual agreements for bulk purchase pricing between the hospital and GSK. Another area of confidentiality was that of the global fees negotiated for deliveries between health care plans and the medical center and the actual figures of patients delivering attributed to each insurance carrier. Thus only generalizations were made in terms of analysis rather than true cost estimates. Bias on the part of the evaluator in favor of immunization may not be shared by others, who may reach different conclusions.

Future Steps

The Tdap project is in the process of seeking resources to educate mothers and families on the need for Tdap. Particular items that are being investigated are: parent newsletter articles, a bassinette informational card, patient instructional videos or DVD's for the patient education TV channel and adult immunization cards for newly immunized mothers. A local college nursing student has expressed interest in working with the hospital on developing an informational card for the newborn bassinet on pertussis and the importance of immunizing the baby's family and care givers as part of an honor project. A group of high school students has in interest in developing a short patient teaching video on pertussis and Tdap vaccination.

The pharmacy department deals with contracting and purchasing of pharmaceuticals and vaccine biologics. Plans for the Tdap initiative in the hospital have been identified through the supply chain via the vaccine company representative. Linking the pharmacy protocol with

communication to the distribution sites was an important part of ensuring sufficient vaccine supplies for the project and ensuring stability of the inventory over time according to the vaccine purchaser. The effect of this communication pathway forestalls any delays in ordering or obtaining vaccine resulting from what might appear to be an inordinate use of vaccine based on historic usage and purchase arrangements. Future meetings will be held between the nursing administration, the pharmacy department, and the Department of Public Health regarding the hospital's enrollment with the state health program and the receipt of state supplied vaccines.

The hallmark of public health is collaboration, characterized by the formation of partnerships to address public health problems. The issue of pertussis transmission is being tackled on the state level by direct and indirect means. The Massachusetts Department of Public Health has cooperated with the executive branch and the state legislature to develop amendments to school entry regulations in Massachusetts that would provide for a Tdap immunization requirement at entry into 7th grade and for college matriculation. This regulation is in the process of promulgation and is expected to be finalized for the start of the 2011 school year.

In November of 2009, MDPH distributed a recommendation for Tdap vaccine, in preference over Td vaccine, for adolescents in all provider settings. The advisory notified all recipients as to the availability of state supplied Tdap vaccine for adolescents 10 – 18 years of age to all health care facilities and to emergency rooms and urgent care settings.

In January of 2010, MDPH distributed a notice of time-limited availability of state supplied Tdap vaccine (as well as HPV, varicella, and zoster vaccine) for all adults 10 -26 years of age seen at public sites. Public sites in Massachusetts are defined as community health centers and local health departments. Hepatitis A and B, MMR and pneumococcal vaccines are already available to these sites through normal ordering channels. The addition of Tdap and

other biologics is being made available until June 2010 and is possible through the use of American Recovery and Reinvestment Act (ARRA) funds.

Implications for Nursing

This program evaluation of the current practices and readiness for implementation of Tdap orders for immunization in a birthing hospital illustrates the problem identified by the Institute of Medicine (IOM) report on the state of health care delivery (Institute of Medicine, 2001). The report emphasized fragmentation of care, including the dilemma of undertaking a financial burden for a new service, as barriers for hospitals in adopting change.

In keeping with the promotion of health care that is “safe, effective, client-centered, timely efficient, and equitable, employing a new setting (the hospital) to provide immunization services rests on the scientific underpinnings of the ACIP statement for pertussis protection (CDC, 2000, p.6). It utilizes organizational skills – the ability to conceptualize new care delivery models, and systems thinking – navigating the policy and quality improvement arenas. One aspect of advanced nursing practice is advocacy for health care policy – designing, influencing and implementing health care policies that frame access, addresses social justice and equity, quality, efficacy, and regulation of practice.

This project designing an evidence based intervention demonstrates the translation of research (conducted by the ACIP) into safe and effective policy. A policy for hospital based Tdap vaccination is an example of nursing leadership aimed at institutionalizing one very specific clinical preventive and population health service for susceptible individuals that will have an ultimate impact on aggregates (inducement of community or herd immunity) and vulnerable populations (newborn infants). This project is a synthesis of academic work at the University of Massachusetts including elements of practice change initiatives. In short, the

project summarizes my growth in knowledge and expertise and serves as the foundation for future scholarly practice within the Department of Public Health related to plans for pertussis prevention, response and surveillance.

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Appendix A

Standard of Care

Tdap immunization of susceptible mothers in birth setting

Centers for Disease Control (2008a) Advisory Committee on Immunization Practices (ACIP)

CDC's Advisory Committee on Immunization Practices recommends that pregnant women who were not vaccinated previously with Tdap: receive Tdap in the immediate postpartum period before discharge from hospital or birthing center.

American Congress of Obstetricians and Gynecologists (formerly American College) ACOG Committee Opinion 438 (replaces 282, January 2003)

The ACIP recommendations for pertussis, tetanus, and diphtheria vaccination have been revised to include routine post-partum Tdap administration if the woman has not had Tdap in the past. **The Committee on Obstetric Practice supports these recommendations:**

To add protection against pertussis, Td vaccination during pregnancy can be deferred and Tdap vaccination given before postpartum discharge from the hospital in women who are likely to have sufficient tetanus and diphtheria protection until delivery, who have not previously received Tdap and in whom it has been 2 years or more since the most recent Td. Having standing orders at the hospital can help facilitate this. If Tdap cannot be administered at or before discharge, the woman should receive the dose as soon as possible thereafter.

American College of Nurse Midwives – Share With Women -

Tetanus, diphtheria, and pertussis (Td or Tdap): Adults who have not had these vaccines in childhood or have not had a booster in 10 years. Those with an injury and no booster in 5 years. Those with no booster with pertussis. *For postpartum women with no recent vaccination, healthcare workers, and persons around infants to age 12 months. (An initial series plus regular boosters.)*

Appendix B

Massachusetts Board of Registration in Nursing Advisory Ruling

Title: Administration of Immunizing Agents or Vaccines

Advisory Ruling Number: 9804

Authority:

The Massachusetts Board of Registration in Nursing (Board) issues this Advisory Ruling on Nursing practice pursuant to Massachusetts General Laws ("G.L."), chapter 30A, section 8 and chapter 112, section 80B.

Date Issued: May 13, 1998

Date Revised: May 2002, March 14, 2007

Scope of Practice: Registered Nurse and Licensed Practical Nurse

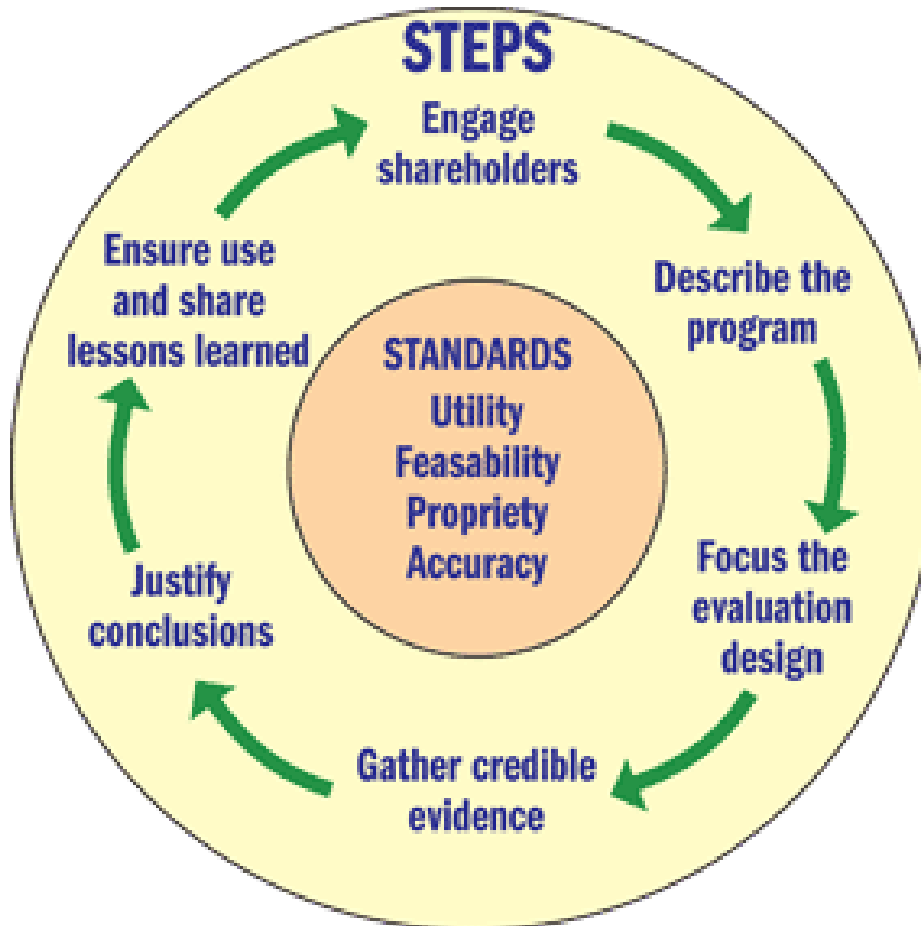
Purpose: To guide the practice of the Registered Nurse and Licensed Practical Nurse ("the nurse") who as part of their nursing practice may administer immunizing agents or vaccines to any member of the public in any and all settings. Such practice must be in compliance "G.L." c. 112, s. 80B, 244 CMR 3.02: Responsibility and Functions - Registered Nurse; 244 CMR 3.04: Responsibilities and Functions - Practical Nurse; 244 CMR 9.03 (8): Identification Badge; 244 CMR 9.03 (9): Responsibility and Accountability; 244 CMR 9.03 (10): Acts within Scope of Practice; 244 CMR 9.03 (11): Performance of Techniques and Procedures; 244 CMR 9.03 (12): Competency; and 244 CMR 9.03 (44): Documentation.

Advisory: Immunizing agents or vaccines may be administered only under the following provisions. The nurse must:

- Verify the orders from a duly authorized prescriber. A nurse may administer an immunizing agent or vaccine ordered from a Standing Order Protocol. A standing order protocol must include:
 - The name(s) of the immunizing agent or vaccine to be administered;
 - The dose to be administered;
 - The route or method of administration;
 - Inclusion/Exclusion criteria that the nurse will assess for before administering the immunizing agent or vaccine; and
 - The signature or approval by a duly authorized prescriber either directly on the standing order or on file with the facility/agency/program providing individual or mass immunization or vaccinations;
- Be properly educated in the:
 - Storage, handling, administration, contraindications, reporting of adverse effects, and documentation of the immunizing agent or vaccine;
- Complete accurate and legible entries in all records required by federal and state law;
- Provide education to the client/patient/resident of the immunizing agent or vaccine on the risks and benefits of accepting or refusing the opportunity to receive the immunizing agent or vaccine;
- Document a process of informed consent with the client/patient/resident of the immunizing agent or vaccine that is reflective of the educational materials provided;
- Complete an assessment including an allergy history of the client/patient/resident of the immunizing agent or vaccine prior to the administration of an immunizing agent or vaccine;
- Know where, and how to access and use emergency devices, techniques and services for adverse reactions; and
- Obtain parental permission in the case of administration to children in compliance with local, state and federal requirements.

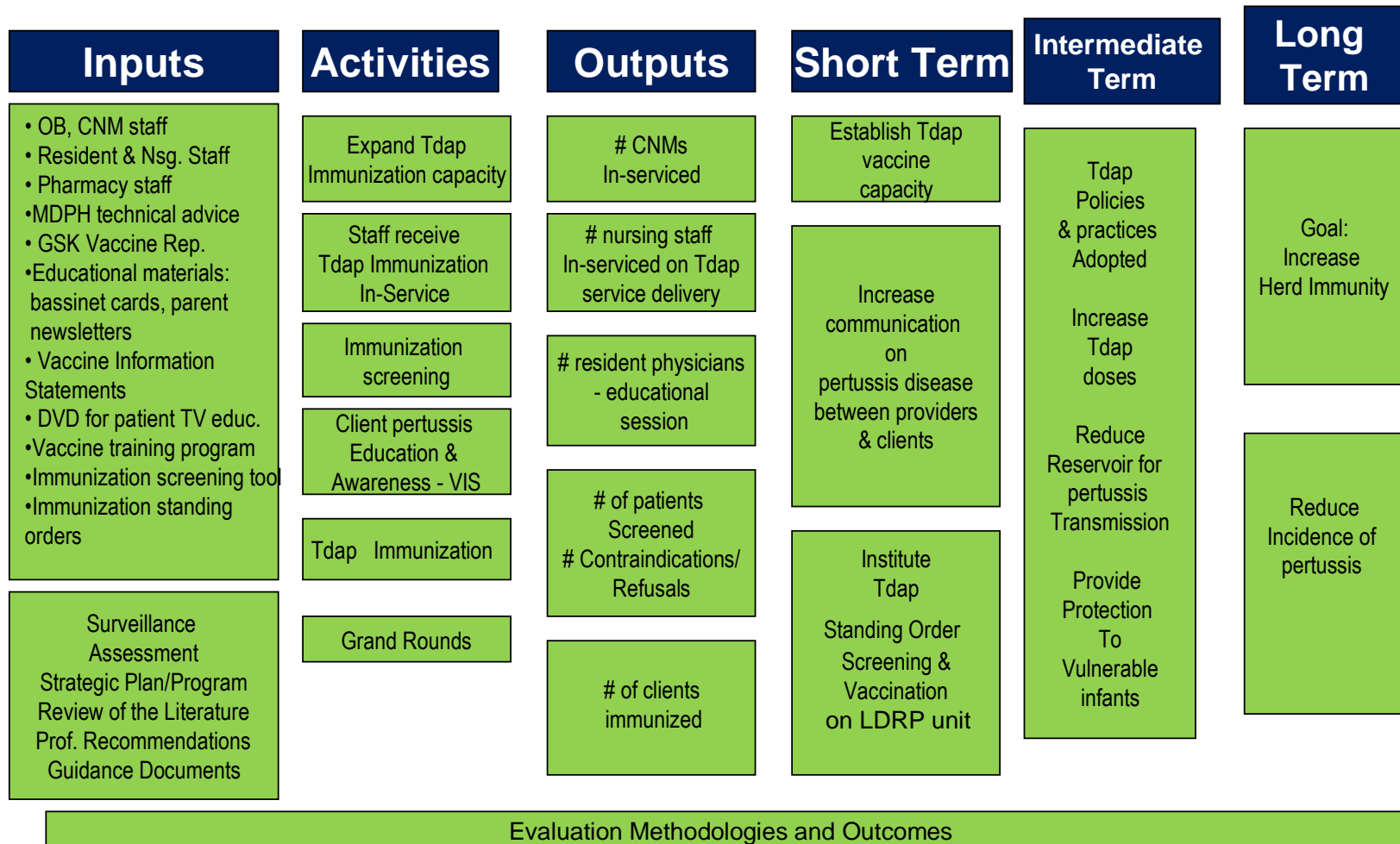
Appendix C

CDC Grantee Guide to Immunization Program Evaluation



Medical Center Logic Model

New mothers Tdap Immunization Program



Appendix E

National Vaccine Advisory Committee	
Standards for Conducting Adult Immunization Programs in Nontraditional Settings	
Standard 1	Information and Education for Vaccinees
Standard 2	Vaccine Storage and Handling
Standard 3	Immunization History
Standard 4	Contraindications
Standard 5	Record Keeping
Standard 6	Vaccine Administration
Standard 7	Adverse Events

Adapted from CDC MMWR 2000, March, 24 49:1-29.

Appendix F

TETANUS, DIPHTHERIA (Td) or TETANUS, DIPHTHERIA, PERTUSSIS (Tdap) **VACCINE**

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 Why get vaccinated?

Children 6 years of age and younger are routinely vaccinated against tetanus, diphtheria and pertussis. But older children, adolescents, and adults need protection from these diseases too. Td (Tetanus, Diphtheria) and Tdap (Tetanus, Diphtheria, Pertussis) vaccines provide that protection.

TETANUS (Lockjaw) causes painful muscle spasms, usually all over the body.

- It can lead to tightening of the jaw muscles so the victim cannot open his mouth or swallow. Tetanus kills about 1 out of 5 people who are infected.

DIPHTHERIA causes a thick covering in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

PERTUSSIS (Whooping Cough) causes severe coughing spells, vomiting, and disturbed sleep.

- It can lead to weight loss, incontinence, rib fractures and passing out from violent coughing. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, including pneumonia.

These three diseases are all caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts, scratches, or wounds.

The United States averaged more than 1,300 cases of tetanus and 175,000 cases of diphtheria each year before vaccines. Since vaccines have been available, tetanus cases have fallen by over 96% and diphtheria cases by over 99.9%.

Before 2005, only children younger than than 7 years of age could get pertussis vaccine. In 2004 there were more than 8,000 cases of pertussis in the U.S. among adolescents and more than 7,000 cases among adults.

2 Td and Tdap vaccines

- Td vaccine has been used for many years. It protects against tetanus and diphtheria.
- Tdap was licensed in 2005. It is the first vaccine for adolescents and adults that protects against all three diseases.

Note: At this time, Tdap is licensed for only one lifetime dose per person. Td is given every 10 years, and more often if needed.

These vaccines can be used in three ways: 1) as catch-up for people who did not get all their doses of DTaP or DTP when they were children, 2) as a booster dose every 10 years, and 3) for protection against tetanus infection after a wound.

3 Which vaccine, and when?

Routine: Adolescents 11 through 18

- A dose of Tdap is recommended for adolescents who got DTaP or DTP as children and have not yet gotten a booster dose of Td. The preferred age is 11-12.
- Adolescents who have already gotten a booster dose of Td are encouraged to get a dose of Tdap as well, for protection against pertussis. Waiting at least 5 years between Td and Tdap is encouraged, but not required.
- Adolescents who did not get all their scheduled doses of DTaP or DTP as children should complete the series using a combination of Td and Tdap.

Routine: Adults 19 and Older

- All adults should get a booster dose of Td every 10 years. Adults under 65 who have never gotten Tdap should substitute it for the next booster dose.
- Adults under 65 who expect to have close contact with an infant younger than 12 months of age (including women who may become pregnant) should get a dose of Tdap. Waiting at least 2 years since the last dose of Td is suggested, but not required.
- Healthcare workers under 65 who have direct patient contact in hospitals or clinics should get a dose of Tdap. A 2-year interval since the last Td is suggested, but not required.

New mothers who have never gotten Tdap should get a dose as soon as possible after delivery. If vaccination is needed during pregnancy, Td is usually preferred over Tdap.

Protection After a Wound

A person who gets a severe cut or burn might need a dose of Td or Tdap to prevent tetanus infection. Tdap may be used for people who have never had a dose. But Td should be used if Tdap is not available, or for:

- anybody who has already had a dose of Tdap,
- children 7 through 9 years of age, or
- adults 65 and older.

Tdap and Td may be given at the same time as other vaccines.

4 Some people should not be vaccinated or should wait

- Anyone who has had a life-threatening allergic reaction after a dose of DTP, DTaP, DT, or Td should not get Td or Tdap.
- Anyone who has a severe allergy to any component of a vaccine should not get that vaccine. Tell your provider if the person getting the vaccine has any severe allergies.

- Anyone who had a coma, or long or multiple seizures within 7 days after a dose of DTP or DTaP should not get Tdap, unless a cause other than the vaccine was found (these people *can* get Td).
- Talk to your provider if the person getting either vaccine:
 - has epilepsy or another nervous system problem,
 - had severe swelling or severe pain after a previous dose of DTP, DTaP, DT, Td, or Tdap vaccine, or
 - has had Guillain Barré Syndrome (GBS).

Anyone who has a moderate or severe illness on the day the shot is scheduled should usually wait until they recover before getting Tdap or Td vaccine. A person with a mild illness or low fever can usually be vaccinated.

5 What are the risks from Tdap and Td vaccines?

With a vaccine (as with any medicine) there is always a small risk of a life-threatening allergic reaction or other serious problem.

Getting tetanus, diphtheria or pertussis would be much more likely to lead to severe problems than getting either vaccine.

Problems reported after Td and Tdap vaccines are listed below.

Mild Problems
(Noticeable, but did not interfere with activities)

Tdap

- Pain (about 3 in 4 adolescents and 2 in 3 adults)
- Redness or swelling (about 1 in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents and 1 in 100 adults)
- Headache (about 4 in 10 adolescents and 3 in 10 adults)
- Tiredness (about 1 in 3 adolescents and 1 in 4 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents and 1 in 10 adults)
- Chills, body aches, sore joints, rash, swollen glands (uncommon)

Td

- Pain (up to about 8 in 10)
- Redness or swelling (up to about 1 in 3)
- Mild fever (up to about 1 in 15)
- Headache or tiredness (uncommon)

Moderate Problems
(Interfered with activities, but did not require medical attention)

Tdap

- Pain at the injection site (about 1 in 20 adolescents and 1 in 100 adults)
- Redness or swelling (up to about 1 in 16 adolescents and 1 in 25 adults)
- Fever over 102°F (about 1 in 100 adolescents and 1 in 250 adults)
- Headache (1 in 300)
- Nausea, vomiting, diarrhea, stomach ache (up to 3 in 100 adolescents and 1 in 100 adults)

Td

- Fever over 102°F (rare)

Vaccine Information Statement (Interim)
Td & Tdap Vaccines (11/18/08) U.S.C. 42 §300aa-26

Tdap or Td

- Extensive swelling of the arm where the shot was given (up to about 3 in 100).

Severe Problems

(Unable to perform usual activities; required medical attention)

Tdap

- Two adults had nervous system problems after getting the vaccine during clinical trials. These may or may not have been caused by the vaccine. These problems went away on their own and did not cause any permanent harm.

Tdap or Td

- Swelling, severe pain, and redness in the arm where the shot was given (rare).

A severe allergic reaction could occur after any vaccine. They are estimated to occur less than once in a million doses.

6 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

A federal program exists to help pay for the care of anyone who has a serious reaction to a vaccine.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Appendix H

Standards for Effective Evaluation

“The accuracy standards are intended to ensure that an evaluation will reveal and convey technically adequate information about the features that determine worth or merit of the program being evaluated”

Program Documentation	The program being evaluated should be described and documented clearly and accurately, so that the program is clearly identified.
Context Analysis	The context in which the program exists should be examined in enough detail, so that its likely influences on the program can be identified
Described Purposes and Procedures	The purposes and procedures of the evaluation should be monitored and described in enough detail, so that they can be identified and assessed
Defensible Information Sources	The sources of information used in a program evaluation should be described in enough detail, so that the adequacy of the information can be assessed
Valid Information	The information gathering procedures should be chosen or developed and then implemented so that they will assure that the interpretation arrived at is valid for the intended use
Reliable Information	The information gathering procedures should be chosen or developed and then implemented so that they will assure that the information obtained is sufficiently reliable for the intended use.
Systematic Information	The information collected, processed, and reported in an evaluation should be systematically reviewed and any errors found should be

	corrected
Analysis of Quantitative Information	Quantitative information in an evaluation should be appropriately and systematically analyzed so that evaluation questions are effectively answered
Analysis of Qualitative Information	Qualitative information in an evaluation should be appropriately and systematically analyzed so that evaluation questions are effectively answered
Justified Conclusions	The conclusions reached in an evaluation should be explicitly justified, so that stakeholders can assess them
Impartial Reporting	Reporting procedures should guard against the distortion caused by personal feelings and biases of any party to the evaluation, so that evaluation reports fairly reflect the evaluation findings. Reporting procedures should guard against the distortion caused by personal feelings and biases of any party to the evaluation, so that evaluation reports fairly reflect the evaluation findings.
Meta-evaluation	The evaluation itself should be formatively and summatively evaluated against these and other pertinent standards, so that its conduct is appropriately guided and, on completion, stakeholders can closely examine its strengths and weaknesses

Appendix I

My thanks to the External Reaction Panel:

Sharon Asher, RN, BSN – Practice Clinical Coordinator

John Crowley - GlaxoSmithKline, Immunization Account Manager

Elizabeth Daake, MPH – MDPH Director of Policy Development & Planning

Lela Hobby-Burns, DNP-c, RN – University of Massachusetts SON

Susan M. Lett, MD, MPH – MDPH Medical Director, Immunization Program

Col. James Linder USAF – Commander 439th Operations Group Westover ARB

Claire Margosiak, RN, BSN – Mercy Medical Center, Director Family Life Center

Eileen McHale, RN, BSN – MDPH Betsy Lehman Center for Patient Safety

Rep. John Scibak – MA state representative, 2nd Hampshire district

Cheryl Sheils, EdD, RN – Elms College assistant professor of nursing

Donna Weaver RN, MSN – CDC National Immunization Program nurse educator

Author's Note

Perseverance can be defined as diligence and determination. Those attributes brought me to the culmination of the DNP program, this Capstone project. There is one piece of scripture that characterizes my thoughts at this juncture.

Phillipians 4:13

I can do all things through Him who strengthens me.

The love and support of my family, my son – Michael, my daughter - Meghan and my anam cara – the friend of my soul, my husband Kevin have sustained me through the extraordinary challenges of the program and over the last year. I thank you from the depths of my heart.

My work is dedicated to my late mother, Eleanor McCurry Crean R.N. who since I first announced at the age of six that I wanted to be a nurse, “just like my mother”, provided me the foundation of caring upon which to base my practice.

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