Vaccine 32 (2014) 901–903

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Brief report

Evaluation of the feasibility of a state-based vaccine safety advice network

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ARTICLE INFO

Article history:
Received 26 August 2013
Received in revised form
18 November 2013
Accepted 27 December 2013
Available online 9 January 2014

Keywords:
Vaccine safety
Adverse events following immunization

ABSTRACT

The vaccine safety advice network is a collaborative pilot project between Vanderbilt University Medical Center, the Tennessee Department of Health, and the Centers for Disease Control and Prevention to assess the feasibility of addressing vaccine safety questions posed by healthcare providers in near real-time. Using a two-tier response system and an electronic database for query submission, the pilot project received ten queries in three and one half months. Two of three pre-specified benchmarks for program evaluation, addressing queries within 24 h of receipt and 100% provider satisfaction, were met; one benchmark, the percentage of questions addressed by Tier 1 staff, was not met. Limitations included few submitted queries primarily involving children in the pilot period, "after-only" program evaluation, and limited geographic generalizability. The study demonstrates a successful partnership between federal, state and academic institutions and a feasible method to respond to healthcare provider inquiries about vaccine safety in near real-time.

1. Introduction

The vaccine safety advice network (VSAN) was designed as a collaborative pilot program between the Vanderbilt Vaccine Research Program (VVRP), the Centers for Disease Control and Prevention (CDC), and the Tennessee Department of Health (TDH), supported through the CDC-funded Clinical Immunization Safety Assessment (CISA) Project [1]. VSAN was modeled after a similar system employed for healthcare providers (HCPs) in Europe, the Info-Vac program [2,3]. This service allows HCPs to contact vaccine experts via electronic mail with questions regarding vaccines, including specific questions pertaining to vaccine safety [2]. Our objective was to assess the feasibility of a state-based mechanism where vaccine safety questions posed by HCPs could be answered in near "real-time" at no-cost to HCPs. Specific goals of the project were to determine: (1) if a collaborative program addressing vaccine safety concerns between an academic institution, the CDC and a state health department immunization office was feasible; (2) whether the program was efficient and responsive to HCPs questions; (3) whether HCPs found the service beneficial, and (4) the types of questions posed.

2. Methods

2.1. Provider survey

In preparation for the VSAN pilot, investigators at the VVRP surveyed pediatricians and family practitioners through the Tennessee chapters of the American Academy of Pediatrics (TNAAP) and the American Academy of Family Practitioners (AAFP), respectively, to assess the need for a VSAN service and the optimal format. Providers of both groups were sent an electronic mailing with the electronic survey attached and asked to participate. Approximately 1000 members of the TNAAP and 45 members of the AAFP received the survey.

2.2. Pilot

The VSAN was advertised to HCPs prior to the pilot period through several methods including: electronic mail notifications

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http://dx.doi.org/10.1016/j.vaccine.2013.12.062

Table 1
VSAN pilot project primary outcomes.

Goal	Outcome	Comments
90% of questions responded to within 2 business days	100% of queries were responded to within 24 h	3 Providers received additional information for queries presented on the CISA CCCR conference calls at a later date
50% of questions addressed by Tier 1 staff	20% of questions addressed by Tier 1 staff	8 of the questions were initially responded to by Tier 2, 2 by Tier 1 Tier 1 staff did not receive notifications from database initially when query was submitted; therefore only Tier 2 received and responded Once the notification system was operational, 2 of the 3 subsequent queries (67%) were handled by Tier 1 staff, supporting that Tier 1 staff were capable of addressing the majority of questions
90% Provider or physician satisfaction with the service	We received feedback surveys from six of the providers who submitted questions to our system (60%). Of these, 100% responded that they were satisfied with the VSAN service	100% answered yes to the following four questions: (1) Were you satisfied with the responses and timeliness of the VSAN service? (2) Was the information you received from your VSAN inquiry beneficial to you as a provider? (3) Was the information you received from your VSAN inquiry beneficial to your patient? (4) In your opinion, is this service valuable to your practice?

to TNAAP and AAFP, a press release from Vanderbilt University, announcements at Vanderbilt Obstetrics and Gynecology grand rounds, electronic advertisements to all participants in Tennessee's federally funded Vaccines for Children Program and electronic advertisements to a large, pediatric network (the Cumberland Pediatric Foundation) for middle Tennessee.

The VSAN was designed as a two-tier system. Tier 1 included four Tennessee Immunization Program (TIP) public health nurses (registered nurses) and the medical director of TIP (physician), while Tier 2 included experts in vaccine safety from VVRP (board certified physicians in pediatrics and/or pediatric infectious diseases). The two-tier design allowed Tier 1 to evaluate each query first; however, if the query involved clinical complexity that could not be addressed by Tier 1 members, a Tier 2 investigator would be notified to address the query. For the pilot, Tier 2 investigators reviewed all responses to queries, regardless of complexity, prior to providing final responses to HCPs.

To submit a question, HCPs either entered a query directly through a secure, web-based data collection tool developed at Vanderbilt called REDCap [4], or telephoned the TIP or VVRP, who then entered the query into the database. The database for this project was compliant with the Federal Information System Management Act (FISMA), which categorizes information and systems in order to provide appropriate levels of information security. The REDCap database developed for VSAN was designated as FISMA-low [5]. The online data collection tool required no log-in information for HCPs and no patient-specific identifiers were collected. Therefore, the project met criteria for non-human research and was exempt from IRB approval.

Tier 1 team members received three training sessions with VVRP investigators prior to beginning the pilot. Training sessions included review of the VSAN process, the procedure to enter the data into the REDCap database, and a detailed discussion of examples of potential vaccine safety questions. VSAN team members were instructed to answer the vaccine questions using resources available through CDC, AAP or clinical expertise [6,7]. In addition to initial telephone or electronic correspondences, all HCPs that submitted queries received written responses to their questions in their preferred format (e.g., email, postal mail, or fax). All correspondence between the VSAN investigators and the HCPs was uploaded to the database.

Specific outcome goals to assess the feasibility and usefulness of VSAN were defined prior to the start of the pilot and included: 90% response to questions within 48 h of submission, 50% response by a Tier 1 member (although all reviewed by Tier 2 for the pilot), and 90% HCP satisfaction with the VSAN service assessed by an end of study survey. If the provider agreed, complex vaccine safety questions which required further discussion were presented to a national network of vaccine safety experts participating in the CISA Clinical Consult Case Review (CCCR) which reviews individual cases of adverse events following immunizations (AEFI) [1,8,9]. Additional case details (without patient identifiers) were collected by Vanderbilt CISA investigators and results of the CCCR discussions were later uploaded to the VSAN case record.

Teleconferences were convened with all Tier 1 and Tier 2 staff every two weeks to discuss program progress.

3. Results

3.1. Provider survey results

There were 54 respondents who reported that: (1) AEFIs were often identified by providers (68% of responding providers had patients who experienced an AEFI), (2) a VSAN service would be beneficial to most physicians (66% yes, 23% not sure, 11% no), and (3) the preferred methods for communicating recommendations, in order of preference, would be through electronic mail (64%), telephone (58%), or secure website (34%).

3.2. VSAN pilot

From May 1 through August 15, 2012, the VSAN pilot program received 10 inquiries from HCPs; 5 via telephone, 4 via direct database entry, and 1 via the pilot met our pre-specified feasibility and utility goals in all areas but one; the percentage of questions addressed by Tier 1 staff (Table 1).

The ages of patients involved in queries ranged from 5 months to 40 years of age; 8 of 10 patients were children. Inquiries were received from 8 physicians, 1 nurse practitioner, and 1 registered nurse. In addition to brief literature reviews and expert opinion, Tier 1 and Tier 2 responders referred to the following sources to address queries: the AAP Redbook [7], the CDC Morbidity and Mortality Weekly Report General Recommendations on Immunizations [6], and the CDC Yellow Book [10]. Question topics included AEFIs ($N = 3$), future contraindications to immunization ($N = 2$) and questions regarding vaccine necessity or administration ($N = 5$). There was also a broad range of vaccines involved, as listed in Table 2. Three queries were presented on CISA monthly CCCR calls. Seven summary responses to HCPs were sent by email and 3 were sent by facsimile.

Table 2
Summary of vaccine types for queries received from May 1 through August 15, 2012.

Vaccine	Number of queries involving this vaccine[a]
DTaP	5
Varicella	4
MMR	4
IPV	4
Zoster	1
Typhoid	1
Hepatitis A	1
Tdap	1

[a] Not mutually exclusive.

4. Discussion

The VSAN pilot project demonstrates a feasible method to respond to healthcare provider inquiries about vaccine safety in near real-time. As the REDCap database is available to all academic institutions [4], this model could be implemented in additional states as a collaborative service between state immunization departments and academic institutions. However, it is of utmost importance that consultation projects such as this safeguard patient data carefully. In this project where personal patient identifiers were not collected, FISMA requirements were implemented and added significant cost and delayed implementation (approximately 1 year). The resources required for implementation included dedicated computer servers; provision of a two-factor authentication system (RSA SecurID tokens for each user); and personnel time for compilation of certification and accreditation documents, user-training, security system monitoring, and database management. Less burdensome information security safeguards would be helpful to enable such projects to be implemented more widely.

Although the program was advertised to multiple HCPs, VSAN received only a modest number of queries during this period which limits the assessment of the efficiency of the program. The pilot was conducted during a limited time period in the summer; thus the demand for the service may grow if it was implemented for a longer time period and continuously advertised. It is difficult to assess how a greater volume would affect provider satisfaction and outcomes; however, because the program addressed all queries within 24 h, staff could have addressed a larger volume within a reasonably short interval, such as 48 h.

Thirty percent of queries resulted in CISA evaluation, suggesting that the system may have been used for more complicated issues. Most queries involved children, though the program was advertised to providers of all age groups; this is likely due to children receiving more vaccines in general and more focused advertising to pediatricians. Future efforts should broaden advertising efforts to internists and obstetricians. Furthermore, if the pilot period was conducted during influenza vaccine season, the number of inquiries for adults may have been greater. We are limited in making broader conclusions given that the study was only conducted in the state of Tennessee and the after-only program evaluation. Also, as we did not receive feedback from 4 of the providers who utilized VSAN, it is possible they were not satisfied with the service.

In summary, the VSAN pilot was a successful partnership between Vanderbilt, CDC, and the Tennessee Department of Health. Nearly all pre-specified benchmarks for program evaluation were met, and given the complexity of the vaccine schedule, multiple vaccines available, and adverse event occurrence and evaluation, the ability to have vaccine safety questions answered in near real-time by local experts is a valuable resource for healthcare providers and their patients.

Disclaimer

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC). This study was funded through a subcontract with America's Health Insurance Plans (AHIP) under contract 200-2002-00732 from CDC.

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