Vaccine Questions in Axion Health Surveys and Charting Forms

Lee Newman, MD, MA, FCCP, FACOEM
Chief Medical Information Officer (CMIO)
Axion Health, Inc.
Professor, Colorado School of Public Health and School of Medicine
University of Colorado Denver

May 24, 2014

Axion Health, Inc.
7403 Church Ranch Blvd
Suite 110
Westminster, CO 80503
www.axionhealth.com

Introduction

The ReadySet™ platform contains a variety of specialized content, including employee/patient surveys, clinician data collection forms, and clinical decision support tools. As a benefit to customers, Axion Health compiles and includes information to support best clinical practices according to reliable, professional resources, such as:

- Government regulations (such as OSHA)
- Guidance documents (CDC, FDA, pharmaceutical manufacturers)
- Safety data sheets (SDS, formerly MSDS)
- Professional organizations
- Academic institutions and peer-reviewed research literature

In response to commonly asked customer questions (*in italics*), this paper provides additional background information about the resources that we use to create the content found in the ReadySet product. This white paper will focus on surveys that are used in vaccination programs, and that draw from resources such as vaccine package insert contraindications, warnings and precautions. As Axion Health does not practice medicine, it's always the practitioner's responsibility to exercise best professional judgment when determining appropriate clinical protocols, treatment and documentation.

Importance of Patient Questions

Question: What process is used by Axion Health to determine which questions an employee should answer on surveys used in immunization/vaccination programs?

For vaccination programs, Axion Health bases survey questions on three categories of information provided in the manufacturers' FDA-reviewed package inserts. This includes:

1) Warnings and precautions
2) Contraindications
3) Boxed Warnings

While many practitioners are accustomed to only asking about contraindications, it is important to also ask patients about their risks related to warnings and precautions, potential contraindications, and black box warnings.

Warnings and Precautions

Question: What are the FDA's recommended criteria for listing a WARNING or PRECAUTION on the labeling and package insert for a vaccine?

A document worth reading was released by the FDA in October 2011, titled: "Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drugs and Biological Products – Content and Format." It can be obtained on the FDA website: http://www.fda.gov/downloads/Drugs/Guidances/ucm075096.pdf.

Here are a few highlights:

According to the FDA, the WARNINGS AND PRECAUTIONS section is "Intended to identify and describe a discrete set of adverse reactions and other potential safety hazards that are *serious* and are *otherwise clinically significant* because they have implications for prescribing decisions or for patient management."[1]

Proven causal relationships between the vaccine/drug and the adverse reaction are not required—an observed association is sufficient evidence.

To be included in the WARNINGS AND PRECAUTIONS section, there must be reasonable evidence of a causal association between the drug (or vaccine) and an adverse event. Adverse event outcomes can include *serious adverse events*, such as:

- Death
- A life-threating adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly or birth defect

As you can see, these are not trivial outcomes.

In addition, the FDA provides guidance that "otherwise clinically significant adverse reactions" may also be included in the WARNINGS AND PRECAUTIONS section of the package insert. These may include some less serious diseases or conditions that could result from administration, as well as consideration of the

[1] FDA Document (italics are FDA's)

high risk or rate of the adverse reaction. So, for example, a less serious side effect, such as nausea, might be listed if it occurs at a very high rate.

Each practitioner or practice should carefully consider FDA and manufacturer's guidance when determining the appropriate vaccine or drug for their patients.

Contraindications

Question: What are the FDA's recommended criteria for listing CONTRAINDICATIONS on the labeling and package insert for a vaccine?

According to the FDA, "A drug should be contraindicated only in those clinical situations for which the risk from use clearly outweighs any possible therapeutic benefit. Only known hazards, and not theoretical possibilities, can be the basis for a contraindication."

The discussion of "when to contraindicate" is complex, but includes a few key considerations:

- Observed adverse reactions can result in CONTRAINDICATION labeling if the risk of the reaction outweighs any potential benefit to any patient and the causal relationship between exposure to the drug/vaccine and adverse reaction is well-established.
- Adverse reactions that are *anticipated to occur* when a drug is used in a specific clinical situation can also be the basis for CONTRAINDICATION labeling. These are not 'theoretical'—there must be supporting data for this relationship.

The FDA guidance document provides clinical examples that may help practitioners decide appropriate questions to ask patients prior to prescribing or administering a medication or vaccine.

Boxed Warnings

Question: What are the FDA's recommended criteria for listing BLACK BOX WARNING on the labeling and package insert for a vaccine?

A "black box warning" is ordinarily used to highlight one of three situations for prescribers:

- There's an adverse reaction that is so serious in proportion to the potential benefit that it is essential that it be considered in assessing the risks and benefits of using the drug or vaccine.
- There's a serious adverse reaction that can be PREVENTED or reduced in frequency or severity by appropriate use of the drug (e.g. patient selection, careful monitoring, avoiding certain concomitant therapy, adding another drug to mitigate the reaction)
- FDA approved the drug with RESTRICTIONS to ensure safe use because the FDA concluded that the drug can be safely used ONLY if distribution or use is restricted.

Sometimes, boxed warnings will be used in other situations to highlight warning information that is especially important to the prescriber.

Manufacturers evaluate the information that they include in both the WARNINGS AND PRECAUTIONS and CONTRAINDICATIONS sections of their package inserts to determine whether a boxed warning is warranted.

Quantity of Questions

Question: Why are there so many questions on some ReadySet patient surveys?

Medical knowledge changes. Best practices change. New guidelines get approved by professional organizations and government agencies. When this happens, it usually adds (and rarely subtracts) questions that need to be asked of patients. In addition, providers and their institutions have an increasing need for "granular" data, in order to provide documentation, ensure compliance, and to make sure that they can run the kinds of reports needed for continuous quality improvement and proof of compliance. The content team at Axion Health considers and integrates information from many of the available sources that practitioners rely on to establish 'best practices.' We prioritize those sources that are evidence based, established by professional organizations, and that are required or recommended by government agencies. In our experience, many practices rarely review the content of their surveys and, as discussed above, may not have asked all of the questions that government agencies, such as the FDA, expect of us. So, ReadySet starts with the full complement of questions, and then works with the client to help them understand why the questions are being asked and help them modify the surveys to meet their practice goals.

Smart Forms

Question: What is a "smart form," and how does it help?

Busy practitioners have a lot of information to review regarding each patient they see. In our experience, it's easy to overlook potentially important information that patients provide in surveys. To help the busy practitioner and to help reduce the risk of medical errors, we developed "Smart Forms." Behind

every answer to every question in a patient survey, the medical content team at Axion Health has programmed the software to 'flag' answers that practitioners do not want to miss. For example, if someone checks the box saying that they have had a life threatening allergic reaction to a vaccine, the practitioner will automatically see an alert, pointing out this information. Researchers have proven statistically that the ReadySet Smart Form significantly improves the completeness of medical documentation and reduces the risk of medical errors.[2]

Question: Can the questions be configured to meet our practice's needs?

Yes. Axion Health recognizes that there are many different ways in which to ask a question. Our goal is to provide each practice with the tools that it wants. Also, there may be situations in which it is not necessary to ask every question that we place in our recommended surveys.

When clients implement ReadySet, they have the opportunity to review the content of every survey and ask our configuration team make modifications prior to launch. We provide opportunities for our clients to sit down with our clinical content experts to discuss the proposed changes. Our team also makes sure that the changes won't affect your ability to run reports needed for tracking and compliance.

[2] Salazar M, Stinson KE, Sillau SH, Good L, Newman LS. Web-based electronic health records improve data completeness and reduce medical discrepancies in employee vaccination programs. Infection Control and Hospital Epidemiology 2012; Jan; 33(1):84-6.

Conclusions

Practitioners need to be fully aware of both the WARNINGS AND PRECAUTIONS and CONTRAINDICATIONS, including any B0XED WARNINGS, for any medication or vaccine that they prescribe or administer.

Practitioners should take appropriate steps to ensure patient safety by inquiring about the patient's potential risk of a serious adverse event related to the warnings, precautions and contraindications found in package inserts.

In deciding what questions to ask patients, carefully consider the potential cost (in time spent answering questions) versus the potential benefits of *asking the question* and *preventing adverse events*.

Please consider the potential impact on the patient's health, the practitioner's license, and the health care organization's liability.

Final decisions and Responsibility for the practice of medicine resides with the client organization and practitioner, not with Axion Health. We endeavor to provide content as a starting point to help support our clients' consideration, review and revision of surveys and charting forms, so that the final content presentation conforms to the practitioners' clinical practice standards.