Electronic Supplementary Material Number One: Survey Questionnaire

Article Title: Study Design: Adverse Event Reporting Practices Among US Health Care Professionals

Journal Title: Drug Safety

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Tufts Center for the Study of Drug Development

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Survey on Adverse Drug Event Reporting Practices

Qualifying questions

The Tufts Center for the Study of Drug Development (Tufts CSDD) is conducting a survey on how health care providers report adverse drug events in the US. The goals are to understand the parties involved, the systems supporting the process, and where there are gaps that result in incomplete reporting as well as the magnitude of these gaps.

Tufts CSDD is an independent, academic, non-profit research group that is part of Tufts University School of Medicine in Boston. Tufts CSDD provides information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical and biopharmaceutical development, review, and utilization.

We expect the survey will take approximately 25 minutes of your time. Responses will be accepted till July 21, 2014. Responses to the survey will be kept confidential and the results will only be reported in the aggregate. If you provide your contact information at the end of the survey, we would be happy to share with you the summary report of the results and enter you into our drawing for $100.

Thank you in advance for your input. If you have any questions or comments please contact Paulami Naik at paulami.naik@tufts.edu or Stella Stergiopoulos at stella.stergiopoulos@tufts.edu.

Definition of Adverse Drug Event (ADE)
Adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, recombinant proteins, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))

Please choose which of the following best describes your role as a health care provider (HCP):

Please note: We are interested in responses from HCPs that are currently practicing or have seen patients in the last 3 years.

- ○ Nurse
- ○ Not a practicing healthcare provider over the last three years
- ○ Physician
- ○ Technician

- ○ Pharmacist
- ○ Other (please specify):

Please choose the state where you have most experience practicing:

▼

Please choose which of the following best describes the setting in which you provide care most often:

- ○ Retail pharmacy
- ○ Hospital pharmacy
- ○ Hospital In-patient Care
- ○ Hospital Ambulatory Care
- ○ Private Practice/Community Clinic
- ○ Other (please specify):

Preliminary Questions

Please enter the number of years you have practiced as a health care provider:

Please enter the number of years you have worked with your current employer:

Which of the following best describes the setting in which you provide care most often:

- Urban
- Sub-urban
- Rural

Is the pharmacy where you provide care most often:

- Large (On average 300 prescriptions/day or more)
- Medium (On average 100-300 prescriptions/day)
- Small (On average fewer than 100 prescriptions/day)

Is the pharmacy where you provide care most often:

- Part of a chain
- Independent

Is the office-based practice where you provide care most often:

- Large (6 or more physicians)
- Medium (2-5 physicians)
- Small (solo practice)

Is the hospital where you provide care most often:

- Large (over 500 beds)
- Medium (250-500 beds)
- Small (fewer than 250 beds)

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- Biologics (including blood components, blood and plasma derivatives, recombinant proteins, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))

To which of the following organizations have you reported an ADE?

Please check **all** that apply:

- [ ] State Board of Pharmacy
- [ ] The healthcare organization where I work (internal reporting e.g. to the hospital's incident reporting system)
- [ ] State Department of Health
- [ ] Drug manufacturer
- [ ] FDA's MedWatch Program
- [ ] Other (Please specify):
- [ ] I have never reported a drug related adverse event

Approximately, how many ADEs have you reported to the FDA or drug manufacturer over the last 5 years:

- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5+

Below are possible reasons health care providers may not report ADEs. Based on your experience, how often do each of these reasons prevent health care providers from reporting ADEs to the FDA or the manufacturer?

	Rarely	Sometimes	Often	Very Often	Unsure
Difficult to establish that the event is caused by a drug.	○	○	○	○	○
Patient:					
--does not report ADE to health care provider.	○	○	○	○	○
--does not bring in the drug, so difficult to fill out drug-related reporting information.	○	○	○	○	○
-- is on more than one therapy, so difficult to establish which drug caused ADE.	○	○	○	○	○

Provider:					
-- unaware of the benefits of reporting.	○	○	○	○	○
-- does not have enough time to devote to reporting activity given priority on provision of care.	○	○	○	○	○
-- is unsure about whom to report to.	○	○	○	○	○
-- is unsure about reporting procedure.	○	○	○	○	○
Electronic records:					
--lack patient's prescription history.	○	○	○	○	○
--lack integration between the disparate electronic systems (EHR, CPOE, e-prescribing etc.) and the reporting form.	○	○	○	○	○

What are some other important reasons why a provider may not report an ADE to the FDA's MedWatch program or the drug manufacturer?

Other place of work

Definition of Adverse Drug Event (ADE)
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- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, recombinant proteins, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))

How do you identify ADEs at your place of work?

Who is responsible for ADE reporting at your place of work?

Process Steps

Primary drug suspect is defined as the drug that the reporter determines to be the primary suspect in relation to the ADE as opposed to other concomitant products.

In the following question, the **"details about the primary suspect drug** " refers to specifics such as product name (including brand when applicable e.g, NOT a generic), label strength, manufacturer, dose, route, frequency, expiration date, lot number, national drug code (NDC), drug start and stop date of the primary suspect drug.

"Details about the ADE" include date of event, outcomes attributed to event (death, life threatening, hospitalization (initial or prolonged), disability or permanent damage, etc.), and any relevant test/laboratory data related to event.

Where does the reporter obtain details about the primary suspect drug?

Where does the reporter obtain details about the ADE?

In your experience, how consistently are the following details about the drug dispensed reported to the FDA's MedWatch program or the drug manufacturer when a typical ADE is reported

	Very consistently	Somewhat consistently	Not very consistently	Not at all consistently	Unsure
National Drug Code (NDC)	○	○	○	○	○
Lot number	○	○	○	○	○
Manufacturer	○	○	○	○	○
Active pharmaceutical ingredient (or other common API name such as USAN or INN)	○	○	○	○	○
Concomitant medications	○	○	○	○	○
Brand name of drug dispensed (where available)	○	○	○	○	○

In your opinion, how important is it that the following details about the drug dispensed are reported to the FDA's MedWatch program or the drug manufacturer when a typical ADE is reported

	Very important	Somewhat important	Not very important	Not at all important	Unsure
Lot number	○	○	○	○	○
Active pharmaceutical ingredient (or other common API name such as USAN or INN)	○	○	○	○	○
Brand name of drug dispensed (where available)	○	○	○	○	○
Manufacturer	○	○	○	○	○
Concomitant medications	○	○	○	○	○
National Drug Code (NDC)	○	○	○	○	○

End

In your opinion, what are the strengths of system/processes currently used by the FDA for receiving and analyzing ADEs reports?

In your opinion, what are some concerns you have about the system/processes used by the FDA for drug safety surveillance?

In your opinion, how can adverse drug event reporting and monitoring be improved?

In your opinion, how will ADE reporting change in the future with the advent of new technologies?

FDA's definition of a biosimilar: A biosimilar is a biological product that is highly similar to a U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product (reference: FDA website).

Some biosimilar products may be approved as interchangeable biologics that may be substituted by a pharmacist without the intervention of the prescriber. Biosimilar products may have unique brand names, but this is not a requirement. FDA has not yet determined if biosimilar products or interchangeable biologics will have the same non-proprietary name (USAN) as the reference product, or if they would have a distinguishable name comprising the non-proprietary name of the reference product combined with a unique prefix or suffix for each biosimilar.

Do you think the introduction of biosimilars will add any complexity to the current system for safety surveillance in the US?

- Yes
- No
- Unsure

How will the introduction of biosimilars add complexity to the current system for safety surveillance in the US?

In your opinion, why will the introduction of biosimilars NOT add complexity to the current system for safety surveillance in the US?

Thank you for your input and feedback on this survey! Responses to the survey will be kept confidential and the results will only be reported in the aggregate. If you would like to receive a summary report of the results, and enter to win $100, please provide your contact information below:

Name:

Title:

Email:

Do not Qualify

Thank you for your interest in our survey. Sorry your responses do not qualify for participation as we are only interested in responses from practicing health care providers familiar with the US healthcare system.

Retail Pharmacy Process

Primary drug suspect is defined as the drug that the reporter determines to be the primary suspect in relation to the ADE as opposed to other concomitant products.

In the following question, the "**details about the drug dispensed**" refers to specifics such as product name (including brand when applicable e.g, NOT a generic), manufacturer, lot number, national drug code (NDC), etc.

"**Details about the ADE**" include date of event, outcomes attributed to event (death, hospitalization, disability, etc.), and any relevant test/laboratory data related to event.

Which of the following are steps that may occur at your pharmacy before an ADE is reported to the FDA's MedWatch program or to the manufacturer?

Please select all that apply and add up to 5 additional steps if they have been omitted from the answer choices below:

- [ ] Pharmacist determines the primary suspect drug.
- [ ] ADE is reported from the pharmacy management software when the pharmacist clicks a reporting button.
- [ ] Reporter retrieves details about the drug dispensed from the patient profile.
- [ ] ADE is automatically reported from the pharmacy management software.
- [ ] Reporter reports the ADE by accessing MedWatch website/calling manufacturer.
- [ ] Reporter retrieves details about the ADE from the patient profile.
- [ ] Details about the ADE are documented in patient profile.
- [ ] Details about drug dispensed are documented in patient profile.

- [ ] Patient complains about an event related to a drug.
- [ ] Reporter contacts the patient for additional information about the ADE.
- [ ] Other1 (please specify):
- [ ] Other2 (please specify):
- [ ] Other3 (please specify):
- [ ] Other4 (please specify):
- [ ] Other5 (please specify):

Rank the following steps in the order in which they occur by **dragging and dropping** each step till the correct order is established:

» Details about drug dispensed are documented in patient profile.

» Reporter retrieves details about the drug dispensed from the patient profile.

» Patient complains about an event related to a drug.

» Pharmacist determines the primary suspect drug.

» Reporter contacts the patient for additional information about the ADE.

» ADE is reported from the pharmacy management software when the pharmacist clicks a reporting button.

» ADE is automatically reported from the pharmacy management software.

» Details about the ADE are documented in patient profile.

» Reporter retrieves details about the ADE from the patient profile.

» Reporter reports the ADE by accessing MedWatch website/calling manufacturer.

» Other1 (please specify):

» Other2 (please specify):

» Other3 (please specify):

» Other4 (please specify):

» Other5 (please specify):

Evaluate each step in terms of how consistently it is carried out in your opinion:

	Very consistently	Somewhat consistently	Not very consistently	Not at all consistently	Unsure
» Details about drug dispensed are documented in patient profile.	○	○	○	○	○
» Patient complains about an event related to a drug.	○	○	○	○	○
» Pharmacist determines the primary suspect drug.	○	○	○	○	○
» Details about the ADE are documented in patient profile.	○	○	○	○	○
» ADE is automatically reported from the pharmacy management software.	○	○	○	○	○
» ADE is reported from the pharmacy management software when the pharmacist clicks a reporting button.	○	○	○	○	○
» Reporter retrieves details about the drug dispensed from the patient profile.	○	○	○	○	○
» Reporter retrieves details about the ADE from the patient profile.	○	○	○	○	○
» Reporter contacts the patient for additional information about the ADE.	○	○	○	○	○
» Reporter reports the ADE by accessing MedWatch website/calling manufacturer.	○	○	○	○	○
» Other1 (please specify):	○	○	○	○	○
» Other2 (please specify):	○	○	○	○	○
» Other3 (please specify):	○	○	○	○	○
» Other4 (please specify):	○	○	○	○	○
» Other5 (please specify):	○	○	○	○	○

Please explain why some steps are carried out “not very consistently” or “not at all consistently”:

Retail Pharmacy Other

Which of the following is available in a patient's profile on your pharmacy's electronic pharmacy management system (e.g. CVS's RxConnect, Walgreen's Intercom Plus, etc.) when a particular product is dispensed to a patient?

Please select all that apply:

- [ ] Active pharmaceutical ingredient (USAN, INN, or other API name)
- [ ] Concomitant medications
- [ ] National Drug Code (NDC)
- [ ] Brand name (when applicable)
- [ ] Manufacturer
- [ ] Lot number

Does your pharmacy have any electronic systems for recording adverse drug events (ADEs)?

- ○ Tracking is integrated with the electronic pharmacy management software. E.g. ADE can be added to the patient profile in this system.
- ○ No tracking system in place.
- ○ Electronic system for tracking ADEs that is separate and independent from the main pharmacy management software. (please name this system):
- ○ Other (please explain):
- ○ Unsure

Who is responsible for reporting ADEs to the drug manufacturer or the FDA's MedWatch program at your organization?

- ○ Pharmacy Technician
- ○ Pharmacy Intern
- ○ Staff Pharmacist
- ○ Corporate Headquarters
- ○ Pharmacy staff member who first became aware of ADE
- ○ Pharmacy Manager
- ○ Other (please explain):

Unsure

In experience, how consistently are the following details about the drug dispensed reported to the FDA's MedWatch program or the drug manufacturer when a typical ADE is reported?

	Very consistently	Somewhat consistently	Not very consistently	Not at all consistently	Unsure
Brand name of drug dispensed (when applicable)					
Active pharmaceutical ingredient (or other common API name such as USAN or INN)					
National Drug Code (NDC)					
Concomitant medications					
Lot number					
Manufacturer					

In your opinion, how important is it that the following details about the drug dispensed are reported to the FDA's MedWatch program or the drug manufacturer when a typical ADE is reported?

	Very important	Somewhat important	Not very important	Not at all important	Unsure
National Drug Code (NDC)					
Active pharmaceutical ingredient (or other common API name such as USAN or INN)					
Concomitant medications					
Lot number					
Brand name of drug dispensed (when applicable)					
Manufacturer					

Private Practice/Community Clinic

Does your office have any of the following electronic systems and can they be used for tracking and reporting adverse drug events to the FDA's MedWatch Program or to the drug manufacturer:

Please select **all** that apply:

	Used by office	Allows documenting/tracking adverse drug event	Allows for one-click forwarding to the FDA	Allows for one-click forwarding to the drug manufacturer
Clinical Decision Support Systems (CDSS)	☐	☐	☐	☐
Electronic Health Records (EHRs)	☐	☐	☐	☐
E-prescribing	☐	☐	☐	☐

If there are any other electronic systems that can be used for tracking and reporting ADEs that are in use at your office, please describe them below:

Are you aware of services that allow you access information about a patient's ambulatory/retail medication history (e.g. which particular product was dispensed to the patient by the pharmacy)? Does your practice subscribe to such a service?

- ○ No, I am not aware of such a service
- ○ Yes, our practice subscribes to such a service
- ○ Yes, I am aware but our practice does not subscribe to such a service

How often does your ambulatory/retail patient medication history service allow you to identify the following specifics about the product that was dispensed?

	Unsure	Never	Rarely	Sometimes	Often	All of the Time
Active pharmaceutical ingredient (USAN, INN, or other API name)	○	○	○	○	○	○
Manufacturer	○	○	○	○	○	○
National Drug Code (NDC)	○	○	○	○	○	○
Concomitant medications	○	○	○	○	○	○
Lot number	○	○	○	○	○	○
Brand name (when applicable)	○	○	○	○	○	○

If you retrieve drug prescribing or dispensing information from an electronic prescribing system, are you aware of how to use the National Drug Code (NDC) to retrieve information about the brand and/or manufacturer of the drug when that information is missing from the e-prescribing or patient medication history record?

- ○ I am familiar with the NDC, and can use this code to identify the associated drug product brand or manufacturer.
- ○ I am familiar with the NDC, but do not know how to use this to identify the drug product brand or manufacturer.
- ○ I am not familiar with the NDC

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Who would typically fill out the paperwork for reporting ADEs to the manufacturer or FDA at your office/ clinic?

- ○ Administrative Staff
- ○ Physician
- ○ Nurse/ Physician's Assistant
- ○ Practice Director
- ○ Other (please explain):
- ○ Unsure

Process Steps

Primary drug suspect is defined as the drug that the reporter determines to be the primary suspect in relation to the ADE as opposed to other concomitant products.

In the following question, the **"details about the drug dispensed**" refers to specifics such as product name (including brand when applicable e.g, NOT a generic), manufacturer, lot number, national drug code (NDC), etc.

"Details about the ADE" include date of event, outcomes attributed to event (death, hospitalization, disability, etc.), and any relevant test/laboratory data related to event.

Which of the following are steps that may occur at your clinic before an ADE is reported to the **FDA's MedWatch program or to the manufacture**r?

Please select all that apply and add up to 5 additional steps if they have been omitted from the answer choices below:

- [ ] Clinician obtains details about the drug used from patient.
- [ ] Reporter retrieves details about the ADE from the CDSS.
- [ ] Dispensing pharmacy is contacted to get details about the drug dispensed.
- [ ] Details about the ADE are documented in patient record.
- [ ] Reporter retrieves details about drug dispensed from patient record.
- [ ] Reporter notes the details about the drug dispensed in patient record.
- [ ] Clinician determines the primary suspect drug.
- [ ] Reporter reports the ADE.
- [ ] Patient complains about an event related to a drug.
- [ ] Reporter retrieves details about the ADE from the e-prescribing system.
- [ ] Reporter retrieves details about the ADE from the patient record.
- [ ] Reporter contacts the patient for additional information about the ADE.
- [ ] Reporter retrieves details about the ADE from the EHR.
- [ ] Other1 (please specify):
- [ ] Other2 (please specify):
- [ ] Other3 (please specify):
- [ ] Other4 (please specify):
- [ ] Other5 (please specify):

Rank the following steps in the order in which they occur by **dragging and dropping** each step till the correct order is established:

» Patient complains about an event related to a drug.

» Clinician obtains details about the drug used from patient.

» Clinician determines the primary suspect drug.

» Details about the ADE are documented in patient record.

» Dispensing pharmacy is contacted to get details about the drug dispensed.

» Reporter notes the details about the drug dispensed in patient record.

» Reporter contacts the patient for additional information about the ADE.

» Reporter retrieves details about the ADE from the EHR.

» Reporter retrieves details about the ADE from the e-prescribing system.

» Reporter retrieves details about the ADE from the CDSS.

» Reporter retrieves details about the ADE from the patient record.

» Reporter retrieves details about drug dispensed from patient record.

» Reporter reports the ADE.

» Other1 (please specify):

» Other2 (please specify):

» Other3 (please specify):

» Other4 (please specify):

» Other5 (please specify):

Evaluate each step in terms of how consistently it is carried out in your opinion

	Very consistently	Somewhat consistently	Not very consistently	Not at all consistently	Unsure
» Patient complains about an event related to a drug.	○	○	○	○	○
» Clinician obtains details about the drug used from patient.	○	○	○	○	○
» Clinician determines the primary suspect drug.	○	○	○	○	○
» Details about the ADE are documented in patient record.	○	○	○	○	○
» Dispensing pharmacy is contacted to get details about the drug dispensed.	○	○	○	○	○
» Reporter notes the details about the drug dispensed in patient record.	○	○	○	○	○
» Reporter contacts the patient for additional information about the ADE.	○	○	○	○	○
» Reporter retrieves details about the ADE from the EHR.	○	○	○	○	○
» Reporter retrieves details					

about the ADE from the e-prescribing system.	○	○	○	○	○
» Reporter retrieves details about the ADE from the CDSS.	○	○	○	○	○
» Reporter retrieves details about the ADE from the patient record.	○	○	○	○	○
» Reporter retrieves details about drug dispensed from patient record.	○	○	○	○	○
» Reporter reports the ADE.	○	○	○	○	○
» Other1 (please specify):	○	○	○	○	○
» Other2 (please specify):	○	○	○	○	○
» Other3 (please specify):	○	○	○	○	○
» Other4 (please specify):	○	○	○	○	○
» Other5 (please specify):	○	○	○	○	○

Please explain why some steps are carried out “not very consistently” or “not at all consistently”

In your experience, how consistently are the following details about the drug dispensed reported to the FDA’s MedWatch program or the drug manufacturer when a typical ADE is reported?

	Very consistently	Somewhat consistently	Not very consistently	Not at all consistently	Unsure
Brand name of drug dispensed (when applicable)	○	○	○	○	○
Manufacturer	○	○	○	○	○
National Drug Code (NDC)	○	○	○	○	○
Concomitant medications	○	○	○	○	○
Active pharmaceutical ingredient (or other common API name such as USAN or INN)	○	○	○	○	○
Lot number	○	○	○	○	○

In your opinion, how important is it that the following details about the drug dispensed are reported to the FDA's MedWatch program or the drug manufacturer when a typical ADE is reported?

	Very Important	Somewhat important	Not very important	Not at all important	Unsure
Brand name of drug dispensed (when applicable)	○	○	○	○	○
Lot number	○	○	○	○	○
Active pharmaceutical ingredient (or other common API name such as USAN or INN)	○	○	○	○	○
Manufacturer	○	○	○	○	○
National Drug Code (NDC)	○	○	○	○	○
Concomitant medications	○	○	○	○	○

Hospital

To what extent are each of the following electronic systems implemented in your hospital?

	Fully implemented	Partially Implemented/ Piloting	Not implemented/Paper-based methods only	Unsure
Electronic Health Records (EHR)/Electronic Medical Records(EMR)	○	○	○	○
Barcode-enabled Medication Administration (BCMA)	○	○	○	○
Computerized Physician Order Entry (CPOE) system	○	○	○	○
Bar-Code Medication Preparation Technologies (BCMP)	○	○	○	○
Electronic incident reporting (IR) system	○	○	○	○
Electronic Medication Administration Record (eMAR)	○	○	○	○

Which of the following data about the particular drug administered to a particular patient are routinely available in your electronic systems?

Please select **all** that apply:

	Brand name (when applicable)	Manufacturer	National Drug Code (NDC)	Active pharmaceutical ingredient (USAN, INN, or other API name)	Label strength	Dose	Route of administration	Expiration date	Lot number	Co me
» Electronic Health Records (EHR)/Electronic Medical Records(EMR)	☐	☐	☐	☐	☐	☐	☐	☐	☐	
» Computerized Physician Order Entry (CPOE) system	☐	☐	☐	☐	☐	☐	☐	☐	☐	
» Electronic Medication Administration Record (eMAR)	☐	☐	☐	☐	☐	☐	☐	☐	☐	
» Barcode-enabled Medication Administration (BCMA)	☐	☐	☐	☐	☐	☐	☐	☐	☐	
» Bar-Code Medication Preparation Technologies (BCMP)	☐	☐	☐	☐	☐	☐	☐	☐	☐	
» Electronic incident reporting (IR) system	☐	☐	☐	☐	☐	☐	☐	☐	☐	

How accurately can the **specific drug administered (NDC#, brand and/or manufacturer name)** be identified by each of the following electronic systems?

	Very accurately	Somewhat accurately	Not very accurately	Not at all accurately	Unsure
» Electronic Health Records (EHR)/Electronic Medical Records(EMR)	○	○	○	○	○
» Computerized Physician Order Entry (CPOE) system	○	○	○	○	○
» Electronic Medication Administration Record (eMAR)	○	○	○	○	○
» Barcode-enabled Medication Administration (BCMA)	○	○	○	○	○
» Bar-Code Medication Preparation Technologies (BCMP)	○	○	○	○	○
» Electronic incident reporting (IR) system	○	○	○	○	○

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- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, recombinant proteins, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))

Who is responsible for reporting ADEs to the drug manufacturer or FDA's MedWatch program at your hospital?

- ○ Risk Management Department
- ○ Healthcare provider who first became aware of the ADE
- ○ Pharmacy Department
- ○ Quality and Safety Department
- ○ Other (please explain):
- ○ Unsure

Is there a formal procedure for reviewing the reports submitted to the Incident Reporting system (either paper based or electronic) and deciding if they qualify for reporting to the FDA's MedWatch program or to the drug manufacturer?

- ○ Yes (please explain the process):
- ○ No
- ○ Unsure
- ○ Not Applicable (please explain):

Who most often submits incident reports at your organization?

- ○ Nurses/Physician's Assistants
- ○ Both Physicians and Pharmacists equally
- ○ Both Physicians and Nurses equally
- ○ Physicians
- ○ All equally
- ○ Pharmacist
- ○ Both Nurses and Pharmacists equally

- ○ Other (please explain):
- ○ Unsure

How often does your paper-based system for capturing incident report information include fields for any of the following:

	Always	Often	Sometimes	Rarely	Never	Unsure
Manufacturer	○	○	○	○	○	○
National Drug Code (NDC)	○	○	○	○	○	○
Lot number	○	○	○	○	○	○
Brand name (when applicable)	○	○	○	○	○	○
Active pharmaceutical ingredient (USAN, INN, or other API name)	○	○	○	○	○	○
Concomitant medications	○	○	○	○	○	○

In what format is the “drug name” field in your hospital’s IR system:

Please select **all** that apply:

- ☐ Free text entry
- ☐ Drop down menu with a formulary
- ☐ Other (please explain):
- ☐ Unsure

Are any of the following integrated with your electronic incident reporting system? (drug and event related data can be automatically transferred without manually typing it in)

Please select **all** that apply:

- ☐ Electronic Health Records (EHR)/Electronic Medical Records(EMR)
- ☐ Barcode-enabled Medication Administration (BCMA)
- ☐ Electronic Medication Administration Record (eMAR)
- ☐ Bar-Code Medication Preparation Technologies (BCMP)
- ☐ Computerized Physician Order Entry (CPOE) system

- [ ] No, the IR system is stand-alone.
- [ ] Unsure
- [ ] Other (please specify):
- [ ] Not applicable (please explain):

Does the formulary available as a drop-down list in your IR system include brand names(when applicable to the specific product selected) ?

- ( ) Yes, but brand names are generally used to refer to any selected product with the same active ingredient
- ( ) Yes, few brand names are included
- ( ) Yes, most brand names are included
- ( ) Yes, many brand names are included
- ( ) Not Applicable (please explain):
- ( ) No, only generic names (API, USAN, INN etc.) are included
- ( ) Other (please explain):
- ( ) Unsure

"**Details about the suspect drug**" refers to specifics such as product name (including brand when applicable e.g, NOT a generic), manufacturer, lot number, national drug code (NDC), etc.

In your opinion, where might an ADE reporter from your organization retrieve **details about the suspect drug** so that s/he may fill out the FDA's MedWatch form or respond to provide specifics to the drug manufacturer?

Please select **all** that apply:

- [ ] Contacting the dispensing Pharmacy
- [ ] Incident Reporting system
- [ ] CPOE
- [ ] eMAR
- [ ] Paper-based incident report
- [ ] Patient chart
- [ ] EHR/EMR

- [ ] Other (please specify):

- [ ] Unsure

"**Details about the ADE**" include date of event, outcomes attributed to event (death, hospitalization, disability, etc.), and any relevant test/laboratory data related to event.

In your opinion, where might an ADE reporter from your organization retrieve **details about the ADE** so that s/he may fill out the FDA's MedWatch form or respond to provide specifics to the drug manufacturer?

Please select **all** that apply:

- [ ] Patient chart
- [ ] EHR/EMR
- [ ] Contacting the patient/caregiver of patient
- [ ] Paper-based incident report
- [ ] Incident Reporting System
- [ ] Other (please specify):

- [ ] Unsure

Which of the following are steps that may occur at your institution before an ADE is reported to the FDA's MedWatch program or to the manufacturer?

Please select all that apply and add up to 5 additional steps if they have been omitted from the answer choices below:

- [ ] Details about drug administered are documented in patient record
- [ ] Reporter retrieves details about the drug administered by contacting the pharmacy
- [ ] Details about the adverse event are documented in patient record
- [ ] Clinician suspects event is related to a drug
- [ ] Reporter retrieves details about the drug administered from the patient chart
- [ ] Reporter retrieves details about the ADE from the EHR/EMR
- [ ] Reporter retrieves details about the drug administered from the Incident Reporting system
- [ ] Reporter retrieves details about the ADE from the paper-based incident report
- [ ] Reporter retrieves details about the drug administered from the EHR/EMR
- [ ] Clinician determines the primary suspect drug

- [ ] Reporter retrieves details about the ADE from ${q://QID118/ChoiceTextEntryValue/2}
- [ ] Reporter retrieves details about the drug administered from ${q://QID117/ChoiceTextEntryValue/2}
- [ ] Reporter retrieves details about the drug administered from the CPOE system
- [ ] Details about the drug administered and ADE are documented in an incident report for internal reporting
- [ ] Reporter retrieves details about the ADE
- [ ] Reporter retrieves details about the ADE by contacting the patient or patient's caregiver
- [ ] Reporter retrieves details about the drug administered from the eMAR system
- [ ] Reporter retrieves details about the ADE from the paper-based incident report
- [ ] Reporter retrieves details about the drug administered
- [ ] Reporter retrieves details about the ADE from the patient chart
- [ ] Reporter retrieves details about the ADE from the Incident Reporting system
- [ ] Reporter reports the ADE
- [ ] Other1 (please specify):
- [ ] Other2 (please specify):
- [ ] Other3 (please specify):
- [ ] Other4 (please specify):
- [ ] Other5 (please specify):

Rank the following steps in the order in which they occur by **dragging and dropping** each step till the correct order is established:

» Details about drug administered are documented in patient record

» Details about the adverse event are documented in patient record

» Clinician suspects event is related to a drug

» Clinician determines the primary suspect drug

» Details about the drug administered and ADE are documented in an incident report for internal reporting

» Reporter retrieves details about the drug administered

» Reporter retrieves details about the drug administered from the patient chart

» Reporter retrieves details about the ADE from the paper-based incident report

» Reporter retrieves details about the drug administered by contacting the pharmacy

» Reporter retrieves details about the drug administered from the EHR/EMR

» Reporter retrieves details about the drug administered from the CPOE system

» Reporter retrieves details about the drug administered from the eMAR system

» Reporter retrieves details about the drug administered from the Incident Reporting system

» Reporter retrieves details about the drug administered from ${q://QID117/ChoiceTextEntryValue/2}

» Reporter retrieves details about the ADE

» Reporter retrieves details about the ADE from the patient chart

» Reporter retrieves details about the ADE from the paper-based incident report

» Reporter retrieves details about the ADE by contacting the patient or patient's caregiver

» Reporter retrieves details about the ADE from the EHR/EMR

» Reporter retrieves details about the ADE from the Incident Reporting system

» Reporter retrieves details about the ADE from ${q://QID118/ChoiceTextEntryValue/2}

» Reporter reports the ADE

» Other1 (please specify):

» Other2 (please specify):

» Other3 (please specify):

» Other4 (please specify):

» Other5 (please specify):

Evaluate each step in terms of how consistently it is carried out in your opinion:

	Very consistently	Somewhat consistently	Not very consistently	Not at all consistently	Unsure
» Details about drug administered are documented in patient record	○	○	○	○	○
» Details about the adverse event are documented in patient record	○	○	○	○	○
» Clinician suspects event is related to a drug	○	○	○	○	○
» Clinician determines the primary suspect drug	○	○	○	○	○

» Details about the drug administered and ADE are documented in an incident report for internal reporting	○	○	○	○	○
» Reporter retrieves details about the drug administered	○	○	○	○	○
» Reporter retrieves details about the drug administered from the patient chart	○	○	○	○	○
» Reporter retrieves details about the ADE from the paper-based incident report	○	○	○	○	○
» Reporter retrieves details about the drug administered by contacting the pharmacy	○	○	○	○	○
» Reporter retrieves details about the drug administered from the EHR/EMR	○	○	○	○	○
» Reporter retrieves details about the drug administered from the CPOE system	○	○	○	○	○
» Reporter retrieves details about the drug administered from the eMAR system	○	○	○	○	○
» Reporter retrieves details about the drug administered from the Incident Reporting system	○	○	○	○	○
» Reporter retrieves details about the drug administered from ${q://QID117/ChoiceTextEntryValue/2}	○	○	○	○	○
» Reporter retrieves details about the ADE	○	○	○	○	○
» Reporter retrieves details about the ADE from the patient chart	○	○	○	○	○
» Reporter retrieves details about the ADE from the paper-based incident report	○	○	○	○	○
» Reporter retrieves details about the ADE by contacting the patient or patient's caregiver	○	○	○	○	○
» Reporter retrieves details about the ADE from the EHR/EMR	○	○	○	○	○
» Reporter retrieves details about the ADE from the Incident Reporting system	○	○	○	○	○
» Reporter retrieves details about the ADE from ${q://QID118/ChoiceTextEntryValue/2}	○	○	○	○	○
» Reporter reports the ADE	○	○	○	○	○
» Other1 (please specify):	○	○	○	○	○
» Other2 (please specify):	○	○	○	○	○
» Other3 (please specify):	○	○	○	○	○
» Other4 (please specify):	○	○	○	○	○
» Other5 (please specify):	○	○	○	○	○

Please explain why some steps are carried out “not very consistently” or “not at all consistently”:

In your experience, how consistently are the following details about the drug dispensed reported to the FDA’s MedWatch program or the drug manufacturer when a typical ADE is reported

	Very consistently	Somewhat consistently	Not very consistently	Not at all consistently	Unsure
Manufacturer	○	○	○	○	○
National Drug Code (NDC)	○	○	○	○	○
Concomitant medications	○	○	○	○	○
Active pharmaceutical ingredient (or other common API name such as USAN or INN)	○	○	○	○	○
Lot number	○	○	○	○	○
Brand name of drug dispensed (when applicable)	○	○	○	○	○

In your opinion, how important is it that the following details about the drug dispensed are reported to the FDA’s MedWatch program or the drug manufacturer when a typical ADE is reported

	Very important	Somewhat important	Not very important	Not at all important	Unsure
Manufacturer	○	○	○	○	○
Active pharmaceutical ingredient (or other common API name such as USAN or INN)	○	○	○	○	○
Concomitant medications	○	○	○	○	○
Lot number	○	○	○	○	○
National Drug Code (NDC)	○	○	○	○	○
Brand name of drug dispensed (when applicable)	○	○	○	○	○