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MEDSTAT

Implementation Planning Study for the Integration of Medical Event Reporting Input and Data Structure for Reporting to AHRQ, CDC, CMS, and FDA

Final Report

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Appendixes

Appendix A Glossary of Terms and Definitions

Term	Definition	Source[1]
Accident	An accident is a series of events that involves damage to a defined system disrupting the ongoing or future output of the system.	(IOM, 1999)
Active error (or active failure)	Active errors (or active failures) occur when the actions and decisions of individuals result in failures that can immediately or directly impact patient safety.	(MERS-TM, undated)
Active error	Active errors are errors that occurs at the level of the frontline operator and whose effects are felt almost immediately.	(IOM, 1999)
Active failure and types of active failure	Active failures can be thought of as occurring at the sharp end of a continuum of decisions, environmental factors, and actions that affect patient care. There are three major types of active failures: 1) Knowledge-based failure – occurs when individuals are unable to apply their existing knowledge to new situations; 2)Rule-based failure – occurs when a person fails to carry out a procedure or protocol correctly or chooses the wrong procedure; 3) Skill-based failure – occurs when a person fails in the performance of a routine task that normally requires little conscious effort. Most of us operate in the skill-based mode for many of the activities that we perform on a daily basis. If a routine is changed or interrupted, an error may occur.	(MERS-TM, undated)
Active failure	An error which is precipitated by the commission of errors and violations. These are difficult to anticipate and have an immediate adverse impact on safety by breaching, bypassing, or disabling existing defenses.	(JCAHO, undated(a))
Adverse drug event (adverse drug error)	Any incident in which the use of a medication (drug or biologic) at any dose, a medical device, or a special nutritional product (e.g., dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient.	(JCAHO, undated(a))
Adverse drug reaction (ADR)	An undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both.	(JCAHO, undated(a))
Adverse event	An untoward, undesirable, an usually unanticipated event, such as death of a patient, and employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient.	(JCAHO, undated(a))
Adverse event	An injury caused by medical mismanagement rather than the underlying disease.	(Brennan et al, 1991)
Adverse event	An injury that was caused by medical management and that results in measurable disability.	(QuIC, 2000)
Adverse event	An injury resulting from a medical intervention.	(IOM, 1999)
Adverse event	Adverse Events that may be candidates for root cause analysis are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center.	(VA NCPS, 2002)
Adverse reaction leading to disability	If the adverse reaction caused a significant or permanent change in a patient's body function, physical activities, or quality of life (examples: strokes or nervous system disorders brought on by drug therapy).	(Henkel, 1998)
Adverse reaction leading to death	If an adverse reaction to a medical product is a suspected cause of a patient's death.	(Henkel, 1998)
Adverse reaction leading to hospitalization	If a person is admitted or has a prolonged hospital stay because of a serious adverse reaction(e.g. a serious allergic reaction to latex)	(Henkel, 1998)
Adverse reaction leading to need for	If use of a medical product required medical or surgical treatment to prevent impairment (examples: burns from radiation equipment or	(Henkel, 1998)

Term	Definition	Source[1]
intervention to avoid permanent damage	breakage of a screw supporting a bone fracture).	
Adverse reaction leading to birth defects, miscarriage, stillbirth or birth with disease	If exposure to a medical product before conception or during pregnancy is suspected of causing an adverse outcome in the child (example: malformation in the child caused by the acne drug Accutane, or isotretinoin).	(Henkel, 1998)
Adverse reaction leading to life-threatening hazard	If the patient was at risk of dying at the time of the adverse reaction or if it is suspected that continued use of a product would cause death (examples: pacemaker breakdown or failure of an intravenous (IV) pump that could cause excessive drug dosing.	(Henkel, 1998)
Antecedent event	An antecedent describes the preceding event, condition, or cause. Therefore, antecedent events are those actions and decisions that led up to the consequent event. An event may have multiple antecedent (or preceding) events leading up to the consequent event. Antecedent events and conditions can be discovered by asking why of the consequent event.	(MERS-TM, undated)
Barrier	A barrier is any action or process built into the work flow to check for accuracy or quality and that may prevent an event. Although barriers are designed to avert accidents (or facilitate recovery), recovery does not always occur as the result of a barrier.	(MERS-TM, undated)
Blunt end of health care system	Those at the blunt end of the system affect safety through their effect on the constraints and resources acting on the practitioners at the sharp end. In medicine, the blunt end includes government regulators, hospital administrators, nursing managers, and insurance companies.	(Cook and Woods, 1994)
Classification system	The categorizing of errors into distinguished levels based upon their behavior, accountability, outcome, context or process. Behavior classifications - omission vs commission, misuse vs overuse vs. underuse; Accountability classifications - individual vs system and intentional vs. unintentional; Outcome classification - a scale from no harm to death; Context classification - low staff; Process classification - wrong dose vs. wrong process.	(NPSF, 1997)
Close Calls	An event or situation that could have resulted in an accident, injury or illness to a patient, a visitor, or staff, but did not, either by chance or through timely intervention.	(VA NCPS, 2002)
Complication	A detrimental patient condition that arises during the process of providing health care, regardless of the setting in which the care is provided. For instance, perforation, hemorrhage, bacteremia, and adverse reactions to medication (particularly in the elderly) are four complications of colonoscopy and its associated anesthesia and sedation. A complication may prolong an inpatient's length of stay or lead to other undesirable outcomes.	(JCAHO, undated(a))
Device-related serious injury	An injury or illness that is life-threatening; results in permanent impairment/damage to body function or structure; or necessitates medical/surgical intervention to prevent impairment/ damage of body function/structure.	(USUHS and FDA, 1997)
Error of commission	An error which occurs as a result of an action taken. Examples include when a drug is administered at the wrong time, in the wrong dosage, or using the wrong route; surgeries performed on the wrong side of the body; and transfusion errors involving blood cross-matched for another patient.	(JCAHO, undated(a))
Error of omission	An error which occurs as a result of an action not taken, for example, when a delay in performing an indicated cesarean section results in a fetal death, when a nurse omits a dose of a medication that should be administered, or when a patient suicide is associated with a lapse in	(JCAHO, undated(a))

Term	Definition	Source[1]
	carrying out frequent patient checks in a psychiatric unit. Errors of omission may or may not lead to adverse outcomes.	
Error	The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.	(QuIC, 2000)
Error	See "active failure" or "latent failure".	(MERS-TM, undated)
Error	Failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim; the accumulation of errors results in accidents.	(IOM, 1999)
Event Codes	Part of describing an event involves assigning codes that tell what happened and where the event first occurred in the organizational process, what happened (or what could have happened) and where it was later discovered in the organizational process. Transfusion Services and Blood Centers each have their own set of event codes because they perform different functions and processes.	(MERS-TM, undated)
Event	An occurrence with a potentially negative outcome that most often results from both latent conditions and human/active error.	(MERS-TM, undated)
Forcing Function	Something that prevents the behavior from continuing until the problem has been corrected.	(Reason, 1990)
Genotype	The characteristic collection of factors that lead to the surface, phenotypical appearance of the event. They refer to patterns of contributing factors.	(NPSF, 1997)
Human error	See "active failure".	(MERS-TM, undated)
Human factors	Study of the interrelationships between humans, the tools they use, and the environment in which they live and work.	(Weinger, 1998)
Intentionally Unsafe Acts	Acts, as they pertain to patients, are any events that result from: a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider and/or staff; or events involving alleged or suspected patient abuse of any kind.	(VA NCPS, 2002)
Knowledge-based failure	When individuals are unable to apply their existing knowledge to new situations.	(MERS-TM, undated)
Latent condition/error	Latent conditions occur when individuals such as managers or administrators take actions and/or make decisions that affect technical or organizational policy and procedures or the work environment. Their actions and decisions may have unintended consequences in the future that negatively impact patient care.	(MERS-TM, undated)
Latent error	Errors in the design, organization, training, or maintenance that lead to operator errors and whose effects typically lie dormant in the system for lengthy periods of time.	(IOM, 1999)
Latent failure	An error which is precipitated by a consequence of management and organizational processes and poses the greatest danger to complex systems. Latent failures cannot be foreseen but, if detected, they can be corrected before they contribute to mishaps.	(JCAHO, undated(a))
Medical error	An adverse event or near miss that is preventable with the current state of medical knowledge.	(QuIC, 2000)
Medical error	An unintended act, either of omission or commission; an act that does not achieve its intended outcome.	(JCAHO, 2001)
Medical error	Failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (error of planning).	(Cooper et al., 2001)
Medication errors	A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in	(NCCMERP, 2001)

Term	Definition	Source[1]
	the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packing and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.	
Mistake	Result of conscious deliberation, when a person generalizes too rapidly, classifying a new situation as similar to an old one when, in fact there are significant discrepancies; false generalizations. Contrasted to slips, which are almost always small things: a misplaced action, the wrong thing moved, a desired action undone. They are relatively easy to discover by simple observation and monitoring. Mistakes can be major events, and they are difficult or even impossible to detect--after all, the action performed is appropriate for the goal.	(Norman, 1990)
Near miss	An event in which the unwanted consequences were prevented because there was a recovery by identification and correction of the failure, either planned or unplanned.	(Van der Schaaf et al., 1991)
Near miss	An event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.	(QuIC, 2000)
Near miss	A near miss event is an event for which unwanted consequences were prevented because some recovery action was taken that identified and corrected the failure. Recovery actions, which are present in all near miss events, can be planned or unplanned. The recovery is planned if it results from a barrier, such as a check point in the work process, that was designed to catch mistakes or ensure quality. However, the recovery is unplanned if it results from an accidental or lucky catch. MERS-TM categorizes events into three types: misadventures, no harm events, and near miss events.	(MERS-TM, undated)
Near miss	Any process variation which did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome.	(JCAHO, undated(a))
Negligence	Failure to use such care as a reasonably prudent and careful person would use under similar circumstances.	(JCAHO, undated(a))
No harm event	A no harm event is an event that has actually occurred (no recovery action was taken) but where no actual harm has come to the patient or the organization. Except for "luck" (or in health care, the robust nature of human physiology), these accidents would have become misadventures.	(MERS-TM, undated)
Omission	Failure to carry out some of the actions necessary to achieve a desired goal.	(Reason, 1990)
Patient safety	Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur.	(IOM, 1999)
Patient safety	The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care. These events include “errors,” “deviations,” and “accidents.” Safety emerges from the interaction of the components of the system; it does not reside in a person, device or department. Improving safety depends on learning how safety emerges from the interactions of the components. Patient safety is a subset of healthcare quality.	(NPSF, 1999)
Patient safety	A process that guards against any adverse condition in a patient occurring as a result of testing or treatment by care giver(s).	(AHRQ, 1999)
Phenotype	The phenotype of an incident is what happens, what people actually do or what they do wrong, what you can observe. They are specific to the local situation and context – the surface appearance of an incident.	(NPSF, 1997)
Proximate cause	An act or omission that naturally and directly produces a consequence. It	(JCAHO,

Term	Definition	Source[1]
	is the superficial or obvious cause for an occurrence. Treating only the "symptoms," or the proximate special cause, may lead to some short-term improvements, but will not prevent the variation from recurring.	undated(a))
Quality of care	Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.	(IOM, 1999)
Risk containment	Immediate actions taken to safeguard patients from a repetition of an unwanted occurrence. Actions may involve removing and sequestering drug stocks from pharmacy shelves and checking or replacing oxygen supplies or specific medical devices.	(JCAHO, undated(a))
Risk management	Clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.	(JCAHO, undated(a))
Root cause analysis	A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.	(JCAHO, undated(a))
Root cause	The underlying factors that, if eliminated, could reduce the risk of similar errors in the future.	(JCAHO, undated(a))
Rule-based failure	When a person fails to carry out a procedure or protocol correctly or chooses the wrong procedure.	(MERS-TM, undated)
Safety	Freedom from accidental injury. This definition recognizes that this is the primary safety goal from the patient's perspective.	(NPSF, 1999)
Sentinel event	An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.	(JCAHO, undated(a)); (VA NCPS, 2002)
Sharp end of healthcare system	Practitioners at the sharp end actually interact with the hazardous process in their roles. In medicine, these practitioners are anesthesiologists, surgeons, nurses, and some technicians who are physically and temporally close to the patient.	(Cook and Woods, 1994)
Skill-based failure	When a person fails in the performance of a routine task that normally requires little conscious effort. (Most of us operate in the skill-based mode for many of the activities that we perform on a daily basis. If a routine is changed or interrupted, an error may occur.)	(MERS-TM, undated)
Slip	Type of error that results from automatic behavior, when subconscious actions that are intended to satisfy our goals get waylaid en route.	(Norman, 1990)
System	A regularly interacting or interdependent group of items forming a unified whole.	(QuIC, 2000)
System	A set of interdependent elements interacting to achieve a common aim. These elements may be both human and non-human (equipment, technologies, etc.).	(IOM, 1999)
Systems error	An error that is not the result of an individual's actions, but the predictable outcome of a series of actions and factors that comprise a diagnostic or treatment process.	(QuIC, 2000)
Underlying cause	The systems or process cause that allow for the proximate cause of an event to occur. Underlying causes may involve special-cause variation, common-cause variation, or both.	(JCAHO, undated(a))
Unpreventable adverse event	An adverse event resulting from a complication that cannot be prevented given the current state of knowledge.	(QuIC, 2000)

[1]References for the National Quality Forum were not included because their Website denies permission to quote.

Appendix B Detailed Descriptions of Adverse Event Reporting Systems of Four DHHS Agencies

AERS

Reporting or Database System:	**Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	N/A
2. Internet Location: http://	http://www.fda.gov/cder/aers/
3. Host Organization(s)	The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER)
4. Primary contact information (e.g. Address, Phone)	Ralph Lillie - (301) 827-3513 LILLIE@CDER.FDA.GOV Roger Goetsch - (301) 770-9299 GOETSCH@CDER.FDA.GOV Sandra Valencia - VALENCIA@CDER.FDA.GOV Carol Holquist – (301) 827-0195
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The Adverse Event Reporting System (AERS) is an information workflow system (including a computerized information database) designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The ultimate goal of AERS is to improve the public health by providing the best available tools for storing and analyzing safety reports. Reports from AERS are used by FDA staff in conducting post marketing drug surveillance and compliance activities and in responding to outside requests for information. One major function of AERS data is to ensure that a product's labeling information correctly captures the adverse events associated with the product. This data can also be used to re-evaluate an approval decision on an established product. The majority of adverse event activity is seen in the first three years of post market surveillance. Among AERS system features are: the on-screen review of reports; searching tools; and various output reports. The reports in AERS are evaluated by clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to detect safety signals and to monitor drug safety. They form the basis for further epidemiological studies when appropriate. Adverse event reports received through form 3500a (mandatory – manufacturers/distributors/packers) or 3500 (voluntary – health professional/consumer) are received by MedWatch and triaged by Logistics Applications who QA's form and sends drug/biologic reports to AERS. Logistic Applications also adds MedDRA codes to describe event/outcome. Also get reports from USP and CIOMS forms (international). Mandatory reporting of serious and unlabelled adverse events is required within 15 days. Periodic reporting of non-serious (labeled or unlabelled) and serious-labeled events. Manufacturer can get exemption from reporting of labeled, non-serious events. Note that this is different from medical device reporting that requires reporting of serious events only. For non-serious, reporter can enter a "medically important event" (ie. In box B2), possibly using MedDRA, rather than selecting "death" etc..
6. What is the geographic scope of data collection (national, state, local, facility etc)?	Data for AERS is received from both national and international sources.

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
7. What is the unit of data entry (e.g., event, patient, product)?	Events covered by AERS include special nutritional products, drugs, and licensed biological products. An adverse event is any undesirable event associated with the use of a drug or therapeutic biologic in humans. An Individual Safety report will not be entered into the database unless it passes certain quality parameters. One of those is to meet a minimum data set - having a valid reported drug, an event (reaction), patient, and reporter.
8. Who is allowed/required to input information?	For licensed biological products - any person whose name appears on the label of a licensed biological product as its manufacturer, packer, or distributor has reporting responsibilities, as does the individual or corporate entity that holds the product license. For drugs - The manufacturer applicant is required to report. In addition, any person whose name appears on the label of a marketed drug as its manufacturer, packer, or distributor has reporting responsibilities, as does the individual or corporate entity that holds an approved new drug application (NDA), abbreviated new drug application (ANDA), or antibiotic application. For purposes of this guideline, "applicant" includes all persons with reporting responsibility under 21 CFR 310.305 and 314.80. Reporting may also be done (and is encouraged) on a voluntary basis from health care professionals and consumers through the MedWatch program. AERS also receives input from the USP Medication Errors Reporting Program. The appropriate fields from these forms are entered into AERS using a MedDRA preferred term of “medication error”.
9. What are the regulations/laws affecting reporting?	Drug manufacturers of NDA and ANDA drugs (See http://www.fda.gov/medwatch/report/mfg.htm) and licensed manufacturers of approved biologic product license applications are required to report adverse experiences to the FDA under 21 CFR 310.305, 314.80, 314.98, and 600.80. See http://www.fda.gov/medwatch/report/guide2.htm and http://www.fda.gov/medwatch/report/mfg.htm for details. Regulations Sheet also has more details on the specific regulations.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	E.5 (Voluntary Form 3500) - Option not to disclose identity to manufacturer to avoid FDA providing reporter name, address and phone number to manufacturer of a suspect drug or biologic. For mandatory reporting (Form 3500a): FDA has promulgated a regulation [21 CFR §20.63(2)] that extends protection against disclosure of voluntary reports held by medical device, pharmaceutical, and biologics manufacturers by preempting state discovery laws. User facility name will not be released to the public under the FDA Modernization Act. FDA will also not release the identity of the patient or any information that can be used to identify the patient, such as the serial number of an implanted device. Nor will it release the name of any person other than the MDR contact. The name of the reporter and facility are deleted from disclosed data. Please note that the FDA is required under the Freedom of Information and Privacy Acts (SEC 552, Title 5, USC) (PL 93-579) to delete, prior to public disclosure, any information that constitutes trade secrets, and confidential, commercial, or financial information; and any personal, medical and similar information that would constitute a clearly unwarranted invasion of personal privacy. Included in the deletion requirements are all identification of the reporters and userfacilities associated with the events. The USP Medication Error Reporting Program allows reporters to submit anonymously but this is rarely done. The system asks for reporter identification but not institution where error occurred. Reporter may maintain confidentiality beyond USP for data sent onto FDA, manufacturers and ISMP.

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	**MedWatch Voluntary form 3500 can be sent by: mail, phone, fax or completed** on-line via the MedWatch homepage: https://www.accessdata.fda.gov/scripts/medwatch/ **Mandatory 3500A forms and the foreign form CIOMS I can be mailed to:** Central Document Room (when duplicate copies for drugs) Center for Drug Evaluation and Research Food and Drug Administration 12229 Wilkins Avenue Rockville, MD 20852 When single copies for drugs are required by regulation: Office of Drug Safety HFD-400 Center for Drug Evaluation and Research Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857 Biologics: Epidemiology Branch, HFM-220 Food and Drug Administration 1401 Rockville Pike Rockville, MD 20852-1448 There are optional electronic versions available for filling out the form using a PC. There is also work being done to report electronically (Expedited Safety Reports) and draft guidance is available at http://www.fda.gov/cder/guidance/4153dft.pdf. 4 Companies are currently using electronic submission. 2 of these have stopped submission via paper reporting. When a report is received, AERS assigns an individual safety report (ISR) for each report with a bar code. As part of processing, paper submissions are scanned and stored in retrieval software. Faxes of biologics and drug forms are also accepted, but only for periodic reports. The USP MERS form is first sent to USP, then sent periodically via courier to AERS where it is entered into the system. Analysts from the Office of Drug safety pull mediation error reports from AERS each month. These reports are used by a staff member at the FDA Office of Drug Safety to enter the ISR# and derived NCCMERP codes into an Oracle database maintained by the Office of Drug Safety.
12. What are the methods of editing information (e.g. correcting/add more information to records)	The 3500a form allows follow-up information:Field H.2 - Correction: Changes to previously submitted information. Additional information: Information not know when the original report was submitted Response to FDA request: Additional information requested by FDA concerning the device/event. Device evaluation: analysis of eventAny change to a previous report must be submitted in writing via a follow-up report. 3500 form - reporter can send in a follow-up form or call to make changes.
13. Where is the collected data stored (name of database, number of data storage locations)?	AERS is the database. The data from all sources eventually arrives at the AERS triage unit – either directly (MedWatch forms) or from USP, CBER or CDER. Under the supervision of FDA staff, data is entered and question and answered by PSI International staff. The database programming and design was created and is maintained by Booz-Allen and Hamilton. Data storage requirements are specified in detailed specifications.

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
14. How often is the system revised (annual, semi-annual etc)?	A timeline was provided that shows the various versions of the AERS database (See PMSS process evolutionary timeline Nov. 1997 to Dec 2001 document.) The timeline shows a total of about 14 revisions over the past 5 years with an average of about 6 months between revisions. Revisions are made based upon issues brought up via Change Control Requests and reviewed by the Change Control Board. One item which is updated on a regular basis is the MedDRA portion of the system. MedDRA is updated 2x per year. AERS updates one time per year to accommodate the semi-annual MedDRA updates.
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	Federal register notice - public comments
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	No minimum. Form 3500 can be written out and mailed to FDA.
17. What new features are being planned and/or are on wish lists?	Providing regulatory submissions of periodic reports in electronic format - see http://www.fda.gov/cder/guidance/4153dft.pdf. Currently 4 companies are submitting electronically using ICH E2B as the standard format for transmission. Goal is to increase this over time in order to reduce processing costs from $18/ISR to $5/ISR
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	MERS data is entered into AERS, then entered into an Office of Drug Safety Oracle database. This data is used to make recommendations for drug name changes and/or issuing of alerts. No links to state systems
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	(P)E.2 - Health professional. If you are not a health professional, write NA Yes No (N) E.3 - OccupationG. All Manufacturers(N) G.1 - Contact Office (name/address and manufacturing site)(N) G.2 - Phone number(P) G.3 - Manufacturer Report source (check all that apply) - Check the box(es) that most accurately describe(s) how the manufacturer [contact office] became aware of the reported adverse event or from where the information about the adverse event originated.Foreign - foreign country etcStudy - study that involves a systematic collection of adverse events from a protocolLiterature - If the report source is the scientific literature or an unpublished manuscript, a copy of the article or manuscript must be attached. Foreign language articles should be translated into English. Record the date of the article as the date of the event (block B3), and provide a full literature citation in block H10;Drugs and Biologics: A separate 3500A form must be completed for each identifiable patient described in the article or manuscript. Consumer - recommend help of care provider; Health professional; User facility - User facility should be checked if the manufacturer received the report from the MDR contact in a user facility as identified in section F. Company rep, Distributor Other - Any source not covered by the previous categories. Note: AERS gets it product/manufacturer information from FDA's CDER dictionaries.

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
20. Is participation mandatory or voluntary?	Mandatory for manufacturers, distributors, packers, and licensees. See items 8 and 9.
21. List fields related to contributor/participant contact information	(N)E.1 - Reporter Address and Phone #
22. List fields related to facility contact information(include type of facility, teaching status, id information)	N/A
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact information	G. All Manufacturers (N) G.1 - Contact Office (name/address and manufacturing site) (N) G.2 - Phone number (N) G.9 - Manufacturer Report # - used by AERS staff to identify potential multiple submission of information on the same event. Mulitple ISRs with the same manufacturer number are stored in the system as a case.
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
25. List fields related to Provider of Care identification	N/A
26. List fields that identify types of care providers included in system	N/A
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	(N)A.1 - Identifier - patient's initials or some other type of information that will allow you, the reporter to readily locate the case if you are contacted for more information. Do not use patient's name or SSN.
28. List fields related to patient contact information (e.g. address, zip code, county, region)	N/A
29. List fields related to patient demographics (e.g. age, sex, race)	(N)A.2 - Age at time of event OR Date of Birth - provide the most precise information available. For age, indicate time units (3 years+-use years, less than 3 years old, use months; less than 1 month old, use days) (P)A.3 - Sex (if congenital anomaly, report sex of the child) Female Male (N)A.4 - Weight (in lbs OR kg) **Race could be included by reporter in medical history of patient, but not a separate field (see question 31)
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)?	No traceable data - patient initials or other reporter assigned ID are entered in database.

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
31. List fields related to pre-existing conditions and/or medical history of patient	(N)Drugs and Biologics - C.10 - Concomitant medical products and therapy dates (exclude tx of event) List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at or around the time of the event. DO NOT include products used to treat the event. (N)B.7 - Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (P)Categories for race (as specified in instructions): Am. Indian – Alaska Native= American Indian or Alaska Native Asian= Asian Continent to include Indian Subcontinent Native Hawaiian or other Pacific Islander= Native Hawaiian or other Pacific Islander Black= Black, not of Hispanic origin Hispanic= Hispanic White= White, not of Hispanic origin
32. List fields that capture the clinical condition of patient at time of event	C.4 - Diagnosis for use of drug, biologic
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	N/A
34. List any other types of information collected about the patient	(P) B.2 - Outcome attributed to adverse event - these are regulatory definitions of serious outcomedeath (date in fixed format)life-threateninghospitalization - initial or prolongeddisabilitycongenital anomaly required intervention to prevent permanent impairment/damageother (narrative description)Note: this is used to classify report and sort for data entry
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Pick list items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Drugs, biological products Product problems include, but are not limited to, such concerns as: Suspected contamination; Therapeutic failures; Product confusion (caused by name, labeling, design or packaging); Suspected super potent or subpotent medication; Labeling problems caused by printing errors/omissions.

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer)	A separate form should be submitted for each individual product problem report. (S - drug trade name) C.1 - Name (give labeled strength and mfr/labeler, if known) Use the trade name as marketed. If unknown use the generic name (with the manufacturer or labeler's name, if known). For quality problem reports, include the manufacturer's name and the labeled strength for both prescription and non-prescription products. (N)C.2 - Dose frequency & route used. Describe how the product was used by the patient. For reports involving overdoses, overdose amt, not prescribed amount. (N)C.3 - Therapy dates (if unknown, give duration). Provide the date administration was started (or best estimate) and the date stopped (or best estimate). If no dates are known, an estimated duration is acceptable or if therapy was less than one day, then duration is appropriate. (P) C.5 - Event abated after medication use stopped or dose reduced Yes No Doesn't apply (N) C.6 - Lot # (if known). If known, include the lot number(s) with all product problem reports, or any adverse event report with a biologic or medication (N) C.7 - Exp. Date (if known). Include with all product problem reports ONLY. (P) C.8 - Event reappeared after reintroduction Yes, No, doesn't apply (S-NDC codes) C.9 - NDC# - for product problems only (if known) National drug code
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer) *continued*	(N) G.5 - Manufacturers should provide whatever information is applicable to the suspect medication identified in section C(S-NDA#)(A)NDA #: The abbreviated new drug application or the new drug application (NDA) number. The report should be filed to the first approved NDA if a product has several NDAs and the specific one cannot be determined (S-IND#) IND #: The investigational new drug (IND) application number (S-PLA#) PLA #: Composed of the 4-digit U.S. License Number followed by a slash, followed by the 4-character Product Code Pre-1938: Check the box if the suspect medication was marketed prior to 1938 and does not have an NDA # OTC Check the box if the suspect medication can be purchased over-Product: the-counter (without a prescription) (S-Protocol #) G.6 - If IND, protocol# Note: CBER supplies a list of products to the contractor(BAH) for insertion into AERS.
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	N/A
38. List fields associated with vaccine related events.	N/A
39. List fields associated with infection related events.	N/A

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
40. List fields associated with any other type of event. List type of event.	N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	(P) B.1 - Classification Adverse Event Product Problem (defects/malfunctions) (N) B.5 - Describe event or problem For an adverse event: Description of the event in detail, including a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, includes synopses of any office visit notes or the hospital discharge summary. Copies of these records are attached with any confidential information deleted. If it is determined that reuse of a medical device labeled for single use may have caused or contributed to an adverse patient outcome, report the facts of the incident in B5 and the perceived contribution of reuse to the occurrence. For a medication or special nutritional product problem, indicate if a sample is available for use by FDA (S-MedDRA, WHOART or custom) G.8 - Adverse event term(s) - Include a list of adverse event terms that most accurately characterize the adverse event described in narrative format in block B5. Terms should be listed with the most important term(s) first. The terminology may be an accepted standard (e.g., MEDDRA or WHOART), a verbatim term, or the manufacturer's own terms. AERS staff use MEDDRA classification of narrative.
42. List fields associated with when the event occurred	(FF) B.3 - Date of event (mo/day/yr) - Provide the actual or best estimate of the date of first onset of the adverse event. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable. When a newborn baby is found to have a congenital anomaly, the event onset date is the date of birth of the child. When a fetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date pregnancy is terminated. If information is available as to time during pregnancy when exposure occurred, indicate that information in narrative block B5.
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	(FF) B.4 - Date of this report (initial reporter)(FF) G.4 - Date received by manufacturer (mm/dd/yy)(P) G.7 - Type of report For licensed biological products, the regulations describe types of adverse experience reports: (a) 15-day Alert reports (15-day)(b) Periodic Adverse Experience reports. (Periodic)For drug adverse events - (a) 15-Day Reports of Serious, Unlabeled Events - ones that AERS staff really look at - manufacturers have responsibility for indicating whether a report involves serious, unlabeled event. Note: AERS only accepts CIOMS reports for this type of event(b) Periodic Reports (serious, labeled or non-serious unlabeled - everything but those identified by manufacturer as 15-day) required for each approved NDA, ANDA, and antibiotic application. Periodic reports are due quarterly for the first three years after approval, and annually thereafter. Serious defined as involving death, life-threatening, hospitalization, disabled, congenital anomaly, important medical event. Reported in H.1 - Type of Reportable event on 3500aThere are also high profile reports that can be for drugs or biologics and involve MedWatch or 15-day reports. These involve drugs which are identified as having potential safety issues. The above are labeled on the 3500a form as:15-dayperiodic

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
44. List fields associated with where the event occurred	N/A
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	(N) B.6 - Relevant tests/laboratory data (with dates) Include: relevant negative test and laboratory findings, in order to most completely convey how the medical work-up/ assessment led to strong consideration of medical product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated; relevant baseline laboratory data prior to the administration or use of the medical product; laboratory data used in diagnosing the event; available laboratory data/engineering analyses (for devices) that provide further information on the course of the event If available, include: any pre- and post-event medication levels and dates (if applicable);synopses of any relevant autopsy, pathology, engineering, or lab reports
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	(P) E.4 - Initial reporter also sent report to FDA? Yes, No, unknown (Allows staff to track multiple reporting of same event) (P) G.7 Type of report - one of the choices is for follow-up with number [manufacturer only] Follow-up: Check if the report is a follow-up to a previously submitted report. Allows user to provide additional or corrected information on the previously reported event. Follow-up reports on drugs and biologics should contain information that was submitted in the original report if the information is still correct.
47. List fields related to the outcome of event	(P) B.2 - Outcome attributed to adverse eventdeath (date in fixed format)life-threateninghospitalization - initial or prolonged disability congenital anomaly required intervention to prevent permanent impairment/damage other (narrative description)
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, results of investigations etc)	Note - PSI international staff receive several sources of information that are not the 3500 or 3500A form - e.g. USP Medication Error Reporting Program, MedWatch direct reports on Biologic Products, international CIOMS I form for reporting of international drug events. Fields in AERS are based upon the 3500a form so whenever data is entered into AERS the data from these forms are 'forced' to fit into the existing AERS fields.
H. Implications	
49. Integration with other systems	Integration with other systems is performed as part of the AERS information flow process. The AERS central triage unit receives and distributes MedWatch direct reports to appropriate divisions of FDA or CDC(See PMSS Document/ISR Process Flow Diagram) - ie MAUDE data goes to CDER, VAERS data goes to CDC, MERS data comes from USP - treated as direct report - sent to Jerry Phillips for entry into his database with addition of NCCMERS, then back to AERS for entry, Biologic Products and Therapeutic biologics go to CBER, Food and Nutrition and Herbal Supplements go to CFSAN. AERS does integrate with the MERS system by accommodating the fields in this reporting system (See template for MERS system for more details on fields used). AERS also allows the use of an international form - CIOMS I. If the CIOMS I form is used, it will be accepted in place of the form FDA 3500A or VAERS form for foreign serious and unexpected reports only (15 day reports) and should contain, at a minimum, information including an identifiable source, a patient (even if not precisely identified by name and date of birth), a suspect product and a suspect event. Also, while the therapeutic biologics (about 10% of reports) are not exactly the same as drugs,

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
	fields identified on the 3500a that refer to drug information are the fields used for entering therapeutic biologic information. Some blood product information is entered into AERS, but that is only if it comes in as a direct report (MedWatch) and can be easily entered into AERS.
50. Methods used to de-identify data	No automated didaction - FOI office - has access to AERS database. They receive a request for information, gets line listing of, send to copy of report to requester, after remove fields. The following fields are removed for MAUDE by FDA The name of the reporter and facility are deleted from disclosed data before release of the report. In addition, an automated process is used to delete the following fields and any proper names in narrative fields (this often must be done manually by an analyst). Double checked by an analyst:A.1 - Patient identifier A.2 - Age at time of event or Date of birth A.3 - Sex A.4 - WeightB.6 - Relevant tests/laboratory data, including dates B.7 - Other relevant history, including preexisting medical conditionsD.7 - If implanted, give date D.8 - If explanted, give date E.1 - Name, address & phone # E.3 - Occupation F.2 - UF/Dist/Importer report number F.3 - User facility or distributor/Importer name & address F.4 - Contact person F.5 - Phone Number F.10 - Event problem codes H.6 - Evaluation codes
51. Technical Information	
Part II. Data Structure & Storage:	
I. Facility/Location	
52. What is the address of the data storage facility?	
53. What type of facility is used to store data (3rd party data center, secured computer room, someone's cubicle)?	secured computer room
54. Is there a network interconnect for physically distributed systems?	fast ethernet
55. What type (private lines, VPN, Internet) of network interconnect is used?	Internet
56. What is the network protocol (TCP/IP, IPX, etc.)?	TCP/IP
57. What is the bandwidth of network the interconnect (dial-up, ISDN, T1, T3, etc.)?	10/100mb
58. What is the network (WAN) topology, including diagram if available?	Fiber Optic with Switches.
59. WHO DESIGNED THE SYSTEM? WHO OPERATES THE SYSTEM?	Booz, Allen, Hamilton designed/developed/maintains the applications; PSI International staffs the operations, including data entry and document management.
J. Data Storage System/Server	**(1) SIMBA - AERS Production Server (2) eSub Gateway server (3) RetrievalWare Server**
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	**(1)** Compaq **(2)** Sun **(3)** Compaq
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	**(1)** Alphaserver 4100 5/600 **(2)** Sun Ultra II **(3)** Proliant 6400

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
62. What is the number/speed (Mhz) of processors?	**(1)** 3 @ 600 Mhz **(2)** 200 MHz, 256MB **(3)** 4/500 mhz
63. How much memory is available (Gb)?	**(1)** 3Gb **(2)** 1Gb **(3)** 4Gb (26B in use)
64. What is the disk - manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	**(1)** 6 internal drives (capacity each = 4Gb, 9Gb) and ~30 external drives (capacity each = 9Gb, 18Gb, 36Gb) **(2)** 6 * 9Gb Drives = 54Gb **(3)** Internal - 4/9 GB disks(2 are Raid 1). 44/18 GB Disks (Raid 0+1) and 4/9 gb Disks, 4/18 GB disks(not mounted)
65. What is the operating system (e.g. Sun Solaris 2.6.1)?	**(1)** VMS 7.2.1 **(2)** NT 4.0 / SP6 **(3)** NT 4.0 / SP6a
OTHER COTS	**(1)** Oracle 7.3.4, MedDRA v4.0 **(2)** RetrievalWare, eSub v2.1, Oracle forms, Templar 4.2 **(3)** Tomcat 2.3, Apache Server 1.3, JRE 1.**3**
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	Oracle Client, Oracle Forms 5.0.6.10, Reports 3.05.9, MS Word 7.0, Rational Rose CASE tool, KAWA 4.0 (Integrated Development Environment for JAVA)
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	Java
68. Which categories best describe this system?	
- Is there an operational data store	Yes
- Is there an all-encompassing data warehouse versus focused data mart(s)?	No
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	Yes
- Is there a data warehouse utilizing a normalized relational database design?	No
- Is there a dimensional data warehouse utilizing a star schema design?	No
- Is there Statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	No
- Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	No
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	No
- Are there other structured data format, such as XML, HTML, or other?	Yes. EDI
- Is there a Data Mart?	Yes

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
69.How is the data structured?	
- An event occurrence (EO) table with one row per event	Event Occurrence data stored in multiple tables in normalized data base structure; ERD provided
- A person table with one row per person, linked to events by PERSONID	No
- An adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID	Adverse Event Categories adhered to in data submission process.
70. How much disk space is currently allocated to the system?	116 GB
71. How much disk space is available on this system?	22 GB
L. For Each Major Data Structure	
72. What is the width of the table / file / subject data area (bytes)?	No information
73. How many data elements (approximate) in the table / file / subject data area?	ISR (Individual Safety Report) table has 50 columns with another 30 columns normalized into 5 other related tables, including free text comment tables.
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	The row length is in bytes, and so is the size of each one of those tables TABLE_NAME,AVG_ROW_LEN SIZE, AERS_CASES,46 115343360;AERS_INDIVIDUAL_SAFETY_REPORTS,208, 602931200; AERS_REACTIONS,86, 555745280;AERS_REPORTED_DRUG_PRODUCTS,166,996147200;AERS_SEARCH_CRITERIA, 198,4014080. We only listed some of the major tables.
75. What is the approximate number of rows in the table, or observations?	suspected drug adverse events reported = 5,500/week or 286K/year; other data=689 (per month?)
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	at least 4 years observed in sample reports - may grow continually with no roll-off
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	According to the hardware configuration that we currently have on the SIMBA (AERS production box) we can support roughly 300-500 concurrent users. To the best of my knowledge, this is the only limitation that out system has.
How many physical tables in the database?	150-200
How many tables containing key data for analysis?	< 10
Part III. Data Use & Analysis:	
78. System Contact	Min Chen, Associate Director of Drug Risk Evaluation, Office of Drug Safety
79. Contact Address	CDER- 5600 Fishers Lane, Rockville, MD, Rm 15B-08
80. Contact Phone	301-827-3169
81. Contact Email	N/A
82. Hardware Platform	N/A
83. Operating System	N/A

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
84. Who is the developer?	The database programming and design was created and is maintained by Booz, Allen, Hamilton
85. Who is responsible for the system architecture?	Booz, Allen, Hamilton
86. User Types	FDA – CDER (Office of Drug Safety, Office of New Drug, Office of Compliance - for drugs), CBER (for biologics/vaccines), users of publicly available FOI available data, FDA also has agreement to allow Canada access to AERS
87. What is the frequency of Reports?	As needed to investigate specific Adverse Event reports
88. Who generates the reports?	See User Types
89. What is the method of access?	AERS software or AERS data mart
90. What is the turnaround time?	Real time
91. What is the level of automation?	N/A – AERS software
92. Type Of Reports	Workload and operational reports to track flow and follow up on AE reports. Query function supports complex querying and a variety of content/format outputs. Can do frequency counts. Approx. 12 - 13 "canned reports". TAS, an MS-Access database tool developed by PSI, captures management metrics allowing the monitoring of reports as they flow through the PMSS process. AERS “data mart” also available to internal FDA users (e.g., Office of New Drug, Review Division). AERS FOI information is made publicly available by providing quarterly CD ROMs in ASCII format and SGML (ICH e2B) format for six AERS data tables. Available through NTIS. Data currently not made publicly available through the FOI or Web because of resource limitations.
93. What is the unit of observation?	Individual report of adverse event associated with a drug or biologic product
94. What are the available data fields?	The terminology may be an accepted standard (e.g., MEDDRA or WHOART), a verbatim term, or the manufacturer's own terms. Contractor adds/updates MEDDRA classification of narrative.
95. Is there a controlled vocabulary?	Event described using MedDRA codes assigned by Logistics Applications.
96. Exportability	Cannot download directly to Excel but can do so indirectly.
97. User Profile	Safety Evaluators in Office of Drug Safety (follow up on AE reports, primarily pharmacists). Office of New Drug (Review Division), Office of Compliance
98. How are the reports used?	Workload module routes reports to inbox of safety evaluators (15 day mandatory report and voluntary reports from consumers/professionals are priority). Biologics reports routed to CBER staff. Safety evaluators determine if event is, in fact, linked to the drug based on their clinical knowledge/experience. Often call reporter for information (eg. missing pat history, labs, diagnosis, duration of therapy, concomitant drugs). Will also use query function to search AERS by drug, MedDRA code, age, timeframes, reporter, and location code. Canned reports used to investigate case series for a specific drug/event. Goal is to determine that there is a "safety signal" to prompt further action. Focus is on investigation of serious, unlabeled events. Will summarize data from the "case series" in AERS. Recommendation may be made to Office of New Drug, Review Division re: labeling change (adverse reaction, precaution, warning, boxed warning, restricted use or contraindication). If warranted, "Dear Doctor" letter sent. If can't find option to manage risk, may result in withdrawal. Reports may prompt further epidemiological studies where appropriate. Once "safety signal" identified, office tries to assess size of risk. Assessment may involve use of other data (see below). Review Division

Reporting or Database System:	Adverse Events Reporting System (AERS) - Drugs and Therapeutic Biological Products
	may also use AERS data as part of acting on safety alert.
99. Report Dissemination	Internal within FDA divisions
100. What is the primary goal?	Meet regulatory compliance demands by identifying and assessing individual reports of adverse drug reactions and taking appropriate action within the scope of FDA authority.
101. Integration	MERS data is entered into AERS. No links to state systems. Safety Evaluators primarily use AERS to investigate reports. May also use Medline to search for published reports. When assessing risk of potential problem, Safety Evaluators attempt to estimate patient exposure (ie. Denominator information) and how much the reported rate truly reflects incidence. This may involve analysis of IMS data (purchased by FDA and available in house). Requests can also be made to have specific analysis done using other databases per FDA cooperative agreements. These include Boston University, Harvard Pilgrim Health Cooperative, Johns Hopkins, Vanderbilt, United Health Group, HMO Research Network, Aetna, State Medicaid databases. FDA in process of acquiring more databases in house. "CBER piloting a large-linked database project that utilizes databases of several MCO's, which will provide the opportunity to study potential rare adverse outcomes". Other related systems: • COMIS (CDER's tracking of IND and NDA info, e.g., pending application, previous reviews etc.) • Drug Filing System (contains information related to new drug application, e.g. pre-approval reviews) Given the specific nature of the analyses conducted, direct integration of AERS with other databases my not produce a significantly enhanced knowledge base. Access to other databases to conduct epidemiological assessment supports follow up regarding specific drug/biologic problems.
102. HIPAA Compliant	Yes
Future	There is a list of possible AERS enhancements (as yet unimplemented) developed during initial system design. Increased data mining. Development of tool to identify change in reporting incidence to alert FDA to potential problems
Note:	There is a Drug Quality Reporting System dealing with product quality problems (eg. Labeling, broken safety seals, wrong dosage dispense, wrong color tablets).
Comments:	AERs has 2 purposes. (1)To meet regulatory requirements that manufacturers report serious problems. (2) As a tool for evaluating post marketing drug safety.

ASR

Reporting or Database System: **Program ID:**	**FDA-CDRH** **Alternative Summary Reporting - Medical Devices**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	Medical Device Reporting-Alternative Summary Program
2. Internet Location: http://	http://www.fda.gov/cdrh/osb/guidance/315.html
3. Host Organization(s)	LAI enters data; TRW works on data storage
4. Primary contact information (e.g. Address, Phone)	Primary Contact - Joyce Siwarski - 301-594-4550 x166; JCS@CDRH.FDA.GOV Data Acquisition - Mary Brady - mwb@cdrh.fda.gov Data Storage – Isaac Hantman 301-827-0036 Data Use/Analysis - 301-594-4550 x166; JCS@CDRH.FDA.GOV
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The alternative summary reporting system replaces individual mandatory reporting from manufacturers for those devices where documented problems with the devices are well understood and there is diminished return in the evaluation of individual event reports for these devices. The manufacturer must request to be accepted into the Alternative Summary program. Products approved for summary reporting require the periodic submission of adverse event data in tabular format. The reason this system was implemented was to reduce the amount of time spent entering these type of events into MAUDE so that the focus could be on less well known or previously undetected events. It also provides significant economies for both the device industry and FDA. In the past year, FDA received approximately 50,000 reports in summary format. While this is a separate database from the MAUDE system, it does access MAUDE for some limited information. Each line corresponds to an event. Patient, device, evaluation/results and evaluation/conclusion codes are provided by manufacturer. No text provided. Currently, approx. 40 products or product/problem combinations report through ASR. Main purposes of ASR software are to: 1) support the management of candidate exemptions (i.e. products exempted from case-level adverse event reporting) 2) manage the receipt and data entry of manufacturer summary reports 3) manage quality control 4) collect, store and perform trending calculations on data from both ASR and MAUDE 5) manage data review by (i) supporting review of trending data exceeding pre-set conditions (ii) enabling ad-hoc query of ASR info and (iii) allowing generation of preformatted reports.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	Same as MAUDE - products used in US, but could have international manufacturer
7. What is the unit of data entry (e.g., event, patient, product)?	The unit of data entry is a medical device with documented problems. Adverse events included in summary reports should be submitted in a line-item format, reporting selected data elements by individual adverse event, rather than by the previous method of grouping adverse events by device identification number.

Reporting or Database System: Program ID:	FDA-CDRH Alternative Summary Reporting - Medical Devices
8. Who is allowed/required to input information?	This is a voluntary system which provides major time savings to manufacturers and FDA. Authorized OSB reviewers can identify candidates and offer exemptions or manufacturers can file for an exemption which is entered into the ASR database and must be approved by the FDA in order to participate in the program.
9. What are the regulations/laws affecting reporting?	21 CFR Part 803.19 - provides authority for the creation of the Alternative Summary Reporting Program 21 CFR Part 803.19(b) specifies that all requests to participate in the ASR program must be in writing and contain the following information: *statement notifying FDA of request to participate *identification of the device manufacturer *product classification code(s) for the device(s) that will be included in the ASR report *the reporting site registration number, contact person and address of the firm who will be submitting the ASR reports to the FDA 21 CFR Part 803.55 - requires filing of initial baseline reports and subsequent annual updates for devices involved in adverse events that are submitted to the FDA on form 3500a for the first time.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	FDA will disclose to a patient requesting a report, all information in the report concerning them, except for trade secret and confidential commercial information. FDA [21 CFR §20.63(2)] extends protection against disclosure of voluntary reports held by medical device, pharmaceutical, and biologics manufacturers by preempting state discovery laws. User facility name will not be released to the public under the FDA Modernization Act of 1997. FDA will also not release the identity of the patient or any information that can be used to identify the patient, such as the serial number of an implanted device. Nor will it release the name of any person other than the MDR contact. The name of the reporter and facility are deleted from disclosed data.Please note that the FDA is required under the Freedom of Information and Privacy Acts (SEC 552, Title 5, USC) (PL 93-579) to delete, prior to public disclosure, any information that constitutes trade secrets, and confidential, commercial, or financial information; and any personal, medical and similar information that would constitute a clearly unwarranted invasion of personal privacy. Included in the deletion requirements are all identification of the reporters and user facilities associated with the events.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	ASR reports are to be mailed to the following address in an envelope or other mailing container marked "ASR Report": Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002 Request for exemption are to be mailed to: Alternative Summary Reporting Coordinator Reporting Systems Monitoring Branch, HFZ-533 Division of Surveillance Systems Office of Surveillance and Biometrics Center for Devices and Radiologic Health 1350 Piccard Drive Rockville, MD 20850

Reporting or Database System: Program ID:	FDA-CDRH Alternative Summary Reporting - Medical Devices
12. What are the methods of editing information (e.g. correcting/add more information to records)	The following updates could occur. *Updates to the Periodic Report detail information - device identifier, event type, mfr aware date, QA functions. These are submitted under Part II - Reportable events page as a separate attachment with the firm's next ASR report. The system has a module called Data Entry/Update-QC which allows the user to select certain records and edit periodic report detail as well as perform a QA review of the data entered into the system. Various reporting functions exist to assist with QA as well as reviewing trends in data and looking for outlying and unusual events- e.g. summary trend analysis, unusual event reports etc. *Updates to exemption information - e.g. status, reviewer, comments, contact information *Updates to exempted Products information - e.g included products, trend groups, unusual events
13. Where is the collected data stored (name of database, number of data storage locations)?	ASR - Oracle based DBMS linked to existing MAUDE DBMS via baseline report information. The FDA is in the process of eliminating baseline reporting. It's initial purpose was to obtain the most updated product and manufacturer contact information. The problem is that manufacturers often do not send the FDA appropriate updates and the FDA ends up making pseudo-baseline entries. FDA staff are working on a different system to validate data entry and link the MAUDE to Alternative Summary Report information.
14. How often is the system revised (annual, semi-annual etc)?	System initiated in February 2000**.** Revised as needed to meet data entry and reporting requirements.
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	ASR can add to the fields collected if the item is already required for MAUDE. However, if any additional information is requested (or goes outside existing regulations), then must send out the proposed change for public comments.
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	No minimum requirements. Manufacturers send mailed reports to FDA for data entry
17. What new features are being planned and/or are on wish lists?	1. Acceptance of electronic summary reports from Manufacturers 2. Addition of trending analysis for ASR and MAUDE-only data 3. Trending analysis using combination of chi2 and poisson
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	This system is linked to MAUDE via the MAUDE baseline tables. Product codes specified in the Exempted Products Information screen on ASR must also be valid codes in MAUDE.

Reporting or Database System: Program ID:	FDA-CDRH Alternative Summary Reporting - Medical Devices
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify); N-Narrative; FF - Fixed Format (e.g. date)**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	ASR Reporting Site Information ASR Exemption Key - system generated (S) - ASR Reporting Site CFN - the unique number assigned to each manufacturing site. After initial creation, it will remain permanently associated with the record (unless on rare occasion it is changed by the system administrator). Accurate entry of a valid CFN will automatically populate the rest of the ASR Reporting Site Information, as well as the Contact Information. (N) - Name - name of reporting site (defaults to manufacturer unless specified) (N) - Street - street of reporting site (N) - City - city, state, zip, country of reporting site (S) - State, (S) Zip Code, (S) Country Code
20. Is participation mandatory or voluntary?	Voluntary - but must meet exemption requirements Fields on Exemption screen: (P) - Offer/Acceptance Letter Required? Y,N (FF) - Date of Offer/Request Letter (FF) - Date of Acceptance Letter (FF) - Date of Grant Letter (P) - Exemption No - the exemption number associated with the product code(s) (P) - Status (Pending Approval, Granted, Closed, Revoked, or Denied). If status is granted, must have exemption no. Note: An exemption number must exist and the exemption status must be "Granted" in order to proceed with data entry of periodic summary reports. (FF) - Status Date - the date of the last exemption status change (N) - Status comment - comments about exemption status (N) - Exemption comment - description of the clinical condition specified for an exemption. (P) - Assigned Reviewer (list of allowable reviewers) - field is required if exemption status is granted
21. List fields related to contributor/participant contact information	N/A
22. List fields related to facility contact information (include type of facility, teaching status, id information)	N/A
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact information (ASR - Exemption Information)	(N) - Name - the name of the contact person at the reporting site. This information is editable. (N) - Phone No - phone of contact person at reporting site, editable (N) - Fax No - fax number of contact person at reporting site, editable (N) - Email - email of contact person at reporting site, editable

Reporting or Database System: Program ID:	FDA-CDRH Alternative Summary Reporting - Medical Devices
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify); N-Narrative; FF - Fixed Format (e.g. date)**
25. List fields related to Provider of Care identification	N/A
26. List fields that identify types of care providers included in system	N/A
F. Fields related to Patient Information:	
27. List fields related to identifying patient – initial data entry (e.g. SSN, initials, system-assigned ID etc)	N/A
28. List fields related to patient contact information (e.g. address, zip code, county, region)	N/A
29. List fields related to patient demographics (e.g. age, sex, race)	N/A
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	N/A
31. List fields related to pre-existing conditions and/or medical history of patient	N/A
32. List fields that capture the clinical condition of patient at time of event	N/A
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage – Medicare, Medicaid, private, CHAMPUS, uninsured etc)	N/A
34. List any other types of information collected about the patient	N/A

Reporting or Database System: Program ID:	FDA-CDRH Alternative Summary Reporting - Medical Devices
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify); N-Narrative; FF - Fixed Format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Medical device events associated with a particular event code, patient problem, device problem, evaluation result and/or evaluation conclusion that have been determined to be exempt from individual event reporting. When an exemption is filed, the FDA enters inclusion and exclusion criteria that fit the exemption. Note that the exemption is only for a particular problem associated with a particular device. The following types of events are always excluded from the ASR system and must be reported as specified in 21 CFR 803.50 and 803.52:*Events that require the submission of a 5-day report under the requirements of 21 CFR 803.53. *Events where the device, other than a mechanical heart valve (product code LWQ), may have caused or contributed to a death. *Events involving mechanical heart valves (product code LWQ) where the implant duration was less than five (5) years. *Events involving a permanent pacemaker electrode (product code DTB) where the manufacturer confirmed a device failure. *Events involving a Class III device that has been marketed under an approved PMA for less than two (2) years. *The occurrence of multiple serious injuries as a result of a single event or device failure. *Events associated with explosion or fire. *Events that the manufacturer considers unusual, unique or uncommon and that would be given an evaluation conclusion code of 66-Unusual event (see Instructions for Completing Form 3500A with Coding Manual for Form 3500A, dated December 14, 1995). FDA also reserves the right to request the submission of an individual event report on Form 3500a for any event included in an ASR report if it determines it needs the report to evaluate the event.
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	N/A
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	Each line item on the ASR report represents one adverse event. (S) - Product Code – enter a product code already associated with the exemption number. Once the product code is saved as part of the record, it may no longer be edited or deleted unless done so by the system administrator. (Same as MAUDE product codes) Report ID No – unique internal identification number assigned by the manufacturer to the individual complaint. This number must be unique within this product code. It must also be different than summary report line item numbers entered in previous reporting periods. (N) - Device Identifier – (same as D.6 - Product Identification Information on Form 3500A) Device code assigned during exemption entry. This will be (S)Model # Found on the device label or accompanying packaging (S)Catalog# Exact number as it appears in the manufacturer's catalog, device labeling, or packaging. (S)Serial # Found on the device label or accompanying packaging; it is assigned by the manufacturer (S)Lot# This number can be found on the label or packaging material. (S)Other# Any other applicable identification number The device identifier will be validated against the exemption device list and baseline info.
38. List fields associated with vaccine related events	N/A

Reporting or Database System: Program ID:	FDA-CDRH Alternative Summary Reporting - Medical Devices
39. List fields associated with infection related events	N/A
40. List fields associated with any other type of event. List type of event.	N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	(P) F.10 - Event problem codes (see http://www.fda.gov/cdrh/mdr/appendixc.pdf - Note: UF is supposed to complete. Mfr fills in if missing.) Patient codes - describe what happened to the patient as a result of the event - approximately 1600 codes (device and patient mixed) Device codes – device problems or failures encountered during the event (P) - Event Type – enter a valid event type code d-death, i-serious injury, m-malfunction.
42. List fields associated with when the event occurred	N/A
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	(P) - Reporting Period (Quarterly, Semi-Annually) - on exemption screen; when mfr will provide periodic reports (FF) - First Period Start Date - when manufacturer will begin to report Report Date – This is a required field. It is the date on which the summary report is prepared by the manufacturer Report Received Date - the date on which the report was received by CDRH Starting Quarter Number – the starting and ending quarters selected must reflect either a quarterly reporting cycle (e.g., Quarter 1 through Quarter 1 of the same year), or if a semi-annual reporting cycle, then two quarters (e.g., Quarter 1 and Quarter 2 of the same year, or Quarter 3 and Quarter 4 of the same year). Reporting periods are defined in the exemption entry process. Starting Quarter Year – the year in which the periodic summary report submissions begin. Ending Quarter Number – See explanation in Starting Quarter Number. This number will be populated based on the reporting period defined for the exemption. Ending Quarter Year - the year of the ending quarter of a submission period, which defaults to the same as the Starting Quarter Year. (FF) - Event Aware Date – enter the date on which the manufacturer became aware of the event. If an Event Aware Date is not entered, it will default to the first day of the reporting period quarter/year, as entered on the previous screen. If the event aware date falls within quarter for which a report was previously submitted, it will be considered a supplemental line item entry to the previous quarter's report. The line item will appear on the Correction/Supplemental Report.
44. List fields associated with where the event occurred	N/A
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	N/A

Reporting or Database System: Program ID:	FDA-CDRH Alternative Summary Reporting - Medical Devices
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	(S-FDA Evaluation Codes for Manufacturers) H.6 - Evaluation codes (4 codes per subtype --see http://www.fda.gov/cdrh/mdrcode.pdf for list of codes - approx 50 codes) Enter the applicable codes from the codes manual for one or more of the categories listed. Conclusion codes must be entered even if the device was not evaluated. If the reuse of a device may have caused or contributed to the adverse event, then the appropriate manufacturer Result codes are to be entered from the codes manual. Applicable reuse codes are 230-233 and may be used alone or with any other applicable results codes. (see H8). Method - Enter Source of evaluated device, type of evaluation performed (4 codes) Results - Enter type of result code (see www.fda.gov/cdrh/mdr/appendixd.pdf- approx 350 codes) Conclusions - Enter conclusions code (approx 20 codes)(S) – Evaluation/Conclusion CodeFor codes listed above, the reporter may provide more than one code per category but should group by category. Should represent the best knowledge of the AE and firm's evaluation results and conclusion codes. Note that 90% of the information is done at the product code level.Special guidelines for reporters - e.g If multiple product codes have been approved under one ASR exemption number, then only one quarterly report is required. If no eligible events in a quarter, must still send in a report saying that.
47. List fields related to the outcome of event	N/A
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, investigations etc)	Assigned Reviewer – if the reviewer assigned to the report needs to be changed, the data entry user must go to a supervisor who can perform the action under Utilities/Assign Reviewer. By default, the reviewer assigned to the summary report is the reviewer assigned to the exemption. Comment - the user may enter comments regarding the summary report information. Quality Control Completion Flag – this field is checked after the data entry user has quality controlled the information submitted by the manufacturer against that which was entered into the ASR System by the data entry user. Mfr QA Flag – this checkbox is accessible after the Quality Control Completion Flag is checked. The box will be checked once any discrepancies in the information submitted by the manufacturer have been cleared up through communication with the manufacturer. Once this box is checked, trend review can be initiated and information in that summary report may no longer be edited.
H. Implications	
49. Integration with other systems	MAUDE
50. Methods used to de-identify data	Aggregate data
51. Technical Information	
Part II: Data Structure & Storage:	
I. Facility / Location	
52.What is the address of the data storage facility?	OSM - 2098 Gaither Road, Rockville, MD 20850
53. What type of facility is used to store data (3rd party data center, secured computer room, someone's	Secured computer room

Reporting or Database System: Program ID:	FDA-CDRH Alternative Summary Reporting - Medical Devices
cubicle)?	
54.Is there a network Interconnect for physically distributed systems?	Yes
55. What type (private lines, VPN, Internet) of network interconnect is used?	WAN
56. What is the network protocol (TCP/IP, IPX, etc.)?	TCP/IP
57. What is the bandwidth of the network interconnect (dial-up, ISDN, T1, T3, etc.)?	T3
58. What is the Network (WAN) topology, including diagram if available?	Not available
J. Data Storage System / Server	
59. Who is the Manufacturer (Sun, HP, IBM, Compaq, etc.)?	Compaq
60. What is the Model Number (Sun Enterprise 10000, HP 9000, etc.)?	AlphaServer 4100
61. What is the number/speed (Mhz) of processors?	4/600
62. How much memory is available (Gb)?	4Gb
63. What is the disk – manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	Compaq StorageWorks 610GB net RAID
64. What is the operating System (e.g. Sun Solaris 2.6.1)?	OpenVMS 7.2-1
K. For Each Application	
65. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	Oracle RDBMS, Oracle Forms, SQR ReportWriter
66. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	C, VB
67. Which categories best describe this system?	
- Is there an operational data store?	Yes
- Is there an all-encompassing data warehouse versus focused data mart(s)?	No
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	No

Reporting or Database System: Program ID:	FDA-CDRH Alternative Summary Reporting - Medical Devices
- Is decision support normalized?	Yes
- Is there a dimensional data warehouse utilizing a star schema design?	No
- Is there a statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	No
- Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	No
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	No
- Are there other structured data format, such as XML, HTML, or other?	No
68. How is the data structured?	Total tables = 50; dictionary provided
-Is there an event occurrence (EO) table with one row per event?	Logical data model has one row per time period that captures # of adverse events of a type for that period.
-Is there a person table with one row per person, linked to events by PERSONID?	
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	
69. How much disk space is currently allocated to the system?	188 Mb
70. How much disk space is available on this system?	81 Mb
L. Major Data Structure	
71. What is the width of the table/file / subject data area (bytes)?	50 tables with approximately 30-5000 bytes per table.
72. How many data elements (approximate) in the table/file/subject data area?	50 tables with approximately 1-30 columns per table.
73. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	N/A
74. What is the approximate number of rows in the table, or observations?	50 tables with approximately 0-90,000 rows per table. A total of about 562,248 rows.
75. What time period is currently represented in the database? Projected change over the next 1-3 years?	
76. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	

Part III. Data Use & Analysis:	
78. System Contact	Pat Kingsley (Division of Post-Market Surveillance), Howard Press (Division of Surveillance Systems, Chief of Information Analysis), Suzanne Rich (Division of Post-Market Surveillance)
79. Contact Address	1350 Piccard Drive, Rockville, MD, 20850
80. Contact Phone	PK: 301-594-2784, HP: 301-827-2983, SR: 301-594-2581
81. Contact Email	PK: pak@cdrh.fda.gov HP: hap@cdrh.fda.gov SR: SER@CDRH.FDA.GOV
82. Hardware Platform	VAX Cluster
83. Operating System	
84. Who is the developer?	TRW under contract
85. Who is responsible for the system architecture?	ORACE-based DBMS linked to existing MAUDE DBMS
86. User Types	FDA -
87. What is the frequency of reports?	Being established
88. Who generates the reports?	CDRH – departmental responsibility being determined
89. What is the method of access?	ASR software
90. What is the turnaround time?	Real time
91. What is the level of automation?	N/A
92. Type Of Reports	Main monitoring reports triggered if the change in rate of reports for a particular product/problem a specified threshold. Statistical tests (Chi-squared, Cox-Stuart) used to assess change in incidence. Software provides a set of reports but, to date, not frequently used. Data most often exported to Excel for ad hoc analysis.
93. What is the unit of observation?	ASR reports cover all adverse events associated with a qualifying device/problem occurring within the reporting timeframe. Line level detail corresponds to an individual adverse event covered within the device/problem exemption.
94. What are the available data fields?	Primary fields are patient, device, product and evaluation codes. See Input template for complete list.
95. Is there a controlled vocabulary?	Patient, device, product and evaluation codes come from list maintained by CDRH. They correspond to the codes captured in MAUDE.
96. Exportability	Yes and frequently done
97/ User Profile	CDRH - Division of Post-Market Surveillance, Division of Surveillance Systems
98. How are the reports used?	Reports ostensibly used to monitor incidence of events, however, most problems are so well known that reports require and prompt little follow up. Unusual change incidence would prompt follow up investigation. Use of system still evolving. May be opportunity to improve existing reports/reporting function. Most assessment done by exporting data and performing specialized analysis in Excel or other software.
99. Report Dissemination	CDRH - Division of Post-Market Surveillance, Division of Surveillance Systems.
100. Primary Goal	Monitoring of known medical devices problems.
101. Linkable to Detail/Integration	Some reports available providing comparative statistics/trends between MAUDE and ASR, however, ASR and MAUDE software and data are not currently connected. Integrating data would allow a complete search of all events related to a specific product type, manufacturer etc.. Currently, reports of exempted product/problem combination are kept separately in ASR, requiring separate querying. Facilities reporting to MedSuN may previously have reported to

	MAUDE. Manufacturers still required to report to MAUDE (through MedWatch). Therefore, if a manufacturer becomes aware of an error within a MedSuN participating facility, it is possible that a report of the same error would be made to MAUDE by the manufacturer and MedSuN by the facility. Note that the post-market surveillance follow up on the MAUDE report may produce information useful to the MedSuN team.
102. HIPAA Compliant	No protected health information collected
Note:	In contrast to MAUDE requirements, manufacturers are required to submit patient and device codes in ASR reports.
	In the past year, FDA received approximately 50,000 reports in summary format.

BPD

Reporting or Database System: Program ID:	**Biological Product Deviation Reporting (BPDR) System (BIODEV)**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	Biological Product Deviation Report
2. Internet Location: http://	http://www.fda.gov/cber/biodev/biodev.htm
3. Host Organization(s)	The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER)
4. Primary contact information (e.g. Address, Phone)	Stan Pawlowski, (301) 827-2728, pawlowski@cber.fda.gov
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	FDA/CBER is responsible for regulatory oversight of the U.S. blood supply. FDA promulgates and enforces standards for blood collection and for the manufacturing of blood products, including both transfusible components of whole blood, pharmaceuticals derived from blood cells or plasma, and related medical devices. CBER works closely with other parts of the Public Health Service (PHS) to establish blood standards, and to identify and respond to potential threats to blood safety or supply. The Biological Product Deviation Reporting system is one method CBER uses to monitor product deviation in manufacturing of products, including testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product or a blood or a blood component, in which the safety, purity, or potency of a distributed product may be affected. There are approximately 25,000 reports submitted per year. Electronic reporting just started in June 2001. On Nov. 7, 2000, the FDA published a final rule to amend the requirements of reporting errors and accidents in manufacturing of products. The amended regulation at 21 CFR 600.14 and the new regulation at 21 CFR 606.171 require reporting of any event associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product or a blood or a blood component, in which the safety, purity, or potency of a distributed product may be affected. To facilitate reporting, the FDA developed a standardized reporting format that may be submitted electronically or in paper form by mail. The BPDR is used to collect this information. Licensed manufacturers, unlicensed registered blood establishments and transfusion services are required to report (must have FDA Establishment Identifier or CLIA #). FDA Consumer Safety Officials then monitor the information coming into BPDR, conduct analyses and take appropriate actions. The Biologics Compliance Information System (BCIS), of which BPDR is a part, also contains functions for "Recall Alert Information", "Recall Tracking Information" and "Enforcement Action Information".
6. What is the geographic scope of data collection (national, state, local, facility etc)?	The scope of the BPD system covers the US and military facilities overseas.
7. What is the unit of data entry (e.g., event, patient, product)?	The unit of data entry is a biological product deviation which includes deviations and unexpected events that may affect distributed products.

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
8. Who is allowed/required to input information?	Licensed manufacturers of blood and blood components including source plasma, unlicensed registered blood establishments, and transfusion services are required to report any event associated with biologics, including blood and blood components and source plasma, that represents a deviation in manufacturing to the BPD system. Specifically, the manufacturer who had "control" over the product when a deviation or event occurred must submit the report. Control includes occurrence at manufacturer's facility or any facility under contract with manufacturer. Can also do via mail or fax All hard copies are entered into the BCIS database by a data entry clerk. All web copies are stored in FDA UUNET, transferred to CBER 1x/day, FDA analysts pull up BIODEV (web) reports via BCIS, then has ability to accept, reject (duplicate), pending (notes button for email to firm). Analysts are notified of possible duplicates when the EIN and tracking number are checked. Coding of events - getting better. Used to write narrative, then assign codes. Now, allow users to enter codes. If code incorrectly, then analyst sends e-mail as feedback to correct code. Most of the time - no harm to patient - has potential to harm. Sometimes even if infused in patient, no harm.
9. What are the regulations/laws affecting reporting?	The Food and Drug Administration amended the regulation at 21 CFR 600.14 for licensed biological products, and added a requirement at 21 CFR 606.171 applicable to all manufacturers of blood and blood components. Requires reporting of any event associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product or a blood or a blood component, in which the safety, purity, or potency of a distributed product may be affected. These events include deviations from current good manufacturing practices, applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of a distributed product. In addition, any unexpected or unforeseeable event associated with manufacturing that may affect the safety, purity, or potency of a distributed product must be reported. The reports must be submitted as soon as possible but not to exceed 45 calendar days from the date the manufacturer acquires information suggesting that a reportable event has occurred. 21 CFR11 – transmission requirements. Required form for input is OMB Form FDA 3486.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	The FDA is required under the Freedom of Information and Privacy Acts (SEC 552, Title 5, USC) (PL 93-579) to delete, prior to public disclosure, any information that constitutes trade secrets, and confidential, commercial, or financial information; and any personal, medical and similar information that would constitute a clearly unwarranted invasion of personal privacy. Included in the deletion requirements are all identification of the reporters and user facilities associated with the events. All requests for reports for BPDR system go through the FDA FOIA office.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Form 3486. The report can be sent by mail to: Director, Office of Compliance and Biologics Quality (HFM-600) Center for Biologics Evaluation and Research 1401 Rockville Pike, Suite 200N Rockville, MD 20852-1448 or submitted electronically via the web at: http://www.fda.gov/cber/biodev/biodev.htm

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
12. What are the methods of editing information (e.g. correcting/add more information to records)	Amended or follow-up reports can be sent via regular mail or e-mail. Follow-up information is tracked in the Remarks section of the BCIS system and the Web Notes window. These are used for internal communication by FDA staff. The system also has a status flag - accepted, rejected, not reviewed, and pending. These flags are used by CBER staff to track a report and to follow-up with reporter if necessary.
13. Where is the collected data stored (name of database, number of data storage locations)?	After a user has entered all required BIODEV information, the report can either be saved or submitted to the FDA. Users receive a confirmation number to identify saved reports. Saved reports can be edited, but are automatically deleted if they are not completed and submitted to FDA/CBER within 30 days of creation. Once a report is submitted it is no longer available to the reporting facility for update. Mailed information is entered into the biological product deviation module (BPD) of the Biologics Compliance Information System (BCIS) - an Oracle 7.3.4 database-by CBER staff. CBER staff also accepts web-based reports via this system. The BCIS not only collects the reporting data, but tracks recall alerts, enforcement actions, and maintains a list of non-blood facilities for use by CBER. Note that the data is initially stored at UUNET, then an automated procedure pull the data inside FDA firewall.
14. How often is the system revised (annual, semi-annual etc)?	As needed, but done approximately quarterly
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	User feedback or change to FDA business rules with approval by BCIS control board
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	Contributors can either mail the BPDR or enter the information in an on-line web browser form. Netscape or IE 4.0 or higher
17. What new features are being planned and/or are on wish lists?	* To allow users to query their submission history - individual reports and aggregate information. Dependent on having an ID/PW protection system. * To Require User ID/PW for web access; currently Consumer Safety Officer at FDA does have user id and password to get into BCIS system, but no ID required to enter reports into BIODEV. Wish list would include wanting to have list of facilities, hospitals, size of facilities - ways to identify who is reporting and who is not reporting (denominator information)
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	Potential link to MERS-TM - both dealing with blood related issues ** See last row at bottom of spreadsheet for narrative of how BPDR differs from MERS-TM

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
D. Fields related to contributor/participant Information:	
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	Only those facilities that have been issued a Central File Number (CFN), FDA Establishment Identifier (FEI), or Clinical Laboratory Improvement Act number (CLIA). The number is validated against a list of existing entries. If the report is from an unidentified facility, then there is follow up to determine if there was a data entry error or if the facility should be added to the valid manufacturer list. *(S) A.2 - Reporting establishment identification number - unique ID used to identify facility CFN Number, FEI Number, CLIA Code [type required for on-line access, otherwise enter in appropriate field on mail-in form] In addition to above - the following fields are pulled from the registration information on each facility: Facility unique identifiers: registration number, (CFN - Central File Number - a 7 digit number), or FDA Establishment Identification (FEI - which may be up to 10 digits assigned to your facility if you have completed an FDA Form #2830 for blood establishments, FDA Form #2656 for drug manufacturers or FDA Form #2891 for device manufacturers. If you have a license number you will also have a registration number), or CLIA number - a 10 character number that is assigned by Center for Medicare and Medicaid Services (CMS - formerly HCFA) to facilities who are eligible for Medicare reimbursement. Only provide this number if you do not have a registration number etc Numbers assigned by Field Accomplishments and Compliance Tracking System maintained by ORA (P) Establishment identification number type - type of number entered in A.2 - see above
20. Is participation mandatory or voluntary?	Mandatory for the facilities and under the conditions specified in the federal regulations. See item 9.
21. List fields related to contributor/participant contact information	From Reporting establishment information in A.1 *(N) - Point of contact name – Name of the person who is the point of contact for the report *(N) - Telephone - telephone number of the person who is the point of contact (N) - Email address of contact – e-mail address, if available, of the person who is the point of contact
22. List fields related to facility contact information (include type of facility, teaching status, id information)	*(N) A.1 - Reporting Establishment Name: Street Address Line 1 Street Address Line 2 City State Zip Code Country [not required] Point of contact Telephone # E-mail [not required Defaults from registration information Reporting Establishment Parent Name - Local Red Cross under license of American Red Cross - legal name of facility they are operating under Reporting Establishment Province Name Reporting Establishment Foreign Postal Code
23. List fields related to distributor contact information	N/A

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
24. List fields related to manufacturer contact information	Facility = Manufacturer in this reporting system. Definition of manufacturer is specified in regulation.
E. Fields related to Provider of Care Information:	
25. List fields related to Provider of Care identification	N/A
26. List fields that identify types of care providers included in system	N/A
F. Fields related to Patient Information:	
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	Not included- form instructions, "DO NOT include donor, patient, or employee personal identification information or other confidential information"
28. List fields related to patient contact information (e.g. address, zip code, county, region)	N/A
29. List fields related to patient demographics (e.g. age, sex, race)	N/A
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	N/A
31. List fields related to pre-existing conditions and/or medical history of patient	Could be included in these: * (N) B.5 - Description of BPD – Describe the event in detail, including description of what happened and a summary of all relevant information (labeling, test results, reason for donor deferral, etc.). Do not include any confidential information, such as patient, donor, or employee names * (N) B.6 - Description of Contributing Factors or Root Cause. Describe all contributing factors or root causes of the deviation or unexpected event. Please indicate, if after investigation, a root cause cannot be determined. Use page 3 for additional space. *(N) B.7 - Follow-up field: describe intended long-term and short-term follow-up action plans.
32. List fields that capture the clinical condition of patient at time of event	Could be included in these: * (N) B.5 - Description of BPD – Describe the event in detail, including description of what happened and a summary of all relevant information (labeling, test results, reason for donor deferral, etc.). Do not include any confidential information, such as patient, donor, or employee names * (N) B.6 - Description of Contributing Factors or Root Cause. Describe all contributing factors or root causes of the deviation or unexpected event. Please indicate, if after investigation, a root cause cannot be determined. Use page 3 for additional space. *(N) B.7 - Follow-up field: describe intended long-term and short-term follow-up action plans.
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage -	N/A

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
Medicare, Medicaid, private, CHAMPUS, uninsured etc)	
34. List any other types of information collected about the patient	N/A
G. Fields related to Event/Error/Product Information:	
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Any event associated with manufacturing to include testing, processing, packing, labeling, or storage and the holding or distribution of blood or blood component. The event must have the potential to affect the purity, safety or potency of a distributed biological product. Deviations and unexpected events that occur after release or distribution of products from the blood establishment, including those related to the administration of blood or blood components are not reportable under 21 CFR 606.171. If patient dies as result of problem - reportable under 21 CFR 606.171
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	N/A
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	N/A
38. List fields associated with vaccine related events	N/A
39. List fields associated with infection related events	N/A
40. List fields associated with any other type of event. List type of event.	Blood Related Unit/Product. (P) C.1 Type of Product Blood - includes products manufactured by blood and plasma establishments, such as whole blood, red blood cells, fresh frozen plasma, platelets, plasma for further manufacture and Source Plasma Non-blood – includes products manufactured by a facility other than blood establishments, such as vaccines, therapeutics, allergenics, in-vitro diagnostics, and plasma derivatives. For Blood related-- (N)Total number of units - Info on up to 18 different unit #s can be entered; reflects total number of components potentially affected. For example, if one unit of whole blood was manufactured into Red Blood Cells, Fresh Frozen Plasma and Platelets, the total number of units is 1(N) - Unit # - donor or bleed number(FF) – Collection date(MM/DD/YYYY) - date unit was collected(FF) - Expiration date(MM/DD/YYYY) - date the component expires(S) - Product Code - code that identifies the blood product [approximately 50 codes for blood products; approximately 1650 for non-blood products - these are broken down into the following categories: Allergenics, Derivatives,In-Vitro Diagnostics, Therapeutics, and Vaccines] Use the code YY01 for products for further manufacture, such as recovered plasma. Use the code DB00 for products not listed on the Blood Product Codes list, such as IVIG or albumin (if the blood establishment distributed it) and specify the product in the comments section.

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
40. List fields associated with any other type of event. List type of event. *(continued)*	(N) - Disposition - description of disposition – DO NOT list any products that were not distributed Allowable list in BCIS: Specify if the unit was distributed: In-house (IH) - distributed from the blood bank within a hospital to another department, e.g., emergency room, surgery, nursing floor, etc. To another facility (AF) - distributed from a blood center to a hospital, from one hospital to another, or from a blood or plasma establishment to a manufacturer of biological products other than blood and blood components. Valid dispositions are: No information - product distributed, information regarding final disposition not available at time of reporting Corrected by consignee - product distributed and deviation corrected by consignee Destroyed by consignee - product distributed and destroyed by consignee Expired - product distributed and is now expired, no other information available Returned and corrected - product distributed, returned to manufacturer and deviation corrected Returned and destroyed - product distributed, returned to manufacturer and destroyed Sent for further manufacturing - product distributed for further manufacture Sent for further manufacturing of non-injectable products only - product distributed for further manufacture into non-injectable products only Transfused - product distributed and transfused to a patient Other - if other is selected, please explain in Additional Comments (P) - Notification - whether consignee was notified Y, N, RN (reverse notification - if consignee notified reporter) Additional Comments (not clear on form) For Non-blood related - (N) - Total number of lots - Info on up to 18 different unit #s can be entered; reflects total number of potentially affected lots (N) - Lot # (FF) - Expiration date(MM/DD/YYYY) (N) - Product type - on form it is narrative. IN BCIS - allergenics derivatives in-vitro diagnostics therapeutics vaccines (S) - Product code (Enter size of coding system) (N) - Disposition - on form it is narrative. IN BCIS - destroyed by consignee distributed expired returned and destroyed returned and reworked sent to distributor other (P) - Notification Y,N Use comments section if do not have all of the required fields for at least one of the affected components.

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	* (N) B.5 - Description of BPD - Describe the event in detail, including description of what happened and a summary of all relevant information (labeling, test results, reason for donor deferral, etc.). Do not include any confidential information, such as patient, donor, or employee names * (N) B.6 - Description of Contributing Factors or Root Cause. Describe all contributing factors or root causes of the deviation or unexpected event. Please indicate, if after investigation, a root cause cannot be determined. Use page 3 for additional space. There are no specific cause codes defined in BPD. * (N) B.7 - Follow up: action plan for follow-up. Describe the intended short term and long term follow-up action plans, if applicable. Any corrective actions identified do not have to be implemented at the time of filing this report. If consignee notification or product retrieval was performed, please include the date and method (letter, telephone, fax, etc.) of notification. Use page 4 for additional space. * (S) B.8 - BPD code - 6 character code made up of three levels. The first level (XX) identifies the system affected in which there was a breakdown or failure, which resulted in the distribution of an unsuitable product. The second level (YY) of the code is a subset of the system affected. The third level (ZZ) contains more detailed information regarding the BPD. Select the code that most closely describes the deviation or unexpected event (see list of Deviation Codes). If you cannot determine the appropriate code, enter question marks. For example ??-??-?? or LA-??-?? Blood Codes are divided into the following major categories: Donor Suitability: PD - Post Donation Information - 82 codes DS - Donor Screening - 197 codes DD - Donor Deferral - 127 codes BC - Blood Collection - 16 codes CP - Component Preparation - 26 codes Laboratory Testing: VT - Viral Testing - 17 codes RT - Routine Testing - 19 codes LA - Labeling - 47 codes QC - Quality Control and Distribution - 85 codes MI - Miscellaneous - 10 codes Non-Blood Codes are divided into the following: IM - Incoming Material Specifications - 12 codes PC - Process Controls - 21 codes TE - Testing - 14 codes LA - Labeling - 16 codes PS - Product Specifications - 25 codes QC - Quality Control and Distribution - 11 codes MI - Miscellaneous - 1 code Additional Information (about specific unit) Comments (general information - if over 18 units, enter the additional information here)
42. List fields associated with when the event occurred	(N) B.2 - Date BPD occurred

Reporting or Database System: Program ID:	**Biological Product Deviation Reporting (BPDR) System (BIODEV)**
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	FDA USE ONLY at top of mail in form: (N) - Date Received (N) - Date Reviewed In BCIS (FF) - Entered date (MM/DD/YYYY) (FF) - Reported date (MM/DD/YYYY) (N) B.2 - Date BPD Occurred - instructions say to use MM/DD/YYYY format *(N) B.3 - Date BPD discovered - The date the deviation or unexpected event was discovered. The date discovered is the date you acquire information reasonably suggesting that a reportable event has occurred. If the event occurred at your contractor, the date of discovery is when the contractor learns about the deviation or unexpected event. Please enter using the format mm/dd/yyyy *(N) B.4 - Date BPD reported - corresponds to reported date in BCIS. The date the report is submitted.
44. List fields associated with where the event occurred	Can either be A.1 Reporting establishment information - see item 19 above OR 'Deviation establishment' *A.3 If the BPD occurred somewhere other than the reporting facility. (N) - Establishment name (N) - Street Address Line 1[not required] (N) - Street Address Line 2 [not required] (N) – City (N) – State (N) - Zip Code [not required] (N) – Country (S) A.4 - Establishment identification number (P) Establishment identification number type – type of number entered in A.4 CFN Number, FEI Number, CLIA Code [type required for on-line access, otherwise enter number in appropriate field on mail-in form] In addition to above, the following fields are pulled from initial registration information: Deviation Establishment parent name - **?** Deviation Establishment province name Deviation Establishment foreign postal code * (S) B.8 BPD code
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	Could be included in these: * (N) B.5 - Description of BPD * (N) B.6 - Description of Contributing Factors or Root Cause * (N) B.7 - Follow-up field: describe intended long-term and short-term follow-up action plans. * (S) B.8 BPD Code
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	*(N) B.7 - Follow-up field: describe intended long-term and short-term follow-up action plans.
47. List fields related to the outcome of event	Could be included in narrative of this field *(N) B.7 - Follow-up field: describe intended long-term and short-term follow-up action plans. (N) C.1, C.2 - Disposition (see item 40 for list of dispositions) (P) C.1, C.2 - Notification - Y,N, RN

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, investigations)	After reviewing the entry of a BioDev Web report, the person at BCIS determines if it is valid. If valid, the user presses the transfer button to transfer all available and appropriate info to the BPD Data table. When all required fields are completed, user presses Save button to save the BPD report to BCIS. BPD ID - generated when BPDR is saved to system BPD No - generated when BPDR is saved to system - status flag changed to "A" for accepted. Also B.1 - Establishment tracking # - user defined number used for internal report identification This number could consist of no more than 14 numbers and/or characters. Additional comments - use this section to further explain any missing information or product information such as product code, product disposition, or notification. If multiple units have the same information (i.e., collection date, expiration date, product, disposition and notification) enter the information for the first unit number and list the additional unit numbers in this section. If more than 18 units were potentially affected, enter the product information for the first 18 units and enter the remaining unit numbers in this section. Would like to use MERS-TM Root Cause Codes.
H. Implications	
49. Integration with other systems	See MERS-TM/Electronic Biological Product Deviation System Interface Feasibility Study dated 11/16/01 – preliminary findings are that varying formats and input rules make building a single portal interface less feasible. (p.15) Integrates with other CBER system to get facility information linked to CFN and FEI #: Regulatory Management System - Biological License Application, and RMS -Blood Establishment Registration. Connecting to get facility information from these.
50. What are the methods used to de-identify data?	Done manually at FDA FOIA office according to CBER regulations.
51. Technical information	
Part II. Data Structure & Storage:	
I. Facility/Location	
52. What is the address of data storage facility?	
53. What is the Facility type (3rd party data center, secured computer room, someone's cubicle)?	3rd party data center
54. Is there a network interconnect for physically distributed systems?	Internet
55. What type (private lines, VPN, Internet) of network interconnect?	Internet
56. What is the network protocol (TCP/IP, IPX, etc.)?	n/a
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)?	n/a
58. Network (WAN) topology, including diagram if available	

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
59. Who designed the system? Who operates the system?	
J. Data Storage System / Server	
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	
62. What is the number/speed (Mhz) of processors?	
63. How much memory (Gb), is available?	
64. What is the disk – manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	
65. What operating system is used (e.g. Sun Solaris 2.6.1)?	
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	Cold Fusion; Oracle 7.3.4
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	SQL; HTML; Cold Fusion
68. Which categories best describe this system?	Internet Web Application
- Is there an Operational Data Store?	No
- Is there an all-encompassing data warehouse versus focused data mart(s)?	No
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	No
- Is there a data warehouse utilizing a normalized relational database design?	No
- Is there a dimensional data warehouse utilizing a star schema design?	No

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
- Is there a statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	No
- Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	No
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	No
- Are there other structured data formats, such as XML, HTML, or other?	No
69. How is the data structured?	
- Is there an event occurrence (EO) table with one row per event?	
-Is there a person table with one row per person, linked to events by PERSONID?	
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	
70. How much disk space is currently allocated to the system?	
71. How much disk space is available on this system?	
L. For Each Major Data Structure	
72. What is the width of the table / file / subject data area (bytes)?	
73. How many data elements (approximate) in the table/file/ subject data area?	
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	
75. What is the approximate number of rows in the table, or observations?	

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	
Part III. Data Use & Analysis:	
78. System Contact	David El-Naggar
79. Contact Address	
80. Contact Phone	301-827-2461
81. Contact Email	El-Naggar@cber.FDA.gov
82. Hardware Platform	Windows 2000 NT
83. Operating System	Oracle 734 with intention to move to 8i later this year
84. Who is the developer?	Information Management Consultants (IMC)
85. Who is responsible for the system architecture?	web-enable front-end for data collection. Oracle Developer/6i (32-bit) in a client-server architecture. No registration or security (also fax, phone, mail).
86. User Types	1. Manufacturers reporting deviations - after reporting, they do not have access to data or reports. FDA is working on setting up and assigning logons to valid manufacturers who would then be able to access information related to their organization. 2. Internal FDA users, principally Office of Compliance and Biologic Quality (OCBQ), Division of Inspections and Surveillance (DIS) and Division of Case Management (DCM). DIS Consumer Safety Officials review submitted reports (web, mail etc.) and accept or reject before being added to BPD Data tab (may also update/correct BPD code). Office of Regulatory Affairs inspectors can also access data through FDA intranet (e.g., prior to site visit). ColdFusion -based query page supports function. Provides summary info with drill down capability and 5-6 search/sort fields. Queries BCIS in real time. Must have secured access to FDA intranet.
87. What is the frequency of reports?	Generated as needed by users. Annual Report published on website.
88. Who is the report generated by?	Principally Consumer Safety Officials.
89. What is the method of access?	Through BCIS software. Set of standard reports. Oracle Discoverer used for ad hoc queries.
90. What is the turnaround time?	real time
91. What is the level of automation?	Oracle Discoverer
92. Type Of Reports	Three principal standard report types: 1) remarks by error code (can produce freq dist) 2) by a number of selection criteria (type of facility, facility ID, facility name, BPD Report #, facility log#, received date, error code, remarks) with sort order options (by facility ID, received date, type of facility, error code (primary and secondary) 3) the Biological Product Deviation Report listing all info for a specific report submitted via the web. Majority of reports generated through Oracle Discoverer. Queries can be saved and rerun. IS team will respond to ad hoc report requests as well.
93. What is the unit of observation?	Incident of deviation in product manufacture

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
94. What are the available data fields?	facility, products, error class, suspected root cause information, follow up information, recall recommendation, manufacturing lot#/unit#, internal FDA comments re: follow up
95. Is there a controlled vocabulary?	Yes for product, type of error (Biological Product Deviation Codes). Open ended text description of problem contained in Biological Product Deviation Report form.
96. Exportability	Can export to other applications using Oracle Discoverer
97. User Profile	DIS Consumer Safety Officers. Also, DIS staff conducting statistical analyses etc.. DCM staff. Office of Regulatory Affairs inspectors can also access data through FDA internet (e.g., prior to site visit).
98. How are the reports used?	Used to meet regulatory compliance obligations. DIS Consumer Safety Officers responsible for review and follow up of reports, initiations of inspections. DCM responsible for reviewing inspectors "list of observations" and following up as needed up to initiating recalls (Class 1, 2, 3), "non-concurrence", market withdrawals and enforcement actions.
99. Report Dissemination	Reports are largely internal to BCIS users who generate and print their own reports from system. DIS, through a series of Oracle Discoverer queries, generates information that feeds into Annual Report which is available on web. Annual Report provides descriptive statistics by type of facility, action taken and BPD code. Also have queries to assess timely submission of reports to FDA. To date, little trend or root cause analysis completed although planned for the future. List of root cause codes applied but may need to be updated. Standard reports not widely used.
100. What is the primary goal	To support identification of manufacturing problems and appropriate recall of biologic products.
101. Integration with other systems	See below re: MERTS-TM/BIODEV integration feasibility study. May be opportunity to rationalize BPD root cause codes with MERS-TM codes. BCIS users draw on CBER/ORA databases to validate FEI information. No other linkages or data sharing with any systems including MedWatch or AERS/VAERS. In most cases, BPD reports do not result in harm, therefore, would not be reported to AERS. Non-blood establishments reporting to BPD include vaccine manufacturers, therefore, may be some overlap with AERS/VAERS.
102. HIPAA Compliant	Yes, no patient-specific information contained in original reports, most data elements are available under FOI (CFR 21 Part 11).
Future	Developing internet-based function to allow manufacturers/reporters to access their reports. Currently working out issues re: protecting data, audit trail etc.. Access to be restricted by logon/password system. Also further opportunity to more completely identify ongoing reporting needs and develop appropriate standard reports.

Reporting or Database System: Program ID:	Biological Product Deviation Reporting (BPDR) System (BIODEV)
Notes:	Recall Alert, Tracking and Enforcement modules also provide reporting functions "Interface Feasibility Study" was undertaken to assess integration of MERS-TM and BIODEV. Study concludes that: "At this time, a recommendation to proceed with interface development cannot be given without numbers to show that sufficient overlap of events reported to both systems exists.". "Data indicating the total number of MERS-TM reports which are FDA reportable should be revisited.." "A comparison of the information reported to each system has identified that similar information is being captured by MERS-TM and BIODEV but often in different formats and where formats are similar different input rules apply." Therefore, single portal interface considered "less feasible". "A one way interface from MERS-TM to BIODEV appears to be the most feasible. Since MERS-TM coded information can be can be translated into BIODEV format by the interface." FDA is also consolidating its recall tracking systems (Sandra Whetstone, Office of Regulatory Affairs - not interviewed) Approx. 25,000 reports per year. Only 348 non-blood facility reports (including vaccine manufacturers) Desired Information: Data on facility characteristics (e.g., total number of facilities, #units transfused/collected, type of facility etc.) Note that there is no mandatory reporting of injuries to FDA (only deaths). This may be a gap in overall assessment of medical errors. These may be reported to MERS-TM but system is voluntary.
Comments	*How BPDR differs from MERS-TM- BPDR is a mandatory requirement based upon federal regulations. MERS-TM is a voluntary reporting system. The MERS-TM focuses on adverse events specifically associated with a blood transfusion. Reporting is done by blood centers and transfusion services. The BPDR system focuses specifically on the manufacturers of blood products, and biological non-blood products, although transfusion services are also included. Events reported are any associated with the manufacturing, testing, processing, labeling, packing, storage, holding or distribution of both licensed and unlicensed blood or blood components that represent a deviation from current good manufacturing practices OR represents an unexpected *event potentially affecting the purity, safety, or potency of the product.* Note that BPD codes are changed every year. Regulations for reporting are complex in terms of which group should report and when gives 7 different scenarios to try to clarify for the reporter. Also gives examples of reportable and non-reportable events by system: Donor suitability variation collection deviation or unexpected event component preparation deviation testing deviation or unexpected event labeling deviation or unexpected event quality control and distribution deviation or unexpected event BIODEV vs BPDR vs BCIS BIODEV is the web front end. BPDR is client server at FDA. BCIS is for entire Biologic Compliance Information System – includes BPDR, but also alerts, recalls etc

Dialysis Surveillance

Reporting or Database System: Program ID:	**Dialysis Surveillance Network (DSN)**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	Dialysis Surveillance Network (DSN)
2. Internet Location: http://	www.cdc.gov/ncidod/hip/DIALYSIS/dsn.htm
3. Host Organization(s)	Centers for Disease Control and Prevention
4. Primary contact information (e.g. Address, Phone)	Teresa C. Horan, MPH, CIC (404) 498-1114 thoran@cdc.gov Jerome I. Tokars, MD, MPH jit1@cdc.gov
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	(DSN) is a voluntary surveillance system-monitoring bloodstream and vascular access infections-initiated by CDC in 1999 and includes adult/pediatric outpatient dialysis centers caring for chronic hemodialysis patients. Dialysis patients are at high risk for infection with antimicrobial-resistant bacteria. The purposes of the DSN are as follows: 1-To provide a method for individual hemodialysis centers to record and track rates of vascular access infections, other bacterial infections, hospitalizations, and intravenous antimicrobial starts. 2-To provide a method to aggregate, compare and distribute data to cooperating dialysis centers and the public health and medical communities. 3-To use these data to prevent infections and slow the spread of antimicrobial resistance. A secondary purpose is to record rates and syndromes prompting use of IV antimicrobials in hemodialysis centers. Participating centers may enter data on paper forms provided by CDC and receive a data analysis report every quarter. Alternatively, they may use the Internet-based system for data entry and analysis and generate and print reports whenever desired. There are no fees or financial remuneration for participating in this system. While summary data are released, the data from individual centers are confidential and cannot be released to anyone other than the dialysis center reporting it. Unique features of the DSN include: User-friendly methods simplify reporting. Data collectors record the presence or absence of criteria for infections, not the infections themselves. A computer algorithm determines whether the infection case definitions are met. The data collector does not have to memorize case definitions. The frequency of blood culturing, a factor that may influence reported infection rates, is determined. Several different rates are reported to better characterize the situation at any given center. For information about enrollment, see the procedure manual for the study or call 404-498-1109.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	National

Reporting or Database System: Program ID:	Dialysis Surveillance Network (DSN)
7. What is the unit of data entry (e.g., event, patient, product)?	Events are hospitalization or in-unit intravascular antimicrobial starts among chronic dialysis patients.
8. Who is allowed/required to input information?	Dialysis center personnel, such as Dialysis RN, dialysis technician, administrator, hospital-affiliated infection control practitioner
9. What are the regulations/laws affecting reporting?	See confidentiality laws in #10.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	In accordance with 'Assurance of confidentiality'--Sections 304, 306, and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and m(d), the information obtained for the surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution. At CDC, all data, including personal identifiers, is stored unencrypted in password-protected data files in a locked file or room, with access restricted to study personnel.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Dialysis center personnel may collect data on paper forms and send to CDC, who will enter the data electronically, or use CDC's Internet-based data entry and analysis system. If the Internet version is used, the data are transmitted to CDC via the CDC/ATSDR Secure Data Network, a secure transmission mechanism that meets the requirements of CDC's Internet security policy.
12. What are the methods of editing information (e.g. correcting/add more information to records)	Correcting and adding data to complete a record are allowed. Monthly submission of data to add to database.
13. Where is the collected data stored (name of database, number of data storage locations)?	Centers for Disease Control and Prevention
14. How often is the system revised (annual, semi-annual etc)?	Revised as needed. Currently in revision, see #17
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	User input is constantly sought and evaluated; internal review and design is ongoing.
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	If using the electronic data capture, Internet access
17. What new features are being planned and/or are on wish lists?	Currently in major revision to move to the new National Healthcare Safety Network (NHSN) using the National Electronic Disease Surveillance System as the architectural foundation. The NHSN will integrate three surveillance systems: NNIS, National Surveillance System for Hospital Healthcare Workers and Dialysis Surveillance Network; revisions include protocols, forms, data elements, web access technology, format etc.
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	No linkage, certain data (e.g.race/ethnicity distribution, age distribution, cause of renal failure, standardized mortality and hospitalization ratios, lists of hospitalizations) is obtained as

Reporting or Database System: Program ID:	Dialysis Surveillance Network (DSN)
	possible from CMS and the US Renal Data Systems and is used to assess representativeness by comparing centers that do with those that do not participate in the surveillance system, and possibly to control for differences among participating centers in patient populations (data is confidential and comply with data user agreements established).
D. Fields related to contributor/participant Information:	
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	Survey form completed when enrolling and annually thereafter. Fields include: name of dialysis center, HCFA provider number, ownership of center (for profit, not for profit, government), location (hospital based, freestanding, freestanding but owned by a hospital), part of a chain or not (Y/N) and name of chain, person responsible for collecting data (RN, technician, administrator, infection-control practitioner or other), who is responsible for infection control (dialysis staff member, hospital infection control practitioner, other), has the center participated in the surveillance system in the past (Y/N).
20. Is participation mandatory or voluntary?	Voluntary
21. List fields related to contributor/participant contact information	On the agreement to participate form: primary contact person: name, title and signature; Medical director or administrator, name, title and signature
22. List fields related to facility contact information (include type of facility, teaching status, id information)	Fields include: name of dialysis center, address, phone, fax, email address, HCFA provider number, ownership of center (for profit, not for profit, government), location (hospital based, freestanding, freestanding but owned by a hospital), part of a chain or not (Y/N) and name of chain, has the center participated in the surveillance system in the past (Y/N).
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact information	No information related to manufacturer contact, data is collected on the brand names of dialysis catheters used in the facility and includes Permanent (cuff, tunneled) catheters: manufacturer and model; Temporary (noncuffed, nontunneled) catheters (manufacturer and model)
E. Fields related to Provider of Care Information:	
25. List fields related to Provider of Care identification	#3 Provider number is requested on each form submitted
26. List fields that identify types of care providers included in system	Name of dialysis center and type, see #19, #22 above
F. Fields related to Patient Information:	
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	A log form is provided to collect information on the patient, but is NOT to be sent to CDC, information collected includes patient name, date of admission (mm/dd), the problem prompting admission. #5 Log number is captured on incident form. The incident forms have 2 versions: Option A relates to recording each hospitalization or outpatient IV antimicrobial start; Option B form is for each IV antimicrobial course. Hospital

Reporting or Database System: Program ID:	Dialysis Surveillance Network (DSN)
	admissions where the patient does not return to the outpatient dialysis unit on an IV antimicrobial are not recorded under Option B. On Option A and B forms, #1.the name of the patient (First, MI, last and #2 identification number (may use hospital number, social security number, or any unique identification number, if forms are sent on paper, this information is removed from the form; if electronically sent, name is optional)
28. List fields related to patient contact information (e.g. address, zip code, county, region)	None
29. List fields related to patient demographics (e.g. age, sex, race)	None
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	If patient name transmitted, information protected as previously noted.
31. List fields related to pre-existing conditions and/or medical history of patient	None
32. List fields that capture the clinical condition of patient at time of event	None
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	None
34. List any other types of information collected about the patient	None
G. Fields related to Event/Error/Product Information:	
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Potential infection as a result of vascular access and dialysis
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	None
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	#7. Vascular access (circle all that the patient has): 1=graft, 2=fistula, 3=temporary catheter, 4=port access device
38. List fields associated with vaccine related events	N/A
39. List fields associated with infection related events	#6. Incident type: H for hospitalization, A for an in-unit IV antimicrobial start, or both if the IV antimicrobials were started in the unit and the patient was subsequently admitted to the hospital.If an in-unit IV amtimicrobial start, answer: IV vancomycin started? Y/N
40. List fields associated with any other type of event. List type of event.	None
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	# 8. Problems that led to hospitalization or IV antimicrobial start (circle all that apply): a. Pus, redness, or increased swelling at vascular access site b. Vasculary access problem without infection (clotting,

Reporting or Database System: Program ID:	Dialysis Surveillance Network (DSN)
	bleeding, etc.) c. Fever (100F oral or 101 rectal) d. Wound (not related to vascular access) with pus or increased redness e. Cellulitis (skin redness, heat, or pain without open wound) f. Pneumonia (a new infiltrate or pneumonia seen on chest x-ray) g. Respiratory infection not meeting above criteria for pneumonia (e.g. bronchitis) h. Urine culture with >100,000 organisms/ml with not more than 2 species isolated i. Cardiovascular event (chest pain, heart attack, other heart problems, stroke, etc.) j. Other, specify: _____
42. List fields associated with when the event occurred	Date: the month, day and year (mm/dd/yyyy) of the hospitalization or IV antimicarobial start.
43. List fields associated with tracking the time between the event, when reported, when acted upon etc.	Date: the month, day and year (mm/dd/yyyy) of the hospitalization or IV antimicrobial start. On incident form A and B, include all IV antimicrobial starts. If IV antimicrobials are stopped for less than 21 days and then restarted, this is NOT considered a new event, if they are stopped for 21 days or more, this is considered a new incident.
44. List fields associated with where the event occurred	#6 Incident type: H hospitalization, A in unit IV antimicrobial start
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	#9. Blood culture: 0=not done, 1=positive, 2=negative, 3=unknown 9a. If positive, suspected source of positive blood culture: 1=vascular access 2=a source other than the vascular access 3=contamination 4=uncertain 9b. If blood cultures were positive, List organisms isolated from blood and antimicrobial susceptibility (methicillin, oxacillin or nafcillin) and Vancomycin (codes S=susceptible, I=Intermediate, R=resistant)
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	N/A
47. List fields related to the outcome of event	None
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, investigations etc)	#10. Comments
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	
51. Technical Information	
Other	Reporting burdened estimated at 1 hour per report

Reporting or Database System: Program ID:	Dialysis Surveillance Network (DSN)
Part II: Data Structure & Storage: The data structure for the Dialysis Surveillance system is in the process of being redesigned as part of a modernization effort. Accordingly, we did not review the data storage/structure of this system since the findings would be of limited utility with respect to development of an integrated system.	
Part III: Data Use & Analysis:	
78. System Contact	Dr. Jerry Tokars
79. Contact Address	1600 Clifton Rd MS E-69 Atlanta, GA 30333
80. Contact Phone	
81. Contact Email	jit1@cdc.gov
82. Hardware Platform	
83. Operating System	
84. Who is the developer?	
85. Who is responsible for the system architecture?	web-enabled front-end for data collection, access
86. User Types	participating facilities use web front-end and can generate site-specific statistics. Internal staff generate summary reports
87. What is the frequency of reports?	monthly event reporting - internal reporting is ad-hoc, monthly, quarterly, and yearly
88. Who generates the report?	internal staff
89. What is the method of access?	
90. What is the turnaround time?	
91. What is the level of automation?	
92. Type Of Reports	Summary level standard reports, facility (masked) comparisons to norms
93. What is the unit of observation?	The reported event within facility
94. What are the available data fields?	facility, date, incident type, vascular access, problem report, blood info
95. Is there a controlled vocabulary?	yes
96. Exportability	
97. User Profile	participating facility QI staff, CDC staff (no public release of data?)
98. How are the reports used?	trends, facility to norm comparisons, facility rates
99. Report Dissemination	participating facilities, public reporting of summary data
100. What is the primary goal?	
101. Integration/Linkable to Detail	no
102. HIPAA Compliant	yes

ESRD

Reporting or Database System:	**CMS End Stage Renal Disease (ESRD) Network** Consolidated Renal Operations Web-based Network (CROWN)
A. General Information	
1. Report Title	
2. Internet Location: http://	http://www.esrdnetworks.org http://www.hcfa.gov/quality/5d.htm
3. Host Organization(s)	Centers for Medicare & Medicaid Services (CMS)
4. Primary contact information (e.g. Address, Phone)	Dennis Stricker (410) 786-2031 DStricker@cms.hhs.gov Bill Crochunis (410) 786-6740 BCrochunis@cms.hhs.gov Roger Milam (410) 786-0613 RMilam1@cms.hhs.gov
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The Renal Beneficiary and Utilization System (REBUS) is the repository for the ESRD program data. It contains data covering the medical and demographic information for the ESRD population. Dialysis facilities and transplant centers report patient data through the Vital Information System to Improve Outcomes in Nephrology (VISION) to 1 of 18 ESRD Network Organizations. These network organizations are connected to one another and to the REBUS through the Standard Information Management System (SIMS). The 18 Networks are currently in immediate contact with 4,153 dialysis facilities and 242 transplant centers, serving approximately 276,106 patients. The REBUS is in the process of migration to a new system called the Renal Management Information System (REMIS). CMS is working to build an integrated ESRD system called Consolidated Renal Operations in a Web-Enabled Network (CROWN). This new system will include VISION, SIMS, and REMIS, and will be implemented about June 30, 2002. CROWN and REBUS will continue to work in parallel until September 30, 2002, the termination date of REBUS.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	National
7. What is the unit of data entry (e.g., event, patient, product)?	Patient
8. Who is allowed/required to input information?	Physician at Dialysis or Transplant facility.
9. What are the regulations/laws affecting reporting?	1972 Amendment to Title XVIII of Social Security Act extended Medicare Part A and Part B benefits to all individuals with ESRD regardless of age. 1978 Public Law 95-292, section (c)(1)(A) mandated the establishment of renal disease medical information system. The resulting system, REBUS, merged from an existing patient dialysis registry, a transplant registry, and Medicare claims and eligibility data from the SSA. 1987 Congress mandated the formation of 18 ESRD Networks to assist in the collection and verification of patient, facility, and provider data.

Reporting or Database System:	**CMS End Stage Renal Disease (ESRD) Network** Consolidated Renal Operations Web-based Network (CROWN)
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	No.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	ESRD facility to ESRD Network: Print forms or Electronic transport in HL7 XML format.
12. What are the methods of editing information (e.g. correcting/add more information to records)	
13. Where is the collected data stored (name of database, number of data storage locations)?	18 ESRD Network Organizations. SIMS Central repository, REBUS, and REMIS at CMS Data Center
14. How often is the system revised (annual, semi-annual etc)?	
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	
17. What new features are being planned and/or are on wish lists?	
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	
D. Fields related to contributor/participant Information:	
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	(N) Physician Identification (N) Physician Signature (S) UPIN of Physician (N) Attending Physician and Phone Number (N) Name of Provider (S) Medicare Provider Number
20. Is participation mandatory or voluntary?	Mandatory
21. List fields related to contributor/participant contact information	
22. List fields related to facility contact information(include type of facility, teaching status, id information)	

Reporting or Database System:	**CMS End Stage Renal Disease (ESRD) Network** Consolidated Renal Operations Web-based Network (CROWN)
23. List fields related to distributor contact information	
24. List fields related to manufacturer contact information	
E. Fields related to Provider of Care Information:	
25. List fields related to Provider of Care identification	(N) Name of Provider (S) Medicare Provider Number for Provider (P) Primary Dialysis Setting (N) Name of Transplant Hospital (S) Medicare Provider Number for Transplant Hospital (N) Name of Preparation Hospital (S) Medicare Provider Number for Preparation Hospital (N) Name of Training Provider (for self-dialysis training) (S) Medicare Provider Number for Training Provider
26. List fields that identify types of care providers included in system	
F. Fields related to Patient Information:	
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	(N) Patient Name (S) Health Insurance Claim Number (S) Social Security Number
28. List fields related to patient contact information (e.g. address, zip code, county, region)	(N) Full Address (N) Phone Number
29. List fields related to patient demographics (e.g. age, sex, race)	(FF) Date of birth (P) Sex (P) Ethnicity (P) Race
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)?	All Contact Information
31. List fields related to pre-existing conditions and/or medical history of patient	(N) Laboratory Values Prior to First Dialysis Treatment or Transplant
32. List fields that capture the clinical condition of patient at time of event	(P) Primary Type of Dialysis
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	(P) Medical Coverage

Reporting or Database System:	**CMS End Stage Renal Disease (ESRD) Network** Consolidated Renal Operations Web-based Network (CROWN)
34. List any other types of information collected about the patient	(N) Primary Cause of Renal Failure; Height; Dry Weight (FF) Date Regular Dialysis Began (FF) Date Patient Started Chronic Dialysis at Current Facility (FF) Date Dialysis stopped (FF) Date of Death (FF) Date of Transplant (FF) Date patient was admitted to Hospital (in anticipation of transplant) (P) Current Status of Transplant (FF) If Nonfunctioning, Date of Return to Regular Dialysis (FF) Date Training Began (for self-dialysis) (P) Type of Training (P) Completion of Training (FF) Date Training Completed
G. Fields related to Event/Error/Product Information:	
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer)	
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer) cont'd	
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	
38. List fields associated with vaccine related events.	
39. List fields associated with infection related events.	
40. List fields associated with any other type of event. List type of event.	
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	
42. List fields associated with when the event occurred	
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	
44. List fields associated with where the event occurred	

Reporting or Database System:	**CMS End Stage Renal Disease (ESRD) Network** Consolidated Renal Operations Web-based Network (CROWN)
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	
46. List fields related to follow-up of event that are not associated with a particular patient(medication/manufacturing/policy actions to correct/update event)	
47. List fields related to the outcome of event	
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, results of investigations etc)	
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	
51. Technical Information	
Part II. Data Structure & Storage:	
I. Facility/Location	
52. What is the address of storage facility?	CMS Data Center 7500 Security Boulevard Baltimore, Maryland 21244-1850. CMS contractors and agents at various locations.
53.What type of facility is used to store the data (3rd party data center, secured computer room, someone's cubicle)?	CMS Data Center
54. Is there a network interconnect for physically distributed systems?	SIMS Virtual Private Network and CMS Wide Area Network
55. What type (private lines, VPN, Internet) of network interconnect?	VPN
56.What is the network protocol (TCP/IP, IPX, etc.)?	TCP/IP
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)?	N/A
58. What is the network (WAN) topology, including diagram if available?	Currently, 4,153 dialysis facilities and 242 transplant centers transmit data to 18 ESRD Network Organizations via the Internet or mail. These 18 Organizations are interconnected through CMS VPN and connected to SIMS central repository. Data from SIMS central repository is fed into REBUS and REMIS.
59. Who designed the system? Who operates the system?	CMS and ESRD Network Organizations

Reporting or Database System:	**CMS End Stage Renal Disease (ESRD) Network** Consolidated Renal Operations Web-based Network (CROWN)
J. Data Storage System / Server	This information is for REBUS and REMIS, the main repositories of all ESRD data. Individual facilities and organizations have their own data storage systems.
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	IBM
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	SP - RS/6000 RISC
62. What is the number / speed (Mhz) of processors?	4 processors; 375 MHz
63. How much memory is available (Gb)?	Shared 4 Gb
64. What is the disk - Manufacturer, amount (Gb) & type (SAN, RAID	EMC Storage Devices
65. What is the operating system (e.g. Sun Solaris 2.6.1)?	IBM AIX 4.3.3 ptf set 9
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	REBUS: Model 204 Database REMIS: Oracle 8i Database
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL,	SIMS uses Crystal Reports for data analysis. REMIS will be using Oracle Discoverer and probably SAS.
68. Which categories best describe this system?	
- Is there an operational data store?	No
- Is there an all-encompassing data warehouse versus focused data mart(s)?	No
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	No
- Is there a data warehouse utilizing a normalized relational database design?	Yes
- Is there a Dimensional Data Warehouse utilizing a star schema design?	No
- Is there a statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS	No
- Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	No
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	No
- Are there other structured data formats, such as XML, HTML, or other?	No

Reporting or Database System:	**CMS End Stage Renal Disease (ESRD) Network** Consolidated Renal Operations Web-based Network (CROWN)
69. How is data structured?	Each table is a person table with one row per person, linked by Social Security number. The SIMS network of patient information is composed of the following tables: DEATH NOTICE (Date, place, and cause of death) FACILITY CERTIFICATION (Annual provider-specific treatment and transplant data) IDENTIFICATION (Basic beneficiary information, entitlement, and ESRD termination date) INPATIENT STAY (Hospital stay dates, provider number, surgery information) MEDICAL EVIDENCE (Medical conditions, lab results) METHOD SELECTION (ESRD payment method chosen by home dialysis patients) PATIENT STATUS (Verified status, dialysis type, most recent treatment setting) QUARTERLY DIAGNOSIS (Aggregated information for all dialysis claims in quarter) TRANSPLANT (Date of transplant, organ donor data) TRANSPLANT FOLLOW-UP (Tracks status of beneficiary transplant)
- Is there an event occurrence (EO) table with one row per event?	
- Is there a person table with one row per person, linked to events by PERSONID?	
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	
70. How much disk space is currently allocated to the system?	Total for SIMS Repository: 18 Gigs
71. How much disk space is available on this system?	Unknown
L. For Each Major Data Structure	
72. What is the width of the table / file / subject data area (bytes)?	
73. How many data elements (approximate) in the table / file / subject data area?	
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	
75. What is the approximate number of rows in the table, or observations?	
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	

HCUP

Reporting or Database System:	**Healthcare Cost and Utilization Project**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	N/A
2. Internet Location: http://	http://www.ahrq.gov/data/hcup/
3. Host Organization(s)	Agency for Healthcare Research and Quality
4. Primary contact information (e.g. Address, Phone)	Jenny Schnaier, Project Officer Agency for Healthcare Research and Quality 2101 East Jefferson St., Suite 605
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	Under the leadership of the Agency of Healthcare Research and Quality (AHRQ), the fourth phase of the Healthcare Cost and Utilization Project (HCUP) aims to bring together the data collection efforts of state data agencies, hospital associations, private data organizations, and the federal government to expand the multifaceted HCUP health services databases from 1988 through 2003. HCUP databases serve a unique function and are being tapped by analysts and researchers interested in hospital utilization, access, charges, quality, and outcomes. Researchers rely on HCUP data to identify, track, analyze, and compare trends at the national, regional, and State levels. Because of their large size, the HCUP databases are used to describe patterns of care for rare as well as common diseases; analyze infrequent as well as common hospital procedures; and track utilization for population subgroups, such as minorities, children, women, and the uninsured. HCUP databases contain a core set of clinical and non-clinical information on all patients, regardless of payer—including persons covered by Medicare, Medicaid, private insurance, and uninsured—translated into a uniform format to facilitate both multi-State and national/State comparisons and analyses. The HCUP databases are available for intramural research within AHRQ. Many of the HCUP databases are available through restricted access, public release through the AHRQ-sponsored HCUP Central Distributor or through the National Technical Information Service (NTIS). The content of the restricted access, public release versions of the HCUP databases is developed in partnership with the participating data organizations. In general, the restricted access, public release databases represent 100% of the records in the intramural databases. Because the participating data organizations dictate the release of specific data elements, the data elements on the restricted access, public release databases are a subset of the data in the intramural databases. HCUP data users must agree to certain conditions: the database can be used only for research and statistical purposes, and patients and institutions cannot be identified in publications. The HCUP family of health services databases includes: A Comprehensive multi-state databases of hospital inpatient and outpatient services. There are four key databases: Nationwide Inpatient Sample (sample of 1,000 hospitals to support extrapolation to nation), State Inpatient Databases (inpatient care in community hospitals from 29 participating states), State Ambulatory Surgery Databases (from 13 participating states), Kids' Inpatient Database (inpatient stays for children 18 and younger). Purpose of databases is to support health services research. AHRQ created Clinical Classifications Software for groups, like ICD-9 codes to facilitate analysis. System is not directly related to

Reporting or Database System:	Healthcare Cost and Utilization Project
	medical error reporting. AHRQ has created a set of Quality Indicators to "highlight potential quality concerns, identify areas that need further study and track changes over time". One set of Quality Indicators currently available: Prevention QI's (identifying potentially avoidable admissions). Inpatient QI's under development (mortality medical condition and procedure, utilization of procedures that may be underused/overused/misused, volume of procedures for procedures where high volume associated with lower mortality). Patient Safety QI's under development.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	The Healthcare Cost and Utilization Project (HCUP) is a Federal-State-industry partnership to build a standardized, multi-State health data system. HCUP is maintained by the Agency for Healthcare Research and Quality (AHRQ, formerly the Agency for Health Care Policy and Research). AHRQ has taken the lead in developing HCUP databases, Web-based products, and software tools and making them available for restricted access public release. HCUP comprises a family of administrative longitudinal databases—including State-specific hospital-discharge databases and a national sample of discharges from community hospitals—and powerful, user-friendly software that can be used with both HCUP data and with other administrative databases.
7. What is the unit of data entry (e.g., event, patient, product)?	HCUP databases contain patient-level information compiled in a uniform format with privacy protections in place. The Nationwide Inpatient Sample (NIS) includes inpatient data from a national sample of over 1,000 hospitals. The State Inpatient Databases (SID) cover inpatient care in community hospitals in participating States that represent more than half of all U.S. hospital discharges. The State Ambulatory Surgery Databases (SASD) contain data from ambulatory care encounters. The project's newest restricted access public release is the Kids' Inpatient Database (KID), containing hospital inpatient stays for children 18 years of age and younger.
8. Who is allowed/required to input information?	N/A
9. What are the regulations/laws affectingreporting?	Protecting the security and confidentiality of information within the HCUP databases is paramount. Federal and state laws, limitations imposed by the statewide data organizations, and MEDSTAT policies govern the use of data used constructing HCUP files. Federal restrictions are described in Privacy Act of 1974 and the Public Health Service Act (42 U.S.C. 299c-3(c)). AHRQ restrictions are described in attachments to the HCUP Memorandum of Agreement (MOA), "HCUP Data Confidentiality Guidelines for AHRQ Staff and Programming Support Contractors" and "HCUP Confidentiality Guidelines for Restricted Access, Publicly Distributed Databases AHRQ-CODS." Before handling HCUP data, MEDSTAT staff and subcontractors are required to sign the AHRQ Staff/Programming Support Contractor Data Security Agreement. A copy of this document is also attached to the HCUP MOA.Restrictions imposed by the HCUP Partner data organizations are specified in Partner-specific MOA. One example is the South Carolina MOA that cites and attaches the South Carolina Code of Law, Section 44-6-170 through 44-6-200 to the HCUP MOA.MEDSTAT policies are detailed in a proprietary document: "Data Privacy and Confidentiality Policies and Procedures Manual for Employees." The key components of this manual are summarized in the document entitled "Summary of Principles, Policies and Procedures Related to the Privacy, Confidentiality and Security of Person-level and Other Confidential Data". A summary of this proprietary document is included in Deliverable #144 Securing Data During HCUP Processing."
10. Does the system allow for/require anonymous input? If	No

Reporting or Database System:	Healthcare Cost and Utilization Project
yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	State Data files received by submission of formal request to state. Data arrives at MEDSTAT in CD-ROM; ASCII (.tx)- Flat text, format.
12. What are the methods of editing information (e.g. correcting/add more information to records)	N/A
13. Where is the collected data stored (name of database, number of data storage locations)?	Physical copies of source data are stored within locked offices or within locked cabinets. On the HCUP servers, source data files are stored separate from other data, on a dedicated partition. This allows source files to be backed up and deleted independent of SAS programs and other HCUP data. Source data files are stored by data type, state, and year. Interim SAS working files re stored separate from copies of source data and final HCUP files. The interim files are stored with copies of the programs used to create and manipulate these files. These files are stored by data type, state, and year. Post-production data files are stored separate from copies of source data, processing programs, and interim SAS working files. Sensitive data development files are also stored separately. The post-production data files are stored by data type, state, and year. Hard copy listings or logs generated from computer runs are stored within locked offices or within locked cabinets.
14. How often is the system revised (annual, semi-annual etc)?	Each year of the HCUP contract involves recruiting additional Partners and obtaining additional types of data from existing Partners.
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	Design under contract with customer input.
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	N/A
17. What new features are being planned and/or are on wish lists?	N/A
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	Yes. Hospital information is linked to Hospital Association files.
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**

Reporting or Database System:	Healthcare Cost and Utilization Project
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	State Hospital Organizations / Data Organizations
20. Is participation mandatory or voluntary?	Mandatory
21. List fields related to contributor/participant contact information	N/A
22. List fields related to facility contact information (include type of facility, teaching status, id information)	N/A
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact information	N/A
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
25. List fields related to Provider of Care identification	Expected principal and secondary payers
26. List fields that identify types of care providers included in system	
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	N/A
28. List fields related to patient contact information (e.g. address, zip code, county, region)	admission type, admission source, admission year
29. List fields related to patient demographics (e.g. age, sex, race)	age in years, age in days, age in months, sex, race,
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	N/A
31. List fields related to pre-existing conditions and/or medical history of patient	N/A
32. List fields that capture the clinical condition of patient at time of event	principal and secondary diagnoses, principal and secondary procedures,

Reporting or Database System:	Healthcare Cost and Utilization Project
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	length of stay, admission type, admission source,
34. List any other types of information collected about the patient	If provided by data organization: birth weight, birth month, birth year, medical record number, zip code,
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	N/A
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer)	N/A
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer) continued	N/A
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	N/A
38. List fields associated with vaccine related events.	N/A
39. List fields associated with infection related events.	N/A
40. List fields associated with any other type of event. List type of event.	N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	N/A
42. List fields associated with when the event occurred	N/A
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	N/A
44. List fields associated with where the event occurred	N/A

Reporting or Database System:	Healthcare Cost and Utilization Project
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	N/A
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	N/A
47. List fields related to the outcome of event	N/A
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, results of investigations etc)	N/A
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	
51. Technical Information	
Part II. Data Storage:	
For Each Facility / Location	
52. What is the address of the data storage facility	MEDSTAT / AHRQ
53. What type of facility is used to store the data (3rd party data center, secured computer room, someone's cubicle)?	3rd party data center, secured computer.
54. Is there a Network Interconnect for physically distributed systems?	No
55. What type (private lines, VPN, Internet) of network interconnect is used?	No
56. What is the network protocol (TCP/IP, IPX, etc.)?	No
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)?	No
58. What is the network (WAN) topology, including diagram if available?	No
59. Who designed the system? Who operates the system?	AHRQ/MEDSTAT
J. For Each Data Storage System / Server	

Reporting or Database System:	Healthcare Cost and Utilization Project
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	Compaq
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	AS-6?-10
62. What is the number / speed (Mhz) of processors?	700 Mhz -1.2 Ghz
63. How much memory (Gb) is available?	10 GB
64. What is the disk - Manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	RAID Array
65. What is the operating system (e.g. Sun Solaris 2.6.1)?	NT/2000
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	SAS
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	SAS
68. Which categories best describe this system?	Statistical analysis system.
- Is there an operational data store?	No
- Is there an all-encompassing data warehouse versus focused data mart(s)?	No
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	No
- Is there a data warehouse utilizing a normalized relational database design?	No
- Is there a dimensional data warehouse utilizing a star schema design	No
- Statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)	Yes
- Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema	No

Reporting or Database System:	Healthcare Cost and Utilization Project
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	No
- Are there other structured data formats, such as XML, HTML, or other?	No
69. How is the data structured?	Core files
- Is there an event occurrence (EO) table with one row per event?	N/A
- Is there a person table with one row per person, linked to events by PERSONID	N/A
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	No
70. How much disk space is currently allocated to the system?	200 GB
71. How much disk space is available on this system?	500 GB
L. For Each Major Data Structure	
72. What is the width of the table / file / subject data area (bytes)?	~ 300 bytes
73. How many data elements (approximate) in the table / file / subject data area?	~100
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	N/A
75. What is the approximate number of rows in the table, or observations?	100,000-3,000,000
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	1998-2001
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	No
Part III. Data Use & Analysis:	
78. System Owner	AHRQ, CODS?
79.System Contact	Anne Elixhauser

Reporting or Database System:	Healthcare Cost and Utilization Project
80. Contact Phone	301-594-6815
81. Contact Email	aelixhau@ahrq.gov
82. Hardware Platform	Set of SAS data files in PC format that can be put on any system (may need to be translated if necessary). Publicly available files in ASCII format. Data packaged as set of CD-ROMs.
83. Operating System and version	N/A
84. Who is the developer?	AHRQ with assistance from MEDSTAT
85. Who is responsible for the architecture?	N/A
86. User types (contributors, maintainers, analysts, policy makers)	Multiple users conducting a variety of research /analysis, primarily unrelated to medical errors. Use of data to create Patient Safety QI's being assessed by UCSF-Stanford Evidence-based Practice Center. Draft report received.
87. What is the frequency of reports?	No users of HCUP data identified who currently/regularly produce medical error-related reports.
88. Who generates (requested) by (system, user, etc) the reports?	N/A
89. What is the method of access to request report (dedicated terminal, remote, service bureau request)	Person must request for, and complete a Data Use Agreement.
90. What is the turnaround time for report?	N/A
91. Level of Automation (canned, custom)?	N/A
92. Type of Reports (hard copy, electronic, screen view only, etc)	Available in electronic and hard copy formats.
93. What is the unit of observation?	Inpatient hospital stay or ambulatory surgery
94. What data fields are available for analysis?	Many hospital, patient demographic and hospital-discharge related fields available in data set.
95. Is there a controlled vocabulary used for all (any) fields?	N/A
96. Exportability	N/A
97. User profile (Agency employee, external researcher)	N/A
98. How are the reports used (support of regulations, research, legal, etc.)	Support of research
99. Dissemination of Reports	N/A
100. What is the primary goal or objective of reports?	Support health services research and hospital operation by making comprehensive, standardized, high quality hospital data sets available.
101. Is the data linkable to detail?	N/A

MAUDE

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	MedWatch - FDA Mandatory safety information and adverse event reporting program - Devices only
2. Internet Location: http://	http://www.fda.gov/cdrh/maude.html http://www.fda.gov/cdrh/mdr.html
3. Host Organization(s)	The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH)
4. Primary contact information (e.g. Address, Phone)	Primary Contact - Joyce Siwarski - 301-594-4550 x166; JCS@CDRH.FDA.GOV Marilyn Flack - MNF@CDRH.FDA.GOV Jim Motz for data structure
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The MAUDE database consists of data representing adverse event reports involving medical devices. The term Medical Device Reporting (MDR) is often used to refer to this program and is the mechanism for the FDA to receive significant medical device adverse events from manufacturers, importers and user facilities to assure the safety, effectiveness, and proper labeling of medical and radiation emitting devices. The FDA has the authority to send out warnings, to stop distribution, and/or to recall devices based upon the level of problem severity. The FDA also has regulatory authority for enforcement of MDR. Manufactures, importers, distributors and device user facilities (hospital, LTC facility, ambulatory surgical facility, outpatient treatment facility and outpatient diagnostic facility, but not physician, dentist, chiropractor, optometrist, nurse practitioner, school-based clinic, employee health clinic or free-standing care unit) are required to complete Form 3500a (mandatory reporting) which is submitted by mail, fax, phone (ie. hardcopy) to MedWatch**.** Contractor, Logistics Applications, triages reports to MAUDE (medical devices) or AERS (drugs/biologics). For device reports, contractor alerts CDRH of high priority reports per set criteria, will assign patient/device/evaluation codes (kept in system in addition to user submitted codes), assigns product code ("procodes" indicating product class), QA's for missing data etc. Contractor is audited by FDA re: data quality. MAUDE also contains voluntary reports from consumers and health professionals received either on line, mail, fax, phone, processed by MedWatch and forwarded to Logistics Applications. Patient, device and evaluation codes not included in voluntary reports. Logistics Applications assigns patient and device codes.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	National, but can include devices manufactured in other countries
7. What is the unit of data entry (e.g., event, patient, product)?	The unit of entry is an adverse event associated with a medical device.

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
8. Who is allowed/required to input information?	Mandatory input Form 3500A - Manufactures, importers, and device user facilities (hospital, LTC facility, ambulatory surgical facility, outpatient treatment facility and outpatient diagnostic facility, but not physician, dentist, chiropractor, optometrist, nurse practitioner, school-based clinic, employee health clinic or free-standing care unit) are required to complete this form within certain time periods based upon the severity of the event. For example, user facilities are required to report a death related to a device both to the FDA and to the manufacturer within 10 days of the death. Manufacturers and importers are required to report adverse events "whenever they receive or otherwise become aware of information that reasonably suggests that a device has or may have caused or contributed to the death, serious illness, or serious injury of a patient in the facility" within 30 days of the event. This includes device malfunction and user error. JCAHO monitors compliance with MDR during site visits to user facilities. See Sheet 2 on this spreadsheet for a summary of device-related reporting requirements by group and severity of event. See http://www.fda.gov/cdrh/manual/mdrman.html for details on reporting requirements by manufacturers. See http://www.fda.gov/cdrh/mdruf.pdf for reporting requirements by user facilities.
9. What are the regulations/laws affecting reporting?	Section 519 of the Food and Drug Administration Modernization act of 1997 is the Statute that affects device reporting and discusses general rules of reporting by group 21 CFR Sec 803 Subpart A-F establishes the reporting requirements for medical device reporting. Says that user facilities, importers and manufacturers must report deaths and serious injuries and that distributors (defined in 803.3) must maintain records of incidents. Sec 803.21 discusses the Medwatch mandatory reporting coding manual with codes for hundreds of adverse events for use with Form 3500a.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	For FDA Device Reporting - FDA will disclose to a patient requesting a report, all information in the report concerning them, except for trade secret and confidential commercial information. FDA has promulgated a regulation [21 CFR §20.63(2)] that extends protection against disclosure of voluntary reports held by medical device, pharmaceutical, and biologics manufacturers by preempting state discovery laws. User facility name will not be released to the public under the FDA Modernization Act. FDA will also not release the identity of the patient or any information that can be used to identify the patient, such as the serial number of an implanted device. Nor will it release the name of any person other than the MDR contact. The name of the reporter and facility are deleted from disclosed data. Please note that the FDA is required under the Freedom of Information and Privacy Acts (SEC 552, Title 5, USC) (PL 93-579) to delete, prior to public disclosure, any information that constitutes trade secrets, and confidential, commercial, or financial information; and any personal, medical and similar information that would constitute a clearly unwarranted invasion of personal privacy. Included in the deletion requirements are all identification of the reporters and user facilities associated with the events.

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Submitted via paper - mail, fax, or phone Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002 301-827-0360 All submitted on Form 3500a 5-day Report - if action is being taken by the manufacturer 10-day Report - UF report medical device death or serious adverse event 30-day Report - Manufacturer Report Follow-up Report for manufacturers or user facilities - any time period
12. What are the methods of editing information (e.g. correcting/add more information to records)	The 3500a form allows follow-up information for device manufacturers. According to 21 CFR 803.56 - In supplemental reports, the manufacturer shall indicate on the form and the envelope that the reprint form is a supplemental report, provide appropriate id numbers of the report that will be updated with supplemental information (e.g. original mfr report number and user facility report number if applicable), and include only new or change information in the supplement. See item 46 for details on fields.
13. Where is the collected data stored (name of database, number of data storage locations)?	MAUDE - Obtain data structure info from FDA staff member - Jim Motz
14. How often is the system revised (annual, semi-annual etc)?	No scheduled revisions - based upon need
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	Federal register notice - public comments for changing reporting requirements. Revisions are made based upon discussions between FDA users and OSM staff.
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	No minimum. Form 3500A can be written out and mailed to FDA.
17. What new features are being planned and/or are on wish lists?	*Analysis modules that can use algorithms and data mining techniques to analyze data - replace ad hoc reporting requests from contractors for MAUDE. *Addition of Race field to better meet federal reporting requirements *MedSun pilot is project to allow electronic submission of device event reporting for selected user facilities *Scanning of reports to reduce paper storage. Would still require data entry by LAI staff.
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	No links to state systems. Older data is stored in MDR database. There is no system link, but there is a process link between LAI Data Acquisition for MAUDE and that of CMS-Medical Restraints. See template for CMS-Medical Restraints for more information.
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	(P)E.2 - Health professional. If you are not a health professional, write NA Yes No (N) E.3 - Occupation F-User Facility/Distributor info - Note distributor is no longer required to report (P) F.1 Type of Reporter (N) F.3 User facility or distributor name/address (N) F.4 Contact Person (N) F.5 Phone number G-Manufacturer info (N) G.1 - Contact Office (name/address and manufacturing site) (N) G.2 - Phone number (P) G.3 - Manufacturer Report source (check all that apply) - How the manufacturer [contact office] became aware of the reported adverse event or from where the information about the adverse event originated. Foreign - foreign country etc Study - study that involves a systematic collection of adverse events from a protocol Literature - If the report source is the scientific literature or an unpublished manuscript, a copy of the article or manuscript must be attached. Foreign language articles should be translated into English. Record the date of the article as the date of the event (block B3), and provide a full literature citation in block H10;Drugs and Biologics: A separate 3500A form must be completed for each identifiable patient described in the article or manuscript. Consumer - recommend help of care provider; Health professional Company rep User facility - User facility should be checked if the manufacturer received the report from the MDR contact in a user facility as identified in section F. Distributor Other - Any source not covered by the previous categories.
20. Is participation mandatory or voluntary?	Mandatory for user facilities, manufacturers, and importers. User facilities must report deaths to both FDA and manufacturer and serious injuries to manufacturer or to FDA if manufacturer unknown. See questions 8 and 9. Also note that JCAHO measures User Facility compliance with reporting. Voluntary (via MedWatch direct reporting) for health care professionals and consumers.
21. List fields related to contributor/participant contact information	(N)E.1 - Reporter Address and Phone #
22. List fields related to facility contact information (include type of facility, teaching status, id information)	(N) F.3 User facility or distributor address (N) F.5 Contact Person Phone number- This is the person designated by the facility's most responsible person as the device user facility/distributor (importer) contact for this requirement. FDA will conduct its MDR correspondence with this individual. The contact person may or may not be an employee of the facility. However, the facility and its responsible officials will remain the parties ultimately responsible for compliance with the MDR requirements

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
23. List fields related to distributor contact information	See Item 22
24. List fields related to manufacturer contact information	G. Manufacturers -- (N) G.1 - Contact Office (name/address and manufacturing site) (N) G.2 - Phone number (N) F.14 - Manufacturer Name/Address - full name and address of the device manufacturer, if available Manufacturer Report Number
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
25. List fields related to Provider of Care identification	(P) D.4 Operator of Device - Indicate the type (NOT the name) of person operating or using the suspect medical device on the patient at the time of the event as follows health professional lay person other
26. List fields that identify types of care providers included in system	Some of this could be in event description and some could be in lab and diagnostic test information. See item 25
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	(N)A.1 - Identifier - patient's initials or some other type of information that will allow you, the reporter to readily locate the case if you are contacted for more information. Do not use patient's name or SSN. Report has ID # assigned to it. (N) D.6 - Product Identification No. - Serial # of device - removed as part of de-identification because it is specific to a particular device and can be tracked back to a patient
28. List fields related to patient contact information (e.g. address, zip code, county, region)	N/A
29. List fields related to patient demographics (e.g. age, sex, race)	(N)A.2 - Age at time of event OR Date of Birth - provide the most precise information available. For age, indicate time units (3 years+-use years, less than 3 years old, use months; less than 1 month old, use days) (P)A.3 - Sex (if congenital anomaly, report sex of the child) Female Male (N)A.4 - Weight (in lbs OR kg) **Race could be included by reporter in medical history of patient, but not a separate field (see question 31)
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	D.6 Serial# and patient initials or other reporter assigned ID are entered in database but removed during de-identification

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
31. List fields related to pre-existing conditions and/or medical history of patient	(N) Medical Devices - D.10 - Concomitant medical products and therapy dates (exclude tx of event) List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at or around the time of the event. DO NOT include products used to treat the event. (N)B.7 - Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (P)Categories for race: Am. Indian – Alaska Native= American Indian or Alaska Native Asian= Asian Continent to include Indian Subcontinent Native Hawaiian or other Pacific Islander= Native Hawaiian or other Pacific Islander Black= Black, not of Hispanic origin Hispanic= Hispanic White= White, not of Hispanic origin
32. List fields that capture the clinical condition of patient at time of event	Some of this could be entered in B.5 - adverse event description (N) B.7 - Other relevant history, including preexisting medical conditions: (N) D.10 - Concomitant medical products and therapy dates - product names and therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that the patient was using at the time of the event. DO NOT include products used to treat the event.
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	N/A
34. List any other types of information collected about the patient	(P) B.2 - Outcome attributed to adverse event death (date in fixed format) life-threatening hospitalization - initial or prolonged disability congenital anomaly required intervention to prevent permanent impairment/damage other (narrative description)

Reporting or Database System:	FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Medical Devices including in vitro diagnostics (P) H.1 - Type of reportable events Death: Check ONLY if the death was an OUTCOME of the adverse event Serious injury: An adverse event that is life-threatening; results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure Malfunction: See the guidelines. ("See the guidelines" refers to the applicable sections in 21 CFR Part 803 reporting guidelines Other: This option is intended to capture reports that the manufacturer believes the agency should be aware of that are not covered by death, serious injury, or malfunction as these terms are defined by the statute, regulation, or guidelines. Use rarely. (P) B.2 Outcomes attributed to adverse event: Indicate ALL that apply to the reported event: death (date in fixed format) life-threatening hospitalization - initial or prolonged disability congenital anomaly required intervention to prevent permanent impairment/damage other (narrative description)
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	N/A
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	(N) B.5 - Describe event or problem Description of details of the event, summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, synopses of any office visit notes or the hospital discharge summary. Copies of relevant info with any confidential information deleted. If reuse of a medical device labeled for single use may have caused or contributed to an adverse patient outcome, report the facts of the incident in B5 and the perceived contribution of reuse to the occurrence. For a product problem: Description of the problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. If available, the results of any evaluation of a malfunctioning device and, if known, any relevant maintenance/service information should be included in this section (S-Brand name - D.1 - Brand Name. The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog (N)D.2 - Type of Device. The generic or common name of the suspect medical device or a generally descriptive name (e.g., urological catheter, heart pacemaker, patient restraint, etc.).DO NOT use broad generic terms such as "catheter", "valve", "screw", etc. (N)D.3 - Manufacturer name and address (N)F.14 - Manufacturer name/address [user facility/distributor only] (P)D.4 - Operator of Device. Indicate the type (NOT the name) of person

Reporting or Database System:	FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices
	Health professional = physician, nurse, respiratory therapist, etc., Lay user/patient = person being treated, parent/spouse/friend of the patient, Other = nurses' aide, orderly, etc. (FF)D.5 - Expiration date (mo/day/yy) D.6 - Product Identification Information (S)Model # Found on the device label or accompanying packaging (S)Catalog# Exact number as it appears in the manufacturer's catalog, device labeling, or packaging. (S)Serial # Found on the device label or accompanying packaging; it is assigned by the manufacturer (S)Lot# This number can be found on the label or packaging material. (S)Other# Any other applicable identification number (N)D.7 - Implant date (if any) For medical devices that are implanted in the patient, provide the implant date. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable D.8 - If explanted, give date: If an implanted device was removed from the patient, provide the explant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable (P)H.8 - Usage of device - If reused, the appropriate manufacturer Result codes for reuse are also to be entered into H6. Initial use of device Reuse Unknown (P) D.9 - Device available for evaluation yes, no, returned to manufacturer on date (FF) G.5 - (S-NDA) (A)NDA#, (S-IND)IND # (FF)PLA# (P) Pre-1938? - yes (P) OTC product? – yes G.6 - If IND, then (N)protocol#, (FF)H.4 - Device manufacture date (mm/day/yy) (P)H.5 - Labeled for single use? Yes No(N) F.9 - Approximate age of device
38. List fields associated with vaccine related events	N/A
39. List fields associated with infection related events	(N) B.5 - Describe event or problem (N) B.6 - Relevant tests/laboratory data, including dates Include: relevant negative test and laboratory findings, in order to most completely convey how the medical work-up/ assessment led to strong consideration of medical product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated; relevant baseline laboratory data prior to the administration or use of the medical product; laboratory data used in diagnosing the event; available laboratory data/engineering analyses (for devices) that provide further information on the course of the event If available, include: any pre- and post-event medication levels and dates (if applicable);synopses of any relevant autopsy, pathology, engineering, or lab reports.

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
40. List fields associated with any other type of event. List type of event.	N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	(P) B.1 - Classification Adverse Event Product Problem (defects/malfunctions) (N) B.5 - Describe event or problem (P) F.10 - Event problem codes (see http://www.fda.gov/cdrh/mdr/appendixc.pdf - Note: UF is supposed to complete. Mfr fills in if missing.) Patient codes - describe what happened to the patient as a result of the event - approximately 1600 codes (device and patient mixed) Device codes - device problems or failures encountered during the event (S-MedDRA, WHOART or custom) G.8 - Adverse event term(s) - Include a list of adverse event terms that most accurately characterize the adverse event described in narrative format in block B5. Terms should be listed with the most important term(s) first. The terminology may be an accepted standard(e.g., MedDRA or WHOART), a verbatim term, or the manufacturer's own terms. No preference for MedDRA
42. List fields associated with when the event occurred	(FF) B.3 - Date of event (mo/day/yr) - Provide the actual or best estimate of the date of first onset of the adverse event. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable. When a newborn baby is found to have a congenital anomaly, the event onset date is the date of birth of the child. When a fetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date pregnancy is terminated. If information is available as to time during pregnancy when exposure occurred, indicate that information in narrative block B5.
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	(FF) B.3 - Date of event(FF) B.4 - Date of this report (initial reporter)(FF) F.6 - Date user facility or distributor became aware of event(FF) F.8 - Date of this report (User/Distributor)(FF) G.4 - Date received by manufacturer (manufacturer)(P) G.7 - Type of report5-day10-day15-dayinitial - Check if the report is the first submission of a manufacturer report. For devices, this is the 30-day report periodicfollow-up, enter number of original report. (see Question 46) Initial:
44. List fields associated with where the event occurred	(P) F.12 - Location where event occurred Hospital Home Nursing Home Outpatient treatment facility Outpatient diagnostic facility Ambulatory surgical facility Other_____

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	B.5 - Describe event or problem (N)B.6 - Relevant tests/laboratory data (with dates) Include: relevant negative test and laboratory findings, in order to most completely convey how the medical work-up/ assessment led to strong consideration of medical product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated; relevant baseline laboratory data prior to the administration or use of the medical product; laboratory data used in diagnosing the event; available laboratory data/engineering analyses (for devices) that provide further information on the course of the event If available, include: any pre- and post-event medication levels and dates (if applicable);synopses of any relevant autopsy, pathology, engineering, or lab reports.
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	(P)E.4 - Initial reporter also sent report to FDA? Yes, No, unknown (P) F.7 Type of report - one of the choices is for follow-up with number [User facility/distributor only] (P) G.7 Type of report - one of the choices is for follow-up with number [manufacturer only] Follow-up: Check if the report is a follow-up to a previously submitted report. Provide additional or corrected information on the previously reported event. Follow-up reports on drugs and biologics should contain information that was submitted in the original report if the information is still correct. (P)H.2 - If follow-up, what type? [manufacturer only] Correction: Changes to previously submitted information. Additional information: Information not know when the original report was submitted Response to FDA request: Additional information requested by FDA concerning the device/event Device evaluation: analysis of event (P) D.9 - Device available for evaluation? Indicate if the device was returned to the manufacturer and, if so, the date of the return. DO NOT send the device to FDA. Yes, No Returned to manufacturer on _____ (mm/day/yr) (P) H.3 - Device evaluated by mfr? Not returned to mfr Evaluation summary attached No (attach page to explain or supply code from instructions) (S-FDA Evaluation Codes for Manufacturers) H.6 - Evaluation codes (4 codes per subtype -- see http://www.fda.gov/cdrh/mdrcode.pdf for list of codes - approx 50 codes) Enter the applicable codes from the codes manual for one or more of the categories listed. Conclusion codes must be entered even if the device was not evaluated. If the reuse of a device may have caused or contributed to the adverse event, then the appropriate manufacturer Result codes are to be entered from the codes manual. Applicable reuse codes are 230-233 and may be used alone or with any other applicable results codes. (see H8). Method - Enter Source of evaluated device, type of evaluation performed (4 codes)

Reporting or Database System:	FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices
	Results - Enter type of result code (see www.fda.gov/cdrh/mdr/appendixd.pdf - approx 350 codes) Conclusions - Enter conclusions code (approx 20 codes)
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event) cont'd	(P)H.7 - If remedial action initiated, check type Recall Repair Replace Relabeling Notification Inspection Patient monitoring Modification/adjustment OtherIndicate the applicable action(s). If other, specify the type of action in the space provided. Most of these terms are defined or further explained in the Act or in the FDA regulations concerning remedial action (see 21 USC 360h and 21 CFR Parts 7, 803 and 806). (FF)H.9 - If action reported to FDA under 21 USC 360I(f), list correction/removal reporting number - If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number: Enter the number that FDA assigned to the corrective action. If a number has not yet been assigned by FDA, the number assigned by the firm for the action may be used. (P)H.10 - Additional manufacturer narrative OR Corrected data: Provide the following additional, corrected, or missing information, identifying each data item by the applicable section and block number: (1) Any information missing on the user facility or distributor (importer) report, including any missing or incomplete event codes required by block F10 (2) Information corrected on the user facility or distributor (importer) report form after verification, including any corrected event codes required by section D (e.g., D6: model number) (3) For each event provided in block F10, an indication of whether the type of event represented by the code is addressed in the device labeling, and (4) An explanation of why any required information was not provided and the steps taken to obtain such information. (P) F.11 Report sent to FDA? Yes, No, Date [To track duplicate reports in the FDA database](P) F.13 Report sent to manufacturer? Yes, No, Date(FF)F.2 - UF/Dist Report number (Filled in by UF/Dist) Enter the complete number of the report exactly as entered in the upper right corner of the front page. For a follow-up report, the UF/Distributor (Importer) report number must be identical to the number assigned to the initial rpt
47. List fields related to the outcome of event (patient)	(P) B.2 - Outcome attributed to adverse event death (date in fixed format) life-threatening hospitalization - initial or prolonged disability congenital anomaly required intervention to prevent permanent impairment/damage other (narrative description) (N) B.5 - Describe event or problem (N) B.6 - Relevant tests/laboratory data, including dates (S) F.10 - Event problem codes (refer to coding manual) patient code device code (S) H.6 - Evaluation codes (refer to coding manual) methods results conclusions

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, investigations etc)	Autopsy reports are sometimes sent to MAUDE, forwarded to analysts to look at when reviewing a certain medical device event.
H. Implications	
49. Integration with other systems	Baseline reports are submitted on Form 3417 when the device model is first reported in an event. Each baseline report should be updated annually. There was discussion at the meeting that baseline reporting information was intended to be used to link records from the various systems, but does not work as well as expected. May be point of further discussion with technical group. MAUDE uses an algorithm looking at UF and manufacturer information and date of event to try to identify multiple reporting of same event. Importance of the system is for detecting signals - provides an effective way to start an entire risk management analysis process which may or may not end up in a recall, MedWatch alert etc.
50. Methods used to de-identify data	The name of the reporter and facility are deleted from disclosed data before release of the report. In addition, an automated process is used to delete the following fields and any proper names in narrative fields (this often must be done manually by an analyst). Double checked by an analyst:A.1 - Patient identifier A.2 - Age at time of event or Date of birth A.3 - Sex A.4 - WeightB.6 - Relevant tests/laboratory data, including dates B.7 - Other relevant history, including preexisting medical conditionsD.7 - If implanted, give date D.8 - If explanted, give date E.1 - Name, address & phone # E.3 - Occupation F.2 - UF/Dist/Importer report number F.3 - User facility or distributor/Importer name & address F.4 - Contact person F.5 - Phone Number F.10 - Event problem codes H.6 - Evaluation codes
51. Technical Information	
Part II. Data Structure & Storage:	
I. Facility / Location	
52. Address of data storage facility	2098 Gaither Road Rockville, MD 20850
53. What type of facility is used to store data (3rd party data center, secured computer room, someone's cubicle)?	Secured Computer Room
54. What is the network interconnect for physically distributed systems?	Multimode fiber cable connects the server and the switch.
55. What type (private lines, VPN, Internet) of network interconnect is used?	The server is behind the firewall. Users from home can dial-up directly into the network or VPN through their ISP.
56. What is the network protocol (TCP/IP, IPX, etc.)?	TCP/IP
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)	FDDI (100Mbps) connection to the server

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
58. What is the network (WAN) topology, including diagram if available	Two FDDI rings (each can transfer100Mbps). Dual Fast Ethernet connections to the NCC of the FDA.
59. Who designed the system? Who operates the system?	
J. Data Storage System / Server	
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	Compaq
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	AlphaServer 4100
62. What is the number / speed (Mhz) of processors?	4/600
63. How much memory is available (Gb)?	gb 4
64. What is the disk - manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	Compaq StorageWorks 610GB net RAID
65. What is the operating system (e.g. Sun Solaris 2.6.1)	OpenVMS 7.2-1
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	Oracle RDBMS Oracle Forms SQR ReportWriter
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	C/VB
68. Which categories best describe this system?	
- Is there an Operational Data Store?	Yes
- Is there an all-encompassing data warehouse versus focused data mart(s)?	No
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design	No
Is Decision Support Normalized?	Yes
- Is there a Dimensional Data Warehouse utilizing a star schema design	No
- Is there a statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	No

Reporting or Database System:	**FDA-CDRH: MAUDE – Manufacture and User Data Experience-Medical Devices**
- Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	No
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	No
- Are there other structured data formats, such as XML, HTML, or other?	No
69. How is data structured?	
- Is there an event occurrence (EO) table with one row per event?	
- Is there a person table with one row per person, linked to events by PERSONID?	
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	
70. How much disk space is currently allocated to the system?	10.5 gb
71. How much disk space is available on this system?	6.1 gb
L. For Each Major Data Structure	
72. What is the width of the table / file / subject data area (bytes)?	Approximately 4-3000
73. How many data elements (approximate) in the table / file / subject data area?	Approximately 1-50
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	N/A
75. What is the approximate number of rows in the table, or observations?	Approximately 224
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	

Reporting or Database System:	**FDA-CDRH: MAUDE –Manufacture and User Data Experience-Medical Devices**
Part III. Data Use & Analysis:	
78. System Contact	Pat Kingsley (Division of Post-Market Surveillance), Howard Press (Division of Surveillance Systems), Suzanne Rich (Division of Post-Market Surveillance)
79. Contact Address	1350 Piccard Drive, Rockville, MD, 20850
80. Contact Phone	PK: 301-594-2784, HP: 301-827-2983 SR: 301-594-2581
81. Contact Email	PK: pak@cdrh.fda.gov HP: hap@cdrh.fda.gov
82. Hardware Platform	VAX Cluster
83. Operating System	
84. Who is the developer?	CDRH
85. Who is responsible for the system architecture?	Relational database
86. User Types	CDRH Clinical Specialists
87. What is the frequency of reports?	As needed to investigate specific adverse event reports.
88. Who generates the report?	MAUDE Users
89. What is the method of access?	MAUDE software
90. What is the turnaround time?	Real time
91. What is the level of automation?	N/A – through MAUDE software
92. Type Of Reports	Two main components: workload module, query/reporting function. Workload module allows analysts to schedule and track follow up on specific adverse event reports. No structured, regular summary reports from MAUDE. Semi-structured query facility used to investigate specific issues. Focus is on individual event reports. MAUDE query functions facilitate look up of reports on same manufacturer, device, device-type, event code. Can print standardized report from query function. Ad hoc querying/reporting also available. Statistical reporting more difficult in MAUDE since there is less consistency between reports than in ASR. Frequency counts and basic cross-tabulations are available. MAUDE data also available to other internal FDA users through APPS (gateway to several FDA databases). Read only. Summary and individual report information available (standardized) as well as query function. Series of data files available on web containing FOI releasable data (see notes for details) for all voluntary reports since June, 1993, user facility reports since 1991, distributor reports since 1993 and manufacturer reports since Aug. 1996. Note that patient, device and evaluation codes are not included in data sets. Also contains base data re: manufacturer and device characteristics. Separate files available containing device data, patient data and text data (linked through a MDR REPORT KEY). Data updates also available separately. Files covering different time periods (eg. 2001, current quarter etc.) also available. FDA does not receive information re: nature of use of data sets by outside parties. No persons outside FDA has access to non-FOI releasable data, however, can be requested (e.g., CDC did request data).
93. What is the unit of observation?	Individual medical device-related event reported on Form 3500 (voluntary) and 3500a (mandatory). EVENT KEY links reports from multiple reporters for the same event.

Reporting or Database System:	**FDA-CDRH: MAUDE –Manufacture and User Data Experience-Medical Devices**
94. What are the available data fields?	Key fields are patient codes (describing effect on patient), device codes (describing nature of failure/event) and three evaluation codes (method, results, conclusions – describing evaluation of problem by manufacturer). User facility submitted reports may not contain evaluation codes. Manufacturer submitted reports may not contain patient and/or device codes. Two main sets of data: complete data set available internally within FDA, and FOI releasable data elements.
95. Is there a controlled vocabulary?	Yes, lists updated regularly for patient, device, evaluation and product codes by CDRH
96. Exportability	Yes. Facility provide through MAUDE software. Frequently done to further define a specific problem and its impacts. Primarily exporting to Excel.
97. User Profile	FDA - Division of Post-Market Surveillance. Division of Surveillance Systems. Office of Device Evaluation, Office of Compliance, Office of Science and Technology and Office of Health Industry Programs. No ongoing users outside FDA of non-FOI data. Others (e.g., CDC) may request data.
98. How are the reports used?	Clinical specialists review reports and generally either 1) monitor 2) follow up with firm (i.e., requesting additional information for an emerging problem) or send investigator (last resort). Urgent reports, per established criteria, followed up immediately. FDA analysts use MAUDE query capabilities to investigate individual reports (ie. search MAUDE history by type of device, exact device, similar problems with similar devices from other manufacturers, problems with devices from same manufacturer, problems within specific populations groups etc.). Each analyst determines how best to conduct follow up analysis. This may involve use of other databases. Can access pre-market approval/application information through APPS (510k and PMA), which includes design changes. If report is of sufficient concern, investigator may be asked to follow up. FACTS system contains information regarding the activities of the regional offices of the Office of Compliance. Recalls initiated by Office of Compliance and tracked in a separate system. Recalls assigned Class 1, 2 or 3. May also ask Epidemiology Branch to conduct a broader analysis. Epidemiology Branch can also initiate its own analysis regarding specific devices/problems and provide consultative services to pre-market group (eg. Examining use of device within “non-perfect” populations). Epidemiology Branch may access other databases to conduct specific analyses. Evaluation Codes (one each for Methods, Results, Conclusions) indicate the follow up undertaken by manufacturer. FDA actions can be of many forms including labeling modification, recall, re-engineering of product. Manufacturers often take action of their own accord. Office of Device Evaluation (pre-market assessment), Office of Compliance (focus at manufacturer level re: ensuring compliance to FDA reporting requirements), Office of Science and Technology (conducting technical research) and Office of Health Industry Programs access MAUDE data through APPS.
99. Report Dissemination	FDA analysts use reporting capabilities to investigate adverse event reports. Special statistical analyses prepared for management on ad hoc basis.
100. What is the primary goal?	Detecting/assessing emerging medical device problems and initiating appropriate action within scope of FDA authority.

Reporting or Database System:	**FDA-CDRH: MAUDE –Manufacture and User Data Experience-Medical Devices**
101. Integration/Linkable to Detail/Overlap	MAUDE uses an algorithm looking at UF and manufacturer information and date of event to try to identify multiple reporting of same event. Only information in MAUDE is from 3500 and 3500a reports. Reports received related to medical restraints that are medical devices are entered into MAUDE and then forwarded to CMS. CMS does not use MAUDE database. FDA staff do not access CMS Medical Restraint database. Facilities reporting to MedSuN may previously have reported to MAUDE. Manufacturers still required to report to MAUDE (through MedWatch). Therefore, if a manufacturer becomes aware of an adverse event within a MedSuN participating facility, it is possible that a report of the same adverse event would be made to MAUDE by the manufacturer and MedSuN by the facility. Epidemiology Branch of Division of Post-Market Surveillance purchases access to other databases to conduct research (eg. Society of Thoracic Surgeons database of complications). May use CMS database.
102. HIPAA Compliant	No direct patient identifiers, may contain services dates and DOB
Future	Analysis modules that can use algorithms and data mining techniques to analyze data - replace ad hoc reporting requests from contractors for MAUDE.
Notes	Baseline reports are submitted on Form 3417 when the device model is first reported in an event. Each baseline report should be updated annually.
	FDA in process of integrating its recall systems.
	Approx. 53,000 total non-ASR reports received of which 48,000 from manufacturers, 2,000 from user facilities, 3,000 voluntary reports
	Desired Information: Denominator information (I.e., number of a specific device in use)
	Only mandatory for User Facilities to report deaths to FDA. MAUDE does not get User Facility injury reports directly.
	Patient and event codes generally completed by User Facility, evaluation codes by manufacturer. Reports from manufacturer may not contain patient and/or event codes (I.e., if manufacturer doesn't know what patient impact was). Similarly, User Facility reports may not contain evaluation codes (identifying manufacturer methods/results/conclusions.

MDS

Reporting or Database System:	**Minimum Data Set (MDS)**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	
2. Internet Location: http://	http://www.hcfa.gov/medicaid/oasis/oasishmp.htm
3. Host Organization(s)	Centers for Medicare & Medicaid Services (CMS)
4. Primary contact information (e.g. Address, Phone)	Dennis Stricker (410) 786-2031 DStricker@cms.hhs.gov John Williams JWilliams2@cms.hhs.gov
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The minimum data set (MDS) is a uniform set of elements extracted from the resident assessment instrument, or RAI. The MDS is designed to collect data about an individual nursing home resident which will ultimately lead to a comprehensive, outcome-oriented care plan for that resident; it consists of specific questions about a resident in several areas. The questions cover factors that place a resident at risk for an adverse outcome. MDS information is transmitted electronically by nursing homes to the MDS database in their respective states. MDS information from the state databases is captured into the national MDS database at CMS.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	national
7. What is the unit of data entry (e.g., event, patient, product)?	patient
8. Who is allowed/required to input information?	Nursing home staff member
9. What are the regulations/laws affecting reporting?	
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	NO
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Mail or electronic form
12. What are the methods of editing information (e.g. correcting/add more information to records)	Correction Request Form
13. Where is the collected data stored (name of database, number of data storage locations)?	CMS Data Center

Reporting or Database System:	Minimum Data Set (MDS)
14. How often is the system revised (annual, semi-annual etc)?	
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	
17. What new features are being planned and/or are on wish lists?	
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	Authorized Nursing Home Staff Member
20. Is participation mandatory or voluntary?	mandatory
21. List fields related to contributor/participant contact information	
22. List fields related to facility contact information(include type of facility, teaching status, id information)	(S) Facility Provider Numbers – State and Federal
23. List fields related to distributor contact information	
24. List fields related to manufacturer contact information	
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
25. List fields related to Provider of Care identification	(N) Signature and Title of Nursing Home Staff Member
26. List fields that identify types of care providers included in system	

Reporting or Database System:	Minimum Data Set (MDS)
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	(N) Resident Name (N) Social Security Number and Medicare Number (N) Medicaid Number
28. List fields related to patient contact information (e.g. address, zip code, county, region)	(N) Resident Name (N) Room number (N) Zip Code of Prior Primary Residence
29. List fields related to patient demographics (e.g. age, sex, race)	(N) Gender (N) Birthdate (N) Race/Ethnicity
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)?	All identification
31. List fields related to pre-existing conditions and/or medical history of patient	(P) Reasons for Assessment (P) Continence in Last 14 Days (P) Special Treatments and Procedures
32. List fields that capture the clinical condition of patient at time of event	(P) Cognitive Patterns (P) Communication / Hearing Patterns (P) Vision Patterns (P) Mood and Behavior Patterns (P) Psychosocial well-being (P) Physical Functioning and Structural Patterns (P) Disease Diagnoses (P) Health Conditions (P) Oral/Nutritional Status (P) Oral/Dental Status (P) Skin Condition (P) Activity Pursuit Patterns (P) Medications (P) Discharge Potential and Overall Status
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	(P) Current Payment Sources for Nursing Home Stay (N) Assessment Reference Date (N) Date of Reentry
34. List any other types of information collected about the patient	(P) Responsibility/Legal Guardian
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Pick list items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	

Reporting or Database System:	Minimum Data Set (MDS)
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer)	
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer) cont'd	(N) List of all Medications given (name and dose, route of administration, frequency, amount administered, PRN, NDC Code)
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	(P) Special Treatments and Procedures – Devices and Restraints
38. List fields associated with vaccine related events.	N/A
39. List fields associated with infection related events.	(P) Disease Diagnoses - Infections
40. List fields associated with any other type of event. List type of event.	(P) Disease Diagnoses 1. Endocrine/Metabolic/Nutritional 2. Heart/Circulation 3. Musculoskeletal 4. Neurological 5. Psychiatric/Mood 6. Pulmonary 7. Sensory 8. Other (Allergies, Anemia, Cancer, Renal Failure)
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	
42. List fields associated with when the event occurred	
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	
44. List fields associated with where the event occurred	
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	
46. List fields related to follow-up of event that are not associated with a particular patient(medication/manufacturing/policy actions to correct/update event)	

Reporting or Database System:	Minimum Data Set (MDS)
47. List fields related to the outcome of event	
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, results of investigations etc)	
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	
51. Technical Information	
Part II. Data Structure & Storage:	
I. Facility/Location	
52. What is the address of the data storage facility?	CMS Data Center 7500 Security Boulevard Baltimore, Maryland 21244-1850. CMS contractors and agents at various locations.
53. What type of facility is used to store the data (3rd party data center, secured computer room, someone's cubicle)?	CMS Data Center
54. What is the network interconnect for physically distributed systems?	CMS Wide Area Network
55. What type (private lines, VPN, Internet) of network interconnect is used?	VPN
56. What is the network protocol (TCP/IP, IPX, etc.)?	TCP/IP
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)?	
58. What is the network (WAN) topology, including diagram if available?	
59. Who designed the system? Who operates the system?	
J. Data Storage System/ Server	
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	IBM

Reporting or Database System:	Minimum Data Set (MDS)
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	SP - RS/6000 RISC
62. What is the number/speed (Mhz) of processors?	4 processors; 375 MHz
63. How much memory is available (Gb)?	Shared 4 Gb
64. What is the disk - Manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	EMC – SAN approximately 1 terabyte for the MDS/HHA project
65. What is the operating System (e.g. Sun Solaris 2.6.1)?	IBM AIX 4.3.3 ptf set 9
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	RAVEN (Resident Assessment Validation and Entry System Software)
68. Which categories best describe this system?	
- Is there an operational Data store?	
- Is there an all-encompassing data warehouse versus focused data mart(s)?	
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	
- Is there a data warehouse utilizing a normalized relational database design?	
- Is there a Dimensional Data Warehouse utilizing a star schema design?	
- Is there a statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	Yes
- Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	
- Are there other structured data formats, such as XML, HTML, or other?	

Reporting or Database System:	Minimum Data Set (MDS)
69. How is the data structured?	
- Is there an event occurrence (EO) table with one row per event?	
- Is there a person table with one row per person, linked to events by PERSONID?	Yes
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	
70. How much disk space is currently allocated to the system?	
71. How much disk space is available on this system?	
L. Major Data Structure	
72. What is the width of the table/file/subject data area (bytes)?	1814 bytes when converted to character as per the input data specifications
73. How many data elements (approximate) in the table / file / subject data area?	Approximately 750 data elements
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	
75. What is the approximate number of rows in the table, or observations?	Approximately 53 million assessments
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	Assessments are submitted at the approximate rate of 1.5+ million per month
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	The intent is to maintain 5 years of data

Medical Restraints

Reporting or Database System:	**Medical Restraints (CMS)**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	
2. Internet Location: http://	http://www.fda.gov/medwatch/ http://www.hcfa.gov/quality/11c.htm
3. Host Organization(s)	Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration
4. Primary contact information (e.g. Address, Phone)	David Eddinger, (410) 786-3429 Fax (410) 786-3517 deddinger@cms.hhs.gov Anna Gibson (410) 786-3505 agibson1@cms.hhs.gov - Division of Lab and Acute Care Services Joan Todd (FDA), (301) 594-3174
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	This program was started as part of the FDA-led Hospital Bed Safety Work Group initiatives and to meet the Medicare requirement that institutions must report incidents of harm to patients involving the use of physical and other restraints as a condition of participation in the program. Rather than CMS creating a new event reporting form and process, the FDA offered to accept physical restraint event reports from hospitals/health care facilities via the FDA Mandatory MedWatch Form 3500a. The FDA sends the received reports to CMS for input into their death reporting log. According to CMS flow chart - when a report is only for CMS, FDA will forward the original report. When a report is for both FDA and CMS, FDA will send a copy of the report to CMS. In addition to forwarding reports from facilities, the FDA has agreed to run reports regarding bed rail deaths/serious injuries from FDA data.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	National
7. What is the unit of data entry (e.g., event, patient, product)?	Physical Restraint - related adverse event. CMS definition - "physical restraints under Interpretive Guidance in the State Operations Manual as: "any manual method or physical or mechanical device, material, or equipment attached or adjacent to the individual's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body." FDA's definition - "a device, including but not limited to a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others"

Reporting or Database System:	Medical Restraints (CMS)
8. Who is allowed/required to input information?	The hospital must report by phone to CMS regional office (by the following business day) any death that occurs while a patient is restrained or in seclusion or where it is reasonable to assume that a patient's death is a result of such an intervention. The hospital is also required to send in a Form 3500A to FDA as backup paperwork to the original report via phone. The hospital send the form to CMS and marks the report with CMS at the top of the form as well as on the envelope and sends to the FDA address given below. LAI staff identify the CMS forms, fax them to CMS, and keep a log of all CMS reports received. Each month, FDA compares the log with the items received at CMS, then the original forms are destroyed.
9. What are the regulations/laws affecting reporting?	The Centers for Medicare and Medicaid Services issued guidelines interpreting the agency's patient rights conditions of participation for hospitals that participated in Medicare and Medicaid which was published as an interim final rule on July 2, 1999. 42 C.F.R.ß 482.13(F). FDA: 21 CFR Section 803 - gives reporting requirements for FDA
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	According to guidelines, CMS will accept anonymous reporting of this information, but the hospital has to report so they are not anonymous. Then it will be investigated (survey) by CMS staff onsite and a report is written and they have to respond within 60 days. For FDA Device Reporting - FDA will disclose to a patient requesting a report, all information in the report concerning them, except for trade secret and confidential commercial information. FDA has promulgated a regulation [21 CFR §20.63(2)] that extends protection against disclosure of voluntary reports held by medical device, pharmaceutical, and biologics manufacturers by preempting state discovery laws. User facility name will not be released to the public under The Federal Food Drug and Cosmetic Act. FDA will also not release the identity of the patient or any information that can be used to identify the patient, such as the serial number of an implanted device. Nor will it release the name of any person other than the MDR contact. The name of the reporter and facility are deleted from disclosed data. Please note that the FDA is required under the Freedom of Information and Privacy Acts (SEC 552, Title 5, USC) (PL 93-579) to delete, prior to public disclosure, any information that constitutes trade secrets, and confidential, commercial, or financial information, and any personal, medical and similar information that would constitute a clearly unwarranted invasion of personal privacy. Included in the deletion requirements are all identification of the reporters and user facilities associated with the events.

Reporting or Database System:	Medical Restraints (CMS)
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Submitted via paper - mail, fax, or phone Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002 301-827-0360 CMS instructs users to mark the front of the envelope with 'User Report-CMS' to indicate that this should be sent to CMS. FDA contract staff have also been trained to search for words such as physical restraint, confinement etc and to pull those reports as potential CMS reports. Reporting started in Summer 2001 - not much reporting of this information so far. Hospitals are required to send in the form by close of business the next day following the death. They are to report the death by phone to their CMS Regional office during the same time period. According to instructions - if user enter to CMS do not have to submit an additional report to FDA
12. What are the methods of editing information (e.g. correcting/add more information to records)	The 3500A form allows follow-up information by checking a box on the form (See item 46)
13. Where is the collected data stored (name of database, number of data storage locations)?	Restraint seclusion death log which is maintained at CMS - Baltimore Centers for Medicare and Medicaid Services Survey and Certification Group 7500 Security Blvd. S2-12-25 Baltimore, MD 21244-1850 Attn: Anna Gibson
14. How often is the system revised (annual, semi-annual etc)?	System originated 4/01. No steps to revise. No database involved.
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	N/A
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	No minimum. Form 3500A can be filled out and mailed to FDA.
17. What new features are being planned and/or are on wish lists?	None at this time.
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	No. LAI staff at FDA (under Office of Surveillance and Biometrics) pull out 'suspected' CMS reports based upon markings on envelope or keywords in the narrative of the event report - e.g. physical restraint. These reports are faxed to CMS, not entered into MAUDE. It is possible that MAUDE will receive reports on the same event, but would typically come from Manufacturer.
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	Hospitals reporting to meet condition of participation requirements for Medicare. See item 9.
20. Is participation mandatory or voluntary?	Mandatory

Reporting or Database System:	Medical Restraints (CMS)
21. List fields related to contributor/participant contact information	
22. List fields related to facility contact information (include type of facility, teaching status, id information)	(N)E.1 - Reporter Name, Address and Phone # - filled out by person completing the form (P)E.2 - Health professional. If you are not a health professional, write NA Yes No (N) E.3 - Occupation F. User Facility (Hospital) - devices only If a restraint device was cause/suspected cause of death, or could be associated with the death, or was in place at time of death, then F should be completed. (P) F.1 Type of Reporter User facility - Check this Distributor (N) F.3 User facility or distributor name/address (N) F.4 Contact Person (N) F.5 Phone number
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact information	N/A
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
25. List fields related to Provider of Care identification	N/A
26. List fields that identify types of care providers included in system	Some of this could be in event description and some could be in lab and diagnostic test information.
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	(N)A.1 - Identifier - patient's initials or some other type of information that will allow you, the reporter to readily locate the case if you are contacted for more information. Do not use patient's name or SSN.
28. List fields related to patient contact information (e.g. address, zip code, county, region)	N/A
29. List fields related to patient demographics (e.g. age, sex, race)	(N)A.2 - Age at time of event OR Date of Birth - provide the most precise information available. For age, indicate time units (3 years+-use years, less than 3 years old, use months; less than 1 month old, use days) (P)A.3 - Sex (if congenital anomaly, report sex of the child) Female Male (N)A.4 - Weight (in lbs OR kg) **Race could be included by reporter in medical history of patient, but not a separate field (see question 31)
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	No traceable data - patient initials or other reporter assigned ID are entered in database.

Reporting or Database System:	**Medical Restraints (CMS)**
31. List fields related to pre-existing conditions and/or medical history of patient	(N) Medical Devices - D.10 - Concomitant medical products and therapy dates (exclude tx of event) List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at or around the time of the event. DO NOT include products used to treat the event. (N)B.7 - Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) - fill out only if it is believed that this was associated with or a contributing factor to the death.
32. List fields that capture the clinical condition of patient at time of event	Some of this could be entered in B.5 - adverse event description
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	N/A
34. List any other types of information collected about the patient	(P) B.2 - Outcome attributed to adverse event - <Check Death for this report> death (date in fixed format) life-threatening hospitalization - initial or prolonged disability congenital anomaly required intervention to prevent permanent impairment/damage other (narrative description)
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Physical restraint-related event as defined in Item 7 above
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	If it is believed that a medication was associated with, or a contributing factor to, the patient's death, then completer section C on Form 3500A.A separate form should be submitted for each individual product problem report.(S - drug trade name) C.1 - Name (give labeled strength and mfr/labeler, if known) Use the trade name as marketed. If unknown use the generic name (with the manufacturer or labeler's name, if known). For quality problem reports, include the manufacturer's name and the labeled strength for both prescription and non-prescription products.(N)C.2 - Dose frequency & route used. Describe how the product was used by the patient. For reports involving overdoses, overdose amt, not prescribed amount.(N)C.3 - Therapy dates (if unknown, give duration). Provide the date administration was started (or best estimate) and the date stopped (or best estimate). If no dates are known, an estimated duration is acceptable or if therapy was less than one day, then duration is appropriate. (P) C.5 - Event abated after medication use stopped or dose reduced Yes No Doesn't apply(N) C.6 - Lot # (if known). If known, include the lot number(s) with all product problem reports, or any adverse event report with a biologic or medication(N) C.7 - Exp. Date (if known). Include with all product problem reports ONLY.(P) C.8 - Event reappeared after reintroduction Yes, No, doesn't apply(S-NDC codes) C.9 - NDC# - for product problems only (if known) National drug code

Reporting or Database System:	Medical Restraints (CMS)
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	If a restraint device was cause/suspected cause of death or could be associated with the death, or was in place at the time of death, complete Section D. (S-Brand name) D.1 - Brand Name. The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog (N)D.2 - Type of Device. The generic or common name of the suspect medical device or a generally descriptive name (e.g., urological catheter, heart pacemaker, patient restraint, etc.).DO NOT use broad generic terms such as "catheter", "valve", "screw", etc. (N)D.3 - Manufacturer name and address (N)F.14 - Manufacturer name/address [user facility/distributor only] (P)D.4 - Operator of Device. Indicate the type (NOT the name) of person Health professional = physician, nurse, respiratory therapist, etc., Lay user/patient = person being treated, parent/spouse/friend of the patient, Other = nurses' aide, orderly, etc. (FF)D.5 - Expiration date (mo/day/yy) D.6 - Product Identification Information (S)Model # Found on the device label or accompanying packaging (S)Catalog# Exact number as it appears in the manufacturer's catalog, device labeling, or packaging. (S)Serial # Found on the device label or accompanying packaging; it is assigned by the manufacturer (S)Lot# This number can be found on the label or packaging material. (S)Other# Any other applicable identification number (N)D.7 - Implant date (if any) For medical devices that are implanted in the patient, provide the implant date. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable (P) D.9 - Device available for evaluationyes, no, returned to manufacturer on date (FF)(N) F.9 - Approximate age of device
38. List fields associated with vaccine related events	N/A
39. List fields associated with infection related events	N/A
40. List fields associated with any other type of event. List type of event.	N/A

Reporting or Database System:	**Medical Restraints (CMS)**
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	(P) B.1 - Classification Adverse Event - only check this one Product Problem (defects/malfunctions) - not used for death (N) B.5 - Describe event or problem Provide a complete description of event. Do not use the name of any person. If space is inadequate, use continuation sheet as necessary. Enter name and address of hospital where event occurred. Enter all of the statements that may apply: 1. Death while in physical restraint 2. Death while drug/medication restraint in use 3. Death while in seclusion 4. Death after restraint discontinued, could be associated with event while in restraint 5. Death after seclusion discontinued, could be associated with event while in seclusion (P) F.10 - Event problem codes (see http://www.fda.gov/cdrh/mdr/appendixc.pdf - Note: UF is supposed to complete. Enter up to 3 patient and 3 device codes that most accurately describe the event. Place one code in each box. Patient codes describe what happened to the patient as a result of the event and device codes describe device failures or problems during the event.
42. List fields associated with when the event occurred	(FF) B.3 - Date of event (mo/day/yr) - Provide the actual or best estimate of the death. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable.
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	(FF) B.3 - Date of event provide the actual or best estimate of death. If day is unknown, month and year are acceptable. If day is unknown, month and year are acceptable, If day and month are unknown, year is acceptable. (FF) B.4 - Date of this report (initial reporter) - date when report was submitted
44. List fields associated with where the event occurred	(P) F.12 - Location where event occurred Hospital Home Nursing Home Outpatient treatment facility Outpatient diagnostic facility Ambulatory surgical facility Other____
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	(N)B.6 - Relevant tests/laboratory data (with dates) If it is believed that this was associated with or a contributing factor to, the patient's death, complete this section: otherwise enter N/A
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	(P) F.7 Type of report - one of the choices is for follow-up with number. If follow-up report, record the user facility or distributor initial report number in block F.2 and the sequence number of this follow-up in the blank after "follow-up" e.g. for first follow-up enter "1", for second enter "2". Do not repeat pervious submitted information on a follow-up report. (P) F.11 Report sent to FDA? Yes, No, Date [To track duplicate reports in the FDA database](P) F.13 Report sent to manufacturer? Yes, No, Date(FF) User facility report number in format NNNNNNNNNN-YYYY-XXXXX where N is 10-character CMS number of user facility; Y is year of report and X is 4 or 5 digit sequence number of the report. In block "FDA Use Only" type the letters "CMS" to alert FDA that this is a CMS reportable event.

Reporting or Database System:	Medical Restraints (CMS)
47. List fields related to the outcome of event	(P) B.2 - Outcome attributed to adverse event [CHECK DEATH] death (date in fixed format) life-threatening hospitalization - initial or prolonged disability congenital anomaly required intervention to prevent permanent impairment/damage other (narrative description) (N) B.5 - Describe event or problem - (N) B.6 - Relevant tests/laboratory data, including dates (S) F.10 - Event problem codes (refer to coding manual) patient code device code
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, investigations)	(FF)F.2 - UF/Dist Report number (Filled in by UF/Dist) Enter the complete number of the report exactly as entered in the upper right corner of the front page.
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	CMS uses this information to send a survey team to the hospital. The results of the survey are public information. Currently, the 3500A forms are not stored in a database and only a log is kept of their receipt so there is no direct public release of the form data.
51. Technical issues	

Part II. Data Structure & Storage

I. Facility / Location	
52. What is the address of the data storage facility?	Centers for Medicare and Medicaid Services Survey and Certification Group 7500 Security Blvd. S2-12-25 Baltimore, MD 21244-1850 Attn: Anna Gibson
53. What type of facility is used to store the data (3rd party data center, secured computer room, someone's cubicle)?	Rather than CMS creating a new event reporting form and process, the FDA offered to accept physical restraint event reports from hospitals/health care facilities via the FDA Mandatory MedWatch Form 3500a. The FDA faxes the received reports to Anna Gibson at CMS for input into a death reporting log. There is no database for this information at CMS. Each time one of these is reported, CMS sends out a field person (from the regional office) to investigate and make recommendations. Facilities must respond to recommendations within a certain time period (45 days?).
54. What is the network interconnect for physically distributed systems?	N/A
55. What type (private lines, VPN, Internet) of network interconnect is used?	N/A
56. What is the network protocol (TCP/IP, IPX, etc.)?	N/A
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)?	N/A

Reporting or Database System:	Medical Restraints (CMS)
58. What is the network (WAN) topology, including diagram if available?	N/A
59. Who designed the system? Who operates the system?	
J. Data Storage System / Server	
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	N/A
61. What is the model Number (Sun Enterprise 10000, HP 9000, etc.)	
62. What is the number/speed (Mhz) of processors?	
63. How much memory is available (Gb)?	
64. What is the disk - manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	
65. What is the Operating System (e.g. Sun Solaris 2.6.1)?	
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	N/A
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	
68. Which categories best describe this system?	Paper forms
- Is there an Operational Data Store?	
- Is there an all-encompassing data warehouse versus focused data mart(s)?	
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	
- Is there a data warehouse utilizing a normalized relational database design?	
- Is there a dimensional data warehouse utilizing a star schema design?	
- Is there a statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	
- Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	
- Are there other structured data formats, such as XML, HTML, or other?	

Reporting or Database System:	**Medical Restraints (CMS)**
69. How is the data structured?	See FDA Form 3500A http://www.fda.gov/medwatch/safety/3500a.pdf
- Is there an event occurrence (EO) table with one row per event?	
- Is there a person table with one row per person, linked to events by PERSONID?	
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	
70. How much disk space is currently allocated to the system?	N/A
71. How much disk space is available on this system?	N/A
L. For Each Major Data Structure	
72. What is the width of the table / file / subject data area (bytes)?	N/A
73. How many data elements (approximate) in the table / file / subject data area?	N/A
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	N/A
75. What is the approximate number of rows in the table, or observations?	N/A
76. What time period is currently represented in the data base? Projected change over the next 1-3 years?	Started 4/2001.
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	
Part III. Data Use & Analysis: Incidents of restraint-related harm to patients are relatively rare – with approximately one event reported per month. Although these data do not lend themselves to statistical analysis, they are used to initiate case review and investigations.	

MedSun

Reporting or Database System:	FDA-CDRH: MedSun
Part I. Data Acquisition:	
A. General Information	
1. Report Title	Medical Product Surveillance Network
2. Internet Location: http://	http://www.fda.gov/cdrh/postsurv/MedSun.html - Discusses design of system https://www.MedSun.net for information https://www.MedSun.fda.gov for login (must have valid id and pw)
3. Host Organization(s)	Contractor: CODA - research organization (http://www.codares.com) that will be responsible for recruiting, training, initial follow-up on reports, and project analysis. U of MD is designing the web data entry system and the database.
4. Primary contact information (e.g. Address, Phone)	Primary Contact - Joyce Siwarski - 301-594-4550 x166; JCS@CDRH.FDA.GOV Coordinating development and implementation of MedSun - Marilyn Flack - 301-594-3661; MNF@CDRH.FDA.GOV
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	Section 213 of the FDA Modernization Act of 1997 required the FDA to explore options for designing a national surveillance system based on a representative sample of medical device user facilities. This new reporting system will eventually replace the mandatory reporting by all user facilities of medical device related deaths and serious injuries. The Medical Device Surveillance Network (MeDSuN) is the project that CDRH has sponsored to meet this requirement. MeDSuN is designed to collect data from user facilities (hospitals, nursing homes and other health care facilities required to report under the Safe Medical Devices Act (SMDA)). Initially, CDRH will invite 50 acute care hospitals to participate. Eventually, several hundred facilities will participate and other types of health care facilities may be included. In order to participate, a hospital must be willing to: *Designate at least 2 MedSuN representatives - one from their QI or Risk Management team; one from their biomedical or clinical engineering team; *Agree to participate in the pilot study for 12 months; *Have the representatives participate in a 4 hour study orientation session; *Agree to report medical device adverse events (as required by 21 CFR 803) and events involving problems in the use or operation of a medical device where the potential for serious injury or illness exists. Participants will be able to provide feedback in the future development of the system and will learn about the experiences of other hospitals. They will also receive special feedback from CDRH via newsletters and will be able to request special analyses of the MeDSun database once enough data has been received. The goal is to improve the protection of the health and safety of patients, users and others by: reducing the occurrence of medical device related events, serving as an

Reporting or Database System:	FDA-CDRH: MedSun
	advanced warning system from the clinical community, improving the frequency and quality of reporting by user facilities, developing feedback and benchmarking information based upon reported incidents and promoting the use of analyzed, aggregated AE reports to improve medical facilities' internal quality systems. It will also allow the FDA to apply the knowledge from reported data to the device approval process and to prevention and control problems.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	The data is collected from medical facilities initially invited by CDRH, but eventually based upon their willingness to meet certain participation criteria (see criteria in item 5).
7. What is the unit of data entry (e.g., event, patient, product)?	The unit of data entry is a medical device adverse event that involves problems in the use or operation of a medical device (including malfunctions), which result in serious illness, injury or death. In addition, the participants agree to report events involving problems in which the potential for serious injury, illness or death exists.
8. Who is allowed/required to input information?	Medical facilities selected and agreeing to participate in the MeDSuN pilot project.
9. What are the regulations/laws affecting reporting?	The Safe Medical Device Act of 1991 requires that user facilities report incidents that reasonably suggest that a medical device has caused or contributed to the death of a patient or to serious injury or illness of a patient. Section 519 of the Food and Drug Administration Modernization act of 1997 requires the FDA to find innovative ways to improve surveillance reporting - MedSun is a response to that requirement. 21 CFR Sec 803 Subpart A-F establishes the reporting requirements for medical device reporting. Says that user facilities, importers and manufacturers must report deaths and serious injuries and that distributors (defined in 803.3) must maintain records of incidents. Sec 803.21 discusses the Medwatch mandatory reporting coding manual with codes for hundreds of adverse events for use with Form 3500a.

Reporting or Database System:	FDA-CDRH: MedSun
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	A major focus of the system is to create a blameless and voluntary system with a third party intervening in the process so that the facilities are not reporting directly to the regulators, similar to the process used by ASRS (NASA). For voluntary reporting - CODA (contractor) will de-identify data after a brief period of time, if requested to do so by reporter (applied to National Archives for 30 days-awaiting approval) to allow for follow-up when CODA staff have questions about individual reports. Data will be categorized by type and size of facility. For mandatory reports (deaths and serious injuries) reports will not be deidentified. Completely anonymous reports can only be made by phone**.** In addition, the FDA is required under the Freedom of Information and Privacy Acts (SEC 552, Title 5, USC) (PL 93-579) to delete, prior to public disclosure, any information that constitutes trade secrets, and confidential, commercial, or financial information; and any personal, medical and similar information that would constitute a clearly unwarranted invasion of personal privacy. Included in the deletion requirements are all identification of the reporters and user facilities associated with the events. All CODA employees and consultants are required to sign an "Assurance of Confidentiality" where they pledge to keep all information about reporters confidential.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	All data is input via web screens that have been developed by Univ. of MD. Initial access is available via an FDA assigned user id and password that is given to the selected medical facilities. Each user must change the initial entry password to one that is known only to them. For any reports that are either called in or mailed in, CODA staff will manually enter into the system.
12. What are the methods of editing information (e.g. correcting/add more information to records)	When the hospital representative enters a report, they can "hold" the report for later edits or they can "submit" the report to FDA. Reports that are held are still in the MedSun database. Deletions of the report can only be made by special request. Every 6 months, those reports that are in 'hold' mode, but have not been submitted, will be purged. Once the hospital rep clicks the submit button, only authorized users from CODA will be able to see the report. If the user needs to make changes, they will have to contact CODA. Follow up reports may also be filed and indicated on the data entry for the report. CODA staff will view the electronic reports and screen them for completeness. CODA will contact the facility if more information is needed, and CODA can edit the report. Once completed, the report is 'released' to FDA nurse analysts who then have access to the completed reports. If the report is mandatory under SMDA and manufacturer is known, then the report will be sent to the manufacturer with the identity of the reporting facility. If the report is not mandatory, then the hospital indicates this during data entry. See items 20 and 50.

Reporting or Database System:	FDA-CDRH: MedSun
13. Where is the collected data stored (name of database, number of data storage locations)?	User facilities participating in MedSun will access this database via the Internet webserver and database within the FDA firewall (clinic webserver sits in a service segment at FDA and the database and internal web server sit within the FDA firewall. There is also a designated "MedSun room" at CODA for data processing. Information about reports (reports, notes, etc.) that identifies the facilities or persons that submitted the reports will be kept in the locked MedSun project office.
14. How often is the system revised (annual, semi-annual etc)?	The user guide and screens were just created in 2/02. System revisions are expected to be made on an ongoing basis based upon feedback from users, and FDA analysts and consultants.
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	Informal meetings between project coordinator and system designers. Users are encouraged to provide feedback. A MedSun Representatives' conference is scheduled to provide a forum for participants and FDA to discuss ways they have used the project and data in their patient safety efforts as well as suggestions for improvement.
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	Reports can be made via internet, fax, mail, email, or phone. If by computer, then user needs internet connection and browser such as Internet Explorer v5.0 or higher or Netscape v6.0 or higher.
17. What new features are being planned and/or are on wish lists?	High-level search-engine tool; additional questions for In-vitro Diagnostic Devices; improved FDA interface; automatic didaction
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	CDRH is planning to merge data from the MedSun system into the MAUDE database, but not in initial project phases.
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	Only authorized users who have signed the FDA Rules of Behavior are allowed to enter MedSun reports online. Each will have a unique id and password (known only to the user) and a facility ID kept by CODA. (N) User Facility name (corresponds to F.3 on paper MedWatch form) (N) Name of initial reporter (E.1) (N) Contact Name (F.4) (N) Occupation of Contact (E3)

Reporting or Database System:	FDA-CDRH: MedSun
20. Is participation mandatory or voluntary?	This system will use a combination of mandatory and voluntary reporting. Under the SMDA, facilities are obliged to report adverse events to FDA and to the manufacturer. Facilities will be able to satisfy these requirements through MedSun reporting. They will also encourage the voluntary reporting of close calls and near misses by utilizing incentives and reducing barriers. One field in the input discusses voluntary reporting: (P) If you did not mark death or serious injury above, this is a voluntary report. Please indicate below if we may release the contact person's identification and your hospital as the reporting facility for this incident when we release this report to the manufacturer. (New Field) Do not release this report to manufacturer; Release this report to the manufacturer, including information that identifies the hospital and contact person
21. List fields related to contributor/participant contact information	(N) Name of initial reporter - E.1 (N) Address of initial reporter - E.1
22. List fields related to facility contact information(include type of facility, teaching status, id information)	(N) User facility address - F.3 from Form 3500A (N) Contact name - F.4 (N) Contact phone# - F.5(N) Contact fax# - New(N) Contact's email - New There is an internal table in the database that stores type of facility, size, etc.
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact information	(N) Device manufacturer's name - F.14 (N) Device manufacturer's address - F.14 City, State, Zip
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
25. List fields related to Provider of Care identification	If answer Yes to (P) "Was someone directly operating the device?" Y,N, then go to (P) "Who was operating the device?" D.4 but more options specified doctor, nurse, allied health provider, family member/visitor, patient, other- DO NOT want person identified personally If select Other from "Who was operating the device?", then go to If you selected other, please describe the type of person who was operating the device (not the person's name)
26. List fields that identify types of care providers included in system	Some of this could be in event description and some could be in lab and diagnostic test information.
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	(N) "Patient Identifier (use something that will help you remember who the patient is, but not the patient's name or SSN):" A.1 (N) Device Serial # D.6 (this may identify patient when the device is an implanted device)
28. List fields related to patient contact information (e.g. address, zip code, county, region)	N/A

Reporting or Database System:	FDA-CDRH: MedSun
29. List fields related to patient demographics (e.g. age, sex, race)	(FF) Patient's Age - days, weeks, months, years, date of birth A.2 (P) Patient's Sex - Male, Female A.3 (FF) Patient's Weight - ounces, pounds, kilograms, grams A.4 (P) Patient's Ethnic Background(optional) - American Indian, Black or African American, Native Hawaiian or other Pacific Islander, Asian, Hispanic or Latino, White, Unknown (Could have been in B.7 before)
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	Product Serial# of an implanted device and patient identifier (which is **not** the patient name or SS#)
31. List fields related to pre-existing conditions and/or medical history of patient	(P) Did the patient have any of the following preexisting characteristics that may have contributed to the event (check all that apply): B.7, but more choicesAllergies, Alcohol/drug use, COPD, Coronary heart disease, Diabetes, Hepatic/renal dysfunction, Hypertension, Immuno-compromised, Morbidly obese, Pneumonia, Pregnancy, Premature infant, Smoking Status, post total hysterectomy or salpingioherectomy, Stroke, Surgery, Relevant accident (e.g. Hit head), Other", text box for relevant patient allergies, text box for "other characteristics or medical injuries," and for "other pertinent patient information"(N) Please list the relevant patient allergies. e.g. latex allergy; a particular medication allergy; allergy to a particular material or biomaterial, etc(N) Please describe the relevant accident preceding the event:(N) Other ; Also, (N) Describe event or problem (B5)
32. List fields that capture the clinical condition of patient at time of event	(N)Other characteristics or medical conditions Also see 31 above and 36 below.
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	N/A
34. List any other types of information collected about the patient	(N) Other pertinent patient information (P) Did this event cause (Check all that apply): H.1 with new options Death (date___/___/_____), Serious injury, Potential harm to a health care provider [indicates voluntary report], Minor injury to the patient or health care provider [Indicates voluntary report], Potential for patient harm [Indicates voluntary report]; If you checked serious injury, then go to the following 3 questions. (P) Was intervention required to prevent permanent impairment or damage? Yes No (P) Outcomes attributed to serious injury (check all that apply): Life threatening, Hospitalization, initial or prolonged, Congenital anomaly, Disability, Other; If you checked “Other,” above, please describe the outcome. B.2
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Adverse medical events associated with medical devices as well as close calls and near misses - can include concomitantly used drugs that may have interacted with the device.

Reporting or Database System:	FDA-CDRH: MedSun
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	(P) Were there other therapies being used on the patient at the time of the event that may have caused or contributed to the event (check all that apply)? D.10, but more specific Cardiac Drugs, Chemo Therapy (date: _____), Dialysis (date: _____), Hormonal Replacement Therapy, Immuno Therapy, Long-Term Antiobiotics, Prenatal medication, Other, No other therapies/Not applicable If the user selects other above, then go to (N) List other therapies used on the patient at the time of the event that may have caused or contributed to the event
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	(N) Device brand name D.6 (N) Type of device D.6 (N) Approx. age of device D.6 (N) Device Numbers D.6 (N) Device serial #s D.6 (N) Device model #s D.6 (N) Device lot # D.6 (N) Device catalog # D.6 (N) Other device # D.6 (N) Expiration date D.5 (P) Has facility discontinued use of device due to event? Y N (FF) If the device was implanted, give implant date (mo/day/year) D.7 (FF) If the device was explanted, give explant date (mo/day/year) D.8 (P) Is device avail. for evaluation? Y N D.9 (P) Check all of the factors you think may have contributed to the event: [New, Optional] - Inadequate equipment, Inadequate systems, Other, Poor device design, Poor device maintenance, Training, Unfamiliar environment, Unfamiliarity with the device, Not Applicable (N) What other factors do you think may have contributed to the event [New, Optional]? (P) Check all the factors you think could prevent future occurrences of this type of event: [New, Optional] Better equipment, Appropriate training, Better device maintenance, New or improved devices, Other, Not applicable If answered above, then go to (N) What other equipment do you think would prevent future occurrences of the event? [new, Optional] (P) Was there a problem with the device (such as a defect, malfunction, break, etc.)? H.1 Yes No If yes, then go to (P) What problem did the user have (check all that apply): New Device failed (e.g. broke, couldn't get it to work or stopped working), Device malfunction, that is, the device did not do what it was supposed to do, Device was hard to use, Other; (N) Were there other devices being used on the patient at the time of the event that may have caused or contributed to the event? D.10
38. List fields associated with vaccine related events	Only if listed as other therapies used on the patient at the time of the event that may have caused or contributed to the event
39. List fields associated with infection related events	(N) Describe the event or problem B.5 (N) Please enter all relevant tests/laboratory data B.6

Reporting or Database System:	FDA-CDRH: MedSun
40. List fields associated with any other type of event. List type of event.	N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	(N) Describe the event or problem. B.5 (P) Check all of the factors you think may have contributed to the event [New, Optional] inadequate equipment, inadequate systems, other, poor device design, poor device maintenance, training, unfamiliar environment, unfamiliarity with the device, not applicable If answer above, then go to (N) What other factors do you think may have contributed to the event? [New, Optional] Also, there will be problem codes that CODA will assign - patient problem codes (MedSRA codes), procode (type of device) and device problem codes (in development)
42. List fields associated with when the event occurred	(P) Time of event (New, Optional): Morning, afternoon, evening, night, not known (FF) When did this event happen? (date) B.3
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	(FF) When did this event happen? (date) B.3(P) How many days ago did you first become aware of the event? (New)Less than or equal to 10 days, More than 10 days ago(FF) Date of this report (mo/day/year) B.4(P) This report is: F.7Initial, Follow-up, Initial Report #
44. List fields associated with where the event occurred	(N) User Facility name F.3 (P) Where did this event occur? F.12 Hospital (where in hosp?), home, nursing home, home, outpatient treatment facility, outpatient diagnostic facility, ambulatory surgical facility, other)
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	(N) Describe the event or problem. B.5 (N) Please enter all relevant tests/laboratory data. B.6 (N) Other pertinent patient information (New)
46. List fields related to follow-up of event that do not involve patient intervention (medication/manufacturing/policy actions to correct/update event) cont'd	(P) Check all the factors you think could prevent future occurrences of this type of event: [New, Optional] Better equipment, Appropriate training, Better device maintenance, New or improved devices, Other, Not applicable If answered above, then go to (N) What other equipment do you think would prevent future occurrences of the event? [New, Optional] (N) What other factors do you think would prevent future occurrences of the event? [New, Optional] (P) This report is: F.7 Initial, Follow-up, Initial Report #

Reporting or Database System:	FDA-CDRH: MedSun
47. List fields related to the outcome of event (patient)	(P) Did this event cause (Check all that apply): H.1 with new options Death (date___/___/_____), Serious injury, Potential harm to a health care provider [indicates voluntary report], Minor injury to the patient or health care provider [Indicates voluntary report], Potential for patient harm [Indicates voluntary report]; If you checked serious injury, then go to the following 3 questions. (P) Was intervention required to prevent permanent impairment or damage? Yes No (P) Outcomes attributed to serious injury (check all that apply): Life threatening, Hospitalization, initial or prolonged, Congenital anomaly, Disability, Other; If you checked "Other," above, please describe the outcome. B.2 (N) Describe event or problem B.5 (N) Please enter all relevant tests/laboratory data B.6
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, investigations etc)	N/A
H. Implications	
49. Integration with other systems	Is expected to link to MAUDE - no date set -- probably not for at least 3 years
50. Methods used to de-identify data	Currently, the information is manually redacted according to FOIA regulations before it is released to the public. All information that has the potential to identify a particular patient is removed. The goal is to create an automated solution to the redaction of data such as is currently available under MAUDE.(P) If you did not mark death or serious injury above, this is a voluntary report. Please indicate below if we may release the contact person's identification and your hospital as the reporting facility for this incident when we release this report to the manufacturer. (New Field)Do not release this report to manufacturer; Release this report to the manufacturer but do not include information that identifies the hospitaland contact person; Release this report to the manufacturer, including information that identifies the hospital and contact person.
51. Technical issues - User interface	
Part II. Data Structure & Storage	
I. Facility / Location	
52. What is the address of the data storage facility?	2098 Gaither Road Rockville, Md. 20850
53. What type of facility is used to store data (3rd party data center, secured computer room, someone's cubicle)?	secured computer room
54.Is there a network interconnect for physically distributed systems?	Internet
55. What type (private lines, VPN, Internet) of network interconnect is used?	Internet
56. What is the network protocol (TCP/IP, IPX, etc.)?	TCP/IP

Reporting or Database System:	FDA-CDRH: MedSun
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)?	100 Mbps
58. What is the network (WAN) topology, including diagram if available?	Fast Ethernet (100baseT)
59. Who designed the system? Who operates the system?	
J. For Each Data Storage System / Server	**Quantity = 2 Web Servers, 1 internal, 1 external**
60.Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	(1) Compaq (2) Compaq
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	(1) ProLiant DL830 (2) ProLiant DL830
62.What is the number / speed (Mhz) of processors?	(1) 2 - PIII 1Ghz (2) 2 - PIII 1Ghz
63. How much memory is available (Gb)?	(1) 896 Mb SDRAM (2) 1.1Gb SDRAM
64. What is the Disk - Manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	(1) 18Gb (2) 54Gb
65. What is the Operating System (e.g. Sun Solaris 2.6.1) used?	(1) & (2) Windows 2000 Server Release: V5.0 (Build 2195 Service Pack 2)
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	MS IIS 5.0, SQL Server Enterprise
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	ASP, JavaScript, VBScript
68. Which categories best describe this system?	
- Operational Data Store	No
- Is there an all-encompassing data warehouse versus focused data mart(s)?	
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	Yes
- Is there a data warehouse utilizing a normalized relational database design?	No
- Is there a Dimensional Data Warehouse utilizing a star schema design?	No
- Is there a Statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	No

Reporting or Database System:	FDA-CDRH: MedSun
- Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	No
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	No
- Are there other structured data formats, such as XML, HTML, or other?	No
69. How is the data structured?	In table of file form.
- Is there an event occurrence (EO) table with one row per event?	
- Is there a person table with one row per person, linked to events by PERSONID?	
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	
70. How much disk space is currently allocated to the system?	3.7Gb
71. How much disk space is available on this system?	21 Gb
L. For Each Major Data Structure	
72. What is the width of the table / file / subject data area (bytes)?	
73. How many data elements (approximate) in the table / file / subject data area?	Approximately 5-20 data elements in the table.
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	N/A
75. What is the approximate number of rows in the table, or observations?	Approximately 0-6,000 rows or observations.
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	
Part III. Data Use & Analysis:	
78. System Contact	Marilyn Flack
79. Contact Address	
80. Contact Phone	301-594-3661
81. Contact Email	MNF@CDRH.FDA.GOV
82. Hardware Platform	
83. Operating System	
84. Who is the developer?	University of Maryland

Reporting or Database System:	FDA-CDRH: MedSun
85. Who is responsible for the system architecture?	
86. User Types	CDRH has just received the first reports submitted by User Facilities. MedSuN project team will be primary users during pilot phase. FDA staff currently using MAUDE/ASR may also use or contribute to the assessment of MedSun data (i.e., Division of Surveillance Systems, Division of Post-Market Surveillance
87. What is the frequency of reports?	n/a, reporting/query function in development
88. Who generates the reports?	n/a, reporting/query function in development
89. What is the method of access?	n/a, reporting/query function in development
90. What is the turnaround time?	Will be real time
91. What is the level of automation?	n/a, reporting/query function in development
92. Type Of Reports	Can print report reflecting data entered regarding an individual event. Currently, no other "canned" reports. University of Maryland team currently developing structured query function containing multiple selection criteria, search/sort functions etc.. Pilot participants will receive MedSuN newletters, CDRH alerts/advisories/recall notices, annual summary report and will be able to request special analyses of MeDSuN and MAUDE databases. As with MAUDE, FDA will make FOI releasable data publicly available.
93. What is the unit of observation?	Adverse event associated with use of operation of a medical device which results in serious illness, injury or death (mandatory reporting) or in which the potential for serious injury, illness or death existed (voluntary).
94. What are the available data fields?	The MedSuN system will collect the data elements on FDA Form 3500A that are pertinent to user facilities, with a few additional data elements included (e.g., time of day, who was operating device). See Data Input template for more detail.
95. Is there a controlled vocabulary?	Yes
96. Exportability	n/a, reporting/query function in development
97. User Profile	User Facilities participating in pilot, CDRH staff
98. How are the reports used?	Initially, reports/queries will be used primarily to assess pilot program
99. Report Dissemination	n/a, reporting/query function in development. Individual event report sent by FDA to manufacturer (mandatory). For voluntary reports, User Facility has option to have report forwarded to manufacturer.
100. What is the primary goal?	To improve the protection of the health and safety of patients, users and others by: reducing the occurrence of medical device related events, serving as an advanced warning system from the clinical community, improving the frequency and quality of reporting by user facilities, developing feedback and benchmarking information based upon reported incidents and promoting the use of analyzed, aggregated AE reports to improve medical facilities' internal quality systems. It will also allow the FDA to apply the knowledge from reported data to the device approval process and to prevention and control problems. A key potential benefit of obtaining a representative sample of User Facilities is to facilitate estimation of national incidence of adverse events.

Reporting or Database System:	FDA-CDRH: MedSun
101. Integration/Linkable to Detail/Integration/Overlap	Manufacturers are still required to report qualifying adverse events through Form 3500a to MAUDE. Participating User Facilities would report same event to MedSuN but not MAUDE. Non-participating User Facilities currently required to report adverse events to MAUDE. Post MedSuN implementation, intention is to remove mandatory reporting requirement from non-participating facilities. CDRH is planning to merge data from the MedSun system into the MAUDE database at some later point. Note that MedSuN developed device codes based on ECRI codes and patient codes are based on MedDRA. These codes are different from corresponding MAUDE codes. Product codes are the same as MAUDE ("procodes").
102. HIPAA Compliant	Yes, no patient identifying detail captured in MedSuN.
Note:	No "denominator" information (I.e., number of a specific device in use and extent of use) currently tracked in MedSuN

MedWatch

Reporting or Database System:	FDA-CDER: MedWatch
Part I. Data Acquisition:	
A. General Information	
1. Report Title	MedWatch - FDA direct reporting program
2. Internet Location: http://	http://www.fda.gov/medwatch/
3. Host Organization(s)	Food and Drug Administration (FDA) Center for Devices and Radiologic Health FDA-CDER FDA Center for Biologics Evaluation and Research FDA-CBER FDA Center for Food Safety and Applied Nutrition FDA-CFSAN
4. Primary contact information (e.g. Address, Phone)	Primary Contact: Norman Marks: 301-827-7246 MARKSN@CDER.FDA.GOV
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	FDA has the responsibility for assuring the safety and efficacy of all regulated marketed medical products, including: drugs, biologics, medical and radiation-emitting devices, and special nutritional products (e.g. medical foods, dietary supplements, and infant formulas. FDA Safety Information and Adverse Event Reporting Program has four goals: 1. To increase awareness of drug and device-induced disease. 2. To clarify what should (and should not) be reported to the agency. 3. To make it easier to report by operating a single system for health professionals to report adverse events and product problems to the agency. 4. To provide regular feedback to the health care community about safety issues involving medical products. MedWatch is an FDA post market surveillance program for reporting adverse events associated with all medical products (drugs, medical devices, biologics, and special nutritional products). MedWatch is an FDA post market surveillance program for reporting serious adverse events (death, life-threatening, hospitalization, disability, congenital anomaly, required intervention to prevent permanent damage) associated with all medical products (drugs, medical devices, biologics, and special nutritional products). It is targeted toward reporting of events by individual health professionals and consumers. Consumers and Health Care professionals fill out voluntary input form 3500. The 3500 form gets triaged by AERS system Central Triage Unit and sent to either MAUDE (medical devices), AERS (drug/biologic) or SNAEMS (special nutrition). MedWatch acts as the interface between the submitters and CTU. E-mail confirmation sent to reporter. Web-based back-end module enables the MedWatch Office to view, print, and distribute (manually) the voluntary report to the respective FDA Center/Office. All analysis and data use by FDA is done from AERS, MAUDE or SNAEMS databases. No regular reports are produced from the MedWatch software.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	National
7. What is the unit of data entry (e.g., event, patient, product)?	Event - drug, device, special nutritional products (dietary supplements, medical foods/infant formulas), blood products - The 3500 form gets triaged by AERS system Central Triage Unit. Food reports go to Center

Reporting or Database System:	FDA-CDER: MedWatch
	for Food Safety. Device reports go to MAUDE. Drugs and biologics reports go to AERS
8. Who is allowed/required to input information?	Voluntary input Form 3500 - Consumers and Health Care professionals fill out voluntary input form 3500. Consumers are encouraged to consult with a health care provider prior to submitting. Healthcare professionals are encouraged to report serious adverse events and product problems with all medical products (i.e. drugs, biologics, medical devices, and special nutritional products) See http://www.fda.gov/medwatch/report/consumer/consumer.htm and http://www.fda.gov/medwatch/report/hcp.htm for details on voluntary reporting
9. What are the regulations/laws affecting reporting?	No regulatory mention of voluntary reporting
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	(P)E.5 (Form 3500) - Option not to disclose identity to manufacturer to avoid FDA providing reporter name, address and phone number to manufacturer of a suspect device. Any report in FDA's control, including an FDA record of a telephone report, is subject to public disclosure in response to a Freedom of Information (FOI) request. However, before public disclosure, FDA will delete from the report: *any information that constitutes trade secret, commercial confidential or financial information; *any personal, medical, and similar information (including the serial number of implanted devices) which would constitute *an unwarranted invasion of personal privacy; and *any names and other identifying information of a third party voluntarily submitting an MDR report. This includes *physicians, health care professionals, or other hospital employees unless they are the designated MDR contact person. Please note that the FDA is required under the Freedom of Information and Privacy Acts (SEC 552, Title 5, USC) (PL 93-579) to delete, prior to public disclosure, any information that constitutes trade secrets, and confidential, commercial, or financial information; and any personal, medical and similar information that would constitute a clearly unwarranted invasion of personal privacy. Included in the deletion requirements are all identification of the reporters and user facilities associated with the events.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Reports can be sent to MedWatch (18,000 per year) by: Mail: use postage-paid MedWatch form to CTU Phone: 1-800-FDA-1088 to MedWatch RX Fax: 1-800-FDA-0178 to MedWatch Rx On-line via the MedWatch homepage: https://www.accessdata.fda.gov/scripts/medwatch/ MedWatch Rx Couriered to CTU
12. What are the methods of editing information (e.g. correcting/add more information to records)	Informal: can send an attachment, phone or fax update with reference that was reported again. Can search by reporter name and patient identifier to track it down. No field on Form 3500 that indicates follow-up.
13. Where is the collected data stored (name of database, number of data storage locations)?	Data from MedWatch is triaged by PSI, Inc (contractor) and sent to the appropriate drug or biologics (AERS), device (MAUDE) , quality, blood (BPD), medication error (AERS), or food database
14. How often is the system revised (annual, semi-annual etc)?	No scheduled revisions
15. What are the methods for system revisions (e.g. internal review and design	Federal register notice - public comments

Reporting or Database System:	FDA-CDER: MedWatch
only, design under contract, with or without customer input)?	
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	No minimum. Form 3500 can be filled in manually and mailed to FDA.
17. What new features are being planned and/or are on wish lists?	Having on-line reports go directly into AERS.
C. Potential to link to other information systems	-
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	The voluntary system feeds into MAUDE (Manufacturer and User Facility Device Experience Database) and AERs based upon type of event. AERS data that is coded with a preferred term "medication error" is entered to a separate database in the Office of Drug Safety on a monthly basis.
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	**(N)**E.1 - Reporter Name **(P)**E.2 - Health professional. If you are not a health professional, write NA Yes No **(N)** E.3 - Occupation
20. Is participation mandatory or voluntary?	Voluntary for MedWatch
21. List fields related to contributor/participant contact information	**(N)** E.1 Reporter Address and Phone number **(N)** Reporter Contact information if follow-up is necessary. This person will also receive an acknowledgment letter from the MedWatch program.
22. List fields related to facility contact information (include type of facility, teaching status, id information)	N/A
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact information	N/A
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
25. List fields related to Provider of Care identification	N/A
26. List fields that identify types of care providers included in system	Some of this could be in event description and some could be in lab and diagnostic test information.
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF - Fixed Format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	**(N)**A.1 - Identifier - patient's initials or some other type of information that will allow you, the reporter to readily locate the case if you are contacted for more information. Do not use patient's name or SSN.
28. List fields related to patient contact information (e.g. address, zip code, county, region)	N/A
29. List fields related to patient demographics (e.g. age, sex, race)	**(N)**A.2 - Age at time of event OR Date of Birth - provide the most precise information available. For age, indicate time units (3 years+-

Reporting or Database System:	FDA-CDER: MedWatch
	use years, less than 3 years old, use months; less than 1 month old, use days) **(P)**A.3 - Sex (if congenital anomaly, report sex of the child) Female Male **(N)**A.4 - Weight (in lbs OR kg) **Race could be included by reporter in medical history of patient, but not a separate field (see question 31)
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	No traceable data - patient initials or other reporter assigned ID are entered in database.
31. List fields related to pre-existing conditions and/or medical history of patient	**(N)Drugs, Biologics and Medical Devices -** C.10, D.10 - Concomitant medical products and therapy dates (exclude tx of event) List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at or around the time of the event. DO NOT include products used to treat the event. **(N)**B.7 - Other relevant history, including preexisting medical conditions (e.g., allergies, **race**, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) **(P)**Categories for race: Am. Indian – Alaska Native= American Indian or Alaska Native Asian= Asian Continent to include Indian Subcontinent Native Hawaiian or other Pacific Islander= Native Hawaiian or other Pacific Islander Black= Black, not of Hispanic origin Hispanic= Hispanic White= White, not of Hispanic origin
32. List fields that capture the clinical condition of patient at time of event	(N) C.4 - Diagnosis for use of medicationSome of this could be entered in B.5 - adverse event description
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	n/a
34. List any other types of information collected about the patient	(P) B.2 - Outcome attributed to adverse event death (date in fixed format) life-threatening hospitalization - initial or prolonged disability congenital anomaly required intervention to prevent permanent impairment/damage other (narrative description)
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Adverse outcome in a patient can be due to: Medication (drug or biologic); Medical device (including in vitro diagnostics); Special nutritional product (e.g., dietary supplement, infant formula or medical food) Product problems include, but are not limited to, such concerns as: Suspected contamination; Questionable stability; Defective components; Therapeutic failures; Product confusion (caused by

Reporting or Database System:	FDA-CDER: MedWatch
	name, labeling, design or packaging); Suspected super potent or subpotent medication; Labeling problems caused by printing errors/omissions
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	A separate form should be submitted for each individual product problem report. (**S - drug trade name)** C.1 - Name (give labeled strength and mfr/labeler, if known) Use the trade name as marketed. If unknown use the generic name (with the manufacturer or labeler's name, if known). For quality problem reports, include the manufacturer's name and the labeled strength for both prescription and non-prescription products. **(N)**C.2 - Dose frequency & route used. Describe how the product was used by the patient. For reports involving overdoses, overdose amt, not prescribed amount. **(N)**C.3 - Therapy dates (if unknown, give duration). Provide the date administration was started (or best estimate) and the date stopped (or best estimate). If no dates are known, an estimated duration is acceptable or if therapy was less than one day, then duration is appropriate. (P) C.5 - Event abated after medication use stopped or dose reduced Yes No Doesn't apply (N) C.6 - Lot # (if known). If known, include the lot number(s) with all product problem reports, or any adverse event report with a biologic or medication (N) C.7 - Exp. Date (if known). Include with all product problem reports ONLY. (P) C.8 - Event reappeared after reintroduction Yes, No, doesn't apply (S-NDC codes) C.9 - NDC# - for product problems only (if known) National drug code
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	**(S-Brand name)**D.1 - Brand Name The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog **(N)**D.2 - Type of Device The generic or common name of the suspect medical device or a generally descriptive name (e.g., urological catheter, heart pacemaker, patient restraint, etc.).DO NOT use broad generic terms such as "catheter", "valve", "screw", etc.**(N)**D.3 - Manufacturer name and address**(P)**D.4 - Operator of Device Indicate the type (NOT the name) of person Health professional = physician, nurse, respiratory therapist, etc., Lay user/patient = person being treated, parent/spouse/friend of the patient, Other = nurses' aide, orderly, etc.**(FF)**D.5 - Expiration date (mo/day/yy) D.6 - Product Identification Information(S)Model # Found on the device label or accompanying packaging(S)Catalog# Exact number as it appears in the manufacturer's catalog, device labeling, or packaging.(S)Serial # Found on the device label or accompanying packaging; it is assigned by the manufacturer(S)Lot# This number can be found on the label or packaging material.(S)Other# Any other applicable identification number(N)D.7 - Implant date (if any) For medical devices that are implanted in the patient, provide the implant date. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable(N)D.8. - Explant date (if any) If an implanted device was removed from the patient, provide the explant date. If day is unknown, month and year are acceptable. If month and day are unknown, year is

Reporting or Database System:	FDA-CDER: MedWatch
	acceptable.(P)D.9 - Device available for evaluation?yes, no, returned to manufacturer on date(FF)
38. List fields associated with vaccine related events	n/a
39. List fields associated with infection related events	n/a
40. List fields associated with any other type of event. List type of event.	n/a
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	**(P)** B.1 - Classification Adverse Event Product Problem (defects/malfunctions) **(N)** B.5 - Describe event or problem For an adverse event: Describe the event in detail, including a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. Attach copies of these records with any confidential information deleted. If it is determined that reuse of a medical device labeled for single use may have caused or contributed to an adverse patient outcome, report the facts of the incident in B5 and the perceived contribution of reuse to the occurrence. For a product problem: Describe the problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. If available, the results of any evaluation of a malfunctioning device and, if known, any relevant maintenance/service information should be included in this section For a medication or special nutritional product problem, please indicate if you have retained a sample that would be available to FDA.
42. List fields associated with when the event occurred	(FF) B.3 - Date of event (mo/day/yr) - Provide the actual or best estimate of the date of first onset of the adverse event. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable. When a newborn baby is found to have a congenital anomaly, the event onset date is the date of birth of the child. When a fetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date pregnancy is terminated. If information is available as to time during pregnancy when exposure occurred, indicate that information in narrative block B5.
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	(FF) B.3 - Date of event (FF) B.4 - Date of this report (initial reporter)
44. List fields associated with where the event occurred	n/a
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	(N)B.6 - Relevant tests/laboratory data (with dates) Include: relevant negative test and laboratory findings, in order to most completely convey how the medical work-up/ assessment led to strong consideration of medical product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated; relevant baseline laboratory data prior to the administration or use of the medical product; laboratory data used in diagnosing the event; available laboratory data/engineering analyses (for devices) that provide further information on the course of the event

Reporting or Database System:	FDA-CDER: MedWatch
	If available, include: any pre- and post-event medication levels and dates (if applicable);synopses of any relevant autopsy, pathology, engineering, or lab reports
46. List fields related to follow-up of event that are not associated with a particular patient(medication/manufacturing/policy actions to correct/update event; distribution of report to other places)	(P)E.4 - Report also sent to Manufacturer User facility Distributor
47. List fields related to the outcome of event	**(P)** B.2 - Outcomes attributed to adverse event (check all that apply) Death: Check ONLY if you suspect that the death was an OUTCOME of the adverse event, and include the date if known. Hospitalization (initial or prolonged): Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event. Disability: Check if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions. Congenital anomaly: Check if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child. Required intervention to prevent permanent impairment/damage: Check if you believe that medical or surgical intervention was necessary to: Preclude permanent impairment of a body function or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.
48. List any other fields related to the event or reporting system	Triage unit sequence #
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	
51. Technical issues	
Part II. Data Structure & Storage: MedWatch is essentially a clearinghouse that routes incoming information to appropriate Centers within the FDA and to domain-specific databases (e.g., AERS, MAUDE). Since there is no permanent data storage, we did not collect information regarding the data structures and technical architecture associated with MedWatch.	
Part III. Data Use & Analysis:	
78. System Contact	Norman Marks
79. Contact Address	
80. Contact Phone	301-827-7246
81. Contact Email	MARKSN@CDER.FDA.GOV
82. Hardware Platform	Front-end on FDA Application server at UUNet. Upon submission a text based file is created an placed on FDA Application server that will be pulled across FDA firewall to back end. Back end resides on NT server at CDER/OIT.
83. Operating System	see above
84. Who is the developer?	Front and back end web processes developed by Booz, Allen, Hamilton.
85. Who is responsible for the system architecture?	ColdFusion for web. Oracle *I database at back end.

Reporting or Database System:	FDA-CDER: MedWatch
86. User Types	MedWatch acts as the interface between report submitters and CTU. All analysis and data use by FDA is done from AERS, MAUDE or SNAEMS databases. No regular reports are produced from the MedWatch software.
87. What is the frequency of reports?	N/A
88. Who generates the reports?	N/A
89. What is the method of access?	N/A
90. What is the turnaround time?	N/A
91. What is the level of automation?	N/A
92. Type Of Reports	N/A
93. What is the unit of observation?	N/A
94. What are the available data fields?	N/A
95. What is the controlled vocabulary?	N/A
96. Exportability	N/A
97. User Profile	N/A
98. How are the reports used?	N/A
99. Report Dissemination	Note: website serves as a consumer/health professional information dissemination point and contains safety alerts, Class 1 recalls and safety-related labeling changes. Also contains continuing education articles etc.. E-mail notifications sent to 200 key organizations and 20,000 individuals when safety alert issued. E-mail confirmation sent to reporters who send in online reports. Reporters submitting by mail, phone or fax receive a mailed confirmation. MedWatch to Manufacturer Program sends voluntary reports received by MedWatch to manufacturers if specific conditions met (report must be serious, on a New Molecular Entity, reporter must have given permission etc.).
100. Primary Goal	To support the submission of FDA Form 3500 (voluntary) reports by health professionals and consumers on line and to transfer information to the Central Triage Unit for entry into the appropriate FDA system.
101. Linkable to Detail	MedWatch feeds into AERS, MAUDE and SNAEMS.
102. HIPAA Compliant	Both MEDWATCH mandatory and voluntary reporting forms ask reporter to provide a patient identifier that "will allow both the submitter and initial reporter to locate the case if contacted for follow-up. DO NOT use the patient's name or SSN."
Future	Having on-line reports go directly into AERS (ie. Electronic vs current hardcopy). Develop on line capability for manufacturers/user facilities to submit mandatory reporting form 3500a.
Notes:	18,000 reports from professionals/consumers received last year by mail (approx 25%), fax (40%), phone (5%) and on line (30%). On line and phone converted to paper form and sent to CTU. Fax and mail go directly CTU Example list of product problems in instructions is: suspected contamination, questionable stability, defective components, therapeutic failures, product confusion (cause by name, labeling, design or packaging), suspected super or sub potent medication, labeling problems caused by printing errors/omissions)

MERP

Reporting or Database System:	MedMARx	Medication Error Reporting System (MERS) or Medication Error Reporting Program (MERP)
Part I. Data Acquisition:		
A. General Information		
1. Report Title		
2. Internet Location: http://	http://www.medmarx.com//mmx2_jsp/index.jsp and http://www.usp.org	http://www.usp.org/ (See Practitioner Reporting)
3. Host Organization(s)	The US Pharmacopeia	The US Pharmacopeia
4. Primary contact information (e.g. Address, Phone)	Diane Cousins, (301) 816-8215	Diane Cousins, USP, (301) 816-8215 Dr. Jerry Phillips, FDA, (301) 827-3242 Carol Holquist, FDA, (301) 827-0195
B. Overall System Features		
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	MedMARx is a proprietary subscription service and Internet-accessible database program whereby hospitals can contribute reports on actual and potential medication errors in their facilities in return for anonymity and feedback of comparisons with all hospitals subscribing to the program. About 500 of the 6,200 hospitals currently subscribe. MedMARx differs from the USP MERP and FDA MEDWATCH in that MedMARx lets hospitals internally monitor their progress toward error prevention and maintain awareness of problems and solutions reported by other institutions. USP is exploring ways for both FDA and ISMP to access the MedMARx database.	MERS is a Web-based error reporting system for health care practitioners and students who encounter actual or potential medication errors to report confidentially to USP. USP reviews all reports for health hazards and sends all reports to the FDA, the manufacturer, and to the Institute for Safe Medication Practices, either anonymously or with identification of the reporter with the reporter's permission. This system is a precursor of MedMARx and was established to collect information on problems with medication products. The data elements and definitions are similar to MedMARx.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	The MedMARx database covers about 500 subscribing U.S. hospitals.	The scope of data reported though the MERS covers the whole nation.
7. What is the unit of data entry (e.g., event, patient, product)?	The unit of data entry is in-hospital medication adverse events.	The unit of data entry is in-hospital medication adverse events.
8. Who is allowed/required to input information?	Only health care professionals in subscribing hospitals can report to MedMARx.	Any health care professional in any setting and consumers.
9. What are the regulations/laws affecting reporting?	The legal ramifications for MedMARx come primarily from State laws of "discoverability" or "privilege". Only internal peer review, quality improvement processes in hospitals enjoy	Voluntary reporting - no USP response on regulations affecting.

Reporting or Database System:	MedMARx	Medication Error Reporting System (MERS) or Medication Error Reporting Program (MERP)
	protection from legal discovery in many States. As soon as identifiable information on a case is released outside of the peer review activities of the hospital to any other entity, the information can be discovered through court processes. Only anonymous reporting (with respect to the reporter, patient, and institution) will fully protect the institution against discoverability in court.	
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	The MedMARx system requires anonymous input. Total anonymity of the program overcomes one of the major obstacles (legal discoverability) to reporting and sharing incident report information and experiences among facilities. (See item 9 above.)	The MERS allows reporters to submit anonymously, but this is rarely done. The system asks for reporter identification but not institution where error occurred. Reporter may maintain confidentiality beyond USP for data sent onto FDA, manufacturers and ISMP.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Direct Web input into database.	Form via Web, mail, phone, or fax.
12. What are the methods of editing information (e.g. correcting/add more information to records)	A PIN number is assigned to the subscribing hospital through a PIN-based email address that does not identify the hospital. Hospitals can alter their own records in the system (via the Web with the PIN). USP does not know the identities of hospitals, although they can communicate (through the PIN) to ask for clarifying information or corrections to reports.	USP does all data entry, verification, and modification. Reporters can submit follow up information to USP.
13. Where is the collected data stored (name of database, number of data storage locations)?	On USP servers.	On USP servers.
14. How often is the system revised (annual, semi-annual etc)?	USP publishes an annual report summarizing the trends in MedMARx data. Other publications related to these data are available on the USP Web site. Revisions may ensue from these analyses or from assessments by USP or their customers.	Publications related to the MERS data are available on the USP Web site.
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?		
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	Internet access.	Any one of: phone, Internet access, or fax access.
17. What new features are being planned and/or are on wish lists?	No response from USP.	No response from USP.

Reporting or Database System:	MedMARx	Medication Error Reporting System (MERS) or Medication Error Reporting Program (MERP)
C. Potential to link to other information systems		
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	MedMARx and the FDA are discussing the potential for future sharing of MedMARx data with the FDA reporting systems.	MERS data are shared once a week with FDA. Copies of all reports received at USP are sent via courier to the FDA offices where AERS contract staff enter the information into the AERS database. The information is also coded into NCCMERP codes and stored in an Office of Drug Safety Oracle database where it is further analyzed. No report-level data or information moves from FDA to USP.
D. Fields related to contributor/participant Information:		
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	Hospitals (see below).	See 21 below.
20. Is participation mandatory or voluntary?	Voluntary	Voluntary
21. List fields related to contributor/participant contact information	Anonymous assigned PIN number	Name, title, department or facility name, address, and phone number.
22. List fields related to facility contact information (include type of facility, teaching status, id information)	Facility Type (drop down menu, includes category for "teaching facility"), Facility demographics (drop down menu), # of beds, ALOS, ADC.	Type of institution (see below)
23. List fields related to distributor contact information	None	N/A
24. List fields related to manufacturer contact information	Generic and/or brand name of drug (whichever is applicable), including manufacturer name.	Brand name of product, generic name, manufacturer, labeler, dosage form, strength/concentration, type and size of container, NDC number. Also, optional data elements requested include product label, copy of prescription order, and other relevant material.
E. Fields related to Provider of Care Information:		
25. List fields related to Provider of Care identification	See facility type, above.	"What type of staff or health care practitioner made the initial error?" "Please describe the error. Include sequence of events, personnel involved, and work environment"
26. List fields that identify types of care providers included in system	See facility type, above.	Level of staff or other individual that made error, Level of staff or other individual that discovered error.

Reporting or Database System:	MedMARx	Medication Error Reporting System (MERS) or Medication Error Reporting Program (MERP)
F. Fields related to Patient Information:		
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	None	"If available, please provide relevant patient information (age, gender, diagnosis, etc.). Patient identification not required." (narrative form)
28. List fields related to patient contact information (e.g. address, zip code, county, region)	None	None
29. List fields related to patient demographics (e.g. age, sex, race)	Age, gender	See 27 above.
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	None	No patient identification required.
31. List fields related to pre-existing conditions and/or medical history of patient	None	See 27 above.
32. List fields that capture the clinical condition of patient at time of event	None unless choose to include in narrative part of error reports	See 27 above.
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	None	None
34. List any other types of information collected about the patient	None	None
G. Fields related to Event/Error/Product Information:		
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Mostly drug; some devices, biologics, and vaccines.	Mostly drug; some devices, biologics, and vaccines.
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	Date of error, time of error, narrative description of error, node in medication process at which error occurred, location where initial error occurred, location detail for facility use only, type of error, cause of error, contributing factors, drug name, strength, manufacturer, therapeutic class, dosage form, type and size of container, intended route of administration, and actions taken and recommendations to prevent recurrence of error.	Brand name of product, generic name, manufacturer, labeler, dosage form, strength/concentration, type and size of container, NDC number. Also, optional data elements requested include product label, copy of prescription order, and other relevant materials.
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	N/A	N/A
38. List fields associated with vaccine	N/A	See 36 above.

Reporting or Database System:	MedMARx	Medication Error Reporting System (MERS) or Medication Error Reporting Program (MERP)
related events		
39. List fields associated with infection related events	N/A	N/A
40. List fields associated with any other type of event. List type of event.	N/A	N/A
41. List fields that allow input and/or classification of the even/harm.		
42. List fields associated with when the event occurred		
43. List fields associated with tracking the time between the event, when reported, when acted upon etc.		
44. List fields associated with where the event occurred	Setting - where the initial error occurred	"Where did the error occur (e.g., hospital, outpatient or retail pharmacy, nursing home, patient's home)?"
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	The levels of intervention differ with each category of event outcome:Category A: No intervention needed, error did not reach the patientCategory B: As error was detected before reaching the patient, no intervention needed (on behalf of the patient)Category C: As patient was not harmed by the error, only diagnoses-related follow-up care (to determine that no further harm has or will occur)Category D: Patient subjected to increased level of monitoring or observation after errorCategory E: Patient's therapy/treatment may be changedCategory F: Patient's therapy/treatment changed, hospital stay may be lengthenedCategory G: Patient will need rehabilitative treatment after errorCategory H: Emergency resuscitative measures taken, patient's treatment possibly changed, hospitalization increasedCategory I: No follow-up, issue a death certificateAlso, level of care administered to patient as result of error.	Whether patient counseling was provided before or after the event was discovered.
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	Actions taken to avoid an actual or similar error (pick list and narrative); root cause analysis summary (narrative). Root cause analysis summary	"Suggest any recommendations you have to prevent recurrence of this error or describe policies or procedures you have instituted to prevent future similar errors."
47. List fields related to the outcome of event	Error outcome categories: A: "No error -- circumstances or events that have capacity to cause error	Error outcome categories: A: "No error -- circumstances or events that have capacity to cause error

Reporting or Database System:	MedMARx	Medication Error Reporting System (MERS) or Medication Error Reporting Program (MERP)
	B: "Error occurred, but medication did not reach the patient" C: "Error occurred, but caused no harm" D: "Error occurred that resulted in the need for increased patient monitoring - no patient harm" E: "Error occurred that resulted in need for treatment or intervention - temporary patient harm" F: "Error occurred that resulted in initial or prolonged hospitalization - temporary patient harm" G: "Error occurred that resulted in permanent patient harm" H: "Error occurred that resulted in a near-death event" I: "Error occurred that resulted in patient death"	B: "Error occurred, but medication did not reach the patient" C: "Error occurred, but caused no harm" D: "Error occurred that resulted in the need for increased patient monitoring - no patient harm" E: "Error occurred that resulted in need for treatment or intervention - temporary patient harm" F: "Error occurred that resulted in initial or prolonged hospitalization - temporary patient harm" G: "Error occurred that resulted in permanent patient harm" H: "Error occurred that resulted in a near-death event" I: "Error occurred that resulted in patient death"
48. List any other fields related to the event		
H. Implications		
49. Integration with other systems	USP views one advantage of Internet-access and Internet-based systems as ease of integration. A few ideas from USP are: 1) Contractor for collection of medication errors reports to the government with electronic transfer of data. 2) Electronic data transfer under contract for USP data. 3) USP database access for Federal staff under contract.	MERS reports are already submitted to FDA for MedWatch. See 18. No information is sent back to USP.
50. Methods used to de-identify data		
51. Technical issues	Definition of medication error: Medication Error Definition "A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems, including prescribing; order communications; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." (NCCMERP)	

Reporting or Database System:	MedMARx	Medication Error Reporting System (MERS) or Medication Error Reporting Program (MERP)
Part II. & III: MERP is a privately operated system maintained by USP. Information about the data model and technical architecture is proprietary in nature and not publicly available. Thus, data collection forms for data structures/storage were not populated.		
86. User Types	Subscribing hospitals can access their own data, aggregations of other subscribing hospitals, and drill down to protected record-level data of other hospitals. Besides subscribers, only USP staff have access to the full database.	FDA, ISMP, manufacturers (for reports related to their products, and USP staff.
88. Who generates the reports?	USP produces an annual summary report. Hospitals can generate spreadsheet, charts/graphs, and download data sets for study at the hospital level.	No response.
94. What are the available data fields?	Subscribing hospitals have access to record-level and summarized data with decisions support software tools.	No response.
98. How are the reports used?	For internal quality improvement only by hospitals. For improvement of safety and quality of healthcare by USP.	For improvement of safety and quality of healthcare by USP. For regulatory requirements of FDA.
Comments:	USP has adapted NCCMERP taxonomy for MEDMARx. Though most of the medication error report form requires a written/typed answer, there are some pull-down menus with the NCCMERP classification.	USP has adapted NCCMERP taxonomy for MERS. NCCMERP classes are applied at FDA, Office of Drug Safety.

MERS-TM

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
Part I. Data Acquisition:	
A. General Information	
1. Report Title	Event Discovery Report Transfusion Service QA Sysop Investigation Report Worksheet - available after discovery report is submitted Root Cause Analysis Report Worksheet - available after discovery report is submitted
2. Internet Location: http://	http://www.mers-tm.net
3. Host Organization(s)	The National Heart, Lung, and Blood Institute, in cooperation with FDA The MERS-TM project is primarily based at Columbia University, with Harold S. Kaplan, MD as the Principal Investigator.
4. Primary contact information (e.g. Address, Phone)	Harold S. Kaplan, MD; hsk18@columbia.edu Columbia University, Harkness 4-418, 622 West 168 St, NY, NY 10032 Quay Mercer - Quay.Mercer@UTSouthwestern.edu - 214-648-8448 Barbara Rabin Fastman - bf216@pop.columbia.edu - 212-305-8719
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The Medical Event Reporting System for Transfusion Medicine (MERS-TM) is an event reporting system developed for transfusion services and blood centers to collect, classify, and analyze events that could potentially compromise transfusion safety. It is offered to organizations as a means to meet FDA regulations and American Association of Blood Bank Standards related to implementing a transfusion related event reporting system. In addition to basic reporting, MERS-TM provides the opportunity to study and monitor both actual and near-miss events to facilitate process improvement efforts. MERS-TM will be most successful in organizations that provide a "just" safety culture which encourages event reporting while affording a safe environment in which to report. The goal is not to punish people for errors, but rather to prevent the events from recurring. There are three levels of reporting which are designed to be integrated into existing QA activities without undue additional burden. The Event Discovery Report collects information on the discovery of the event and the event itself. The QA Sysop Investigation Report is completed by a trained QA staff member who classifies the event and determines the need for further review based upon a calculated risk assessment index. The Root Cause Analysis report is filled out in those cases where the organization is try to improve processes by identifying the precursors which led up to the event under analysis.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	Accommodates international reporting. Currently, hospitals from Canada and the US participate in the program, but there is interest from many other countries.
7. What is the unit of data entry (e.g., event, patient, product)?	The unit of entry is an adverse or potential adverse event associated with the collection, manufacturing, testing, storage, distribution and administration of blood and blood products.

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
8. Who is allowed/required to input information?	The transfusion service or blood center assigns the individual who will input data. This is usually a QA Systems Operator who are encourage to take the on-line training available via the MERS-TM web site. The system allows the QA SysOp to add new users with levels of user security based upon individual profiles.
9. What are the regulations/laws affecting reporting?	On November 7, 2000, the U.S. Food and Drug Administration (FDA) published a final rule expanding the requirement for the reporting of errors and accidents in the manufacturing of biological products to include unlicensed registered blood establishments and transfusion services, in addition to licensed manufacturers. The rule, effective May 7, 2001, requires that hospitals and blood centers maintain a method to report, investigate, and track errors and accidents. Both the American Association of Blood Banks and JCAHO have established their own standards - included in these is the requirement to create an adverse event reporting system. In addition, individual countries have regulations relating to the reporting of blood component and transfusion events.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	Yes. Hospitals/Blood Centers may collect identifying information, but there are no fields for entry into the database. Policies on the collection and reporting of patient or facility identifying data are specific to the organization.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	An ID and PW are required for input to the system via an on-line web form.
12. What are the methods of editing information (e.g. correcting/add more information to records)	Edits/additions are made online by authorized users who have editing privileges (as specified by user profiles). Edits can be made by searching for a record by accession number and making changes.
13. Where is the collected data stored (name of database, number of data storage locations)?	The database for an organization's event information is stored on one server at MERS-TM Each organization's data is stored on in a unique database, but Staff at MERS-TM do not have the ability to match each database with the particular reporting organization that supplies the data. Currently, the MERS-TM research group aggregates the data into two major groups - one set of data belongs to the core group of blood centers and transfusion services that worked on the initial research project, the other set belongs to those who have joined the program since it went on-line in December 2001. As of 1/2002, 11 organizations had registered for IDs and passwords to the on-line database.
14. How often is the system revised (annual, semi-annual etc)?	As needed.
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	MERS-TM staff make revision decisions based on experience and user input.
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	Internet Explorer v.5.x or above. On-line training requires download of Adobe Acrobat and Flash plug-in.

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
17. What new features are being planned and/or are on wish lists?	The system has only been up since December 2001. Current efforts are focused on increasing participation in the system, and providing education and supporting new members. In the near future, MERS-TM staff will be shifting focus to begin analyzing the data that has been collected to look for trends and identify important areas for further review. They will also use the data to deal with the hypotheses presented in their original grants. For example, one of their hypotheses was " The safety culture of an organization will change as an event reporting system is implemented." They performed a survey to obtain a baseline of cultural factors for those hospitals that chose to implement MERS-TM. They plan to do a follow-up to determine whether their hypothesis was correct. They have also received a grant from AHRQ to generalize their tool to overall hospital events, to focus on the patient as reporter, and to look at simulation methods. For status report, see 2002_progess_report.doc under Task 3 - FDA Reporting Systems folder
C. Potential to link to other information systems	
18. Is information from this system linked to other systems? If yes, which data is linked?	No. Currently there is a feasibility study underway to link to FDA's BPD system.
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	As stated above, there are no fields that capture the reporting facility and MERS-TM purposely avoids identification of data source to increase likelihood of reporting. If MERS-TM maintained this information they would be subject to Discovery laws in some states and would be required to turn over error reporting information and source as evidence.
20. Is participation mandatory or voluntary?	Current FDA regulations and accrediting groups (e.g. AABB and JCAHO) require transfusion services and blood centers to maintaining an event reporting system is mandatory, but do not require the use of a particular reporting system. MERS-TM meets and exceeds reporting requirements for these accrediting and regulatory bodies. It also includes features beyond the reporting of the event which assist in process improvements - the investigation report and the root cause analysis report.

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
21. List fields related to contributor/participant contact information	(P) A.5 - Discoverer's job description: - Describe the person who actually discovered the event. First, professional training (i.e. MT, RN etc) is described using one of the categories provided. The 'other' choice is to be used when none of the professional training categories apply. If the discoverer is a supervisory-level person or a qa/qc staff member, also mark 'supervisor.' Clerk House staff MD/DO MLT MT QA/QC RN LVN/LPN Supervisor Other
22. List fields related to facility contact information(include type of facility, teaching status, id information)	When registering as a participating organization, the facility does not enter its name or other identifying information. Demographic information includes: (N) Center code name - assigned by center (P) Geographic Setting - Urban, Suburban, Rural (P) Academic - Y,N (P) Pediatric - Y,N (P) Number of FTEs 1-2 3-10 11-20 21-30 >30 (P) Number of RBC Units transfused per year <500 501-1000 1001-3000 3001-5000 5001-10000 10001-20000 >20000 (P) Number of samples processed per year <1000 1001-2000 2001-5000 5001-10000 10001-20000 >20000 (P) Collect blood on site - Y,N (P) Perform viral testing - Y,N (P) Country - US, CA (N) Code name of parent site, if applicable - assigned by center
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact	N/A

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
information	
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
25. List fields related to Provider of Care identification	See Item 26. No specific identification of a particular person
26. List fields that identify types of care providers included in system	(P) B.4 - Persons involved (with event) Clerk House staff MD/DO MLT MT QA/QC RN LVN/LPN Supervisor Other
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	N/A
28. List fields related to patient contact information (e.g. address, zip code, county, region)	N/A
29. List fields related to patient demographics (e.g. age, sex, race)	N/A
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	N/A
31. List fields related to pre-existing conditions and/or medical history of patient	Could be in Narrative of event descriptions, but users are trained not to include patient identifiers
32. List fields that capture the clinical condition of patient at time of event	Could be in Narrative of event descriptions, but users are trained not to include patient identifiers
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	N/A
34. List any other types of information collected about the patient	N/A

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	This system was developed for transfusion services and blood centers to collect, classify, and analyze events that could potentially compromise transfusion safety. Events to be monitored and study include both actual and near-miss events.
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	Could be in Narrative of event descriptions
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	Could be in Narrative of event descriptions
38. List fields associated with vaccine related events	N/A
39. List fields associated with infection related events.	Could be in Narrative of event descriptions
40. List fields associated with any other type of event. List type of event.	N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	(N) A.7 - Describe briefly the event you discovered - Factual description of what was discovered from the discoverer's viewpoint. (4 lines). (N) A.8 - How did you discover this event? - Circumstances of the discovery, i.e. routine review process that allowed capture of the event, or did someone discover the event by chance? **Investigation Report Fields--** (S) 1. Consequent (Discovery) Code (6 digits) - From left to right - first space record event type 1-no recovery, harm;2-no recovery, no harm;3-near miss, unplanned recovery;4- near miss, planned recovery. Two middle spaces are for the consequent process code (where the event was discovered. Three spaces are for the subprocess code that further describes the event. Use Event Codes for this - (~100 codes for transfusion services; ~200 codes for blood centers) (S) 2. Antecedent (1st Occurrence) Code - From left to right - first two spaces are for the antecedent (1st Occurrence) process code (where in the process did the event first occurred). The remaining three spaces are for the subprocess code that further describes the initial antecedent event. Use Event Codes for this - see #1 above) (S) 3. Significant Antecedent (Occurrence) Code - Same as 2 except this code describes the antecedent event the QA Sys Op feels is most amenable to a system improvement. Use Event codes for this - see #1 above) (N) 4. Additional description of the event - add key descriptors about the event not contained in A.7 or A.8 on the Event Discovery Report. (No thesaurus used) (P) 5. Risk Assessment QES - .99 .90 .75 .50 .25 .1 quantified estimate of severity of actual or potential harm to a patient

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
	QEP - .99 .90 .75 .50 .25 .1 quantified estimate of the probability of this event recurring (P) 6. Organizational Risk - Hi, Low, N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms) (cont'd)	(FF) 7. Final RAI Calculation that either the QA Sys Op or the system can calculate. Multiply the QES and QEP risk values. (QASys Op Investigation Report #5). This is the initial Risk Index. b. refer to the event type Investigation Report #1, a number (1-4) on far left). If the event is a near miss, unplanned recovery (3), then add 0.1 to the initial risk index. c. refer to 'Was product issued?' (Event Discovery Report, B.7). If the product was issued, add 0.2 to the initial risk index. d. The Final RAI is the initial risk assessment, plus b and c above. **Root Cause Analysis Report** (Filled out after causal tree built Root cause identified) - Accession Number (S) Consequent Event Code (6 digit code) (N) Describe what happened - associated with consequent event code (S) Antecedent Event Code 1 (5 digit code) + (S) Cause Code 1a, 1b, 1c -(N) Describe what happened - associated with antecedent event (P) Are there additional root causes for antecedent event 1? Yes, No (S) Antecedent Event Code 2 (5 digit code) + (S) Cause Code 2a, 2b, 2c (N) Describe what happened - associated with antecedent event (P) Are there additional root causes for antecedent event 2? Yes, No [Above repeated for Event Code 3 and Event Code 4]
42. List fields associated with when the event occurred	(FF) B.1 - Date the event occurred (mo/day/yr) - Date the first antecedent event occurred. (P) B.2 - Time event occurred - Time of day the first antecedent event occurred. 12-4am 4-8am 8-12noon 12-4pm 4-8pm 8-12mid (P) B.3 - Day of event - weekday, weekend/holiday (P) B.5 - When in process the event first occurred - Captures where in the process of transfusion the initial antecedent event originated. product check in patient/product request order entry sample collection sample handling sample testing product storage product selection product manipulation available for issue product issue product administration miscellaneous

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	(FF) A.1 - Report Date (mo/day/yr) - Date the Event Discovery Report is completed. (FF) A.2 - Discovery date (mo/day/yr) - Date the consequent event is detected. (P) A.3 - Day of discovery - weekday, weekend/holiday (P) A.4 - Discovery time - 12-4am 4-8am 8-12noon 12-4pm 4-8pm 8-12mid
44. List fields associated with where the event occurred	(P) B.6 - Where event occurred - Captures general location where the first antecedent event occurred. Trans service OR ER ICU L&D Clinic Hosp. Ward Other Location Code (optional) - Any combination of alpha and numeric characters can be entered that will help an organization further identify the location of the initial antecedent.
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	(P) A.10 Product/Record action: Floor/Clinic notified Additional testing Pt. sample recollected
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	(P) A.10 Product/Record action: Product retrieved Product destroyed Floor/Clinic notified Other **From Investigation Report --** (P) 8. Follow up - Based on the results of the Final RAI, select a recommended action(s). Propose Action - Further directions for choosing propose change, consider change and/or monitor are on the RAI tool. Consider Action Monitor External report to other dept/org - External report indicates that the event was discussed /formally reported to another department or organization. FDA reportable - FDA Reportable is selected if the event meets the criteria for a report to the FDA - requires reporting of any event associated with manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product or a blood or a blood component, in which the safety, purity, or potency of a distributed product may be affected.

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event) *continued*	(N) 9. If appropriate, describe the long-term preventive action to be taken - MERS-TM encourages preventive actions based on aggregate data rather than an individual event. However, occasionally there will be a very simple preventive action that can be easily implemented without assessing the effects of the change. This area is for the description of such a preventive action. (4 lines) (P) 10. What type of investigation will this event receive? -An expanded investigation is recommended in the following circumstances: events with a Final RAI of greater than or equal to 0.5;a high Organizational Risk estimate; if in the QA Sys Ops expert opinion, the benefit of doing an expanded investigation outweighs the cost. The investigation decision may be changed in either direction based on information obtained from the software tools in Database Functions. Routine Investigation, Expanded Investigation If routine investigation -- Rough or linked? Y, N (S) Rough/link cause code 1 - Enter an 'R' if the following root cause code fields contain estimated root cause codes. The event has neither undergone an expanded investigation nor is it linked to a previous event that did undergo an expanded investigation. Enter an 'L' if: the event has been found to be similar to previous events by the software tools in Database Functions, and the event has been linked to one of the previous events that has undergone an expanded investigation. The 'L' indicates the root cause codes listed in this section have been transcribed from root cause analysis of the previous event. Enter up to 4 root cause codes included in the Eindhoven Classification Model – Medical Version (total of 20 codes). Rough root cause codes are estimates of the causes based on the QA Sys Ops expert knowledge of their system. The event does not warrant a root cause analysis, but they have an idea of what caused the event. Linked root cause codes are transcribed to the current event from a previous event that has had a root cause analysis. (S) Rough/link cause code 2 (S) Rough/link cause code 3 (S) Rough/link cause code 4 Link to Accession Number - If the current event undergoing a routine investigation and it is to be linked to a previous event that has had an expanded investigation, then the accession number of the previous event should be recorded here. (In my notes I had 'Algorithm for causal codes'. Do you know what that refers to?) (N) Notes - any other narrative about event not previously recorded.

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
47. List fields related to the outcome of event	(P) B.7 Product issued? Yes, No If the event involved a product and the product left the control of the transfusion service, then yes. If the event involved a product and was discovered before it left the transfusion service, then no. If the event did not involve a product, then no. (P) B.8 Product administered? Yes, No If the event involved a product and the product was administered to the patient, then yes. If the event involved a product and was discovered before administering it to the patient, then no. If the event did not involve a product, then no. **Investigation Report** (S) 1. Consequent (Discovery) Code (6 digits) - From left to right - first space record event type 1-no recovery, harm;2-no recovery, no harm;3-near miss, unplanned recovery;4- near miss, planned recovery. Two middle spaces are for the consequent process code (where the event was discovered. Three spaces are for the subprocess code that further describes the event. Use Event Codes for this - (~100 codes for transfusion services; ~200 codes for blood centers)
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, investigations)	Accession Number - used to track this record Fields related to event DISCOVERY (P) A.6 Where discovered - Captures general location of where the event was discovered. Trans service OR ER ICU L&D Clinic Hosp. Ward Other Location Code (optional) - organization user defined field (P) A.9 - This event was discovered - Captures where in the process the event was captured. Events that affected the safety, purity, potency and/or efficacy of the product should be categorized according to where the product was at time of discovery. If the event did not affect safety, purity, potency or efficacy, then categorize according to the process that was being carried out at the time of discovery. If the event did not involve a patient or product, mark the choice 'event did not involve a product.' product check in before testing patient sample after pt test verif//before xmatch during xmatch/processing after xmatch/processing before issue after issue, before administration after administration subsequent pt test event did not involve a product other

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
H. Implications	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
49. Integration with other systems	Looking at feasibility of linking to BPD at FDA. What is status of this?
50. Methods used to de-identify data	Individual databases without knowing identity of source - only basic demographic information is taken during registration
51. Technical Information	To be completed by data storage staff

Part II. Data Structure & Storage:	
I. Facility/Location	
52. Address of data storage facility	600 W. 168 St. NY 10032
53. What type of facility is used to store data (3rd party data center, secured computer room, someone's cubicle)?	Secured Computer Room
54. Is there a network interconnect for physically distributed systems?	SSL
55. What type (private lines, VPN, Internet) of network interconnect?	Internet
56. What is the network protocol (TCP/IP, IPX, etc.)?	SSL over TCP/IP
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)?	T1
58. What is the network (WAN) topology, including diagram if available?	
59. Who designed the system? Who operates the system?	
J. Data Storage System / Server	
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	Dell
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	PowerEdge 2450
62. What is the number/speed (Mhz) of processors?	2 x1GHz
63. How much memory is available (Gb)?	1 GB
64. What is the disk - manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	9 x 18 GB
65. What is the operating system (e.g. Sun Solaris 2.6.1)?	Windows 2000
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	IBM DB2

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	Java Servlets
68. Which categories best describe this system?	
- Is there an Operational Data Store?	No
- Is there an all-encompassing data warehouse versus focused data mart(s)?	No
-Is there Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	No
- Is there a data warehouse utilizing a normalized relational database design?	Yes
- Is there a dimensional Data Warehouse utilizing a star schema design?	No
- Is there a statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	No
- Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	No
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	No
- Are there other structured data formats, such as XML, HTML, or other?	No
69.. How is the data structured?	
- Is there an event occurrence (EO) table with one row per event?	Yes. Centers - 1 row per hospital or center PK: CenterId
- Is there a person table with one row per person, linked to events by PERSONID?	Yes. Users - 1 row per user, PK: centerId+userId
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	Yes. EventDiscovery: 1 row per event. PK: centerId+report_accession_no
70. How much disk space is currently allocated to the system?	QaSysopReport 1 row per event PK: centerId+report_accession_no
71. How much disk space is available on this system?	RCAReport - 0 or 1 root cause analysis per event PK: centerId+report_accession_no
L. Major Data Structure	**MERS-TM**
72. What is the width of the table/file/ subject data area (bytes)?	(1) EventDiscovery table 1100 bytes per record/event (2) RootCause table 1000 bytes per record/event (3) QA Sysops 1000 bytes per record/event. (4) users 55 bytes per record/user. (5) Centers 65 bytes per record/center (6) Authorization ~50 bytes per record
73. How many data elements (approximate) in the table / file / subject data area?	

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	
75. What is the approximate number of rows in the table, or observations?	
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	
Part III. Data Use & Analysis	
78. System Contact	Harold S. Kaplan, MD, Quay Mercer and Barbara Rabin Fastman, Ron Levitanat. System Location: on-site at hospital participants. System Owner: Columbia University, with Univ. Kansas and UT Southwestern - grant form NHLBI
79. Contact Address	
80. Contact Phone	Ron - 917-566-3716
81. Contact Email	
82. Hardware Platform	Web-based
83. Operating System	Server: Windows 2000 or Red Hat Linux 7.2; IBM DB2 7.2
84. Who is the developer?	Columbia Univ. with Univ. Kansas and UT Southwestern
85. Who is responsible for the architecture?	Web Browser -> Java Servlet Engine -> RDBMS (DB2)
86. User Types	Hospital transfusion services, blood centers, FDA, researchers
87. What is the frequency of reports?	Done in real time, interactively
88. Who generates the reports?	User
89. What is the method of access?	Interactive web page
90. What is the turnaround time?	Done in real time
91. What is the level of automation	1. Single click (find similar cases); 2. Query by form (find cases that match one or more form values); 3. Parameterized canned (frequency distributions, trend charts); 4. SQL for power users
92. Type Of Reports	HTML links to forms in result set; screen view with graphics, exportable downloads
93. What is the unit of observation?	the reported event
94. What are the available data fields?	see web-based forms??
95. Is there a controlled vocabulary?	yes
96. Exportability	ASCII, XLS (MS Excel), .MDB (MS Access) (DB2 tables - can create nearly any export format, ODBC?)
97. User Profile	Hospital/University, blood center staff; FDA; researchers - primarily internal hospital
98. How are the reports used?	Support of regulations and standards, Quality Assurance, Quality Improvement, Risk Management, research

Reporting or Database System:	Medical Event Reporting System for Transfusion Medicine (MERS-TM)
99. Report Dissemination	Reports are user-generated and distributed. All participants are granted access to the aggregate (multi-hospital) database for report generation and benchmarking.
100. What is the primary goal?	Quality Assurance; Process improvement leading to patient safety
101. Linkable to Detail	no
102. HIPAA Compliant	yes
Comments:	· MERS-TM has a unique way of protecting identity of facility. Each facility has its own database on the MERS-TM server, but MERS-TM has no way to identify which database belongs to a particular database · MERS-TM uses Eindhoven Classification coding system for error classification, also has event codes – more broad than NCCMERP · Reporting system uses fuzzy matching and conjunctive for identifying related errors and improving relevance of reporting. Also uses Accession number to link discovery reports, investigation reports, and RCAs. Prefix can be applied to accession number to further assist in classification · Access to databases by MERS-TM staff allows them to monitor coding practices, event reporting practices and guide organizations toward more standardized methods. MERS-TM staff can send users 'broadcast' messages without knowing identity of organization Differences with FDA BPD reporting system - MERS_TM staff see 2 major differences between their system and the FDA Biologics Product Deviation Reporting System. One - MERS-TM uses more standard fields, codes vs. 'fill in the blanks' to make it easier to sort and analyze data. Two - they developed and standardized the entry for root cause analysis so that it was much easier to identify what major CAUSES of errors and to work on ways to do something about them. FDA BPD system (like the other FDA systems) focuses on the what, when, where, but not on the why?

MPSMS

Reporting or Database System:	**CMS Medicare Patient Safety Monitoring System (MPSMS)**
Part I. & III: The MPSMS system is in the process of being developed, and at the time of our inquiry few details were available with respect to the specific measures, data structures, and analyses. As a result, data collection forms are incomplete for several aspects of the system.	
Part II. Data Structure & Storage:	
I. Facility/Location	
1. System Description	The MPSMS is a new system, which is currently in the conceptualization phase, that is being considered for pilot stage development by CMS and its partners on the Patient Safety Task Force. The overall goal of the MPSMS is to produce rates of adverse patient events and risk factors that contribute to them among the Medicare population.
52. Address of data storage facility	Qualidigm, 100 Roscommon Drive, Middletown, CT 06457-1591
53. What type of facility is used to store data (3rd party data center, secured computer room, someone's cubicle)?	
54. Is there a network interconnect for physically distributed systems?	
55. What type (private lines, VPN, Internet) of network interconnect is used?	
56. What is the network protocol (TCP/IP, IPX, etc.)?	
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)?	
58. What is the network (WAN) topology, including diagram if available?	
59. Who designed the system? Who operates the system?	
J. Data Storage System/Server	
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	
62. What is the number/speed (Mhz) of processors?	
63. How much memory is available (Gb)?	
64. What is the disk - manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	
65. What is the operating system (e.g. Sun Solaris 2.6.1)	MS Windows NT, 2000, or XP
Other COTS	

Reporting or Database System:	**CMS Medicare Patient Safety Monitoring System (MPSMS)**
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	Access database
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	MedQuest Clinical Data Collection Design System
68. Which categories best describe this system?	Statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)
- Is there an Operational Data Store?	
- Is there an all-encompassing data warehouse versus focused data mart(s)?	
- Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	
- Is there a Data warehouse utilizing a normalized relational database design?	
-Is there a Dimensional Data Warehouse utilizing a star schema design?	
- Is there a statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	
-Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	
- Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	
- Are there other structured data formats, such as XML, HTML, or other?	
- Data Mart	
69.How is the data structured?	A person table with one row per person, linked to events by Provider Number (or HIC ?)
- Is there an event occurrence (EO) table with one row per event?	
- Is there a person table with one row per person, linked to events by PERSONID?	

Reporting or Database System:	**CMS Medicare Patient Safety Monitoring System (MPSMS)**
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	
70. How much disk space is currently allocated to the system?	
71. How much disk space is available on this system?	
L. Major Data Structure	
72. What is the width of the table/file/subject data area (bytes)?	
73. How many data elements (approximate) in the table / file / subject data area?	(According to draft data dictionary) 183 fields
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	
75. What is the approximate number of rows in the table, or observations?	55 - 60 K (approximately 1100 taken from each state; a 10% random sample)
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	

NHANES

Reporting or Database System:	**National Health and Nutrition Examination Survey**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	N/A
2. Internet Location: http://	http://www.cdc.gov/nchs/nhanes.htm
3. Host Organization(s)	National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention
4. Primary contact information (e.g. Address, Phone)	National Center for Health Statistics Division of Data Services Hyattsville, MD 20782-2003 (301) 458-4636
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The National Health Survey Act, passed in 1956, provided the legislative authorization for a continuing survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. To comply with the 1956 act, the National Center for Health Statistics (NCHS), a branch of the U.S. Public Health Service in the U.S. Department of Health and Human Services, has conducted seven separate examination surveys to collect interview and physical examination data. The first three of these national health examination surveys (NHES) were conducted in the 1960s: NHES I focused on selected chronic disease of adults aged 18-79. NHES II and NHES III focused on the growth and development of children. The NHES II sample included children aged 6-11, while NHES III focused on youths aged 12-17. All three surveys had an approximate sample size of 7,500 individuals. Beginning in 1970 a new emphasis was introduced. The study of nutrition and its relationship to health status had become increasingly important as researchers began to discover links between dietary habits and disease. In response to this concern, under a directive from the Secretary of the Department of Health, Education and Welfare, the National Nutrition Surveillance System was instituted by NCHS. The purpose of this system was to measure the nutritional status of the U.S. population and changes over time. A special task force recommended that a continuing surveillance system include clinical observation and professional assessment as well as the recording of dietary intake patterns. Thus, the National Nutrition Surveillance System was combined with the National Health Examination Survey to form the National Health and Nutrition Examination Survey (NHANES). Four surveys of this type have been conducted since 1970: The goals of NHANES are as follows: 1. To estimate the number and percent of persons in the U.S. population and designated subgroups with selected diseases and

Reporting or Database System:	**National Health and Nutrition Examination Survey**
	risk factors; 2. To monitor trends in the prevalence, awareness, treatment, and control of selected diseases; 3. To monitor trends in risk behaviors and environmental exposures; 4. To analyze risk factors for selected diseases; 5. To study the relationship between diet, nutrition, and health; 6. To explore emerging public health issues and new technologies; and 7. To establish a national probability sample of genetic material for future genetic testing.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	National
7. What is the unit of data entry (e.g., event, patient, product)?	Patient responses to questionnaires. As in the previous NHANES people are screened using sample selection. This is followed by detailed household interviews. Sample persons are invited to receive physical examinations and health and dietary interviews in mobile examination centers (MECs). Home examinations consisting of a subset of exam components are offered to those sample persons who are unwilling or unable to come to the MEC for the full examination. Various medical tests and procedures are conducted to enable analysis of the relationship between health and nutrition status and disease risk factors, to measure the prevalence and comorbidity of diseases and disorders, to establish reference standards, and to monitor secular trends in health and nutrition status.
8. Who is allowed/required to input information?	Interviewers/Researchers
9. What are the regulations/laws affecting reporting?	Information is gathered and protected according to requirements of Federal Laws: the Public Health Service Act (42 USC 242K) authorizes collection and Section 308 (d) of that law (42 USC 242m) and the Privacy Act of 1974 (5 USC 552A) Prohibits screeners from giving out information that identifies individuals or their family without their consent, even if a court of law asks for it. When researchers are allowed use of the survey data, code numbers are used to replace names or other facts that could identify persons. Individual answers are combined with those from thousands of other people. Survey findings are reported in percentages and totals to protect the privacy of those who took part in the survey.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	N/A

Reporting or Database System:	**National Health and Nutrition Examination Survey**
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Selected persons are invited to take part in the survey by being interviewed in their homes. Household interview data is collected via Computer Assisted Personal Interviewing (CAPI) and includes demographic, socioeconomic, dietary, and health-related questions. Upon completion of the interview, sample persons are asked to participate in a physical examination. The examination will be conducted in a specially equipped and designed Mobile Examination Center (MEC), consisting of four trailers. The MEC houses all of the state-of-the are equipment for the physical exam and test conducted. The trailers are divided into rooms to assure the privacy of exact study participant during the examination and interview. This examination includes a physical and dental examination conducted by a physician and a dentist, laboratory tests, x-rays, and other health interviews conducted by highly trained medical personnel.
12. What are the methods of editing information (e.g. correcting/add more information to records)	When an interview has been completed, interviewers will edit their work, carefully reviewing all forms for completeness and legibility. To insure the accuracy and completeness of the survey, all of interviewer work will be edited by the field office staff, and then validated by recontacting respondents.
13. Where is the collected data stored (name of database, number of data storage locations)?	Some NCHS data systems and surveys are ongoing annual systems while others are conducted periodically. NCHS has two major types of data systems: systems based on populations, containing data collected through personal interviews or examinations; and systems based on records, containing data collected from vital and medical records.
14. How often is the system revised (annual, semi-annual etc)?	Annually (Current NHANES is a continuous national sample)
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	Internal review
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	Data collection involves at least 3 sources: (1) Direct interview (2) clinical tests, measurements, and physical examinations on sample persons; and (3) places where persons received medical care such as hospitals, clinics, and doctors offices.

Reporting or Database System:	**National Health and Nutrition Examination Survey**
17. What new features are being planned and/or are on wish lists?	The National Nutrition Monitoring and Related Research Act of 1990 set goals and mechanisms to bring about greater coordination of nutrition monitoring across agencies. In 1998 the leadership of DHHS and USDA identified a more comprehensive integration of these two surveys as a major priority. The framework for this integration includes a common dietary intake methodology and processing system provided by USDA and the sample and data collection capability provided by the National Health and Nutrition Examination Survey (NHANES) of DHHS. Survey integration will occur in phases to permit successful testing and implementation of the new USDA Automated Dietary Intake System into the NHANES, to decide on what dietary and related nutrition information should be included in data collection to meet policy and program needs of users, and to prepare data processing and release plans. In 2001, considered to be the testing and implementation phase, the new USDA Automated Multiple-Pass Method is being adapted for implementation into the NHANES integrated survey information system and operationally tested on 100 individuals. Dietary data collection for the integrated survey is scheduled to begin in NHANES 2002.
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	Beginning in 1999, NHANES is a continuous, annual survey that can be linked to related Federal Government surveys of the general United States (U.S.) population, specifically, the National Health Interview Survey (NHIS) and, in the future, the U.S. Department of Agriculture's (USDA) Continuing Survey of Food Intakes by Individuals (CSFII). NHANES is linked to NHIS at the Primary Sampling Unit (PSU) level (i.e., the same counties, but not necessarily the same individuals, will be in both surveys). NHANES is linked to NHIS with regard to questionnaire content of the household interview, for selected topics. Links to Medicare and National Death Index records will permit longitudinal/historical studies of disease. These interrelationships with existing surveys and databases follow the Department of Health and Human Services' Survey Integration Plan. Beginning in January 2002, the USDA CSFII study will merge with NHANES. The merged survey sample will be composed of the NHANES examination sample and an additional sample whose characteristics will be defined at a later date. The integrated survey—the National Food and Nutrition Survey (NFNS) will provide comprehensive information on health and nutrition characteristics of the U.S. population. NCHS and USDA are working to finalize the NFNS sample design, core questionnaires, dietary interview protocol, and data processing and reporting plans.

Reporting or Database System:	National Health and Nutrition Examination Survey
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	There are two levels of field organizations for this study-the home office staff and the field staff. **(1) Home Office Staff from Westat**- Project staff from Westat are responsible for overseeing the field work. **(2) Field Staff**- Field staff consists of three groups of employees: The stand office staff, the interviewers, and the MEC staff. The number of people examined in a 12-month period will be about the same as in previous NHANES, about 7,000 persons per year in 15 locations. Data collection for NHANES main survey began in early 1999. Westat has been contracted to conduct the study for approximately six years at 88 locations (stands) across the United States. Nearly 7,000 individuals per year of all ages in households across the United States will be randomly selected to participate in the main survey. The study respondents include whites as well as an over sample of blacks and Mexican Americans. The study design also includes a representative sample of these groups by age, sex, and income level. Adolescents, older persons, and pregnant women will also be over sampled. Survey questionnaires are administered in person at the respondents home and in the MEC. Data is collected by Household interviewers and MEC interviewers. Depending on the context of the data, data collected in the MEC can also be collected with the use of CAPI and ACASI (audio computer assisted self interview) technique so that the participant can answer the question in total privacy.
20. Is participation mandatory or voluntary?	Participation is not mandatory. Participants are selected through a complex statistical process using the most current Census information. In simple terms, NHANES divides the United States into communities. The communities are divided into neighborhoods. The neighborhoods are selected at random. From each neighborhood, housing units are selected at random. Selected households are approached by our interviewers who ask residents a few short questions to determine if their household is eligible for the study. You have a unique health profile; if you are selected to be a participant, no other person can be substituted for you. You were selected based on your age, gender, and racial/ethnic background. No one can take your place in this survey.
21. List fields related to contributor/participant contact information	(P)- random selection of participants

Reporting or Database System:	**National Health and Nutrition Examination Survey**
22. List fields related to facility contact information(include type of facility, teaching status, id information)	To discuss any aspect of the survey, you can make a free call to Dr. Kathryn Porter at the U.S. Public Health Service office at 1-800-452-6115. If you have questions about your rights as a survey participant, call Dr. Lester R. Curtin at 1-800-223-8118. Staff - The NHANES staff consist of professional individuals with a variety of health, research, and academic backgrounds. The staff at the mobile examination center include: a doctor, a dentist, a phlebotomist, health technicians and highly trained interviewers. The home interviewers have varied backgrounds in fields such as social work, the military, and education. The staff at headquarters include: medical doctors, PhDs, nurses, health educators, and engineers.
23. List fields related to distributor contact information	Public Use Data Files for the third National Health and Nutrition Examination Survey will be available from the National Technical Information Service (NTIS). Information regarding a bibliography on disk of journal articles citing data from all the NHANES and the availability of NHANES III data in CD-ROM/SETS software format can be obtained from the Data Dissemination Branch (301) 436-8500 or by writing to: Data Dissemination Branch National Center for Health Statistics Room 1018 6525 Belcrest Road Hyattsville, Maryland 20782
24. List fields related to manufacturer contact information	N/A
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
25. List fields related to Provider of Care identification	N/A
26. List fields that identify types of care providers included in system	N/A
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	
28. List fields related to patient contact information (e.g. address, zip code, county, region)	Address, zip code, county, region
29. List fields related to patient demographics (e.g. age, sex, race)	Sample weights, age, race, sex, ethnic background, household composition, individual characteristics, health insurance, family background, occupation of family head, housing characteristics, family characteristics, orientation.

Reporting or Database System:	**National Health and Nutrition Examination Survey**
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	Psuedo id is assigned
31. List fields related to pre-existing conditions and/or medical history of patient	Diabetes questions, high blood pressure and cholesterol questions, cardiovascular disease questions, musculoskeletal conditions, physical functioning questions, gallblader disease questions, Kidney conditions, respiratory and allergy questions, diet questions, alcohol and drug use, reproductive health.
32. List fields that capture the clinical condition of patient at time of event	Blood pressure measurements; vision questions, hearing questions, diet questions
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	N-Who in the "family" is covered by health insurance or some other kind of health care plan (including government programs like Medicare and Medicaid)? Type of coverage (does it include dental care, is it an HMO, IPA, PPO, POS, Other)?
34. List any other types of information collected about the patient	
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer)	
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	N/A
38. List fields associated with vaccine related events.	N/A
39. List fields associated with infection related events.	N/A
40. List fields associated with any other type of event. List type of event.	N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	
42. List fields associated with when the event occurred	
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	
44. List fields associated with where the event occurred	N/A

Reporting or Database System:	**National Health and Nutrition Examination Survey**
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	N/A
46. List fields related to follow-up of event that are not associated with a particular patient(medication/manufacturing/policy actions to correct/update event)	N/A
47. List fields related to the outcome of event	N/A
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, results of investigations etc)	The results of surveys, analyses, and studies are made known through a number of data release mechanisms including publications, mainframe computer data files, CD-ROMs (Search and Retrieval Software, Statistical Export and Tabulation System (SETS)), and the Internet (http://www.cdc.gov/nchswww/nchshome.htm).
H. Implications	
49. Integration with other systems	The National Nutrition Monitoring and Related Research Act of 1990 set goals and mechanisms to bring about greater coordination of nutrition monitoring across agencies. In 1998 the leadership of DHHS and USDA identified a more comprehensive integration of these two surveys as a major priority. The framework for this integration includes a common dietary intake methodology and processing system provided by USDA and the sample and data collection capability provided by the National Health and Nutrition Examination Survey (NHANES) of DHHS. Survey integration will occur in phases to permit successful testing and implementation of the new USDA Automated Dietary Intake System into the NHANES, to decide on what dietary and related nutrition information should be included in data collection to meet policy and program needs of users, and to prepare data processing and release plans. In 2001, considered to be the testing and implementation phase, the new USDA Automated Multiple-Pass Method is being adapted for implementation into the NHANES integrated survey information system and operationally tested on 100 individuals. Dietary data collection for the integrated survey is scheduled to begin in NHANES 2002.
50. Methods used to de-identify data	
51. Technical Information	
Part II. & III.: NHANES and NHIS are families of surveys and other information collected from subsets of the general population rather than the specific populations (e.g., Medicare patients) and events (e.g., biological product deviations, adverse drug events) that comprise other data systems. Although results from NHANES and NHIS are designed to be generalizable, the sample-based design is such that it does not facilitate linkage of records across systems. Thus, we did not explore the data storage and data structure components of these systems. We did not populate the data use and analysis form since these are research databases with virtually limitless uses and possible analyses.	

NHIS

Reporting or Database System:	**National Health Interview Survey**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	N/A
2. Internet Location: http://	http://www.cdc.gov/nchs/nhis.htm
3. Host Organization(s)	National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention
4. Primary contact information (e.g. Address, Phone)	For publications and information: Data Dissemination Branch National Center for Health Statistics Centers for Disease Control and Prevention 6525 Belcrest Road, Room 1064 Hyattsville, Maryland 20782-2003 (301) 458-4636 Internet home page address: www.cdc.gov/nchs/
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The main objective of the NHIS is to monitor the health of the United States population through the collection and analysis of data on a broad range of health topics. A major strength of this survey lies in the ability to display these health characteristics by many demographic and socioeconomic characteristics. The NHIS covers the civilian noninstitutionalized population of the United States living at the time of the interview. Because of technical and logistical problems, several segments of the population are not included in the sample or in the estimates from the survey. Persons excluded are patients in long-term care facilities; persons on active duty with the Armed Forces (though their dependents are included); and U.S. nationals living in foreign countries.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	National The National Health Interview Survey (NHIS) is the principal source of information on the health of the civilian noninstitutionalized population of the United States and is one of the major data collection programs of the National Center for Health Statistics (NCHS). The National Health Survey Act of 1956 provided for a continuing survey and special studies to secure accurate and current statistical information on the amount, distribution, and effects of illness and disability in the United States and the services rendered for or because of such conditions. The survey referred to in the Act, now called the National Health Interview Survey, was initiated in July 1957. Since 1960, the survey has been conducted by NCHS, which was formed when the National Health Survey and the National Vital Statistics Division were combined.

Reporting or Database System:	**National Health Interview Survey**
7. What is the unit of data entry (e.g., event, patient, product)?	Person response to questionnaire. All the counties in the United States, as reported in the 1990 Decennial Census, are examined. From each group, one or more counties is selected to represent all of the counties in the group. The selected counties are called primary sampling units (PSU). Within each PSU small land areas and groups of addresses are selected and referred to as segments. Each segment contains addresses which are assigned for interview in one or more quarterly samples.
8. Who is allowed/required to input information?	Interviewers/Researchers
9. What are the regulations/laws affecting reporting?	The National Health Interview Survey is part of the National Health Survey, which began in May 1957. Despite extensive research on individual diseases in the years 1937-1957, one important element had been missing. We had piece-meal information from the people themselves on their illness and disability, or the medical care they obtained. Many persons, although sick or injured, never became a "health statistic" because requirements for reporting illnesses were limited to hospitalized illnesses and certain contagious diseases. In recognition of the fact that current information on the Nation's health was inadequate, and that national and regional health statistics are essential, the Congress authorized a continuing National Health Survey (Public Law 652 of the 84th Congress). Since May 1957, the United States Public Health Service has regularly collected health statistics under Congressional authority. Information is gathered and protected according to requirements of Federal Laws: the Public Health Service Act (42 USC 242K) authorizes collection and Section 308 (d) of that law (42 USC 242m) and the Privacy Act of 1974 (5 USC 552A) Prohibits screeners from giving out information that identifies individuals or their family without their consent, even if a court of law asks for it. When researchers are allowed use of the survey data, code numbers are used to replace names or other facts that could identify persons. Individual answers are combined with those from thousands of other people. Survey findings are reported in percentages and totals to protect the privacy of those who took part in the survey.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	N/A

Reporting or Database System:	**National Health Interview Survey**
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Data are collected through a personal household interview conducted by interviewers employed and trained by the U.S. Bureau of the Census according to procedures specified by NCHS. For the Family Core component of the Basic module, all adult members of the household 17 years of age and over who are at home at the time of the interview are invited to participate and to respond for themselves. For children and for adults not at home during the interview, information is provided by a responsible adult family member (18 years of age and over) residing in the household. For the Sample Adult questionnaire, one adult per family will be randomly selected; this individual must respond for themselves to the questions in this section. Information for the Sample Child questionnaire will be obtained from a knowledgeable adult in the household. The Bureau of the Census under a contractual agreement is the data collection agent for the NHIS. Nationally, the NHIS uses about 400 interviewers, trained and directed by health survey supervisors in each of the 12 Bureau of the Census Regional Offices. The supervisors are career Civil Service employees whose primary responsibility is the National Health Interview Survey. The interviewers are part-time employees, selected through an examination and testing process. Interviewers receive thorough training in basic interviewing procedures and in the concepts and procedures unique to the NHIS. In the past the NHIS interview have been conducted using paper and pencil. The revised NHIS questionnaire is conducted using a computer assisted personal interviewer (CAPI). The CAPI version of the NHIS questionnaire is administered using a laptop computer and interviewers enter responses directly into the computer during the interview. This computerized mode offers distinct advantages in terms of timeliness of the data and improved data quality.
12. What are the methods of editing information (e.g. correcting/add more information to records)	N/A
13. Where is the collected data stored (name of database, number of data storage locations)?	In the past the NHIS interview have been conducted using paper and pencil. The revised NHIS questionnaire is conducted using a computer assisted personal interviewer (CAPI). The CAPI version of the NHIS questionnaire is administered using a laptop computer and interviewers enter responses directly into the computer during the interview. This computerized mode offers distinct advantages in terms of timeliness of the data and improved data quality.
14. How often is the system revised (annual, semi-annual etc)?	The National Health Interview Survey is conducted annually by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). Each week a probability sample of the civilian non-institutionalized population of the United States is interviewed by personnel of the U.S. Bureau of the Census.

Reporting or Database System:	National Health Interview Survey
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	The NHIS is a personal visit survey, not a telephone survey. Households must be visited to conduct the interviews. Telephone contacts may be used-once the initial personal contact has been made-to complete partial interviews, complete the HIS-2A(PT) Immunization Form, or to collect other missing parts of the interview for which a callback has been made.
17. What new features are being planned and/or are on wish lists?	N/A
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	The NHIS also has a central role in the ongoing integration of household surveys in DHHS. The designs of two major DHHS national household surveys are already linked to the NHIS, the National Survey of Family Growth and the Medical Expenditure Panel Survey. Other DHHS surveys will be linked to the NHIS in the future. These linked surveys will use the NHIS respondent sample as a sampling frame, will obtain additional information from their sample drawn from the NHIS, and will then combine that data with the information collected in the original NHIS interview.
D. Fields related to contributor/participant Information:	
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	The National Health Interview Survey is authorized by title 42, Unites States Code, section 242k. All information that would permit identification of the individual is held strictly confidential, seen only by persons engaged in the National Health Interview Survey (including related studies carried out by the Public Health Service) and not disclosed or released to others for any other purpose without the written consent of the individual.
20. Is participation mandatory or voluntary?	The fact that participation in the NHIS is voluntary does not diminish interviewers responsibility to convert reluctant respondents. Remind the participant of the confidential nature of the survey. Inform them that they can refuse to answer any question they feel is too personal.
21. List fields related to contributor/participant contact information	It would be too costly and time-consuming to interview everyone in the United States and therefore a sample of addresses was selected. The respondent lives at one of the representative addresses picked. The selection was not based on who lives at the address, nor whether they have problems with their health. Each person represents approximately 2,500 other persons. Taken as a group, the people living at these sample addresses will represent the total population of the United States in the health statistics produced and published by the U.S. Public Health Service.
22. List fields related to facility contact information (include type of facility, teaching status, id information)	

Reporting or Database System:	National Health Interview Survey
23. List fields related to distributor contact information	-
24. List fields related to manufacturer contact information	N/A
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
25. List fields related to Provider of Care identification	N/A
26. List fields that identify types of care providers included in system	N/A
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	
28. List fields related to patient contact information (e.g. address, zip code, county, region)	Address, zip code, county, region
29. List fields related to patient demographics (e.g. age, sex, race)	name, age, race, sex, place of birth, citizenship status, education, main activity last week, hours worked last week, total earnings in last calendar year.
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	
31. List fields related to pre-existing conditions and/or medical history of patient	
32. List fields that capture the clinical condition of patient at time of event	Questions regarding limitations due to physical, mental, or emotional problems.
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	N-Who in the "family" is covered by health insurance or some other kind of health care plan (including government programs like Medicare and Medicaid)? Type of coverage (does it include dental care, is it an HMO, IPA, PPO, POS, Other)?
34. List any other types of information collected about the patient	Questions regarding injuries or poisonings that may have occurred in the past three months which caused a person to get medical advice or treatment.
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	N/A
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer)	N/A

Reporting or Database System:	National Health Interview Survey
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	N/A
38. List fields associated with vaccine related events.	N/A
39. List fields associated with infection related events.	N/A
40. List fields associated with any other type of event. List type of event.	N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	N/A
42. List fields associated with when the event occurred	N/A
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	N/A
44. List fields associated with where the event occurred	N/A
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	N/A
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	N/A
47. List fields related to the outcome of event	N/A
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, results of investigations etc)	
H. Implications	
49. Integration with other systems	NHIS data are used widely throughout the Department of Health and Human Services (DHHS) to monitor trends in illness and disability and to track progress toward achieving national health objectives. The data are also used by the public health research community for epidemiologic and policy analysis of such timely issues as characterizing those with various health problems, determining barriers to accessing and using appropriate health care, and evaluating Federal health programs. The NHIS also has a central role in the ongoing integration of household surveys in DHHS. The designs of two major DHHS national household surveys are already linked to the NHIS, the National Survey of Family Growth and the Medical Expenditure Panel Survey. Other DHHS surveys will be linked to the NHIS in the future. These linked surveys will use the NHIS respondent sample as a sampling frame, will obtain additional information from their sample drawn from the NHIS, and will then combine that data with the information collected in the original NHIS interview.

Reporting or Database System:	National Health Interview Survey
50. Methods used to de-identify data	
51. Technical Information	
Part II. & III.: NHANES and NHIS are families of surveys and other information collected from subsets of the general population rather than the specific populations (e.g., Medicare patients) and events (e.g., biological product deviations, adverse drug events) that comprise other data systems. Although results from NHANES and NHIS are designed to be generalizable, the sample-based design is such that it does not facilitate linkage of records across systems. Thus, we did not explore the data storage and data structure components of these systems. We did not populate the data use and analysis form since these are research databases with virtually limitless uses and possible analyses.	

NHSN

The NHSN is in the process of being developed, and at the time of our inquiry few details were available with respect to the specific data elements, architecture, and reporting functions. Although essentially a revision of the NNIS and Dialysis Surveillance systems, the design is sufficiently different from either of the existing systems. As a result, data collection forms are incomplete for this system.

NNIS

Reporting or Database System:	**The National Nosocomial Infections Surveillance System (NNIS)**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	NNIS
2. Internet Location: http://	http://www.cdc.gov/ncidod/hip/nnis/@nnis.htm
3. Host Organization(s)	Center for Disease Control
4. Primary contact information (e.g. Address, Phone)	Teresa C. Horan, MPH, CIC (404) 498-1114 thoran@cdc.gov
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The National Nosocomial Infections Surveillance (NNIS) System is a cooperative effort that began in 1970 between the Centers for Disease Control and Prevention (CDC) and participating hospitals to create a national nosocomial infections database. The database is used to: describe the epidemiology of nosocomial infections, describe antimicrobial resistance trends, and produce nosocomial infection rates to use for comparison purposes. The data are collected uniformly by trained infection control personnel using explicitly defined terms and surveillance protocols that target inpatients at high risk of infection and are reported monthly to CDC where they are aggregated into the database. Participation in the NNIS System is voluntary and involves only acute care general hospitals with an average daily census of at least 100 patients in the United States. Long term care facilities, such as rehabilitation, mental health, and nursing homes are not included in the NNIS System. At the beginning of 2000, approximately 315 hospitals were participating in the NNIS System. The NNIS System is not accepting new applications for membership at this time, but plans to expand participation with the new system. The data from the NNIS System are reported annually in the NNIS Report located on the NNIS web page and in the November-December issue of the American Journal of Infection Control.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	National scope; over represented in the Mid Atlantic and South Atlantic US; under represented in the West North Central and West South Central US.
7. What is the unit of data entry (e.g., event, patient, product)?	Patient, event, location within the hospital; also to calculate rates, there are data elements on overall utilization that are required, e.g. number of patient days in ICU vs. number of central line days. The ICU, high-risk nursery, surgical site infections and antimicrobial use and resistance surveillance are all components that require denominator data for analysis.
8. Who is allowed/required to input information?	Infection control professionals who have been trained on the system, protocols etc.
9. What are the regulations/laws affecting reporting?	

Reporting or Database System:	The National Nosocomial Infections Surveillance System (NNIS)
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	Patients and organizations are identified through codes (patient by the hospital; hospital by NNIS assigned code) In accordance with Sections 304, 306, and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and m(d), the information obtained for the surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Currently, through the IDEAS (DOS based microcomputer system) data is entered, then transmitted to CDC by modem for aggregation in the NNIS database
12. What are the methods of editing information (e.g. correcting/add more information to records)	Corrections and additions to previously entered data may be made at any time through the IDEAS system.
13. Where is the collected data stored (name of database, number of data storage locations)?	CDC stores the data; data from each hospital is available at their site and facilities can grant other users access to their data.
14. How often is the system revised (annual, semi-annual etc)?	Currently under revision.
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	Since 1986, data is entered through the IDEAS system, Interactive Data Entry and Analysis system, which will be replaced by the NHSN.
17. What new features are being planned and/or are on wish lists?	Currently in major revision to move to the new National Healthcare Safety Network (NHSN) using the National Electronic Disease Surveillance System as the architectural foundation and the Program Area Modules that include NNIS, National Surveillance System for Hospital Healthcare Workers and Dialysis Surveillance Network; revisions include forms, data elements, web access, technology, format etc.
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	
D. Fields related to contributor/participant Information:	
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	Those infection control professionals who have been trained on the system; CDC assigns a unique 3-digit identification number to each NNIS hospital at the time of enrollment; it is automatically attached through IDEAS to each record
20. Is participation mandatory or voluntary?	Voluntary, but in order to remain a NNIS hospital, hospitals are required to file for six months of a 12 month period, and present a monthly surveillance Plan that indicates use of the surveillance components for the month, send data for the month that are consistent with the options of the surveillance components listed on the plan and satisfy data quality acceptance checks applied to the data upon receipt at CDC.

Reporting or Database System:	The National Nosocomial Infections Surveillance System (NNIS)
21. List fields related to contributor/participant contact information	A unique 3-digit identification number is assigned by CDC to each NNIS hospital at the time of enrollment; it is automatically attached to each record via IDEAS system. NNIS has a hospital personnel list that asks about name/contact info for the NNIS primary contact person, administrative responsibility, infection control committee chair, hospital epidemiologist, director of microbiology laboratory, and other infection control professional and support staff (form is under redesign and will be incorporated into the enrollment process).
22. List fields related to facility contact information (include type of facility, teaching status, id information)	Participation is limited to hospitals with 100 beds or more providing general medical-surgical inpatient services to adults or children requiring acute care. To participate, there are minimum staffing requirements for infection control 1 FTE/100 occupied beds and 1 FTE for additional 250 beds (these restrictions will be eliminated under the new system). Surveys have been done to determine hospital characteristics (1999).
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact information	N/A
E. Fields related to Provider of Care Information:	
25. List fields related to Provider of Care identification	Same as #21
26. List fields that identify types of care providers included in system	The name or code of the nursing care area where the patient was assigned is required, including specific ICU designation (Y/N) 12 codes for different ICUs provided for pick list; NICU is a separate category
F. Fields related to Patient Information:	
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	Patient identifier assigned by the hospital and may consist of any combination of no more than 12 letters and/or numbers (may be patient admission number, medical record number or social security number); patient name is optional, not required; admission date (mm/dd/yy)
28. List fields related to patient contact information (e.g. address, zip code, county, region)	None
29. List fields related to patient demographics (e.g. age, sex, race)	Sex is required (enter M, F); age of patient in years, months, days; birth weight in grams (pick list of 4 ranges)
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)?	Patient identifier assigned by the hospital

Reporting or Database System:	The National Nosocomial Infections Surveillance System (NNIS)
31. List fields related to pre-existing conditions and/or medical history of patient	If the patient underwent an operation (Y/N); defined as a surgeon makes at least one incision through the skin or mucous membrane and closes the incision before the patient leaves the OR and performs at least one NNIS operative procedure (defined by ICD9 codes); the principal operative procedures are presented in a hierarchy of highest risk by abdominal, thoracic, neurosurgical spine, neurosurgical brain--e.g.in abdominal category, organ transplant is #1; laparotomy is #22; some conditionally required fields for surgery include date of operation (mm/dd/yy), duration of operation (hrs min), wound class (clean, clean contaminated, contaminated, dirty/infected, unknown); general anesthesia (Y/N); ASA classification (1-5); if it were an emergency (Y/N); trauma (Y/N), endoscopic approach (Y/N), multiple procedures. NNIS has a risk index based on ASA preoperative assessment score, if the operation is contaminated or dirty/infected and the number of hours the operation lasts. Additionally, there is a risk index for SSI rate and use of laproscope.
32. List fields that capture the clinical condition of patient at time of event	Unique identification number of each nosocomial infection reported to NNIS; consists of the year the infection was acquired and the infection sequence number. The service is a required data field and has defined codes (Burn, trauma, cardiac surgery, otolaryngology, general surgery, urology, gynecology, high risk nursery, medicine, neurosurgery, obstetric, medical oncology, ophthalmology, orthopedic, pediatric, plastic surgery, well baby nursery).
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	
34. List any other types of information collected about the patient	
G. Fields related to Event/Error/Product Information:	
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	For urinary tract infections: ASB for asymptomatic bacteriuria; SUTI symptomatic urinary tract infection, OUTI other urinary tract infection; For surgical site infection: a list of 23 codes designating specific organ/space site For infections other than UTI, SSI, PNEU, BSI anatomical body system groupings (9 codes) For infections other than UTI, SSI, PNEU, BSI, anatomical location or type of infection within the grouping 40 codes
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	N/A

Reporting or Database System:	**The National Nosocomial Infections Surveillance System (NNIS)**
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	For urinary tract infections: was an indwelling urinary catheter in place (Y/N); other bladder instrumentation (Y/N) For pneumonia, was the patient on a ventilator (Y/N) For blood stream infection BSI, was a vascular access device terminated at or near the heart or in one of the great vessels within 48 hours before the development of the infection BSI: Central line (Y/N) For blood stream infection, did the patient have a vascular access device in place in a peripheral vessel within the 48 hour period before developing the infection BSI: Peripheral line: (Y/N) For BSI, did patient have total parenteral nutrition therapy either central or peripheral within 48 hours BSI:TPN: (Y/N) For BSI: did the patient have an umbilical catheter (Y/N) For BSI: what is the location of the exit site of the central or peripheral line: central line EC, peripheral line EP, Arterial line EA, central line-associated tunnel T, central line-associated pocket site infection P; none of the above N For BSI: for only select hospitals (Central line No) participating in a study For infections other than UTI, SSI, PNEU, BSI; did patient have an invasive device or procedure within 48 hrs. (Y/N) and what was the location central line EC, peripheral line, EP, arterial line EA, central line tunnel T, central line pocket P none of the above N For infections other than UTI, SSI, PNEU, BSI; the number of the central line (for select hospitals)
38. List fields associated with vaccine related events	N/A
39. List fields associated with infection related events	The areas of NNIS Surveillance Components include: Adult and pediatric intensive care units surveillance, high risk nursery surveillance, surgical patient surveillance (in the past Hospital-wide surveillance was done, but is no longer because of burden and lack of comparative integrity because of small numbers) There are major and specific sites of nosocomial infections have unique codes that were developed for NNIS: urinary tract infections: 3 codes; surgical site infections 7 general codes, pneumonia 1 code, BSI 2 codes, bone and joint infection 3 codes, central nervous system infection 3 codes, cardiovascular system infections 4 codes, eye ear nose throat or mouth 6 codes, gastrointestinal 5 codes, lower respiratory tract infections 2 codes, reproductive tract infection 4 codes, skin and soft tissue 8 codes, systemic infections 1 code For each nosocomial infection, up to four pathogens can be reported to NNIS; the system offers a complete pathogen list and a two to five character code for each pathogen.
40. List fields associated with any other type of event. List type of event.	
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	There are explicit key terms used in the NNIS System with specific definitions. NNIS operative procedure categories use ICD9CM codes that are specified and a list of ICD9CM that DO NOT qualify as NNIS operative procedures. All infection sites are categorized into major and specific infection sites by using standard CDC definitions that include laboratory and clinical criteria.
42. List fields associated with when the event occurred	For surgery: date of operation, infection date (mm/dd)
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	For surgery: date of operation, infection date (mm/dd) For surgical site infection: detected during A admission, P post-discharge surveillance, R readmission to the hospital

Reporting or Database System:	**The National Nosocomial Infections Surveillance System (NNIS)**
44. List fields associated with where the event occurred	Data is collected on all sites of nosocomial infection in patients located in **ICUs**, as well as ICU-specific denominator data. Site specific infection rates can be calculated by using as a denominator the number of patients at risk, patient days, and days of indwelling urinary catheterization, central vascular cannulation (central line) or ventilation. Data is collected on all sites of nosocomial infection in patients in the **High risk nursery** Data is collected on operative procedures from the NNIS operative procedure list, which includes **surgical patients throughout the organization.**
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	For diagnosis of pneumonia (PNEU), the contribution of a chest xray (Def-shows evidence, Poss-possiblity, Neg-negative, Not done)For Blood stream infection, laboratory confirmed bloodstream infection LCBI or clinical sepsis CSEPFor secondary bloodstream infection the patient has a culture-confirmed bloodstream infection and a related nosocomial infection at another site : Secondary infection (Y/N)The laboratory method used to identify the pathogen causing the infection: Laboratory diagnosis C culture, A antigen/antibody test, V visualization, N noneThe specimen from which the pathogen was identified: 12 codes listedThe etiologic agent of the nosocomial infection: Pathogen (3 codes), susceptibility of pathogen to antimicrobial agents; antibiogram (3 codes)
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	
47. List fields related to the outcome of event	In addition to the above infection related items, did the patient die during the hospital admission: Died (Y/N) Relationship of the infection to patient's death: Four codes CA caused the death, CO contributed to death, NR not related, U unknown Secondary bloodstream infection: (Y/N)
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, investigations etc)	
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	
51. Technical Information	
Part II: Data Structure & Storage: The data structure for the NNIS is in the process of being redesigned as part of a modernization effort. Accordingly, we did not review the data storage/structure of this system since the findings would be of limited utility with respect to development of an integrated system.	
Part III. Data Use and Analysis:	
78. System Contact	Teresa Horan
79. Contact Address	CDC
80. Contact Phone	(404) 498-1114
81. Contact Email	thoran@cdc.gov
82. Hardware Platform	PC based (moving to more robust platform)
83. Operating System	DOS based (IDEAS with PRODAS)

Reporting or Database System:	**The National Nosocomial Infections Surveillance System (NNIS)**
84. Who is the Developer?	CDC
85. Who is responsible for the architecture?	closed DOS-based
86. User Types	internal participating facility experts with training, CDC staff
87. What is the frequency of reports?	annual CDC report of summary level info, facilities can do ad hoc analysis as needed
88. Who generates the report?	on-site users, CDC staff
89. What is the method of access?	
90. What is the turnaround time?	
91. What is the level of automation?	SAS is used to do most CDC analyses
92. Type Of Reports	scheduled production reports, ad hoc using SAS
93. What is the unit of observation?	the reported event, infection/procedure/ICU/facility
94. What are the available data fields?	ICU type, Procedure, various utilization stats, Selected antimicrobial resistant pathogens associated with nonsocomial infections, dates
95. Is there a controlled vocabulary?	yes
96. Exportability	yes
97. User Profile	facility QI staff, CDC staff
98. How are the reports used?	quality improvement
99. Report Dissemination	public summary reports are public, facilities have access to all their own data
100. What is the primary goal?	describe the epidemiology of nosocomial infections and describe antimicrobial resistance trends
101. Is the system linkable to detail?	no
102. HIPAA Compliant	yes

OASIS

Reporting or Database System:	**Outcome and Assessment Information Set (OASIS)**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	
2. Internet Location: http://	http://www.hcfa.gov/medicaid/oasis/oasishmp.htm
3. Host Organization(s)	Centers for Medicare & Medicaid Services (CMS)
4. Primary contact information (e.g. Address, Phone)	Dennis Stricker (410) 786-2031 DStricker@cms.hhs.gov John Williams JWilliams2@cms.hhs.gov
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The OASIS is a group of 79 data elements that represent core items of a comprehensive assessment for an adult home health care patient and form the basis for measuring patient outcomes for purposes of outcome-based quality improvement. Medicare-certified home health agencies (HHAs) report OASIS data to their local state organization. These state organizations report to the national repository with capabilities to store, access, and provide billing information and analysis of patient data. Under current CMS requirements, all Medicare certified home health agencies have been collecting, encoding and transmitting data on all Medicare and Medicaid skilled patients since August 24, 1999.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	Home health agencies report to their state organizations. State organizations then report to a national repository.
7. What is the unit of data entry (e.g., event, patient, product)?	Patient
8. Who is allowed/required to input information?	Care providers
9. What are the regulations/laws affecting reporting?	CMS HHA Condition of Participation requires that HHAs report OASIS data. One of the goals for OASIS automation is to fulfill the HHA provisions of the Balanced Budget Act (BBA) of 1997. The BBA includes a Medicare requirement for HHA prospective payment that depends on the data acquired by the OASIS system.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	No
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Electronic transmission via Home Assessment Validation and Entry System Software (HAVEN)
12. What are the methods of editing information (e.g. correcting/add more information to records)	Corrections can be made to assessments that have been previously completed, locked, and exported. The user can specify the type of correction (e.g., inactivation), and make the necessary changes. There is an OASIS correction policy which HAVEN enforces.

Reporting or Database System:	Outcome and Assessment Information Set (OASIS)
13. Where is the collected data stored (name of database, number of data storage locations)?	At each HHA, HAVEN utilizes a Microsoft Access database. On the national level, data is stored at CMS Data Center.
14. How often is the system revised (annual, semi-annual etc)?	
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	
17. What new features are being planned and/or are on wish lists?	
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
	Note: There are four versions of the OASIS form (each is used where appropriate): Start of Care, Follow-Up, Transfer, and Discharge. Unless indicated, a field occurs on all versions.
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	(S) Agency Medicare Provider Number (S) Agency Medicaid Provider Number
20. Is participation mandatory or voluntary?	Mandatory for Medicare certification
21. List fields related to contributor/participant contact information	(S) Agency Medicare Provider Number (S) Agency Medicaid Provider Number
22. List fields related to facility contact information(include type of facility, teaching status, id information)	N/A
23. List fields related to distributor contact information	N/A
24. List fields related to manufacturer contact information	N./A
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
25. List fields related to Provider of Care identification	(N) Primary Referring Physician ID (L) Assisting Persons other than Home Care Agency Staff (Start of Care and Follow-Up only)

Reporting or Database System:	Outcome and Assessment Information Set (OASIS)
	(L) Primary Caregiver (Start of Care and Follow-Up only) (L) Type of Assistance (Start of Care and Follow-Up only) Caregiver Management of Equipment (Start of Care and Follow-Up only)
26. List fields that identify types of care providers included in system	
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	.(S) Patient ID Number (N) Patient Name (S) Patient Medicare Number (if there is one) (S) Social Security Number (S) Medicaid Number (if there is one)
28. List fields related to patient contact information (e.g. address, zip code, county, region)	Patient State of Residence Patient Zip Code
29. List fields related to patient demographics (e.g. age, sex, race)	Birth Date Gender (L) Race/Ethnicity (Start of Care only) (L) Current Payment Sources for Home Care
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)?	Patient ID number
31. List fields related to pre-existing conditions and/or medical history of patient	(L) Inpatient discharge in last 14 days, diagnoses, and treatments (L) Prior conditions (Start of Care and Follow-Up only) (L) Prior therapies (Start of Care and Follow-Up only)
32. List fields that capture the clinical condition of patient at time of event	(L) Overall Prognosis (Start of Care only) (L) Rehabilitative Prognosis (Start of Care only) (L) Life Expectancy (Start of Care and Follow-Up only) (L) High Risk Factors (Start of Care and Follow-Up only) (L) Vision (Start of Care and Follow-Up only) (L) Speech and Oral Expression (Start of Care and Follow-Up only) (L) Frequency of Pain (Start of Care and Follow-Up only) (L) Integumentary Status (Ulcers or Surgical Wounds, Start of Care and Follow0-Up Only) (L) Respiratory Status (Start of Care and Follow-Up only) (L) Elimination Status (Start of Care and Follow-Up only) (L) Neuro/Emotional/Behavorial Status (Start of Care and Follow-Up only) (L) Emergent Care (Transfer and Discharge only) (L) Emergent Care Reason (Transfer and Discharge only) (L) Inpatient Facility (Transfer and Discharge only) (L) Inpatient Facility Admission Information (Transfer and Discharge only) (L) Discharge/Transfer/Death Date (Transfer and Discharge only)
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	(L) Current Payment Sources for Home Care (L) Financial Factors limiting Patient/Family to meet basic health needs

Reporting or Database System:	Outcome and Assessment Information Set (OASIS)
34. List any other types of information collected about the patient	(L) Current Residence (Start of Care and Follow-Up only) (L) Structural Barriers (Start of Care and Follow-Up only) (L) Safety Hazards (Start of Care and Follow-Up only) (L) Sanitation Hazards (Start of Care and Follow-Up only) (L) Patient Lives With (Start of Care and Follow-Up only) (L) Grooming, Bathing, Ability to Dress (Start of Care and Follow-Up only) (L) Feeding or Eating (Start of Care and Follow-Up only) (L) Transportation (Start of Care and Follow-Up only) (L) Laundry and Housekeeping (Start of Care and Follow-Up only) (L) Shopping (Start of Care and Follow-Up only) (L) Ability to Use Telephone (Start of Care and Follow-Up only) (L) Management of Medications (Start of Care and Follow-Up only) (L) Patient Management of Equipment (Start of Care and Follow-Up only)
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Pick list items (list); S-Industry Standard (identify) ; N-Narrative; FF- fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	N/A
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer)	N/A
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy, manufacturer) cont'd	N/A
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	N/A
38. List fields associated with vaccine related events.	N/A
39. List fields associated with infection related events.	N/A
40. List fields associated with any other type of event. List type of event.	N/A
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	N/A
42. List fields associated with when the event occurred	N/A

Reporting or Database System:	Outcome and Assessment Information Set (OASIS)
43. List fields associated with tracking the time between the event, when reported, when acted upon etc	N/A
44. List fields associated with where the event occurred	N/A
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	N/A
46. List fields related to follow-up of event that are not associated with a particular patient(medication/manufacturing/policy actions to correct/update event)	N/A
47. List fields related to the outcome of event	N/A
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, results of investigations etc)	N/A
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	
51. Technical Information	
Part II. Data Structure & Storage:	
I. Facility/Location	
52. Address of data storage facility	CMS Data Center 7500 Security Boulevard Baltimore, Maryland 21244-1850. CMS contractors and agents at various locations.
53. What type of facility is used to store the data (3rd party data center, secured computer room, someone's cubicle)?	CMS Data Center
54. What is the network interconnect for physically distributed systems?	Home health agencies use dial-up access to Medicare Data Communication Network (MDCN, operated by AT&T Global Services). State organizations are on the CMS wide area network.
55. What type (private lines, VPN, Internet) of network interconnect is used?	private lines, SecureIP
56. What is the network protocol (TCP/IP, IPX, etc.)?	TCP/IP

Reporting or Database System:	Outcome and Assessment Information Set (OASIS)
57. What is the bandwidth of network interconnect (dial-up, ISDN, T1, T3, etc.)?	
58. What is the network (WAN) topology, including diagram if available?	
59. Who designed the system? Who operates the system?	
J. Data Storage System/ Server	
60. Who is the manufacturer (Sun, HP, IBM, Compaq, etc.)?	IBM
61. What is the model number (Sun Enterprise 10000, HP 9000, etc.)?	SP - RS/6000 RISC
62. What is the number/speed (Mhz) of processors?	4 processors; 375 MHz
63. How much memory is available (Gb)?	Shared 4 Gb
64. What is the disk - Manufacturer, amount (Gb) & type (SAN, RAID Array, etc.)?	EMC – SAN approximately 1 terabyte for the MDS/HHA project
65. What is the operating System (e.g. Sun Solaris 2.6.1)?	IBM AIX 4.3.3 ptf set 9
K. For Each Application	
66. What commercial off-the-shelf (COTS) software (e.g. RDBMS, Query/Reporting Tools, etc.) is utilized?	
67. What custom-programmed application software is utilized? Using which language(s) (e.g. C,C++, PERL, ASP, VB/COM)?	HAVEN (Resident Assessment Validation and Entry System Software), Designed with MedQuest
68. Which categories best describe this system?	
- Operational Data Store	
-Is there an all-encompassing data warehouse versus focused data mart(s)?	
-Is there an Online Transaction Processing (OLTP) system utilizing a normalized relational database design?	
-Is there a data warehouse utilizing a normalized relational database design?	
-Is there a Dimensional Data Warehouse utilizing a star schema design?	

Reporting or Database System:	Outcome and Assessment Information Set (OASIS)
-Is there a Statistical analysis system utilizing flat files, either raw data or in a format intrinsic to the system (e.g. SAS or SPSS internal system format)?	Yes
-Is there an Online Analytical Processing (OLAP) utilizing denormalized relational design such as star-schema or snowflake schema?	
-Is there an OLAP system utilizing multidimensional design (e.g. hypercubes)?	
-Is there any other structured data format, such as XML, HTML, or other?	
69. How is the data structured?	
- Is there an event occurrence (EO) table with one row per event?	
- Is there a person table with one row per person, linked to events by PERSONID?	Yes
- Is there an adverse-event (AE) taxonomy table, with one row per event type, linked one-to-many to the EO table by AEID?	
70. How much disk space is currently allocated to the system?	
71. How much disk space is available on this system?	
L. Major Data Structure	
72. What is the width of the table/file/subject data area (bytes)?	1448 bytes when converted to character as per the input data specifications
73. How many data elements (approximate) in the table / file / subject data area?	Approximately 350 data elements
74. What is the raw data record size (bytes) or structured raw data such as HTML or XML?	
75. What is the approximate number of rows in the table, or observations?	Approximately 27 million assessments
76. What time period is currently represented in the database? Projected change over the next 1-3 years?	Assessments are submitted at the approximate rate of 900,000 per month.
77. Are there any theoretical maximums that cannot be exceeded? (e.g. # providers, # recipients, etc.)	The intent is to maintain 5 years of data.

VAERS

Reporting or Database System:	**Vaccine Adverse Event Reporting System (VAERS)**
Part I. Data Acquisition:	
A. General Information	-
1. Report Title	Assumptions in this document are made based on the Form VAERS-1 (FDA)
2. Internet Location: http://	http://www.vaers.org/
3. Host Organization(s)	Co-administered: US Food and Drug Administration and Center for Disease Control (CDC focuses on collective reports for detection of unusual epidemiologic trends/associations. FDA reviews reports to assess whether event is reflected in product labeling and to report trends for vaccine manufacturers and vaccine lots.) Analytical Sciences, Inc. (ASI) provides operational support for VAERS and has complied the VAERS data into 52 relational databases so it can be queried and summarized.
4. Primary contact information (e.g. Address, Phone)	Scott Campbell, RN, MSN sic3@CDC.gov 404 639-8834 fax 404 639-8579 phone reviewed this form Project Officer for VAERS at CDC is Dr. John Iskander
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	"The Vaccine Adverse Event Reporting System (VAERS) is a tool for post-marketing safety surveillance (monitoring after a product has been approved and is on the market) of US licensed vaccines. Although extensive studies are required for licensure of new vaccines, post-marketing research and surveillance are necessary to identify safety issues that may only be detected following vaccination of a much larger and more diverse population. Rare events may not come to light before licensure. Sometimes an event is noted, but the evidence may not be adequate to conclude that a noted event is due to the vaccine." "VAERS is a program created as an outgrowth of the National Childhood Vaccine Injury Act of 1986 (NCVIA) and is administered by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC). VAERS accepts reports of adverse events that may be associated with U.S. licensed vaccines from health care providers, manufacturers, and the public. The FDA continually monitors VAERS reports for any unexpected patterns or changes in rates of adverse events." Actual meaningful rates cannot be calculated alone from this data because no denominator of vaccines are calculated to be able to derive a rate. The system is a first pass detection screen. Biologics Surveillance Summary produced by DHHS provides # of vaccine units sold/distributed/etc, but not # of doses administered. VAERS receives approximately 800-1000 reports each month with 125,000 since 1991 collected. The de-identified database can be downloaded from the web site in one year increments. All reports are coded and entered into the VAERS database. The adverse events described in each report are coded utilizing the FDA's Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART) which are key words representing the medical condition(s) described in the case report. An individual report in these files may include up to a total of 8 vaccines administered and 20 COSTART terms describing the event.

Reporting or Database System:	**Vaccine Adverse Event Reporting System (VAERS)**
6. What is the geographic scope of data collection (national, state, local, facility etc)?	National, on occasion manufacturers provide information from foreign subsidiaries, often not reliable.
7. What is the unit of data entry (e.g., event, patient, product)?	Adverse events (side effects) following vaccine administration
8. Who is allowed/required to input information?	Anyone including consumers (vaccine recipients or parents/guardians), health professionals, vaccine manufacturers, state health agencies. Patients/parents/guardians are encouraged to seek help of health care professional in reporting to VAERS.
9. What are the regulations/laws affecting reporting?	In 1986, Congress passed the National Childhood Vaccine Injury Act to ensure vaccine safety, availability and to compensate people injured by vaccination. The Act established the National vaccine Injury Compensation Act to ensure vaccine safety, availability and compensate people injured by vaccination. Applicable regulations: 21 CFR 600.80(c)(1) Reporting Requires the licensed manufacturer to report each adverse experience that is both serious and unexpected, regardless of source, as soon as possible but in any case within 15 working days of initial receipt of the information. 21 CFR 600.80(c)(2) Reporting Requires the licensed manufacturer to report all adverse experiences in a narrative summary, not reported under paragraph (c) (1) (i) at quarterly intervals for 3 years from the date of issuance of the product license, and then at annual intervals. 21 CFR 600.80(e) Reporting Requires the licensed manufacturers to submit a 15-day Alert report obtained from a postmarketing clinical study only if there is a reasonable possibility that the product caused the adverse experience. 21 CFR 600.81 Reporting Requires the licensed manufacturers to report semiannually the quantity of the product distributed under the product license, including the quantity distributed to distributors. 21 CFR 600.90 Reporting Requires the licensed manufacturer to submit a waiver request with supporting documentation for waiving the requirements under 21 CFR 600.80 and 600.81. Refer to the Reportable Events Table (RET) for events mandated for reporting by law. To protect the privacy of the individual, the Freedom of Information Act restricts public access to certain information in reports submitted to the government. After the removal of identifying information such as the patient's name, compiled VAERS data are made available to the public for a fee, through the National Technical Information Service. The data file containing information from VAERS is updated through NTIS on a monthly basis. These data are used to increase understanding of adverse events following vaccination and become a part of the CDC Privacy Act System 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative. § 164.512 Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required. A covered entity may use or disclose protected health information without the written consent or authorization of the individual as described in §§ 164.506 and 164.508, respectively, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual

Reporting or Database System:	Vaccine Adverse Event Reporting System (VAERS)
	may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	While not encouraged, the system does allow anonymous input. Any information sent is retained in the database. The National Childhood Vaccine Injury Act of 1986 provides liability protection through the Vaccine Injury Compensation Program. In light of this protection, practitioner liability is unaffected by the VAERS reporting requirement.This system requires that no information can be used for any purpose other than the purpose for which it was supplied, nor be published or released in an identifiable format unless the establishment or person supplying the information or described in it has consented to such release.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Surface mail with business reply mail provided, fax, call 800 number for assistance in completing the form if the submitter cannot read/write, plan is to move to web-based, beta test underway for electronic reporting
12. What are the methods of editing information (e.g. correcting/add more information to records)	ASI sends requests for follow up information directly to the person who filled out the original form; all data that was submitted by the reporter is edited in follow up forms, thereby maintaining the integrity of the original submission Box G- P Type of secondary report--initial, follow up, mfrs.15 day Letters to follow-up serious reports and obtain the recovery status are mailed to the reporters at 60 days and 1 year after vaccination. For composite form reporting to the agencies: FDA gets daily reports for deaths, weekly summary reports for data integrity issues; CDC also reviews summary information for patterns and data integrity; these composite reports are edited and revised based on internal review from the users group (of FDA, CDC and contractor representatives)
13. Where is the collected data stored (name of database, number of data storage locations)?	Analytical Sciences, Inc. (ASI) provides operational support for VAERS and has complied the VAERS data into 52 relational databases so it can be queried and summarized.
14. How often is the system revised (annual, semi-annual etc)?	There has been no revisions since Nov 1990 form; in process of updating
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	FDA provides request for public comment through the Federal Register; internal reviews are ongoing to modify and refine the system reports from the contractor.
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	Access to form, surface mail
17. What new features are being planned and/or are on wish lists?	Web based reporting; modification of the form in process (VAERS-1); the COSTART (FDA developed classification system is going away, to be replaced by MedRA; they are standardizing the Contractor nurse follow up with the patients e.g. pediatric, neurological questions. Improved denominator data via incorporation of VAERS module into immunization registries.
C. Potential to link to other information systems	-
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data is linked?	Concerns surfaced by VAERS information are investigated through CDC project (Vaccine Safety Datalink VSD). VSD is a large-liked database including six million people, for vaccine safety studies and hypothesis testing. No electronic linkages available.

Reporting or Database System:	Vaccine Adverse Event Reporting System (VAERS)
D. Fields related to contributor/participant Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF-fixed format (e.g. date)**
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data.	Form completed by (Name) Relation to patient P-vaccine provider, patient/parent, manufacturer, other
20. Is participation mandatory or voluntary?	Both: "The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturers package insert. In addition, individuals are encouraged to report any clinically significant or unexpected events (even if you are not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (2ICFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine. Effective December 18, 1999" The RET conditions by vaccine is attached. Under FDA regulations, if a manufacturer is notified of a foreign case report that describes an event that is both serious and unexpected (i.e. not in product labeling), they are required to submit it to VAERS.
21. List fields related to contributor/participant contact information	Name Address (if different from patient or provider) City, State, Zip Telephone number Only for reports submitted by manufacturer/immunization project: #24 Mfr.Imm proj report no, #25 Date received by mfr/imm proj, #26 15 day report? Yes, no, #27 Report type initial, follow up
22. List fields related to facility contact information(include type of facility, teaching status, id information)	Facility name/address City State Zip Telephone no. #15, Vaccinated at: P private doctor's office, military clinic/hospital, public health clinic/hospital, other/unknown
23. List fields related to distributor contact information	none
24. List fields related to manufacturer contact information	#13 Enter all vaccines given on date listed in no. 10: Vaccine (type), Manufacturer, Lot number, route/site, No. previous doses #14 Any other vaccinations within 4 weeks prior to the date listed in no. 10: Vaccine (type), manufacturer, Lot number, route/site, No. Previous doses, date given
E. Fields related to Provider of Care Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF-fixed format (e.g. date)**
25. List fields related to Provider of Care identification	Vaccine administered by (Name) Responsible physician Facility name/address, City, State, Zip Telephone number #1 State #2 County where administered
26. List fields that identify types of care providers included in system	#15 Vaccinated at :P- private doctor's office/hospital, public health clinic/hospital, military clinic/hospital, other/unknown.
F. Fields related to Patient Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF-fixed format (e.g. date)**
27. List fields related to identifying patient - initial data entry (e.g. SSN,	Patient's last name, first name, middle initial #3 Date of birth mm/dd/yy

Reporting or Database System:	Vaccine Adverse Event Reporting System (VAERS)
initials, system-assigned ID etc)	Patient age Sex P-M F
28. List fields related to patient contact information (e.g. address, zip code, county, region)	Address; City, State, Zip; Telephone number
29. List fields related to patient demographics (e.g. age, sex, race)	#3 Date of birth mm/dd/yy #4 Patient age #5 Sex P: M F Only for children 5 and under #22 birth weight lb __oz___ #23 No of brothers and sisters
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	Everything recorded is a retained image with the contractor's office. Information provided to FDA and CDC is stripped of all personal identification (age and gender are provided but not DOB) and a number is linked backed to the original information.
31. List fields related to pre-existing conditions and/or medical history of patient	#18 N-Illness at time of vaccination (specify) #19 N-Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify) #17 N-Other medications #21 Adverse event following prior vaccination (check all applicable, specify) P in patient, in brother or sister: adverse event, onset age, type vaccine, dose No. in series
32. List fields that capture the clinical condition of patient at time of event	#12 could collect this information; relevant diagnostic and laboratory data and # 17 other medications; some reporters use these fields to document clinical condition unrelated to the event.
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS, uninsured etc)	#16 Vaccine purchased with: P-private funds, public funds, military funds, other/unknown
34. List any other types of information collected about the patient	Though not specified on the form, sometimes medical record data is requested if the event is severe enough and follow up investigations are pursued.
G. Fields related to Event/Error/Product Information:	**Use the following codes to classify each identified field in the reporting system. P-Picklist items (list); S-Industry Standard (identify) ; N-Narrative; FF-fixed format (e.g. date)**
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	n/a
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	n/a
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	n/a
38. List fields associated with vaccine related events	#7 N-Describe adverse event(s) (symptoms, signs, time course) and treatment, if any #10 Date of vaccination mm/dd/yy Time ___AM, PM #11 Adverse event onset mm/dd/yy Time___AM, PM #12 Relevant diagnostic tests/laboratory data
39. List fields associated with infection related events	n/a

Reporting or Database System:	Vaccine Adverse Event Reporting System (VAERS)
40. List fields associated with any other type of event. List type of event.	n/a
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	All narrative text taken from VAERS reports are coded and entered into the VAERS database using FDA's Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART), which are key words representing the medical condition described in the report. Reporters are encouraged to use an accepted standard (e.g. MedDRA or COSTART)
42. List fields associated with when the event occurred	#10 Date of vaccination mm/dd/yy Time ___AM, PM #11 Adverse event onset mm/dd/yy Time___AM, PM
43. List fields associated with tracking the time between the event, when reported, when acted upon etc.	#10 Date of vaccination_mm/dd/yy: time ____AM, PM #11 Adverse event onset mm/dd/yy #6 Date form completed_mm/dd/yy #20 Have you reported this adverse event previously? P no, to health department, to doctor, to manufacturer
44. List fields associated with where the event occurred	
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event	
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	no fields, but ad hoc disease/patient specific investigations are done for mitigating factors e.g. SIDS
47. List fields related to the outcome of event	#8 Check all appropriate: P Patient died (date mm/dd/yy) Life threatening illness Required emergency room/doctor visit Required hospitalization (___days) Resulted in prolongation of hospitalization Resulted in permanent disability None of the above #9 Patient recovered P yes, no, unknown
48. List any other fields related to the event	
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	
51. Technical issues	receives 12,000 reports/yr. Database has appx 125,000 reports since November 1991, resides with the contractor
Definitions	There are no definitions of an adverse event; it is consumer driven and by design there are no limits/restrictions for deciding what constitutes adverse event. No near miss information is collected.
Comments on integration with other systems	" It is well people oriented, would not be a good match for inpatient, so few vaccines given inpatient, bias toward a healthy population" AERS/VAERS are the most logical integration, would make it easier for one stop shopping for consumers. But for administrative simplification, no economies of scale could be realized; each system needs resources it has. VSD is complementary, but data sources are different--HMO over time.
Part III. Data Use and Analysis:	
78. System Contact	Scott Campbell

Reporting or Database System:	**Vaccine Adverse Event Reporting System (VAERS)**
79. Contact Address	Atlanta, GA mailstop E61
80. Contact Phone	(404) 639-8579
81. Contact Email	Sic3@cdc.gov
82. Hardware Platform	Windows NT server
83. Operating System	NT 4.0 Server
84. Who is the developer?	McKesson/HBOC initial developer - redesigned by ASI (complete new design)
85. Who is responsible for the system architecture	SQL Server 7 relational
86. User Types	internal only - FDA and CDC staff for internal purposes. External research is ad hoc via CDC/FDA as intermediary
87. What is the frequency of reports?	calendar year up to prior quarter (01/01 - 9/30 available now) 1990-2001 available (123,000 + reports total) daily extracts sent to FDA/CDC as SAS dataset. No other internal reporting done by ASI, but some extracts are coordinated through them (but CDC/FDA sends data).
88. Who generates the reports?	daily reports are system generated and extracts are created
89. What is the method of access?	LAN or VPN access to subset of data (strict security)
90. What is the turnaround time?	varies, but can very short
91. What is the level of automation?	moving to highly automated for daily extracts, ad hoc require manual intervention (manual de-identification of paper reports)
92. Type Of Reports	Both the CDC and the FDA review data reported to VAERS. The FDA reviews reports to assess whether a reported event is adequately reflected in product labeling, and closely monitors reporting trends for individual vaccine lots. Copies of published reviews are available from VAERS. Many different types of events occur after vaccination. Approximately 85% of the reports describe mild events such as fever, local reactions, episodes of crying or mild irritability, and other less serious experiences. The remaining 15% of the reports reflect serious adverse events involving life-threatening conditions, hospitalization, permanent disability, or death, which may or may not have been truly caused by an immunization.
93. What is the unit of observation?	the reported event, at the patient level with provider identification - Vaccine info/manufacturer is available
94. What are the available data fields	
95. Is there a controlled vocabulary?	yes, COSTART
96. Exportability	yes, standard datasets are available on-line for free (stripped of identifiers)
97. User Profile	internal staff - FDA looks at events, CDC looks at trends; external - various research topics
98. How are the reports used?	passive surveillance, trend identification, vaccine labeling issues
99. Report Dissemination	primarily internal to FDA/CDC. Review summaries available upon request, standard data available on line
100. What is the primary goal?	The primary purpose for maintaining the database is to serve as an early warning or signaling system for adverse events not detected during pre-market testing. The FDA reviews reports to assess whether a reported event is adequately reflected in product labeling, and closely monitors reporting trends for individual vaccine lots. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report: Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine. Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination.
101. Linkable to Detail	yes, although linkage would be complex
102. HIPAA Compliant	yes

VSD

Reporting or Database System:	**Vaccine Safety Datalink (VSD)**
Part I. Data Acquisition:	
A. General Information	
1. Report Title	
2. Internet Location: http://	http://www.cdc.gov/nip/vacsafe/vsd/default.htm http://www.who.int/bulletin/pdf/2000/issue2/bu0338.pdf
3. Host Organization(s)	The Centers for Disease Control and Prevention (CDC), National Immunization Program
4. Primary contact information (e.g. Address, Phone)	Robert Davis, MD, MPH (206) 685-4028 Robert Chen, MD, MA (404) 639-8256 rte1@cdc.gov
B. Overall System Features	
5. System purpose/mandate (any information on role in mission, leadership support, integration with quality assurance activities and history)	The Vaccine Safety Datalink began in 1990 as a collaborative effort involving the CDC and several large health-maintenance organizations. The VSD project prospectively collects computerized medical record data under a joint protocol at HMOs on vaccinations, medical outcomes (e.g. outpatient visits, emergency room visits, hospitalizations, and deaths), and covariates (e.g. birth certificates, census data). The data are then linked under joint protocol at multiple health maintenance organizations for analysis. Approximately 6 million persons (2% of the U.S. population) are members of the HMOs that participate in the VSD; the population size for children is 500,000+ (0 to 6 years), both vaccinated and not vaccinated. The databases and infrastructure created for the VSD have provided opportunities to address vaccination coverage and cost effectiveness related to immunization. The VSD enables large eipdemiologic studies of vaccine adverse events, captures information on less commonly occurring types of adverse events, and helps determine whether an event is linked with a vaccine or with some other cause. The VSD allows for planned vaccine safety studies as well as timely investigations of hypotheses. All vaccines administered within the study population are recorded. Available data include vaccine type, date of vaccination, concurrent vaccinations (those given during the same visit), the manufacturer, lot number and injection site. Medical records are then monitored for potential adverse events resulting from immunization. The VSD project allows for planned vaccine safety studies as well as timely investigations of hypotheses. At present, the VSD project is examining potential associations between vaccines and a number of serious conditions. The database is also being used to test new vaccine safety hypotheses that result from the medical literature, VAERS, changes in the immunization schedule or from the introduction of new vaccines. This project is a powerful and cost-effective tool for the on-going evaluation of vaccine safety.
6. What is the geographic scope of data collection (national, state, local, facility etc)?	Seven HMOs including Group Health Cooperative of Puget Sound, Seattle WA; Kaiser Permanente Northwest, Portland OR; Kaiser Permanente Medical Care Program of Northern California, Oakland, CA; Southern California Kaiser Permanente Health Care Program, Los Angeles, CA, Harbour Medical Center LA
7. What is the unit of data entry (e.g., event, patient, product)?	The VSD links medical event information, vaccine history, and selected demographic information.
8. Who is allowed/required to input	Data are only derived from participating HMOs.

Reporting or Database System:	Vaccine Safety Datalink (VSD)
information?	
9. What are the regulations/laws affecting reporting?	
10. Does the system allow for/require anonymous input? If yes, describe. (include any consequences to contributor for reporting, confidentiality policies that apply to entered data)	Health service use information for each patient is computerized and continuously compiled by each HMO indexed by a unique identifier. Each site encodes their patients' clinical data with these unique study identifiers before shipping the data to the CDC annually for merging and analysis, thereby preserving patient confidentiality. Institutional review boards at each HMO have approved only analyses with aggregate data for presentation. Confidentiality policy: This system requires that no information can be used for any purpose other than the purpose for which it was supplied, nor be published or released in an identifiable format unless the establishment or person supplying the information or described in it has consented to such release.
11. What is the mode of data acquisition or input (mail, web form, phone etc)?	Vaccination data are derived from computerized immunization tracking systems maintained by each HMO.
12. What are the methods of editing information (e.g. correcting/add more information to records)?	The individual HMO inpatient databases are both routinely and specially audited for quality control purposes, data quality is high because of staff training, standardized coding protocols, reliability monitoring and routine audits. In addition to routine checks, a random 2% sample of the study populations is selected periodically to review the quality of automated vaccination and diagnostic data.Quality control comparisons of the computerized immunization data with information recorded in the paper medical record have shown high levels of agreement.
13. Where is the collected data stored (name of database, number of data storage locations)?	All VDS data are stored at the CDC
14. How often is the system revised (annual, semi-annual etc)?	
15. What are the methods for system revisions (e.g. internal review and design only, design under contract, with or without customer input)?	
16. What are the minimal interface requirements for contributors (e.g. phone, internet access, certain level of PC memory)?	
17. What new features are being planned and/or are on wish lists?	Issues with Congress surrounding confidentiality; system as is today may change.
C. Potential to link to other information systems	
18. Is information from this system linked to other systems (including State or other Federal Reporting Systems? If yes, which data are linked?	The database is considered an example of a large-linked database (LLDB) including information on more than six million people. No links to other databases in other federal systems; however, the VSD and VAERS are complementary methods of monitoring data. VAERS is a signal generator, designed to provide clues that there may be problems with specific lots of vaccine that require more investigation. VSD provides actual incident rate of diseases and events that occur around the time of vaccination and at times, not linked to vaccination, making it possible to evaluate whether the vaccine actually caused the adverse event and, if so, the magnitude of the problem. VSD can help FDA and the Vaccine Injury Compensation Program.

Reporting or Database System:	Vaccine Safety Datalink (VSD)
D. Fields related to contributor/participant Information:	There is no publicly available form (and therefore no fields) connected with the VSD per se. Data are shipped as files to the CDC where the database is constructed.
19. What types of contributors are included in data acquisition? List fields that indicate who/what facility submitted the data	
20. Is participation mandatory or voluntary?	Voluntary due to nature of partnership between HMOs and CDC
21. List fields related to contributor/participant contact information	
22. List fields related to facility contact information (include type of facility, teaching status, id information)	Assumed that the system has all pertinent data on facilities due to partnership with HMOs
23. List fields related to distributor contact information	
24. List fields related to manufacturer contact information	Manufacturer name and lot number
E. Fields related to Provider of Care Information:	
25. List fields related to Provider of Care identification	
26. List fields that identify types of care providers included in system	
F. Fields related to Patient Information:	
27. List fields related to identifying patient - initial data entry (e.g. SSN, initials, system-assigned ID etc)	"Each site encodes their patient's clinical data with unique study identifiers before shipping the data to the CDC annually for merging and analysis, thereby preserving patient confidentiality." (Chen et al. 1997)
28. List fields related to patient contact information (e.g. address, zip code, county, region)	ZIP code, street address, census tract blocks. "…additional information on socioeconomic status is obtained on the VSD study cohort by linking the ZIP codes and street addresses of the patients with their respective census tract blocks via 'geocode.'" (Chen et al. 1997)
29. List fields related to patient demographics (e.g. age, sex, race)	Birth date, gender are recorded. Race and/or ethnicity data are not collected
30. What patient identification is retained after verification of event information (e.g. all contact information or pseudo id assigned, is patient ID available for follow-up/outcome information)	
31. List fields related to pre-existing conditions and/or medical history of patient	Past medical diagnoses- ICD 9, codes for prior hospitalizations
32. List fields that capture the clinical condition of patient at time of event	Laboratory--selected results of pathogen-specific cultures and other diagnostic tests Ancillary procedures--selected procedures (e.g. CT scans; MRI) Pharmacy--drug use by classification (e.g. anticonvulsants)
33. List fields related to financial/charge information (e.g. length of stay, charge or payment for care, insurance coverage - Medicare, Medicaid, private, CHAMPUS,	Selection of staff model prepaid health plans minimized potential bias resulting from data generated from FFS claims, the information includes single provider health care systems and Medicaid programs.

Reporting or Database System:	**Vaccine Safety Datalink (VSD)**
uninsured etc)	
34. List any other types of information collected about the patient	Birth certificates, review of state death certificates, chart review, start and stop dates of enrollment in the study, reason for stopping, selected procedures.
G. Fields related to Event/Error/Product Information:	
35.Type of events included (e.g. drug, device, biologic, vaccine, nosocomial infection, surgery mishaps, etc)	Immunization, medical outcomes, potential confounders (factors that affect both vaccination status and incidents of medical events)
36. List fields associated with medication-related events (e.g. drug name, dose, dates of therapy)	All vaccines administered within the study population are recorded. Available data include vaccine type, date of vaccination, concurrent vaccines--those given during the same visit), the manufacturer, lot number and injection site.
37. List fields associated with medical device-related events (e.g. brand name of device, type of device, usage, manufacturer name, operator of device)	N/A
38. List fields associated with vaccine related events	Immunization records, vaccine type, date of administration, vaccine manufacturer, lot number, site of vaccination (all information required by the National Childhood Vaccine Injury Act of 1986).
39. List fields associated with infection related events	Laboratory--selected results of pathogen-specific cultures and other diagnostic tests Pharmacy--drug use by classification (e.g. anticonvulsants).
40. List fields associated with any other type of event. List type of event.	
41. List fields that allow input and/or classification of the event/harm (narratives, problem codes, adverse event terms)	Medical records are monitored for potential adverse events resulting from immunization captured using ICD 9 codes. VSD focused its initial efforts on examining potential associations between immunizations and 34 serious neurologic, allergic, hematologic, infectious/inflammatory, metabolic conditions. Other outcomes include site abscesses, persistent crying, collapse-hypotonic hyporesponsive episodes, breath holding, SIDS, Apnea, vaccine adverse events and practices such as simultaneous/combine vaccinations and observations of contraindications.
42. List fields associated with when the event occurred.	Date of vaccination
43. List fields associated with tracking the time between the event, when reported, when acted upon, etc.	
44. List fields associated with where the event occurred	Outcome- hospital and emergency dept. visits (all sites), outpatient clinic visits (2 sites only)
45. List fields associated with patient diagnosis, care, treatment, tests, and other follow-up provided to patient because of the event.	Ancillary information: procedure--selected procedures such as CT and MRI; laboratory--selected results of pathogen-specific cultures and other diagnostic tests; pharmacy--drug use by classification (e.g. anticonvulsants)
46. List fields related to follow-up of event that are not associated with a particular patient (medication/manufacturing/policy actions to correct/update event)	Multiple research studies testing ad hoc vaccine safety hypothesis are performed arising from medical literature, VAERS, changes in immunization schedules, introduction of new vaccines. Examples include risk of hospitalization because of aseptic meningitis after MMR vaccine of children ages 1-2; safety of 2nd dose of MMR for children 4-6 & 10-11; safety of revaccination with pneumococcal polysaccharide vaccine; varicella serology among school-age children with a negative or uncertain hx of chickenpox; impact of the inactivated poliovirus vaccine/oral poliovirus vaccine sequential schedule on vaccination coverage.

Reporting or Database System:	Vaccine Safety Datalink (VSD)
47. List fields related to the outcome of event	
48. List any other fields related to the event or any other information collected by the reporting system (e.g. root cause analysis, investigations etc.)	Hypothesis testing via formal research methods attempts to discover causal relationship between adverse outcomes and vaccination from a macro-population oriented perspective, not from an individual patient perspective.
H. Implications	
49. Integration with other systems	
50. Methods used to de-identify data	
51. Technical issues	

Part III. Data Use and Analysis:	
78. System Contact	Dr. Bob Davis
79. Contact Address	
80. Contact Phone	(206) 685-4028
81. Contact Email	rad2@cdc.gov
82. Hardware Platform	n/a
83. Operating System	n/a
84. Who is the developer?	n/a
85. Who is responsible for the system architecture?	n/a
86. User Types	n/a
87. What is the frequency of reports?	on-going analysis as needed, annual summaries
88. Who generates the reports?	SAS ad-hoc analysis
89.What is the method of access?	CDC - SAS analysis
90. What is the turnaround time?	
91. What is the level of automation?	
92. Type Of Reports	internal reports vary by HMO, CDC receives data annually for merging/analysis
93. What is the unit of observation?	the vaccine (antigen), patient, event
94. What are the available data fields?	standard HMO clinical, claim (utilization), membership, plus CDC/VSD standard format and 34 standard outcomes
95. Is there a controlled vocabulary?	yes
96. Exportability	yes
97. User Profile	HMO -researchers, QI staff, QM staff, CDC- internal staff
98. How are the reports used?	QI, QM, research
99. Report Dissemination	public via CDC summary reports, internal HMO as needed
100. What is the primary goal?	improve post-licensure monitoring of drug safety (vaccines)
101. Linkable to Detail	yes at HMOs only
102. HIPAA Compliant	yes

Appendix C Members of the External Advisory Panel

Geri Amori, Communicating HealthCare

Anne Berdahl, AHA

Robert Crane, Kaiser Foundation Health Plan

Tim Flaherty, AMA

Denise Love, National Association of Health Data Organizations

David Marx, David Marx Consulting

Nancy Foster, AHA

Tom Safranek, Nebraska Department of Health and Human Services

Paul Schyve, JCAHO

Karen Shoos-Lipton, American Association of Blood Banks

Mary Wakefield, University of North Dakota

Appendix D Goals for Integrated Reporting System as Derived from EAP Working Sessions

Identify links between locations, procedures, history and events over time-create episode of care.

Minimize burden of reporting on reporters.

Identify opportunities for patient safety improvement.

Reduce risk of harm to patients.

Identify and address data gaps.

Federal agencies should perform level of analysis and provide more timely dissemination of information.

Provide public with assurance that the federal government is tracking errors and designing solutions.

FDA and other individual agencies would be able to analyze big picture – denominators, background rates.

Improved access to users who might use it in interest of safety – improve public health and reduce individual avoidance of harm.

To combine or eliminate individual systems to reduce burden on agency, burden of ownership (e.g. administrative simplification) and increase efficiency and effectively both at State and Federal level.

Discover causal links between latent errors and adverse events and between adverse events and longer term use of services, patient outcomes and costs.

New system should maximize the input of data; easy to report, minimize cost of report (including fear), maximize benefit of reporting.

Facilitate retrieval of info to serve as pt safety mgt tool for healthcare facilities and organizations to improve local system.

Uniform standardized access protections for reporting of information and feedback to public. New integrated database would provide a standard means of protection for public accountability – release of information is done in a standard manner and protection of information is done in a standardized way. Currently, varying levels of protection of the disparate databases.

Release of information for public accountability.

Aggregated information will be forcing function for alignment of the disparate systems, common taxonomy, and so forth.

Reduce training requirements and learning curves.

Better allocation of fed resources for attacking issues important to all of HHS (e.g., allocation of dollars and set priorities in a rational way).

One set of patient safety coding standards, indicator standards and transaction standards

Systematic feedback loop to reporting facilities and individuals

Use as an assessment of the success of federal pt safety interventions – evaluative function over time

Increase accountability of government actions regarding patient safety—easier to take action. Will also provide info to private agencies for use in the public good. Will be better able to see latent errors, will promote informed decision-making. Assume will take action, create a prudent purchaser/ regulator.

Identify which reporting systems should be grouped together.

Improve and demonstrate ROI for the reporting systems.

Provide a research base to identify risks and hazards for patient care.

Eliminate existing standalone databases if possible.

Ensuring patient safety can mean ‘law suits’, help consumers select providers; help states evaluate providers, help identify levels of practice.

Appendix E Anticipated and Potential User Groups Affected by Development of Integrated System

Patients

Purchasers of healthcare, insurance co, employers, government-state, federal

Agencies involved in quality improvement and /or patient safety (e.g., public and private, accreditation agencies)

PSTF agencies (i.e., CMS, FDA, CDC, AHRQ)

Public policy makers-local, state, and federal agencies, congress

Patient safety improvement team at point of care – any facility

State departments of health in regulatory responsibilities

Media

Lawyers--plaintiff and defense attorneys

Health services researchers

Pharmaceutical companies, manufacturers, PHRMA and others who currently use reporting systems based upon compliance with regulations

Federal and state agencies from regulatory perspective (e.g. attorneys general)

PROs and quality improvement organizations

State and Federal executive branches

Educational institutions and students

Other countries, international policy makers

Commercial vendors of products, services, Rx companies, consultants

Labor unions (as health care purchasers and representatives of employees)

Managed care organizations

Health care organizations and associations (AHA, AMA)

Hospital boards of directors

Medical liability insurers

Local departments of health

Executive management team at a health care facility (e.g., CEO, CIO)

Legislative fiscal analysts – prepare budgets, state and federal government legislation

Patient care givers

Alternative medicine care givers

Patient families and/or personal representatives

Advocacy groups

Patient representatives

Non-governmental funders of research, foundations

Public (not necessarily in healthcare)

State board of professionals licensing responsibility

Providers conducting research for their own practice

Medical record coders

Standards organizations (e.g., ISO, ANSI, ICH)

Other industries, benchmarking (e.g., aviation, high risk industries for sharing best practices)

Accreditation agencies

Risk managers, underwriters, actuaries- who are looking to purchase liability insurance

Anyone with FOIA request

Hospital supply purchasers

Federal agencies

Medical staff offices

Appendix F Sample Data Collection Forms

FDA Form 3500

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291 Expires: 04/06/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. **Patient identifier** — In confidence
2. **Age at time of event:** or **Date of birth:**
3. **Sex** ☐ female ☐ male
4. **Weight** ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☐ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)
2. **Outcomes attributed to adverse event** (check all that apply)
   - ☐ death ____ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization - initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ____
3. **Date of event** (mo/day/yr)
4. **Date of this report** (mo/day/yr)
5. **Describe event or problem**
6. **Relevant tests/laboratory data,** including dates
7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. **Name** (give labeled strength & mfr/labeler, if known) #1 #2
2. **Dose, frequency & route used** #1 #2
3. **Therapy dates** (if unknown, give duration) from/to (or best estimate) #1 #2
4. **Diagnosis for use** (indication) #1 #2
5. **Event abated after use stopped or dose reduced** #1 ☐ yes ☐ no ☐ doesn't apply; #2 ☐ yes ☐ no ☐ doesn't apply
6. **Lot #** (if known) #1 #2
7. **Exp. date** (if known) #1 #2
8. **Event reappeared after reintroduction** #1 ☐ yes ☐ no ☐ doesn't apply; #2 ☐ yes ☐ no ☐ doesn't apply
9. **NDC #** (for product problems only) - -
10. **Concomitant medical products** and therapy dates (exclude treatment of event)

D. Suspect medical device

1. **Brand name**
2. **Type of device**
3. **Manufacturer name & address**
4. **Operator of device**
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: ____
5. **Expiration date** (mo/day/yr)
6. **model #** ____ **catalog #** ____ **serial #** ____ **lot #** ____ **other #**
7. **If implanted, give date** (mo/day/yr)
8. **If explanted, give date** (mo/day/yr)
9. **Device available for evaluation?** (Do not send to FDA) ☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)
10. **Concomitant medical products** and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. **Name & address** **phone #**
2. **Health professional?** ☐ yes ☐ no
3. **Occupation**
4. **Also reported to**
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. **If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box.** ☐

FDA

Mail to: **MEDWATCH** 5600 Fishers Lane Rockville, MD 20852-9787 **or FAX to:** 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- cosmetics
- medication errors

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling
- therapeutic failures

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-1088 to report by phone or for more information
- 1-800-822-7967 for a VAERS form for vaccines

To Report via the Internet:

https://www.accessdata.fda.gov/scripts/medwatch/

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

Form 3500A

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page ____ of ____

Form Approved: OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

Mfr report #

UF/Dist report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. **Patient identifier** In confidence
2. **Age at time of event:** or **Date of birth:**
3. **Sex** ☐ female ☐ male
4. **Weight** _____ lbs or _____ kgs

B. Adverse event or product problem

1. ☐ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)
2. **Outcomes attributed to adverse event** (check all that apply)
   - ☐ death _____ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: _____
3. **Date of event** (mo/day/yr)
4. **Date of this report** (mo/day/yr)
5. **Describe event or problem**
6. **Relevant tests/laboratory data**, including dates
7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. **Name** (give labeled strength & mfr/labeler, if known)
   #1
   #2
2. **Dose, frequency & route used**
   #1
   #2
3. **Therapy dates** (if unknown, give duration) from/to (or best estimate)
   #1
   #2
4. **Diagnosis for use** (indication)
   #1
   #2
5. **Event abated after use stopped or dose reduced**
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. **Lot #** (if known)
   #1
   #2
7. **Exp. date** (if known)
   #1
   #2
8. **Event reappeared after reintroduction**
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. **NDC # –** for product problems only (if known)
   – –
10. **Concomitant medical products** and therapy dates (exclude treatment of event)

D. Suspect medical device

1. **Brand name**
2. **Type of device**
3. **Manufacturer name & address**
4. **Operator of device**
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: _____
5. **Expiration date** (mo/day/yr)
6. **model #** _____
   catalog # _____
   serial # _____
   lot # _____
   other #
7. **If implanted, give date** (mo/day/yr)
8. **If explanted, give date** (mo/day/yr)
9. **Device available for evaluation?** (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on _____ (mo/day/yr)
10. **Concomitant medical products** and therapy dates (exclude treatment of event)

E. Initial reporter

1. **Name & address**
   phone #
2. **Health professional?** ☐ yes ☐ no
3. **Occupation**
4. **Initial reporter also sent report to FDA** ☐ yes ☐ no ☐ unk

FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Medication and Device Experience Report

(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

FDA Use Only

F. For use by user facility/distributor – devices only

1. **Check one** ☐ user facility ☐ distributor
2. **UF/Dist report number**
3. **User facility or distributor name/address**
4. **Contact person**
5. **Phone Number**
6. **Date user facility or distributor became aware of event** (mo/day/yr)
7. **Type of report** ☐ initial ☐ follow-up # ____
8. **Date of this report** (mo/day/yr)
9. **Approximate age of device**
10. **Event problem codes** (refer to coding manual) patient code ___ – ___ – ___ device code ___ – ___ – ___
11. **Report sent to FDA?** ☐ yes ____ (mo/day/yr) ☐ no
12. **Location where event occurred** ☐ hospital ☐ home ☐ nursing home ☐ outpatient treatment facility ☐ other: ____ specify ☐ outpatient diagnostic facility ☐ ambulatory surgical facility
13. **Report sent to manufacturer?** ☐ yes ____ (mo/day/yr) ☐ no
14. **Manufacturer name/address**

G. All manufacturers

1. **Contact office – name/address** (& mfring site for devices)
2. **Phone number**
3. **Report source** (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☐ other: ____
4. **Date received by manufacturer** (mo/day/yr)
5. (A) NDA # ____ IND # ____ PLA # ____ pre-1938 ☐ yes OTC product ☐ yes
6. **If IND, protocol #**
7. **Type of report** (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ Initial ☐ follow-up # ____
8. **Adverse event term(s)**
9. **Mfr. report number**

H. Device manufacturers only

1. **Type of reportable event** ☐ death ☐ serious injury ☐ malfunction (see guidelines) ☐ other: ____
2. **If follow-up, what type?** ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. **Device evaluated by mfr?** ☐ not returned to mfr. ☐ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code: ____
4. **Device manufacture date** (mo/yr)
5. **Labeled for single use?** ☐ yes ☐ no
6. **Evaluation codes** (refer to coding manual) method ___ – ___ – ___ – ___ results ___ – ___ – ___ – ___ conclusions ___ – ___ – ___ – ___
7. **If remedial action initiated, check type** ☐ recall ☐ repair ☐ replace ☐ relabeling ☐ other: ____ ☐ notification ☐ inspection ☐ patient monitoring ☐ modification/ adjustment
8. **Usage of device** ☐ initial use of device ☐ reuse ☐ unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ **Additional manufacturer narrative** and/or 11. ☐ **Corrected data**

Please DO NOT RETURN this form to this address.

FDA Form 3500A - back

FDA form 3486

Department of Health and Human Services
Food and Drug Administration

Biological Product Deviation Report

FDA Use Only

Date Received:
Date Reviewed:
BPD ID:
BPD No:

* Indicates Required Information

A. Facility Information

1. Reporting Establishment Information:

* Reporting Establishment Name:	
* Street Address Line 1:	
Street Address Line 2:	
* City:	
* State:	* Zip Code:
Country:	
* Point of Contact:	
* Telephone #:	E-mail:

2. * Reporting Establishment Identification Number:

FDA Registration #: CLIA #:

3. If the BPD occurred somewhere other than the above facility, please complete this Section and Section A4, otherwise continue onto Section B1.

* Establishment Name:	
Street Address Line 1:	
Street Address Line 2:	
* City:	
* State:	Zip Code:
* Country:	

4. Establishment Identification Number:

FDA Registration #: CLIA #:

B. Biological Product Deviation (BPD) Inform

1. Establishment Tracking #:
2. Date BPD Occurred:
3. * Date BPD Discovered:
4. * Date BPD Reported:
5. * Description of BPD (use Page 2 for additional space):
6. * Description of Contributing Factors or Root Cause (use for additional space):
7. * Follow-Up (use Page 4 for additional space):
8. * Please Enter the 6 character BPD Code: [ ][ ]-[ ][ ]-[ ][ ]

C. Unit/Product Information

Please check the type of product:

☐ Blood (Continued on Page 5)

Non-Blood ☐ (Continued on Page 6)

Form FDA 3486 (3/01)
Form Approved: OMB No: 0910-0458 Expires: 2/29/2004

Biological Product Deviation Report

B5. Description (continued)

Biological Product Deviation Report

B6.Description of Contributing Factors or Root Cause (Continued)

Biological Product Deviation Report

B7.Follow-Up (Continued)

Biological Product Deviation Report

C1. Blood Products/Components

Total Number of Units: _____

** RN = Reverse Notification

Unit #	Collection Date (MM/DD/YYYY)	Expiration Date (MM/DD/YYYY)	ProductCode		Notification (Y, N, RN**)
1.)					
2.)					
3.)					
4.)					
5.)					
6.)					
7.)					
8.)					
9.)					
10.)					
11.)					
12.)					
13.)					
14.)					
15.)					
16.)					
17.)					
18.)					

Biological Product Deviation Report

C2. Non-Blood Products

Total Number of Lots: _____

Lot #	Expiration Date (MM/DD/YYYY)	Product Type	Product Code	Distribution	Notification (Y, N)
1.)					
2.)					
3.)					
4.)					
5.)					
6.)					
7.)					
8.)					
9.)					
10.)					
11.)					
12.)					
13.)					
14.)					
15.)					
16.)					
17.)					
18.)					

Biological Product Deviation Report

D. Additional Comments

Appendix G Definitions and Classification Systems

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Adverse Events - near misses	Safety Assessment Code Matrix, VA NCPS Department of Veterans Affairs National Center for Patient Safety (10X) 24 Frank Lloyd Wright Drive Lobby M PO Box 486 Ann Arbor, MI 48106-0486 http://www.va.gov/ncps/matrix.html	Developed by staff at the National Center for Patient Safety, this matrix provides a standard set of criteria for VA hospital staff to use in assessing whether to proceed with further investigation following an adverse event or close call. Its criteria are consistent with the Safe Medical Devices Act, JCAHO patient safety standards and OSHA requirements for worker safety. The matrix consists of two dimensions - level of severity and probability of occurrence. The tool describes each level of severity with specific examples and includes harm to visitors, staff and patients. A Matrix score of 3 or higher is the requisite for performing a root cause analysis in VA facilities.	Incorporates various JCAHO, FDA, and OSHA standards into the severity level categories. Similar to MERS-TM in terms of using a risk assessment index for determining further investigation of an event or near miss.
Adverse events - near misses	Risk Assessment Index MERS-TM Medical Event Reporting System - Transfusion Medicine Sponsored by The National Heart, Lung, and Blood Institute, in cooperation with FDA Primarily based at Columbia University, Harold S. Kaplan, MD as the Principal Investigator. hsk18@columbia.edu Columbia University, Harkness 4-418, 622 West 168 St, NY, NY 10032	In MERS-TM all events receive routine investigation - gathering basic information about the event. Selecting an event for more thorough investigation (root cause analysis) involves assessing the risk involved with the event - how much harm could or did occur. Risk is dependent on: the severity of the event, the probability that it will happen again, whether or not a product was issues, they type of recovery. As with the VA index, the MERS-TM index is measured along two dimensions - Quantified Estimate of Severity (QES) * Quantified Estimate of Priority (QEP). A root cause analysis is recommended if the risk assessment index (RAI) is >=.5 or RAI is low, but risk to organization is high. In addition, if the risk assessment index (RAI) is <.5, then MERS-TM recommends monitoring the event type. If the RAI >=.5 and <= .7, the monitor the event type and consider change. If the RAI is >.7, monitor the event type and propose change. If the organizational risk is high, action steps are determined by management.	Offers a more granular assessment of risk than VA index. Also has adjustment based upon whether the product was issues and the type of recovery from the event. Like the VA, MERS-TM offer training in determining the RAI and using the model

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Adverse events - drug-diagnosis interactions	MediSpan GPI Code MediSpan, Inc. 8425 Woodfield Crossing Boulevard, Indianapolis, IN 46240. Tel: (800)428-4495 http://www.medispan.com/products.htm	Proprietary software produce of drugs and drug-diagnosis adverse interactions for checking potential interactions. Hierarchical drug codes for identifying drugs down to manufacturer and pill size.	
Adverse events - drug-diagnosis interactions	Durg-Reax and Drug-Dex MicroMedex, Inc. http://www.micromedex.com/products/	Proprietary software information on known adverse drug reactions (Drug-Reax and Drug-Dex) and poisonings (Poisindex), among other modules of information. For example, Drug-Reax allows users to search for drug-drug, drug-food, drug-disease, drug-ethanol, drug-tobacco, and drug-laboratory-test interactions, along with known allergic reactions. It provides information on dosage, pharmacokinetics, cautions, interactions, clinical applications, adverse effects, comparative efficacy, drug of choice information, and orphan drug status. Drug-Dex, the drug-disease module, is based on and documents the evidence related to FDA-approved and investigational prescription and non-prescription drugs, as well as products produced outside the U.S. Module info: http://www.micromedex.com/products/healthcare/druginfo/ Drug-Reax Fact sheet: http://www.micromedex.com/products/drugreax/drugreax_factsheet.pdf Drug-Dex Fact sheet: http://www.micromedex.com/products/drugdex/drugdex_factsheet.pdf	

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Adverse events - drugs	COSTART - Coding Symbols for Thesaurus of Adverse Reaction TermsFood and Drug Administration (FDA)Available from National Technical Information Service http://www.ntis.gov/fcpc/cpn5580.htm	COSTART is the terminology developed by the FDA for the coding, filing and retrieving of post-marketing adverse reaction reports. It was designed to reduce the variation in vocabulary used by those who submit adverse event reports to the FDA. Still used by some manufacturers who submit adverse events to FDA, but is being phased out.	FDA AERS (Adverse Event Reporting System) will be creating a regulation soon to require the manufacturers to use MedDRA, especially those who submit information electronically. The other event reporting systems in FDA (e.g. MAUDE, MedWatch, MERS-TM, BPD) do not require the use of MedDRA for classifying events. MAUDE will accept COSTART, MedDRA, or any other classification terminology system. MERS-TM and BPD have their own classification terminologies. MedWatch does not require the use of a terminology by the user. Terminology depends of type of adverse event reported on the MedWatch voluntary form.
Adverse events - drugs	Definitions and Basic Requirements for the Use of Terms for Reporting Adverse Drug Reactions CIOMS: Council for International Organizations of Medical Sciences, Drug Development and Use Program Book and CD are available for purchase at: http://www.cioms.ch/	CIOMS: Council for International Organizations of Medical Sciences, Drug Development and Use Program	CIOMS forms are currently accepted by AERS in place of the form FDA 3500A or VAERS form for foreign serious and unexpected reports only (15 day reports) and should contain, at a minimum, information including an identifiable source, a patient (even if not precisely identified by name and date of birth), a suspect product and a suspect event.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Adverse events - drugs	ICH E2B: International Conference on Harmonization of Technical Requirements for registration of Pharmaceuticals for Human Use, E2B Committee International Federation of Pharmaceutical Manufacturers Association (IFPMA) http://www.ifpma.org/pdfifpma/e2bm.pdf	ICH E2B provides a format for transmitting all relevant data elements useful to assess an adverse drug reaction or adverse event report. It was created by IFPMA which represents the international pharmaceutical industry. The purpose was to standardize data elements for transmission of individual case safety reports by identifying, and where necessary or advisable, by defining the data elements for the transmission of all types of individual case safety reports, regardless of source and destination. This included case safety reports for both pre and post approval periods and covers both adverse drug reaction and adverse event reports. Data elements include: 1. ID of report - e.g. sender, country, date of transmission, type of report, seriousness (criteria=results in death, life-threatening, requires inpatient hospitalization, prolongs hospitalization, results in persistent or significant disability, is congenital/birth defect, other medically important condition, date received, etc 2. Primary source - e.g. reporter identifier, reporter address, country, qualifications=physician, pharmacist, other health professional, lawyer, consumer, reference to literature, etc 3. Information on sender and receiver of case safety report - e.g. sender with type=drug company, regulatory authority, health professional, regional pharmacovigilance center, WHO collaborating center for drug monitoring, other, sender ID, receiver with type=drug company, regulatory authority, health professional, regional pharmacovigilance center, WHO collaborating center for drug monitoring, other, receiver id, receiver contact info. 4. Patient characteristics - e.g. name, MR#, age, weight, height, sex, medical history, concurrent conditions, past drug history, death info (if applicable), parent info (if applicable)5. Reaction/event (narrative, MedDRA term - note use of ICH E2A criteria to classify seriousness of event, dates, duration, outcome)6. Results of tests relevant to AE investigation7. Drug info - e.g. drug id, dosage, route of admin, start date, relatedness of drug to event8. Narrative case summary and further information - e.g. clinical course, reporter comments, sender commentsHas lists for units of measure, time intervals, route of admin, etc codes	Currently used in AERS electronic transmission of periodic reports from select manufacturers (pilot has 4 members). Not used in other FDA event reporting systems. CDC and FDA both recommend the work of the harmonization group. ICH E2B categories can be converted to NCCMERP.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Adverse events - drugs	National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy of Medication Errors http://www.nccmerp.org	To provide a standard language and structure of medication-error related data for use in developing databases to analyze medication error reports. Some fields require selection from a defined list of choices and other require entry of free text. Major categories: 10 - Patient Information 20 - The Event; 21 - Date; 22 - Time; 23 - Setting of initial error; 24 - Setting where error perpetuated; 25 - Description of Event 30 - Patient outcome; 31 - No error; 32 - Error, no harm; 33 - Error, harm; 34 - Error, death 50 - Product Information; 51 - General; 52 - Dosage Form; 53 - Packaging - container; 54 - Pharmacologic/therapeutic classification (use AHFS codes or VA codes); 55 - Product information; 56 - status; 57 - dosage form; 58 - packaging container; 60 - Personnel involved; 61 Initial error made by; 62 - Error perpetuated by; 63 - Error discovered by; 70 - Type - used for errors only, not near misses - examples dose omission, improper dose, wrong dose, wrong time, wrong rate, wrong patient, wrong route of admin, wrong duration, deteriorated drug, wrong strength/concentration, wrong drug, wrong dosage form, wrong technique 80 - Causes - 81- Communication; 83 - Name confusion; 85 - Labeling; 87 - Human Factors; 89 - Packaging/Design; 90 - Contributing Factors (systems related)	Besides the major listed categories, NCCMERP worked with ISMP and FDA to come up with customizations to taxonomy for classifying errors under the US Pharmacopeia MERS system. A utility takes the data from AERS, adds NCCMERP classification to adverse drug event then transfers to another database. Note: At AHRQ patient safety conference there was discussion among patient safety grantees that the NCCMERP error/harm classification confuses too many dimensions of the problem - harm to the patient, severity of the incident etc.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Adverse events - drugs and devices	MedDRA: Medical Dictionary for Regulatory ActivitiesInternational Federation of Pharmaceutical Manufacturers Association (IFPMA) http://www.meddramsso.com/default.htm	MedDRA is a standard international terminology for regulatory communication in the registration, documentation, and safety monitoring of medical products throughout all phases of their regulatory cycle. MedDRA, a controlled clinical vocabulary, is used for the electronic transmission and retrieval of adverse event data. It also is applicable to the health effects of devices. The MedDRA system can link with Autocode CS to automatically identify and assign classification terms from narrative text. Unlike ICD or SNOMED, MedDRA was specifically developed to classify the health effects of drugs. For example, instead of identifying abdominal pain as a symptom - MeDDRA has terms for low abdominal pain vs. upper abdominal pain to more clearly reflect the adverse reaction that is occurring as a result of the medication or device. Categories of terms include: symptoms, signs, diseases, diagnoses, therapeutic indications, names and qualitative results of investigations, including pharmacokinetics, surgical and medical procedures, medical/social/family history. The structure is:System organ class (SOC) - highest level of hierarchy (26 broad concepts for data retrieval), including etiology (e.g., infections and infestations); manifestation site (e.g., gastrointestinal disorders), purpose (e.g., Surgical and medical procedures).High level group term (HLGT) - 333 superordinate descriptors for one or more "high level terms (HLTs)," related by anatomy, pathology, physiology, etiology, or function; used solely for data retrieval.High level term (HLT) - 1,685 superordinate descriptors for the preferred terms(PTs) linked by anatomy, pathology, physiology, etiology or function.Preferred term (PT) - 14,287 single medical concepts for a symptom, sign, disease, diagnosis, therapeutic indication, investigation, surgical or medicalprocedure, medical, social or family history characteristic.Low level term (LLT) - 51,083 termsExcludes equipment, device and diagnostic product and failure terms, patient demographic terms, numeric values associated with investigations or observation (e.g. lab results), and severity indicators. Verified by MSSO help desk on 3/11.	MedDRA is currently updated 2x per year. MedDRA is recommended by AERS at FDA as the sole error classification system. CBER and CFSAN are getting ready to use MedDRA. MedDRA is also being considered by CDRH to classify the health effects of devices. Also, recommended as a standard by the ICH E2B committee and regulatory authorities of Europe, US, and Japan as a controlled vocabulary for electronic transmission. MedDRA and ICH E2B are both IPHMA entities. Difficult to obtain details on system due to proprietary nature of product. Cost is $3000-10000/year depending on non-profit status and size of company. From the AERS manual for data entry staff, coding the narrative portion of an AE form into key words from MedDRA allows a consistent description of events while retaining the essence of the initial reporter's own words. AERS coders are instructed to code only signs and symptoms of adverse events, reporter assigned diagnoses, relevant lab test results, and significant medical/surgical procedures that provide important information about the AE. Prior medical history should not be coded unless the history was aggravated by the event. There is a crosswalk between MedDRA and ICD terms, but ICD numeric codes are not used. According to Pat Revelle, MedDRA includes all of COSTART, WHO-ART and

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Adverse Events -- Devices	Cause of Device-Related Incident ECRI http://www.ecri.org/documents/448207.htm for product information	ECRI assigns a "Cause of Device-Related Incident" to each filed report. There are five broad "cause" categories with each having a sub-category: 1) Device Factors – design/labeling error; device failure; device interaction; failure of accessory; improper maintenance/testing/repair/or lack or failure of incoming inspection; improper modification; invalid device foundation; manufacturing error; packaging error; random component failure; software deficiency. 2) External Factors – electromagnetic or radio-frequency interference; environment/temperature/humidity/light; medical gas/vacuum supplies; power supply/including compressed medical gasses; water supply. 3) Support System Failures – error in hospital policy; failure to impound; failure to train and/or credential; improper storage; lack of competent accident investigation; lack or failure of incoming and pre-use inspections; poor incident/recall reporting systems; poor pre-purchase evaluation; use of inappropriate devices. 4) Tampering and/or Sabotage. 5) User Errors – abuse of device; accidental spill; device mis-assembly; failure to perform pre-use inspection; failure to read label; improper connection; inappropriate reliance on an automated feature; incorrect clinical use; incorrect control settings; incorrect programming.	May be valuable as a comprehensive root cause analysis classification for devices.
Adverse events - transfusion medicine	Eindhoven Classification Model, Medical VersionT.W. Van der Schaaf - created model for chemical industry and adapted it for medicine with J. Battles and MERS-TM teamhttp://www.mers-tm.net	Nineteen codes to classify events based upon the results of a root cause analysis: 1) technical; 2) organizational; and 3) human causes, consistent with latent and active error theory and with the classification of human behavior into skill-, rule-, and knowledge-based behavior: Latent errors, Technical - external, design, construction, materials, Organizational - external, protocols/procedures, transfer of knowledge, management priorities, culture Active Errors (Human) Knowledge-based behavior - KB errors Rule-based behavior - qualifications, coordination, verification, intervention, monitoring Skill-based behavior - slip, tripping Other factors - patient-related factors, unclassifiable. In MERS-TM, these categories are assigned as the end result of a formal root cause analysis. Used for searching for errors that are similar.	Use of this system requires training, especially for those with non-QA background. May require monitoring and guidance to ensure consistency of coding between systems. See article - "A system of analyzing errors to improve GME curricula and programs" for examples of its use in patient care examples.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Clinical alerts	HL7 Arden Syntax Columbia University http://www.cpmc.columbia.edu/arden/	The Arden Syntax for Medical Logic Modules (MLMs) is a language for encoding medical knowledge. It was previously adopted as a standard by ASTM Subcommittee E31.15 on Health Knowledge Representation. An MLM produces a message based upon some triggering criteria in an application. MLMs can trigger each other, perform institution-specific actions and/or communicate with applications. Arden Syntax is currently used for sharing of clinical practice guidelines among institutions and for compliance with institution specific quality assurance activities. The message (any coded or narrative result) the MLM produces can be in the following forms: Alert - a clinical message sent to the provider taking care of a patient, warning her of some concern; it is usually flagged in some way; Interpretation - a non-emergent message for the provider, intended to supply passive information; Diagnosis Support Screen - a message sent to a researcher or quality assurance officer informing them of a patient that fits some criteria (often sent over e-mail).	Has been used for generating messages to healthcare professional regarding clinical practice guidelines. Has the potential to be used as a way to remind staff of important patient safety considerations - e.g. length of time from initial admit to initiate antibiotics, test level exceeds recommended standards, drug interaction.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Computerized medical records	SNOMED: Systematized Nomenclature of Human and Veterinary MedicineCollege of American Pathologists325 Waukegan Rd, Northfield, IL 60093; jnrs@cap.org http://www.snomed.org/snomedct.html - for product documentation and information	SNOMED CT is the latest release of the SNOMED product. It is a relational database of the entire medical vocabulary including symptoms, diagnoses, and procedures, created to code information in the medical record into machine readable form. Among its purposes: to collection of clinical data, linking clinical knowledge databases, case retrieval, sharing and exchanging of data, data aggregation and reuse. It has been cited as a strong candidate as the standard vocabulary and data model for computer-based patient records. SNOMED International indicates that it is widely used (e.g., in electronic health records, clinical laboratory and radiology systems, infectious disease reporting, HEDIS reporting, emergency rooms, case reports for clinical research, cancer registries, literature search, outcomes assessment, telemedicine, autopsy databases, and web-based consumer information). SNOMED CT is the result of collaboration between the College of American Pathologists and the National Health Service (NHS) that combined SNOMED RT (Reference Terminology) and Clinical Terms Version 3 of the NHS thesaurus of health care terms (Read Codes V3). This product combines the strength of SNOMED RT in specialty medicine, including pathology, and the richness of Read Codes V3 in primary care. [I made changes to this narrative and column "L"]in primary care.	Rated number 1 by CPRI which evaluated all available coding systems for their ability to be used as a common medical terminology. [Tried to find out more about this rating from CPRI via email and phone - no success as of 3/11 -TR] NCVHS characterized SNOMED as a system that represents a convergence of the various diagnosis, procedure, medical language, nursing, and drug codes (NCVHS, 2000, p. 36), which makes it more comprehensive than ICD codes. Should be evaluated against MedDRA as a standard for coding narrative text. SNOMED concepts that can be viewed as adverse events are similar to ICD-9-CM, for example, adverse drug reactions, complications of surgical procedures, and injury concepts. SNOMED International has not yet identified which of these would be included in an adverse event subset, but anticipate that this may be a future project (LaJoie P. Personal Communication, February 27, 2002). Example from UMLS: UMLS term - Adverse Effect of Medication NOSSNOMED v2 - Adverse Drug Effect (F-Y0200), drug reactionRead Code 99 - Drug Reaction, adverse reaction to drugAbove are arrived at through different semantic trees. Would be true of any selected term.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Devices	UMDNS: Universal Medical Device Nomenclature System ECRI http://www.ecri.org/documents/448207.htm for product information	To facilitate identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices.	Adopted by European Union at the recommendation of the European Standards body. Free to nonprofits, government and device manufacturers, but must sign license agreement. ECRI and FDA's CDRH agreed in 1997 to harmonize both UMDNS and FDA's device classification system, but was superceded by work with GMDN. FDA is going to adopt GMDN when that becomes available.
Devices	GMDN: Global Medical Device Nomenclature	The GMDN is a collection of internationally recognized terms used to accurately describe and catalogue medical devices into 12 categories. In particular, the products used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans. It will be used for: data exchange (e.g. as used in the Eudamed - European Database on Medical Devices); vigilance (transfer of information following specific incidents); conformity assessment (CE marking and certification marks); and procurement More than 70 experts from Europe, Japan and the United States of America, including manufacturers, healthcare authorities and regulators, compiled the GMDN. The work was supported financially by the European Commission and the secretariat was provided by the British Standards Institution.	CDRH is participating in CEN sponsored effort to develop this nomenclature system. MedSun Pilot will begin using GMDN after obtaining licensing rights.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Diagnoses	ICD-9 and ICD-10: International Classification of Disease, Ninth Edition and Tenth EditionWorld Health Organization (WHO), Collaborating Center for Classification of Disease for North America (located at the USDHHS, CDC, National Center for Health Statistics)http://www.cdc.gov/nchs/icd9.htm	ICD-9 and ICD-10 are used for classification of mortality throughout the world. They are the parent system of the US ICD-9-CM and ICD-10-CM and Australian ICD-10-AM. ICD-10 and ICD-10-CM have not yet been implemented in the US, but have updates to both content and format. These include: the addition of information relevant to ambulatory and managed care encounters; expanded injury codes; the creation of combination diagnosis/symptom codes to reduce the number of codes needed to fully describe a condition; the addition of a sixth character; incorporation of common 4th and 5th digit subclassifications; laterality; and greater specificity in code assignment. The new structure will allow further expansion than was possible with ICD-9-CM. See ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD9-CM/2001/ for complete list of terms. Includes over 10,000 diagnoses and 7,000 procedures.	Groups in various countries (including the US and Australia) are reviewing how ICD-9 and ICD-10 coding systems can be used to enhance and/or standardize error reporting. See entry for National Center for Classification in Health and ICD-9-CM entry for details.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Diagnoses and procedures	ICD-9-CM and ICD-10-CM: International Classification of Disease, Ninth and Tenth Editions, Clinical Modification National Center for Health Statistics (NCHS) and the Centers for Medicare and Medicaid Services (CMS) http://www.cdc.gov/nchs/icd9.htm for more information Donna Pickett 301-458-4434 dfp4@cdc.gov	Sole classification system used for morbidity reporting in the US. All health care claims in US must list the ICD-9-CM diagnosis code. The code set is also widely accepted and used by the public and private sector for - data collection, quality of care analysis, resource utilization, research and reimbursements, and statistical reporting. ICD-10-CM has not yet been implemented. ICD-9-CM is also used in Australia and Israel. In addition - ICD-9-CM volume 3 is used for coding of procedures for inpatients. CMS is developing ICD-10-PCS to replace volume 3 procedures. See ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD9-CM/2001/ for complete handbook.	A recent study by the Utah Department of Health (6-2001) attempted to use ICD-9-CM e-codes and n-codes to estimate the prevalence and nature of adverse events in Utah facilities. E-codes are used to code external causes of injury and poisoning. N-codes are non-injury/poisoning codes. Utah used the codes to classify according to the following categories: *misadventures of surgical and medical care - harm due to medical intervention *complications of surgical or medical procedures - hard to determine whether due to poor care or patient factors *adverse drug events and complications of medications - hard to determine if occurred during stay or prior, due to poor care or patient factors. This and other studies have identified the following problems with the use of ICD-9-CM coding schemes for reporting safety events.*E-codes usually are not required for billing purposes and thus are not always entered, except E930-E949, related to adverse effects of medication, are required in some States (per Cathy Barnes at MEDSTAT). See details of E930-949 at http://www.e-mds.com/icd9/E930-E949/index.html*Codes are not comprehensive for classifying all possible adverse events and there is no coding scheme (structure/hierarchy etc.) for

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Diagnoses	ICD-10-AM: International Statistical classification of Disease, Australia ModifiedNational Center for Classification in Health (Australia)http://www.cchs.usyd.edu.au/ncch/	Used for classification of morbidity and mortality. ICD-10-AM will supersede ICD-9-CM in Australia.	To improve classification of adverse events, NCCH is proposing a third edition of ICD-10-AM to include a 'flag' for each morbidity that would indicate whether the morbidity occurred before, during, or after hospitalization. One such scheme in Australia (Victoria) uses alphabetic prefixes on each diagnosis code to indicate the time of occurrence. A few States in USA also use a separate flag for occurrence of diagnosis in discharge records (e.g., NY and CA). NCCH proposes to implement the flag in Australia by July 2002 and included it in the National Health Data Dictionary.
Diagnoses and procedures and other	Canonical Clinical Problem Statement System Version 1 Vanderbilt University Steven Brown, MD, Dept of Biomedical Informatics	Listing of clinical problem terms connecting diagnosis to therapy, prognosis, and psychosocial issues. Developed to reduce the amount of time that clinicians take to enter information into a computerized patient record. Authors identified 23,503 problem relations (co-occurrences, sign-symptom complexes, and differential diagnoses) and 22,690 modifier words that categorize canonical problems.	Unclear whether there are patient safety terms in this vocabulary. Potentially, similar function to HL7-Arden Syntax in that it could be used to tie patient condition to frequently used terms. Listed in UMLS.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Diagnoses for primary care	ICPCS: International Classification of Health Problems in Primary Care World Organization of National Colleges (WONCA) International Classification Committee http:www.ulb.ac.be/esp/wicc/wicc.html Australian version: http://www.fmrc.org.au/classifi.htm#3	Modified version of ICD-9 intended for use in general practice. Used in the UK and Australia. ICPC-2 Plus was released in 1998 and is specifically designed for use in computerized patient record, disease registers and secondary coding of clinical data. Terminology for identifying - patient reason for encounter, symptoms, diagnosis, procedures, counseling services, referrals, radiology ordered, and administrative procedures.	Primary care version of ICD plus additional information not covered by ICD (see focus).
Drugs	First Data Bank	Supplier of knowledge bases and software concerning drug, medical, and nutrition information	
Drugs	Multum Lexicon Multum Information Services http://www.multum.com/Lexicon.htm	Codes for all prescription and over the counter drugs approved for marketing in the U.S. The system goes to the level of NDC but with a built-in classification structure for aggregating drugs of similar content and therapeutic use. The classification system is maintained and distributed by Multum. A relational database with all detail on the NDCs and about 10 to 15 thousand aggregated terms.	SAMHSA has added illegal drugs for the Drug Abuse Warning Network (DAWN) in a format compatible with Multum's and is currently using the Lexicon for data entry and reporting from hospital emergency departments and medical examiners. And they are using the classification system for analytic reports.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Drugs	National Drug CodesFood and Drug Administration (FDA)http://www.fda.gov/cder/ndc/database/default.htm	An inventory of commercially available drug products approved for marketing in the U.S. Ten-digit codes are assigned by pharmaceutical manufacturers and are maintained by the FDA. The 10-digit codes can be linked directly to the labeling for the product.	NDCs are not designed to support patient care per se (for example, NDCs do not capture the route, dosage, or frequency of administration). The codes are not readily publicly accessible. There is no hierarchy or classification scheme within the drug codes. Other organizations have enhanced the codes to make them more accessible and useable analytically (e.g., Multum Information Services), but these modifications impede standardization of the codes. In decisions by USDHHS on standards to be used under HIPAA law for electronic transactions, NDCs were selected as the single standard for identifying drugs, with the expectation that a classification would be developed and that the NDCs would become publicly available (NCVHS, 2000). However, CMS objected to the replacement of HCPCS "J-codes" with NDCs due to the technical readjustments needed for reimbursement processes; thus, the NDCs may be rescinded as the one definitive standard. Private sector drug claims now use and will continue to use NDCs. NDCs are not assigned to drugs marketed outside the U.S. and are not assigned to blood products, medical devices, in vitro diagnostic products, dietary supplements, or investigational new drugs (NCVHS, 2000). Source(s): National Committee on Vital and Health Statistics (NCVHS). Uniform Data Standards for Patient

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Functioning and disability	ICIDH: International Classification of Functioning and Disability	A classification first issued by the WHO as a common language on disability for clinical use, data collection, and research.	May be relevant for classifying the outcomes of serious adverse events.
Mental illness and substance abuse	DSM: Diagnostic and Statistical Manual of Mental Disorders American Psychiatric Association http://www.psych.org/clin_res/dsm_iv_pc.cfm	Terms and codes for diagnoses and treatments related to mental illness and substance abuse problems, developed to facilitate communication, more reliable diagnoses, education in psychopathology, and collection of statistical data about mental disorders.	Incorporated into the ICD-9-CM classification system of diagnosis and procedure codes.
Meta-thesaurus	UMLS: Unified Medical Language SystemNational Library of Medicinehttp://umlsks.nlm.nih.gov Requires license agreement for id and password	The Metathesaurus contains information about biomedical concepts and terms from approximately 60 controlled vocabularies and classifications used in patient records, administrative health data, bibliographic and full-text databases and expert systems. It is meant for use by developers of classification systems. It preserves the meaning, attributes, hierarchal connections, and other relationships between terms in the source vocabularies, while adding certain basic information about each of its concepts and establishing new relationships between concepts from different source vocabulariesThe Metathesaurus 2002 contains about 777,000 concepts and 2.1 million concept names and more than 11 million relationships in over 60 different vocabularies. It is a tool used by a wide range of applications to: link between different clinical or biomedical vocabularies; link patient records to related information in bibliographic, full-text or factual databases; perform natural language processing and automated index searching; assist in information retrieval from databases with human assigned subject indexes. It supplies linking information that computer programs can use to interpret user inquiries, interact with users to refine their questions, identify which databases contain information relevant to particular inquiries, and convert the users' terms into the vocabulary used by a particular information source. Used by developers as a method for improving search strategies and linkages within a particular application.	The UMLS contains the major adverse event vocabularies, but does not allow access to proprietary systems (e.g., MedDRA) without obtaining copyright from the source. External system team used UMLS (65 systems) and HISB Inventory of Standard Classification Systems (16 systems) as sources for identifying classification systems here.
Nursing diagnoses	NANDA: North American Diagnosis Association	Nursing diagnoses that describe patient reactions to disease.	
Nursing diagnoses	NIC: Nursing Intervention Classifications	Classification that names and describes treatments performed by nurses.	

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Nursing outcomes	NOC: Nursing Outcomes Classification	A standard language with measures for patient outcomes influenced by nursing practices.	
Nursing services	Omaha System Visiting Nurse Association of Omaha	A problem classification system, an intervention scheme, and a problem rating scale for outcomes related to nursing and other healthcare professional services. A multi-disciplinary model of treatment.	
Nursing services	PCDS: Patient Care Data Set American Nurses Association	Compilation of terms actually used in patient records to record patients' problems, therapeutic goals, and care actions. Source material for building searchable structure text that closely approximates clinical vernacular.	
Patient safety	Shared MeaningsAustralian Council for Safety and Quality in Healthcare. Subcommittee: Australia Medical Error Action GroupCouncil Contact: julie.bate@health.gov.au. Subcommittee Contact: Lorraine Long: persistence@bigpond.com http://www.safetyandquality.org/definition/smhome.htm	The Shared Meanings project goal is to work toward agreed definitions for the language used to describe safety and quality issues in the health care system and to achieve a degree of consistency in how the terms are used.	Contains shared meanings and background analysis for pertinent safety terms. The Sequential List orders terms from most to least useful, given that many terms are closely related to each other terms. The Alphabetic List includes preferred term, alternatives and background information.
Procedures	CPT-4: Current Procedural Terminology, Fourth Edition American Medical Association For purchase: http://webstore.ama-assn.org/Merchandiser/catalog/Category.jhtml?CATID=357	To provide descriptive terms and numeric codes for reporting medical, surgical, and diagnostic services and procedures by doctors and outpatient facilities in the US. Used by Medicare and all third party payors including workers compensation and Medicaid. Hospitals use CPT-4 codes on reimbursement claims for outpatient treatment of Medicare patients. CPT is used as level I of HCPCS (see HIPAA standards below). Over 7300 codes divided into 6 major sections - Evaluation and Management Services, Anesthesia, Surgery, Radiology, Pathology and Medicine. Surgery is divided anatomically. Medicine is divided by medical subspecialties.	Similar problems to ICD-9-CM v.3 in using as a method for coding external causes of injury or complications of procedures. Controversy as to whether HCPCS or CPT would be used as procedure standard in HIPAA. It appears that both will be used.
Procedures	HCPCS: HCFA Common Procedure Coding System	A procedure coding system used for classifying treatments and submitting claims for Medicare and Medicaid covered services. Incorporates and expands CPT-4 for supplies, durable medical equipment, and other services not in CPT-4, and for local Medicaid codes.	

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Procedures	ICD-10-PCS: International Classification of Disease, Tenth Edition, Procedures Centers for Medicare and Medicaid Services	ICD-10-PCS was developed as a replacement for ICD-9-CM Procedures (Volume 3) for reporting hospital inpatient services. The goal was to improve coding accuracy and precision, reduce training effort, and improve communication with clinicians. ICD-10-PCS has been developed and undergone testing. No date is set for implementation.	Was originally recommended as a HIPAA standard as a replacement for CPT codes. The AMA and other organizations opposed this move due to costs and training issues for physician offices - no patient safety issues involved. From public documents at the NCVHS web site, CPT codes will remain the coding standard for physician offices. ICD-10-PCS will be the standard for institutions. Relevance for patient safety reporting unknown.
Procedures	Read Classification: Read Clinical Classification of Medicine, Crown Copyright UK Department of Health http://www.cams.co.uk/readcode.htm for description	A comprehensive list of terms intended for use by all healthcare professionals (extensively used by family practitioners in UK) to describe the care and treatment of patients. Read codes enable the capture and retrieval of patient-centered information in natural clinical language within computer systems. They are compiled and updated twice a year for a full release and monthly for drugs. This work is co-coordinated by the NHS Information Authority working closely with all the clinical professions including doctors, nurses, professions allied to medicine and pharmacists. Listed in UMLS. Cross-mapped to ICD-9 and ICD-10 terms, e.g., in use of 'iatrogenic' terms.	In some cases, more specific error related terms from Read could be incorporated into ICD 10. For example, "error: entry deleted" (under administration-patient record status), "acquisition/hardware ECG error" (under inadequate ECG tracing). Note: Read Codes are integrating with SNOMED.
Procedures - radiological	MRI hazard classificationAmerican College of Radiologyhttp://www.acr.org/cgi-bin/fr?mast:masthead-publications,text:/departments/stand_accred/standards/standards	Guidelines on the proper performance of radiology procedures, MRI safety, coverage of the ER, etc. For a list of types of hazards in performing MRI procedures, see http://www.patientsafety.gov/alerts/mri.doc. (J Gosbee, VA)	See MRI Hazard classification from John Gosbee at VA - http://www.patientsafety.gov/alerts/mri.doc. For a list of types of hazards in performing MRI procedures. Maybe applicable to CDRH radiological reports (?)

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Severity of illness - anesthesia	ASA physical status classification system American Society of Anesthesiologists http://www.apsf.org	Used for classifying severity of illness for patients who will undergo surgery and anesthesia. P1 normally healthy patient P2 patient with mild systemic disease P3 patient with severe systemic disease P4 patient with severe systemic disease that is constant threat to life P5 A moribund patient who is not expected to survive without the operation P6 A declared brain-dead patient whose organs are being removed for donor purposes	ASPF has also established a data dictionary task force to create a common language to identify specific perioperative outcomes that should be investigated; i.e., what are the important questions in anesthesia that should be asked and answered through data collection and analysis to achieve the greatest immediate patient benefit? No data dictionary available on-line. Does not appear to be complete. (as of 2/02)
Test results - laboratory	LOINC®: Logical Observation Identifier Names and Codes Regenstrief Institute http://www.regenstrief.org/loinc	The LOINC database provides a set of universal names and ID codes for identifying laboratory and clinical test results. The purpose is to facilitate the exchange and pooling of results, such as blood hemoglobin, serum potassium, or vital signs, for clinical care, outcomes management, and research. Currently, many laboratories are using ASTM 1238 or its sister standard, HL7, to send laboratory results electronically from producer laboratories to clinical care systems in hospitals. Most laboratories identify tests in these messages by means of their internal (and idiosyncratic) code values. Receiving medical informatics systems cannot fully "understand" the results they receive unless they either adopt the producer's laboratory codes (which is impossible if they receive results from multiple source laboratories, e.g.; the hospital lab, the local commercial lab, and a nursing home lab), or invest in the work to map each laboratory's code system to their internal code system.	Applicability to patient safety - provides universal codes to translate lab results from internal lab equipment codes to hospital information systems. However, unclear whether the data collected are extensive enough to improve safety.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Transaction standards for health data (including drugs)	HIPAA Health Data StandardsUSDHHS with standards setting groups and advisors: NUCC - National Uniform Claims Committee; NUBC -National Uniform Billing Committee. ASC X12N - American Standards Committee X12N. NCPDP 0 National Council for Prescription Drug Programs; NCVHS - National Committee on Vital and Health Statistics http://aspe.hhs.gov/admnsimp/faqcode.htm - FAQ about code sets adopted under HIPAA (date 9/2000)	The ASC X12N and NCPDP standards determine the size and format of the transactions being sent between health care claim systems. X12N standards will be required for all electronic claims transactions except for pharmacy claims that will use NCPDP (see below). Nine different standards will be required for the different types of information transmitted (e.g. payroll deduction, claim from a professional, claim from an institution etc.). The following code sets will be used:International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) for diagnoses on inpatient hospital claims; International Classification of Diseases, 9th Edition, Clinical Modification, (ICD-9-CM), Volume 3 Procedures (including The Official ICD-9-CM Guidelines for Coding and Reporting), as updated and distributed by HHS, for the procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals: National Drug Codes (NDC), as updated and distributed by HHS, in collaboration with drug manufacturers, for the following: [Note that Secretary Thompson has indicated in a letter to the NCVHS that HHS will publish an NPRM in the near future proposing to retract the adoption of NDC for all transactions save those for retail pharmacies. See http://www.fda.gov/cder/ndc/index.htm for NDC information. Code on Dental Procedures and Nomenclature, as updated and distributed by the American Dental Association; HCFA Common Procedural Coding System (HCPCS) for services at institutions; Current Procedural Terminology (CPT-4) for physician services.	In its development of standards for the computerized patient record, the NCVHS has set compliance with HIPAA standards as one of its guiding principles. Those standards will be used by all health care organizations to submit claims. We reviewed those systems for relevance to standardization and coding of errors and related information. See entries above and below.

Type of System	Name of System Organization Contact Information	Description and Purpose	Information Relevant for Integration
Transaction standards for health data (including drugs)	International Organization for Standardization See http://www.iso.ch/iso/en/aboutiso/introduction/whowork.html – for who does the work of setting standards in ISO	"The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies from some 140 countries, one per country member. ISO is a non-governmental organization established in 1947. The mission of ISO is to promote the development of standards and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity. "The major responsibility for administrating an ISO standards committee is accepted by one of the national standards bodies that make up the ISO membership - AFNOR, ANSI, BSI, CSBTS, DIN, SIS, etc. The member body holding the secretariat of a standards committee normally appoints one or two persons to do the technical and administrative work. A committee chairman assists committee members in reaching consensus. Generally, a consensus will mean that a particular solution to the problem at hand is the best possible one for international application at that time." --Excerpts from Website in contact info	

Appendix H HIPAA Standards for Demographic and Other Characteristics of Individuals

Data Element	Category Code	Category Definition
Birth Date	CCYYMMDD =	Century/Year/Month/Day
Gender	F = M = U =	Female Male Unknown
Marital Status	B = D = I = M = R = S = U = W = X =	Registered Domestic Partner Divorced Single Married Unreported Separated Unmarried (Single or Divorced or Widowed, used if status is unknown) Widowed Legally Separated
Race or Ethnicity	7 = A = B = C = H = I = N = O =	Not Provided Asian or Pacific Islander Black Caucasian Hispanic American Indian or Alaskan Native Black (Non-Hispanic) White (Non-Hispanic)
Citizenship Status	1 = 2 = 3 = 4 = 5 = 6 = 7 =	U.S. Citizen Non-Resident Alien Resident Alien Illegal Alien Alien U.S. Citizen – Non-Resident U.S. Citizen – Resident
Employment Status	AO = AU = FT = L1 = PT = RT = TE =	Active Military – Overseas Active Military – USA Full-time Leave of Absence Part-time Retired Terminated
Student Status	F = N = P =	Full-time Not a Student Part-time

Appendix I NQF and JCAHO Serious Reportable Events

The serious reportable event definitions of the National Quality Forum (NQF) and the Joint Commission on Accreditation of Health Care Organizations (JCAHO) are a useful backdrop for comparing USDHHS medical error reporting and related data systems and for assessing State medical event reporting systems. Table I-1 displays this comparison. When the NQF and JCAHO definitions were slightly different, both are listed and identified. When State definitions are similar but different, they also are noted. When State definitions are more general or entirely different from NQF and JCAHO, the State definitions are listed separately. The USDHHS medical event related data systems are those examined for this study. Our assessment of their relevance to the NQF and JCAHO definitions is based on a cursory review of the systems. Sixteen State systems were reviewed based on several studies of State systems (IOM, 1999; Rosenthal et al., 2001, and Flowers, 2002). The States reviewed include CA, CO, FL, KS, MA, ME, NJ, NY, OH, PA, RI, SC, SD, TN, UT, WA. A few States were excluded because errors were not specifically defined (CT, MS) or systems that existed were not targeted on medical errors (NE, TX).

Table I-1 shows that for 21 of the NQF/JCAHO serious reportable events, there is some type of relevant data in USDHHS systems. For 17 events, multiple USDHHS systems may provide information. Only 9 of the 31 events could not be addressed by any of the USDHHS systems; these relate to surgery errors, criminal events, and delay of care.

Some State collects information related to 19 of the NQF/JCAHO serious reportable events. Multiple States collect data for 16 of the events. Twelve of the NQR/JCAHO events are not collected by any of the States examined. These relate to serious events related to hypoglycemia, hyperbilirubinemia, perinatality, pressure ulcers, and spinal manipulation. Eleven of the events are addressed by both USDHHS systems and State systems. Despite some overlap between DHHS and State systems related to these events, definitions are likely to vary enough to make comparisons problematic.

Table I-1. NQF and JCAHO Serious Reportable Events Compared to DHHS and State Error Reporting Systems

Domain	Abbreviated Definitions (And alternative language when NQF, JCAHO, and State definitions differ)	NQF	JCAHO	USDHHS Medical-Event-Related Data Systems	State Systems
Surgery	Wrong site surgery	X	X		FL, MA, ME, OH, PA, TN, UT, WA
	Surgery on wrong patient	X			FL, MA, ME, OH, PA, RI, TN, UT, WA
	Wrong surgical procedure performed on patient	X			FL, MA, RI, TN
	Foreign object left in a patient after surgery or other procedure	X		HCUP, NNIS	FL, MA, TN
	Intraoperative or immediately post-operative death in an ASA Class I patient (NQF) Anesthesia-related event (JCAHO) Death or near death for anesthesia and cardiac procedures (NJ)	X	X	HCUP, BPD, MERS, MEDMARX, NNIS ASA Class I patient designation unlikely to be available.	CO, NJ

Domain	Abbreviated Definitions (And alternative language when NQF, JCAHO, and State definitions differ)	NQF	JCAHO	USDHHS Medical-Event-Related Data Systems	State Systems
	[Intra]operative or Post-operative complication		X	HCUP Often not specific.	RI, TN
	Surgical repair or damage resulted from planned surgical procedure where damage was not disclosed or documented to the patient (FL)				FL
Product or Device Events	Death or serious disability from use of contaminated drugs, devices, or biologics by facility	X		AERS, ARS, BPD, DSN, MAUDE, MEDSUN, MEDWATCH, MERS, MEDMARX, NNIS, VAERS, VSD	
	Aspiration in non-intubated patient related to conscious/moderate sedation (TN)				TN
	Death or serious disability from use or function of a device in patient care, when other than intended (NQF) Medical equipment-related event (JCAHO) Intravascular catheter related events (TN)	X	X	AERS, ARS, DSN, MAUDE, CMS, MEDSUN, MEDWATCH, MERS, MEDMARX, NNIS	CO, MA, ME, NY, OH, TN
	Death or serious disability from intravascular air embolism during care at a facility	X		AERS, ARS, DSN, MAUDE, MEDSUN, MEDWATCH, MERS, MEDMARX, MPSMS	CO
	Ventilator death or injury		X		CO
Patient Protection Events	Infant discharge to the wrong person (NQF) Infant abduction or discharge to wrong family (JCAHO)	X	X		ME, PA, TN, UT, WA
	Death or serious disability from patient disappearance for more than four hours (NQF) Patient elopement (JCAHO)	X	X		CA, CO, NY, PA, SD, TN
	Patient suicide, or attempted suicide resulting in serious disability, while in a facility (NQF) Patient suicide (JCAHO)	X	X	HCUP	MA, ME, PA, SD, TN, UT, WA
Care Manage-ment Events	Death or serious disability from medication error (e.g. wrong drug, dose, patient, time, rate, preparation, or route (NQF) Medication error (JCAHO)	X	X	HCUP, MEDSUN, MEDWATCH, MERS, MEDMARX, NNIS, VAERS	MA, ME, PA, TN
	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products (NQF) Transfusion error (JCAHO)	X	X	HCUP, BPD, DSN, MEDWATCH, MERS, MEDMARX	CO, MA, ME, PA, TN, WA

Domain	Abbreviated Definitions (And alternative language when NQF, JCAHO, and State definitions differ)	NQF	JCAHO	USDHHS Medical-Event-Related Data Systems	State Systems
	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility (NQF) Maternal death (JCAHO)	X	X	HCUP, MAUDE, MEDSUN, MEDWATCH, MERS, MEDMARX, NNIS	MA
	Hysterectomy in a pregnant woman, ruptured uterus (TN)				TN
	Birth injury (RI)				RI
	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	X		HCUP*, DSN, MAUDE, MEDSUN, MEDWATCH, MERS, MEDMARX *Timing of onset may only be known for a few States in HCUP	
	Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates	X		HCUP, MAUDE, MEDSUN, MEDWATCH, MERS, MEDMARX, NNIS, VAERS	
	Perinatal death or loss of function		X	HCUP, MAUDE, MEDSUN, MEDWATCH, MERS, MEDMARX, NNIS, VAERS	
	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	X		HCUP*, CMS, MEDSUN, MEDWATCH *Timing of onset may only be known for a few States in HCUP	
	Patient death or serious disability due to spinal manipulative therapy	X		MAUDE, MEDSUN, MEDWATCH	
	Delay in treatment		X		
	Infectious disease epidemics or outbreaks (CA, FL, MA)				CA, FL, MA
	Infestation by parasites or vectors (CA)				CA
	Death due to malnutrition, dehydration, or sepsis (PA)				PA
Environ-mental Events	Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	X		AERS, ARS, MAUDE, MEDSUN, MEDWATCH, MERS, MEDMARX	ME
	Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	X		AERS, ARS, MAUDE, MEDSUN, MEDWATCH, MERS, MEDMARX	
	Death or serious disability from a burn incurred while in facility (NQF) Fire (JCAHO)	X	X	AERS, ARS, MAUDE, MEDWATCH, MERS, MEDMARX	CA, CO, MA, ME, NJ, NY, TN
	Death from a fall while in facility	X	X	MAUDE, CMS, MEDSUN, MEDWATCH, MERS, MEDMARX	

Domain	Abbreviated Definitions (And alternative language when NQF, JCAHO, and State definitions differ)	NQF	JCAHO	USDHHS Medical-Event-Related Data Systems	State Systems
	Falls within facility not related to patient treatment that result in serious head injury, coma, or permanent injury or requires significant intervention (ME) Less serious complications of surgery, burns, falls, etc. (NY) Falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, etc. (TN)				ME, NY, TN
	Death or serious disability from restraints or bedrails in a facility (NQF) Patient death or injury due to restraints (JCAHO)	X	X	AERS, ARS, MAUDE, CMS, MEDSUN, MEDWATCH, MERS, MEDMARX	
	Patient death associated with transfer		X	HCUP (transfer in only)	
Criminal Events	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed healthcare provider	X			
	Abduction of a patient within or on the grounds of the healthcare facility	X			NY, TN, UT
	Death or significant injury of a patient or staff member from a physical assault (i.e., battery) within or on grounds of facility (NQF) Assault, rape, or homicide (JCAHO) Accident, abuse, negligence (SD)	X	X		CA, CO, ME, NJ, PA, SD, TN, UT, WA
	Poisoning (States shown)				CA, MA, ME, NY, TN
	Any drug for use by resident that is diverted for use by others (CO)				CO
Site-specific outcome events (States only)	Any injury that is the result of an occurrence and causes functional loss consistent with spinal cord injuries (temporary or permanent) (CO, FL)				CO, FL
	Any injuries that occur to the brain and, as a result, cause a change in the level of consciousness and/or loss of bodily function (CO, FL) Brain injury, mental impairment (RI)				CO, FL, RI
	Fracture or dislocation of bones or joint related to medical intervention (FL)				FL

Domain	Abbreviated Definitions (And alternative language when NQF, JCAHO, and State definitions differ)	NQF	JCAHO	USDHHS Medical-Event-Related Data Systems	State Systems
	A resulting limitation of neurological, physical, or sensory function resulting from medical intervention and which continues after discharge (FL) Incident involving impairment of sight or hearing (RI)				FL, RI
	Incident resulting in paraplegia, quadriplegia, any type of paralysis, loss or use of limb or organ (RI) Intervention resulting in loss or impairment of limb – and impairment is present at discharge or for at least two weeks after occurrence (TN) Intervention resulting in major loss of physical or mental function (UT)				RI, TN, UT
General Outcomes	Deaths arising from an unexplained cause or under suspicious circumstances that are reportable to the coroner as suspicious or unexplained (CO) Death due to unnatural causes (Other States)				CA, CO, FL, MA, NY, PA, SC, SD, UT, WA
	Treatment to correct adverse incident (FL, TN)				FL, TN
	Transfer required due to adverse incident (FL, PA)				FL, PA
	Serious injury, impairment, death, or further treatment due to adverse incident (States listed)				KS, MA, ME, NY, SC, WA
	Facility failure with potential adverse outcome for patients (TN, WA)				TN, WA

Appendix J Health Level 7 Reference Information Model

The Reference Information Model

Entities: Entities involved in health care activities include:

- Living subject (person, non-person living subject (i.e., animals))
- Entity heir
- Place
- Organization
- Material
  Manufactured material (device (imaging modality), container)

Roles: Health care providers have people with various roles in the organization:

- Employee
- Access
- Guarantor
- Schedulable resource
- Role heir
- Patient
- Assigned entity
- Certified entity

Acts: Actions taken in delivering health care that have been specified in the Reference Information Model are:

- Acts – Clinical
  - Patient encounter
  - Referral
  - Supply (diet)
  - Procedure
  - Observation (diagnostic image, public health case)
  - Device task
  - Substance administration
- Acts – Financial
  - Financial contract
  - Financial act (account; invoice element, financial transaction)
  - Act heir
  - Act context

Infrastructure: Infrastructure for documents and messages to be exchanged include:

- Structured documents
  - Context structure
    - Clinical document
    - Table structure (table cell, table-column structure)
    - Table
    - Local attribute
    - Local markup
    - Link html
- Message control
  - Communication function
  - Attention line

- Transmission
    - Batch,
    - Message
    - Acknowledgement
    - Control event
        - Query event
            - Sort control
            - Query specification (parameters, query by parameters/selection, selection expression, etc.)
            - Query acknowledgement
            - Query continuation

Appendix K The Unified Medical Language System (UMLS)

The UMLS project is a long-term National Library of Medicine research and development effort designed to facilitate the integration of information from a variety of medical data sources. These data sources include: bibliographic databases, computerized clinical records, factual databanks, expert systems and directories of people and organizations.

The UMLS approach involves the development of “intellectual middleware” that can be used by a wide variety of application programs to compensate for differences in terminology and the scattering of relevant information across many databases. The middleware provides three “knowledge sources”:

- The Metathesaurus provides a uniform, integrated distribution format from over 60 biomedical vocabularies and classifications, and links many different names for the same concepts. It interconnects many standard clinical and biomedical vocabularies.
- The Semantic Network contains information about the types or categories (e.g., "Disease or Syndrome," "Virus") to which all Metathesaurus concepts have been assigned and the permissible relationships among these types (e.g., "Virus" causes "Disease or Syndrome").
- The Specialist Lexicon contains syntactic information for many terms, component words, and English words, including verbs, that do not appear in the Metathesaurus.

NLM also distributes associated lexical programs and software helpful in searching, indexing and lexical processing including producing customized versions of the UMLS Metathesaurus. The UMLS system is not designed as “off the shelf” software but rather intended primarily for use by system developers and as a reference tool for database builders, librarians, and other information professionals.

Biomedical categories that are relevant to MERIP and are part of the Metathesaurus include:

- Clinical Classifications Software (CCS) Categories
- Coding Symbols for Thesaurus of Adverse Reaction Terms (COSTART)
- Physicians’ Current Procedural Terminology (CPT)
- Diagnostic and Statistical Manual of Mental Disorders (DSM)
- HCFA Common Procedure Coding System (HCPCS)
- Health Level Seven Vocabulary (HL7)
- International Classification of Diseases and Related Health Problems (ICD 9, 10)
- Logical Observations Identifiers, Names and Codes (LOINC)
- Medical Dictionary for Regulatory Activities Terminology (MedDRA)
- Systematized nomenclature of medicine (SNOMED)
- Universal Medical Device Nomenclature System (UMD)
- WHO Adverse Drug Reaction Terminology (WHOART)

The UMLS project is directed by a multi-disciplinary team of NLM staff and is support by Apelon, a contractor. NLM makes use of the UMLS Metathesaurus in NLM Gateway and PubMed to enhance MEDLINE searching. UMLS products are distributed annually, free-of-charge under a license agreement.

The Metathesaurus

The metathesaurus preserves the names, meanings, hierarchical contexts, attributes, and inter-term relationships present in its source vocabularies; adds certain basic information to each concept; and establishes new relationships between terms from different source vocabularies.

The goal of the development of the Metathesaurus is to supply information that computer programs can use to interpret user inquiries, interact with users to refine their questions, identify which databases contain information relevant to particular inquiries, and convert the users' terms into the vocabulary used by relevant information sources.

The 2002AA edition of the Metathesaurus includes 776,940 concepts and 2.1 million concept names in over 60 different biomedical source vocabularies, some in multiple languages.

The Metathesaurus is used in a wide range of applications including: linking between different clinical or biomedical vocabularies; information retrieval from databases with human assigned subject index terms and from free-text information sources; linking patient records to related information in bibliographic, full-text, or factual databases; natural language processing and automated indexing research; and structured data entry.

The Specialist Lexicon

The SPECIALIST lexicon has been developed to provide the lexical information needed for the SPECIALIST Natural Language Processing System. It is intended to be a general English lexicon that includes many biomedical terms. Coverage includes both commonly occurring English words and biomedical vocabulary. Lexical information includes parts of speech, inflectional variation (e.g., singular and plural for nouns, the conjugations of verbs, the positive, comparative, and superlative for adjectives and adverbs), and allowable complementation patterns (i.e., the objects and other arguments that verbs, nouns, and adjectives can take). The lexical programs generate a range of variations for English lexical items and are useful for recognizing lexical variation in biomedical terminologies and texts.

The Semantic Network

The Semantic Network, through its 134 semantic types, provides a consistent categorization of all concepts represented in the UMLS Metathesaurus®. The 54 links between the semantic types provide the structure for the Network and represent important relationships in the biomedical domain. All information about specific concepts is found in the Metathesaurus; the Network provides information about the basic semantic types that are assigned to these concepts, and it defines the relationships that may hold between the semantic types.

Appendix L Examples of New ICD-10-CM Codes Related to Medical Misadventures

Code	Category Description
Y70	Anesthesiology devices with associated adverse events[1]
Y71	Cardiovascular devices associated with associated adverse events[1]
Y72	Otorhinolaryngological devices with associated adverse events[1]
Y73	Gastroenterology and urology devices with associated adverse events[1]
Y74	General hospital and personal-use devices with associated adverse events[1]
Y75	Neurological devices with associated adverse events[1]
Y76	Obstetric and gynecological devices with associated adverse events[1]
Y77	Ophthalmic devices with associated adverse events[1]
Y78	Radiological devices with associated adverse events[1]
Y79	Orthopedic devices with associated adverse events[1]
Y80	Physical medicine devices with associated adverse events[1]
I97.41	Intraoperative and post procedural hemorrhage and hematoma complicating a circulatory procedure
I97.410	Intraoperative hemorrhage of a circulatory system organ or structure during a cardiac catheterization
I97.411	Intraoperative hemorrhage of a circulatory system organ or structure during a cardiac bypass
I97.418	Intraoperative hemorrhage of a circulatory system organ or structure during an other circulatory system procedure
I97.42	Intraoperative hemorrhage of a non-circulatory system organ or structure during a circulatory system procedure
I97.43	Intraoperative hematoma of a circulatory system organ or structure during a circulatory system procedure
I97.44	Intraoperative hematoma of a non-circulatory system organ or structure during a circulatory system procedure
I97.45	Postprocedural hemorrhage of a circulatory system organ or structure following a circulatory system procedure
I97.46	Postprocedural hemorrhage of a non-circulatory system organ or structure following a circulatory system procedure
I97.47	Postprocedural hematoma of a circulatory system organ or structure following a circulatory system procedure
I97.48	Postprocedural hematoma of a non-circulatory system organ or structure following a circulatory system procedure
I97.5	Accidental puncture and laceration during a circulatory system procedure
I97.51	Accidental puncture and laceration of a circulatory system organ or structure during a circulatory system procedure
I97.52	Accidental puncture and laceration of a non-circulatory system organ or structure during a circulatory system procedure
ICD-10-CM Injury, poisoning chapter	This chapter contains code extensions to distinguish initial treatment versus subsequent treatment.

Appendix M NCCMERP Adverse Event Classification Regarding Harm to the Patient

Type of Error	Category Label	Description
No Error	A	Circumstances or events that have the capacity to cause error
Error, No Harm[1]	B	An error occurred but the error did not reach the patient (An "error of omission" does reach the patient.)
	C	An error occurred that reached the patient, but did not cause patient harm (e.g. medication reaches the patient and is administered or medication reaches the patient but is not administered).
	D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
Error, Harm	E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
	F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
	G	An error occurred that may have contributed to or resulted in permanent patient harm
	H	An error occurred that required intervention necessary to sustain life
Error, Death	I	An error occurred that may have contributed to or resulted in the patient's death.

Appendix N The Aviation Safety Reporting System (ASRS)

Integration of USDHHS medical event reporting system as currently configured would include only adverse events, which are identified by an event (e.g., drug reaction) occurring to a patient. Battles (1998) identified two other situations in which reporting can reduce the *risk* of harm to patients: "no harm" events and "near misses, known collectively as "close calls." "No harm" events occur when an error occurred but there was no adverse effect on the patient. An example would be administration of a medication other than the one prescribed, and the patient had no adverse reaction to the substitute medication. "Near misses" occur when the error was caught before it reached a patient. An example would be dispensing the wrong prescription but noting and retrieving it before it was administered to the patient. It has been widely acknowledged that errors resulting in serious patient harm are merely the tip of an iceberg (IOM, 1999). And much less is known about close calls. Knowledge of them would present opportunities to learn before actual mistakes occur and to take corrective action before patients are injured.

The Aviation Safety Reporting System (ASRS) is designed to identify and prevent safety slips or lapses in the aviation industry. Although aviation is different from medicine, features of the ASRS can be adapted to health care. The Department of Veterans Affairs (VA) has designed its Patient Safety Reporting System (PSRS) after the model of ASRS.

PSRS encourages reporting of medical adverse events, sentinel events, and close calls through a fully anonymous, externally managed system that covers all types of adverse events in the VA health care system and complements the mandatory internal VA reporting system, known as the Patient Safety Information System. Under PSRS, all VA facility staff can voluntarily report any event or concern for patient safety to NASA, a separate and independent agency, which processes these reports to maintain anonymity and confidentiality of the reporter. The PSRS embraces principles of non-punitive reporting.[1] As such, PSRS has the potential to identify many system vulnerabilities. However, specific solutions may not be forthcoming from the PSRS because details of the event or close call are seldom specific enough to allow a root cause analysis of the problem. The mandatory internal system is directed toward root cause analysis and corrective action.

The Patient Safety Reporting System has adopted some and not other characteristics of the ASRS to health care. Features adopted by PSRS include:

- A organization without regulatory or enforcement powers collecting reports
- Strict privacy and confidentiality of the reporter
- Inclusion of "close calls"
- A focus on identifying safety risks, not corrective action for a specific events.

Features of ASRS not adopted by PSRS, but which could be, include:

- Use of the database by agency staff to conduct and disseminate research on medical events.
- Availability of the database on CD-ROM for other researchers (de-identification of the data makes this feasible).
- Agency analyses of ASRS data in response to public queries about aviation safety, with responses returned directly to the inquirers.

These latter features of the ASRS also could be applied to a fully functioning USDHHS integration of medical error reporting, if the system were to expand the definition of events that will be collected through the integrated system.

[1] Non-punitive reporting is more feasible in the VA system than in community medicine because VA employees are not subject to personal liability to the same extent as community practitioners and because Veterans who are injured by medical mistakes may receive a workers-compensation-type administrative benefit.

Although the aviation model applies in many ways to health care, it may not apply in all ways. The IOM (1999) identified two potential problems in applying the ASRS to health care. First the volume of reports may be excessive. The number of patients seen in hospitals, physicians' offices and clinics each day means that the volume of adverse and close call reports might be considerably higher in health care than in aviation. Second, effective analysis of event reports will require experts from many medical specialties such as cardiology, internal medicine, and drug therapy, to name a few. Health care is much more specialized than aviation, and experts will be needed to review and understand lessons from the reports. Furthermore, the legal liability of health care providers outside of government, the fear of discoverability even when reporting is anonymously, and the uncertainty around legal protections for reported data make the likelihood of voluntary reporting less for health care than for aviation.