

**ADVERSE EVENT REPORT FORM**

For the purposes of this form, a serious adverse event is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, results in congenital anomalies/birth defects, or in the opinion of the investigators represents other significant hazards or potentially serious harm to research subjects or others. A serious adverse event is considered unexpected if it is not described in the Package Insert or in the Investigator's Brochure (for FDA investigational agents), in the protocol, or in the informed consent document.

**INSTRUCTIONS:**

Please complete the information requested below and forward \_\_\_ copies to the IRB as soon as possible, but not later than seven (7) days in the case of death or life-threatening serious adverse events or within fifteen (15) days after the occurrence of all other forms of serious adverse events. The IRB office will immediately forward a copy to the Clinical Director. In addition, continue to follow FDA and the NIH Office reporting requirements if your research involves an IND/IDE or gene transfer.

<b>PROTOCOL #:</b>	<b>PROTOCOL TITLE:</b>	
<b>PRINCIPAL INVESTIGATOR:</b>	Institute: Fax:	Office Phone: E-mail:
<b>DATE OF SERIOUS ADVERSE EVENT:</b>	___/___/___	
<b>LOCATION OF SAE (e.g., at CCC or elsewhere):</b>		
<b>WAS THIS AN UNEXPECTED ADVERSE EVENT?</b>	Yes [ <input type="checkbox"/> ] No [ <input type="checkbox"/> ]	
<b>WAS THIS A SERIOUS ADVERSE EVENT?</b>	Yes [ <input type="checkbox"/> ] No [ <input type="checkbox"/> ]	
<b>BRIEF DESCRIPTION OF SUBJECT(S) (Do NOT include identifiers.)</b>	SEX: M/F      AGE: _____ Diagnosis:	
<b>BRIEF DESCRIPTION OF THE NATURE OF THE SERIOUS ADVERSE EVENT:</b>		

# Adverse Event Report Emama

**Katrin Zwirgmaier**



## **Adverse Event Report Emama:**

Clinical Trials Adverse Event FDAnews,2015      *Analysis and Use of Adverse Event Report Data and Data Obtained from Investigation and Analysis of Adverse Events for the Purpose of Preventing Reoccurrence of These Events in a Multiple Hospital System* Christy L. Bourne,2012 Abstract Since *To Err is Human* was published in 2000 much has been researched and written about the topic of medical errors or adverse events A key recommendation of that report was the implementation of aggregate reporting systems where data could be compiled and analyzed to provide actionable knowledge about how these events could be prevented There is debate in the literature about the potential effectiveness of such systems in preventing medical errors and adverse events due to inherent challenges in the voluntary reporting of events The purpose of this project was to create such a system in a multi hospital system together with additional strategies to attempt to reduce the number of adverse events Key elements of the project included the system the data the analysis and the feedback Although it is relatively early in the process the project is so far proving to be effective      *Adverse Event Reporting System (AERS)*. ,2009 The Adverse Event Reporting System AERS contains over four million reports of adverse events and reflects data from 1969 to the present presented as summary statistics      *Adverse Drug Events* United States. General Accounting Office,2000

*Adverse drug events the magnitude of health risk is uncertain because of limited incidence data : report to congressional requesters.* ,      Serious Reportable Adverse Events in Health Care ,2005 Health care errors resulting in patient harm are a leading cause of morbidity and mortality in the United States although there is no national reporting of such occurrences A number of States require reporting of at least some types of these adverse events however it is widely agreed that even where there is required reporting such events are grossly underreported due in part to ambiguity about what is to be reported In 1999 the Institute of Medicine IOM recommended that health care errors and adverse events be reported in a systematic manner The Federal Government s Quality Interagency Coordination Committee concurred with the IOM s recommendation for greater health care error and adverse event reporting and the National Quality Forum NQF was asked to identify a standardized list of preventable serious adverse events that would facilitate reporting of such occurrences This article presents the NQF endorsed consensus list of 27 serious reportable events in health care along with a discussion of the criteria used in selecting the list and various issues related to implementing reporting of these events Since the NQF promulgated this list of serious reportable events in 2002 several States and other entities have enacted legislation or taken administrative action to require reporting of these never events      **Use of an Electronic Reporting System to**

**Determine Adverse Event Rates, Adverse Event Costs, and the Relationship of Adverse Events with Patients' Body Mass Index** Muhammad Fazal Zeeshan,2013 In conclusion the event reporting system data used in combination with patient medical records can help improve quality of care and cost reductions by early detection of adverse events followed by workflow and care coordination improvements      *Adverse Event Reporting for Dietary Supplements* Michael F.

Mangano,2001-05-01 Assesses the effectiveness of the FDA s AER system for DS in protecting the Amer consumer 60% of Amer take some form of DS every day without any problems They include vit minerals botanicals and amino acids FDA does not have the authority to require DS to undergo pre market approval for safety and efficacy Instead it relies mostly on its AER system to identify safety problems However FDA lacks key med product mfr trend and clinical info to generate signals of public health concerns from the AER system Offers actions that FDA can take to strengthen its ability to detect adverse events appropriately assess reported events and disclose more useful info to the public *MedWatch* ,2001 Presents MedWatch the FDA Safety Information and Adverse Events Reporting Program serves both healthcare preffessionals and the medical product using public Provides clinical information about safety issues involving medical products including drugs biologics medical and radiation emitting devices and special nutritional products Allows healthcare professionals and consumers to report adverse events and problems to the FDA and or manufacturer *A Feasibility Study of an Adverse Event Reporting Program* Joanne Cowan,2001 [WHO Draft Guidelines for Adverse Event Reporting and Learning Systems](#) Lucian L. Leape,Susan Abookire,World Health Organization,World Alliance for Patient Safety,2005 **Adverse Drug Event Reporting** Board on Health Sciences Policy,Institute of Medicine,2007-04-12 Recent concerns about the unexpected adverse effects of marketed drugs such as COX 2 cyclooxygenase 2 inhibitors or specific statins raise concerns not only about reporting these events during premarket studies but also about the responsibility for ongoing surveillance of drugs once they are on the market Sometimes serious adverse drug reactions are fully appreciated only after a drug has been on the market for years Therefore when a drug is approved and released to the market large numbers of patients will be exposed before all the potential adverse effects have been identified and thoroughly studied Currently there is no clearly defined process for addressing safety questions about drugs after premarketing research has occurred In November 2005 the Institute of Medicine s Forum on Drug Discovery Development and Translation convened a workshop to explore issues associated with the reporting of ADEs The workshop addressed the following questions How can ADEs be effectively identified particularly when the adverse effects are rare How can the direct causal effects of drugs be distinguished from simple associations How can health care professionals and their patients aid in the identification of drug related adverse events How can knowledge of ADEs be more effectively used in clinical practice Adverse Drug Event Reporting reviews current sources of information on adverse drug events including the FDA s MedWatch program and the AERS institutional review boards and the CMS This report considers the ways that consumers and advocacy groups can be involved in reporting adverse events and discusses drug interactions problems with current databases for capturing and evaluating interactions and difficulties in communicating information about adverse drug interactions This report also describes new requirements for information contained on drug labels and how labels can be used to communicate information about risks and drug interactions to consumers and practitioners **A Review of Current State-level Adverse Medical Event Reporting Practices** Megan

K. Beckett, 2006 Nearly half of states require or request the reporting of adverse medical events In 2003 the Institute of Medicine Patient Safety Achieving a New Standard of Care called for the use of consistent standards for medical error reporting Standardization will facilitate the creation of a national patient safety repository that aggregates data from states and enable policymakers to track trends in adverse events nationally The Agency for Healthcare Research and Quality AHRQ is leading the national Patient Safety Initiative to combat medical errors This report summarizes the results of an AHRQ sponsored 50 state survey of adverse reporting systems in 2004 It documents the consistency of information that states are collecting as part of their reporting systems identifies issues related to establishing a national patient safety repository and presents an action plan to implement a standardized nationwide system elicited from an external advisory panel that was convened explicitly for this purpose A replication of the Webber Effect using post-marketing adverse event reports submitted to the spontaneous reporting system and adverse event reporting system of the United States Federal Food and Drug Administration Nicole Rhiana Crawford, 2002 **Adverse Event Reports** Harry Enchin, Oregon Health & Science University. School of Medicine, 2011 **Clinical Adverse Event Reporting** Barbara Wilson, University of York, 2004

**Managing the Risks from Medical Product Use** United States. Food and Drug Administration. Task Force on Risk Management, 1999 FDA Drug Bulletin, 1990 *A Review of Current State-level Adverse Medical Event Reporting Practices*, 2006 Nearly half of states require or request the reporting of adverse medical events In 2003 the Institute of Medicine Patient Safety Achieving a New Standard of Care called for the use of consistent standards for medical error reporting Standardization will facilitate the creation of a national patient safety repository that aggregates data from states and enable policymakers to track trends in adverse events nationally The Agency for Healthcare Research and Quality AHRQ is leading the national Patient Safety Initiative to combat medical errors This report summarizes the results of an AHRQ sponsored 50 state survey of adverse reporting systems in 2004 It documents the consistency of information that states are collecting as part of their reporting systems identifies issues related to establishing a national patient safety repository and presents an action plan to implement a standardized nationwide system elicited from an external advisory panel that was convened explicitly for this purpose Analysis of Data on Spontaneous Reports of Adverse Events Associated with Drugs Emmanuel Mensah Baah, 2014

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