

Utah Patient Safety Update

Utah Department of Health ♦ Utah Hospitals & Health Systems Association ♦ *HealthInsight*

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Adverse Drug Events (ADEs) Among Hospitalized Patients in Utah, January 1, 2001 – December 31, 2002

This update describes the incidence of potential adverse drug events (ADEs) among hospitalized patients in 41 Utah acute care hospitals over four six-month time periods from January 2001 through December 2002. The update reflects efforts of the Utah Patient Safety Consortium to utilize the Hospital Inpatient Discharge Database to facilitate patient safety efforts in Utah's hospitals.

This update has four main objectives. First, it shows trends in the reported numbers and rates of ADEs. The update also shows trends in the rates of rash as an example of a common ADE and in the rates of adverse effects of agents affecting blood constituents (such as anticoagulants) as an example of a potential high-harm ADE. Third, the update reports the rates of ADEs by hospital peer group in 2002. Finally, the update includes a brief report on a successful anticoagulation program implemented at a small rural hospital.

Like the previous updates, this update's objectives are to report some of the Consortium's findings to increase understanding of ADEs. Previous studies have indicated that adverse events may be underreported. The Consortium expects that better recognition, documentation, and reporting will lead to more accurate estimates of rates of ADEs.



Chart review data indicates that one third of Clinical Side Effects of Drugs and Adverse Effects of Drugs are in-hospital ADEs. One sixth of Poisoning by Drugs are in-hospital ADEs in Utah 2001.

About the Data

The Utah Hospital Discharge Database has nine fields for reporting ICD-9-CM diagnosis codes and one field for reporting the principal E-code. The database contains patient-level information about all hospitalizations that occur in all of Utah's licensed hospitals. The Utah Health Data Committee, through its staff in the Utah Department of Health, collects the data under the authority of the Utah Health Data Authority Act. This update compares hospital inpatient discharge data across four half-year periods: (1) January 1 through June 30, 2001 (discharges = 121,403), (2) July 1 through December 31, 2001 (discharges = 118,415), (3) January 1 through June 30, 2002 (discharges = 124,131), and (4) July 1 through December 31, 2002 (discharges = 122,680, see Tables 1 and 2 and Figures 1, 2, and 3). Information about each discharge, or hospitalization, includes patient characteristics, diagnosis codes, etc. Like the previous updates, analysis for this update was restricted to hospitalizations in 41 Utah acute care hospitals, excluding specialty hospitals (such as rehabilitation and psychiatric hospitals).

About ICD-9-CM Codes

The International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM) has diagnosis and procedure codes and E-codes. Diagnosis (DX) codes describe the nature of the patient's diagnosis whereas E-codes describe the possible external cause of the injury, where appropriate. For example, if a drug were thought to have caused a rash, the diagnosis code would address the rash (e.g., 782.1), while the E-code would describe the drug class that was the external cause of the rash (e.g., E943). While diagnosis codes play a critical role in determining how much a provider is paid for a service, E-codes are not directly related to reimbursement. Currently there is little financial incentive for E-code reporting. Therefore, ADEs identified by E-codes probably are under recorded.

The potential ADEs identified in this analysis may or may not have occurred prior to contact with a given hospital's personnel. While principal discharge diagnosis codes (the codes causing hospitalization) were excluded, secondary diagnosis and E-codes may represent potential ADEs that occurred before the patient was hospitalized or potential ADEs that occurred in the hospital.

Limitations of Using the Administrative Data and the ICD-9-CM Classification for Detecting Adverse Drug Events

- Unable to separate the events that occurred prior to current hospitalization from those that occurred during hospitalization
- Unable to categorize degree of harm
- Unable to capture near misses
- Unable to perform reliable inter-institutional comparisons due to coding variation among facilities

About Adverse Drug Events

Definitions: For the Utah patient safety project, an adverse event (AE) is defined as an undesirable and unintended injury resulting from a medical intervention (an act of care provided by the hospital or by the omission of necessary care), rather than from the patient's underlying disease process. An adverse drug event (ADE) is an adverse event associated with a drug.

Classification: ADEs were detected in the Utah Hospital Discharge Database using a classification scheme validated by the project's expert panel for the ICD-9-CM Classification of Adverse Events. The scheme designates a set of approximately 420 ICD-9-CM codes including diagnosis codes (DX codes) and external-injury codes (E-codes) as potential ADE codes. These codes are classified into 26 ADE classes (see Table 1 and Table 2).

Grouping: The 26 ADE classes fall into three groups: (1) clinical side effects of drugs (DX codes), (2) poisoning by drugs (DX codes and E-codes), and adverse effects of drugs (E-codes). While the clinical side effect classes describes similar clinical diagnoses, e.g., rash and dermatitis, the adverse effect and poisoning classes are grouped by type of drug, such as agents affecting blood constituents (see Tables 1, 2 and Figure 1).

The Utah Patient Safety Consortium wishes to thank the hospitals for their cooperation in the pre-intervention chart review last year. *HealthInsight* will conduct the post-intervention chart review starting in October 2003. We greatly appreciate the continued support from the participating hospitals.

**TABLE
1**

Number of Inpatient Discharges with Adverse Drug Event (ADE)
By ICD-9-CM Code ADE Group and ADE Class and 6 Month Period
41 Utah Acute Care Hospitals
2001-2002

ICD-9-CM ADVERSE DRUG EVENT GROUP AND CLASS	JAN-JUN	JUL-DEC	JAN-JUN	JUL-DEC
	2001	2001	2002	2002
Total Discharges With At Least One Adverse Drug Event	3,834	3,836	4,237	4,320
Clinical Manifestations of Adverse Drug Events	888	923	1,029	1,041
Drug psychoses	366	441	443	561
Dermatitis	238	224	261	235
Maternal causes of perinatal morbidity and mortality, drug reaction	21	15	18	12
Rash, spontaneous ecchymoses	265	252	310	237
Poisoning by Drugs	681	722	765	805
Poisoning by antibiotics and other antiinfectives	5	7	8	8
Poisoning by hormones and synthetic substitutes	16	26	33	20
Poisoning by primarily systemic agents	34	50	33	35
Poisoning by agents affecting blood constituents	18	14	20	18
Poisoning by analgesics, antipyretics, antirheumatics	215	214	248	237
Poisoning by anticonvulsant and anti-Parkinsonian drugs	43	37	41	45
Poisoning by sedatives and hypnotics	46	64	68	66
Poisoning by other CNS depressants, stimulants, anesthetics	40	51	54	48
Poisoning by psychotropic agents	256	287	306	316
Poisoning by other agents	117	116	123	134
Poisoning, undetermined whether accidentally or purposely inflicted	77	85	79	114
Adverse Effects by Drugs	2,542	2,483	2,745	2,839
Adverse effects of antibiotics and other antiinfectives	220	228	279	260
Adverse effects of hormones and synthetic substitutes	349	296	322	382
Adverse effects of primarily systemic agents	285	273	295	311
Adverse effects of agents primarily affecting blood constituents	211	208	230	246
Adverse effects of analgesics, antipyretics, antirheumatics	493	520	553	651
Adverse effects of anticonvulsant and anti-Parkinsonian drugs	72	64	81	74
Adverse effects of sedatives and hypnotics	97	102	137	104
Adverse effects of other CNS depressants, stimulants, anesthetics	112	95	135	94
Adverse effects of psychotropic agents	124	150	153	166
Adverse effects of agents affecting cardiovascular system	288	258	269	294
Adverse effects of other drugs, biological, medicinal substances	378	370	380	386
Total Inpatient Discharges For 6-Month Period	121,403	118,415	124,131	122,676

SOURCE: Utah Hospital Discharge Database, 2001-2002, Utah Department of Health.

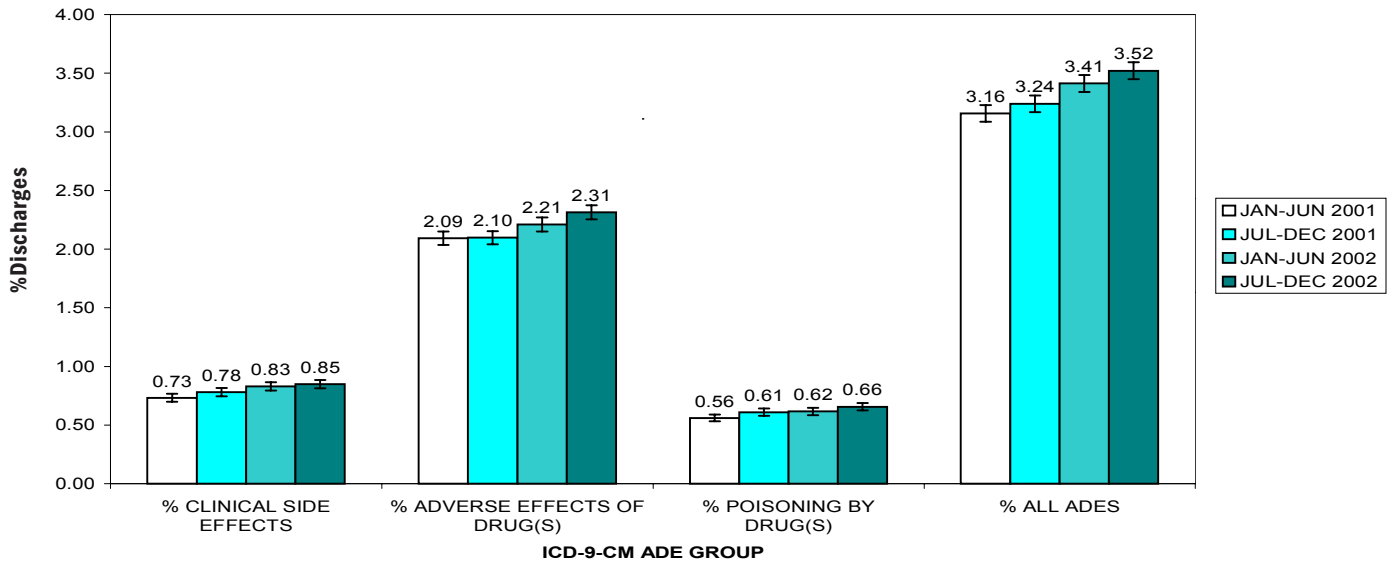
**TABLE
2**

Percentage of Inpatient Discharges with Adverse Drug Event (ADE)
By ICD-9-CM Code ADE Group and ADE Class and 6 Month Period
41 Utah Acute Care Hospitals
2001-2002

ICD-9-CM ADVERSE DRUG EVENT GROUP AND CLASS	JAN-JUN	JUL-DEC	JAN-JUN	JUL-DEC
	2001	2001	2002	2002
Total Discharges With At Least One Adverse Drug Event	3.158	3.239	3.413	3.521
Clinical Manifestations of Adverse Drug Events	0.731	0.779	0.829	0.849
Drug psychoses	0.301	0.372	0.357	0.457
Dermatitis	0.196	0.189	0.21	0.192
Maternal causes of perinatal morbidity and mortality, drug reaction	0.017	0.013	0.015	0.01
Rash, spontaneous ecchymoses	0.218	0.213	0.25	0.193
Poisoning by Drugs	0.561	0.61	0.616	0.656
Poisoning by antibiotics and other antiinfectives	0.004	0.006	0.006	0.007
Poisoning by hormones and synthetic substitutes	0.013	0.022	0.027	0.016
Poisoning by primarily systemic agents	0.028	0.042	0.027	0.029
Poisoning by agents affecting blood constituents	0.015	0.012	0.016	0.015
Poisoning by analgesics, antipyretics, antirheumatics	0.177	0.181	0.2	0.193
Poisoning by anticonvulsant and anti-Parkinsonian drugs	0.035	0.031	0.033	0.037
Poisoning by sedatives and hypnotics	0.038	0.054	0.055	0.054
Poisoning by other CNS depressants, stimulants, anesthetics	0.033	0.043	0.044	0.039
Poisoning by psychotropic agents	0.211	0.242	0.247	0.258
Poisoning by other agents	0.096	0.098	0.099	0.109
Poisoning, undetermined whether accidentally or purposely inflicted	0.063	0.072	0.064	0.093
Adverse Effects by Drugs	2.094	2.097	2.211	2.314
Adverse effects of antibiotics and other antiinfectives	0.181	0.193	0.225	0.212
Adverse effects of hormones and synthetic substitutes	0.287	0.25	0.259	0.311
Adverse effects of primarily systemic agents	0.235	0.231	0.238	0.254
Adverse effects of agents primarily affecting blood constituents	0.174	0.176	0.185	0.201
Adverse effects of analgesics, antipyretics, antirheumatics	0.406	0.439	0.445	0.531
Adverse effects of anticonvulsant and anti-Parkinsonian drugs	0.059	0.054	0.065	0.06
Adverse effects of sedatives and hypnotics	0.08	0.086	0.11	0.085
Adverse effects of other CNS depressants, stimulants, anesthetics	0.092	0.08	0.109	0.077
Adverse effects of psychotropic agents	0.102	0.127	0.123	0.135
Adverse effects of agents affecting cardiovascular system	0.237	0.218	0.217	0.24
Adverse effects of other drugs, biological, medicinal substances	0.311	0.312	0.306	0.315
Total Inpatient Discharges For 6-Month Period	121,403	118,415	124,131	122,676

SOURCE: Utah Hospital Discharge Database, 2001-2002, Utah Department of Health.

FIGURE 1. PERCENTAGE OF INPATIENT DISCHARGES WITH AT LEAST ONE ADE BY ADE GROUP AND SIX-MONTH TIME PERIOD, UTAH, 41 ACUTE CARE HOSPITALS, 2001- 2002



Tables 1 and 2 and Figure 1 show that number and percentage of inpatient discharges with at least one ADE have increased over the four six month time periods. The confidence intervals (shown as an I symbol on the upper edge of each bar in Figure 1) indicate that some increases are statistically significant and other increases are not. For all three sub-groups and for all ADEs, the increases from January-June 2001 to July-December 2002 are significant, as are the increases from January-June 2001 to January-June 2002. For adverse effects and all ADEs the increases from July-December 2001 to January-June 2002 are significant. "Significant" means that the probability that the increases in reported adverse drug events are due to chance is less than 5%.

FIGURE 2. PERCENTAGE OF INPATIENT DISCHARGES WITH RASH BY SIX-MONTH PERIOD, UTAH, 41 ACUTE CARE HOSPITALS 2001 - 2002

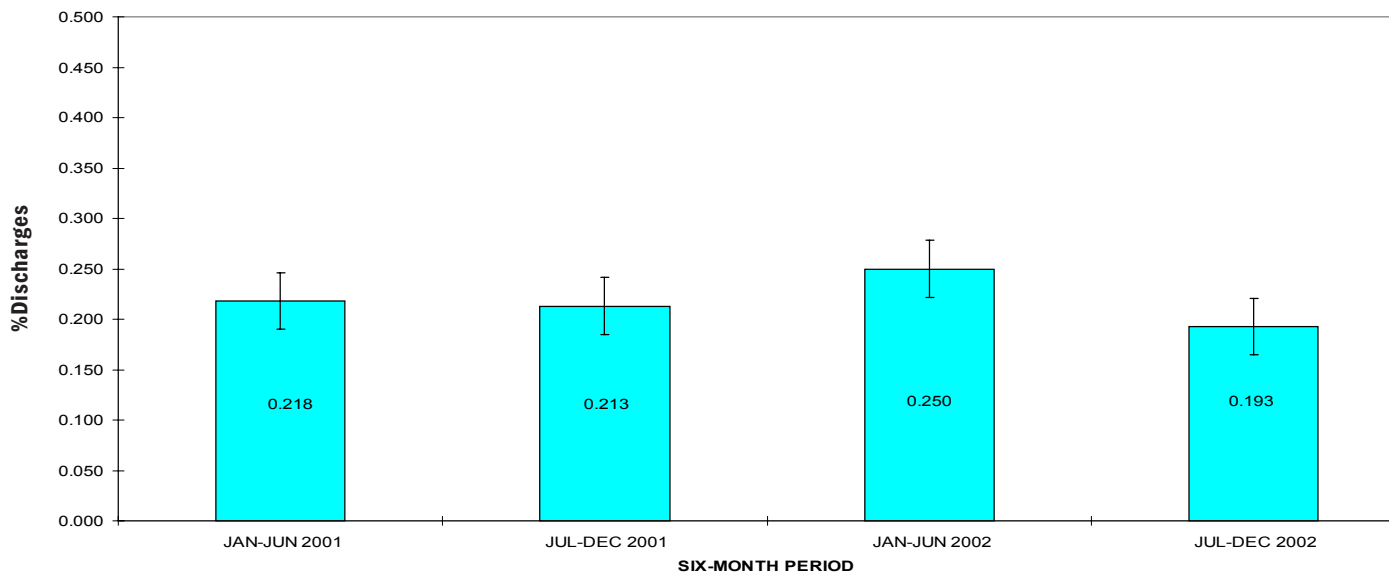


Figure 2 shows that the percentage is stable across the four six month time periods for inpatient discharges that have at least one ICD-9-CM code for the ADE Class of Rash. The confidence intervals (shown as an I symbol on the upper edge of each bar in Figure 2) indicate that the differences are not significant.

FIGURE 3. PERCENTAGE OF INPATIENT DISCHARGES WITH ADVERSE EFFECTS OF BLOOD CONSTITUENTS BY SIX-MONTH PERIOD, UTAH, 41 ACUTE CARE HOSPITALS 2001 - 2002

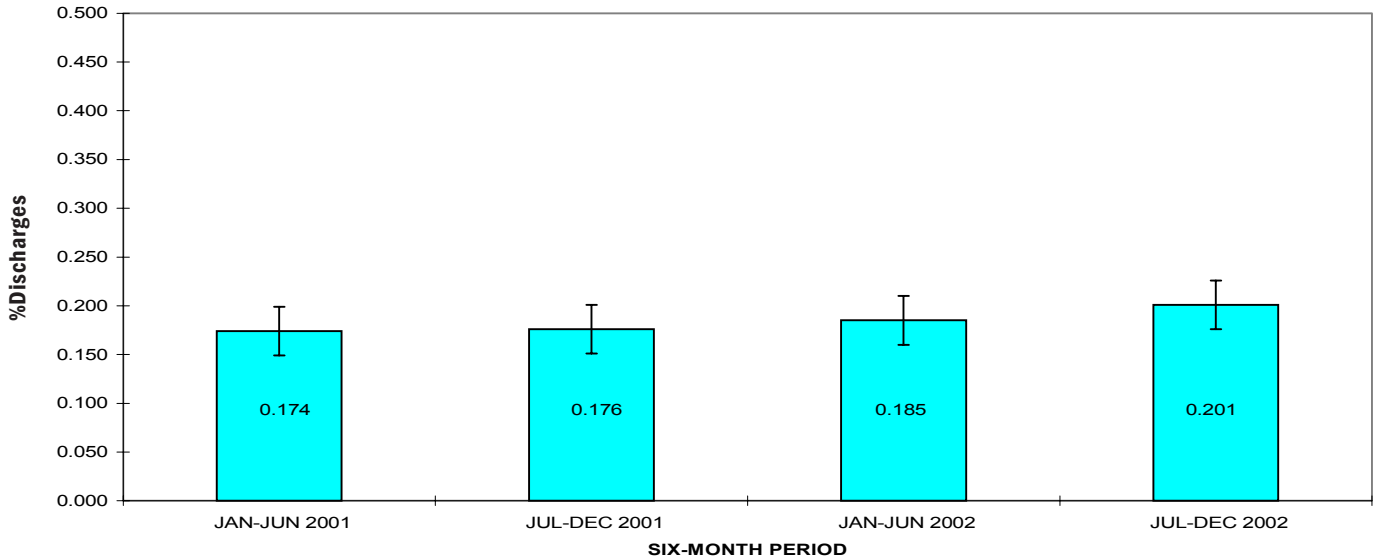


Figure 3 shows that the percentage is stable across the four six month time periods for inpatient discharges that have at least one ICD-9-CM code for the ADE Class of Adverse Effect of Agents Affecting Blood Constituents. The confidence intervals (shown as an I symbol on the upper edge of each bar in Figure 3) indicate that that the differences are not significant.

FIGURE 4. PERCENTAGE OF INPATIENT DISCHARGES WITH AT LEAST ONE ADE BY CASE MIX INDEX, UTAH, 39 ACUTE CARE HOSPITALS, 2002

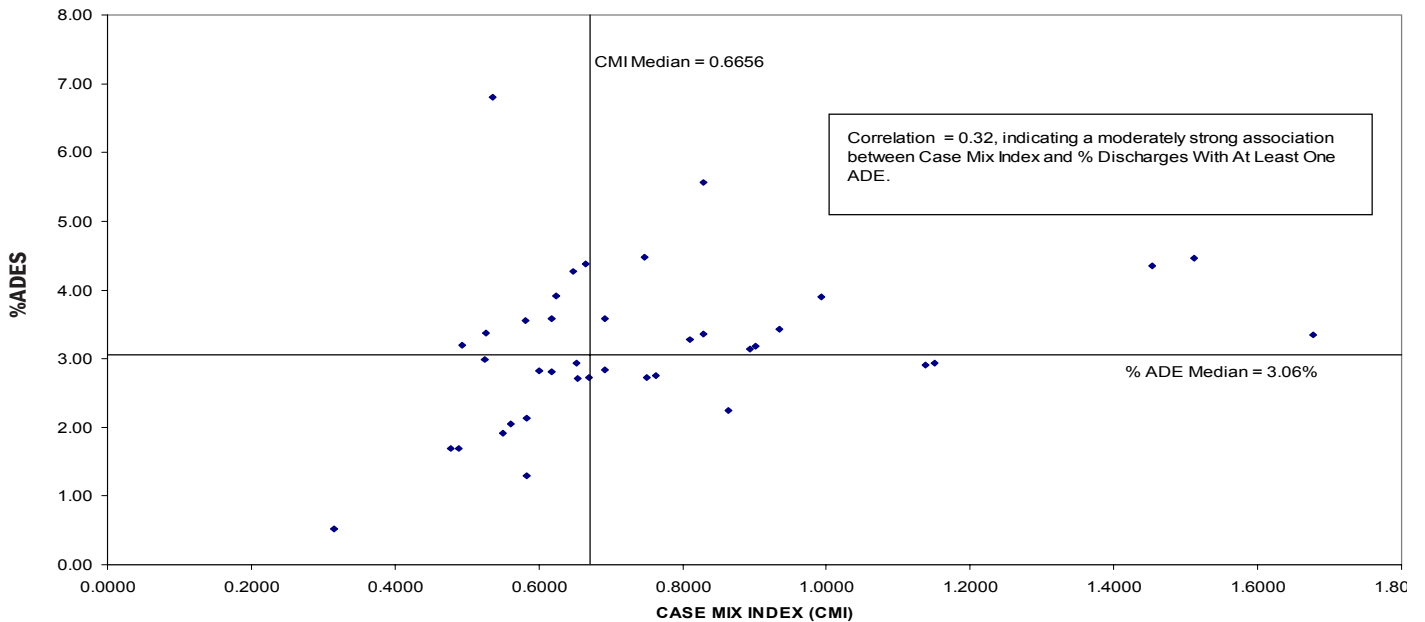


Figure 4 shows the percentage of discharges with at least one ADE by hospital peer group. The percentage is highest for urban hospitals with high CMI and lowest for rural hospitals with low CMI. High CMI appears to drive the percentage up for rural hospitals.

**TABLE
3**

The ICD-9-CM Codes of Adverse Drug Events (ADE)
by ADE Class, Utah, 41 Acute Care Hospitals, 2002 Version

Class #	Adverse Event Class	ICD-9-CM Codes Included
1	Drug psychoses	292
2	Dermatitis	692.3,692.9,693.0,693.8,693.9
3	Maternal causes of perinatal morbidity and mortality, Drug reactions and intoxications specific to newborn	760.72,760.74,763.5,779.4
4	Rash, spontaneous ecchymoses	782.1,782.7
5	Poisoning by antibiotics and other antiinfectives	960-961, E856-857
6	Poisoning by hormones and synthetic substitutes	962, E858.0
7	Poisoning by primarily systemic agents	963, E858.1
8	Poisoning by agents primarily affecting blood constituents	964, E858.2
9	Poisoning by analgesics, antipyretics, antirheumatics	965, E850
10	Poisoning by anticonvulsant and anti-Parkinsonian drugs	966, E855.0
11	Poisoning by sedatives and hypnotics	967, E851-852
12	Poisoning by other CNS depressants, stimulants, anesthetics, nervous system agents	968, E855.1-855.9
13	Poisoning by psychotropic agents	969, E853, E854
14	Poisoning by other agents	909.0, 970-979, E858.3-858.9, E929.2
15	Adverse effects of antibiotics and other antiinfectives	E930-E931
16	Adverse effects of hormones and synthetic substitutes	E932
17	Adverse effects of primarily systemic agents	E933
18	Adverse effects of agents primarily affecting blood constituents	E934
19	Adverse effects of analgesics, antipyretics, antirheumatics	E935
20	Adverse effects of anticonvulsant and anti-Parkinsonian drugs	E936
21	Adverse effects of sedatives and hypnotics	E937
22	Adverse effects of other CNS depressants, stimulants, anesthetics, nervous system agents	E938, E940-941
23	Adverse effects of psychotropic agents	E939
24	Adverse effects of agents primarily affecting the cardiovascular system	E942
25	Adverse effects of other drugs, biological, medicinal substances in therapeutic use	E943-E949.909.5
26	Poisoning (undetermined whether accidentally or purposely inflicted)	E980.0-E980.5,E980.9

Source: The Utah/Missouri Patient Safety Project, National Expert Panel for ICD-9-CM Classification of Adverse Events, 2002

Table 3 shows the classification of 420 Drug ICD-9-CM DX codes and E-codes in 26 classes of ADEs as described in this report's section, "About Adverse Events." A detailed list of the codes for these 26 ADE classes, as well as the other 40 classes of adverse events, is available on the website health.utah.gov/psi.

Health Care Facility Patient Safety Program and Administrative Rule

The Utah Hospitals and Health Systems Association (UHA), jointly with the Utah Medical Association (UMA) and Utah Department of Health (UDOH), established a patient safety task force in 2000. This task force initiated the discussion of and endorsed the administrative rule on patient safety that went into effect on October 1, 2001.

The Health Care Facility Patient Safety Program Rule requires that:

- 1) Each facility shall implement processes to effectively identify and report to the Department the incidence of all:
 - a) adverse drug events.
- 2) Reporting to the Department may occur through established, statewide, electronic health care facility reporting systems managed by the Department.
- 3) The report shall include codes applicable to the event from the current International Classification of Diseases Clinical Modification (ICD-CM) diagnosis coding, including codes for external cause of injury (E-codes) and codes for place of occurrence.

A variety of methods are available for detecting and tracking adverse drug events. They are:

- Traditional incident reporting
- Retrospective chart review
- Automated detection based on clinical response
- Daily pharmacist chart review
- Hospital discharge data reporting

Hospitals can select any of the methods and report quarterly the aggregated number of ADEs to the Utah Department of Health

Anti-Coagulation in a Rural Setting

Sanpete Valley Hospital Anti-Coagulation Clinic, Mt. Pleasant, Utah
 Brent W. Peterson, Pharm.D. Email: spbpeter@ihc.com Phone: 435-462-4159

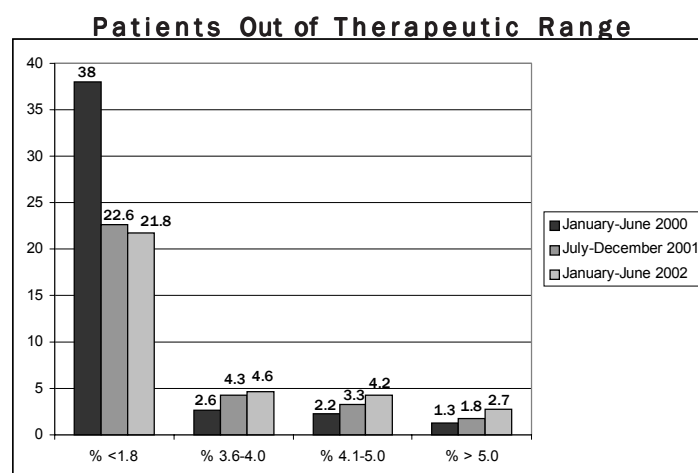
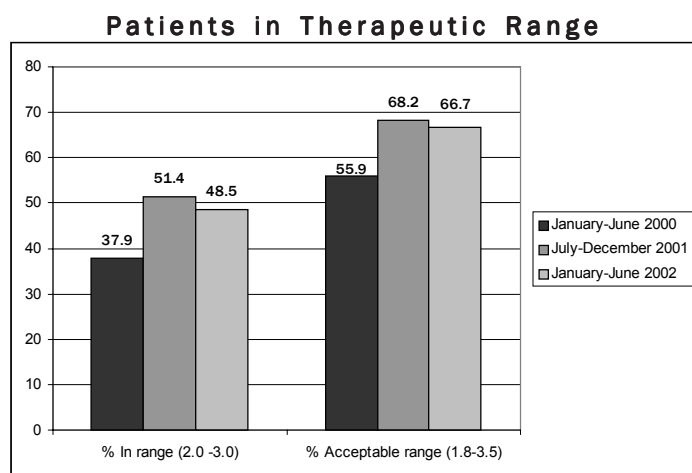
It has been well documented that proper anti-coagulation for a given patient with a given disease state is important. Unfortunately, such “proper anti-coagulation” is also often times very difficult to achieve. Today the most common long-term anti-coagulant used is warfarin (trade name Coumadin). While warfarin is a life-saving drug it is also a very difficult drug to manage. It has a very narrow therapeutic range and has hundreds of documented drug-drug, drug-food, and drug-herbal interactions all of which make patients taking it prone to have potentially serious adverse effects. Its dose must be individualized for each patient through strict monitoring of the patient’s blood which may be done as often as every day or two for patients not within therapeutic range, or every 4 weeks for those stable on a given dose. Monitoring warfarin therapy tends to be tedious and time consuming, but the outcomes of improper monitoring can be life threatening.

In an attempt to better serve its patients, in January of 2001 Sanpete Valley Hospital implemented an anti-coagulation clinic. The main goal of the clinic was to improve the time a patient’s INR (International Normalized Ratio) was within therapeutic range, thus minimizing the risk of blood clots (if INR is too low) as well as bleeding (if INR is too high). The clinic is operated by the hospital’s clinical pharmacist, who monitors INRs for all out-patients seen by physicians in the area (as well as all patients in the hospital), thus ensuring a smooth transition from in-patient to out-patient care. Prior to the clinic’s inception each physician managed his/her own patients’ warfarin therapy.

Before the clinic was initiated, baseline INR data were obtained. After having been in place for 1 year, the clinic then compared its data to that of the data collected prior to the clinic and again at 18 months after initiation. Using the two-by-two matrix chi-square test it was found that the clinic in fact made a statistically significant improvement in the time patients spent within therapeutic range as compared to prior to the clinics inception. The figures below represent those patients’ INRs whose target goal was 2.5.

Figure 5

Figure 6



The number of INRs in range was statistically greater in the clinic when compared to baseline (Figure 5). Also of note was the fact that the number of low INRs (<1.8) went down significantly (P values all < 0.008 for first 3 range sets), while the number of high INR’s (>3.6) did not differ significantly (P values all > 0.20 for last 3 range sets) (Figure 6).

Now nearing the end of its third year in operation, the anti-coagulation clinic remains in full swing. It has approximately 140 patients in the clinic at any time and handles over 120 INRs per month. The pharmacist tries to meet with each patient face-to-face at the time of the blood draw to help minimize lag time between getting the INR results and relaying the appropriate information to the patient. Feed back concerning the clinic from both patients and physicians has been extremely positive. Those involved with the clinic believe they are making a significant impact in patient safety by minimizing the inherent risks of anti-coagulation therapy.

Acknowledgments

To receive additional copies of this update, or back issues of the Utah Patient Safety Update, contact the Office of Health Care Statistics at:

Phone: 801-538-6938
Fax: 801-538-9916
Email: rsimmeri@utah.gov
Internet: health.utah.gov/psi

“[Our] success will be indicated initially by seeing an increased number of events detected and reported across the state.”

Scott D. Williams, MD
Deputy Director,
Utah Department of Health

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Utah Department of Health

HealthInsight

UHA, Utah Hospitals and Health Systems Association

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LDS Hospital, Intermountain Health Care

Missouri Department of Health and Senior Services

Missouri Patient Care Review Foundation

University of Missouri-Columbia, School of Medicine

This report was developed by Dr. Carol Masheter, formatted by Rachele Simmering and reviewed by Dr. Paul Hougland and Dr. Wu Xu.

For more information about this project, contact Paul Hougland at (801) 538-6353 or HealthCareStat@utah.gov.

**Office of Health Care Statistics
Utah Department of Health
P O Box 144004
Salt Lake City, Utah 84114-4004**

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