

Health studies document effects of social crisis

## Drug reaction epidemic in the US

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Serious adverse drug reactions (ADRs) are epidemic in the US. According to a study reported in the mid-April issue of the *Journal of the American Medical Association* ( *JAMA*), they are the fourth leading cause of death in America. ADRs rank behind only heart disease (743,460 deaths), cancer (529,904 deaths), and stroke (150,108 deaths). More people die in the US from ADRs than from pneumonia and diabetes.

The analysis was drawn from 39 previous studies from various US hospitals beginning in the 1960's. In 1994 2,216,000 US hospital patients had serious ADRs and 106,000 deaths resulted. "Perhaps the most surprising result was the large number of fatal ADRs," the researchers commented.

The data on serious ADRs (adverse reactions that required or prolonged hospitalization, was permanently disabling, or resulted in death) was compiled from patients admitted with adverse drug reactions (ADRAd) and those who experienced reactions while in the hospital (ADRIn). The combined overall incidence (including both serious and non-serious ADRs) was 15.1 percent of all hospital patients.

The researchers, led by University of Toronto masters candidate Jason Lazarou, emphasized that this research excluded errors in drug administration, noncompliance, overdose, abuse, therapeutic failures and ADRs listed as only possible. The plan was to show the extent of serious ADRs when drugs are properly prescribed and administered.

The Toronto group's statistics also revealed a large number of the ADRIns (76.2 percent) being type A or dose dependent, leading the authors to point to possible inadequate monitoring of therapies and doses in hospitals. Data showed no change in the rate of serious ADRs in the 30-year period studied, another surprise for the researchers. They commented, "Perhaps while length of hospital stay is decreasing, the number of drugs per day may be rising to compensate."

There is no mention of the cuts in nurses and other hospital staff that have accompanied the reductions in the length of patient hospital stays. Both have emanated from recent deep

cost cutting in the US healthcare industry.

The *JAMA* published an accompanying editorial, "Drugs and Adverse Drug Reactions, How Worried Should We Be?", in which Dr. David W. Bates of Partners Healthcare System in Boston comments that these figures are much higher than generally recognized, pointing out, "One reason is that hospitals have had strong incentives not to identify too many of these events."

Bates goes on to claim that the requirement for routine chart review included in new regulations proposed by the government Health Care Financing Administration is too expensive. The regulations, proposed last November, would require hospitals to routinely monitor for adverse drug events and would impose sanctions if they fail to do so.

Although the *JAMA* report on drug reactions received the most coverage in the US media, it was only one of three articles in the same issue demonstrating the link between social conditions and deteriorating health care.

In a very different commentary in the same issue, Dr. Alan D. Wolfe refers to Dante's *Inferno* in describing the horrific conditions that led to the death of at least 88 Haitian children in 1995 and 1996. An accompanying study entitled, "Epidemic of Pediatric Deaths from Acute Renal Failure Caused by Diethylene Glycol Poisoning," by doctors from the US National Center for Infectious Disease and others, followed the efforts to uncover the source and to contain an epidemic of acute renal failure. This unusual cause of childhood death was found in 32 children admitted to the University General Hospital in Port-au-Prince from November 1995 until May 1996.

The deaths were traced to contaminated acetaminophen syrup manufactured in Haiti. It was found the glycerin used in the process, which was procured by the manufacturer from European suppliers but originated in China, was contaminated. Researchers were unable to find at what point in the manufacturing process this had taken place.

Wolfe, of the Massachusetts Poison Control System, quotes from *The Divine Comedy*: "In the middle of the journey of our life I found myself in a dark wood, having

lost the straight path.” He then comments on the childrens’ deaths: “Such a tragedy alone is heartrending, but within the context of the pharmaceutical history of previous DEG poisonings, it is even more unbearable. For unlike the redoubtable poet, who was required to traverse the rings of hell and the plateaus of purgatory only once, we seem to be returning to this dark wood again and again.”

The study reviewed the grim medical record of DEG contamination. DEG is a toxic chemical found in, among other things, anti-freeze. It was the source of epidemics of acute renal failure in Argentina, Bangladesh, Spain, Nigeria and South Africa. The first reported DEG contamination in the United States, which occurred in 1937, led to the 1938 Federal Food, Drug and Cosmetic Act to regulate medicinal products. In that case the Massengill Company used a 72 percent solution of DEG to dissolve sulfanilamide, resulting in 105 deaths, 34 of them children. In the subsequent epidemics a large number of deaths were among children whose smaller size and dose-related vulnerability to toxins put them at greater risk for death.

Wolfe calls for more regulation of drug manufacture in underdeveloped countries but cites the current high cost of testing glycerin, which he calls the “smoking gun” in the Haitian incident.

Of the 109 children identified as stricken, 85 were confirmed dead, another 11 left the hospital in dire straits and were lost to followup. Of 11 others who were taken to the US for care, 8 survived.

But rather than health care in underdeveloped countries rising to the level of that now available in the US, a third study reported in the same issue of JAMA found deteriorating social conditions in America adversely affecting the quality of health care. Dr. Karin Nelson led a study at the Hennepin County Medical Center in Minneapolis, Minnesota which found hunger and food insecurity common among patients seeking care at the hospital. Citing estimates that 30 million people cannot obtain enough food to meet their daily needs, her study charges that hunger is now as prevalent as such common medical conditions as hypertension, diabetes and heart disease.

Of those surveyed at the county medical facility, 35 percent reported worrying that their food supply would not last until they had money to buy more, 28 percent reported putting off paying a bill to buy food, 27 percent reported receiving emergency food during the last year, and 13 percent reported obtaining food at a soup kitchen.

Thirteen per cent reported not eating for an entire day and 14 percent reported going hungry but not eating because they could not afford food. Some 40 percent reported three or fewer servings of fruits and vegetables in a two-day

period and nearly 19 percent reported having eaten none.

The researchers wrote, “During the past year, we have observed increasing numbers of patients in our practice setting who lack money to buy food. This is particularly troubling given the current implementation of welfare reform, in which nearly half of the cost saving come from reduction in food and nutrition programs.”

Later they amplified this statement: “We first undertook this study because of clinical observations of inadequate food supply in some of our diabetic patients, leading to discontinuation of insulin and hospitalization for ketoacidosis.”

Similar rates of food insecurity and hunger were reported in their secondary survey of insulin-dependent diabetics, with 61 percent reporting that they had experienced hypoglycemic reactions in the previous year, and 31 percent attributing the hypoglycemic reactions to being unable to afford food. Eight percent decreased or stopped taking their insulin because they did not have enough to eat. Of those unable to afford food, 26 percent required treatment in the emergency department or were hospitalized.

Over half the primary sample had an annual income of less than \$10,000, yet nearly 20 percent of them had not received any food stamps in the past year. Of all those who did receive food stamps in the past year (40 percent of the total respondents) half had had benefits reduced or eliminated.

The doctors noted, “Patients whose food stamp benefits were eliminated or reduced were more likely to report hunger and food insecurity.” Since their surveys were conducted at various times from April to June 1997, the cutbacks patients reported may have resulted from early local imposition of the federal cuts in food stamps mandated in January 1998.



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