

## **Death by Medicine**

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## **ABSTRACT**

A definitive review and close reading of medical peer-review journals, and government health statistics shows that American medicine frequently causes more harm than good. The number of people having in-hospital, adverse drug reactions (ADR) to prescribed medicine is 2.2 million.<sup>1</sup> Dr. Richard Besser, of the CDC, in 1995, said the number of unnecessary antibiotics prescribed annually for viral infections was 20 million. Dr. Besser, in 2003, now refers to tens of millions of unnecessary antibiotics.<sup>2, 2a</sup> The number of unnecessary medical and surgical procedures performed annually is 7.5 million.<sup>3</sup> The number of people exposed to unnecessary hospitalization annually is 8.9 million.<sup>4</sup> The total number of iatrogenic deaths shown in the following table is 783,936. It is evident that the American medical system is the leading cause of death and injury in the United States. The

2001 heart disease annual death rate is 699,697; the annual cancer death rate, 553,251.<sup>5</sup>

**TABLES AND FIGURES** (see Section on Statistical Tables and Figures, below, for exposition)

**ANNUAL PHYSICAL AND ECONOMIC COST OF MEDICAL INTERVENTION**

Condition	Deaths	Cost	Author
Hospital ADR	106,000	\$12 billion	Lazarou <sup>1</sup> Suh <sup>49</sup>
Medical error	98,000	\$2 billion	IOM <sup>6</sup>
Bedsore	115,000	\$55 billion	Xakellis <sup>7</sup> Barczak <sup>8</sup>
Infection	88,000	\$5 billion	Weinstein <sup>9</sup> MMWR <sup>10</sup>
Malnutrition	108,800	-----	Nurses Coalition <sup>11</sup>
Outpatient ADR	199,000	\$77 billion	Starfield <sup>12</sup> Weingart <sup>112</sup>
Unnecessary Procedures	37,136	\$122 billion	HCUP <sup>3,13</sup>
Surgery-Related	32,000	\$9 billion	AHRQ <sup>85</sup>
<b>TOTAL</b>	<b>783,936</b>	<b>\$282 billion</b>	

We could have an even higher death rate by using Dr. Lucien Leape’s 1997 medical and drug error rate of 3 million.<sup>14</sup> Multiplied by the fatality rate of 14% (that Leape used in 1994<sup>16</sup> we arrive at an annual death rate of 420,000 for drug errors and medical errors combined. If we put this number in place of Lazarou’s 106,000 drug errors and the Institute of Medicine’s (IOM) 98,000 medical errors, we could add another 216,000 deaths making a total of 999,936 deaths annually.

Condition	Deaths	Cost	Author
ADR/med error	420,000	\$200 billion	Leape 1997 <sup>14</sup>
<b>TOTAL</b>	<b>999,936</b>		

## ANNUAL UNNECESSARY MEDICAL EVENTS STATISTICS

Unnecessary Events	People Affected	Iatrogenic Events
Hospitalization	8.9 million <sup>4</sup>	1.78 million <sup>16</sup>
Procedures	7.5 million <sup>3</sup>	1.3 million <sup>40</sup>
<b>TOTAL</b>	<b>16.4 million</b>	<b>3.08 million</b>

The enumerating of unnecessary medical events is very important in our analysis. Any medical procedure that is invasive and not necessary must be considered as part of the larger iatrogenic picture. Unfortunately, cause and effect go unmonitored. The figures on unnecessary events represent people (“patients”) who are thrust into a dangerous healthcare system. They are helpless victims. Each one of these 16.4 million lives is being affected in a way that could have a fatal consequence. Simply entering a hospital could result in the following:

1. In 16.4 million people, 2.1% chance of a serious adverse drug reaction,1 (186,000)
2. In 16.4 million people, 5-6% chance of acquiring a nosocomial infection,9 (489,500)
3. In 16.4 million people, 4-36% chance of having an iatrogenic injury in hospital (medical error and adverse drug reactions),16 (1.78 million)
4. In 16.4 million people, 17% chance of a procedure error,40 (1.3 million)

All the statistics above represent a one-year time span. Imagine the numbers over a ten-year period. Working with the most conservative figures from our statistics we project the following 10-year death rates.

## TEN-YEAR DEATH RATES FOR MEDICAL INTERVENTION

Condition	10-Year Deaths	Author
Adverse Drug Reaction	1.06 million	(1)
Medical error	0.98 million	(6)
Bedsore	1.15 million	(7,8)
Nosocomial Infection	0.88 million	(9,10)
Malnutrition	1.09 million	(11)

Outpatients	1.99 million	(12, 112)
Unnecessary Procedures	371,360	(3,13)
Surgery-related	320,000	(85)
<b>TOTAL</b>	<b>7,841,360 (7.8 million)</b>	

Our projected statistic of 7.8 million iatrogenic deaths is more than all the casualties from wars that America has fought in its entire history.

Our projected figures for unnecessary medical events occurring over a 10-year period are also dramatic.

### TEN-YEAR STATISTICS FOR UNNECESSARY INTERVENTION

Unnecessary Events	10-year Number	Iatrogenic Events
Hospitalization	89 million <sup>4</sup>	17 million
Procedures	75 million <sup>3</sup>	15 million
<b>TOTAL</b>	<b>164 million</b>	

These projected figures show that a total of 164 million people, approximately 56% of the population of the United States, have been treated unnecessarily by the medical industry – in other words, nearly 50,000 people per day.

We have added, cumulatively, figures from 13 references of annual iatrogenic deaths. However, there is invariably some degree of overlap and double counting that can occur in gathering non-finite statistics. Death numbers don't come with names and birth dates to prevent duplication. On the other hand, there are many missing statistics. As we will show, only about 5 to 20% of iatrogenic incidents are even recorded.<sup>16,24,25,33,34</sup> And, our outpatient iatrogenic statistics<sup>112</sup> only include drug-related events and not surgical cases, diagnostic errors, or therapeutic mishaps.

We have also been conservative in our inclusion of statistics that were not reported in peer review journals or by government institutions. For example, on July 23, 2002, The Chicago Tribune analyzed records from patient databases, court cases, 5,810 hospitals, as well as 75 federal and state agencies and found 103,000 cases of death due to hospital infections, 75% of which were preventable.<sup>152</sup> We do not

include this figure but report the lower Weinstein figure of 88,000.<sup>9</sup> Another figure that we withheld, for lack of proper peer review was The National Committee for Quality Assurance, September 2003 report which found that at least 57,000 people die annually from lack of proper care for common diseases such as high blood pressure, diabetes, or heart disease.<sup>153</sup>

Overlapping of statistics in Death by Medicine may occur with the Institute of Medicine (IOM) paper that designates "medical error" as including drugs, surgery, and unnecessary procedures.<sup>6</sup> Since we have also included other statistics on adverse drug reactions, surgery and, unnecessary procedures, perhaps as much as 50% of the IOM number could be redundant. However, even taking away half the 98,000 IOM number still leaves us with iatrogenic events as the number one killer at 738,000 annual deaths.

## **INTRODUCTION**

Never before have the complete statistics on the multiple causes of iatrogenesis been combined in one paper. Medical science amasses tens of thousands of papers annually - each one a tiny fragment of the whole picture. To look at only one piece and try to understand the benefits and risks is to stand one inch away from an elephant and describe everything about it. You have to pull back to reveal the complete picture, such as we have done here. Each specialty, each division of medicine, keeps their own records and data on morbidity and mortality like pieces of a puzzle. But the numbers and statistics were always hiding in plain sight. We have now completed the painstaking work of reviewing thousands and thousands of studies. Finally putting the puzzle together we came up with some disturbing answers.

### **Is American Medicine Working?**

At 14% of the Gross National Product, healthcare spending reached \$1.6 trillion in 2003.<sup>15</sup> Considering this enormous expenditure, we should have the best medicine in the world. We should be reversing disease, preventing disease, and doing minimal harm. However, careful and objective review shows the opposite. Because of the extraordinary narrow context of medical technology through which contemporary medicine examines the human condition, we are completely missing the full picture. Medicine is not taking into consideration the following monumentally important aspects of a healthy human organism: (a) stress and how it adversely affects the immune system and life processes; (b) insufficient exercise; (c) excessive caloric intake; (d) highly-processed and denatured foods grown in denatured and chemically-damaged soil; and (e) exposure to tens of thousands of environmental toxins. Instead of minimizing these disease-causing factors, we actually cause more illness through medical technology, diagnostic testing, overuse of medical and surgical procedures, and overuse of pharmaceutical drugs. The huge disservice of this therapeutic strategy is the result of little effort or money being appropriated for preventing disease.

### **Under-reporting of Iatrogenic Events**

As few as 5% and only up to 20% of iatrogenic acts are ever reported.<sup>16,24,25,33,34</sup> This implies that if medical errors were completely and accurately reported, we would have a much higher annual iatrogenic death rate than 783,936. Dr. Leape, in 1994,

said his figure of 180,000 medical mistakes annually was equivalent to three jumbo-jet crashes every two days.<sup>16</sup> Our report shows that 6 jumbo jets are falling out of the sky each and every day.

### **Correcting a Compromised System**

What we must deduce from this report is that medicine is in need of complete and total reform: from the curriculum in medical schools to protecting patients from excessive medical intervention. It is quite obvious that we can't change anything if we are not honest about what needs to be changed. This report simply shows the degree to which change is required. We are fully aware that what stands in the way of change are powerful pharmaceutical companies, medical technology companies, and special interest groups with enormous vested interests in the business of medicine. They fund medical research, support medical schools and hospitals, and advertise in medical journals. With deep pockets they entice scientists and academics to support their efforts. Such funding can sway the balance of opinion from professional caution to uncritical acceptance of a new therapy or drug. You only have to look at the number of invested people on hospital, medical, and government health advisory boards to see conflict of interest. The public is mostly unaware of these interlocking interests. For example, a 2003 study found that nearly half of medical school faculty, who serve on Institutional Review Boards (IRB) to advise on clinical trial research, also serve as consultants to the pharmaceutical industry.<sup>17</sup> The authors were concerned that such representation could cause potential conflicts of interest. A news release by Dr. Erik Campbell, the lead author, said, "Our previous research with faculty has shown us that ties to industry can affect scientific behavior, leading to such things as trade secrecy and delays in publishing research. It's possible that similar relationships with companies could affect IRB members' activities and attitudes."<sup>18</sup>

### **Medical Ethics and Conflict of Interest in Scientific Medicine**

Jonathan Quick, Director of Essential Drugs and Medicines Policy for the World Health Organization wrote in a recent WHO Bulletin: "If clinical trials become a commercial venture in which self-interest overrules public interest and desire overrules science, then the social contract which allows research on human subjects in return for medical advances is broken."<sup>19</sup>

Former editor of the New England Journal of Medicine (NEJM), Dr. Marcia Angell, struggled to bring the attention of the world to the problem of commercializing scientific research in her outgoing editorial titled "Is Academic Medicine for Sale?"<sup>20</sup> Angell called for stronger restrictions on pharmaceutical stock ownership and other financial incentives for researchers. She said that growing conflicts of interest are tainting science. She warned that, "When the boundaries between industry and academic medicine become as blurred as they are now, the business goals of industry influence the mission of medical schools in multiple ways." She did not discount the benefits of research but said a Faustian bargain now existed between medical schools and the pharmaceutical industry.

Angell left the NEMJ in June, 2000. Two years later, in June, 2002, the NEJM announced that it will now accept biased journalists (those who accept money from drug companies) because it is too difficult to find ones that have no ties. Another former editor of the journal, Dr. Jerome Kassirer, said that was just not the case, that there are plenty of researchers who don't work for drug companies.<sup>21</sup> The ABC

report said that one measurable tie between pharmaceutical companies and doctors amounts to over \$2 billion a year spent for over 314,000 events that doctors attend.

The ABC report also noted that a survey of clinical trials revealed that when a drug company funds a study, there is a 90% chance that the drug will be perceived as effective whereas a non-drug company-funded study will show favorable results 50% of the time. It appears that money can't buy you love but it can buy you any "scientific" result you want. The only safeguard to reporting these studies was if the journal writers remained unbiased. That is no longer the case.

Cynthia Crossen, writer for the Wall Street Journal in 1996, published *Tainted Truth: The Manipulation of Fact in America*, a book about the widespread practice of lying with statistics.<sup>22</sup> Commenting on the state of scientific research she said that, "The road to hell was paved with the flood of corporate research dollars that eagerly filled gaps left by slashed government research funding." Her data on financial involvement showed that in 1981 the drug industry "gave" \$292 million to colleges and universities for research. In 1991 it "gave" \$2.1 billion.

## **THE FIRST IATROGENIC STUDY**

Dr. Lucian L. Leape opened medicine's Pandora's box in his 1994 JAMA paper, "Error in Medicine".<sup>16</sup> He began the paper by reminiscing about Florence Nightingale's maxim – "first do no harm." But he found evidence of the opposite happening in medicine. He found that Schimmel reported in 1964 that 20% of hospital patients suffered iatrogenic injury, with a 20% fatality rate. Steel in 1981 reported that 36% of hospitalized patients experienced iatrogenesis with a 25% fatality rate and adverse drug reactions were involved in 50% of the injuries. Bedell in 1991 reported that 64% of acute heart attacks in one hospital were preventable and were mostly due to adverse drug reactions. However, Leape focused on his and Brennan's "Harvard Medical Practice Study" published in 1991.<sup>16a</sup> They found that in 1984, in New York State, there was a 4% iatrogenic injury rate for patients with a 14% fatality rate. From the 98,609 patients injured and the 14% fatality rate, he estimated that in the whole of the U.S. 180,000 people die each year, partly as a result of iatrogenic injury. Leape compared these deaths to the equivalent of three jumbo-jet crashes every two days.

Why Leape chose to use the much lower figure of 4% injury for his analysis remains in question. Perhaps he wanted to tread lightly. If Leape had, instead, calculated the average rate among the three studies he cites (36%, 20%, and 4%), he would have come up with a 20% medical error rate. The number of fatalities that he could have presented, using an average rate of injury and his 14% fatality, is an annual 1,189,576 iatrogenic deaths, or over ten jumbo jets crashing every day

Leape acknowledged that the literature on medical error is sparse and we are only seeing the tip of the iceberg. He said that when errors are specifically sought out, reported rates are "distressingly high". He cited several autopsy studies with rates as high as 35-40% of missed diagnoses causing death. He also commented that an intensive care unit reported an average of 1.7 errors per day per patient, and 29% of those errors were potentially serious or fatal. We wonder: what is the effect on someone who daily gets the wrong medication, the wrong dose, the wrong procedure; how do we measure the accumulated burden of injury; and when the patient finally succumbs after the tenth error that week, what is entered on the death certificate?

Leape calculated the rate of error in the intensive care unit. First, he found that each patient had an average of 178 “activities” (staff/procedure/medical interactions) a day, of which 1.7 were errors, which means a 1% failure rate. To some this may not seem like much, but putting this into perspective, Leape cited industry standards where in aviation a 0.1% failure rate would mean 2 unsafe plane landings per day at O’Hare airport; in the U.S. Mail, 16,000 pieces of lost mail every hour; or in banking, 32,000 bank checks deducted from the wrong bank account every hour.

Analyzing why there is so much medical error Leape acknowledged the lack of reporting. Unlike a jumbo-jet crash, which gets instant media coverage, hospital errors are spread out over the country in thousands of different locations. They are also perceived as isolated and unusual events. However, the most important reason that medical error is unrecognized and growing, according to Leape, was, and still is, that doctors and nurses are unequipped to deal with human error, due to the culture of medical training and practice. Doctors are taught that mistakes are unacceptable. Medical mistakes are therefore viewed as a failure of character and any error equals negligence. We can see how a great deal of sweeping under the rug takes place since nobody is taught what to do when medical error does occur. Leape cited McIntyre and Popper who said the “infallibility model” of medicine leads to intellectual dishonesty with a need to cover up mistakes rather than admit them. There are no Grand Rounds on medical errors, no sharing of failures among doctors and no one to support them emotionally when their error harms a patient.

Leape hoped his paper would encourage medicine “to fundamentally change the way they think about errors and why they occur”. It’s been almost a decade since this groundbreaking work, but the mistakes continue to soar.

One year later, in 1995, a report in JAMA said that, "Over a million patients are injured in U.S. hospitals each year, and approximately 280,000 die annually as a result of these injuries. Therefore, the iatrogenic death rate dwarfs the annual automobile accident mortality rate of 45,000 and accounts for more deaths than all other accidents combined."<sup>23</sup>

At a press conference in 1997 Dr. Leape released a nationwide poll on patient iatrogenesis conducted by the National Patient Safety Foundation (NPSF), which is sponsored by the American Medical Association. The survey found that more than 100 million Americans have been impacted directly and indirectly by a medical mistake. Forty-two percent were directly affected and a total of 84% personally knew of someone who had experienced a medical mistake.<sup>14</sup> Dr. Leape is a founding member of the NPSF.

Dr. Leape at this press conference also updated his 1994 statistics saying that medical errors in inpatient hospital settings nationwide, as of 1997, could be as high as three million and could cost as much as \$200 billion. Leape used a 14% fatality rate to determine a medical error death rate of 180,000 in 1994.<sup>16</sup> In 1997, using Leape’s base number of three million errors, the annual deaths could be as much as 420,000 for inpatients alone. This does not include nursing home deaths, or people in the outpatient community dying of drug side effects or as the result of medical procedures.

### **ONLY A FRACTION OF MEDICAL ERRORS ARE REPORTED**

Leape, in 1994, said that he was well aware that medical errors were not being reported.<sup>16</sup> According to a study in two obstetrical units in the U.K., only about one

quarter of the adverse incidents on the units are ever reported for reasons of protecting staff or preserving reputations, or fear of reprisals, including law suits.<sup>24</sup> An analysis by Wald and Shojania found that only 1.5% of all adverse events result in an incident report, and only 6% of adverse drug events are identified properly. The authors learned that the American College of Surgeons gives a very broad guess that surgical incident reports routinely capture only 5-30% of adverse events. In one surgical study only 20% of surgical complications resulted in discussion at Morbidity and Mortality Rounds.<sup>25</sup> From these studies it appears that all the statistics that are gathered may be substantially underestimating the number of adverse drug and medical therapy incidents. It also underscores the fact that our mortality statistics are actually conservative figures.

An article in *Psychiatric Times* outlines the stakes involved with reporting medical errors.<sup>26</sup> They found that the public is fearful of suffering a fatal medical error, and doctors are afraid they will be sued if they report an error. This brings up the obvious question: who is reporting medical errors? Usually it is the patient or the patient's surviving family. If no one notices the error, it is never reported. Janet Heinrich, an associate director at the U.S. General Accounting Office responsible for health financing and public health issues, testifying before a House subcommittee about medical errors, said that, "The full magnitude of their threat to the American public is unknown." She added, "Gathering valid and useful information about adverse events is extremely difficult." She acknowledged that the fear of being blamed, and the potential for legal liability, played key roles in the under-reporting of errors. The *Psychiatric Times* noted that the American Medical Association is strongly opposed to mandatory reporting of medical errors.<sup>26</sup> If doctors aren't reporting, what about nurses? In a survey of nurses, they also did not report medical mistakes for fear of retaliation.<sup>27</sup>

Standard medical pharmacology texts admit that relatively few doctors ever report adverse drug reactions to the FDA.<sup>28</sup> The reasons range from not knowing such a reporting system exists to fear of being sued because they prescribed a drug that caused harm.<sup>29</sup> However, it is this tremendously flawed system of voluntary reporting from doctors that we depend on to know whether a drug or a medical intervention is harmful.

Pharmacology texts will also tell doctors how hard it is to separate drug side effects from disease symptoms. Treatment failure is most often attributed to the disease and not the drug or the doctor. Doctors are warned, "Probably nowhere else in professional life are mistakes so easily hidden, even from ourselves."<sup>30</sup> It may be hard to accept, but not difficult to understand, why only one in twenty side effects is reported to either hospital administrators or the FDA.<sup>31,31</sup>

If hospitals admitted to the actual number of errors and mistakes, which is about 20 times what is reported, they would come under intense scrutiny.<sup>32</sup> Jerry Phillips, associate director of the Office of Post Marketing Drug Risk Assessment at the FDA, confirms this number. "In the broader area of adverse drug reaction data, the 250,000 reports received annually probably represent only 5% of the actual reactions that occur."<sup>33</sup> Dr. Jay Cohen, who has extensively researched adverse drug reactions, comments that because only 5% of adverse drug reactions are being reported, there are, in reality, five million medication reactions each year.<sup>34</sup>

It remains that whatever figure you choose to believe about the side effects from drugs, all the experts agree that you have to multiply that by 20 to get a more

accurate estimate of what is really occurring in the burgeoning “field” of iatrogenic medicine.

A 2003 survey is all the more distressing because there seems to be no improvement in error-reporting even with all the attention on this topic. Dr. Dorothea Wild surveyed medical residents at a community hospital in Connecticut. She found that only half of the residents were aware that the hospital had a medical error-reporting system, and the vast majority didn't use it at all. Dr. Wild says this does not bode well for the future. If doctors don't learn error-reporting in their training, they will never use it. And she adds that error reporting is the first step in finding out where the gaps in the medical system are and fixing them. That first baby step has not even begun.<sup>35</sup>