

Update 26

What's The Truth Regarding Adverse Drug Events?

Adverse drug events (ADEs) are defined as instances where patients are unintentionally harmed as a result of drug use (This includes harm that occurs due to either an adverse drug reaction or a medication error).

Up until recently a wide range of figures have been reported in the peer-reviewed literature suggesting that ADEs occur in anything from 0.7% to 6.5% of hospital inpatients. However the results from two new unrelated studies, one published in the journal of Quality and Safety in Health Care (QSHC), and the other published in the NEJM, have widened that range considerably with the finding that **25% of hospital inpatients suffered an ADE (1) and 25% of outpatients suffered an ADE (2).**

The author of an accompanying commentary, after discussing the relevant literature and taking into account the findings from the new study in QSHC, contends that,

“...it is clear that adverse drug events (ADEs) represent an epidemic.” (3)

The author of the commentary, B. Dean, Director of the Academic Pharmacy unit at the School of Pharmacy, University of London, poses the question,

“So why this range of figures?”

In answer to his own question he concludes that three reasons may explain the wide range of figures:

1. Within the general definition of an ADE given above, there is wide discrepancy in what is considered to constitute “harm”.

This can certainly be seen to be the case when examining the different studies. Professor Dean points out that in the Harvard Medical Practice study, which found that only 0.7% of inpatients experienced an ADE, that in order for an event to be labeled an ADE there had to be measurable disability at discharge or increased length of stay due to the event. Therefore less serious injuries may have been excluded from the study. On the other hand, both the US ADE Prevention study group, which found that 6.5% inpatients experienced an ADE, and the new study published in QSHC, in which 25% of inpatients had an ADE, suggested that all ADEs were included. This helps explain why these two later studies found that inpatients experience higher rates of ADEs.

2. A wide range of data collection methods have been used.

The Harvard, Australian and UK studies were all based on retrospective reviews of medical notes. This method is very likely to lead to under-reporting for a number of reasons. The ADE Prevention Study group used a method called targeted self-reporting and daily medical record review. This approach is better than the retrospective review but still leads to some under-reporting. The latest study, by Rozich et al., manually and prospectively screened for ADEs based on what are called ‘triggers’. It is believed that the method is much better but still not perfect.

3.) There may be differences in the underlying ADE rates in the different institutions.

At this point in time it is not known whether the ADE rate is significantly different between different hospitals because no standardised method exists across studies.

In conclusion Professor Dean states, “reasons for the wide range in reported ADE rates include discrepancies in the definitions and data collection methods used. Great care must be taken when interpreting the results of studies of ADEs and other types of medical harm, and standardised methods and definitions are needed to compare ADE rates.”

Ultimately, the truth is that medication errors and ADEs continue to be the single largest source of repetitive healthcare mishaps, continually placing patients at risk.

Summary of the Frequency of ADEs amongst hospital patients from 4 different studies

25.0% of inpatients (1.)
25.0% of outpatients (2.)
0.7% of inpatients (4.)
1.7% of inpatients (5.)
6.5% of inpatients (6.)

Related LINKS:

Abstract for new NEJM study (Ref no.2) -

<http://content.nejm.org/cgi/content/abstract/348/16/1556>

Abstract for new QHSC study (Ref no.1) -

<http://qhc.bmjournals.com/cgi/content/abstract/12/3/194>

References:

1. Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. *Quality and Safety in Health Care* 2003;12:194-200.
2. Gandhi TK, et al. Adverse drug events in ambulatory care. *NEJM* 2003;348:1556-64.
3. Dean B. Adverse drug events: what's the truth? *Quality and Safety in Health Care* 2003;12:165-6.
4. Leape LL, et al. The nature of adverse events in hospitalized patients. *N Eng J Med* 1991;324:377-84.
5. Classen MD, et al. Computerized surveillance of adverse drug events in hospital practice. *J Am Med Assoc* 1991;266:2847-51.
6. Bates DW, et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. *JAMA* 1995;274:29-34.