

costs needed to cover additional tests, longer patient stays, and other direct expenses. Based on published studies, the estimated average direct cost of an ADE not attributable to prescribing error is \$2,257 (Classen et al., 1997; Bates et al., 1997; and Senst et al., 2001). This figure represents a weighted average of direct hospital costs over all degrees of ADE severity and does not include patient pain and suffering or liability. Second, ERG and FDA estimated the monetized value of avoiding decreases in quality-adjusted life years (QALYs) due to ADEs. This latter approach attempts to value a patient's subjective ADE experience, including inconvenience, pain and suffering, foregone earnings, and other out-of-pocket costs.

ERG examined the literature to determine the probability distribution of specific symptoms associated with ADEs. These reported symptoms range from rashes and itching to cardiac arrhythmia, renal failure, and mortality. The duration of each symptom (additional length of hospital stays) ranged from about 0.7 days to 5.5 days (except for mortality). ERG then examined reported preference scores from the Harvard Center for Risk Analysis' (HCRA) Catalog of Preference Scores, which includes a survey of the health economics literature and presents published estimates of preferences for defined symptoms. The preference scores ranged from 0.95 (for significant but not serious ADEs) to 0.00 for death. Typical symptoms encountered with serious ADEs had a preference score of 0.8, while life-threatening ADEs had a derived preference score of 0.6. We note

that the reported preference scores vary widely by definition and methodology and must be interpreted with great caution.

ERG calculated the change in QALYs expected from an avoided ADE as one minus the preference score multiplied by the duration of the event. For example, minor drug toxicity (such as a rash) has a derived preference score of 0.95 and a reported duration of 2 days (0.005 years). The change in QALYs expected for such an event is 0.05 (one minus 0.95) times 0.005, or 0.0003 QALYs. There are no precise means of valuing QALYs. One approach is to derive the value from studies that estimate the willingness-to-pay to avoid a statistical death. For example, values derived from occupational wage-premiums to accept measurable workplace risk suggest a figure of about \$5 million per statistical death avoided. Apportioning this value over the remaining life expectancy of the average workforce member and adjusting for future disability implies (at a 7-percent discount rate) a value per QALY of about \$373,000. Thus, in the example above, the value of the decrease in QALYs due to minor drug toxicity would be \$102.

ERG examined the literature and found that by combining several published accounts, 36.1 percent of the outcomes associated with preventable ADEs were deemed significant, 41.7 percent were deemed serious, 19.4 percent were deemed life threatening (of which 10 percent (or 1.9 percent of the total) result in permanent conditions), and 2.8 percent resulted in fatalities. Overall, these assumptions indicate that

the weighted average preference value for each avoided preventable ADE is \$181,600. We note that this value is very sensitive to the number of fatal preventable ADEs.

J. Aggregate Benefit of Avoiding ADEs

FDA and ERG estimated the benefit of avoiding ADEs due to the use of bar code reading systems by multiplying the value of each avoided preventable ADE by the expected number of ADEs avoided. As stated earlier, an average hospital is expected to have 12.8 fewer preventable ADEs each year after installing bar code reading technology. The direct cost savings by avoiding treatment (\$2,257 per ADE) and the weighted preference value (\$181,600 per ADE) indicate a societal value of \$183,900 per average ADE avoided, and a societal benefit of about \$2.35 million per facility per year. We multiplied this derived value per hospital by the expected difference in the number of hospitals with installed bar code technology under the proposed rule. For example, during the 10th evaluation year, an estimated 3,245 additional hospitals would have installed bar code reading systems due to the proposed rule. We would expect the increased use of these systems to result in 42,182 fewer ADEs. The estimated PV of avoiding these ADEs is \$7.7 billion. The PV of the societal benefits that would result from reductions in ADEs over the entire 20- evaluation period is \$41.4 billion. The annualized societal benefit of the reduced number of ADEs is \$3.9 billion. Table 5 illustrates the expected reduction in ADEs for the entire evaluation period.

TABLE 5.—EXPECTED REDUCTION IN ADEs BY YEAR WITH BAR CODE (SOCIETAL BENEFITS IN MILLIONS)

Evaluation Year	Additional ADEs Avoided	Societal Benefit of Avoided ADEs
1	38	\$7.0
2	627	\$113.7
3	4,314	\$781.9
4	16,845	\$3,053.5
5	39,462	\$7,153.4
6	60,634	\$10,991.1
7	68,646	\$12,443.6
8	64,486	\$11,689.5
9	54,144	\$9,814.7
10	41,344	\$7,494.5
11	28,493	\$5,164.9
12	17,523	\$3,176.5
13	9,510	\$1,724.0
14	4,531	\$821.4
15	1,882	\$341.1
16	678	\$123.0
17	218	\$39.4
18	51	\$9.3
19	13	\$2.3
20	0	0