Survey/Cross sectional study

Estimates of complications of medical care in the adult US population

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Abstract

Background: Total US population estimates of complications of medical care have relied on extrapolations of state-specific estimates. Generalizability is suspect because findings are limited by geographical location or time. We describe the relationship between the annual prevalence of complications of medical care (CM) and socio-demographic characteristics in the adult US population.

Methods: We used data from the National Health Interview Surveys, annual nationwide surveys of the resident, civilian, noninstitutionalized population of the United States. The main outcome of interest was self-reported conditions from CMs (ICD-9 996-999) and activity limitations that arise from such events. Univariate estimates and multivariably adjusted models accounting for selected socio-demographic characteristics and health status were derived.

Results: A total of 618,167 reports of conditions from 313,438 subjects 18 years and older from 1987 to 1994 were examined. In 1987, 830,386 adults reported complications of medical care, increasing by about 40% to 1,174,089 adults in 1994. Based on an extrapolation to the US adult population, rates increased by 25% from 558 to 678 per 100,000 during the same period. One-third reported onset a year prior to the interview; two-thirds visited a doctor six months prior; half experienced limitation in major activities; a quarter reported limitation in personal care activities. In the two weeks preceding the interview, complications of medical care caused an average of 1.72 days of restricted activity, 0.79 days spent in bed, and 0.58 days of work lost. Race modified the age-specific risk of these complications.

Conclusions: Complications of medical care impose heavier morbidity than previously considered with some indication that socio-demographic variables modify the risk for injuries.

Background

The Harvard Medical Practice Study (HMPS) examined the epidemiology of iatrogenic injuries arising from unintended adverse reactions and complications of medical care, termed "adverse events" [1, 2]. The study recruited a random sample of patients discharged from hospitals in New York state in 1984. Adverse events were found to occur in 3.4% of patients undergoing medical management. Of these, 14% died [1].

Apart from raising awareness of the magnitude of the problem [3–8], data from the HMPS has been used to es-

timate rates for the entire US general population [9]. There is concern that the scope of the HMPS might produce inappropriate population estimates, given that it was limited to a single state and collected data for a single year. For instance, a recent hospital-based study conducted in Utah and Colorado [5] reported an adverse event rate of 2.9% following hospitalization. The authors' extrapolation of this data to the general US population produced estimates that were lower that those derived from HMPS.

We present the results of analyses of self-reported complications of medical care using several years of cross-sectional data from a nationwide survey of US adults. We attempted to estimate the population prevalence of medical complications and examine the relationship between the self-reported complications of medical care and selected socio-demographic variables.

Materials and Methods

The US Bureau of Census, under the specifications of the National Center for Health Statistics (NCHS), conducts the National Health Interview Survey (NHIS) to obtain data on the health of the resident, civilian, noninstitutionalized population of the United States. The NHIS, one of the oldest US national health surveys, has a complex multistage probability design that uses clustering and stratification with oversampling of selected population subgroups [10, 11]. The overall response rate has consistently been about 95%.

We evaluated NHIS data from 1987 to 1994 focusing on 313,438 participants aged 18 or older. The main outcome variable of interest was the occurrence of a injury condition reported by the respondent to have been due to (1) acute or chronic conditions associated with disability days, doctor visits and/or hospitalizations in the two weeks preceding the NHIS interview; (2) chronic conditions reported to be the main or secondary cause of activity limitation; or (3) chronic conditions reported in response to a checklist of conditions for each body system.

In the NHIS, this data was collected by asking the subject to identify conditions that impacted on their health ("Is [subject] limited in any activities because of an impairment or health problem?" and "What condition caused this?") and by reading a standard list of chronic conditions and asking the subject whether he or she had any of the listed conditions. Responses were recoded by nosologists according to classifications based on the ninth revision of the International Classification of Diseases (ICD-9) [12]. This study focuses on ICD-9 codes 996 to 999 referring to injuries due to complications of surgical and medical care (subsequently recoded by the NHIS as an "adverse reaction or complication of medical care"). The range of conditions included in these codes are listed in Table 1 and excludes adverse drug reactions.

Secondary outcomes included the onset of complications; the last time a physician was visited for the condition; the level of restrictions in major, work-related, and personal care activities imposed by medical complications; and the number of total bed-days and days lost from work in the two-week period preceding the NHIS interview. Except for the latter two outcomes, all were coded using indicator variables.

The following socio-demographic variables were considered: age (7 categories), sex, race (white, black, other), region (US Northeast, Midwest, South, West), education (7 categories), annual family income (6 categories), major activity (work, housekeeping, school, other), and health status (excellent, very good, good, fair, poor). All socio-demographic variables were coded using indicator variables.

Race was coded as White, Black, or Other following NHIS data structures. The last category is obviously racially heterogeneous and contributes about 2.5% of the total survey population. Nevertheless, we recognized the paucity of extant information and chose to retain the category in all analyses.

General population estimates of complications of medical care took into account the complex sampling procedure employed by the National Center for Health Statistics. All analyses used methods to account for the sampling design of the study by utilizing weights provided on the NHIS data tapes to yield population estimates. All analyses were conducted using Stata 6.0 (College Station, Texas, USA).

We derived annual estimates of the prevalence of these complications of care from 1987 to 1994 and according to the selected socio-demographic variables. Contingency tables were analysed using chi-square tests corrected for the complex sampling design to test for differences between variables [13, 14]. Univariate prevalence odds ratios of medical complications were calculated for each of the socio-demographic variables previously identified. The two-way interaction between race and age was examined by including the relevant terms into the model. Three multivariable logistic regression models were applied to adjust for potentially confounding factors. Model 1 adjusted for the year of the survey. Model 2 included survey year plus education and annual income. Model 3 adjusted for all the variables in Model 2 plus major activity and self-reported health status. Tests were considered significant at $P < 0.05$.

Table 1: Conditions listed under ICD-9 codes 996-999.

Code	Condition
996.0	Mechanical complication of cardiac device, implant, and graft
996.1	Mechanical complication of other vascular device, implant, and graft
996.2	Mechanical complication of nervous system device, implant, and graft
996.3	Mechanical complication of genitourinary device, implant, and graft
996.4	Mechanical complication of internal orthopedic device, implant, and graft
996.5	Mechanical complication of other specified prosthetic device, implant, and graft
996.6	Mechanical complication of other specified prosthetic device, implant, and graft
996.7	Other complications of internal (biological) (synthetic) prosthetic device, implant, and graft
996.8	Complications of transplanted organ
996.9	Complications of reattached extremity or body part
997.0	Nervous system complications during or resulting from a procedure
997.1	Cardiac complications during or resulting from a procedure
997.2	Peripheral vascular complications during or resulting from a procedure
997.3	Respiratory complications during or resulting from a procedure
997.4	Digestive system complications during or resulting from a procedure
997.5	Urinary complications during or resulting from a procedure
997.6	Late amputation stump complication during or resulting from a procedure
997.9	Complications affecting other specified body systems during or resulting from a procedure
998.0	Postoperative shock during or resulting from a procedure
998.1	Hemorrhage or hematoma complicating a procedure
998.2	Accidental puncture or laceration during a procedure
998.3	Disruption of operation wound
998.4	Foreign body accidentally left during a procedure
998.5	Postoperative infection
998.6	Persistent postoperative fistula
998.7	Acute reaction to foreign substance accidentally left during a procedure
998.8	Other specified complications of procedures
998.9	Unspecified complication of procedure
999.0	Generalized vaccinia
999.1	Air embolism to any site following infusion, perfusion, or transfusion
999.2	Other vascular complications following infusion, perfusion, or transfusion
999.3	Other infections following infusion, perfusion, or transfusion
999.4	Anaphylactic shock due to serum
999.5	Other serum reaction
999.6	ABO incompatibility reaction
999.7	Rh incompatibility reaction
999.8	Other transfusion reaction
999.9	Other and unspecified complications of medical care

Results

From 1987 to 1994, the NHIS sampled a total of 313,438 subjects aged 18 years or older. These subjects provided a total of 618,167 reports of conditions of which 3,740 were complications of medical care.

Annual estimates of the prevalence of the condition in the total population are shown in Figure 1. The results point to a generally increasing trend in both the number and proportion of the total population. In 1987, 830,386 adults reported complications of medical care, increasing by about 40% to 1,174,089 adults in 1994. Based on an extrapolation to the US adult population, rates increased by 25% from 558 to 678 per 100,000 during the same period, although in a non-monotonic manner. The average increase in rates was about 3.38% (95% confidence interval [CI] = 1.85-4.93) annually over the study period.

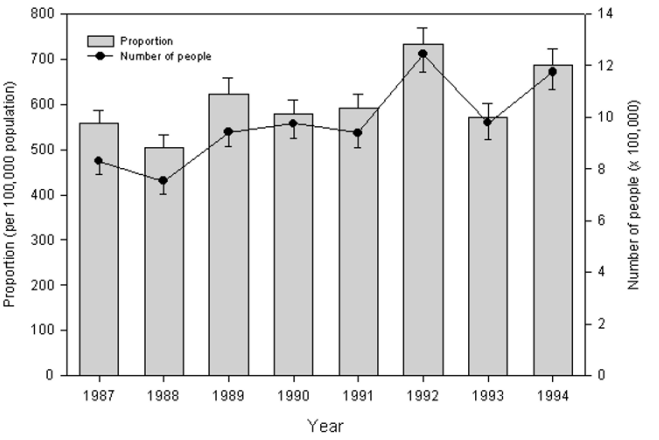

Figure 1
Proportion and number of subjects with self-reported complications of medical care extrapolated to the US adult population, by year, National Health Interview Surveys, 1987 to 1994.

The socio-demographic characteristics of the study population and corresponding total population estimates are presented in Table 2. Univariate analyses suggest that there were no statistically significant differences in the risk of an injury due to medical complications by gender ($P = 0.581$). There was some evidence of an increasing trend by age ($P < 0.001$). Significant associations in risk according to regional ($P = 0.041$), racial ($P < 0.001$), educational ($P < 0.001$), and annual income ($P = 0.001$) variables were also present. A statistically significant inverse relationship was seen between health status and the risk for complications ($P < 0.001$).

31.6% of all subjects reporting complications of medical care stated it occurred within a year of the interview (Table 3). About 75% said they had visited a doctor within the past year to discuss the condition (about 66% in the past six months). About half said they experienced some degree of limitation in the performance of their major activities and a quarter reported some limitation in performing personal care activities due to their condition.

Overall, there was an average of 1.72 days of restricted activity, 0.79 days spent in bed, and 0.58 days of work lost due to these complications of medical care. When

limited to medical complications occurring in the two weeks prior to the interview, the results are 3.52, 1.90, and 1.51 days, respectively.

The interaction between race and age was found to be statistically significant in the base model (P = 0.016). In whites, Model 1 suggested a steadily increasing trend in the risk of complications of medical care according to age, at least until the middle of the seventh decade of life (Table 4). Full adjustment verified that subjects aged 25 and older were at a statistically significantly increased risk for medical complications. The highest risk corresponded to an 81% increase (95% CI = 38%-138%) compared to the youngest age group. In blacks, adjustment for all variables suggested a 45% greater risk for complications of medical care in persons aged 25 to 35 and those 35 to 44 years compared to those aged 18 to 24. All other age groups did not show statistical significance.

Table 2: Descriptive characteristics of the study population according to selected socio-demographic variables, National Health Interview Surveys, 1987-1994.

Characteristic	Number (%*) of subjects	Number (%*) reporting complication of medical care	Estimated size of total population reporting complication of medical care	Estimated percentage of total population reporting complication of medical care (95% confidence interval)†	Univariate prevalence odds ratio (95%) confidence interval†
Sex					
Male	133,533 (42.61)	1,467 (39.22)	3,148,699	0.59 (0.55-0.62)	1.00
Female	179,885 (57.39)	2,273 (60.78)	4,686,767	0.62 (0.59-0.65)	0.98 (0.91-1.05)
Age, y					
18-24	26,484 (8.45)	137 (3.66)	318,035	0.36 (0.30-0.42)	1.00
25-34	54,177 (17.28)	437 (11.68)	964,060	0.52 (0.46-0.57)	1.48 (0.21-1.80)
35-44	58,533 (18.67)	593 (15.86)	1,234,644	0.59 (0.54-0.64)	1.68 (1.37-2.05)
45-54	47,343 (15.10)	582 (15.56)	1,202,700	0.64 (0.58-0.70)	1.77 (1.45-2.16)
55-64	46,321 (14.78)	675 (18.05)	1,402,819	0.67 (0.61-0.73)	1.77 (1.46-2.14)
65-74	46,266 (14.76)	774 (20.70)	1,577,256	0.70 (0.65-0.76)	1.80 (1.48-2.18)
75 and older	34,314 (10.95)	542 (14.49)	1,135,952	0.63 (0.56-0.69)	1.58 (1.30-1.93)
Race					
White	264,759 (84.47)	3,248 (86.84)	6,964,509	0.62 (0.59-0.65)	1.00
Black	40,936 (13.06)	416 (11.12)	681,855	0.49 (0.44-0.55)	0.78 (0.70-0.88)
Other	7,743 (2.47)	76 (2.03)	189,102	0.60 (0.46-0.75)	0.98 (0.77-1.26)
Region					
Northeast	60,690 (19.36)	640 (17.11)	1,301,268	0.54 (0.49-0.60)	1.00
Midwest	79,717 (25.43)	1,020 (27.27)	2,063,524	0.65 (0.59-0.70)	1.20 (1.06-1.37)
South	107,068 (34.16)	1,325 (35.43)	2,844,560	0.62 (0.57-0.66)	1.14 (1.01-1.29)
West	65,963 (21.04)	755 (20.19)	1,626,114	0.60 (0.55-0.65)	1.16 (1.02-1.31)
Education					
None	2,338 (0.75)	17 (0.46)	36,156	0.34 (0.17-0.50)	1.00
Elementary	38,727 (12.48)	627 (16.86)	1,253,608	0.65 (0.59-0.71)	1.99 (1.20-3.31)
Some high school	42,311 (13.63)	626 (16.83)	1,270,559	0.69 (0.63-0.75)	2.19 (1.31-3.65)
High school graduate	113,582 (36.60)	1,304 (35.06)	2,753,220	0.61 (0.57-0.65)	1.95 (1.17-3.24)
Some college	59,247 (19.09)	643 (17.29)	1,380,437	0.59 (0.54-0.64)	1.90 (1.14-3.17)
College graduate	30,244 (9.75)	286 (7.69)	631,982	0.56 (0.49-0.63)	1.74 (1.04-2.92)
Post-graduate	23,901 (7.70)	216 (5.81)	464,106	0.50 (0.44-0.57)	1.56 (0.93-2.63)
Annual family income, × $1,000					
less than 5	14,133 (5.39)	209 (6.53)	399,542	0.59 (0.50-0.68)	1.00
5-14	58,044 (22.12)	910 (28.42)	1,840,201	0.65 (0.60-0.70)	1.10 (0.92-1.31)
15-24	54,733 (20.86)	760 (23.74)	1,593,795	0.70 (0.64-0.75)	1.19 (1.01-1.40)
25-34	42,195 (16.08)	450 (14.05)	976,522	0.60 (0.54-0.65)	1.02 (0.85-1.22)
35-44	30,964 (11.80)	310 (9.68)	676,843	0.59 (0.52-0.66)	1.00 (0.83-1.22)
45 and over	62,295 (23.74)	563 (17.58)	1,225,607	0.54 (0.49-0.59)	0.91 (0.76-1.09)
Major activity					
Work	160,556 (51.22)	1,320 (35.29)	2,817,570	0.50 (0.47-0.54)	1.00
Housekeeping	72,629 (23.17)	1,094 (29.25)	2,213,449	0.67 (0.63-0.71)	1.25 (1.14-1.36)

Table 2: Descriptive characteristics of the study population according to selected socio-demographic variables, National Health Interview Surveys, 1987-1994.

School	12,911 (4.12)	94 (2.51)	219,536	0.48 (0.37-0.59)	0.95 (0.75-1.21)
Other	67,342 (21.48)	1,232 (32.94)	2,584,911	0.73 (0.68-0.78)	1.40 (1.28-1.53)
Health status					
Excellent	63,171 (20.23)	397 (10.65)	864,061	0.45 (0.40-0.50)	1.00
Very good	79,749 (25.54)	581 (15.59)	1,216,534	0.45 (0.41-0.49)	0.98 (0.86-1.13)
Good	92,786 (29.71)	1,067 (28.64)	2,201,757	0.60 (0.56-0.64)	1.33 (1.17-1.50)
Fair	51,499 (16.49)	938 (25.17)	1,949,144	0.72 (0.66-0.78)	1.57 (1.37-1.80)
Poor	25,092 (8.03)	743 (19.94)	1,571,466	0.87 (0.80-0.94)	1.89 (1.64-2.17)

* Figures are percentages of the total characteristic. † Figures take into consideration sampling weights due to complex sampling methodology.

Table 3: Characteristics of complications of medical care in US adults, National Health Interview Surveys, 1987-1994.

Characteristic	Estimate	Estimated size of total population	Estimate for those with onset within the last two weeks
Onset of injury, % (SE)			
Within last 2 weeks	8.36 (0.48)	655,431	
2 weeks to less than 3 months	8.77 (0.48)	687,454	
3 months to less than 1 year	14.50 (0.72)	1,136,380	
1 year to less than 5 years	27.09 (0.78)	2,122,473	
5 years or more	41.27 (0.88)	3,233,728	
Last seen doctor for injury, % (SE)			
Within last 2 weeks	33.23 (0.83)	2,603,844	
2 weeks to less than 6 months	33.07 (0.76)	2,591,469	
6 months to less than 1 year	9.24 (0.52)	724,278	
1 to less than 2 years	6.34 (0.41)	496,974	
2 to less than 5 years	6.06 (0.43)	474,608	
5 years or more	6.46 (0.45)	506,082	
Doctor seen but not known when	1.15 (0.18)	89,916	
Not known whether doctor seen	0.48 (0.12)	38,015	
No doctor seen for condition	3.96 (0.34)	310,280	
Activity limitation due to injury, % (SE)			
Inability to perform major activity	27.58 (0.86)	2,161,159	
Limited in kind or amount of major activity	22.68 (0.76)	1,776,688	
Limited in other activities	16.68 (0.68)	1,307,326	
Not limited	33.06 (0.90)	2,590,293	
Assistance with personal care, % (SE)			
Inability to perform personal care needs	7.57 (0.67)	313,375	
Limited in performing other routine needs	17.93 (1.14)	742,373	
Not limited	74.50 (1.22)	3,084,719	
Number of days of restricted activity within the last two weeks, mean (SE)	1.72 (0.08)		3.52 (0.23)
Number of bed-days within the last two weeks, mean (SE)	0.79 (0.06)		1.90 (0.21)
Number of days of work lost within the last two weeks, mean (SE)	0.58 (0.06)		1.51 (0.20)

Table 4: Odds ratios for complications of medical care with control for socio-demographic variables, by race and age, in US adults, National HealthInterview Surveys, 1987-1994

Age, y	Model 1*	Model 2†	Model 3‡
	Whites, odds ratio (95% confidence interval)		
18-24	1.00	1.00	1.00
25-34	1.48 (1.18-1.86)	1.53 (1.19-1.96)	1.56 (1.19-2.05)
35-44	1.75 (1.39-2.19)	1.88 (1.47-2.41)	1.81 (1.38-2.38)
45-54	1.83 (1.47-2.28)	1.97 (1.54-2.51)	1.77 (1.34-2.32)
55-64	1.89 (1.51-2.35)	1.93 (1.52-2.45)	1.61 (1.22-2.12)
65-74	1.85 (1.50-2.28)	1.85 (1.46-2.33)	1.51 (1.14-2.00)
75 and older	1.67 (1.34-2.08)	1.71 (1.34-2.18)	1.40 (1.06-1.86)
	Blacks, odds ratio (95% CI)		
18-24	1.00	1.00	1.00
25-34	1.40 (1.00-1.96)	1.50 (1.04-2.17)	1.47 (1.01-2.15)
35-44	1.60 (1.20-2.14)	1.61 (1.18-2.20)	1.44 (1.02-2.02)
45-54	1.47 (1.07-2.04)	1.60 (1.12-2.28)	1.33 (0.90-1.97)
55-64	1.22 (0.87-1.70)	1.23 (0.85-1.77)	0.99 (0.67-1.47)
65-74	1.45 (1.05-1.99)	1.48 (1.03-2.13)	1.21 (0.82-1.78)
75 and older	0.81 (0.52-1.26)	0.82 (0.49-1.36)	0.67 (0.40-1.12)
	Others, odds ratio (95% CI)		
18-24	1.00	1.00	1.00
25-34	2.26 (1.28-4.01)	2.44 (1.31-4.56)	2.36 (1.26-4.41)
35-44	0.66 (0.28-1.52)	0.80 (0.34-1.86)	0.73 (0.31-1.72)
45-54	1.72 (0.93-3.19)	1.73 (0.86-3.49)	1.49 (0.74-3.02)
55-64	1.51 (0.78-2.90)	1.72 (0.88-3.36)	1.42 (0.72-2.79)
65-74	2.58 (1.48-4.52)	3.04 (1.69-5.45)	2.47 (1.37-4.47)
75 and older	2.12 (0.92-4.87)	2.88 (1.20-6.92)	2.22 (0.93-5.33)

* Adjustment for survey year † Model 1 plus adjustment for education and annual income ‡ Model 2 plus adjustment for major activity and health status

Results from the base model for other races indicate a bimodal pattern with peaks at 25 to 34 years and above 65 years of age that did not change appreciably with adjustment for all other confounders. For these age groups, the risk for complications of medical care was more than twice that of the youngest age group.

Risk derived after adjustment for all variables are displayed graphically in Figure 2.

Discussion

While a number of studies have quantified the occurrence of adverse events in health systems [1, 2, 8, 15, 16], none have examined the impact of these events in a population-based sample of the US population. Using eight years of cross-sectional data from an on-going, annual population-based survey of the US adult population, we have attempted to measure the burden of morbidity arising from these events and to determine the relationship between complications of medical care and socio-demographic variables.

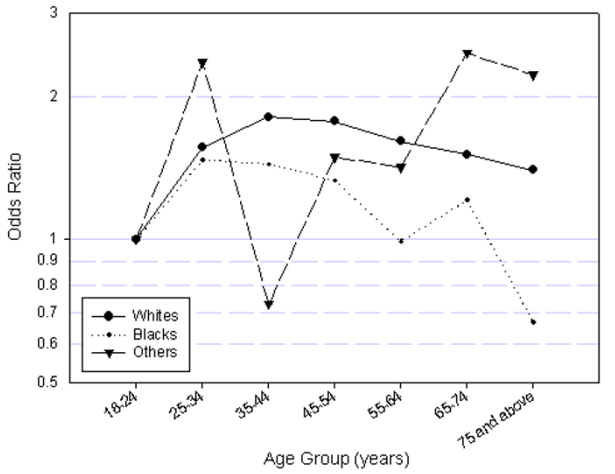

Figure 2
Multivariably adjusted race- and age-specific odds ratios for complications of medical care in US adults, National Health Interview Surveys, 1987 to 1994.

Our estimates of prevalence differ from those conducted by other studies. Extrapolations to the US general population of data from HMPS [1, 2] conducted in New York State in 1984 have indicated that over a million hospitalized patients suffered an injury due to medical treatment [9, 16]. Using similar methodology, a more recent study made similar extrapolations from data collected in Utah and Colorado, arriving at a total population figure slightly less than one million [5]. Even when limited to adults, our results point to population numbers averaging about 1 million over the seven-year period, with a suggestion of a generally increasing trend to values above this level.

Our findings are strengthened by the use of data from subjects randomly selected from the total US population over eight years. Previous research has used hospital-based data to reach conclusions about the experience of the total population. The external validity of such inferences are conditioned on the representativeness of the study population on which the results are based. Hospitals often lack clear indications of the catchment populations to which such generalizations are to be made. This progressive hierarchical leap is hard to justify, especially if primary data from the total population of interest is publicly available, as is the NHIS. Furthermore, our data suggest that a statistically significant relationship exists between such injuries and certain US geographical regions, implying that estimates derived from localities may not correctly reflect the total population's experience.

The NHIS lacks both the ability to externally validate the veracity of self-reported claims of complications of medical care and the specificity of classification offered by hospital-based studies. For instance, one cannot measure the extent to which subjects reported conditions that were due to some disease process instead of a particular complication of medical care. In some cases, medical complications are an unavoidable outcome of therapy. In spite of this, our data captures a feature of inquiry that is missed by hospital-based studies: population estimates include injuries that arise from community-based sources. Thus, two different aspects of the same question are addressed.

A recent Australian study attempted to measure such incidents arising from the general practice setting. Of about 1,500 reports of adverse events received, 44% were due to premature or inappropriate use and 26% reported problems occurring during therapeutic use. About 15% of adverse events were due to the use of contraindicated medication and 11 percent were due to unintended medications or use that was not medically indicated at the time [17]. It has been estimated that such incidents give rise to comparable costs to the health system as that due to all other forms of injury combined (including suicide, falls, homicide, etc.) [18].

In this study, injuries arising from complications of medical care were self-reported. This dependence on the subject's self-reported recall of events is problematic only if differential recall is related to the outcome of interest. However, due to a lack of validation from external sources (i.e., medical records, case notes, etc.), we are unable to exclude the possibility that point estimates within populations or specific subgroups are misrepresented, especially since some subjects were asked to recall events that took place up to one year from the interview.

Plausible situations arise that might account for differential reporting or misclassification. These might take the form of differences in awareness that injuries may be related to certain medical complications, or local or nationwide publicity related to high-profile cases of complications of medical care being applied to personal situations. We do not have enough data to speculate as to how, or to what extent, these differences might have affected the results. However, biases arising from misclassification in this setting will tend to attenuate any relationships found, since there is no a priori evidence that one categorization was more likely than another. We propose four situations in which misclassification might be plausible.

Firstly, reporting behaviour, as with medication compliance or dietary recall, is a complex activity affected by numerous external factors [19, 20]. Secondly, subjects may attribute outcomes of the disease to outcomes of

therapy, or vice-versa. Thirdly, the litigious character of participants in the US health system (in both providers and consumers of medical care) has been widely recognized [21, 22]. Lastly, increased media publicity about the impact of adverse events is known to make evaluation of symptoms difficult [23].

Prevalence data was used to estimate risk, but its interpretation is relevant only insofar as it is related to the associations with relevant covariates or groups of covariates suggested by the statistical models. Any suggestion that these results imply causality is an inappropriate appreciation of the complexity of the subject matter and the inadequacy of the primary design of the NHIS. For instance, the prevalence odds ratio is an unbiased estimate of the incidence odds ratio only if the exposure is unrelated to prognosis (ie., duration of illness is the same for exposed and unexposed groups). Since self-reported, cross-sectional data were used, we have no direct information about the longitudinal features of the condition. Hence, even the most fundamental criterion in arguing for the presence of causation - temporality - is unfulfilled.

When modelling the risk for injuries due to complications of medical care, we found significant interaction between age and race. The effect of age had been previously examined in the HMPS [2]. In that study, subjects above 64 years of age were more than twice as likely to have complication arising from medical care compared to those under 45 years. We hypothesized that some degree of residual confounding was present when broad age ranges were used. Our unadjusted results mirror those of the HMPS findings. However, after adjustment for multiple variables, differences emerged. To our knowledge, this is the first indication of the presence of such an interaction. We explored the possibility that these results were due to some bias in the design of the study. The NHIS is known for the consistency of its data checks and response rates for the analysis period were consistently above 90%. Selection bias is unlikely in this setting.

We recognize the limitation of the racial classifications used by the NHIS, especially in the category labelled "Others". However, the lack of available information for persons that could potentially be included in this category prompted us to keep the three-category coding. The results are admittedly unstable, given that analyses were based on much smaller sample sizes. Future research could examine this issue more finely.

If present, non-differential misclassification will generally tend to attenuate predicted differences between groups. For instance, this attenuation might have been the cause of the non-significant results seen in the older age groups. However, if present, the results for the younger age groups are expected to be underestimates of the true value.

The potential immediate and long-term research and policy implications of these findings are many and have been discussed previously in other fora [24–28]. This study lends support for the development of common definitions and systems for the routine collection and analysis of data from complications of medical care. These information systems should not only have the capacity to exploit the inherently hierarchical nature of specific health service boundaries (ie., hospitals within counties within states within regions), but also provide a means of promoting a systematic method to the strengthening of approaches to quality of care within the larger health care community.

Conclusions

These data suggest that self-reported injuries due to complications of medical care impose heavier morbidity than previously considered with some indication that socio-demographic variables modify the risk for injuries. Further studies are required to better understand these relationships.

Abbreviations

CI, confidence interval; HMPS, Harvard Medical Practice Study; ICD-9, Ninth Revision of the International Classification of Diseases; NCHS, National Center for Health Statistics; NHIS, National Health Interview Survey; OR, odds ratio;

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