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Drug related admissions to medical wards: a population based survey

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1 In total 1999 consecutive admissions to six medical wards were subjected to a prospective high-intensity drug event monitoring scheme to assess the extent and pattern of admissions caused by adverse drug reactions (ADRs) or dose related therapeutic failures (TF), in a population-based design. The wards were sub-specialised in general medicine, geriatrics, endocrinology, cardiology, respiratory medicine and gastroenterology.

2 Considering definite, probable and possible drug events, the prevalence of drug related hospital admissions was 11.4% of which 8.4% were caused by ADRs and 3.0% by TFs. There were large inter-department differences.

3 The six classes of drugs most frequently involved in admissions caused by ADRs were anti-rheumatics and analgesics (27%), cardiovascular drugs (23%), psychotropic drugs (14%), anti-diabetics (12%), antibiotics (7%), and corticosteroids (5%). Non-compliance accounted for 66% of the TFs with diuretics and anti-asthmatics most frequently involved.

4 The pattern of drugs involved in ADRs was compared with the regional drug sales statistics. Drugs with a particularly high rate of ADR related admissions per unit dispensed were nitrofurantoin and insulin (617 and 182 admissions per 1,000,000 defined daily doses), while low rates were seen for diuretics and benzodiazepines (10 and 7 admissions per 1,000,000 defined daily doses). Confidence intervals were wide.

5 Patients who had their therapy prescribed by a hospital doctor had a slightly higher prevalence of drug events than those who were treated by a general practitioner (12.6% *vs* 11.8%). The reverse applied for drug events assessed as avoidable (3.3% *vs* 4.6%). Although these differences were not statistically significant, it may suggest general practitioners as the appropriate target for interventive measures.

6 Only one ADR was reported to The Danish Committee on Adverse Drug Reactions, indicating a severe under-reporting and a potential for gross selectivity. The data collection system used here is expensive, but may be modified to provide reliably representative data on serious ADRs in a more cost-effective fashion.

Keywords adverse drug reactions hospital admission non-compliance spontaneous reporting

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Introduction

The contribution of drug related hospital admissions (DRH) to the admission rates of medical wards has been the subject of a number of studies (Bergman & Wiholm, 1981; Caranasos *et al.*, 1974; Ghose, 1980; Hallas *et al.*, 1990a,b, 1991; Hurwitz, 1969; Levy *et al.*, 1980; Miller, 1974; Seidl *et al.*, 1966). Quite varying results have been reported. Apart from what can be explained by obvious differences in scope, definitions, imputability criteria and intensity of data collection (Hallas *et al.* 1990a), some variation may originate from differences in pre-admission selection of subjects. For example, the extremely high proportions of admissions caused by intentional overdose reported in some papers (Cooke *et al.*, 1985; Ghose, 1980) is most likely to be explained by these studies having been carried out in a ward with particular interest in the treatment of poisoning. Investigating a specific ward may thus produce results whose external validity—or generalisability—may be questioned. This problem may not necessarily be solved by covering the entire range of medical subspecialities within a hospital and collecting a representative sample of admissions. University hospitals provide some highly specialised services to neighbouring regions, and private hospitals have their patient population skewed by income. These problems may be reduced by defining one's patient population geographically. Finally, it has been shown that drug utilization may vary considerably between regions (Bergman *et al.*, 1975), a factor which may also affect the external validity of a survey.

The aim of the present study was to describe the extent and pattern of clinical pharmacological problems as a cause of admission to medical wards within an epidemiological frame, i.e. in reference to a geographically defined population and to the population's drug consumption.

The study was carried out using standardised definitions and cause-effect criteria with particular emphasis on the prescribing behaviour that caused the DRHs and an evaluation of the prospects for an educational intervention.

Methods

Patients

The material included 1999 admissions to six medical departments in Odense University Hospital during the period March 1988–May 1989. The participating departments were sub-specialised in general and infectious medicine (n = 333), geriatrics (n = 294), general medicine and endocrinology (n = 365), cardiology (n = 366), respiratory medicine (n = 313) and gastroenterology (n = 328). Within each department, the sample was all consecutive admissions within a predefined period estimated to yield 300–350 admissions. Details on the drug event pattern in selected departments have been published previously (Hallas *et al.*, 1990 a,b, 1991). The patients (972 men and 1027 women) had a median age of 68.5 years with 10 and 90 percentiles of 36.4 and 84.7 years. There were 1359 acute admissions, 442 planned and 198 transfers from other departments. Two of the approached patients refused participation, all others (n = 1999) consented to participate after written and verbal information.

Data collection

The drug events considered were adverse drug reactions (ADR), defined as any unintended and undesirable effect of a drug, and dose related therapeutic failures (TF), defined as a lack of therapeutic effect that could be ascribed to either non-compliance, recent dose reduction/discontinuation, interaction, a too low dose prescribed or inadequate therapeutic monitoring.

The patients were contacted within 2–4 days after hospital admission by one of two investigators (JH or EG), and a detailed history of recent drug use was taken with special emphasis on any possible link between drug intake and any of the symptoms for which the patient was referred. If necessary, additional information was sought from relatives, the family doctor, the home nurse or others. In the cases where a fully satisfactory drug history could be obtained from the medical record and a suspicion of a DRH could be ruled out, the interview was omitted (n = 897). A blood sample for prospective drug analysis was taken immediately on admission in 1441 cases (72%).

Evaluation

The cases with a suspected drug event contributing to the admission (n = 416) were evaluated in joint meetings with the investigator, the chief physician of the department, a general practitioner and a clinical pharmacologist. The evaluation followed a three-dimensional scheme: 1) The causal relationship between the drug intake and a subsequent adverse event, 2) the role of this adverse event as cause of admission, irrespective of its causality and 3) a characterization of the prescribing behaviour that led to the DRH in terms of potential avoidability. Unless otherwise specified, the data presented here concern definite, probable or possible drug events rated as a dominant or partly contributing cause of the admission. The last stage in the evaluation, avoidability, required a reasonable certainty of a true drug event and was only carried out in those classified as definite or probable. The categories used were definitely avoidable, possibly avoidable and not avoidable, scored 3–1. The criteria for classification have been described in detail previously (Hallas *et al.*, 1990a).

Data on drug utilization and demographics

Data on the age and sex distribution of the Odense citizens in 1988 were obtained from the Danish Statistical Institute (Danmarks Statistik, 1989). Drug sales statistics were obtained specifically for The Funen County, an area with 458,000 inhabitants including the Odense district (Dansk Laegemiddelstatistik, 1989). Drug sales were expressed by the 'defined daily doses' (DDD) methodology (Nordic Council of Medicine, 1985) to combine data for different drugs within the same treatment category.

Analysis

Odense University Hospital provides all hospital care facilities in a district with approximately 205,000 inhabitants. In addition, a number of patients are referred from neighbouring regions for highly specialised examinations or therapeutic procedures not available in their home region. To calculate a truly population-based estimate of the proportions and incidences of DRHs, all admissions of Odense citizens should be included. However, Odense citizens are likely to be admitted to some extent to foreign hospitals due to development of an acute event while temporarily staying away from home, e.g. on a family visit. This was observed to be the most common mechanism for acute admissions of non-Odense patients to Odense Hospital. Instead of collecting data for distant admissions of Odense subjects, which was considered unfeasible, the acute or transferred non-Odense patients were used as substitutes under the assumption that Odense citizens are acutely admitted to foreign hospitals at approximately the same rate and for approximately the same reasons. The planned admissions of non-Odense patients, however, were excluded from the population based analyses.

Some of the departments were over-represented in the study sample. For example the gastroenterological department was represented by 328 cases (16.4%) but accounted for only 9.7% of all medical hospital admissions on a yearly basis. This could result in an over-representation of gastroenterological reactions and related drugs in the study material, for example upper gastrointestinal bleeding and aspirin. It was adjusted for by using a direct standardization procedure in which the characteristics observed in the studied sample in a given department was extrapolated to apply for the entire number of patients admitted within 1 year to that department (Odense patients and acute patients residing elsewhere). The calculations of DRH prevalences and incidences were then performed on a compilation of these 1 year patient populations from each participating department. The figures in parentheses in Tables 2 and 3 show estimates of the specified drug event's contribution to 10,000 medical admissions with a standardised composition. With 9,837 such admissions occurring in 1988 and a population of 205,000 inhabitants, these figures multiplied by 0.48 yield an estimate of the incidence of hospital admissions caused by the given drug event, expressed in numbers per 100,000 per year.

The statistical tests used were Mann-Whitney's test, Fisher's exact test and the Chi-square test where appropriate. Ninety-five percent confidence interval (CI) for a given estimate was based on the Poisson distribution corresponding to the number of observations which the estimate was based on.

Results

Prevalence and pattern of drug events

Out of the 1999 admissions, 212 DRHs were seen, giving a crude proportion of 10.6%. Out of these, 157 (7.9%) were ADRs, and 55 (2.8%) were TFs. In 186 of the 212 DRHs (88%), the suspected drug event was rated a dominant cause of admission.

Table 1 Characteristics of admissions caused by adverse drug reactions (ADR) *vs* non-drug related admissions

	ADRs	*Non-drug related*	*Statistical evaluation*
Total number	157	1787	
Average age (years)	68.4	63.6	$P = < 0.001$
Average number of drugs	4.29	3.29	$P < 0.0001$
Female/male ratio	1.66	1.02	$P = 0.005$
Average time in hospital (days)	12.8	13.1	$P = 0.20$
Acute admissions	125 (80%)	1178 (66%)	$P < 0.0001$
Drug therapy established by +):			
– family doctor	75 (48%)	705 (40%)	
– hospital doctor	65 (41%)	679 (38%)	
– other doctor	5 (3%)	22 (1%)	
– patient exclusively	10 (6%)	72 (4%)	
– unknown	3 (2%)	98 (5%)	
No drugs taken	0 (0%)	242 (14%)	

+ The percentages may not add to 100 as the categories are not mutually exclusive.

An analysis of the characteristics of ADR admissions compared with non-drug related admissions (Table 1) showed a higher average number of drugs taken, even when drug non-users were excluded (4.39 *vs* 3.79, $P < 0.001$, adjusted for ties), a female dominance, a higher age and a marked preponderance of acute admissions. These characteristics were all statistically significant. The 55 TF cases showed the same characteristics when compared with non-drug related admissions, except lower age for the TFs (59.7 *vs* 63.6) and a roughly equal distribution of sexes.

Odense Hospital's specialised services to neighbouring districts were found to introduce a bias by attracting patients with a particularly low prevalence of drug events. Out of the 151 planned admissions of non-Odense patients, no drug events were recorded (one sided exact CI: 0–2.0%). The crude proportion of DRHs was found to vary between departments from 5.7% to 13.5% with ADRs accounting for 3.8%–11.6%. The highest proportions of DRHs were found in the departments of general medicine (13.5%), geriatrics (13.3%), and gastroenterology (11.9%). These proportion of ADRs and DRHs differed significantly between departments (both $P < 0.01$). The exclusion of non-Odense patients and the direct standardization procedure resulted in an adjusted DRH proportion higher than the crude figure: 11.4% DRHs with 8.4% ADRs and 3.0% TFs.

The pattern of drugs involved in the ADRs showed six classes of drugs to be responsible for 88% of the adjusted ADR proportion (Table 2). These classes were: anti-rheumatics and analgesics (27%), cardiovascular drugs (23%), psychotropic drugs (14%), antidiabetics (12%), antibiotics (7%), and corticosteroids

Table 2 Observed numbers of adverse drug reactions as cause of admission among 1999 consecutive patients. In parentheses the drug event's estimated contribution to 10,000 representative medical admissions. CI = 95% confidence interval

Drugs	*Symptoms*
Analgesics and anti-rheumatics	
NSAID	14 gastro-duodenal lesions, 2 fluid retention, 1 diarrhoea
Salicylates	9 gastro-duodenal lesions, 4 poisoning, 1 constipation
NSAID + salicylates	5 gastro-duodenal lesions
Opioid analgesics	3 pneumonia, 3 sedation, 1 anaphylaxis, 2 dyspepsia
	45 cases (224, CI: 163–300)
Cardiovascular drugs	
Diuretics	12 electrolyte disturbances, 6 dehydration or dizziness
Digoxin	7 toxic symptoms
Calcium antagonists	1 depression, 1 syncope
β-adrenoceptor blockers	1 asthma, 1 cardiac failure
Quinidine	1 intoxication
Nitrates	2 syncope
Antihypertensives	1 postural hypotension, falling
	33 cases (197, CI: 136–277)
Psychotropic drugs	
Benzodiazepines	8 dizziness, 3 intentional overdose
Neuroleptics anaphylaxis	1 parkinsonism, 2 hypotension and falling, 1 stupor
Lithium	1 intoxication
Antidepressants	1 hepatitis, 2 syncope
Chloral hydrate	2 intoxication
	22 cases (114, CI: 71–173)
Anti-diabetics	
Insulin	14 hypoglycaemia
Oral anti-diabetics	1 dyspepsia
	15 cases (98, CI: 55–161)
Antibiotics	
Nitrofurantoin	1 alveolitis, 2 hepatitis, 1 neuropathy
Erythromycin	2 drug fever
Miscellaneous antibiotics	2 rash, 1 gastritis, 1 colitis, 1 seizures, 1 pancreatitis
	12 cases (61, CI: 32–107)
Hormones	
Corticosteroids	4 upper gastrointestinal bleeding, 1 fluid retention, 3 osteoporosis
	8 cases (45, CI: 19–88)
Miscellaneous	22 cases (101, CI: 64–154)
All drugs	157 cases (841, CI: 711–986)

(5%). For each of these drug classes, their estimated contribution to 10,000 medical admissions with a representative composition is shown in parentheses, calculated by the direct standardization. The adjusted DRHs proportion attributable to intentional overdose was 0.49% of all admissions, or 4.3% of all DRHs. Non-compliance accounted for 66% of the adjusted TF proportion with diuretics and anti-asthmatics most frequently involved (Table 3).

The age-specific incidence rates of the various categories of DRH could be calculated for the Odense population by using the age-characteristics of the DRHs in the standardised patient population and the age distribution of the Odense population. This showed a marked age-dependency within both categories of DRHs (Figure 1).

An estimated number of DRHs per million defined daily doses could be calculated for each of the drug classes involved by using the regional drug sales statistics and the drug-specific adjusted DRH incidences (Table 4). This resulted in a marked change of the ranking of the drugs involved in ADRs with anti-diabetics, antibiotics and cardiovascular drugs now ranking on top. The two single drugs with the highest number of DRHs per DDD dispensed were nitrofurantoin and insulin. Diuretics and benzodiazepines appeared to be relatively safe in terms of risk of drug related admission.

Avoidability

According to the criteria for evaluation, DRHs assessed as definite or probable were subjected to an assessment of the responsible health service personnel's possibility of having avoided the DRH. One hundred and forty-

Table 3 Observed numbers of dose related therapeutic failure as cause of admission among 1999 consecutive patients. In parentheses the drug event's estimated contribution to 10,000 representative medical admissions. CI = confidence interval

Drugs	*Symptoms*
Non-compliance	
Diuretics	7 heart failure, 2 ascites
Anti-asthmatics	6 asthma
Anti-diabetics or insulin	2 precoma, 2 ketoacidosis
Analgesics	3 pain
Coronary drugs	3 suspected MI
Anti-ulcer drugs	3 gastro-duodenal lesions
Miscellaneous	7 cases
	35 cases (200, CI: 140–279)
Dose reduction/discontinuation	
Corticosteroids	1 s.l.e. recurrence, 6 asthma recurrence, 1 Crohn's disease deterioration, 1 polymyalgia
Phenobarbital	2 seizures
Diuretics	3 cardiac failure
Miscellaneous	1 cases
	16 cases (77, CI: 44–125)
Too low dose prescribed	
Miscellaneous	2 cases
	2 cases (15, CI: 2–55)
Interaction	
Diuretics—NSAID	2 poor hypertensive control
	2 cases (11, CI: 1–38)
Inadequate TDM	
None	
All causes	55 (303, CI: 228–394)

three such DRHs were seen, giving a crude proportion of 7.2%. The corresponding adjusted proportion was 8.0%, with ADRs accounting for 5.8% and TFs for 2.2%. Of these 143 DRHs, 26 (18%) were rated as definitely avoidable, 41 (29%) as possibly avoidable and 76 (53%) as not avoidable. The pattern of the 46 definitely avoidable or possibly avoidable ADRs was similar to the ADRs in general with the six dominant drug classes constituting 91% of the adjusted ADR proportion. The mechanisms involved in the definitely avoidable and

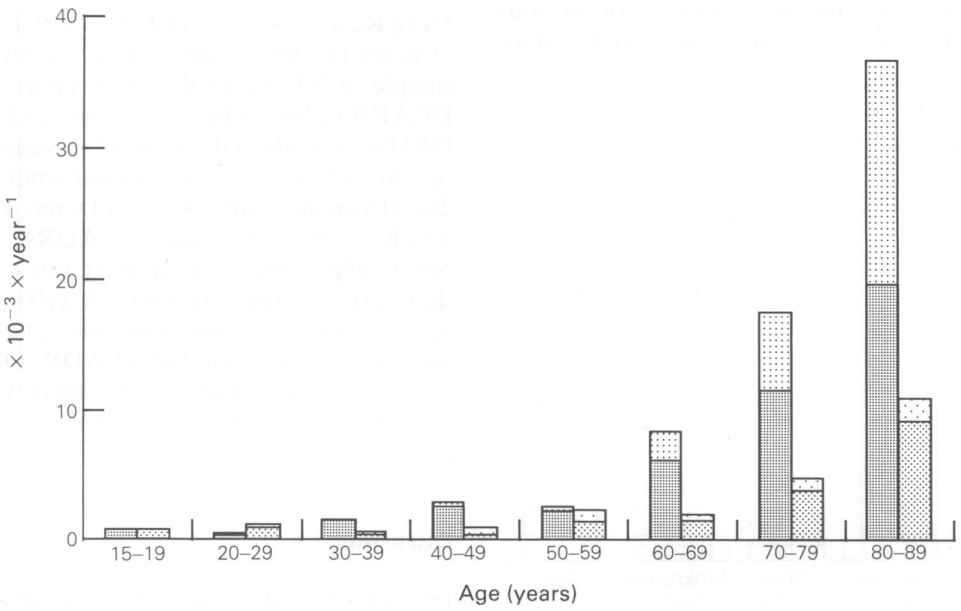

Figure 1 Age-specific incidence of drug related hospital admissions among residents of Odense Hospital's referral area (pop = 205,000). ADR = adverse drug reaction. TF = dose related therapeutic failure. ▩ Definite/probable ADR, ⬚ possible ADR, ▩ definite/probable TF, ⊡ possible TF.

Table 4 1988 Funen's County sales statistics of the drug classes most frequently involved in hospital admission caused by adverse drug reactions. DDD = defined daily dose, CI = 95% confidence interval, ADR = adverse drug reaction

Drug class	*DDD per 1,000 inhabitants per day*	*ADRs per 1,000,000 DDD (CI)*
Anti-rheumatics and analgesics		
Anti-rheumatics	18.0	71 (44–107)
Aspirin	43.1	27 (17–43)
Opioid analgesics	11.8	63 (29–119)
Cardiovascular drugs		
Diuretics	137.3	10 (6–16)
Digoxin	8.0	61 (24–126)
Anti-diabetics		
Insulin	6.8	182 (100–306)
Psychotropic drugs		
Benzodiazepines	92.7	7 (4–13)
Neuroleptics	8.3	45 (15–104)
Antibiotics	13.1	61 (32–107)
Nitrofurantoin	0.4	617 (168–1583)
Corticosteroids	8.5	69 (30–137)

possibly avoidable DRHs were: Inadequate laboratory control (n = 16), non-compliance (n = 14), a predictably too high (n = 12), or too low dose prescribed (n = 6), failure of recognising an ADR as such (n = 5), a dubious indication (n = 4), neglecting a risk factor (n = 3), a treatment persisting too long (n = 3), or others (n = 4).

Patients who had their therapy prescribed by a hospital doctor had a slightly higher prevalence of drug events than those who were treated by a general practitioner (12.6% *vs* 11.8%). The reverse applied for drug events assessed as avoidable (3.3% *vs* 4.6%), but none of these differences was statistically significant. The avoidable DRHs occurring among patients who had their therapy prescribed by other or unknown doctors, or by self-medication was found to be quantitatively unimportant (Figure 2).

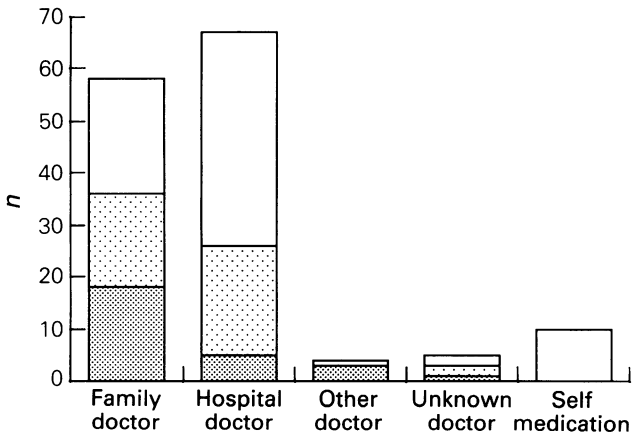

Figure 2 Avoidability, arranged by person establishing drug therapy. ☐ Not avoidable, ▒ possibly avoidable, ▓ definitely avoidable.

Validation

Sixty randomly selected case abstracts were evaluated by an external group consisting of an experimental pharmacologist, a clinical pharmacologist and a general practitioner. The cases were stratified to give 28 DRHs and 32 non-DRHs, as classified by the study group. By use of the same criteria as the study group, the external group classified 32 of the cases as DRHs and 28 as non-DRHs, and could confirm 23 of the 28 DRHs found by the study group. Disagreements were most often related to causality assessment. The external group found more definite/probable DRHs than the study group (27 *vs* 20), and among the 14 cases which both groups had classified as such, the summed score of avoidability was 28 for the external group and 27 for the study group (Spearman's rank correlation = 0.60, adjusted for ties).

Sources of information

The data collection scheme used in this study is one of the more intensive used in a hospital-based drug event monitoring system. We found it of interest to assess the impact of the various measures on the number of DRHs found and the number of DRHs that could have been detected by use of simpler and less laborious means, e.g. by use of computerised information or by self-reporting. The most valuable study-specific information source was the supplementary drug history obtained by the investigators, providing crucial information, i.e. information without which the case could not have been detected or would have attained a different rating, in 32 cases. Of these, non-compliance accounted for 34% and adverse reaction to aspirin bought over the counter for 13%. Only 5 cases (2%) were established by use of the blood sample taken on admission. The drug event was indicated in 59% of the discharge summaries, in 24% of admission papers and in 27% of coded discharge diagnoses (ADRs only).

Only one of the 157 ADR cases was reported by the ward physicians to the Danish Committee on Adverse Drug Reactions (DCADR) (0.6%, CI: 0.02–3.5%). To evaluate this low reporting rate, we reviewed a random sample of 300 out of the 1834 reports received by the DCADR in 1988. Thirty-one of these (10.3%) concerned DRHs in a medical department, resulting in an estimate of 190 such admissions reported annually. There were 264,118 medical admissions in Denmark in 1988, out of which 22,300 were caused by ADRs, according to the observed proportion of ADRs in this study, and it could therefore be estimated that 0.9% (190/22,000) of ADRs severe enough to cause admission to a medical department were reported to the DCADR. Our finding of one in 157 cases was thus in agreement with this general pattern of severe under-reporting.

Discussion

Intensive hospital based drug event monitoring was, when introduced in the 1960s, primarily intended to document the existence of causal relationships between drug intake and subsequent adverse events (Lawson &

Beard, 1989). With the advent of sensitive and less expensive methods to produce and verify such hypotheses, among others spontaneous reporting (Rawlins, 1988), prescription-event monitoring (Inman, 1982), record-linkage (Strom & Morse, 1988) and prescription sequence analyses (Petri *et al.*, 1988), intensive hospital monitoring would now serve a different purpose in pharmacoepidemiology. It can provide a pragmatic quantitation of actual ADRs of a certain severity, possibly used as a basis for quality assurance or intervention programs. However, to be interpretable as such, certain requirements to its external validity must be fulfilled. The highly variant proportions of DRHs between departments and the absence of DRHs among non-Odense patients show that the pre-admission selection is an important factor in this context and should be properly controlled or accounted for.

The nephrology and the rheumatology departments were not included in the study due to a lack of resources. These departments' share of the intake in medical departments was 7.5%. The proportion of newly diagnosed renal parenchymal diseases attributable to drugs has been estimated to be very low (Beard *et al.*, 1988). Assuming, as the most extreme, a nil DRH proportion in the departments not included in the study, this bias has not affected the incidence estimates or the estimated DRHs per DDD, while the adjusted DRH proportions are 7.5% too high. Departments with a marginal relationship to the medical field, such as neurology, oncology, pediatrics and dermatology were not included either, and major between-hospital differences in referral patterns between these and the strictly medical departments may affect the generalisability of the results.

The relatively high prevalence of avoidable drug events among patients treated by a general practitioner does not infer that they prescribe more poorly than others. Seventy-two percent of all prescription drugs in 1988 in Denmark were issued by general practitioners, estimated on an expenditure basis (The Association of the Danish Pharmaceutical Industry, 1990), and general practitioners should thus—*ceteris paribus*—be entitled to commit 72% of all serious prescription errors, which they did not. Our experience with evening symposia and distribution of written material related to the study was a generally larger interest among general practitioners than among junior doctors. This feature, combined with the general practitioners' large share of avoidable DRHs, suggests that an intervention based on drug education could most effectively be targeted toward the primary health care.

The quantitation of ADRs provided by this study design cannot reliably be obtained by spontaneous reporting, since the very low reporting rate provides an ample margin for selective reporting. Rates in the order of 20–40% have been demonstrated for some dramatic or characteristic ADRs, for example drug-induced blood dyscrasias (Arneborn & Palmblad, 1982) or Steven-Johnson syndrome (Böttiger *et al.*, 1975). This study shows an extremely low reporting rate for representative, banal ADRs causing hospital admission in a country that has one of the worlds highest spontaneous reporting rates per inhabitant or per physician (Griffin, 1986). An almost bizarre example demonstrating this margin for selectivity in a comparable country was the reporting of more ADRs for triazolam than for all other drugs put together in 1979 in Holland, after a heated press campaign had emphasised the drug's potential for psychiatric reactions (Lasagna, 1980). It has been shown that the reporting rate can be increased by campaigns of various designs (O'Connor *et al.*, 1988), but to achieve a reliable representativity by these means seems unrealistic. The pattern of ADRs cannot be described by automated methods like record-linkage (Strom & Morse, 1988), as the variability in coding of diagnoses renders the case identification extremely difficult, except for certain well defined problems.

The amount of work invested in data collection was in the order of 0.75 man-year, once the system was established. In view of the 212 DRHs found, this may seem a relatively expensive way of collecting data. The intensive method was primarily chosen because of uncertainty of how the relevant information would emerge and what loss of information a given reduction in intensity would entail. However, it permitted a process evaluation concerning the possibility of reducing the cost by modifying the design.

A considerable amount of work would be saved by excluding the TFs from monitoring. A lot of time was spent investigating the very large proportion of patients who were admitted because of symptoms for which they were already in treatment (Hallas *et al.*, 1990a,b), and as such were potential non-compliance cases. As shown here, the study specific blood sample could be omitted with little loss of information. The proportion of cases with the drug event mentioned in the discharge summary, 59%, probably reflects the upper limit of what can be detected by any system based on self-reporting. The threshold for mentioning a perceived ADR while dictating the mandatory discharge summary is likely to be lower than for spending time reporting it to monitors. This proportion may even have been affected by the study itself and would have been lower under other circumstances. Data collection techniques that rely on self-reporting may also be biased or underestimate the problem on account of individual doctors' differences in the conceptual delimitation of ADRs (Hallas *et al.*, 1990a). The data suggest that a retrospective scrutiny of the medical records may be a fairly reliable collection scheme. The investigators provided crucial information on drug history in only 15% of the DRH cases, of which roughly half concerned non-compliance or self-medicated aspirin. The margin for selectivity in the pattern of the remaining drug events is consequently small. In addition, by retrospective scrutiny, the problems of fitting the monitoring procedures into the sometimes tightly scheduled routines of some wards are avoided.

By these modifications, a hospital based drug event monitoring can be a useful supplement to spontaneous reporting systems.

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