

## **Paracetamol Availability and Overdose in Ireland**

**Laffoy M\***  
**Scallan E\***  
**Byrne G\*\***

\*Department of Public Health, Eastern Regional Health Authority, Dr. Steeven's Hospital, Dublin 8, Ireland

\*\* General Medical Services (Payments) Board, Finglas, Dublin 11.

Correspondence to Marie Laffoy, Department of Public Health, Eastern Regional Health Authority, Dr. Steeven's Hospital, Dublin 8. Phone: 00 353 1 6790700.

Fax: 00 353 1 6710606

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## **Abstract**

*Study aims:* to establish whether the hospital admission rate due to paracetamol overdose in Ireland dropped since the introduction of revised conditions for the supply and sale of paracetamol in 1997 and to determine compliance of non-pharmacy outlets with these conditions of sale.

*Design:* a) retrospective review of national data on hospital admissions due to paracetamol poisoning between 1993 and 1999  
b) attempted purchase of paracetamol from 100 non-pharmacy outlets in Dublin (48 tablets to be purchased either as 2 x 24 packs or 4 x 12 packs).

*Setting:* Dublin and Ireland.

*Participants:* a) national hospital data on paracetamol admissions between 1993 and 1999  
b) 100 non-pharmacy outlets in Dublin.

*Results:* Paracetamol overdose is the most common reason for hospital admission due to poisoning in Ireland. Admissions increased by 29% between 1993 and 1999. In 1997 The Irish Medicines Board (IMB) revised conditions for the supply and sale of paracetamol. These conditions have no statutory basis. Under the conditions non-pharmacy outlets should now only sell emergency supplies in a maximum pack size of 12 tablets and just one pack can be sold on each occasion. We found that Irish admissions dropped by only 1.9% since the introduction of the revised conditions and that non-pharmacy outlets do not comply with the IMB conditions of sale. We bought 48 paracetamol tablets as a single purchase from 100 outlets. The shops stocked a wide variety of paracetamol, often in pack sizes of 24 tablets.

*Conclusions:* In the UK since legislation was introduced in 1997 in relation to paracetamol supply and sale there has been a substantial drop in the occurrence and severity of paracetamol poisoning. There is an urgent need for legislation in Ireland to give effect to the IMB's conditions for the supply and sale of paracetamol .

*Keywords:* Paracetamol, overdose, intent

## **Introduction**

Paracetamol is a commonly used medicine. It is usually safe when taken correctly. It is widely available and cheap. Paracetamol is also regularly used in suicide attempts. Intentional and unintentional overdose are a frequent cause of hospital admission on both sides of the Atlantic where it is the single most common identifiable cause of fulminant hepatic failure<sup>1,2,3</sup>.

Revised conditions for the supply and sale of paracetamol were published by the IMB and took effect from October 1997<sup>4</sup>. The revised conditions which do not have a statutory basis are:

1. The statement **“CONTAINS PARACETAMOL”** should be clearly carried in contrasting boxed bold type on the package together with the warning: **DO NOT TAKE ANY OTHER PARACETAMOL CONTAINING PRODUCTS”**.
2. The package label should contain the precaution **“IMMEDIATE ADVICE SHOULD BE SOUGHT IN THE EVENT OF OVERDOSAGE EVEN IF YOU FEEL WELL. PLEASE READ THE ENCLOSED LEAFLET CAREFULLY”**.
3. The package leaflet should contain the following: **“IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF OVERDOSAGE, BECAUSE OF THE RISK OF IRREVERSIBLE LIVER DAMAGE”**. If the package does not contain a leaflet, then the latter statement should replace the former on the package label.
4. All over-the-counter paracetamol tablets should be packaged in blister packs or in comparable individually wrapped, child resistant, dosage units.
5. For pharmacy sales the maximum pack size of paracetamol containing products for over-the-counter sales is restricted to 24 x 500mg tablets. Supply of more than one pack should be supervised by and at the discretion of the pharmacist. Supply of 50 tablets should be on the basis of prescription.
6. Non-pharmacy outlets can provide emergency supplies of paracetamol as single ingredient preparations. The maximum pack size is restricted to 12 x 500mg tablets. Only one pack should be supplied on each occasion of purchase.

The aims of this study were to establish whether the hospital admission rate due to paracetamol overdose in Ireland dropped since the introduction of the revised conditions for the supply and sale of paracetamol and to determine compliance of non-pharmacy outlets with the conditions of sale.

## Methods

Data on hospital admissions due to paracetamol overdose between 1993 and 1999 were obtained from the Hospital Inpatient Enquiry System (HIPE), including the number of admissions per year, age group, sex and poisoning intent. The HIPE information system gathers data on all acute hospital admissions. The national coverage rate is over 95%.

A survey of one hundred non-pharmacy outlets in Dublin was undertaken to determine compliance with the IMB's conditions for the supply and sale of paracetamol. These outlets were selected arbitrarily and incorporated the major residential and shopping areas of the City and County of Dublin. They were combination of large supermarkets, mini-markets, other grocery shops and petrol stations. In each outlet a researcher attempted to buy two packs of any paracetamol product containing 24 tablets or four packs containing 12 tablets i.e. four times more than the conditions of sale stipulate. Four packs of 12 tablets were sought only when packs of 24 tablets were not in stock. If challenged by a sales assistant, the researchers were to say that the paracetamol was for themselves. If a sales assistant refused to sell the paracetamol for any reason, including the IMB conditions, this was to be accepted without question. The variety and quantity of paracetamol products on sale in each outlet was observed together with the presence of notices / warnings of the dangers of paracetamol and the quantity which could be bought at any one time.

## Results

Paracetamol overdose was the main reason for admission to hospital due to poisoning between 1993 and 1999. In each of these years it was responsible for approximately one-quarter of all poisoning related admissions and for 2% of all injury admissions.

Table 1a shows the number of hospital admissions from paracetamol overdose, intentional and unintentional, and the yearly rate of change in admissions between 1993 and 1999. Admissions increased by 29% over the seven-year period. Females had almost twice as many admissions as males. After the introduction of the new conditions for the supply and sale of paracetamol there was an overall reduction in admissions of 1.9%. Admissions increased in 1998 by 0.6% and dropped in 1999 by 2.5%. Over the seven-year period the admission rate per 100,000 population increased from 31.1 to 38.3, table 1b. The admission rate increased in both sexes but it was more than twice as great in females than males. The mean length hospital of stay was 2.5 days (1 to 149 days).

**Table 1a** Number of paracetamol overdose admissions to hospital 1993-1999

	1993	1994	1995	1996	1997	1998	1999
Male	404	408	430	425	466	514	475
Female	707	754	872	866	995	956	958
Total	1111	1162	1302	1291	1461	1470	1433
% Yearly change		+4.6%	+12.0%	- 0.8%	+13.2%	+0.6%	-2.5%

**Table 1b** Paracetamol admission rate per 100,000 national population 1993-1999

Admission rate (male)	22.7	22.9	24.0	23.6	25.6	27.9	25.6
Admission rate (female)	39.4	41.8	48.1	47.4	54.0	51.2	50.8
Admission rate (total)	31.1	32.4	36.2	35.6	39.9	39.7	38.3

The completeness of HIPE data in relation to poisoning intent was 99% for each year except for 1998 and 1999 where it was 94.8% and 92.2% respectively. Between 1993 and 1999 the proportion of paracetamol overdoses that were intentional rose from 54.4% to 72.3%. Female intentional overdoses increased from 56.3% to 74.1% and male intentional overdoses increased from 51.1% to 68.6% over this period. Figure 1 shows the number of admissions by sex and intent. Female intentional overdose was the main cause of admission.

Figure 2 shows the proportion of hospital admissions due to intentional overdose by age group. Most, approximately 50%, were in the 15 to 24 age group. However in 1999 a slightly greater proportion (48% v 46%) were in the 25-64 age group. Intentional overdose was unusual in young children and over the age of 65.

Though the most common age group for accidental paracetamol poisoning was also 15-24, the pattern of accidental poisoning was different from intentional overdose, as children under the age of 5 years accounted for approximately 20% of admissions, figure 3.

Additional analysis of poisoning intent was undertaken for the 5-14 age group by individual age. Data on intent were available for 621 children between 5-14 years of which 369 (59.4%) were intentional overdoses. Figure 4 shows that paracetamol poisoning was uncommon between the age of 5 and 12 years. The admission pattern followed a J shaped curve due to a small number of accidental overdoses between the age of five and seven years. After the age of 11 years admissions escalated steeply and intentional overdose accounted for almost twice as many admissions as accidental overdose.

Table 2 gives results of the purchases of paracetamol in non-pharmacy outlets. Purchases of 48 paracetamol tablets (either 2 x 24 packs or 4 x 12 packs) were successfully made in each shop without difficulty or questions from a sales assistant. However, in three shops a sales assistant commented on the researcher's presumed poor health. In one shop a sales assistant hesitated when asked for 4 x 12 packs of paracetamol but did not comment. No retail outlet displayed the IMB's conditions of sale or any other notice on restrictions of sale. There were no displays in any shop on the dangers of paracetamol. In all cases the tablets were sold in blister packs.

**Table 2      Type of retail outlet visited**

<b>Type of shop</b>	<b>No. = %</b>
Large supermarket	30
Mini-market	24
Smaller shops / newsagents	29
Petrol stations	17
<b>Total</b>	<b>100</b>

The quantity and variety of paracetamol and the amount of shelf space allocated appeared to reflect the size of the shop. In large supermarkets pack sizes of 24 tablets were always available. These supermarkets stocked a wide variety of paracetamol products including Tramil, Hedex, Anadin and Panadol. Paracetamol products were prominently displayed in the cosmetics section of the supermarket. Smaller shops generally stocked a 12-tablet pack of paracetamol. They had a smaller variety of products on display but often 2-3 different products. In petrol stations paracetamol was usually limited to one or two product types, available as a 12 pack, and in some cases there were stored behind the counter.

### **Discussion**

Paracetamol poisoning is an important public health issue. It is the main drug used in self-poisoning<sup>5</sup>. It is the most common cause of hospital admission from poisoning in Ireland. Admissions increased by 29% since 1993 from 1,111 to 1,433. This persistently high number is a source of concern especially as most cases are young people.

The incidence of paracetamol poisoning is related to its ease of access<sup>5</sup>. Ready availability was shown to be associated with 43% of admissions to hospital from self-poisoning in the UK<sup>6</sup>. In the US, paracetamol accounted for 4.1% of deaths from poisoning reported to American Poison's Centres in 1997<sup>7</sup>. Most deaths were due to deliberate self-poisoning. A strong positive association has been found between trends in paracetamol sales and trends in non-fatal paracetamol overdose. This adds to the body of evidence that reductions in the quantity of paracetamol available as a single purchase might reduce suicide and liver failure related to paracetamol<sup>8</sup>.

Young people have ready access to paracetamol. They commonly and naively take it in suicide gestures when they do not wish to die<sup>9,10</sup>. They do not have insight into the serious complications associated with paracetamol misuse and they underestimate the potential for toxicity. One study of 569 adolescents found that 42% of them felt that paracetamol could do no harm and 50% overestimated the dose that would be necessary to kill<sup>9</sup>. Another study of 1147 American and British adolescents regarding their knowledge of paracetamol toxicity showed that, although 90% of them recognised that paracetamol could kill, the great majority overestimated the lethal dose. They also had a poor knowledge of side effects. These findings together with the wide availability of paracetamol were considered to contribute to its frequent use in adolescent suicidal behaviour<sup>11</sup>. Gazzard et al found that none of the 48 patients they interviewed would have chosen paracetamol had it been known there would be a 2-3 day interval before the onset of serious symptoms. Only five of them receive the drug on prescription<sup>12</sup>.

The IMB's revised conditions for the sale and supply of paracetamol were designed to reduce the incidence of poisoning and the potentially severe consequences of overdose. Our study shows that these conditions currently have little influence on the sale of paracetamol from non-pharmacy outlets. Consequently the mere 1.9% reduction in admissions since the introduction of the revised conditions is not surprising. It is unlikely that these statistics will improve unless the IMB receives legislative backing in relation to paracetamol.

The IMB conditions are being ignored in a number of ways:

1. All large supermarkets and some other non-pharmacy outlets sell paracetamol products in pack sizes of 24.
2. Supermarkets display large quantities and a wide variety of paracetamol products.
3. Stocks are not limited to emergency supplies.
4. Sales in excess of the guidelines (12 tablets) can easily be made in non-pharmacy outlets. The researchers bought 48 tablets in 100 such outlets. This quantity is enough to cause liver failure and possibly death. Paracetamol was stocked in each of the 100 non-pharmacy outlets visited.

Following the introduction of legislative limitations on paracetamol sales in the UK in 1997<sup>13</sup> there has been a substantial reduction in severe paracetamol hepatotoxicity locally and nationally. This was considered to be directly related to the legislative changes in availability<sup>14</sup>. It was further assumed that any increased awareness of the dangers of paracetamol was unlikely to explain the reduction as knowledge does not deter use<sup>5</sup>. Other UK research found a 21% reduction in the occurrence and a 64% reduction in the severity of overdoses presenting to accident and emergency departments since the legislation was introduced<sup>15</sup>. The authors attributed the significant change in overdose behaviour to both the introduction of blister packs and reduced availability. In Ireland blister packs are used routinely but there has been little reduction in poisoning. Therefore, it appears that the legislation in relation to limiting paracetamol supply may be the main factor that has contributed to the reduction in paracetamol poisoning in the UK rather than the use of blister packs. The non-statutory basis of the IMB's conditions of supply and sale particularly in relation to availability may explain our failure in Ireland to substantially reduce paracetamol poisoning.

A number of steps are urgently needed to give effect to the IMB conditions of sale of paracetamol in non-pharmacy outlets:

1. The IMB's conditions require legislative backing.
2. Non-pharmacy outlets should be made aware of the IMB conditions and of the dangers of paracetamol.
3. Non-pharmacy outlets should comply with IMB conditions. They owe a duty of care to the public and currently many do not show this.
4. Cash registers in non-pharmacy outlets should be programmed to allow only one sale of paracetamol (12 x 500mg). Therefore, multiple purchases, as occurred in this research would be more difficult to make.
5. Once legislation is enacted the IMB should ensure their conditions are enforced. There is little point advocating evidence-based practice if, in not being implemented, it cannot support public health.

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Figure 1 Number of paracetamol overdose admissions by intent

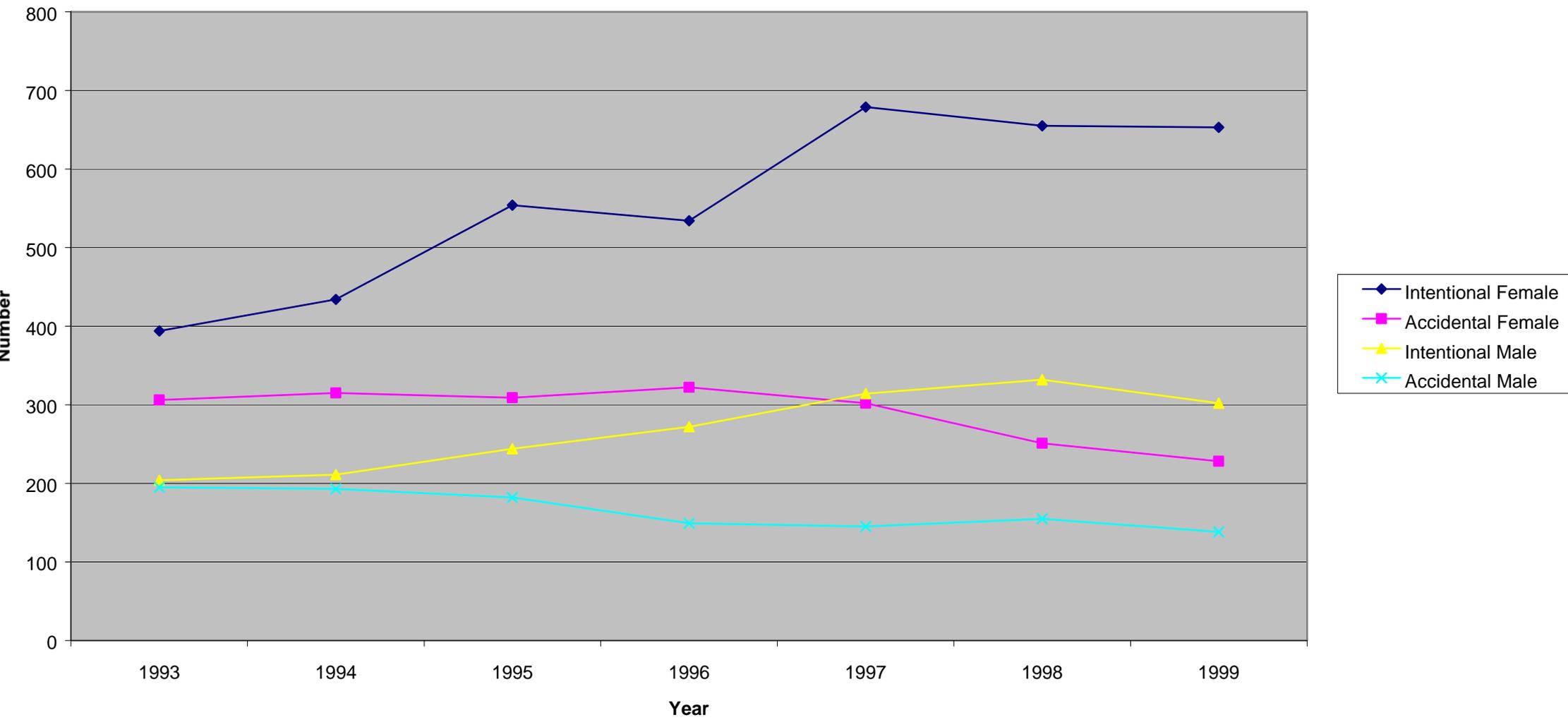


Figure 2 Intentional Paracetamol Overdose by Age Group

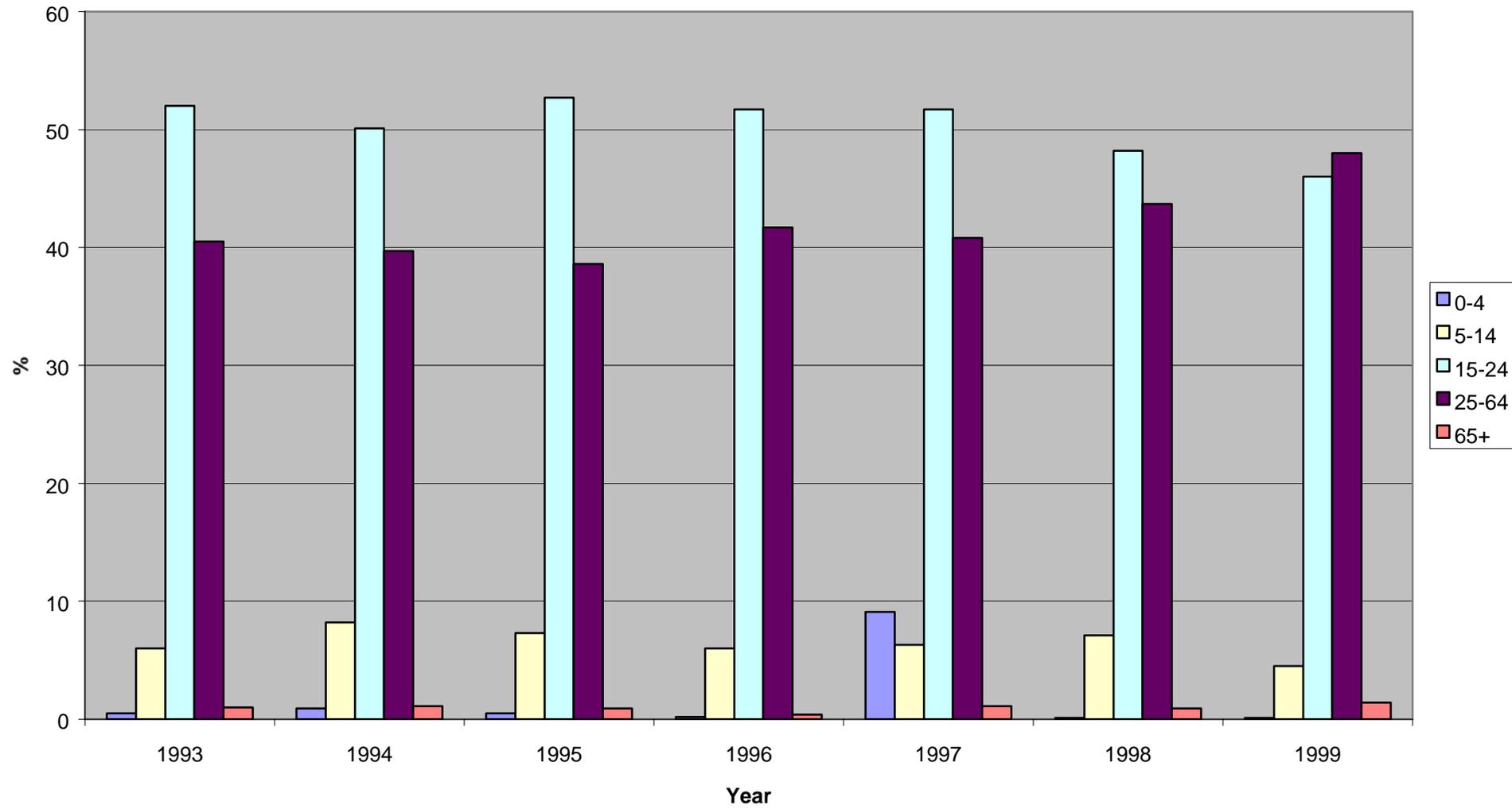


Figure 3 Accidental Paracetamol Overdose by Age Group

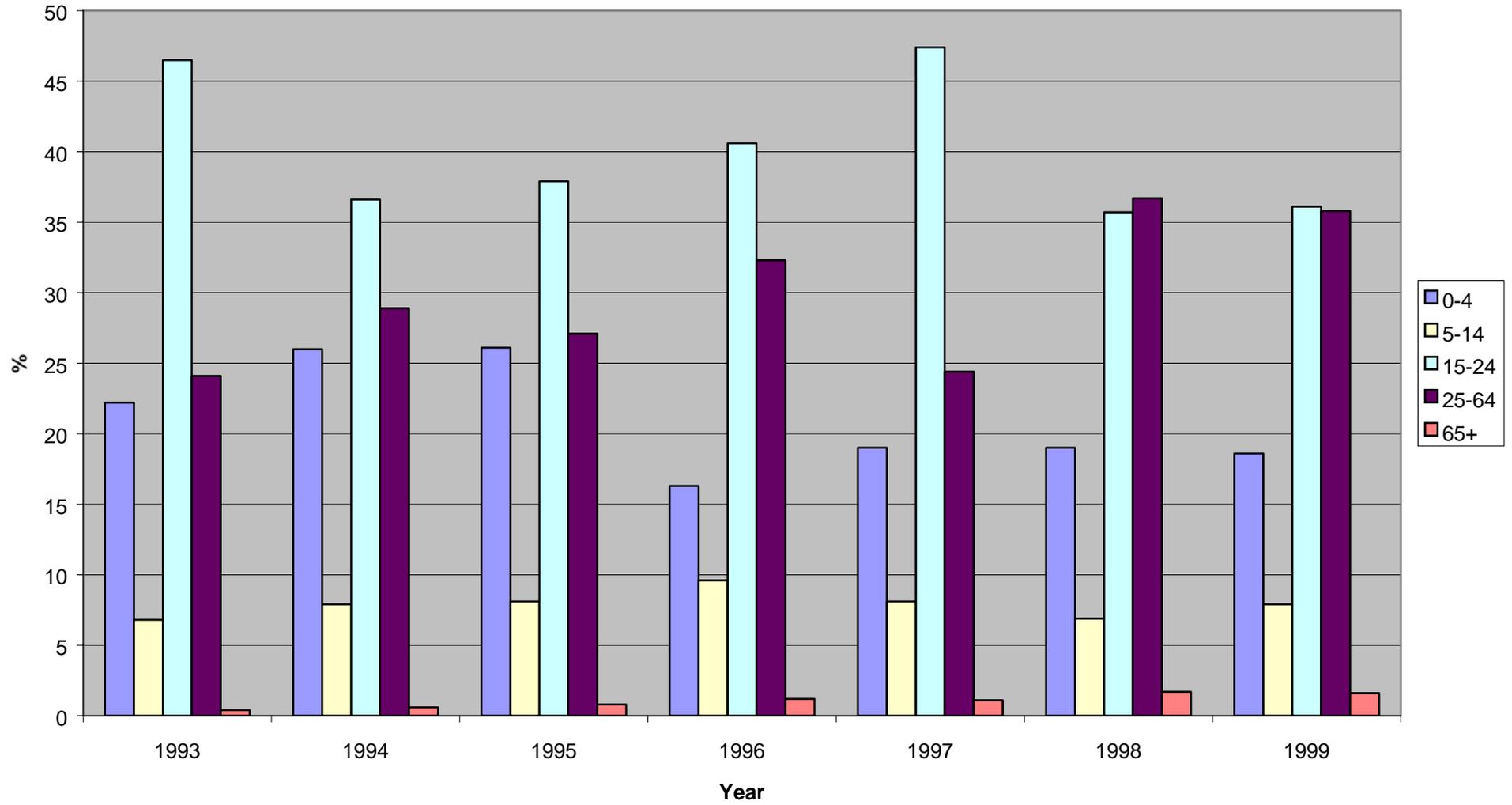


Figure 4 Paracetamol poisoning admissions - age 5-14 years (1993-1999)

