

Position Paper 1, 2001

Child Resistant Packaging(CRP) for Medicines

Safekids Position Statement:

Childhood poisoning is a significant child health problem in New Zealand.

Child resistant packaging (CRP) is a proven injury prevention strategy in reducing child poisonings.

Under Section 37 of the Medicine Regulations (1984) six classes of medicines must be supplied in strip or blister packaging. In addition, as from 1st November 1997 Pharmac has funded child resistant caps for subsidised oral liquid preparations of the so-called "dirty dozen" medications. It appears that child safety caps have been effective in reducing paracetamol poisonings in New Zealand. Whilst this is extremely positive to see, clearly child safety caps need to be extended to other medicines in order to reduce the incidence of childhood poisoning in New Zealand.

Safekids recommends that Standards approved child resistant packaging be extended. At a minimum, child safety packaging should be mandatory for the medicines currently listed in the recently released (2001) Code of Ethics for Pharmacists.

PART 1: BACKGROUND

1.1 Childhood Poisoning in New Zealand

Poisonings (after falls) are the second leading cause of an injury admission to hospital for children 0-4. Poisonings account for 13% of injury hospitalisations overnight or longer for children in this age group. If day admissions are included, this increases to 16%.ⁱ

Each year around 500 children under 5 are admitted to hospital overnight or longer for a poisoning. Pre-schoolers are easily the age group at greatest risk of a poisoning accounting for 88% of all paediatric admissions to hospital, with poisonings peaking at ages 1 and 2. Under 2s appear to be at risk of cleaner/chemical poisonings while 2-3 year olds are most at risk of pharmaceutical poisonings.ⁱⁱ

Common poisonings from drugs and medicines include paracetamol, sedatives, anti-depressants, and cardiovascular medication and cannabis.ⁱⁱⁱ

At the pre-school age, children are constantly exploring their environment and do not have the developmental skills to recognise the potential hazards associated with poisons.

1.2 What is Child Resistant Packaging?

Child resistant packaging includes both non-recloseable and recloseable packaging. Non-recloseable packaging generally contains a single tablet in either aluminium foil (strip packaging) or opaque/clear laminated plastic (blister packaging). Recloseable packaging involves a container fitted with a recloseable top, or a child safety cap such as the Palm-n-Turn or Clic-Loc variety.^{iv}

In New Zealand, child safety caps are required to meet the current New Zealand Standard (NZS 5825:1991). The majority of caps are mainly of the “palm-n-turn” variety. Recently on the market, there are the “3rd generation caps” available which allow an increased level of protection whilst providing easier access for adults.

A common misconception surrounding child safety caps (CSCs) is that they are child proof, they are not. In New Zealand child safety caps have been tested in Australia using panels of young children. To meet the current standard at least 85% of the children must be unable to open the CSC. Therefore a small number of children will still be able to gain access to the medication. CSCs are simply designed to delay the time in which a child is able to open the container increasing the probability of adult intervention before the child ingests the contents.

There are also concerns from older people and people with disabilities that child safety caps make it more difficult to open the medicines. However, studies have indicated that most older people and people with arthritis actually do not have difficulty with CSCs, particularly the third generation technology caps which allow a high level of child safety (up to 96% or 1 in 25 children) and are still easily accessed by adults including seniors.

1.3 The Current New Zealand Situation

The Medicines Regulations (1984) state that there must be strip or blister packaging which is “reasonably resistant” to attempts of young children to gain access to contents on the following medicines: aspirin, paracetamol, iron (high dose only), barbiturates (no longer prescribed), phenothiazines (only those for mental illness; excludes sedating antihistamines), and antidepressants. The definition of child safety packaging under this legislation is not tied to any safety standard and excludes child safety caps.

In addition, Pharmac funds child safety caps for oral liquid preparations of the so-called “dirty dozen” medications. As of 1 November 1997 it is a requirement under the Pharmacy Contractors Section 51 Advice Notice that child safety caps must be placed on the subsidised, dispensed oral liquid formulations for paracetamol, salicylates/NSAIDs, anticonvulsants, thyroxine, antidepressants, narcotics, beta-2-agonists, benzodiazepines, theophylline, iron salts, digoxin, cardiac drugs, and phenothiazines including sedating antihistamines.

There is some evidence that child safety caps may have been effective in reducing paracetamol poisonings in New Zealand. In 1998 41 children 0-4 were hospitalised for paracetamol poisonings. In 1999 and following the introduction of child safety caps in November 1997, this figure had reduced to 12 children, a reduction of 71%.^v

^{iv} Australian Therapeutic Goods Administration (2004) Child Resistant Packaging for Medicines. Canberra: Australian Government Publishing Service.

^v Australian Therapeutic Goods Administration (2004) Child Resistant Packaging for Medicines. Canberra: Australian Government Publishing Service.

to place CSCs on a wider range of dispensed medicines. This list is based on “potential for harm” and intended to harmonise with the current situation in Australia which provides for more extensive coverage. The Code of Ethics is however a voluntary industry based code and not enshrined in a legislative framework.

1.4 International Evidence of the use of Child Resistant Packaging

International evidence has identified that CRCs have been effective in reducing childhood poisonings. In particular, research has shown that CRCs prevent 40% to 80% of childhood poisonings^{vi}

The Poison Prevention Packaging Act (PPPA) was introduced in the United States in 1970 to reduce accidental childhood poisoning. The law requires for all toxic, corrosive, or irritant substances to be packaged so that it is difficult for children under 5 years old to open these. Under this legislation CSCs were introduced for aspirin during the 1970s in the United States.^{vii} Since 1970 there has been an extension in the number of substances with safety packaging to include prescription medicines, non-prescription and household products.^{viii} This has resulted in a significant mortality rate reduction of 45% from levels projected without child-resistant packaging requirements.^{ix}

In 1997, the Federal Register, FDA in the United States introduced unit-dose packaging for iron-containing products with 30 milligrams or more of iron per dosage unit. FDA believed that the unit-dose packaging would increase the time and effort required to open the unit-dose and hence limit the number of tablets a child could swallow.^x

In Britain since 1 January 1976 all aspirin and paracetamol dispensed for children had to be dispensed in CRCs. This was followed later (April 1976) by a voluntary agreement to dispense aspirin and paracetamol for adults in CRCs. This action resulted from 2nd March 1981 in all members of the pharmaceutical profession agreeing that all prescribed medicines would be dispensed in CRCs unless requested in an ordinary container.^{xi}

Figure 1: Change in the number of hospital admissions from 4 causes of poisoning in Newcastle and Cardiff following the introduction of child-resistant containers.

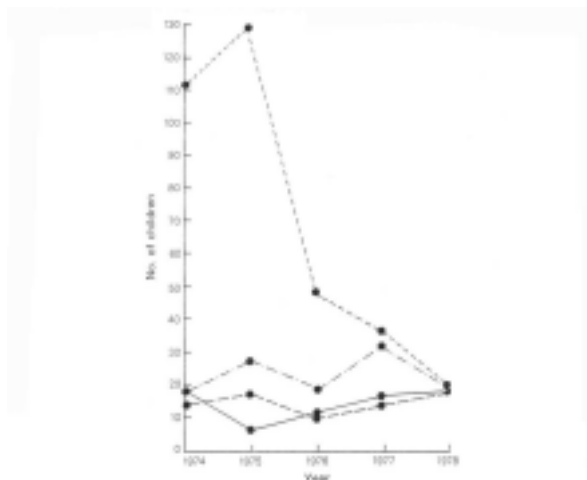


Figure 2 Change in the number of hospital admissions from 4 causes of poisoning in Newcastle and Cardiff following the introduction of child-resistant containers (----- = salicylate; ----- = benzodiazepine; ----- = tricyclic antidepressant; ----- = paracetamol)

Holland, France, Germany and Canada have also adopted standards for child resistant packaging to reduce the incidence of child poisoning.^{xii} As already mentioned, Australia also has a more comprehensive list of drugs and poisons required to have child resistant closures.

PART 2: ASSESSMENT OF OPTIONS

There is a range of options for addressing the safety of poisons – both regulatory and non-regulatory. These are discussed below:

2.1 Education campaigns

In New Zealand several education campaigns have been promoted via the Ministry of Health, National Poisons Centre, Safekids, ACC, Plunket, the Consumer's Institute, Pharmacy Guild and the Standards Association to promote the safe storage and use of poisons. Some of these programmes have also targeted pharmacists and GPs to encourage the adoption of CSCs on prescribed medicines.

In 1997, with the introduction of caps for subsidised oral liquid preparations of the “dirty dozen” medications, there was a strong push to promote the use of child safety caps to prescribers, pharmacists and the public.

Although, these campaigns may have had some benefit in raising the awareness of safety with poisons the lack of well-evaluated evidence makes their effectiveness difficult to demonstrate.

2.2 Warning Labels

Warning labels on medicines have not been demonstrated to be an effective strategy to address the rate of childhood poisoning. In New Zealand, under the Toxic Substances Regulations 1983 there are labelling requirements alerting people to the toxicity of substances and advising that these should be kept out of reach of children.^{xiii}

Additional warning labels have also been utilised in the form of colourful stickers placed on the container. In the United States, warning label stickers were used, commonly referred to as “Mr Yuk” to warn children to stay away from the poisonous substance. However, studies have indicated that this has been ineffective in reducing childhood poisoning. Infact, one study indicated that the “Mr Yuk” warning labels resulted in an increase in children's handling of the labelled medicine, due to the attractiveness of the label to children.

The Pharmacy Guild of New Zealand has also created warning labels, for oral medications covered with child safety caps with the slogan “check the click”, to ensure that child-safety caps are placed back on medicine bottles correctly.

2.3 Industry compliance

The uptake of CSCs use through voluntary use is limited and varies between manufacturers and pharmacists. In 1997, the School of Pharmacy at the University of Otago launched a project to promote the availability of new technology child safety caps (CSCs) to prescribers, pharmacists and the public. Of the 32 pharmacists interviewed it was found that 31 would place a CSC of any medication requested by the patient. However, only about two-thirds of the pharmacists used 10 or less CSCs

There have been a number of reasons documented for the limited use of CSCs. These have included:

- The additional cost passed to the consumer for a CSC for non-subsidised medicines;
- The perceived inconvenience in opening a CRC for older people and people with arthritis.
- Low levels of public awareness;
- Inadequate supply and distribution systems for CSCs for solid medicines.

2.4 Extension of the Contractual Agreement between Ministry of Health and the Pharmaceutical Industry

This is not the preferred option. It would only cover subsidised medicines and would exclude non-subsidised medicines and over the counter medicines. The degree of coverage would also vary according to movements of medicines on and off the Pharmac Schedule.

2.5 Amendment of the Medicines Regulations

International evidence has identified that child safety caps have been effective in reducing childhood poisonings. Amending the Medicines Regulations (1984) is the preferred option for increasing the coverage of medicines with child safety packaging.

Under this legislative framework Safekids recommend an:

- extension of the list of medicines requiring child resistant packaging based on the existing code of ethics and Australian Medicines & Poisons Regulations (to harmonise with Australia and other international standards);
- extension of the definition of Child Resistant Packaging under the regulations to include recloseable child safety caps that meet the NZ Standard.

ⁱ Safekids, Kidsafe Week 2001 Fact Sheet, Poisonings – Children 0-14 years old.

ⁱⁱ Safekids, Kidsafe Week 2001 Fact Sheet, Poisonings – Children 0-14 years old.

ⁱⁱⁱ Safekids, Kidsafe Week 2001 Fact Sheet, Poisonings – Children 0-14 years old.

^{iv} Smith N., and Temple W., (1996) *The 'Dirty Dozen CRC' Project*, Investing in Children Primary Prevention Strategies, Proceedings of the Children's Issues Centre Inaugural Child and Family Policy Conference 10-13 July 1996, Dunedin.

^v Injury Prevention Research Unit., (1998-1999) Morbidity data from the New Zealand Health Information Service (NZHIS).

^{vi} Clarke and Walton 1979, Walton 1982, Krug et al 1994 p.14).

^{vii} Clarke and Walton 1979

^{viii} Smith N., and Temple W., (1996) *The 'Dirty Dozen CRC' Project*, Investing in Children Primary Prevention Strategies, Proceedings of the Children's Issues Centre Inaugural Child and Family Policy Conference 10-13 July 1996, Dunedin.

^{ix} Smith N., and Temple W., (1996) *The 'Dirty Dozen CRC' Project*, Investing in Children Primary Prevention Strategies, Proceedings of the Children's Issues Centre Inaugural Child and Family Policy Conference 10-13 July 1996, Dunedin.

^x Hingley A.T (1997) *Preventing Childhood Poisoning (FDA Consumer Reprint)*, U.S. Food and Drug Administration.

^{xi} Jackson R.H., (1983) *Childhood Poisoning: Perspectives and Problems*, The Macmillan Press Ltd.

^{xii} Smith N., and Temple W., (1996) *The 'Dirty Dozen CRC' Project*, Investing in Children Primary Prevention Strategies, Proceedings of the Children's Issues Centre Inaugural Child and Family Policy Conference 10-13 July 1996, Dunedin.

^{xiii} Blakely TA (1997) *Child Resistant Packaging for Medicines and Toxic Substances*, Submitted to the Australasian Faculty of Public Health Medicine for the Part II examination, 1998.

^{xiv} Smith N.A., (no date) *Implementing the Dirty Dozen Project in Dunedin Pharmacies*, School of Pharmacy, University of Otago, Dunedin.

Appendix 1

(excerpt from Pharmaceutical Society of NZ – Code of Ethics, April, 2001)

3.17 Child Resistant Packaging

This obligation extends to those medicines and poisons which are implicated in childhood poisonings. A list of these is provided below. Liquid AND solid dose oral forms of: aspirin, paracetamol, opioids, NSAIDs, benzodiazepines, anticonvulsants, antidepressants, antipsychotics, antihistamines, cardiovascular drugs, beta-2-agonists, theophylline, thyroxine, iron, quinine and, colchicine.

Non-oral liquid forms of: liniments, inhalations, paints, and mouthwashes.

The exceptions to this provision are noteworthy, namely:

- where, after instruction, the patient has difficulty opening a child resistant closure.
- where a specific request is made that the preparation must not be dispensed with a child resistant packaging.
- where no suitable child resistant packaging exists for a particular medicine or poison.