

INJURY BULLETIN

Queensland Injury Surveillance Unit

No 101 May 2008

QISU collects and analyses data from emergency department injury presentations on behalf of Queensland Health. Participating hospitals represent three distinct areas of Queensland.

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Medicinal Poisoning in Queensland Toddlers

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Summary:



More than 1000 toddlers present to Queensland emergency departments every year following a medicinal poisoning



Many more toddlers access a medicinal product but are able to be managed at home



Queensland Poisons Information Centre deals with up to 20 calls per day from parents of toddlers who have accessed a medicinal product (more than 7000 per year)



Child-resistant packaging helps to delay and minimise exposure to potential poisons but does not prevent all poisonings



Conventional blister packs have to date been considered to be "inherently child-resistant" but are easily defeated by toddlers



Failure of the child-resistant mechanism to re-engage contributes to some medicinal poisoning in toddlers

Introduction

Ingestion of/ exposure to medicinal products by toddlers is a common reason for Queensland parents to access health advice. The Queensland Poisons Information Centre (QPIC) answers up to 40 calls per day from parents/ caregivers seeking advice after a child under the age of 5 years accessed a potential poison. In half of those calls, the substance accessed is a medicinal product (drug or health related product). This issue of the bulletin uses data from QISU and QPIC to examine medicinal poisonings in toddlers.

Methods

The QISU database was searched for the eight year period, 1999 to 2007 for emergency department presentations related to exposure to a medicinal product in children under the age of 5 years. This data set includes ingestions of / exposure to medicinal products (pharmaceutical agents, topical creams, essential oils used in health care), but *excludes* ingestion/ exposures to other chemicals (cleaning agents, household chemicals) and prescription infant formulae. Medicinal poisoning includes inadvertent administration of medication by care givers as well as unintended access by the child. QISU data is collected from participating Queensland emergency departments representing approximately one quarter of the state population. The Queensland Poisons Information Service is a 24 hour telephone advice service based at the Royal Children's Hospital in Brisbane. The service is staffed by pharmacists, and aims to provide first aid and triage advice for callers after a potential poison exposure.

Advice is based on the poison the child is exposed to and the potential maximal poison exposure proportional to body weight. QPIC maintains a database of all calls. Standard data includes the child's age, weight, product/products the child was exposed to, product formulation, route of exposure and advice given. In April 2007, as a joint project with QISU and the Griffiths School of Pharmacy, QPIC ran a pilot project where additional data was collected for ingestion of solid medications in children under the age of 5 years. This additional data included the mode of access, place of access, person for whom the medication was intended and packaging type (blister pack, bottle with child-resistant cap (CRC), bottle with non-CRC, dosette/ Webster pack).

Note: Webster pack is a multidose drug packaging system where weekly drug regimes are packaged in a large blister pack.

This pilot was designed to give additional information on the frequency of toddlers accessing medication from different forms of packaging. Death data was sourced from the Annual Report Deaths of Children and Young People 2004/5 and the NCIS database.

Results:

Death data

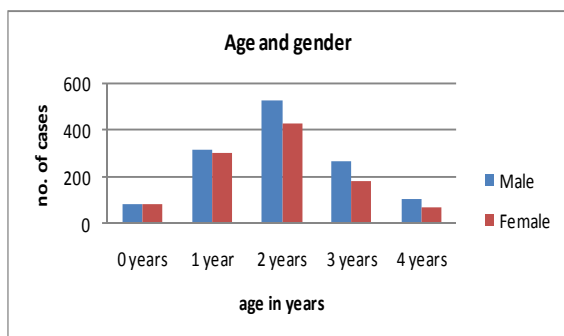
The 2004/5 Annual Report: Deaths of Children and Young People reported on Australian child poisoning deaths for the 13 year period 1991 to 2003. Of 33 poisoning related child deaths during that time period, 9 were aged between 1 and 4 years. ⁽¹⁾ No child less than 1 year of age died from poisoning during that time period. The type of poison was not identified in the report. The National Coroners Information System (NCIS) database gives details on one toddler death during that time period. In 2002 a Queensland toddler aged 2 years died following an ingestion of Quinine tablets. ⁽²⁾

QISU data

During the eight year study period, there were 2332 children under the age of 5 years who presented to participating Queensland emergency departments following exposure to a medicinal product. This represents 56% of all poisoning presentations and 4% of all injury presentations in that age group. It is estimated that more than 1000 toddlers present to Queensland emergency departments annually following a medicinal poisoning (3 toddlers per day).

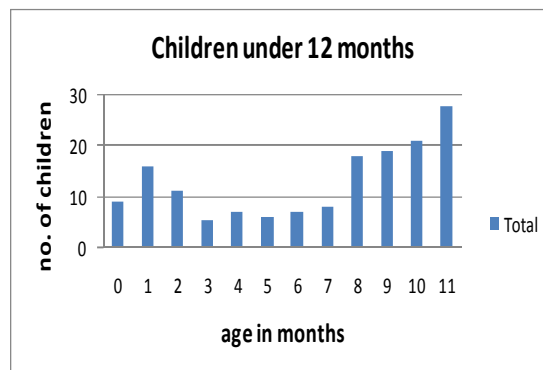
Age and Gender:

The peak age for presentation was 2 years with 957 presentations (41% of all presentations). Few children presented under the age of 12 months (155 or 7%). Overall, males attended more frequently than females in a ratio of 1.2:1. Males predominated in all age groups except in children under the age of 12 months. The gender difference was most noticeable for 3 year olds with a male to female ratio of 1.4:1. For infants under the age of 12 months, there was a biphasic peak in presentations at 1 month of age and again at 11 months of age.



Graph 1: Number of children presenting following medicinal exposure by age in years and gender.

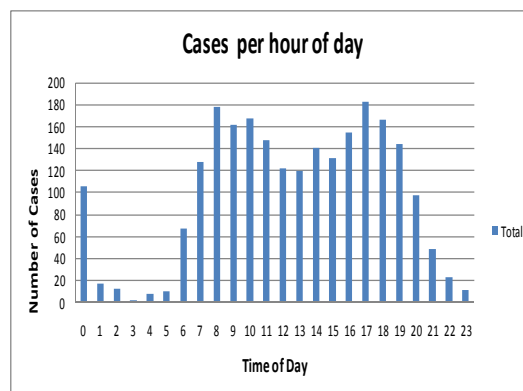
The mode of access to medication for children under the age of 6 months is predominantly by dosing/ medication error, while the mode of access for infants aged between 6 and 11 months is a combination of dosing/ medication error and access to medication within reach.



Graph 2: Number of children under the age of 12 months presenting following a medicinal exposure.

Time of exposure:

There was variation in the time of medication exposure with peaks at 0800h and again at 1700h with few exposures before 0600h and after 2000h. A smaller peak was evident at 0000h and again was likely due to inadvertent dosing / medication error by caregivers.



Graph 3: Number of Cases according to time of ingestion

Location of injury:

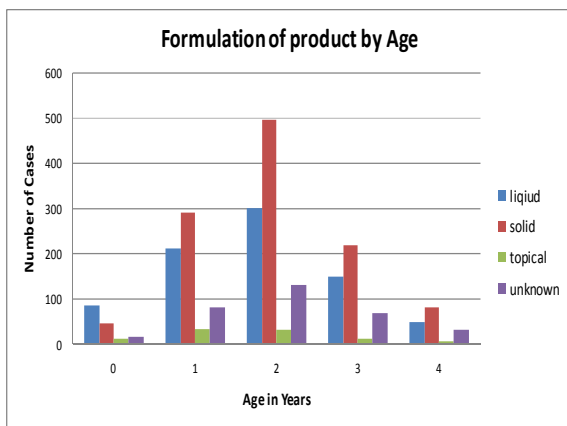
Over 96% of exposures to medicinal products in children under the age of 5 years occurred in homes (2230/2332). The data does not record whether it is the child's usual residence or not. Of the remaining 4% (102), 51 occurred in an unspecified location, 9 occurred in a vehicle, 8 in child care centres and 5 in an unspecified institution. For exposures that occurred within the home, the majority occurred in the kitchen (686 or 31%) followed by the bedroom (635 or 29%)

Formulation and Packaging:

QISU data does not routinely collect information on the formulation of the drug or the packaging. However, QISU data was analysed where information on the drug formulation was mentioned or could be deduced from the text description. In some instances there was insufficient information to be able to type the formulation. In Graph 4, "topical" includes creams, lotions, ointments and patches that are intended for topical use.

“Solid” includes tablets, capsules, ‘gel caps’, powders and wafers. “Liquid” includes suspensions and syrups intended for ingestion as well as topical preparations, oils, inhalation/ vaporiser solutions and nebuliser solutions not intended for ingestion. There was one case of exposure to injected insulin and one exposure to Ventolin aerosol. In general, formulation correlates with packaging type. Liquids are packaged in bottles with simple or child resistant closures. Some bottles have flow limiting inserts (essential oil bottles). Solids are packaged in bottles as above or in blister packs or dosette/ Webster packs. “Topical” agents (non liquid) are packaged in tubes/ tubs with simple screw caps, or as adhesive patches.

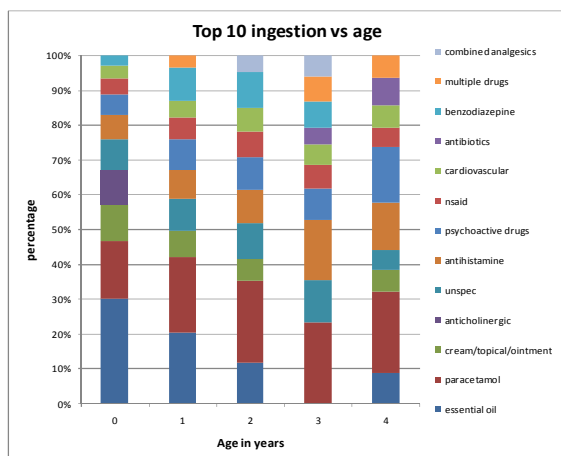
Analysis of the QISU data shows that ingestion of solid medications increases with age, representing 52% of all ingestions in children aged 2 years. For infants under the age of 12 months, 56% of all medicinal poisonings were due to liquids. Many of these will be inadvertent administration/ incorrect doses of infant medication. The proportion of liquid medicinal poisonings falls to 31% for children aged 2 years.



Graph 4: Formulation of product exposed to according to age of the child

Medicinal Exposure

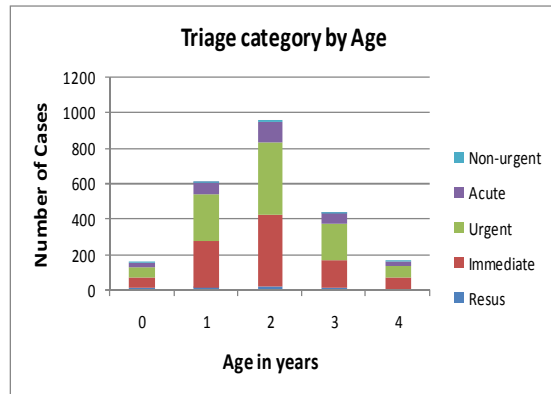
The type of medicinal product responsible for emergency department presentations varies according to age. The most common exposure for children aged less than 12 months was essential oils (29% of medicinal exposures in that age group). Paracetamol was consistently common for all age groups (ranging from 16 to 23% of exposures in each age group). Graph 5 represents the top 10 medicinal exposures by drug type in each age category.



Graph 5: Top 10 medicinal exposures by age in years

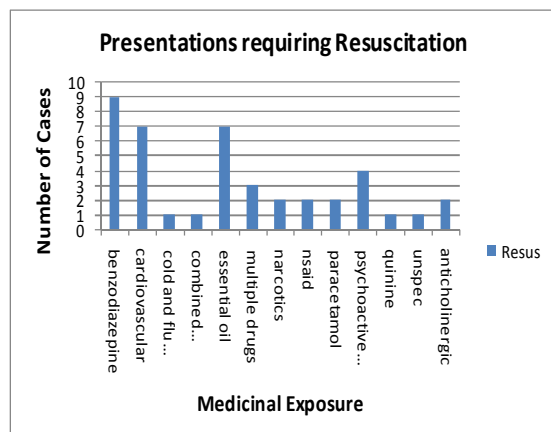
Severity

The majority of children 1007 (43%) presented as triage category 3 (requiring urgent attention). Almost as many (947 or 41%) presented as a category 2 (requiring immediate attention). Only 42 toddlers (2%) presented with a medicinal exposure requiring resuscitation. Triage category did not vary significantly according to the age of the child nor the formulation of the ingestion.



Graph 6: Triage category according to the age of the child

For the 42 toddlers who presented requiring resuscitation, the type of medicinal exposure was varied. However, benzodiazepines, cardiovascular medications, essential oils, psychoactive drugs and multiple drugs accounted for the majority of exposures in the group (30/42).



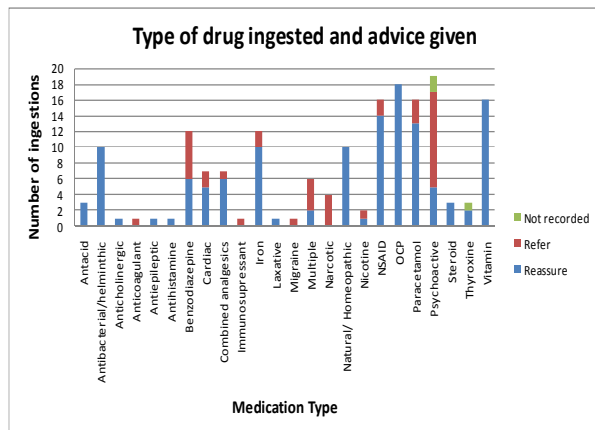
Graph 7: Medicinal exposures for toddlers presenting requiring resuscitation.

Overall, 811 children (35%) were admitted for observation or management following exposure to a medicinal product (19 were transferred for admission to another hospital). Few (11) did not wait for treatment/ left after treatment commenced. The proportion admitted did not vary significantly with the formulation of drug, or the age of the child.

QPIC Data

Additional data on **solid medication** ingestions in children under the age of 5 years was collected by **QPIC for the month of April, 2007**. Over the one month period, there were 171 calls following toddler exposure to a solid formulation pharmaceutical agent (**5.7 calls per day**). Of the 171 calls, 53 toddlers (31%) were referred to a medical facility for further management because of the potential toxicity of the exposure (**1.8 toddlers per day**).

Graph 8 outlines medication by type ingested and the advice given by QPIC staff for these 171 calls. Analgesics overall are the most common group, but are divided into paracetamol (16 ingestions), non-steroidal analgesics (16 ingestions) and combined analgesic preparations (7 cases). Following analgesics, the common drug types ingested are psychoactive drugs (19), oral contraceptive pills (18) and vitamins (16 ingestions).

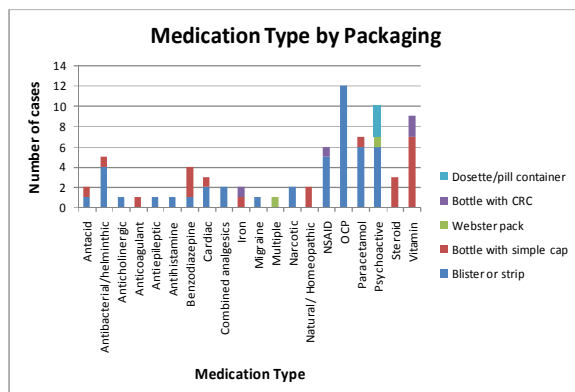


Graph 8: QPIC data: Type of drug ingested and referral advice (total number = 171)

Referral to a medical facility most commonly followed ingestion of psychoactive agents (11 cases), benzodiazepines (5), multiple drugs (4) and narcotics (4). Of the 171 callers, 80 (47%) agreed to answer detailed questions about how the agent was accessed. Of those 80, 16 (20%) were referred to hospital.

The agent was accessed from blister packs in 45 cases (56%), from bottles with CRC in 4 cases, from bottles with simple cap in 21 cases, and from dosette or Webster packs (foil backed multi dose dispenser) in 5 cases. In the 5 remaining cases, the medication was accessed as individual loose tablets in 3 cases and the mechanism of access was not stated in 2 cases. Therefore, of the 80 cases, 70 toddlers were known to have accessed the agent from the original packaging. A further 5 toddlers accessed medication from Webster packs or dosette devices. One of these involved ingestion of multiple drugs.

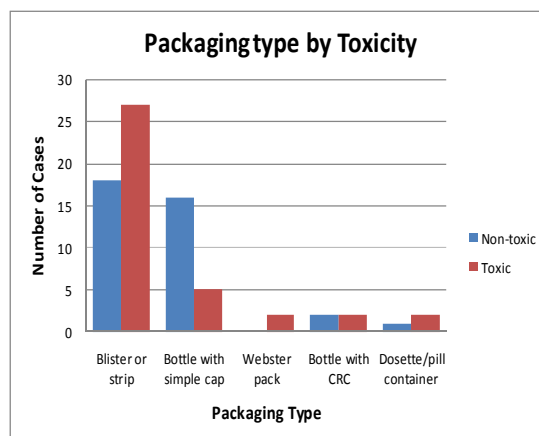
Graph 9 shows a comparison of medication type by all types of packaging (number = 75).



Graph 9: Medication type by packaging (total number = 75)

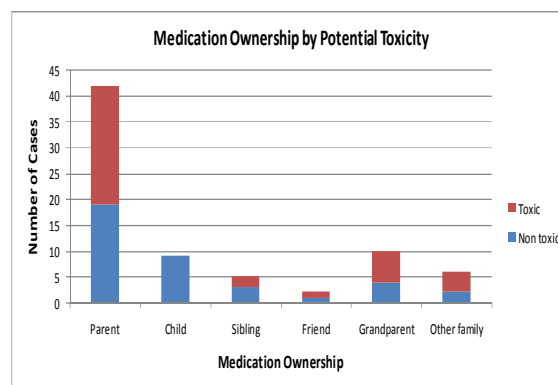
Of the 80 solid medication ingestions, potential for toxicity could be established for 79 cases. In most cases information included the brand of medication and / or packaging and a pack size could be calculated.

For the purposes of this bulletin, the potential for toxicity was calculated based on the total potential exposure, had the toddler accessed all medication available in a new package. Toddler body weight was estimated as the average weight for age based on the standard Australian growth chart. In the 5 cases where the toddler accessed the medication from a multidose dispenser (Webster pack or dosette), although the total amount of medication in the dispenser was unknown, all 5 were referred to hospital for the known ingestion, therefore the exposure was known to be toxic. In three cases, the toddler accessed loose tablets. None of these ingestions were potentially toxic. In the two remaining cases, whilst the packaging type was not stated, one was referred to hospital and therefore had a known potentially toxic exposure. The majority of solid medications ingested by toddlers were prescription drugs (47/79 or 60%) and a significant proportion of these ingestions were potentially toxic (29/47 or 62%). However, 9 out of 19 ingestions of "over the counter" medications were also potentially toxic (47%) and one of 13 ingestions of herbal/ vitamin/ homeopathic preparations (FerroGradumet containing iron).



Graph 10: Access to potentially toxic versus non toxic solid poisons by packaging (total number = 75)

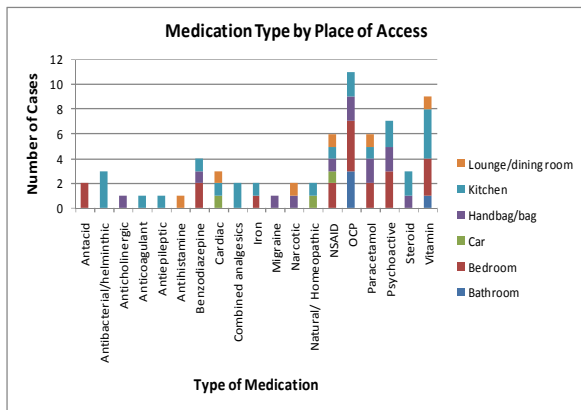
Of those 75 toddlers who were known to have accessed the medication from some form of packaging, 34 were potentially exposed to toxic doses of medication. Of those 34 potentially toxic exposures, 27 (79%) accessed the agent from conventional blister packs and 2 from Webster packs.



Graph 11: Medication ownership by number of cases and potential for toxicity (total number = 74)

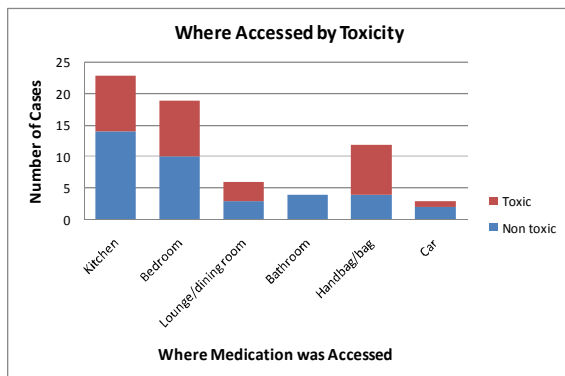
In 74/80 cases the intended recipient of the medication was stated. In most instances, the medicine was intended for the parent followed by grandparent/ other relative. Ingestions of solid medications intended for the child were all non-toxic (9/70 or 13%). There were 42 solid ingestions where the medication belonged to a parent (54%) of which 23 (55%) were considered potentially toxic. There were 10 ingestions of medication belonging to grandparent and 6 of these were considered toxic (60%). In 67 of 80 cases, the place or mode of access was recorded. In keeping with the QISU data, the majority of children accessed solid medication in the kitchen (23/67 cases or 34%) followed by the bedroom (19/67 cases or 28%).

Graph 12 shows 67 of 80 solid medication ingestions where the place/ mode of access was known displayed according to medication type.



Graph 12: Place where toddler accessed medication according to drug type (total number = 67)

When the same 67 cases were analysed according to toxicity, the largest proportion of potentially toxic ingestions occurred for medication accessed from handbags (8/12 ingestions from handbags or 67%). This is compared to 39% of solid medication ingestions in the kitchen being toxic and 47% of solid medication ingestions occurring in the bedroom. Of the 12 ingestions where the child accessed the medication from the handbag, the medication was in a blister strip in 8 cases, one child accessed the medication from a Webster pack and in one case the tablets were loose in the bottom of the bag. In the remaining 2 cases the medication was in a bottle with a simple cap. Four of the 12 children who accessed medicine from a handbag were referred to hospital. In 6 of the 12 cases the handbag belonged to a parent and only in one instance did the grandparent own the bag.



Graph 13: Place of toddler access to medication by potential for toxicity

Discussion:

The Queensland Poisons Information Service provides a vital service for Queensland families and Queensland Health. Qualified staff are able to provide timely, consistent and evidence based information on acute management following a potential poisoning. This includes triage of cases that require medical observation or intervention. For the solid poisons data presented in this bulletin, QPIC referred only 31% of cases to a medical facility. The remainder of cases were able to be safely managed at home. Where children do present to a medical facility, care at that facility is also directed by advice from QPIC staff. This advice takes into consideration recent advances in toxicology, new drugs and reflects global changes in poisoning management. Advice is practical, and enables patients to be managed consistently from Brisbane to the bush. Whilst triage and management of toddler poisoning has improved over the years, primary prevention of toddler poisoning remains problematic. Strategies used to date have included:

- Regulation and Scheduling of products by the Therapeutic Goods Administration (TGA) and the National Drugs and Poisons Scheduling Committee (NDSPC)
- Graduated labelling of scheduled products with warning labels such as "Poison" or "Caution: Keep Out of Reach of Children"
- Child resistant packaging
- Public education campaigns reinforcing the "Keep Out of Reach of Children" message

Regulation and Scheduling

Regulation and scheduling of products is an ongoing process requiring regular revision as new drugs are introduced and older drugs are phased out. This process involves limitations on the availability and prescription of certain medications within Australia including formulation and packaging. The scheduling process informs the labelling requirements as discussed below. Within this regulation and scheduling process, the TGA stipulates which drugs are required to be packaged in child resistant packaging. Many newer drugs have safer toxicological profiles, and drug company marketing as well as prescribing patterns may influence availability more than scheduling bodies. For example, newer antidepressants such as Selective Serotonin Reuptake Inhibitors (SSRIs) have largely replaced Tricyclic Antidepressants (TCAs) in the management of depression. In overdose, SSRIs have a safer toxicity profile when compared to TCAs which may cause fatal cardiac arrhythmias.

Labelling

Graduated labelling of products with appropriate warnings such as "poison" and "keep out of reach of children" directs pharmacists on how to dispense products and parents on how to store products. Injury prevention advocates recommend the use of locked medicine cabinets and locked fridge storage containers. Whilst some children will climb chairs to access medication in high cupboards, most toddlers are opportunistic acquirers of medication and frequently access medicine when it is in use.

In many households, it is not practical to store medication away from sight, as regular medications may be missed. The QISU and QPIC data are consistent in showing that medication is accessed in the location in which it is used, with most ingestions occurring in the kitchen followed by the bedroom.

Child Resistant Packaging

Where a toddler manages to access a medication, the amount ingested will depend on the duration of the lapse in parental/caregiver supervision and the ability of the toddler to open the packaging. Medication packaging comes in 2 main forms, reclosable packaging (bottles or containers with reclosable caps) and blister packs intended for single dosing of medication. In addition, flow restrictors are required under scheduling regulations for some products (mainly essential oils). Following the introduction of the Poison Prevention Packaging Act in America in 1970, the first Australian Standard for child resistant packaging (AS 1928:1976) was introduced in 1976. This standard applied to **reclosable packaging only**. Blister packaging was considered to be inherently child resistant. As with other international standards, the current Australian Standard (AS 1928:2007) requires that reclosable packages are tested on panels of toddlers aged 42 to 51 months to ensure that the majority of toddlers (more than 80%) **are not able to defeat the closure**. A similar test panel is run with adults to ensure that the majority of adults (more than 80%) are able to open the closure and access the medication. Where other international standards currently have similar testing processes for both reclosable and non-reclosable child resistant packaging, **Australia lacks a testing standard for child resistance of blister packs.** ^(3,4,5)

Reclosable Child Resistant Packaging

Reclosable child resistant packaging takes the form of a container with a child resistant closure (CRC). This form of packaging is used for both solid and liquid drug formulations. Most CRCs are either a "squeeze and turn" mechanism or a "push down and turn" mechanism. Testing requires that more than 80% of the adult test panel are able to demonstrate that they can **both remove and re-engage the CRC**.

Consumer advocacy groups have raised concerns that adults with disabilities (visual, cognitive or manual disabilities) may have difficulty accessing medication packaged with a CRC. Anecdotal evidence suggests that adults who experience difficulty in opening CRCs are likely to leave closures part closed for ease of access or tip medication into other containers. Alternatives such as Webster packs or dosette containers may assist in these circumstances. Webster packs are widely used in aged care facilities and have been shown to significantly improve patient adherence to medication regimes and reduce medication error. Whilst children may freely access medication that has been tipped into a non child resistant container, Webster packs and dosette containers too pose a risk. In the QPIC series of 80 solid medication ingestions in toddlers, only 5 toddlers accessed medication from multidose containers. However; all 5 ingestions involved psychoactive drugs and all of the toddlers were referred to a medical facility for further care. There is a significant bias in that patients using multidose packs are more likely to be elderly or mentally debilitated and taking psychoactive, cardiac or antiepileptic medications.

Even when parents/caregivers intend to re-engage the CRC, this process may fail and the closure behaves as simple screw closure. Reasons for failure to re-engage the CRC include crystallisation of medication on the rim, poor fit, requirement to turn the closure an additional quarter turn ⁽⁶⁾ **Few CRCs on the market have a single obvious point of closure and re-engagement of the child-resistant mechanism. Most require testing once closed to ensure that the CRC is activated.**

Flow Restrictors

QISU recently identified eucalyptus oil as the single most commonly ingested medicinal agent for children under the age of 12 months ⁽⁷⁾. Oil was either accessed from a vaporizer, directly from the packaging, or more frequently inadvertently given by a care giver. Very small doses of eucalyptus oil (as little as 5ml) and other essential oils can cause central nervous system depression and seizures in young children.

Under the current TGA working order 65, CRCs are required for most *ESSENTIAL OILS in a volume of 200 millilitres or less, when included in Schedule 5 or 6 of the Poisons Standard.. and for... eucalyptus oil in a volume of 2 litres or less, when included in Schedule 6 of the Poisons Standard* ⁽⁷⁾

Under the proposed revision TGA working order 80, eucalyptus oil will require a CRC except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or (b) in a preparation containing 25 per cent or less of eucalyptus oil, or a combination of eucalyptus oil and any other essential oil named in this Part ⁽⁹⁾

A flow restrictor provides reasonable protection to a young child accessing a bottle of eucalyptus oil. However, in our series, care givers inadvertently administered eucalyptus oil drawn up from larger bottles with a CRC but no flow restriction. Further, eucalyptus oil marketed as a non-medicinal agent (cleaning, aromatherapy, massage) is neither required to have a flow restrictor nor a CRC.

To prevent inadvertent oral administration and limit exposure in the event that a child breaches a CRC, all eucalyptus oil marketed in bottles holding 200ml or less should be packaged with a non-removable flow restrictor. This should apply whether the oil is marketed for medicinal or non-medicinal purposes.

Non-Reclosable Child Resistant Packaging

The ability of toddlers to access medication from conventional blister packs has been demonstrated in standardised testing scenarios in the USA, UK and Australia. In the study conducted in 1998 by the US Consumer Product Safety Commission, toddlers aged 42 to 51 months were tested according to the PPPA test parameters described by the regulations (Poison Prevention Packaging Act) ^(10,11) Toddlers were provided with an unlimited supply of blister packs. Comparison was made between conventional blister packs (plastic blister film and foil backing), and child-resistant blister packs (plastic blister film with paper/plastic or foil/plastic backing where a tablet is removed by first peeling back an outer layer then pushing through the foil).

Toddlers given an unlimited supply of medication in conventional blister packs were able to access from 0 -85 tablets during the 10 minute testing period (average 23).

This is compared to toddlers given an unlimited supply of medication in child-resistant blister packs, where the number of tablets accessed in the 10 minute testing period ranged from 0-8 (average 3).

Packaging in blister packs has undoubtedly improved the ease of use of medications by making the product more transportable and giving a visual guide as to the number of tablets taken. This may also inform parents when trying to determine how many tablets were accessed by a toddler. The downside of this is that this is likely to have increased the exposure of toddlers to medications carried on one's person (in handbags, pockets etc). This is evident in the QPIC data, in the significant number of medications that were accessed from blister packs found in handbags. A more detailed analysis of the rate of toddler poisoning due to medications accessed from different packaging is not feasible, as it would require an estimate of the overall exposure of a population of toddlers to all medication (including formulation and packaging) in their environment.

However, the QPIC pilot study demonstrates that **toddlers are accessing medication from blister packs that are currently considered "child-resistant", and that blister packs appear to be overrepresented in the potentially toxic solid medication exposures.** This finding is consistent with a similar study published from the NSW Poisons Information Centre based at the Children's Hospital, Westmead⁽¹²⁾

In February 2007, Standards Australia conducted a stakeholder forum and canvassed opinions from industry, government and health groups regarding the need for an Australian child resistance standard for blister packs. Consensus from the forum was to develop a new Australian Standard for non-reclosable child resistant packaging. Although that process has still not commenced, the TGA, is currently developing a best practice guideline on non-reclosable child resistant packaging. This will hopefully inform development of the new standard by assessing the impact on industry and other stakeholders of more robust blister packaging. Consumer groups have again expressed concerns that adults with disabilities will not be able to access medication if blister packs require greater dexterity/ cognitive skills to open. Consideration must be given to the ability of elderly or disabled adults to access medication from improved blister packs. Webster packs are currently being promoted for private use, and will also be influenced by the development of the new standard.

This challenge has been addressed in other jurisdictions where a child-resistant standard applies for non-reclosable packaging (EU, UK, USA). Packaging solutions have already been implemented that pass both adult and child testing scenarios.

Ongoing Education

Despite the wide range of potentially toxic pharmaceutical agents currently available in Australia there is little "point of prescription" or "point of sale" consumer information regarding the potential danger of these agents to toddlers. Many people place medication within sight and easy reach as a reminder to take regular doses. Parents do not perceive that many seemingly "innocuous" medications can potentially be fatal.

This includes medications commonly used by parents of young children such as aspirin/ NSAIDs and iron supplements. As a paediatrician seeing ingestions in the emergency department, it is apparent that the majority of ingestions by toddlers occur when the medication is in use and within reach. Parents often refer to child-resistant closures as being "child-proof" and are surprised when toddlers are able to defeat them.

The current advice to "store medication out of reach of children" holds only for infrequently used medication and does not address the known mode of access to medications by toddlers.

Summary:

QISU estimates that over 1000 Queensland toddlers present to emergency departments annually following a medicinal exposure. Many of these exposures occur when toddlers opportunistically access medication that is in view and in use. Where the message "Keep out of reach of children" is failing, **effective child-resistant packaging** has the potential to both delay and minimize access to medications for the majority of toddlers.

However, **"real life" failure of child-resistant closures and ease of access of medication packaged in blister packs continues to contribute to toddler medicinal poisoning in Queensland.**

Recommendations



Standards Australia and the TGA act urgently to develop an Australian Standard for child-resistant non-reclosable packages (blister packs)



Industry develop a CRC that has a single clear point of closure and activation of the child resistant mechanism



Industry develop quality assurance strategies to ensure that packaging that meets Standards testing continues to function in a child-resistant capacity throughout production



Pharmacists and medical practitioners improve "point of sale" and "point of prescription" advice regarding the potential toxicity of medicinal products



Continue public education to improve the understanding of the mechanisms of toddler access to medicinal products

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