

Button battery safety

Assessment of regulatory options Consultation paper

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accc.gov.au

Acknowledgments

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Disclaimer

The ACCC has developed this consultation paper to seek the views of stakeholders about proposals to introduce safety standards for button batteries and consumer goods that use button batteries.

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Glossary

Term	Definition
ACCC	Australian Competition and Consumer Commission
ACL	Australian Consumer Law, Schedule 2 of the Competition and Consumer Act 2010
APSU	Australian Paediatric Surveillance Unit
AS	Australian Standard
AS/NZS	Australian/New Zealand Standard
CCA	Competition and Consumer Act 2010 (Cth)
СВА	cost-benefit analysis
CPSC	Consumer Products Safety Commission (USA)
EN	European Standard
HSP	Hearing Services Program
HORC Framework	Hierarchy of Risk Control Framework
IEC	International Electrotechnical Commission
Industry code	Industry Code for Products Containing Button Batteries
ISO	International Organization for Standardization
Issues paper	Button Battery Safety Issues Paper released by the ACCC on 16 August 2019
National strategy	National strategy for improving the safety of button battery consumer products
NBIH	National Battery Ingestion Hotline (USA)
NCPC	National Capital Poison Center (USA)
OBPR	Office of Best Practice Regulation
OECD	Organisation for Economic Co-operation and Development
PIC	Poisons Information Centre
QISU	Queensland Injury Surveillance Unit
TGA	Therapeutic Goods Administration
VISU	Victorian Injury Surveillance Unit

Button battery types and related products

For the purpose of this consultation paper, button cell batteries and coin cell batteries are each referred to as 'button batteries'. In the battery industry, the term 'coin' is associated with lithium batteries and the term 'button' is associated with non-lithium batteries.

The range of different button batteries and related products is referenced below.¹ There is a wide variety of button batteries available in different sizes, shapes and electrical charges.

Battery type		Description
Alkaline	LR44 + NON	Alkaline button cell batteries have a nominal voltage of 1.5 volts and are generally less than 16 mm in diameter. Alkaline voltage drops gradually with use and alkaline button cell batteries average around half the life of lithium and silver oxide batteries.
Lithium	Luning Coll CR2032	Lithium coin cell batteries have a nominal voltage of 3 volts. They are available in a range of sizes, including the larger coin size, with diameters ranging from 9.5 mm to 32 mm and height from 1.2 mm to 10.8 mm.
Silver oxide	SR44SW J57 +	Silver oxide button batteries have a nominal voltage of 1.5 volts and range in diameter from 4.8 mm to 11.6 mm and in height from 1.3 mm to 5.4 mm.
Zinc air	9 🕂	Zinc air batteries have a nominal voltage of 1.4 volts and are typically smaller. They are available in a range of sizes (5.8 mm x 3.6 mm, 7.9 mm x 3.6 mm, 7.9 mm x 5.4 mm and 11.6 mm x 5.4 mm. These batteries are commonly found in hearing aid devices and require access to air (oxygen) to produce a current.

Table 1:Button battery types

Button batteries are found in a broad range of consumer and household products including, but not limited to, remote controls (television remotes, car keys, garage door openers), watches, computers, cameras, calculators, torches, flameless candles, fitness devices, digital kitchen and bathroom scales, toys, games, novelty items, musical greeting cards and home medical devices (digital thermometers, pedometers, glucometers, heart rate monitors, hearing aids).

¹ Coin Cell/Button Cell Battery Guide, <u>www.batteries.com/pages/coin-cell-button-cell-battery-guide</u>, viewed 9 December 2019.

Figure 1: Common button battery-powered products



Source: consumersfederation.org.au.

Questions for response

Questions and points for feedback:

- 1. The ACCC considers the status quo and proposes three options to improve the safety of button batteries. Which is your preferred option and why do you prefer it to the others?
- 2. What effect do you believe each of the proposed options will have in saving lives and reducing severe injuries caused by button batteries?
- 3. Provide comment on the ACCC's essential requirements for secure battery compartments, child-resistant packaging and warnings and information. Are there any additional requirements that should be included?
- 4. In relation to the requirement for secure battery compartments in which button batteries are only accessible with the use of a tool, do you consider that the use of a 'tool' should include the use of a coin? Why/why not?
- 5. Do you supply products that currently meet the essential requirements for secure battery compartments, child-resistant packaging and warnings and information? If not, which requirements do your products not meet and why?
- 6. Provide comment on the ACCC's proposed information standard for warnings and information to be made available at point of sale. Are there any additional requirements that should be included for products sold online, or for unpackaged products supplied to consumers?
- 7. If you are a manufacturer, importer, distributor or retailer of button batteries or consumer goods that use button batteries, what impact will the proposed options have on your business?
- 8. Do you agree with the proposed exemption for hearing aid devices and associated zinc air batteries? Why/why not? (see section 5.2)
- 9. Do you consider that any other categories of consumer goods should be exempt from any of the proposed requirements? Do you have information and data you can provide to the ACCC in support of your view?
- 10. What are the likely costs to implement each of the requirements (design changes, child resistant packaging, labelling), and what do you consider is the likely effect on prices for consumers?
- 11. Do you think that all potential costs to business have been considered? Can you provide any further information about likely costs/impacts of each of the options?
- 12. Provide comment on the transition period for the proposed options (see section 7).
- 13. Provide comment on the principles-based approach to a mandatory safety standard (see section 7.2). A principles-based approach:
 - sets out safety principles that need to be met rather than specifying detailed standards
 - incorporates external instruments for compliance tests only
 - includes administrative guidance which provides examples of relevant clauses in external standards that are considered to comply with each requirement.
- 14. Provide any additional information or data that you think may be useful to informing the ACCC's recommendation to the Minister.

About this consultation paper

The Australian Competition and Consumer Commission (ACCC) is a whole-of-economy regulator that promotes competition and fair trading in markets to benefit consumers, businesses and the Australian community. Our primary responsibility is to ensure that individuals and businesses comply with the *Competition and Consumer Act 2010* (the CCA), which includes the Australian Consumer Law (ACL).

Through the application of the ACL, the ACCC aims to prevent misleading behaviour and unconscionable conduct, minimise the risk posed by unsafe consumer products and ensure consumers are fully informed about safety risks.

Consumer product safety regulation in Australia is a shared responsibility between Commonwealth, and state and territory consumer protection regulators. The ACCC's product safety role involves identifying, prioritising and addressing risks to persons arising from unsafe consumer goods and product-related services.

We do this by administering the consumer product safety provisions of the ACL, which include powers for the Minister responsible for product safety to issue compulsory recalls, product bans, safety warning notices, and mandatory safety and information standards.

Mandatory safety and information standards under the ACL make particular safety or information features compulsory for the legal supply of a specific product into the Australian market. They are introduced when considered reasonably necessary to prevent or reduce the risk of injury to a person, or to provide important information about a product to assist consumers in making purchasing decisions.²

For the purposes of this consultation paper, all flat, disc-shaped cells or batteries are referred to as 'button batteries' regardless of their size or chemistry. 'Coin', 'disc' and 'button' cells or batteries are taken be one and the same article.

Button batteries can cause severe injury and death if ingested, particularly by children aged 0–5 years. Two Australian children have tragically lost their lives following the ingestion of a button battery and many others have suffered serious injuries.

In response to continuing concerns about the hazards button batteries pose to children, the ACCC has prepared this consultation paper to consult on the costs and benefits of proposed regulatory options available under the ACL. The ACCC is seeking feedback on the baseline (status quo) assumptions and the costs and benefits of the regulatory options presented in this consultation paper.

In undertaking a cost-benefit analysis of each policy option to improve button battery safety, it is important to highlight that not all factors or impacts can be readily quantified or reducible to a monetary amount. To address this, the ACCC's analysis of costs associated with button battery incidents includes both quantitative and qualitative considerations.

The ACCC will consider stakeholder responses to this consultation paper and these will be used to inform the development of a Final Recommendation. The ACCC intends to provide a Final Recommendation to the Assistant Treasurer in 2020.

² Australian Government, *Federal Register of Legislation 2010*, Australian Government, Canberra, <u>www.legislation.gov.au/</u> Details/C2020C00006 ss. 104, 105 and 135 of the Australian Consumer Law, viewed 5 February 2020.

Have your say

The ACCC welcomes submissions from parents, health and medical professionals, manufacturers, importers, retailers, community organisations, regulators, government departments, members of the public and other parties that have an interest in, manufacture, import, sell, use, store, handle, generate or dispose of button batteries.

This consultation paper includes questions that are designed to elicit feedback and information on the proposed options. Respondents may answer some or all of the questions posed, or can raise a matter not explicitly addressed, as long as it is relevant to button/coin cell battery safety. Consultation questions have been collated above for convenience and are also repeated below in relevant sections of this paper.

Submissions must be provided on or before **30 April 2020**.

Online	ACCC consultation hub at: <u>consultation.accc.gov.au/</u>		
By email or post	Director Button Batteries Taskforce Australian Competition & Consumer Commission		
	GPO Box 3131 CANBERRA ACT 2601		
	nationalprojects@accc.gov.au		
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Website	productsafety.gov.au/		

Submissions can be lodged

All submissions will be treated as public documents and published on the ACCC website, <u>productsafety.</u> <u>gov.au</u>, unless otherwise requested. Parties wishing to submit confidential information are requested to:

- clearly identify the information that is the subject of the confidentiality claim—the identified information must be genuinely of a confidential nature and not otherwise publicly available
- provide a non-confidential version of the submission in a form suitable for publication—this public version should identify where confidential information has been redacted.

The ACCC will not disclose the confidential information to third parties, other than advisers or consultants engaged directly by the ACCC, except where permitted or required by law. For more information, see the <u>ACCC & AER Information Policy: Collection and disclosure of information</u>. For further information, see the <u>ACCC's Information Policy</u> (June 2014).

1. Executive summary

Button batteries are flat, round, single cell batteries with diameters up to 32 mm and heights ranging from 1–11 mm in thickness. Button batteries are available separately and as components of a huge range of consumer goods and household products. It is estimated that approximately 69 million button batteries were sold to the Australian market in 2019.³

Button batteries are a severe injury risk, particularly for young children. When lodged in the body and in contact with bodily fluid, button batteries can burn through tissue and cause catastrophic bleeding. Serious injury can occur in as little as two hours.

There are a growing record of these severe injuries and deaths all over the world, including Australia. In Australia, two children, Summer Alice Steer and Isabella Estelle Rees, have died from injuries sustained after ingesting a button battery in 2013 and 2015 respectively. There have also been at least 27 individual cases where young children have suffered severe injuries following the ingestion or insertion of button batteries in Australia since December 2017.

Globally, there is a growing record of injuries and deaths from button batteries. At least 64 children have died and thousands have been injured from button batteries with some children sustaining lifelong injuries requiring ongoing treatments. Based on US data, the number of severe injuries resulting from the ingestion of button batteries has increased significantly over the last 10 years.⁴ Australian emergency department records also indicate a significant increase in button battery incidents.⁵



Button battery emergency department presentations in Australia

Source: Queensland Injury Surveillance Unit, Victorian Injury Surveillance Unit, NSW Health, ABS Population Estimates.

³ XYZ Research Energy Centre, Global button cell batteries market report 2019 by manufacturer, region, type and application, 2019.

⁴ Injury and fatality records were sourced from literature review and through contacts to the United States National Battery Ingestion Hotline. Data for severe injuries is available from 1982-2019 and from 1977-2019 for fatal cases.

⁵ Emergency presentation rates calculated using data provided to the ACCC by the Queensland Injury Surveillance Unit, Victorian Injury Surveillance Unit, NSW Health and Australian Bureau of Statistics Population estimates and projections.

The safety risk to children from button batteries arises when they can get access to them.

This may occur in different ways:

- children gain access directly from consumer goods which use button batteries that do not have secure battery compartments—this may occur when poor quality products are dropped or broken
- children gain access directly from packaging—this may be new/replacement batteries made available for sale, or consumer goods supplied with loose batteries, in packaging that is not child-resistant
- children gain access when batteries are removed from consumer goods or packaging and are not stored safely prior to being installed, or otherwise not properly disposed of—old or spent button batteries can still hold a charge capable of causing injury.

Product safety best practice involves manufacturers adopting a precautionary approach when assessing the safety of consumer goods. Where possible, manufacturers should make design modifications to eliminate hazards caused by products associated with injuries at the design stage.⁶

The Hierarchy of Risk Control Framework (HORC Framework) assists in considerations for the management of identified hazards and risks and outlines the most and least effective control measures for eliminating or reducing risks. The HORC Framework identifies that the most effective measure to reduce risk is elimination of the hazard. Where elimination of a hazard is not feasible, other control measures include substitution, isolation, engineering controls, administrative controls and the use of personal protective equipment.

The use of button batteries in a wide variety of products means that elimination of button batteries and products that use button batteries is not a feasible risk control measure. Therefore, the next most effective measures, including substitution and engineering controls, should be considered.

For a third consecutive year, the Australian Competition and Consumer Commission (ACCC) has identified button battery hazards as a product safety priority.

This follows the implementation of the two-year National strategy for improving the safety of button battery consumer products 2016–2018. The strategy began alongside the release of the voluntary Industry Code for Consumer Goods that Contain Button Batteries, developed by industry and published in 2016. The ACCC and other ACL regulators conducted market surveillance throughout the course of the strategy to gauge the uptake of the industry code by suppliers. The voluntary industry code includes requirements only for consumer goods that use button batteries, but does not include any child-resistant packaging or warnings and information requirements for button batteries sold separately.

The ACCC examined trends in injury reporting to see if there were any indications that exposures and injuries associated with button batteries were decreasing.

In early 2019, the ACCC evaluated the impact of the national strategy and found voluntary supplier self-regulation had not sufficiently reduced the risk of injury or death to children from exposure to button batteries. The ACCC considers that there is a market failure with regard to the safety of button batteries and consumer goods that use these batteries.

The ACCC is aware of significant efforts made by some suppliers but overall there continues to be a high number of unsafe consumer goods that use button batteries available in the Australian market, and there is not yet any meaningful decrease apparent in the rate of button battery exposures or injuries.

In March 2019, after issuing a Safety Warning Notice to the Australian public about the dangers of button batteries, the Hon. Stuart Robert, then Assistant Treasurer, asked the ACCC to expedite the regulatory impact assessment process for developing regulation to address button battery safety.⁷

⁶ Standards Australia, Consumer Product Safety–Guidelines for Suppliers (AS ISO 10377:2017), section 3.6.

⁷ ACCC, Safety warning notice (button batteries), ACCC, Canberra, 2019, <u>www.productsafety.gov.au/publication/safety-</u> <u>warning-notice-button-batteries</u>, viewed 1 August 2019.

The ACCC established a taskforce to conduct an investigation into button battery safety and consider regulatory options available under the ACL.

In making a mandatory safety standard, the responsible Minister must be satisfied that the requirements are reasonably necessary to prevent or reduce risk of injury.

There is currently no specific regulation, in Australia or internationally, to address the hazard of button batteries. There is also no general legislative provision on the supply of unsafe goods in Australia.⁸ A wide range of existing national and international voluntary standards include requirements for button batteries; however, these do not effectively address safety as many suppliers do not comply with them.

In the event that regulation is introduced in Australia to address the hazard of button batteries, the ACCC considers that there is the potential for Australia to have a leading role in the development of button battery requirements globally, such as through the adoption of international standards. In recent years, the ACCC has led global product safety campaigns facilitated by the OECD. In the event that a mandatory standard for button batteries is introduced in Australia, the ACCC would propose to collaborate with the OECD and international standards bodies on the development of button battery requirements that can be adopted in other jurisdictions.

The ACCC has prepared this consultation paper to consult on the costs and benefits of proposed regulatory options available under the ACL to improve button battery safety.

The ACCC has considered the status quo of taking no action and has proposed three regulatory options. It is likely that if no government action is taken deaths and severe injuries associated with button batteries will persist and possibly increase as button batteries become more common in consumer products, including children's toys.

If no government action is taken, it is estimated that four fatalities, 138 to 331 severe injuries and 8600 emergency presentations will occur during the forecast period of 2020–2029. Quantitatively derived estimates of the cost of these button battery incidents are in the range of \$26.4-\$62.3 million. The true total costs of fatalities and severe injuries to children that have resulted from button batteries are impossible to quantify.

As part of this regulatory impact assessment, the following three options are proposed:

• **Option 1**: Make a mandatory safety standard that includes requirements for secure battery compartments in consumer goods that use button batteries. Consumer goods that use button batteries that are intended to be replaced would be required to have a secure battery compartment such that batteries are only accessible with the use of a tool. Consumer goods that use button batteries that are not intended for user removal or replacement would be required to have the batteries fully secured inside the product.

All consumer goods that use button batteries would be required to incorporate mechanisms to prevent removal of the battery by children under normal use or foreseeable misuse.

- **Option 2**: Make a mandatory safety standard that adopts all requirements in Option 1, and includes a requirement for all button batteries available for sale or supplied with consumer goods (where the battery is not pre-installed in a secure battery compartment) to be supplied in child-resistant packaging.
- **Option 3**: Make a mandatory safety and information standard that includes all requirements in Options 1 and 2 and includes a requirement for warnings and information to be provided:
 - on the packaging and instructions for all button batteries available for sale
 - on the product (where practicable), packaging and instructions of consumer goods that use button batteries
 - at point of sale (and prior to purchase) for all button batteries and consumer goods that use button batteries that are sold online
 - at point of sale (and prior to purchase) for unpackaged consumer goods that use button batteries that are supplied to consumers.

⁸ In October 2019, the Commonwealth Treasury began consultation on potential reform options for a General Safety Provision.

Option 3 is the ACCC's preferred option. The ACCC considers that a combination of requirements for secure battery compartments and child-resistant packaging as well as the inclusion of warnings and information is likely to prevent more deaths and serious injuries by reducing incidents of child exposure to button batteries. This approach would also best address information asymmetry issues by improving awareness of the hazard so that appropriate action can be taken when an incident occurs.

The ACCC considers an exemption for hearing aid devices and associated zinc air batteries is appropriate. Hearing aids do not pose the same risk as other products because of their exclusive use of zinc air batteries which pose lower risks than other button battery types. A mandatory requirement for secure battery compartments and child-resistant packaging for hearing aid devices and batteries would significantly reduce the usability and accessibility of the devices for these consumers, especially those with poor dexterity or vision impairment. The ACCC considers this exemption should be limited to the secure battery compartment requirements and child-resistant battery packaging, while warnings and information requirements should continue to apply. Inclusion of warnings on packaging and information provided with hearing aids and zinc air batteries should make these products safer by raising awareness of the possible risks associated with the batteries.

As part of a holistic approach to mitigate the safety risks associated with button batteries, the ACCC notes that additional risk mitigation measures should be considered by relevant agencies such as national awareness-raising campaigns and further development of secure containers for the safe disposal of button batteries.

2. Introduction

The ACCC has prepared this consultation paper to consult on regulatory options to reduce the number of severe injuries and deaths associated with children ingesting or inserting button batteries.

Button batteries are flat, round, single cell batteries with diameters up to 32 mm which range in thickness from 1-11 mm. These batteries are referred to as button or coin cell batteries. They are used in a broad range of consumer and household products including remote controls (television remotes, car keys, garage door openers), watches, computers, cameras, calculators, torches, flameless candles, fitness devices, digital kitchen and bathroom scales, toys, games, novelty items, musical greeting cards and home medical devices (digital thermometers, pedometers, glucometers, heart rate monitors, hearing aids).

Their small size, while suited to many uses, makes it easy for children to ingest them. Button batteries can cause severe injury and death if ingested, particularly in children aged 0–5 years. Severe injury can occur in as little as two hours. There is a growing record of these injuries and deaths globally, including Australia. In Australia, two children, Summer Alice Steer and Isabella Estelle Rees, have tragically died as a result of ingesting a button battery, and there are a growing number of young children suffering severe injuries following exposure to button batteries.⁹

Button battery safety and supporting strategies to prevent injuries and deaths in children is an ACCC product safety priority. The ACCC has identified key safety measures that could be implemented under the ACL to improve the safety of button batteries and consumer goods that use these batteries. These include:

- secure battery compartment requirements for consumer goods that use button batteries to prevent children from gaining access to the batteries
- **child-resistant packaging** for all button batteries available for sale or supplied with consumer goods to prevent children from gaining access to the batteries
- warnings and information to alert consumers that a button battery is included with the product and of their dangers, and provide clear directions on what to do in the event of suspected ingestion/ insertion. Warnings and information are to be provided:
 - on the packaging and instructions for all button batteries available for sale
 - on the product (where practicable), packaging and instructions of consumer goods that use button batteries
 - at point of sale (and prior to purchase) for all button batteries and consumer goods that use button batteries that are sold online
 - at point of sale (and prior to purchase) for unpackaged consumer goods that use button batteries that are supplied to consumers.

For the purposes of this consultation paper, consumer goods that 'use' button batteries include consumer goods that are supplied with, contain, are powered by or are intended to operate with button batteries.

In August 2019, the ACCC released a <u>Button Battery Safety Issues Paper</u> (the Issues Paper) for consultation. The options set out in this consultation paper have been developed from the results of the ACCC's investigation into button battery safety and in response to the views expressed by stakeholders involved in the consultation.

The ACL empowers the Minister responsible for product safety to make mandatory safety standards and information standards for consumer goods.

⁹ T Litovitz, N Whitaker, L Clark, NC White, M Marsolek, *Emerging battery-ingestion hazard: clinical implications*, Pediatrics, 125(6), 2010, 1168-1177.

The ACL defines 'consumer goods' as 'goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption'.¹⁰

A mandatory safety and information standard that applies to consumer goods that use button batteries would have broad application to a wide range of products, including some medical devices and electrical appliances that are subject to regulatory control by specialist regulators, such as electrical safety regulators and the Therapeutic Goods Administration (TGA).

The use of button batteries in diverse consumer goods indicates that any regulation, such as a mandatory standard, would need to be able to be applied horizontally. Only a horizontal standard could efficiently address a common hazard across multiple product types. Currently, Australian standards generally focus 'vertically'—addressing multiple hazards in a particular category of goods, such as children's toys. However, there is currently no mandatory safety standard in Australia or internationally that horizontally addresses the hazard of button batteries across all consumer goods.

As a horizontal standard would apply to a wide range of consumer goods, the ACCC proposes a principles-based approach to the regulation of button batteries. This approach would involve a mandatory standard that details a minimum set of requirements that can be applied across relevant product types. This approach to a horizontal standard would also seek to limit any accessibility or financial issues associated with the need to purchase voluntary standards referenced in any mandatory standard.

Following consideration of responses to this consultation paper, the ACCC intends to provide a Final Recommendation to the Hon Michael Sukkar MP, Minister for Housing and Assistant Treasurer, in 2020.

ACCC recent consultation on the mandatory standard for toys for children up to and including 36 months of age

In November 2019, the ACCC published a separate consultation paper seeking views on proposed updates to the mandatory standard for toys for children up to and including 36 months of age (the mandatory toy standard).

This consultation paper sought views on proposed updates to the mandatory toy standard and considered the adoption of requirements in international standards to warn of the hazard of button batteries through labelling requirements. In addition, the further consultation on the mandatory toy standard considers the adoption of requirements in international standards relating to battery compartment security.

Stakeholders have submitted that the introduction of any additional requirements related to button batteries in the mandatory toy standard should be consistent with any mandatory requirements that may be introduced for consumer goods that use button batteries more broadly.

The ACCC considers that toys for children up to and including 36 months of age that use button batteries should be treated on a similar basis to other consumer goods that use button batteries, unless there is a demonstrated reason why this should not be the case. This will provide consistency of regulation for manufacturers and suppliers.

The current mandatory toy standard includes specific requirements for secure battery compartments on toys that use button batteries as these batteries fit within the standard small parts cylinder and are considered a choking hazard for children.

The ACCC intends to finalise the recommendation to the Minister on the broader regulation of button batteries—which is intended to apply to all consumer goods that use button batteries, including toys for children irrespective of their age—before recommending any updates to the mandatory toy standard.

¹⁰ Australian Government, *Federal Register of Legislation 2010*, Australian Consumer Law, Schedule 2, s. 2(1), https://www.legislation.gov.au/Details/C2020C00006/Html/Volume_3#_Toc28948885.

3. Background

3.1 The button battery hazard

Button batteries are most hazardous to children because of their size, shape, design and electrical charge. For the purposes of this consultation paper, button batteries include all flat, disc-shaped cells or batteries regardless of their size or chemistry. 'Coin cell', 'disc' and 'button cell' batteries are taken to be the same article. Button batteries are defined in most international standards as small single cell devices having a diameter greater than their height.¹¹

When a child ingests or inserts a button battery, it can get stuck or lodged in their body. When a battery is lodged in the body and in contact with bodily fluid, the energy contained within the battery can generate a chemical reaction called electrolysis. An electrical potential of as little as 1.229 volts is sufficient to cause the reaction.¹² At the negative terminal of the battery, hydroxide ions and hydrogen gas will be produced. The hydroxide ions act like caustic soda, chemically burning tissues and causing liquefactive necrosis.¹³ The terminals of a button battery collectively cover almost the entire battery surface area and are often separated by less than a millimetre. This greatly increases the chances of bodily fluids completing a circuit between the terminals and releasing the energy in the battery to create the corrosive hydroxide ions. Other types of batteries that can be ingested (such as AAA batteries) have comparatively smaller terminals separated by a greater distance, which decreases the chances of a circuit being completed between the terminals.

Tissue damage occurs when a battery is lodged in the oesophagus, gut, ear, nose or other orifice, rather than free-floating and in transit through the gastrointestinal tract. Following ingestion, a caustic burn can breach the oesophageal wall in as little as two hours, causing severe and life-threatening injuries, which may cause death. Death typically results from excessive blood loss and cardiac arrest.¹⁴ Recent studies indicate that ingestion can also result in gastric injury and perforation of the stomach.¹⁵ Insertion into body orifices such as ears and noses can also lead to significant injuries including permanent hearing loss, facial nerve palsies and nasal deformities.¹⁶

Children are at the greatest risk of injury because of their narrower oesophagus and tendency to place small objects into their mouths, ears and noses. Diagnosis is challenging as many button battery ingestions go unwitnessed by parents and carers, and children are either non-verbal or generally do not say that they ingested a battery. The symptoms of a button battery ingestion are often non-specific and are similar to many other conditions, so it may not be suspected that the child has ingested a battery. Delays in presentation to a hospital, diagnosis and removal of a battery can have tragic consequences given that severe injuries can occur in only two hours.

When it is suspected that a child has ingested a battery, an X-ray needs to be conducted as soon as possible to confirm the location of the battery and determine if it has lodged in the oesophagus. Many regional hospitals throughout Australia have limited or no X-ray facilities on site.¹⁷ This can lead to delays in diagnosis and removal of the battery.

¹¹ In many international standards, single use and disposable button/coin cell batteries are referred to as primary cell batteries. Rechargeable batteries are referred to as secondary cell batteries.

¹² M Chaplin 2019, London South Bank University, London, <u>http://www1.lsbu.ac.uk/water/electrolysis.html</u>, viewed 1 August 2019.

¹³ T Litovitz 2019, NCPC, Washington DC, <u>https://www.poison.org/battery/mechanism-of-injury</u>, viewed 1 August 2019.

NCPC 2019, Washington DC, <u>https://www.poison.org/battery/fatalcases</u>, viewed 1 August 2019.
 Alok S Patel, MD; Racha T Khalaf, MD, *With Button Battery Ingestion, Watch for Gastric Injury*, Medscape Gastroenterology

Alok S Patel, MD; Racha F Khalal, MD, *With Button Battery Ingestion, Watch for Gastric Injury*, Medscape Gastroenterology <u>www.medscape.com/viewarticle/915379</u> retrieved 9 October 2019.

¹⁶ R Barker and co-signatories submission to ACCC Button Battery Safety Issues Paper <u>https://consultation.accc.gov.au/</u> product-safety/button-battery-safety-issues-paper/consultation/published_select_respondent, viewed 19 October.

¹⁷ R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, *Button battery exposures in Australian children: a prospective observational study highlighting the role of poisons information centres, Clinical Toxicology*, vol. 57, no. 6, 2019, pp. 404–410.

Battery removal is also technically challenging with children because of their small size and the potential complications of operating on the gastrointestinal tract.¹⁸ The damage caused by an ingested button battery continues to pose a significant risk even after the battery has been removed. Complications such as aorto-oesophageal fistula, exsanguination and cardiac arrest have been reported in children following the removal of a button battery from the oesophagus. There have been cases of severe uncontrollable internal bleeding leading to death occurring in patients up to 28 days after the battery has been removed.¹⁹

In many cases children also require ongoing treatment and follow-up plans for injuries sustained from button battery ingestion for many years after battery removal.

In particular, oesophageal tissue damage in young children is life changing because the scar tissue does not grow with the child. Caustic injury at a young age often requires many repeated oesophageal dilatations for the child to be able to swallow solids and carries a lifelong risk of oesophageal cancer.²⁰

As detailed in table 2, the risk associated with battery exposure is determined by a number of interrelated factors. It is the combination of larger battery diameter, higher (and residual) voltage and exposure via swallowing that results in the most catastrophic injuries and death.

Factor	Risk
Charge/voltage of the battery	The greater the charge, the greater the propensity for the battery to cause tissue damage when ingested or inserted.
Time from exposure to diagnosis and removal	Delays in diagnosis and removal of the battery often lead to more severe injuries.
Size of the battery	The size of the battery determines both the nature of the injury (insertion or ingestion) and likelihood of the battery becoming lodged in the oesophagus.
Age of the patient	Children from 0–5 years old are at the greatest risk of injury because of their narrower oesophagus and tendency to place small objects into their mouths, ears and noses.
Age of the battery	The age of the battery determines the charge; new batteries have the greatest potential to cause harm but even old or spent batteries can have enough residual charge (<1.229V) to cause damage.
Quantity of batteries supplied	The quantity of batteries supplied can increase the risk of injury, particularly when multiple batteries are ingested or inserted.

Table 2: Button battery risk factors

Button batteries generally operate using one of four chemistries: alkaline, lithium, silver oxide and zinc air.

A risk analysis by button battery chemistry is provided in table 3.

¹⁸ Gastrointestinal tract includes the mouth, oesophagus, stomach, small intestine and large intestine.

¹⁹ NCPC, Fatal Cases, 2019, Washington DC, <u>www.poison.org/battery/fatalcases</u>, viewed 28 January 2019.

²⁰ R Barker and co-signatories submission to ACCC Button Battery Safety Issues Paper <u>https://consultation.accc.gov.au/</u> product-safety/button-battery-safety-issues-paper/consultation/published_select_respondent, viewed 19 October.

Table 3: Risk analysis by button battery chemistry

Battery chemistry	Risk analysis
Lithium ²¹	Lithium batteries generally have a 3 volt electrical output. These batteries pose the highest risk when new and can have sufficient charge at the end of their functional life to still cause tissue damage. The higher voltage coupled with the larger size of lithium batteries (16–32 mm diameter) pose the highest risk.
	Their larger size means that they are more likely to become stuck in a child's oesophagus and their higher voltage means they can injure more quickly and for longer. Where the battery type is known, ingested lithium button batteries lead to the most severe injuries and most deaths. The two deaths recorded in Australia have been associated with 3 volt lithium batteries.
Alkaline	Alkaline batteries are 1.5 volts or less and are generally less than 16 mm in diameter. Ingested alkaline batteries are more likely to pass through the gastrointestinal tract without causing significant problems. However, if an ingested alkaline battery remains undetected in the oesophagus for some time, it can produce damage comparable to a lithium battery, particularly if it is relatively new.
	There have been three known deaths associated with the ingestion of alkaline chemistry batteries. ²² The smaller alkaline batteries can also be inserted in body orifices such as ears and noses, causing severe injuries if undetected for some time. In addition there have been cases where a flat alkaline battery has been stuck in a child's oesophagus for an extended time (weeks to months) and has corroded releasing the chemicals within. ²³
Silver oxide	Silver oxide batteries have a nominal voltage of 1.5 volts and are available in sizes ranging from 4.8 mm x 1.6 mm to 11.6 mm x 5.4 mm. Silver oxide batteries have a greater leakage resistance than alkaline batteries and are also more lightweight and heat/cold resistant. This gives them a longer shelf life when compared with alkaline batteries which are more susceptible to corrosion. ²⁴
	Their smaller size again means that they are more likely to pass through the gastrointestinal tract without causing significant problems. While they supply sufficient voltage to cause injury, available records have not indicated them becoming lodged in a child's oesophagus. Smaller batteries are more usually implicated in insertions which can also lead to severe injuries.
Zinc air	Zinc air batteries are quite small, have a nominal voltage of 1.4 volts and come in a range of sizes. Zinc air batteries are predominantly used in hearing aid devices and the size of battery needed depends on the hearing device. Zinc air batteries require access to air (oxygen) to produce a current and so, when ingested, they are unlikely to produce an electrical current as other batteries may.

Figure 2 also demonstrates the tissue damage that batteries of various chemistries can cause.

²¹ Lithium batteries intended for single use have a different chemistry to rechargeable lithium-ion batteries. However, rechargeable lithium-ion button batteries present the same hazard to children if ingested or inserted. Lithium-ion chemistry is favoured for rechargeable tools, phones and similar devices and by some electric vehicle manufacturers. In most cases lithium-ion batteries are fully enclosed inside a product and are not intended to be replaced by the consumer.

²² According to US data captured by the National Capital Poison Center. The NCPC publishes detailed information about severe and fatal button battery ingestion cases on its website. Fatal cases are recorded from 1977-2019 and severe from 1982-2019. Records were sourced from research, NBIH contact records and subsequent follow-up with health professionals. See: www.poison.org/battery/severecases; www.poison.org/battery/fatalcasess.

²³ T Litovitz, Mechanism of battery-induced injury, National Capital Poison Center, Washington US <u>www.poison.org/battery/</u> mechanism-of-injury, viewed 12 August 2019.

²⁴ Coin Cell/Button Cell Battery Guide, <u>www.batteries.com/pages/coin-cell-button-cell-battery-guide</u>, viewed 9 December 2019.

Figure 2: Tissue damage caused by batteries of various chemistries after 6 hours²⁵



Source: Kris R. Jatana, MD; Keith Rhoades, BS; Scott Milkovich, PhD; Ian N. Jacobs, MD, *Basic Mechanism of Button Battery* Ingestion Injuries and Novel Mitigation Strategies After Diagnosis and Removal, Laryngoscope, 127:1276–1282, 2017.

3.2 Supply chain and applications of button batteries

According to *Global button cell batteries market report 2019,* approximately 69 million button batteries were sold to the Australian market in 2019.²⁶ Button batteries are not manufactured in Australia. Energizer and Duracell currently account for the largest share of button battery sales in Australia. Other major brands include Gold Peak, Varta, Renata, Panasonic, Sony, Maxell (Hitachi) and Toshiba.

Button batteries are sold as both wholesale and retail products. Button batteries are supplied wholesale and rebranded for sale by specific retailers and to manufacturers who make products powered by button batteries. Button batteries are also supplied as retail products for sale as replacements and as a component of a huge range of consumer goods. Replacement batteries are sold online and by many bricks-and-mortar retail stores including supermarkets, discount stores, hardware stores, service stations and department stores and by various specialist parts suppliers and repairers.

Their small size makes them suitable to power small electrical devices and they can be found in dozens of common household appliances, toys and novelty items. There has been a significant increase in the use of button batteries in digital and portable electronic consumer goods over recent years.²⁷

Table 4 shows the breakdown of button batteries sold in Australia by product application category. Data is not available detailing how many different consumer product categories use button batteries.

Table 4: Major product categories

Market share
53%
25%
15%
7%

Source: XYZ Research Energy Centre, Global button cell batteries market report 2019 by manufacturer, region, type and application, 2019

Products that use button batteries are also available second hand and given away as part of promotions at community, cultural and sporting events which means they can also be brought into the home without being purchased from a retail outlet.

27 ibid.

²⁵ Kris R. Jatana, MD; Keith Rhoades, BS; Scott Milkovich, PhD; Ian N. Jacobs, MD, Basic Mechanism of Button Battery Ingestion Injuries and Novel Mitigation Strategies After Diagnosis and Removal, Laryngoscope, 127:1276-1282, 2017.

²⁶ XYZ Research Energy Centre, Global button cell batteries market report 2019 by manufacturer, region, type and application, 2019.

3.3 Stakeholder engagement and consultation

In August 2019, the ACCC released the Issues Paper for public consultation. The Issues Paper invited responses from interested stakeholders on button battery safety, the perceived safety risks, the effectiveness of the voluntary <u>Industry Code for Products Containing Button Batteries</u> (the industry code), consumer information and the button battery market in Australia.

The ACCC received 29 public submissions in response to the Issues Paper from a broad range of stakeholders including manufacturers, representative bodies, individual consumers, businesses, health professionals and government agencies. A list of stakeholders that provided submissions in response to the Issues Paper is provided at **appendix A**.

Since the release of the Issues Paper, the ACCC has been analysing existing national and international standards and conducting targeted consultation with key stakeholders including:

- industry stakeholders
- medical experts
- relevant government agencies
- international product safety regulators, and
- international testing houses.

3.4 International approaches

There is currently no specific regulation, in Australia or internationally, to address the hazard of button batteries across all consumer products. Many countries, however, have general safety requirements which provide some protections to address button battery and similar hazards through requiring suppliers to ensure the safety of their products before placing them on the market.

There is a wide range of existing national and international voluntary standards that have been developed which include requirements for products that use button batteries. Many of these relate to specific product ranges such as electrical equipment or audiovisual equipment or more generally to products that use lithium batteries. The requirements for products that use button batteries in these standards vary widely. These standards rely on manufacturers and suppliers adopting safety measures and requirements voluntarily.

Safety standards for toys also typically include provisions to ensure children's toys do not include small parts that present a choking hazard to children.^{28, 29, 30} These standards cover toys and parts of toys for children up to 36 months and require that small parts that fit within the small parts cylinder (2.25 inches long by 1.25 inches wide) are not accessible to children under normal use and foreseeable misuse.³¹

Button batteries and AAA batteries fit within the standard small parts cylinder and are considered a choking hazard for children. Many of these mandatory toy standards include specific requirements for secure battery compartments and specific warnings on toys that use button batteries.

Further information about international approaches to managing button battery safety in the United States, New Zealand and United Kingdom is available at **appendix B**.

²⁸ Government of Canada, 2019, Canada, www.canada.ca/en/health-canada/services/consumer-product-safety/reportspublications/industry-professionals/industry-guide-safety-requirements-children-toys-related-products-summary/ guidance-document.html#a3241, viewed 17 July 2019.

²⁹ Hong Kong Standards and Testing Centre, Choking/Suffocation/Hazardous Shape Requirements of Different Countries for Toys Testing, Hong Kong, 2019, <u>stc.dev1.ysdhk.com/getfile/index/action/images/name/566a2a7f73bdf.pdf</u>, viewed 17 July 2019.

³⁰ Public.Resource.Org, 2014, California US, <u>https://law.resource.org/pub/eu/toys/en.71.1.2014.html#s8.2</u>, viewed 17 July 2019.

A small parts cylinder is 2.25 inches long by 1.25 inches wide and approximates the size of the fully expanded throat of a child under three years old. It is roughly the size of an old film canister.

4. The problem and need for government intervention

4.1 What is the problem?

Button batteries can cause severe injury and death if ingested, particularly in children aged from 0–5 years. If swallowed, a button battery can become stuck in a child's throat and cause a chemical reaction that burns through tissue and can cause catastrophic bleeding. Severe injury can occur in as little as two hours.

In Australia two children, four-year-old Summer Alice Steer and 14-month-old Isabella Estelle Rees, have died from injuries sustained after ingesting a battery.

Summer Steer

Summer was four years old when she died on 30 June 2013 after ingesting a 20 mm lithium button battery. Summer had presented to both her local general practitioner and her local hospital emergency department many times in the days prior to her death. The battery ingestion was not witnessed and the source of the battery remains unknown. The button battery lodged in Summer's throat burned a hole in her oesophagus and created an aorto-oesophageal fistula. This fistula led to profuse bleeding and eventually to her death.³²

Isabella Rees

Isabella was 14 months old when she died on 4 February 2015 after ingesting a 3 volt lithium button battery. The ingestion of the battery was not witnessed and the source of the battery remains unknown. Isabella had a 19-day period of ill health prior to her death which included four presentations to an emergency department. The cause of Isabella's death was a gastrointestinal haemorrhage resulting from damage caused by the button battery lodged in her oesophagus.³³

There is no national database for consumer product-related injuries or attendances at hospital emergency departments in Australia. Consequently, there is no single point of reference for nationwide data on button battery exposures (ingestions or insertions) in Australia. Based on an extrapolation of the available data from NSW Health, VISU and QISU for the year 2017, the ACCC estimates that many thousands of Australian children have presented to emergency departments nationally after ingesting or inserting batteries, with approximately 873 presentations in 2017 alone.³⁴

Children are at the greatest risk of injury because of their narrow oesophagus and tendency to place small objects into their mouths, ears and noses. While children more often ingest batteries, insertion of button/coin cell batteries into body orifices can also lead to significant injuries.

The severity of injuries from ingestion and insertion of button batteries ranges from mild burns and ulcers to severe perforations, trachea-oesophageal fistulas, aorto-oesophageal fistulas, corrosion, twisting or inflammation of the spine, heavy metal poisoning, permanent hearing loss, facial nerve and vocal cord palsies and nasal deformities.

³² Office of the State Coroner 2015, Queensland Courts, Brisbane, <u>https://www.courts.qld.gov.au/__data/assets/pdf_file/0004/444289/cif-steer-sa-20151103.pdf</u>, viewed 20 February 2019.

³³ Coroners Court of Victoria at Melbourne 2019, Coroners Court of Victoria at Melbourne, <u>https://www.coronerscourt.vic.gov.au/sites/default/files/2019-04/IsabellaEstelleRees_059215.pdf</u>, viewed 1 August 2019.

As outlined in appendix D, data from NSW Health, VISU and QISU was extrapolated to estimate the number of emergency department visits nationally. The ACCC estimates there were 873 button battery presentations in 2017 alone.

Examples of severe button battery injuries from across Australia

Queensland

A one-year-old boy was brought to hospital 19 hours after choking on a foreign object. A chest X-ray revealed a coin-shaped object in his upper oesophagus. He was transferred to a larger hospital where the object was removed, by which time approximately 24 hours had elapsed. The object was a button battery. The battery had burned a part of his oesophagus. A week later, the boy had developed a trachea-oesophageal fistula which is a hole in his oesophagus that had created a passage into his windpipe. A feeding tube was inserted directly into his stomach because he could not swallow food through his oesophagus.³⁵

A four-month-old boy was referred to hospital for an X-ray by his GP after he developed a cough and breathing difficulties. An X-ray identified a small round object lodged in the child's oesophagus. The object was a small button battery which was removed approximately 14 hours later. The boy was taken home following the removal but returned to the hospital the next day when he began frothing at the mouth. Four weeks later the boy was taken back to hospital after becoming critically ill. He was placed in an induced coma and was transferred to a children's hospital. Scans revealed that the button battery had corroded the child's spine resulting in severe spinal damage. He was placed into a full body cast for eight months. At five years of age, the child is able to walk but will have severe restriction of movement for the rest of his life as he is unable to fully raise his head.³⁶

Western Australia

A 10-month-old boy from Bunbury ingested a button battery from his father's guitar. The doctors removed the battery from his oesophagus 12 hours after he had ingested it. Four weeks after the removal, he was taken to hospital because he couldn't breathe and blood was coming out of his mouth. He was urgently flown to Princess Margaret Hospital for Children in Perth, where doctors found that the button battery he had ingested had burned a hole in his oesophagus and caused an aorto-oesophageal fistula, the same injury that killed Summer Steer and Isabella Rees. The boy survived after 14 hours of surgery and a blood transfusion. He spent another two weeks in intensive care and almost three months in hospital, returning home two days before Christmas. One of the doctors on the medical team that treated the boy described the baby's injury as 'dreadful' and said that he was the only survivor in the world of this type of injury.³⁷

³⁵ R Jarugula and T Dorofaeff, 'Oesophageal button battery injuries: Think again', *Emergency Medicine Australasia*, vol. 23, no. 2, 2011, pp. 220–223.

³⁶ Gail Greatorex, Product Safety Solutions, Button Battery Hazard - Size Does Matter!, <u>https://productsafetysolutions.com.au/button-battery-hazard-size-does-matter/</u>, October 16. 2019; Peter Hall 2015, *The Courier Mail*, 'Boy's spine corroded after he swallowed lithium battery, viewed 27 February 2020.

L Burke 2012, The West Australian, Perth, thewest.com.au/news/australia/a-battery-nearly-killed-our-son-ng-ya-334118, viewed 1 August 2019.

Victoria

This report is from the Monash Medical Centre in Clayton, Victoria. A 14-month-old boy with abnormal neck posture, poor feeding, drooling, cough and fever was taken to hospital where an X-ray found that he had ingested a button battery. The doctors removed the corroded battery and surrounding dead tissue. One week later the baby was taken to hospital again because of excessive bending of his neck and difficulty in breathing. The doctors found that the button battery had caused a condition called spondylodiscitis, which is infection and inflammation of a part of his spine.³⁸

Another case from Victoria is a five-year-old girl who complained that her throat hurt and that food wouldn't go down. She was tired and lethargic and lost a lot of weight. She was taken to a GP a number of times and eventually to a paediatrician. She suddenly started getting worse, developed a fever and started vomiting. She was taken to hospital where an X-ray eventually revealed the presence of a rusty eroded button battery in her oesophagus. Doctors estimated that the battery had been in her throat for about six months, blocking the flow of food to her stomach. She was rushed to Monash Children's Hospital, put in an induced coma and the battery was surgically removed. She recovered from the surgery and was tube fed for a period of time. She will need to have ongoing treatment on her throat.³⁹

New South Wales

A seven-month-old girl presented to the ED at a district hospital after a choking episode and a reluctance to eat. She showed no signs of distress and was discharged. Her parents noticed a remote control in pieces with the button battery missing and took her to hospital the next day. A chest X-ray revealed a button battery stuck in her oesophagus. She was transferred to a larger hospital where a 3 volt lithium button battery was removed from her throat. There was severe corrosive damage to her oesophagus, a section of which was perforated and narrow. After one week of observation, she was discharged with a treatment and follow-up plan.⁴⁰

The safety risk to children from button batteries arises when they can gain access to the batteries. This may occur in different ways:

- children gain access directly from consumer goods that require button batteries to operate, but which do not have secure battery compartments—this may occur when poor quality products are dropped or broken
- children gain access directly from packaging—this may be new/replacement batteries made available for sale, or consumer goods supplied with loose batteries, or in packaging that is not child-resistant
- children gain access when batteries are removed from consumer goods or packaging and are not stored safely prior to being installed, or otherwise not properly disposed of—old or spent button batteries can still hold a charge capable of causing injury.

As shown in figure 3, a study of button battery ingestion cases in the US between 1990 and 2008 found that in cases where the source of the battery was known (3989 cases), children gained access to the battery directly from the product in 61.8 per cent of cases; when batteries were left loose around the home in 29.8 per cent of cases; and directly from packaging in 8.2 per cent of cases.⁴¹

V Kieu, S Palit, G Wilson, M Ditchfield, J Buttery, D Burgner, and PA Bryant, 'Cervical Spondylodiscitis Following Button Battery Ingestion', The Journal of Pediatrics, vol. 165, no. 6, 2014, pp. 1500–1500e.1.

³⁹ K Caines 2019, Nine News, Australia, <u>www.9news.com.au/national/button-battery-shaylah-carmichael-monash-hospital-</u> melbourne-isabella-rees-inquest/164e95e5-a948-43a2-b8c8-f031353e6ea9, viewed 1 August 2019.

⁴⁰ AY Liao and D McDonald, 'Oesophageal complication from button battery ingestion in an infant', *Journal of Paediatrics and Child Health*, vol. 49, no. 4, 2013, pp. 330-332.

⁴¹ T Litovitz, N Whitaker, L Clark, *Preventing Battery Ingestions: An analysis of 8648 Cases*, American Academy of Pediatrics, 2010.

Figure 3: Source of button batteries involved in paediatric ingestions in the US between 1990 and 2008



Source: T Litovitz, Preventing Battery Ingestions.

Button battery ingestions can be very difficult to diagnose for a range of reasons. Many ingestions go unwitnessed by parents and carers, and in many cases children are either non-verbal or do not say that they ingested a battery. Symptoms of a battery ingestion are generally non-specific and may not appear for some time which can lead to delays in diagnosis and removal of the battery. Button batteries can also be mistaken for coins or other foreign objects when an X-ray is conducted. Since severe injury can occur in as little as two hours, a delayed presentation or misdiagnosis can result in severe injury or death.

Button battery exposures in Australia

Button battery exposures include all situations where an individual has been exposed to a button battery through ingestion or insertion, irrespective of whether the battery has actually caused an injury.

There is no national database for consumer product-related injuries or attendances at emergency departments in Australia. Consequently, there is no single point of reference for nationwide data on button battery exposures (ingestions or insertions) in Australia.

The ACCC has obtained available exposure data from hospital emergency departments and calls to Poisons Information Centres which reveals some common patterns and trends. See **appendix D** for further information about data availability.

Poisons Information Centres data shows that button battery exposures occur all over Australia and the number of exposures occurring in each jurisdiction is broadly consistent with relative population sizes in each state and territory.

State/territory	Number of paediatric cases	Annual rate of exposures (per 100 000 people)
New South Wales	284	4.88
Victoria	229	4.96
Queensland	180	4.70
Western Australia	87	4.42
South Australia	85	6.92
Australian Capital Territory	18	5.83
Tasmania	16	4.26
Northern Territory	6	2.9
Total	905	

Table 5: Reported button battery exposures in Australia (2015 to 2018)

Source: NSW Poisons Information Centre.

Young children are most prone to button battery exposures. Emergency department and Poisons Information Centres data (figure 4) shows this pattern is consistent across all time periods and jurisdictions.

Figure 4: Reported button battery exposures-children aged under 10 years in Australia (1999 to 2018)



Source: NSW Poisons Information Centre, Kidsafe WA, QISU, VISU, NSW Health, WA Poisons Information Centre.

While most button battery exposures occur in children, adult exposures occur as well, although these represent a minor percentage of exposures.⁴²

Long-term data from Victoria (figure 5) and Queensland (figure 6) indicates that the numbers of reported button battery exposures in children under the age of five have been increasing.⁴³

⁴² Poisons Information Centres data indicates that from 2015 to 2017, there were 72 accidental adult exposures to button batteries. Where known (53 cases), hearing aids or cochlear implants were by far the most common products involved in adult exposures (89 per cent of cases). During this period, Poisons Information Centres also recorded 12 cases of intentional adult ingestion of button batteries attributed to self-harm.

⁴³ VISU data 1999-2011 and 2013-2018 were extracted from the Victorian Emergency Minimum Dataset which comprises de-identified demographic, administrative and clinical data detailing presentations at Victorian public hospitals with designated emergency departments. Both datasets are from similar numbers of hospitals.

Figure 5: Average reported button battery exposures per year in Victorian children under five years of age (VISU) (1999 to 2018)



Source: VISU.44

Figure 6: Confirmed and suspected button battery exposures – Queensland children under five years of age by year (1999–2017)



Source: QISU, Report on button battery-related injury January 1999–December 2017.45

⁴⁴ Data was available to the ACCC for these two non-contiguous date ranges only. Data provided by VISU are extracted from the Victorian Emergency Minimum Dataset which includes records from all Victorian hospitals with a 24-hour emergency department.

⁴⁵ Data from participating Queensland emergency departments that together account for about one-fifth to one-quarter of all Queensland emergency department activity. Trends may be influenced by the number of participating hospitals each year. The introduction of a new electronic management system in 2016 resulted in a decrease in the number of reported incidents from that time.

Deaths and severe injuries

The ACCC has obtained data from a number of organisations tracking button battery ingestions and insertions. These organisations collect data from hospital emergency departments, injury surveillance units or calls to Poison Information Centres. As there is no standardised dataset for button battery injuries, these organisations have collected different types and ranges of data.

There is a growing record of severe injuries to, and deaths of children following exposure to button batteries. Globally, since 1977, there have been at least 64 confirmed child deaths from battery ingestions and thousands of exposures and injuries. It is also likely that many cases have gone unreported.⁴⁶ In Australia, two children have died from injuries sustained after ingesting a battery.

The Australian Paediatric Surveillance Unit (APSU) is conducting a study into severe injury related to button batteries.⁴⁷ The purpose of the study is to collect information about injuries resulting from ingested or inserted button batteries as well as information about the battery-operated products associated with the injuries. The study began in December 2017.

Between December 2017 and January 2020, the study identified 27 confirmed individual cases of severe injury following exposure to a button battery.⁴⁸ It is likely that this is an under-representation of the number of cases nationally as the study relies on doctors and individuals reporting severe incidents.

The average age of the injured children was three years. In most cases (20), the button battery was located in the oesophagus. The button battery was found in the ear in two cases, the stomach in three cases and not found on X-ray in the other two cases. In all 27 cases, a medical procedure was required to remove the battery.

The data also included an estimate of the size of the button battery involved—see table 6 below.

Table 6:	Size of battery involved in severe injuries in APSU study between December 2017 and
	January 2020

Size	Diameter	Number of cases	%
Large	≥20 mm	16	59
Medium	10-19 mm	5	19
Small	≤10 mm	2	7
Multiple*		1	4
Unknown		3	11
Total		27	100%

* In one case a child ingested 20 small and eight medium batteries.

The most comprehensive set of information on fatalities and severe injuries resulting from button batteries is available from the United States' National Capital Poison Center (NCPC).⁴⁹ The NCPC has collated and published details of button battery severe injury and fatality cases from around the world from 1977 to 2019.

The NCPC data demonstrates that fatality and injury rates are increasing and that batteries of various chemistries and sizes have been responsible for severe injuries and fatalities.

⁴⁶ NCPC, Button Battery Ingestion Statistics, 2019, Washington DC, <u>www.poison.org/</u>.

⁴⁷ Australian Paediatric Surveillance Unit, 2017, Sydney, <u>www.apsu.org.au/assets/new-studies/SIRDB-APSU-Protocol-FINAL-V5.1.pdf</u>, viewed 1 August 2019.

⁴⁸ A severe injury as defined in the APSU study as a 'newly diagnosed injury related to disc or button battery ingestion or insertion that required procedural intervention either to remove the battery or to assess or repair damage related to the battery'.

⁴⁹ NCPC, Fatal Cases (www.poison.org/battery/fatalcases) NCPC, Severe Cases (www.poison.org/battery/severecases).

Figure 7 shows the rapid increase in the frequency of reported button battery fatalities and severe injuries during the past five decades. In this dataset, severe injuries are those that involve debilitating and prolonged compromise of feeding or breathing and require multiple surgical procedures, tube feedings or tracheostomies.⁵⁰ On average, 1.9 severe injuries were reported per year in the 1990s. This increased to an average of 16 severe injuries per year during the 2010s. Fatality rates have also increased markedly. During the 1990s, 0.3 button battery fatalities were recorded per year; this increased to 4.2 fatalities recorded per year during the 2010s.

It is expected that the NCPC data understates the true number of global button battery fatalities as it is likely that many cases have gone unreported.





Source: NCPC, Severe Cases: NCPC, Fatal Cases; Labadie et al, Severity of button batteries ingestions.

Table 7 provides the button battery chemistries responsible for deaths and severe injuries as published by the NCPC.⁵¹ Although lithium and alkaline batteries are known to have caused the majority of the major injuries and fatalities, all button batteries present a risk when ingested or inserted.⁵²

Importantly, the NCPC data is limited to battery ingestions only and does not include battery insertions, which can also result in severe injuries.

In addition, the NCPC data includes a large proportion of deaths and severe injuries that have resulted from button batteries where the battery chemistry is unknown. It is therefore possible that a greater proportion of non-lithium batteries have been responsible for deaths and severe injuries.

⁵⁰ The NCPC definition of 'severe injury' is different from the definition used by the APSU. The rate of severe injuries reported by the NCPC is not commensurate with the rates used for analysis in the cost-benefit analysis.

⁵¹ Injury and fatality records were sourced from literature review and through contacts to the United States National Battery Ingestion Hotline. Data for severe injuries is available from 1982–2019 and from 1977–2019 for fatal cases.

⁵² ibid.

Chemistry	Deaths	%	Severe injury	%
Chemistry	Deatlis	78	Severe injuly	/0
Alkaline	3	5%	12	5%
Lithium	40	63%	174	71%
Mercury			2	1%
Unknown	21	33%	57	23%
Total	64	100%	245	100%

Table 7: Global severe injuries and deaths by battery chemistry 1977-2019⁵³

Source: NCPC, Severe Cases; NCPC, Fatal Cases; Labadie et al, 'Severity of button batteries ingestions'.

Table 8 provides an overview of button battery sizes responsible for deaths and severe injuries. Button batteries with a diameter of 15-25 mm are responsible for the majority of severe injuries and fatalities.

While 20 mm batteries are the most likely to cause death and severe injury, smaller batteries still present a risk of severe injury. As the NCPC data is limited to battery ingestions only and does not include battery insertions, this data is likely to understate the proportion of severe injuries resulting from smaller batteries being inserted into body orifices. Batteries with diameters as small as 10 mm have been responsible for a fatality and as small as 5 mm have been responsible for severe injuries.

In addition, the NCPC data includes a large proportion of deaths and severe injuries that have resulted from button batteries where the battery size is unknown. It is therefore possible that a greater proportion of smaller batteries have been responsible for deaths and severe injuries.

Diameter	Deaths	%	Severe injury	%
>20 mm	4	6%	17	7%
20 mm	37	58%	158	64%
<20 mm	5	8%	12	5%
Unknown	18	28%	58	24%
Total	64	100%	245	100%

Table 8: Global fatalities and severe injuries by battery diameter⁵⁴

Source: NCPC, Severe Cases; NCPC, Fatal Cases; Labadie et al, 'Severity of button batteries ingestions'.

An analysis of the NCPC data reveals patterns relating to button battery ingestions similar to Australia:

- Most injuries and deaths have occurred in children aged 0-5 years.
- A growing number of children are suffering severe injuries and dying following exposure to button batteries.⁵⁵

While lithium batteries and batteries with a diameter of 20 mm are responsible for the majority of severe injuries and fatalities, other non-lithium and smaller batteries have been responsible for severe injuries and deaths.

Non-lithium batteries have caused severe injuries on at least 14 occasions and three deaths. Batteries smaller than 20 mm have been responsible for at least 17 severe injuries and four deaths.

While the above data provides a general overview of button battery injury statistics in Australia, it does not demonstrate the extent of injuries button batteries have caused or can cause. Examples of severe button battery injuries from across Australia are provided in section 4.1. These examples provide a clear picture of the severe injuries and damage that button batteries can cause when ingested.

⁵³ All severe and 62 fatal cases sourced from NCPC: www.poison.org/battery/fatalcases; www.poison.org/battery/ severecases. Two fatal cases sourced from Labadie M, et al, 'Severity of button batteries ingestions: data from French Poison Control Centres between 1999 and 2015', European Journal of Emergency Medicine, 2018 Aug 1;25(4):e1-8.

⁵⁴ ibid.

⁵⁵ NCPC, Severe Cases, 2019, Washington DC, <u>www.poison.org/battery/severecases</u>, viewed 6 February 2020; NCPC, *Fatal Cases*, 2019, Washington DC, <u>www.poison.org/battery/fatalcasess</u>, viewed 6 February 2020.

4.2 Does the government have the capacity to intervene successfully?

There is currently no specific regulation, in Australia or internationally, to address the hazard of button batteries. There is also no general legislative provision restricting the supply of unsafe goods in Australia.⁵⁶

Button batteries are manufactured overseas and imported into Australia. While there may be some local manufacturing of products that contain button batteries in Australia, the majority of the products that require button batteries are also imported from overseas.

The emergence of online shopping as well as significant technological advancements over the past two decades has meant that there is now a huge range of low-cost products manufactured overseas available in the domestic market. While consumers can benefit from increased access, innovation and choice, this also increases the risk of unsafe products being supplied to consumers.⁵⁷

Coronial inquests into the deaths of Summer Steer and Isabella Rees have identified a clear need to develop a consistent national approach to consumer product safety that captures the broad range of products that contain button batteries.

While there is a range of voluntary international and national standards for various products and equipment which include requirements for button battery safety (see **appendix C**), the scope and the detail of the requirements vary between different standards.

In making a mandatory safety standard, the responsible Minister must be satisfied that the requirements are reasonably necessary to prevent or reduce risk of injury.

A mandatory safety and information standard may be made under the ACL that imposes consistent requirements to apply 'horizontally' to all consumer goods that use button batteries, as well as button batteries made available for sale.

Mandatory safety standards in Australia generally focus 'vertically'—that is, they seek to address multiple hazards in a particular type of good, such as children's toys. For example, the Australian mandatory standard for toys for children up to and including 36 months of age prescribes requirements to ensure children's toys do not include small parts that present a choking hazard—these requirements incidentally cover button batteries as they fit the definition of a 'small part'. However, this requirement is limited to toys for this age group only.

It should be noted that under the ACL, a mandatory safety standard for button batteries and consumer goods that use them can only specify safety requirements that products must meet before they are supplied into the Australian market. As such a safety standard cannot mandate requirements for the disposal of button batteries. However, this does not preclude other jurisdictions and agencies from pursuing battery disposal requirements as supplementary risk controls.

In Australia, state and territory governments have the primary responsibility for regulating and administering waste, including waste management, licensing and regulation of waste transport, storage, treatment and resource recovery and disposal.

⁵⁶ In October 2019, the Commonwealth Treasury began consultation on potential reform options for a General Safety Provision.

⁵⁷ OECD, Online product safety: trends and challenges, OECD Digital Economy Papers, No. 261, OECD Publishing, Paris, 2016.

About mandatory standards

Mandatory safety standards

Mandatory safety standards specify minimum requirements that products must meet before they are supplied. They are introduced when considered reasonably necessary to prevent or reduce the risk of injury to a person. If a product is subject to a mandatory standard, it must meet specific safety criteria before it can be sold in Australia.

A mandatory safety standard can include requirements for:

- the performance, composition, contents, method of manufacture or processing, design, construction, finish or packaging of consumer goods
- the testing of consumer goods during or after the completion of manufacture or processing
- the form and content of labelling, including markings, warnings or instructions to accompany consumer goods.

Mandatory information standards

Mandatory information standards ensure that consumers are provided with information about a product to assist them in making a purchasing decision.

A mandatory information standard is required in order to specify the nature and form of information to be provided with consumer goods.

A mandatory information standard is required in addition to a safety standard to mandate that warnings and information must be made available to consumers at the point of sale.

4.3 Government measures so far to address the problem

The ACCC and other government agencies have implemented a range of measures to reduce the risks posed by button batteries. Some examples are as follows:

- In 2012 the Battery Controlled campaign was launched to raise awareness about the risks associated with button batteries and provide key information on what to do if a child ingests a battery. The campaign was supported by ACCC in partnership with Energizer and Kidsafe Australia.
- In 2013 the ACCC met with industry stakeholders to discuss the issue of button battery safety. Following the meeting, many industry stakeholders agreed to voluntarily adopt a range of measures to improve the safety of button batteries and the products that contain them. These measures were subsequently incorporated in the industry code prepared by an industry working group assisted by the ACCC. The industry code was published in 2016 and promoted by the ACCC and state and territory ACL regulators.
- In 2014 the OECD organised the International Awareness Week on Button Battery Safety. The event aimed to raise awareness worldwide of the risks and dangers posed by button batteries.⁵⁸ Twenty-six countries, including Australia, participated in the initiative to raise awareness of the issue and encourage authorities to take the necessary precautions to reduce the risk of injury and death from button batteries.
- From 2016-2018 the ACCC led the implementation of a two-year <u>National strategy for improving</u> the safety of button battery consumer products (the national strategy) with the assistance of other ACL regulators. The objective of the national strategy was to monitor the effectiveness of voluntary safety actions by industry, raise awareness of the issue and collect evidence to inform regulatory approaches to improve button battery safety.

⁵⁸ OECD (2014), Paris, <u>www.oecd.org/science/button-battery-safety-awareness-week.htm</u>, viewed 3 December 2019.

- In 2016 the Therapeutic Goods Administration (TGA) began a review of home medical devices including hearing aids, thermometers and glucometers to determine if these products met the essential principles of the industry code. The TGA liaised with suppliers and encouraged them to adopt the industry code where possible.
- In 2018 and 2019 the ACCC identified button battery hazards as a product safety priority.
- On 30 March 2019, the Minister issued a Safety Warning Notice, and on 5 April 2019 the Minister wrote to the ACCC requesting that the regulatory impact assessment process required to support the development of future regulation, such as a mandatory standard, be expedited.
- In 2019, the ACCC evaluated the effectiveness of the industry code and concluded that there was evidence of market failure in the safety of button battery consumer goods and that the voluntary industry code had not achieved a significant reduction in the risks posed by button batteries, and that regulatory intervention should be considered. The voluntary industry code includes requirements for consumer goods that use button batteries, but does not include any child-resistant packaging or warning and information requirements for button batteries sold separately.

In addition to government measures, a number of improvements have been made to clinical practice guidelines used by medical practitioners and hospitals to respond to the ingestion of foreign bodies including specific advice for managing suspected button battery ingestions.

4.4 Why have previous measures not worked?

The issue of button battery safety is complex, in part because of the use of button batteries in a wide range of consumer goods. Button batteries are sold individually and in multipacks as consumer-replaceable batteries or supplied either pre-installed in or packaged with consumer goods. The safety hazard is pervasive throughout the lifecycle of consumer goods that use button batteries—primary supply, use, servicing, repair, secondary supply, disposal and recycling.

Children gain access to button batteries in a variety of ways including from products that do not have secure battery compartments such as when products are dropped or broken, directly from product packaging when spare batteries are provided loose, or when batteries are left loose around the home. Injuries can occur when button batteries are ingested or inserted into body orifices. Ingestion of button batteries poses the highest risk of injury and this risk increases when ingestion is not witnessed.

The development of the industry code in 2016 was a significant step in attempting to improve the safety of consumer goods that use button batteries. Some suppliers and retailers made significant efforts to adopt the principles of the industry code and ensure that the products they supplied met the requirements of the code. While many major retailers adopted the industry code, market surveillance activities conducted as part of the national strategy found that many high-risk button battery-powered products continued to be sold and many suppliers and manufacturers were either unaware of the industry code and its requirements or did not adopt the requirements as they were not mandatory. The voluntary nature of the industry code also made surveillance activities and enforcement action difficult in cases when suppliers resisted taking voluntary action to address safety concerns.

Despite previous efforts by federal, state and territory governments, medical and healthcare providers, industry representative bodies, retailers and some manufacturers to raise awareness of the issue and encourage the adoption of voluntary safety measures, there has been no meaningful decrease in the number of severe injuries resulting from exposure to button batteries.

To reduce risk, product safety is best addressed when a product is at the design stage. The Australian Standard Consumer Product Safety—Guidelines for Suppliers (AS ISO 10377:2017) supports the application of the HORC Framework. It encourages suppliers (designers, manufacturers, importers, distributors and retailers) to consider consumer product safety at the design stage and, where potential risks are identified with their products, manage these risks by eliminating them or reducing them to a tolerable level.^{59.}

⁵⁹ ISO 10377:2013, Consumer Product Safety—Guidelines for Suppliers.

To date, despite some efforts, battery manufacturers have not made any safety improvements to button batteries to reduce the risk to children if batteries are ingested. Solutions such as pressure-sensitive coatings are being investigated but have not yet been adopted by battery manufacturers. The design of button batteries themselves and their packaging should include consideration of safety under conditions of reasonable foreseeable use and misuse to ensure they are stored safely until they are enclosed within another product for use. Similarly, manufacturers of products that are powered by button batteries should consider safety and ensure that batteries are not accessible under reasonably foreseeable use or misuse. While some responsible manufacturers, suppliers and retailers are adopting measures to improve the safety of their products, a wide variety of products that pose an unacceptable safety risk remain available.

Risk communication is also an important component of an overall risk management strategy. Markings, warnings or instructions are administrative controls that may help to further reduce the risk of exposure or facilitate injury aftercare. While they are more reliant on consumer behaviour than engineering changes to counteract inherent design limitations, they remain a valid tool especially when integrated with higher level controls such as design changes.

Market surveillance of button batteries and consumer goods that use button batteries undertaken by ACCC and ACL regulators as part of the national strategy has found that current warning labelling included on these products is highly variable and many products do not include any button battery warnings at all.

A number of awareness campaigns have been run by various agencies and organisations over recent years to educate parents and carers about the dangers of button batteries.

Summer Steer's family honour her memory and work to raise awareness of the dangers of button battery ingestion in children through the Summer's Day program and website.⁶⁰ In 2017, the ACCC undertook paid Facebook promotion of the button battery safety video to coincide with the 'Summer's Day' awareness campaign. The ACCC also support the campaign by sharing social media posts and button battery safety messages.

Isabella Rees' family have established Bella's Footprints in her memory, a social media awareness program and foundation, to improve community awareness of the dangers of button batteries and provide education.⁶¹

While there is anecdotal evidence that these campaigns have been somewhat effective, education needs to be ongoing to ensure that new parents and caregivers continue to be informed of the dangers of button batteries and the risk they pose to children.

4.5 Support for government action

Coronial inquests into the deaths of Summer Steer and Isabella Rees have recommended mandatory requirements for products that use button batteries, including secure battery compartments and child-resistant packaging.

In 2016, an industry working group consisting of retailers, associations and product safety consultants developed the industry code, with input from the ACCC and other ACL regulators. Industry working group members were strong advocates for improved button battery safety. Since the publication of the industry code in 2016, the industry working group have met regularly to discuss how they are applying the principles of the industry code within their own businesses, opportunities for further promotion of the industry code and possible revisions or improvements that could be incorporated into future iterations such as expanding the scope of the code to include requirements for secure battery packaging.

⁶⁰ Kidsafe 2019, Australia, https://www.summersday.com.au, viewed 4 March 2020.

⁶¹ http://bellasfootprints.com.au; https://www.facebook.com/bellasfootprints, viewed 4 March 2020.

The National Retailers Association (NRA) was involved in establishing the Technical Standards Committee responsible for the development of the industry code. The NRA provides support and guidance for retail and service sector businesses. The NRA's Technical Standards Committee supports the implementation of a stronger regulatory tool to improve button battery safety.

In February 2019, CHOICE ran specific product testing and found that 10 out of 17 common household products that use button batteries were not safe and did not meet the requirements of the industry code. The products presented a high risk to children as the batteries were easily accessible and warnings and labelling were inadequate.

In August 2019, the ACCC released the Issues Paper for consultation. The Issues Paper contained a broad discussion on button batteries including what they are, the dangers they pose, the current efforts to manage button battery safety and potential approaches to deal with the hazard.

In response, the ACCC received 29 submissions from a range of stakeholders including manufacturers, representative bodies, individual consumers and businesses, health professionals and government agencies.⁶²

Overall, there was strong support for the introduction of a mandatory safety standard to improve the safety of button batteries and consumer goods that use them.

4.6 Alternatives to government action

Industry self-regulation and awareness-raising activities are the primary alternative to mandatory regulation by government.

Industry safety initiatives to date have involved adoption of the voluntary industry code by some suppliers of consumer goods that use button batteries. In addition, some major battery manufacturers have developed improved child-resistant packaging.

There is also a range of relevant voluntary national and international standards in place and under development that address some but not all risks of exposure to button batteries. The ACCC has found that national and international standards vary in their scope and requirements and do not effectively address the hazard presented by button batteries in the wide range of consumer goods for which they are used.

The ACCC has found that although significant efforts have been made by some suppliers, a high level of unsafe products remained in the market and there had been no meaningful decrease in the rate of button battery injuries or exposures.

In 2019 the national standard-setting body, Standards Australia, proposed to facilitate the development of a national standard for button batteries, being a voluntary horizontal standard covering all products with button batteries.

The ACCC will participate in the Technical Committee to be convened by Standards Australia to develop a voluntary horizontal standard. It is not clear whether the requirements to be included in this voluntary horizontal standard will mirror the requirements recommended by the ACCC to address button battery safety.

The ACCC considers that mandatory regulation is necessary to prevent deaths and severe injuries to children resulting from button batteries. The ACCC's recent evaluation of the impact of the National Strategy found that voluntary supplier self-regulation had not sufficiently reduced the risk of injury or death to children from exposure to button batteries.

⁶² Submissions in response to the ACCC's 2019 Button Battery Safety Issues Paper are available on the <u>ACCC</u> <u>Consultation Hub</u>.

4.7 Cost of no government action

It is likely that if no government action is taken the number of deaths and severe injuries associated with button batteries will persist and possibly increase as button batteries become more common in consumer products, including children's toys.

If no government action is taken, it is estimated that four fatalities, 138 to 331 severe injuries and 8600 emergency presentations will occur during the forecast period of 2020–2029. Quantitatively derived estimates of the cost of these button battery incidents are in the range of \$26.4-\$62.3 million. The true total costs of fatalities and severe injuries to children that have resulted from button batteries are impossible to quantify.

Injuries sustained by children following exposure to button batteries can range in magnitude from minor (where the battery passes without incident) to life changing.

While no economic analysis can account for the devastating impact of losing a child, there are also wide-ranging and long-term costs faced by families as well as the government following the death of a child. The loss of a child has strong effects on the economic wellbeing of parents in subsequent years, including the likelihood of reduced family income, increased unemployment, increased likelihood of divorce and reduced mental health.
5. Options considered

Key points

- This consultation paper presents the status quo of taking no action and three regulatory options to address the hazard of button batteries.
- **Option 1**: Make a mandatory safety standard that includes requirements for secure battery compartments in consumer goods that use button batteries. Consumer goods that use button batteries that are intended to be replaced would be required to have a secure battery compartment such that batteries are only accessible with the use of a tool. Consumer goods that use button batteries to be fully secured inside the product. All consumer goods that use button batteries would be required to incorporate mechanisms to prevent removal of the battery by children under normal use or foreseeable misuse.
- **Option 2**: Make a mandatory safety standard that adopts all requirements in Option 1, and includes a requirement for all button batteries available for sale or supplied with consumer goods (where the battery is not pre-installed in a secure battery compartment) to be supplied in child-resistant packaging.
- **Option 3**: Make a mandatory safety standard that includes all requirements in Options 1 and 2 and includes a requirement for warnings and information to be provided:
 - on the packaging and instructions for all button batteries available for sale
 - on the product (where practicable), packaging and instructions of consumer goods that use button batteries
 - at point of sale (and prior to purchase) for all button batteries and consumer goods that use button batteries that are sold online
 - at point of sale (and prior to purchase) for unpackaged consumer goods that use button batteries that are supplied to consumers.
- Option 3 is the ACCC's preferred option. The ACCC considers that a combination of requirements for secure battery compartments and child-resistant packaging as well as the inclusion of warnings and information is likely to prevent more deaths and serious injuries by reducing incidents of child exposure to button batteries. This approach would also best address information asymmetry issues by improving awareness of the hazard so that appropriate action can be taken when an incident occurs.

This section sets out the key features of the options under consideration, stakeholder feedback and evidence relating to the proposed requirements, including potential exemptions from a mandatory safety standard.

5.1 Analysis of the status quo and regulatory options

Maintaining the status quo (take no action)

Maintaining the status quo involves no additional regulation and uses existing regulatory process and voluntary self-regulation to address the risks posed by button batteries.

Retailers, manufacturers and importers would still need to comply with relevant provisions of the ACL, including the consumer guarantees that require goods will be of acceptable quality, fit for purpose and free from defects. Aside from this, the majority of button battery products supplied in Australia would not have to meet any additional safety requirements.

Suppliers would continue to be required to comply with the existing mandatory standard for toys for children up to and including 36 months of age. This mandatory safety standard applies only to toys for this age group and includes requirements that indirectly cover button batteries as they meet the definition of a 'small part' that presents a choking hazard.

Suppliers would also continue to be required to comply with electrical safety laws of relevant Australian states and territories that cover household products. In states where compliance is mandatory, electrical laws require suppliers to ensure the safety of electrical equipment generally through adherence to the national standard AS/NZS 3820: Essential Safety Requirements for Electrical Equipment. This is an overarching standard that provides a high-level generic description of safety outcomes to be achieved and is intended to provide a basis for regulatory uniformity. This national standard does not include any specific requirements related to button batteries.

Under the status quo, industry safety initiatives may be adopted on a voluntary basis by suppliers, including the measures outlined in the industry code, developing child-resistant packaging for batteries made available for sale and compliance with a range of national and international standards.

While there is a range of existing voluntary national and international standards that address some risks of exposure to button batteries, the scope of these standards is limited to particular products or otherwise is only applicable to batteries of a particular chemistry (such as lithium batteries only).

Standards Australia is currently working on developing a national standard for button batteries, being a horizontal standard covering all products with button batteries. Once this standard has been developed, it may lead to improvements in button battery safety if it is voluntarily adopted by all manufacturers and suppliers.

Technological developments are likely to increase the availability of consumer goods with fully enclosed rechargeable batteries, although this future state remains some years away for the wide range of consumer goods that use button batteries.

Existing mandatory and voluntary standards only capture a small proportion of the wide variety of household products that young children play with and can access that use button/coin cell batteries. Voluntary self-regulatory measures have not effectively addressed the hazard of button batteries for the wide range of consumer goods in which they are used.

The ACCC has found through surveillance activities that although significant efforts have been made by some suppliers, a substantial number of unsafe products remain available for sale and there has been no meaningful decrease in the rate of button battery injuries or exposures. The ACCC considers that regulatory action is necessary to address the hazard of button batteries and improve safety.

Option 1: Make a mandatory safety standard that includes secure battery compartment requirements

Option 1 is to make a mandatory safety standard that includes secure battery compartment requirements for consumer goods that use button batteries.

Under this option, subject to exemptions, secure battery compartment requirements would apply for all consumer goods that use button batteries, regardless of the size or chemistry of the button battery suitable for the product.

The application of secure battery compartment requirements would depend on whether button batteries are intended to be replaced, or are otherwise not intended for user removal or replacement, in the consumer good.

The ACCC considers that secure battery requirements are the most crucial safeguard to improve safety and address the hazard of button batteries.

Stakeholder feedback

Stakeholder feedback received in response to the Issues Paper indicated that there is broad support for a mandatory requirement for consumer goods that use button/coin cell batteries to have a secure battery compartment.

The majority of stakeholders were of the opinion that a secure battery compartment was the most critical requirement for preventing young children from accessing batteries. It was also raised that any requirement for a secure battery compartment should include a clear agreed set of performance/ durability tests to ensure the battery compartment is durable.

Some manufacturers and industry associations submitted that the mandatory compartment requirements should apply only to products using lithium batteries which are most commonly associated with severe injuries and fatalities.

There are two variations on requirements for the accessibility of secure battery compartments in existing Australian and international standards:

- a requirement that button batteries are not accessible without the use of a tool
- a requirement that button batteries are not accessible without the use of a tool or unless at least two independent movements have been applied simultaneously to the battery compartment.

Some submissions suggested that the requirement for two independent and simultaneous movements can lead to misinterpretation and confusion and ultimately decreased safety. A battery compartment secured with a screw or bolt and only accessible with the use of a tool was put forward as the preferable requirement to improve safety.

It was also suggested that battery compartments accessible by two independent and simultaneous movements would not necessarily prevent young children from accessing batteries. Data provided in a submission from the NSW Poisons Information Centre (NSW PIC) indicates that many children are able to access medicines from bottles with child-resistant lids which require two independent and simultaneous actions (i.e. push down and twist) to open. Since January 2014, NSW PIC has received more than 6000 calls regarding children under the age of five years accessing paracetamol liquid from bottles with 'child-resistant' lids.⁶³

Stakeholders also suggested that having a single requirement for secure battery compartments, such as requiring a tool to gain access, would reduce the cost of compliance testing for suppliers and regulators.

Several submissions from hearing aid manufacturers, hearing care industry associations and individual users raised concerns about the implications of mandating a secure battery compartment for hearing aids and hearing devices.

Evidence supporting the requirements

In 2015, following the coronial inquest into the death of Summer Steer, Coroner Hutton made a range of recommendations including that manufacturers, distributors and retailers of products containing button batteries implement the requirements of the existing toy standard to ensure that batteries are secured in a child-resistant battery compartment within the product.⁶⁴

In 2019, following the coronial inquest into the death of Isabella Rees, Coroner English accepted the view that primary prevention is the most important aspect of treatment and that the battery compartment on all devices requiring button batteries should be secured with a screw (or similar).⁶⁵

⁶³ NSW Poisons Information Centre submission to ACCC Button Battery Safety Issues Paper, <u>https://consultation.accc.gov.au/product-safety/button-battery-safety-issues-paper/consultation/view_respondent?uuld=813813927</u>, viewed 30 October 2019.

⁶⁴ Office of the State Coroner 2015, Queensland Courts, Brisbane, <u>www.courts.qld.gov.au/__data/assets/pdf_file/0004/444289/cif-steer-sa-20151103.pdf</u>, viewed 18 November 2019.

⁶⁵ Coroners Court of Victoria at Melbourne 2019, Coroners Court of Victoria at Melbourne, <u>www.coronerscourt.</u> vic.gov.au/sites/default/files/2019-04/IsabellaEstelleRees_059215.pdf, viewed 18 November 2019.

A study by Litovitz et al in 2010 analysed 8648 cases of battery ingestion reported to the US National Battery Ingestion Hotline between July 1990 and September 2008. The study found that batteries ingested by children from 0–5 years were obtained directly from the product in 61.8 per cent of the 3989 cases where the source of the battery was known.⁶⁶

Given that the majority of button batteries involved in reported incidents have been accessed directly from products, a requirement for consumer goods that use button batteries to have secure battery compartments has been identified as a key requirement to improving safety.

Lithium batteries and batteries with a diameter of 20 mm or more were responsible for the majority of severe injuries and fatalities. Non-lithium and smaller batteries have also been responsible for severe injuries and deaths. Non-lithium batteries were responsible for at least 14 severe injuries and three deaths. Batteries smaller than 20 mm have caused at least 17 severe injuries and four deaths (see section 4.1). There is also a high number of incidents where the chemistry and size of the battery is unknown.⁶⁷

Assessment of the requirements

The ACCC has undertaken a detailed analysis of the industry code and existing national and international standards that include requirements for secure battery compartments for products that use button batteries (see **appendix C** for a list of relevant standards considered).

The ACCC considers the essential requirements for consumer goods that use button batteries are that:

- 1. consumer goods that use button batteries that are intended to be replaced shall have a battery compartment that is secured by screw or similar fasteners such that batteries are only accessible with the use of a tool (such as a screwdriver or spanner)
- 2. consumer goods that use button batteries shall prevent removal of the battery by children under normal use or foreseeable abuse
- 3. where the battery compartment is secured by screws or similar fasteners, the fasteners shall be captive to ensure that they remain with the door, cover or equipment
- 4. when not intended for user removal or replacement, the button battery shall be held fully secured inside the product by the use of soldering, fasteners such as rivets, or equivalent means.

The ACCC considers that secure battery requirements should apply to all products that use button batteries regardless of size or chemistry of the battery as severe injuries and deaths have been associated with lithium as well as other non-lithium batteries. Small button batteries can also result in severe injuries when inserted into body orifices such as ears and noses and pose a choking hazard to children.

A difference between existing requirements in the voluntary industry code and the requirements proposed by the ACCC is proposing that secure battery compartments only be accessible with the use of a tool. Certain national and international voluntary standards provide alternative options for battery compartments to be secured either by the use of a tool or the application of two or more independent and simultaneous movements to open. The ACCC considers it is preferable that a requirement for secure battery compartments is limited to only being accessible with the use of a tool (such as a screwdriver or spanner). This would improve the security of the battery compartment, avoid potential misinterpretation, increase clarity of the requirement and reduce the likelihood of young children accessing the battery.

The ACCC considers that a requirement that fasteners used to secure a battery compartment remain captive to the door, cover or equipment is important to prevent loss or damage of fasteners, such as screws. This requirement is aimed at promoting the security of battery compartments for consumer goods on a prolonged basis.

⁶⁶ T Litovitz, N Whitaker, L Clark, 'Preventing battery ingestions: an analysis of 8648 cases', *Pediatrics*, 2010.

⁶⁷ All severe and 62 fatal cases sourced from NCPC: <u>www.poison.org/battery/fatalcases</u>; <u>www.poison.org/battery/</u> <u>severecases</u>. Two fatal cases sourced from Labadie M, et al, 'Severity of button batteries ingestions: data from French Poison Control Centres between 1999 and 2015', *European Journal of Emergency Medicine*. 2018 Aug 1;25(4):e1-8.

Where button batteries are not intended for user removal or to be replaced in a consumer good, such as for many novelty and lower value items, the ACCC considers that the batteries must be fully secured inside the consumer good such that the batteries do not become accessible to children when subjected to normal use or foreseeable abuse.

All consumer goods that use button batteries would be required to prevent removal of the battery by children under normal use or foreseeable misuse.

Compliance testing

To ensure an acceptable level of safety flows from secure battery compartment requirements (1) to (4), the ACCC considers that it is necessary that consumer goods that use button batteries be subjected to certain compliance tests contained in existing voluntary standards.

The ACCC has selected tests that are specifically focused on the security and ongoing durability of battery compartments and their doors/covers to ensure that the design and manufacture of secure battery compartments is adequate to prevent button batteries becoming accessible.

Similarly, the ACCC has selected tests that are specifically focused on ensuring that batteries remain fully secured inside consumer goods when subjected to normal use and foreseeable abuse.

The ACCC proposes that manufacturers and importers would be required to test consumer products that contain button batteries for compliance with the following tests.

Table 9: Compliance tests for secure battery requirements

Compliance with secure battery compartment	nt requirement (1) an	d (2) to be checked by one of the following:
UL4200A:2015 Standard for Safety— Products Incorporating Button or Coin Cell Batteries of Lithium Technologies	Clauses 6.2 and 6.3 *	The tests outlined in each of these standards are near identical and are designed to test security and durability of products that use button batteries,
AS/NZS 60065:2018 Audio, video and similar electronic apparatus—Safety	Clauses 12.7.3 and 12.7.4 *	including certain tests which are focused on testing battery compartments.
requirements (IEC 60065:2014)		_ Tests include pre-conditioning tests (stress relief test
IEC 62368-1:2018 Audio/video, information and communication technology equipment Part 1: Safety requirements	Clauses 4.8.4 and 4.8.5 *	and battery replacement test); abuse tests (drop test, impact test, crush test) and compliance test (force test applying a rigid test finger).
Compliance with battery compartment captive	ve fastener requirem	ent (3) to be checked by one of the following:
IEC 62115:2017 Electric toys—Safety	Clause 13.4.6	The tests outlined in each of these standards are
AS/NZS 60598.1:2017 Luminaires, Part 1: General requirements and tests	Clause 4.101.2	near identical and are designed to test battery compartment fasteners.
		Test involves a force being applied to the screw or similar fastener.
Compliance with secure non-replaceable bat	teries requirement (4	4) to be checked by the following test:
UL4200A:2015 Standard for Safety— Products Incorporating Button or Coin Cell Batteries of Lithium Technologies	Clause 6.4	This is a secureness test which involves the application of a test hook with specific force to check if the button battery can become separated from the product.

* The tests in these clauses are to be applied to all consumer goods that use button batteries, regardless of their size or chemistry.

For secure battery compartment requirements (1) to (3), the ACCC has identified multiple voluntary standards that include near identical compliance tests. The ACCC considers that it is only necessary for consumer goods that use button batteries to be checked for compliance with any one of the standards listed for each secure battery compartment requirement.

Option 2: Make a mandatory safety standard that adopts requirements in Option 1 and includes child-resistant packaging requirements

Option 2 is to make a mandatory safety standard that adopts all requirements in Option 1, and includes a requirement for all button batteries available for sale or provided with consumer goods (where the battery is not pre-installed in a secure battery compartment) to be supplied in child-resistant packaging.

Button batteries can be sold individually or in multipacks. They can also be supplied as spare batteries inside the packaging of a consumer good that is powered by a button battery for installation by the consumer.

Under this option, subject to exemptions, child-resistant packaging would apply to all button batteries regardless of their size or chemistry.

In addition, all spare button batteries that are supplied with a consumer good (where the battery is not pre-installed in a secure battery compartment) would need to be enclosed in child-resistant packaging.

Stakeholder feedback

Stakeholder feedback received in response to the Issues Paper indicated broad support for a mandatory requirement for child-resistant packaging for both button batteries made available for sale and when supplied with consumer goods.

There was broad support for child-resistant packaging to be applicable for all battery chemistries and sizes. This is on the basis that fully charged new batteries pose the greatest risk when inserted or ingested and all button batteries pose a risk to children. Further, it would be complicated and confusing for suppliers and consumers if regulation varied for different chemistry types.

Director of QISU, Dr Ruth Barker, submitted that child-resistant packaging of high-risk pharmaceuticals and household chemicals has dramatically reduced rates of significant poisoning on a global scale. It is therefore considered likely that adopting existing child-resistant packaging standards for batteries will incrementally reduce unintended access by young children.⁶⁸

Submissions from some industry associations indicated support for child-resistant packaging for lithium batteries only.

The majority of stakeholders were of the opinion that button batteries supplied with consumer goods should either be supplied in a secure battery compartment in the consumer good, or provided in child-resistant packaging within the outer packaging of the consumer good (i.e. not loose or unsecured inside packaging).

Several submissions from hearing aid manufacturers, hearing care industry associations and individual users raised concerns about the implications of mandating child-resistant packaging for batteries used in hearing aid devices.

Evidence supporting the requirement

The safety risk to children from button batteries arises when they can gain access to the batteries. Child-resistant packaging is used to create a physical barrier between a child and a potentially hazardous product. It is designed in a way that limits the ability for a child to access the product from the packaging.

⁶⁸ R Barker and co-signatories submission to ACCC Button Battery Safety Issues Paper <u>https://consultation.accc.gov.au/</u> product-safety/button-battery-safety-issues-paper/consultation/published_select_respondent, viewed 19 October 2019.

The use of child-resistant packaging is proven as an effective measure for preventing children from accessing consumer goods that pose a hazard or high risk to children. A report by Sarika Malhotra et al (2013) on the effectiveness of child-resistant packaging on medical products in the Netherlands found that following the introduction of legislation requiring child-resistant packaging on household chemicals and human medications, the number of hospitalisation and treatments following ingestion of these products decreased by around 33 per cent.⁶⁹

In 2015, following the coronial inquest into the death of Summer Steer, Coroner Hutton recommended that the ACCC should develop a regulation mandating the Australian standard for child-resistant packaging of non-pharmaceutical products to apply to all battery packaging, including button batteries.⁷⁰

Exposure data from the US National Battery Ingestion Hotline (NBIH) indicates that where the source of the battery is known, batteries were removed from the original battery packaging by the child in around 8 per cent of cases.

While some major battery manufacturers such as Energizer have introduced child-resistant packaging for lithium coin cell batteries, recent market surveillance of packaging of button batteries more generally has shown that child-resistant packaging has not been commonly adopted. Market surveillance of packaging of button batteries by the ACCC and state and territory regulators found that child-resistant packaging has not been commonly adopted to be child-resistant.

Lithium chemistry batteries with a diameter of 20 mm or more are the most dangerous. However, non-lithium batteries and smaller batteries are also hazardous.

The ACCC considers that, based on the above evidence and reports, child-resistant packaging is likely to be effective in preventing children from accessing button batteries direct from packaging, and hence substantially reducing the risk these products pose to the health of children.

Assessment of the requirement

The ACCC has undertaken a detailed assessment of existing national and international standards that include requirements for child-resistant packaging (see **appendix C** for a list of relevant standards considered). The ACCC considers that the essential child-resistant packaging requirements for button batteries are as follows:

- 1. Button batteries made available for sale or provided with consumer goods (where the battery is not pre-installed in a secure battery compartment) shall be enclosed in child-resistant packaging.
- 2. Where multiple button batteries are supplied in the same packaging, each individual battery shall be separately contained, such that each battery is enclosed in child-resistant packaging even when another battery is removed from the packaging.

The ACCC considers that where button batteries are provided with a consumer good, these should also be enclosed in child-resistant packaging. This may involve button batteries being supplied in child-resistant packaging within the outer packaging of a consumer good. Child-resistant packaging requirements would not apply to button batteries that are supplied pre-installed and secured inside the battery compartment of a consumer good, or held fully secured inside a consumer good (in the case of batteries that are not intended for user removal or replacement).

Where multiple button batteries are supplied in the same packaging (commonly referred to as multipacks), the ACCC considers that each individual battery should be separately enclosed in child-resistant packaging such that multiple batteries do not become accessible after an individual battery is removed from the packaging.

⁶⁹ S Malhotra, RK Arora, B Singh, U Gakhar, R Tonk, 'Child resistant packaging: a prime concern for packaging of medicinal products', *International Journal of Pharmaceutical Sciences Review and Research*, <u>globalresearchonline.net/journalcontents/v22-2/16.pdf</u>, viewed 5 February 2020.

⁷⁰ Office of the State Coroner 2015, Queensland Courts, Brisbane, <u>www.courts.qld.gov.au/__data/assets/pdf_</u> file/0004/444289/cif-steer-sa-20151103.pdf, viewed 28 January 2020.

Compliance testing

To ensure an acceptable level of safety results from the adoption of child-resistant packaging requirements, the ACCC considers that it is necessary that packaging of button batteries be subjected to packaging tests contained in national and international voluntary standards.

The ACCC is aware of the following national and international standards that outline either specific tests for battery packaging (IEC 60086-4) or outline performance requirements and test procedures for assessing if packaging is to be deemed child-resistant. The ACCC considers that compliance with any one of these child-resistant packaging compliance tests in these standards will provide for an acceptable level of safety and clarity for manufacturers and suppliers.

The ACCC proposes that manufacturers and importers would be required to test consumer products that use button batteries for compliance with one of the following tests.

IEC 60086-4:2019 Primary batteries—Part 4: Safety of lithium batteries	Packaging tests described in E.3	These packaging tests are specific to battery packaging. Tests include a bending test, torsion test, tearing test and pushing test.	
USA:16 CFR §1700 Poison Prevention Packaging	15(b)(1)	These standards specify near-identical performance requirements and methods of test procedures for	
EN 862, Packaging. Child-resistant packaging. Requirements and testing	All clauses	assessing if non-reclosable packaging is to be deemed child-resistant.	
procedures for non-reclosable packages for non-pharmaceutical products		Tests involve providing the relevant packaging for assessment to a test group of 200 children. These	
AS 5808-2009, Child-resistant packaging— Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products	All clauses	standards specify the percentage of packages that should be able to be opened by children within a specific timeframe to determine whether the packaging is child-resistant.	

Table 10: Compliance tests for child-resistant packaging

For child-resistant packaging requirements (1) and (2), the ACCC has identified a single international voluntary standard that outlines specific tests for battery packaging and multiple voluntary standards that include near-identical test procedures for deeming packaging to be child-resistant.

The ACCC considers that it is only necessary for packaging of button batteries to be checked for compliance with any one of the standards listed for child-resistant packaging requirements.

Option 3: Make a mandatory safety and information standard that adopts requirements in Options 1 and 2 and includes warnings and information requirements

Option 3 is to make a mandatory safety standard that includes all requirements in Options 1 and 2 and includes a requirement for warnings and information to be provided on the packaging and instructions for all button batteries available for sale as well as the product (where practicable), packaging and instructions of consumer goods that use button batteries.

In addition, this option also introduces a requirement for warnings and information to be made available to consumers at the point of sale, and prior to purchase. This point of sale requirement would apply to:

- all button batteries and consumer goods that use button batteries that are sold online
- unpackaged consumer goods that use button batteries that are supplied to consumers.

Under this option, warnings and information would be required for all button batteries regardless of their size or chemistry.

Stakeholder feedback

Stakeholder feedback in response to the Issues Paper indicated general support for improved warnings and labelling on button batteries available for sale as well as consumer goods that use button batteries. It was noted that warnings should include graphical symbols as well as text to improve effectiveness.

There was general acknowledgment from stakeholders of the inconsistency of existing warning labels and strong support for improved and consistent labelling on packaging. Some stakeholders noted that instructions and labels are often not read or ignored by consumers.

The industry code recommends that warning labels should include advice to immediately contact the Australian Poisons Information Centre (PIC) if it is suspected that a child has swallowed a button battery in addition to other warnings.

Stakeholders held divergent views on labelling requirements that include information specific to Australia, such as contact details for the Australian PIC hotline.

Some industry stakeholders oppose any labelling requirements that would be specific only to Australia. They suggest that this would impose additional costs on suppliers and create barriers to trade. They state that given the size of the Australian market, requiring a separate production run for the Australian market may be uneconomical for many suppliers.

In contrast, stakeholders from the government, health and medical sectors believe that labels should include advice to call the Australian PIC hotline immediately following any suspected insertion or ingestion.

Reasons provided include that:

- batteries should be treated the same as other 'agents with potential to cause serious corrosive injury' and as per the Poisons Standard include advice to call the PIC hotline immediately following ingestion or other exposure (many products sold in Australia such as fly spray and other common household goods containing poisonous substances contain the PIC hotline information on labels)
- PIC is the appropriate national organisation to provide the public with prompt, up-to-date and evidence-based clinical information
- PIC contact is crucial to provide essential time-critical advice
- many regional areas do not have access to hospitals or to hospitals with the required diagnostic equipment such as X-ray. PIC provides advice on where the patient should be taken and phones ahead to ensure hospitals are prepared to take immediate action when the patient arrives
- inclusion of PIC advice assists to raise awareness of the hazard and signal the inherent danger of the batteries.

Stakeholder feedback in response to the Issues Paper indicated support for improved information to ensure that consumers are provided with relevant safety information at the point of sale. It was noted that industry have a duty of care to provide safety advice to the consumer when they are buying a product.

Evidence supporting the requirements

A foundation of consumer protection is that products are suitably labelled to warn consumers of any hazard the product may encompass.

In 2018, the ACCC commissioned a review of the research relating to the Efficacy of Warning Labels.⁷¹ The review confirmed that warning labels can be effective in highlighting hazards to consumers. The review also noted that symbols and wording should be provided together to limit the confusion or misinterpretation the display of symbols alone may provide.

⁷¹ Austin Adams from the School of Psychology at the University of New South Wales and James Cook University undertook the research review.

The warning label guidelines in the international standard ISO 3864-1:2011 Graphical symbols—Safety colours and safety signs—Part 1: Design principles for safety signs and safety markings indicate that a warning label should indicate the hazard, the consequence and the mitigation actions.

Market surveillance and consultation with industry indicate a vast difference in the safety symbols and warning messages included on packaging of button batteries. While major brands and Australian suppliers are already including some form of safety symbol and/or warning on battery packaging, there are large differences in the wording of the warnings and use of pictograms. A review of safety symbols used on the packaging of button battery products identified at least 12 different symbols currently being used.

The lack of consistency in the market in relation to the warnings provided on packaging supports the view that mandating the use of warnings is warranted.

Given the time-critical nature of button battery incidents, the inclusion of contact information for the Australian PIC on products, packaging and instructions of consumer goods that use button batteries can reduce delays in diagnosis and therefore button battery injury severity.

The PIC can provide expert and timely advice in emergency situations, including directing callers on the best course of action. The PIC can also direct callers, in particular those in regional and remote areas, to hospitals that have X-ray facilities and assist clinicians in the initial management of a suspected button battery exposure.

A study by Cairns et al examined button battery exposure data captured by NSW PIC over the 19-month period from November 2015 to May 2017. The study found that children in outer regional, remote and very remote areas were over-represented in the exposure data. It also identified at least 15 cases where patients were referred to a different hospital because X-ray facilities were not available locally.⁷² The study concluded that a PIC-led protocol to direct initial management of button battery exposures could reduce delays and improve outcomes.

In 2015, following the coronial inquest into the death of Summer Steer, Coroner Hutton recommended that PICs serve as first point of contact for potential battery exposures.⁷³

In 2019, following the coronial inquest into the death of Isabella Rees, this was further supported by Coroner English's recommendation that PICs should be promoted as the first point of contact in clinical guidelines.⁷⁴

Further, a study of paediatric exposure cases by NSW PIC (November 2015–October 2018) identified inconsistencies in the triage approaches of first responders and knowledge gaps about the dangers of button batteries and management of cases among some healthcare providers.⁷⁵

Assessment of the requirement

The ACCC has undertaken a detailed assessment of the industry code and existing national and international standards that include warnings and information text related to button batteries (see **appendix C** for a list of relevant standards considered).

The ACCC considers that the essential requirements for warnings and information are as follows:

- (1) Warnings and information on packaging of button batteries shall:
 - a) be clearly visible on the exterior packaging and provided in the form of text and a safety symbol

⁷² R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, 'Button battery exposures in Australian children: a prospective observational study highlighting the role of poisons information centres', *Clinical Toxicology*, vol. 57, no. 6, 2019, pp. 404-410.

⁷³ Office of the State Coroner 2015, Queensland Courts, Brisbane, <u>www.courts.qld.gov.au/_data/assets/pdf_file/0004/444289/cif-steer-sa-20151103.pdf</u>, viewed 28 January 2020.

⁷⁴ Coroners Court of Victoria at Melbourne 2019, Coroners Court of Victoria at Melbourne, Melbourne, <u>www.coronerscourt.</u> <u>vic.gov.au/sites/default/files/2019-04/IsabellaEstelleRees_059215.pdf</u>, viewed 28 January 2020.

⁷⁵ R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, Button Battery Exposures in Australia, November 2015—May 2017, NSW Poisons Information Centre.

- b) alert consumers to the dangers of button batteries and to keep button batteries away from children
- c) indicate what to do if it is suspected that a battery has been ingested or inserted, and provide contact details for the Australian PIC.
- (2) Warnings and information to be provided on a product that uses button batteries shall:
 - a) be clearly visible on the product (where practicable) and provided in the form of text and a safety symbol
 - b) alert consumers that button batteries are included with, or are required to operate, the consumer good (or any included peripheral device)
 - c) alert consumers to the dangers of button batteries and that these are hazardous to children.
- (3) Warnings and information on the packaging and instructions of a consumer good that uses button batteries shall:
 - a) be clearly visible on the exterior packaging and instructions, and provided in the form of text and a safety symbol
 - b) alert consumers that button batteries are included with, or are required to operate, the consumer good (or any included peripheral device)
 - c) alert consumers to the dangers of button batteries and that these are hazardous to children
 - d) provide clear directions on what to do if it is suspected that a battery has been ingested or inserted and provide contact details for the Australian PIC.
- (4) Warnings and information to be provided at the point of sale (and prior to purchase) shall:
 - a) be consistent with warnings and information provided on the packaging and instructions of a consumer good that uses button batteries
 - b) be made available for all button batteries and consumer goods that use button batteries sold online
 - c) be made available for unpackaged consumer goods that use button batteries that are supplied to consumers.

The ACCC considers that warnings and information should be required for all button batteries regardless of size or chemistry as severe injuries and deaths have been associated with lithium as well as other non-lithium batteries. Small button batteries can also result in severe injuries when inserted into body orifices such as ears and noses. This is one of the key differences between requirements in existing standards and what the ACCC is proposing, as the warning requirements in most current standards either apply specifically to lithium coin cell batteries or provide different requirements for lithium coin cell batteries and smaller button batteries of other chemistries.

To aid low-literacy users, it is important that warnings and information content is provided in the form of text and a safety symbol that is clearly visible.

Our preliminary view is that it is appropriate to include warnings and information on both the packaging and instructions (where applicable) of button batteries available for sale and consumer goods that use button batteries:

- Warning and information on packaging will enable consumers to make an informed purchase and should also assist in increasing consumer awareness of the hazard of button batteries.
- Warnings and information in instructions provide an opportunity for information to be available for future reference and in the event of a suspected ingestion or insertion.

Where practicable, warnings and information should be included (either embossed or by affixing labels) on products that use button batteries. Warnings and information on products should be placed alongside the battery compartment. This will enable consumers of products to be made aware of the hazard of button batteries when packaging and instructions are either disposed of or otherwise not available.

In circumstances where it is not possible to physically inspect the packaging of button batteries available for sale or consumer goods that use button batteries, such as when sold online or when the consumer good is sold unpackaged, warnings and information should be made available to consumers at the point of sale, and prior to purchase:

- When supplying button batteries or consumer goods that use button batteries online, warnings and information should be clearly visible in the online description and/or images of the product, and made available prior to the consumer committing to an online purchase.
- When supplying unpackaged products to consumers, warnings and information should be made available prior to purchase in a notice that is clearly visible next to where the product is displayed and either tagged to the product or provided to the customer at the retail checkout prior to purchase.

The ACCC considers that warnings and information made available at the point of sale, and prior to purchase, should be consistent with warnings and information provided in the packaging and instructions of consumer goods that use button batteries.

The ACCC considers that the requirement for warnings and information should include the provision of the Australian PIC hotline as per the recommended text in the industry code.

The ACCC considers that the inclusion of the PIC hotline is especially important given many regional hospitals throughout Australia have limited or no X-ray facilities on site. This can lead to delays in diagnosis and removal of an ingested battery. Australian PICs call ahead to local hospitals to ensure X-ray availability or arrange for diversion to a different hospital which results in reduced delays in treatment and improved injury outcomes. This is another key difference between existing standards and what the ACCC is proposing, as there are currently no standards that include a requirement to provide Australian PIC contact details either on the product, on the packaging or in the instructions. The existing voluntary industry code does recommend that this information is included.

Compliance

There is currently no national or international standard that applies to all button batteries and consumer goods that use button batteries that would meet the essential requirements for labelling and information identified above. There is a range of existing national and international standards that outline specific warnings relating to button batteries for certain product types. Some of the warning requirements in these standards apply to product packaging and some apply to warnings included in instructions. Some standards provide different warning requirements for batteries of different sizes or chemistries. The ACCC considers that there are useful examples of warning text and symbols in some existing standards that may be used in combination to achieve an acceptable level of safety and clarity for consumers, manufacturers and suppliers.

Warnings and information on packaging of button batteries

The essential requirements for warnings and information to be provided on the packaging of button batteries are that the warnings and information shall:

- a) be clearly visible on the exterior packaging and provided in the form of text and a safety symbol
- b) alert consumers to the dangers of button batteries and to keep button batteries away from children
- c) indicate what to do if it is suspected that a battery has been ingested or inserted, and provide contact details for the Australian PIC.

Examples of warnings and information that may be included on the packaging of button batteries to comply with the essential requirements are provided in table 11.

Table 11: Examples of warnings and information appropriate to include on packaging of button batteries

Source	Description	
IEC 60086-4:2019 Primary batteries—Part 4: Safety of lithium batteries*	This standard specifies warning text and safety symbols to alert consumers to keep batteries out of the reach of children. The specified text details the appropriate action to take if ingestion occurs.	
Warnings described in clause 7.2(a) and displayed in figure 9, and as per best practices for marking the packaging as outlined in annexure F	The warning text and symbols as displayed in figure 9 are appropriate to include on the packaging of button batteries.	
ACCC symbol	The warning symbol is approporiate to include on the packaging of button batteries.	

Contact information for	If you think batteries might have been swallowed or placed inside any part of the body, seek
Australian PIC	immediate medical attention. Call the 24-hour Poisons Information Centre on 131 126 for
	fast, expert advice.

* The requirements are to be applied to all button batteries, regardless of their size or chemistry.

Warnings and information on the product

The essential requirements for warnings and information to be provided on the product (where practicable) are that the warnings and information shall:

- a) be clearly visible on the product and provided in the form of text and a safety symbol
- b) alert consumers that button batteries are included with, or are required to operate, the consumer good (or any included peripheral device)
- c) alert consumers to the dangers of button batteries and that these are hazardous to children.

Examples of warnings and information that may be included on the product (where practicable) to comply with the essential requirements are provided in table 12.

Table 12: Example	s of warnings and information	on appropriate to	include on the product	(where practicable)
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Source	Description	
AS/NZS 62115:2018 Electric toys—Safety	tric This warning symbol is appropriate to include on the product (where practicable) th button batteries.	
Warning symbol specified in clause 7.2.6 to indicate a coin battery is contained in the product.		
	Note: The warning symbol should be placed close to the battery compartment.	
ACCC symbol	This warning symbol is appropriate to include on the product (where practicable) that uses button batteries.	
UL4200A:2015 Standard for Safety—Products	This warning text is appropriate to include on the product (where practicable) that uses button batteries.	
Incorporating Button or Coin Cell Batteries of Lithium Technologies*	WARNING: Chemical Burn Hazard. Keep batteries away from children.	

* The requirements are to be applied to all consumer goods that use button batteries, regardless of their size or chemistry.

Warnings and information on the packaging and instructions of consumer goods

The essential requirements for warnings and information to be provided on the packaging and instructions of consumer goods that use button batteries are that the warnings and information shall:

- a) be clearly visible on the exterior packaging and instructions, and provided in the form of text and a safety symbol
- b) alert consumers that button batteries are included with, or are required to operate, the consumer good (or any included peripheral device)
- c) alert consumers to the dangers of button batteries and that these are hazardous to children
- d) provide clear directions on what to do if it is suspected that a battery has been ingested or inserted and provide contact details for the Australian PIC.

Examples of warnings and information that may be included on the packaging and instructions of consumer goods that use button batteries to comply with the essential requirements are provided in table 13.

Table 13: Examples of warnings/information appropriate to include on the packaging and instructions of consumer goods

Source	Description		
AS/NZS 62115:2018 Electric toys—Safety	This warning symbol is appropriate to include on the packaging and instructions of consumer goods that use button batteries.		
Warning symbol specified in clause 7.2.6 to indicate a coin battery is contained in the product.			
ACCC symbol	This warning symbol is appropriate to include on the packaging and instructions of consumer goods that use button batteries.		
ASTM F963-17 Standard Consumer Safety	This warning text is appropriate to include on the packaging and instructions of consumer goods that use button batteries.		
Specification for Toy Safety Warnings specified in clause 5.15.2(2)	WARNING: This product contains a Button or Coin Cell Battery. A swallowed Button or Coin Cell Battery can cause internal chemical burns in as little as two hours and lead to death. Dispose of used batteries immediately. Keep new and used batteries away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.		
UL4200A:2015 Standard for Safety for Products	This warning text is appropriate to include on the packaging and instructions of consumer goods that use lithium button batteries.		
Incorporating Button or Coin Cell Batteries of Lithium	WARNING: Chemical Burn Hazard. Keep batteries away from children.		
Technologies*	This product contains a lithium button battery. If a new or used lithium button battery is		
Warnings specified in clause 8.2	swallowed or enters the body, it can cause severe internal burns and can lead to death in as little as 2 hours. Always completely secure the battery compartment. If the battery compartment does not close securely, stop using the product, remove the batteries, and keep it away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.		

AS/NZS 60065:2018 Audio, video and similar electronic	This warning text is appropriate to include on the packaging and instructions of consumer goods that use button batteries.	
apparatus Warnings specified in clause 5.5.2(j)	WARNING: Do not ingest the battery, Chemical Burn Hazard. This product contains a coin/button cell battery. If the coin/button cell battery is swallowed, it can cause severe internal burns in just 2 hours and can lead to death. Keep new and used batteries away from children. If the battery compartment does not close securely, stop using the product and keep it away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.	
IEC 62368-1:2018 Audio/ video, information and	This warning text is appropriate to include on the packaging and instructions of consumer goods that use button batteries.	
communication technology equipment—Part 1: Safety	Do not ingest battery, Chemical Burn Hazard	
requirements	This product contains a coin/button cell battery. If the coin/button cell battery is	
Warnings specified in clause 4.8.2	swallowed, it can cause severe internal burns in just 2 hours and can lead to death. Keep new and used batteries away from children. If the battery compartment does not close securely, stop using the product and keep it away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.	
AS/NZS 60598.1:2017 Luminaires Part 1: General	This warning text is appropriate to include on the packaging and instructions of consumer goods that use button batteries.	
requirements and tests	CAUTION: Do not ingest battery—Chemical burn hazard (or equivalent wording).	
Warnings specified in appendix ZZ (3.3.102)	This product contains a coin/button cell battery. If the coin/button cell battery is swallowed, it can cause severe internal burns in just 2 hours and can lead to death.	
	Keep new and used batteries away from children.	
	If the battery compartment does not close securely, stop using the product and keep it away from children.	
	If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.	
Contact information for Australian PIC	If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention. Call the 24-hour Poisons Information Centre on 131 126 for fast, expert advice.	

* The requirements are to be applied to all consumer goods that use button batteries, regardless of their size or chemistry.

Warnings and information to be provided at point of sale

The essential requirements for warnings and information to be provided at the point of sale (and prior to purchase) are that warnings and information shall:

- a) be consistent with warnings and information provided on the packaging and instructions of a consumer good that uses button batteries
- b) be made available for all button batteries and consumer goods that use button batteries sold online
- c) be made available for unpackaged consumer goods that use button batteries that are supplied to consumers.

When supplying button batteries or consumer goods that use button batteries online, warnings and information should be clearly visible in the online description and/or images of the product, and made available prior to the consumer committing to an online purchase.

When suppling unpackaged consumer goods that use button batteries to consumers, warnings and information should be made available to consumers prior to purchase in a notice that is clearly visible next to where the product is displayed and either tagged to the product or provided to the customer at the retail checkout prior to purchase.

Option 3: Summary of proposed requirements

Option 3 involves both a mandatory safety standard and an information standard.

A mandatory safety standard is required in order to specify the minimum requirements that consumer goods must meet before they are supplied. A mandatory safety standard would specify secure battery compartment requirements, child-resistant packaging requirements, and warnings and information requirements for products (where practicable), packaging and instructions.

A mandatory information standard is required in order to specify the nature and form of information to be provided with consumer goods. An information standard is required in addition to a safety standard to mandate that warnings and information must be made available to consumers at the point of sale.

Option 3 requires all of the following:

Secure battery compartment requirements:

- (1) Consumer goods that use button batteries that are intended to be replaced shall have a battery compartment that is secured by screw or similar fasteners such that batteries are not removable without the use of a tool (such as a screwdriver or spanner).
- (2) Consumer goods that use button batteries shall prevent removal of the battery by children under normal use or foreseeable abuse.
- (3) Where the battery compartment is secured by screws or similar fasteners, the fasteners shall be captive to ensure that they remain with the door, cover or equipment.
- (4) When not intended for user removal or replacement, the button battery shall be held fully secured by the use of soldering, fasteners such as rivets, or equivalent means.

Child-resistant packaging:

- (1) Button batteries available for sale or provided with consumer goods (where the battery is not pre-installed in a secure battery compartment) shall be enclosed in child-resistant packaging.
- (2) Where multiple button batteries are supplied in the same packaging, each individual battery shall be separately contained, such that each battery is enclosed in child-resistant packaging even when another battery is removed from the packaging.

Warnings and information:

- (1) Warnings and information on packaging of button batteries shall:
 - a) be clearly visible on the exterior packaging and provided in the form of text and a safety symbol
 - b) alert consumers to the dangers of button batteries and to keep button batteries away from children
 - c) indicate what to do if it is suspected that a battery has been ingested or inserted, and provide contact details for the Australian PIC.
- (2) Warnings and information to be provided on a product that uses button batteries shall:
 - a) be clearly visible on the product (where practicable) and provided in the form of text and a safety symbol
 - b) alert consumers that button batteries are included with, or are required to operate, the consumer good (or any included peripheral device)
 - c) alert consumers to the dangers of button batteries and that these are hazardous to children.
- (3) Warnings and information on the packaging and instructions of a consumer good that uses button batteries shall:
 - a) be clearly visible on the exterior packaging and instructions, and provided in the form of text and a safety symbol

- b) alert consumers that button batteries are included with, or are required to operate, the consumer good (or any included peripheral device)
- c) alert consumers to the dangers of button batteries and that these are hazardous to children
- d) provide clear directions on what to do if it is suspected that a battery has been ingested or inserted and provide contact details for the Australian PIC.
- (4) Warnings and information to be provided at the point of sale (and prior to purchase) shall:
 - a) be consistent with warnings and information provided on the packaging and instructions of a consumer good that uses button batteries
 - b) be made available for all button batteries and consumer goods that use button batteries sold online
 - c) be made available for unpackaged consumer goods that use button batteries that are supplied to consumers.

The ACCC considers that regulation targeted at improving button battery safety is essential to ensure that manufacturing and design changes are implemented and that improved safety information is provided to consumers. These changes are likely to protect Australian children from avoidable severe injuries and death.

The ACCC considers that Option 3 is likely to prevent more deaths and severe injuries than all of the other options by reducing incidents of child exposure to button batteries. It also best addresses information asymmetry by improving consumer awareness of the hazard and directing appropriate action when an incident occurs.

Questions for response

- 1. The ACCC considers the status quo and proposes three options to improve the safety of button batteries. Which is your preferred option and why do you prefer it to the others?
- 2. What effect do you believe each of the proposed options will have in saving lives and reducing severe injuries caused by button batteries?
- 3. Provide comment on the ACCC's essential requirements for secure battery compartments, child-resistant packaging and warnings and information. Are there any additional requirements that should be included?
- 4. In relation to the requirement for secure battery compartments in which button batteries are only accessible with the use of a tool, do you consider that the use of a 'tool' should include the use of a coin? Why/why not?
- 5. Do you supply products that currently meet the essential requirements for secure battery compartments, child-resistant packaging and warnings and information? If not, which requirements do your products not meet?
- 6. Provide comment on the ACCC's proposed information standard for warnings and information to be made available at point of sale. Are there any additional requirements that should be included for products sold online, or for unpackaged products supplied to consumers?
- 7. If you are a manufacturer, importer, distributor or retailer of button batteries or consumer goods that contain button batteries, what impact will these options have on your business?

5.2 What exemptions are being considered?

The Minister responsible for product safety has discretion to exempt goods from a mandatory standard where the Minister considers it appropriate.

The Minister may consider including in any mandatory standard an exemption for hearing aid devices and zinc air batteries intended for hearing aid devices.

Stakeholder feedback on hearing aid devices and zinc air batteries

A number of submissions from hearing aid manufacturers and industry associations raised concerns about the implications of a mandatory requirement for secure battery compartments on hearing aid devices. The main points raised included the following:

- Hearing aids do not pose the same risk as other products because of their exclusive use of zinc air batteries which have a lower risk profile relative to other button battery types. Zinc air button batteries pose a low risk because they are typically smaller, have a lower voltage and are chemically different to button batteries implicated in severe injuries and death.
- Zinc air batteries require access to air (oxygen) to produce a current and when ingested do not establish an electric current as other batteries may. This lower risk profile needs to be weighed against the clinical and therapeutic benefits of hearing aids.
- Hearing aid batteries need to be changed approximately once per week and hearing aids need to be designed to ensure they can be independently managed by elderly users—the average age of a hearing aid user in Australia is 78 years.
- A mandatory requirement for a secure battery compartment would make independent management of hearing aid battery changes virtually impossible for many users (particularly for elderly users with vision impairment and/or poor dexterity) and the likely result would be that many users would stop using their hearing aids because of difficulties with changing the batteries.
- The economic and social costs of mandating this requirement for hearing aids and hearing devices would far outweigh the safety benefit achieved by including them in the mandatory standard.
- Technological developments will increase the availability of hearing aids with rechargeable batteries although this remains some years away.

Similar to the concerns detailed above in relation to secure battery compartments for hearing aid devices, concerns have been raised about child-resistant packaging for hearing aid batteries. Several submissions from hearing aid manufacturers and industry associations raised concerns that a requirement for child-resistant packaging on zinc air hearing aid batteries could negatively affect hearing aid users because of the poor eyesight and limited dexterity of many elderly users.

Submissions from health professionals observed that smaller batteries such as zinc air batteries are more usually implicated in insertions (as such batteries tend not to get lodged in the oesophagus when ingested). Severe injuries can still occur from insertions of button batteries, including permanent hearing loss, facial nerve palsies and nasal deformities. Health professionals also suggest it is unclear whether zinc air batteries pose a significant risk of tissue destruction when lodged for prolonged periods in the oesophagus, which is not an anoxic (no oxygen) environment.

Evidence supporting the exemption

Hearing aids and other hearing devices commonly used by consumers meet the broad definition of a consumer good under the ACL. These products are also subject to regulatory control by the specialist regulator the TGA. Medical devices such as hearing aids are assessed by the TGA and must be included on the Australian Register of Therapeutic Goods before they may be supplied in Australia. The TGA approves and regulates products based on an assessment of risks against benefits. The Therapeutic Goods (Medical Devices) Regulations 2002 contain 'essential principles' of quality and safety which apply to medical devices including hearing aids and are monitored by the TGA.

It is estimated that in Australia, 3.6 million people are affected by some sort of hearing impairment with the majority (75 per cent) of those affected being over 60 years of age. A report by Deloitte Access Economics estimated that the total cost of hearing loss in Australia in 2017 was \$33.3 billion. This includes financial costs as well as the value of lost wellbeing.⁷⁶

Hearing aids are designed to be fit for purpose for the intended consumer. It is estimated that the average hearing aid user in Australia is 78 years of age and hearing aids are generally designed to be independently managed by this consumer demographic. A mandatory requirement for hearing aids to include a secure battery compartment would significantly reduce the usability and accessibility of the devices for these consumers, especially those with poor dexterity or vision impairment.

Hearing impairment can reduce an individual's ability to communicate and participate in social situations and can affect a person's education and employment opportunities. Communication problems can lead to mental health issues which can then lead to or exacerbate physical conditions. Studies have also shown that there is an association between hearing loss and increased mortality rates.⁷⁷

Government responsibility for hearing services and issues in this sector sits across multiple Commonwealth and state and territory agencies including disability services, indigenous affairs, mental health, education, employment, innovation, criminal justice, communications, infrastructure and social inclusion portfolios. To manage this complexity, a Roadmap for Hearing Health was developed and published in February 2019. The roadmap seeks to 'foster collaboration between stakeholders in agreeing priorities and aspirations addressing the challenges facing an estimated 3.6 million Australians who experience some form of hearing impairment'.⁷⁸

The Department of Health is responsible for managing and administering the Australian Government Hearing Services Program (HSP). This program aims to reduce the incidence and consequences of avoidable hearing loss in the Australian community by providing access to high-quality hearing services and devices. This program provides vouchers to eligible people, which allows them to purchase a hearing aid and have the cost refunded by the government.

The HSP accounts for a majority share of the Australian hearing services market, estimated to be approximately 68 per cent of the measurable market in the 2015–16 financial year.⁷⁹ The program includes two schedules for hearing aid devices, one being a partially subsidised schedule and the second a fully subsidised schedule of approved devices. There are currently no devices available on the fully subsidised schedule that include a fully enclosed rechargeable battery. The devices on the partially subsidised schedule have additional features, some of which include a rechargeable battery option at significant additional cost. In financial year 2018–19, 398 874 hearing devices were provided as part of the HSP.⁸⁰

Leading hearing aid manufacturers estimate that around 15 per cent of hearing aids currently available in the Australian marketplace include a fully enclosed rechargeable battery. The rechargeable hearing aid technology is currently only available for specific devices. The rechargeable devices use lithium-ion rechargeable technology which is comparatively more expensive to manufacture and supply into the Australia market. The other 85 per cent of devices require replaceable zinc air batteries to operate. The battery compartment of these devices is designed to be easily accessible so that the user is able to independently manage the device. It is likely that technological developments will increase the availability of rechargeable hearing aids and significantly reduce the reliance on replaceable button batteries in the longer term.

⁷⁶ Deloitte Access Economics: An Update of the Social and Economic Cost of Hearing Loss and Hearing Health Conditions in Australia, July 2017.

⁷⁷ ibid.

⁷⁸ Department of Health, Roadmap for Hearing Health—Supporting all Australians who are deaf or hard of hearing to live well in the community, February 2019.

⁷⁹ PwC Report Executive Summary, Australian Government Department of Health, <u>www.hearingservices.gov.au/wps/portal/</u> <u>hso/site/about/whoarewe/publications/pwc_report_executive_summary_html/</u>, viewed 5 November 2019.

⁸⁰ Annual Program Statistics 2018-2019, Australian Government Department of Health, <u>hearingservices.gov.au/wps/portal/</u> <u>hso/site/about/program_stats/annual-program-stats/annual-stats-2018-2019</u>, viewed 5 November 2019.

Many of the major hearing aid manufacturers have advised that hearing aids designed and intended for use by children incorporate a tamper-resistant battery compartment that requires a tool to remove the battery. This is in line with the current international standard IEC 60601: Medical electrical equipment—Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems, which applies to instruments intended for use by infants under 36 months. This solution is not suitable for geriatric patients because of their need to independently manage their devices.

Assessment of the exemption

The ACCC considers that in implementing a mandatory safety standard, the following exemptions are appropriate:

- an exemption from the secure battery compartment requirement for hearing aid devices that use button batteries that are intended to be replaced
- an exemption from child-resistant packaging requirements for zinc air batteries intended for hearing aid devices (that is, zinc air batteries that are packaged in a dial mechanism for accessibility by hearing aid users).

The ACCC considers that hearing aid devices and zinc air batteries intended for hearing aid devices should be subject to the warnings and information requirements outlined in Option 3.

As an alternative to the above exemptions, a broader exemption could be applied to zinc air batteries, the type of battery exclusively used in hearing aids. This broader exemption would exclude zinc air batteries from secure battery compartment requirements as well as child-resistant packaging requirements.

The ACCC's preliminary view is that it is preferable to apply a narrower exemption which exempts only hearing aid devices from the secure battery compartment requirement and zinc air batteries intended for hearing aid devices from the child-resistant packaging requirement.

The data available from the Australian PIC and the US National Battery Ingestion Hotline indicates that hearing aids are the most common source of batteries involved in paediatric ingestions. Despite this, zinc air batteries are not represented in the injury data. This may be because of their smaller size and lower voltage, and because they require access to oxygen to create a charge. While these batteries have a lower risk profile in comparison with other chemistry types, their smaller size predisposes them to be inserted into body orifices such as the ear and nose where oxygen is available and they can cause tissue damage. For the reasons outlined above, it appears appropriate to limit an exemption to hearing aid devices and zinc air batteries intended for hearing aid devices, while still requiring other products that use zinc air button batteries to be subject to the requirements of a mandatory safety standard.

The ACCC considers that hearing aid devices should be exempt from a secure battery compartment requirement and zinc air batteries intended for hearing aid devices should be exempt from child-resistant packaging requirements. The economic and social costs of mandating these requirements for hearing aids and zinc air batteries intended for hearing aid devices would outweigh the safety benefit achieved by including them in the mandatory standard.

The ACCC strongly encourages measures to improve the safety of hearing aids, including an increased adoption of hearing aids that include a fully enclosed rechargeable battery.

Questions for response

- 8. Do you agree with the proposed exemption for hearing aid devices and associated zinc air batteries? Why/why not?
- 9. Do you consider that any other categories of consumer goods should be exempt from any of the proposed requirements? Do you have information and data you can provide to the ACCC in support of your view?

6. Impacts of the options (costs and benefits)

This section sets out the estimated regulatory cost impacts of each of the policy options under consideration. A cost-benefit analysis is undertaken to assess the net economic impacts of the policy options. The cost-benefit analysis compares the base case (take no action) against the net benefit of each policy option.

Introducing safety regulations can provide a range of benefits that can be hard to measure, including avoiding the loss of life. In undertaking a cost-benefit analysis of each policy option to improve button battery safety, it is important to highlight that not all factors or impacts can be readily quantified or reduced to a monetary amount.

The true total costs of fatalities and severe injuries to children that have resulted from button batteries are impossible to quantify. As recognised by the OECD⁸¹ and the National Research Centre for OHS Regulation⁸², strict cost-benefit analysis focused on quantitatively derived estimates can narrowly define economic impacts and ignore other significant effects. To address this, the ACCC's analysis of costs associated with button battery incidents includes both quantitative and qualitative considerations.

There are wide-ranging and long-term costs faced by families as well as the government following the death of a child. These costs are important factors in considering the effect of introducing safety regulations to address the hazard of button batteries. Data is not available to project these costs into the future for the purposes of a quantitative analysis.

Data is also not available to conduct a full quantitative analysis in other respects—particularly in estimating costs to industry. Given the uncertainty of future costs, and the impact each regulatory option will have, a range of costs and benefits are presented to demonstrate a range of possible outcomes for each option. See **appendix D** for details of the methodology used to arrive at the figures presented below.

⁸¹ OECD Regulatory Policy Outlook 2018.

⁸² Hopkins, 'The Cost-Benefit Hurdle for Safety Case Regulation', January 2014.

Social impact and economic costs to families following the death of a child

Losing a child has been classified as one of the most extreme stressors a human can face.⁸³

While no economic analysis can account for the devastating impact of losing a child, it is important to highlight the wide-ranging and long-term costs that can be faced by families following a button battery-related fatality.

The Compassionate Friends (Victoria) commissioned a study to measure the economic cost and social impact to families following the death of a child.⁸⁴ The findings include the following:

- There are significant unbudgeted expenses that many families experience considerable difficulty in meeting following the death of a child, including funeral and burial costs.
- Ongoing medical expenses are also commonly borne by families following the death of a child for a number of years, including mental and psychological health-related expenses.
- Substantial and persistent financial costs include a loss of income from employment. This can arise form premature retirement, premature resignation, voluntary or involuntary demotion, leave without pay, absences and selling or leaving a business. The most common impact of the death of a child on employment involves parents taking leave without pay, often after exhausting other forms of leave. In many cases, parents choose or are forced to resign from their employment following the death of a child.

In Australia, coronial inquests have occurred following the deaths of Summer Steer and Isabella Rees. Coronial inquests result in substantial costs, including legal expenses and representation, which are borne both directly by families, as well as funded by government.

The loss of a child has strong effects on the economic wellbeing of parents in subsequent years, including the likelihood of reduced family income, increased unemployment, increased likelihood of divorce and reduced mental health.85 Reduced health, income and employment as well as family breakdown typically result in a range of costs that are borne by families as well as the government.

It is estimated that the financial loss faced by one bereaved Australian family following the death of their child after ingesting a button battery amounts to approximately \$3.6 million, based on immediate and long-term costs including reduced employment and loss of future income, legal fees including coronial inquest-related expenses, funeral expenses and ongoing medical and mental health counselling expenses.

6.1 Maintaining the status quo (take no action)

No additional regulatory costs would be imposed on battery manufacturers or retailers and passed on to consumers and no restrictions would be placed on the supply of consumer goods that use button batteries if the status quo is maintained.

Industry safety initiatives may be adopted on a voluntary basis by suppliers. Manufacturers and retailers who have not already voluntarily adopted safer practices are not likely to do so. Unsafe products will continue to flow into the market and many more children and their families are likely to suffer significant harm or death as a result of button battery incidents.

Maintaining the status quo (taking no action) will result in button battery incidents continuing to occur at the current rate.

Table 15 shows the upper and lower estimates of the number of incidents estimated to occur during the forecast period, and health costs associated with those incidents. The ACCC will assess the net benefits of the three policy options against the base case of maintaining the status quo.

⁸³ American Psychiatric Association (1987), 'Diagnostic and Statistical Manual of Mental Disorders', 3rd ed, revised, Washington DC, American Psychiatric Press.

⁸⁴ Stebbins and Batrouney, The Compassionate Friends (Victoria), 'Beyond the death of a child', July 2007.

⁸⁵ Berg, Lundborg and Vikstrom, IZA Discussion Paper No. 7010, 'The Economics of Grief', November 2012.

Throughout this section, forecast incidents account for population growth and assume that emergency presentation, injury and fatality rates will remain constant on a per person basis. Economic costs are discounted at 10 per cent (lower estimate) and 3 per cent (upper estimate) discount rates with a base year of 2019 to account for uncertainty with respect to future costs. **Appendix D** provides detailed information about how the figures presented were calculated.

Table 15: Forecast button incidents and costs: 2020-2029⁸⁶

Incident category	Incidents forecast (2020–2029)	Cost (\$2019)
Emergency presentations	8609	\$3.5m-\$5.0m
Severe injuries	138-331	\$6.3m-\$21.0m
Fatalities	4	\$11.9m-\$20.4m
Ongoing severe injury costs		\$4.8m-\$16.0m
Total		\$26.4m-\$62.3m

If no government action is taken, it is estimated that four fatalities, 138 to 331 severe injuries and 8600 emergency presentations will occur during the forecast period of 2020–2029. Quantitatively derived estimates of the cost of these button battery incidents are in the range of \$26.4-\$62.3 million. The true total costs of fatalities and severe injuries to children that have resulted from button batteries are impossible to quantify.

No economic analysis can appropriately account for the devastating impact on a child, their parents, family, carers and medical staff when a serious button battery incident occurs.

The costs identified above do not account for factors such as emotional distress, long-term psychological impacts and disruptions to family life and employment.

6.2 Benefits and costs of Option 1: Mandatory safety standard that includes secure battery compartment requirements

Option 1 is to make a mandatory safety standard that includes secure battery compartment requirements for consumer goods that use button batteries.

Under this option, subject to limited exemptions, secure battery compartment requirements would apply for all consumer goods that use button batteries, regardless of the size or chemistry of the button battery suitable for the product.

Suppliers of consumer goods that use button batteries that are intended to be replaced would be required to ensure their products have a battery compartment that is secured by screw or similar fastener, such that batteries are only accessible with the use of a tool.

Suppliers of consumer goods that use button batteries that are not intended to be replaced would be required to ensure that batteries are fully secured inside the product and not accessible under normal use or foreseeable abuse.

Estimated impact

Suppliers are currently only required to comply with the mandatory standard for toys for children up to and including 36 months of age, which are the only products that are currently required to have secure battery compartments. This captures only a small proportion of the wide variety of household products that young children play with and can access that use button batteries.

⁸⁶ See appendix D for detailed information about how the figures presented in this section were calculated.

To comply with the requirements in the existing mandatory standard for toys for children up to and including 36 months of age, suppliers have redesigned their products that use button batteries to have a secure battery compartment.

Another manufacturing option available to suppliers is to use alternative batteries to power the device such as larger batteries that do not pose the same risk to children or fully enclosed rechargeable batteries. It is likely that these changes would cost significantly more than the redesign costs discussed above.

The economic benefits associated with introducing a requirement for secure battery compartments on products that use button batteries will begin to accrue once products that do not have button batteries secured in a battery compartment are replaced with products in which batteries are secured. These benefits will accrue in relation to products manufactured in the forecast period and to products manufactured after the forecast period.

Cost to industry

Under this option, manufacturers and suppliers of consumer goods that use button batteries could opt to redesign their products and retool their production line to include a secure battery compartment, or where practicable to redesign products to include an alternative power source that does not include a button battery.

Costs to industry are expected to be minimal if sufficient time is allowed for transition.⁸⁷ In addition, the compliance cost of this requirement on suppliers that already comply with the industry code will be minimal.

Adopting Option 1 would require businesses that supply consumer goods that use button batteries in Australia to:

- implement design and manufacturing changes to consumer goods that have an unsecured button battery compartment, or
- stop selling certain product lines and source different products in which button batteries are in secure compartments.

Information provided to the ACCC by industry associations indicates that there would be a modest cost—approximately \$3000 per product line or 10c per unit—to transition a product to comply with Option 1. The ACCC notes that there are a wide variety of products that use button batteries on the market, and that these costs are likely to vary between product types. In some cases, it may not be economical to implement manufacturing changes for a particular product line. This is likely to be the case only for very low-value items—often novelty items.

Data is not available to identify how many product lines would be affected by the adoption of Option 1. Therefore, it is not possible to estimate the total cost of implementing the changes that this option would require.

Stakeholder feedback in response to the Issues Paper indicates that industry supports implementing a regulation that mandates a secure battery compartment for consumer goods that use button batteries.

⁸⁷ The ACCC expects there to be a transition period if any of options 1 to 3 are adopted. Because of uncertainty about when the transition period might finish, the ACCC adopted a forecast period of 2020–2029. In the event that there is a delay before the end of a transition period, a forecast period of 2021–2030 may be more suitable. However, the ACCC does not expect a later forecast period to have a significant impact on the costs and benefits forecast.

Submissions also indicate that the cost of compliance with Option 1 would be 'minimal'⁸⁸, not 'unduly burdensome'⁸⁹ or only significant for 'irresponsible suppliers'⁹⁰ if sufficient time is allowed to transition⁹¹ and compliance with relevant existing voluntary standards is acceptable.⁹²

In addition to costs associated with changes to manufacturing processes, the ACCC anticipates suppliers will incur costs associated with testing products for compliance with the new requirement. The exact combination of tests outlined in Option 1 is not currently offered by testing and certification companies. For products with removable batteries, we anticipate the cost of testing to be roughly equivalent to the cost of testing to AS/NZS 60065:2018 Audio, video and similar electronic apparatus—Safety requirements clauses 12.7.3–12.7.4. A leading testing and certification company advised the ACCC that this series of tests currently costs US\$650, which equates to about AUD\$960⁹³ per product line.

The ACCC is not aware of any testing labs in Australia that would be able to conduct the range of compliance testing outlined above. It is likely that, initially, products would need to be tested by overseas testing houses.

Cost to government

Costs to government are expected to be negligible with respect to Option 1 if an exemption is applied for hearing aid devices. In the event that Option 1 is adopted, surveillance and enforcement of compliance with the requirements will be subsumed into existing ACL regulator work streams. If this option is adopted, there will be minimal costs associated with consumer and industry awareness campaigns, but no significant ongoing costs are expected.

Cost related to hearing aid devices (if no exemption is applied)

The costs of Option 1 to industry, government and users of hearing aid devices are substantially higher should a secure battery compartment requirement apply to hearing aid devices.

The average age of hearing aid users in Australia is 78. Hearing aid batteries generally require changing about once per week. The ACCC has been advised that because of the degree of miniaturisation in hearing aids, it would be very difficult to design acceptably small hearing aids that secure batteries with a screw. Design challenges aside, it would still be impractical for hearing aids to have batteries secured with a screw given the dexterity required to open a secure battery compartment on such a small device, the age of many hearing aid users, and the frequency with which batteries need to be changed.

Were Option 1 to apply to hearing aids, the only practical course of action for hearing aid suppliers would be the sale of hearing aids with fully enclosed, rechargeable batteries. Currently, only about 15 per cent of hearing aids on the market use this technology. None of the devices fully subsidised by the HSP use fully enclosed, rechargeable batteries. Hearing aids with this newer technology are much more expensive. The adoption of Option 1 with respect to hearing aids would result in significant costs to industry, consumers and government.

Benefits

This requirement will help to reduce the number and cost of button battery-related exposures, injuries and fatalities as older, unsafe products are replaced or discarded.

⁸⁸ Infant and Nursery Products Alliance of Australia and Kmart submissions to ACCC Button Battery Safety Issues Paper https://consultation.accc.gov.au/product-safety/button-battery-safety-issues-paper/consultation/view_ respondent?uuld=398892754 https://consultation.accc.gov.au/product-safety/button-battery-safety-issues-paper/ consultation/view_respondent?uuld=576679785.

⁸⁹ Woolworths submission to ACCC Button Battery Safety Issues Paper <u>https://consultation.accc.gov.au/product-safety/</u> <u>button-battery-safety-issues-paper/consultation/view_respondent?uuld=621707741</u>.

⁹⁰ Catch.com.au Pty Ltd submission to ACCC Button Battery Safety Issues Paper <u>https://consultation.accc.gov.au/product-safety/button-battery-safety-issues-paper/consultation/view_respondent?uuld=950100591</u>.

⁹¹ Kmart submission to ACCC Button Battery Safety Issues Paper <u>https://consultation.accc.gov.au/product-safety/button-battery-safety-issues-paper/consultation/view_respondent?uuld=576679785</u>.

⁹² Australian Toy Association submission to ACCC Button Battery Safety Issues Paper <u>https://consultation.accc.gov.au/</u> product-safety/button-battery-safety-issues-paper/consultation/view_respondent?uuld=821241151.

^{93 6} February 2020 exchange rate. See: <u>www.rba.gov.au/statistics/frequency/exchange-rates.html</u>.

The voluntary industry code has been in place for over two years and some suppliers already meet the requirements outlined in that code. The compliance cost of this requirement on suppliers that already comply with the industry code will be minimal.

Mandating secure battery compartment requirements for consumer goods that use button batteries will enable compliance measures to be taken where products do not meet these safety requirements. Implementing a clear set of enforceable rules for all manufacturers and suppliers means that all suppliers will be required to meet the same requirements and the responsibility for reducing incidents is placed on all suppliers, not just those who voluntarily meet the requirements of the industry code or existing standards.

While there are a number of voluntary standards that include requirements for secure battery compartments for various products that use button batteries, these requirements are not consistent across all standards, do not capture the breadth of products available in the Australian market that use button batteries and are not readily and freely accessible, which further discourages compliance.

Results from market surveillance activities undertaken by the ACCC and state and territory ACL regulators indicate that the majority of products identified that did not comply with the voluntary industry code were purchased from discount variety stores.

It is likely that secure battery requirements as well as mandated compliance tests will remove many of these disposable novelty items from the Australian market.

In 62 per cent of button battery incidents, the button batteries are obtained from a consumer product.⁹⁴ Secure battery compartment requirements are therefore assumed to impact 62 per cent of current button battery incidents. The ACCC estimates that adopting Option 1 would result in an economic benefit of between \$9.6 million and \$32.1 million during the forecast period of 2020–2029.

Table 16 shows the button battery incidents that are estimated to be prevented and economic benefits if Option 1 is adopted.

Table 16: Opt	tion 1—forecast incide	ents prevented and	l economic benefit,	2020-2029
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Incident category	Incidents prevented (2020-2029)	Economic benefits (\$2019)
Emergency presentations	3196-5338	\$1.5 m-\$3.1 m
Severe injuries	63-205	\$2.5 m-\$13.0 m
Fatalities	2	\$4.8 m-\$12.6 m
Ongoing severe injury costs	_	\$0.8 m-\$3.3 m
Total		\$9.6 m-\$32.1 m

Net benefits of Option 1

Data is not available to calculate the total cost to industry of implementing Option 1. Therefore, it is not possible to quantify the total net benefit of implementing this option. However, consultation with industry suggests that a secure battery compartment requirement is unlikely to be unduly burdensome if phased in over an appropriate period, and this option is likely to prevent a significant number of severe injuries and fatalities.

⁹⁴ T Litovitz, N Whitaker, L Clark, 'Preventing Battery Ingestions: An analysis of 8648 Cases', *Pediatrics*, 2010.

6.3 Benefits and costs of Option 2: Mandatory safety standard that adopts requirements in Option 1 and includes child-resistant packaging requirements

Option 2 is to make a mandatory safety standard that adopts all requirements in Option 1, and includes a requirement for all button batteries available for sale or provided with consumer goods (where the battery is not pre-installed in a secure battery compartment) to be supplied in child-resistant packaging.

Under this option, subject to exemptions, child-resistant packaging would apply to all button batteries available for sale or provided with consumer goods, regardless of their size or chemistry.

Estimated impact

There is currently no requirement to supply button batteries in child-resistant packaging. Three major suppliers have introduced child-resistant packaging for lithium button batteries on a voluntary basis.

To comply with this option, suppliers would need to make all button batteries available for sale in child-resistant packaging. This would require suppliers to change their manufacturing processes which will involve costs associated with setting up manufacturing equipment and additional per unit costs because of the higher grade plastic required for child-resistant packaging.

Benefits

Adopting child-resistant packaging will reduce the risk of exposure and injury rates by preventing children from accessing button batteries direct from packaging. Further, the lack of consistency in child-resistant packaging creates confusion among consumers who may not be aware of the hazard of these products for children.

Improvements to packaging will likely reduce risk and injury rates. Batteries obtained from packaging account for approximately 8 per cent of button battery incidents.

The ACCC estimates that Option 2 would result in an economic benefit of \$11.2 million to \$35.9 million during the forecast period of 2020-2029.

Table 17 shows the button battery incidents that are estimated to be prevented if Option 2 is adopted.

Incident category	Incidents prevented (2020–2029)	Economic benefits (\$2019)
Emergency presentations	4557-5979	\$1.7m-\$3.4m
Severe injuries	73-230	\$3.0m-\$14.6m
Fatalities	2-3	\$5.7m-\$14.1m
Ongoing severe injury costs	-	\$0.9-\$3.8m
Total		\$11.2 m-\$35.9 m

Table 17: Option 2—forecast incidents prevented and economic benefit, 2020-2029

Cost to industry

In addition to the costs outlined in Option 1, introducing a requirement for child-resistant packaging may result in increased manufacturing costs for battery manufacturers. There may also be small additional costs to confirm the testing requirements are met. This increase in costs to manufacturers may be passed on to consumers. It is noted that some major suppliers are already meeting child-resistant packaging standards, so the impact on those suppliers should be minimal.

Suppliers that have transitioned button batteries to child-resistant packaging advised the ACCC that setup costs of about \$14 000 and an ongoing per unit price increase of \$0.10-\$0.15 can be expected.

Suppliers will also incur costs associated with testing for compliance with a new requirement. The ACCC has not received information about the cost of testing child-resistant packaging for compliance with a standard. Testing for compliance with IEC 60086-4:2019 Primary batteries—Part 4: Safety of lithium batteries (E.3) does not require any specialised equipment, so the cost of testing is not anticipated to be significant.

Cost to government

Costs to government are expected to be negligible with respect to the child-resistant packaging requirements in Option 2. In the event that Option 2 is adopted, surveillance and enforcement of compliance with the requirements will be subsumed into existing regulators' work streams. If this option is adopted, there will be minimal costs associated with consumer and industry awareness campaigns, but no significant ongoing costs are expected.

Cost related to hearing aid devices (if no exemption is applied)

The adoption of Option 2 including applying child-resistant packaging to zinc air batteries intended for hearing aid devices would result in costs to users of hearing aids. Elderly users of hearing aids with poor eyesight or limited dexterity may have difficulties accessing batteries in child-resistant packaging.

Zinc air batteries intended for hearing aid devices are packaged in a dial mechanism that requires the dial to be turned to allow a new battery to be released. The packaging has an open top slot at the back of the packaging card that allows the batteries to be dialled and easily released individually. This type of packaging is not child-resistant. Advice from industry suggests that this form of packaging allows aged users with dexterity issues to more easily access replacement batteries.

Net benefit of Option 2

Data is not available to calculate the total cost to industry of implementing Option 2. Therefore, it is not possible to quantify the total net benefit of implementing this option.

A set-up cost of about \$14 000 per manufacturer, a per-unit price increase of up to \$0.10-\$0.15 related to child-resistant packaging and minimal testing costs are expected to prevent two severe injuries, 104 hospital admissions and 702 non-admitted hospital presentations during the forecast period.

Overall, Option 2 is expected to prevent two to three fatalities, up to 249 severe injuries and reduce the burden on the health system.

6.4 Benefits and costs of Option 3: Make a mandatory safety and information standard that adopts requirements in Options 2 and 3 and includes warnings and information requirements

Option 3 is to make a mandatory safety standard and an information standard that includes all requirements in Options 2 and 3 and includes a requirement for warnings and information.

Under this option, warnings and information would be required on the packaging and instructions for all button batteries made available for sale as well as the packaging and instructions of consumer goods that use button batteries.

In addition, this option includes an information standard that would require warnings and information to be made available to consumers prior to purchase. This point-of-sale requirement would apply to all button batteries and consumer goods that use button batteries sold online, and for unpackaged consumer goods that use button batteries supplied to consumers.

Estimated impact

Suppliers of button batteries and consumer goods that use button batteries are not currently required to provide warnings and information on packaging or instructions, or make information available at point of sale about button battery safety.

To comply with Option 3, suppliers would need to make changes to the artwork on packaging, update instructions and implement processes to make information available to consumers at point of sale (for button batteries and consumer goods that use button batteries sold online, and for unpackaged consumer goods that use button batteries supplied to consumers).

The warnings and information requirements proposed in Option 3 go beyond voluntary international standards by requiring warnings and information to be provided in relation to all battery sizes and chemistries. This option also requires suppliers to include the contact details for the Australian PIC in their warnings and information.

Stakeholder feedback on this issue has been mixed. Some stakeholders are concerned that any divergence from international standards will result in significant costs, while others don't expect the cost to be significant assuming that the transition period is long enough to allow for changes to be implemented. Smaller suppliers may find it difficult to convince overseas manufacturers to implement Australian-specific labelling requirements which may necessitate the sourcing of alternative products.

Online suppliers of button batteries and consumer goods that use button batteries will be required to make available warnings and information about their products at point of sale and prior to purchase.

Suppliers that sell unpackaged consumer goods that use button batteries will be required to make available warnings and information about their products at point of sale and prior to purchase.

Over time, adoption of this option is expected to reduce the number and rate of button battery injuries among children and the overall burden of button battery injuries on Australian society.

This offset estimate does not include the costs imposed on the broader community or additional benefits needed to offset any increased compliance costs incurred by industry to meet mandated standards. This is because the extent of the impacts on the broader community and industry compliance costs is not yet known.

Cost to industry

Warning and information costs are in addition to the costs outlined in Option 2.

As the warning and information requirements proposed in Option 3 go beyond voluntary international standards, suppliers may encounter resistance from overseas manufacturers to apply Australian-specific requirements that are inconsistent with other markets.

However, there is currently significant inconsistency in warnings and information provided on the packaging of button batteries and consumer goods that use button batteries.

In addition, a number of Australian retailers and distributors have already implemented changes to comply with the warning requirements detailed in the voluntary industry code. These changes have been implemented gradually over a period of time.

It has been generally noted, however, that Australian-based suppliers and distributors support increasing consumer understanding of the hazards of button batteries and reducing the risk of injury and death and that this can be achieved through improving the warnings and information on packaging and instructions.

Raising awareness of the need to contact the Australian PIC to quickly facilitate the most appropriate care is seen as essential by stakeholders in the health industry.

Cost to government

Cost to government is expected to be negligible with respect to the warnings and information requirements in Option 3. In the event that Option 3 is adopted, surveillance and enforcement of compliance with the requirements will be subsumed into existing regulator work streams. If this option is adopted, there will be minimal costs associated with consumer and industry awareness campaigns, but no significant ongoing costs are expected.

Benefits

The inclusion of warnings and information for all button batteries and consumer goods that use button batteries, irrespective of chemistry or size, will ensure that consumers are alerted to the hazards associated with these products. Consistent warnings and safety symbols will ensure that consumers can readily understand the messages and that they are effective in communicating actions to be taken. IEC 60086-4 provides clear warnings, and details the appropriate action to take if ingestion occurs. The key messaging contained within this standard is consistent with the industry code. The use of both the safety symbol and wording will aid low-literacy users.

A key aspect of the proposed warnings and information requirement is publication of the PIC hotline number. PIC hotline calls are handled by experts who provide accurate, timely advice in emergency situations. Ingested button batteries can burn through tissue and cause catastrophic bleeding in as little as two hours. The quicker a button battery incident is properly assessed, investigated and treated, the better the outcome is likely to be. The expert advice provided by staff at the PIC hotline is crucial to promptly determining the best course of action and reducing button battery injury severity.

Loose batteries account for 30 per cent of button battery incidents.⁹⁵ This analysis assumes that warnings will impact incidents resulting from loose batteries. In combination with targeted education campaigns, warnings will increase consumer awareness of the risks associated with button batteries. Increased awareness is likely to reduce the number of incidents associated with loose batteries. A range of possible outcomes has been calculated to demonstrate the possible benefits resulting from Option 3 being implemented.

The ACCC estimates that Option 3 will result in an economic benefit of \$13.5 million-\$46.2 million during the forecast period of 2020-2029.

Table 18 outlines the number of incidents this option is likely to prevent.

Table 18:	Option 3—forecast incidents prevented and economic benefit, 2020-2029
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Incident category	Incidents prevented (2020-2029)	Economic benefits (\$2019)	
Emergency presentations	5412-7689	\$2.1m-\$4.4m	
Severe injuries	87-295	\$3.6m-\$18.8m	
Fatalities	3-4	\$6.8m-\$18.2m	
Ongoing severe injury costs	-	\$1.0m-\$4.8m	
Total		\$13.5 m-\$46.2m	

Net benefit of Option 3

Data is not available to calculate the total cost to industry of implementing Option 3. Therefore, it is not possible to calculate a dollar figure for the total net benefit of implementing this option.

Requiring warning labels and information be provided on products and at the point of sale will carry a minor to moderate cost to industry and negligible cost to government.

Overall, Option 3 is expected to prevent as many as four fatalities, up to 320 severe injuries and thousands of emergency presentations over the forecast period from 2020 to 2029.

⁹⁵ ibid.

6.5 Summary of net benefit of Option 3

An integrated approach to button battery safety regulation will provide children with the highest degree of protection. Adopting all requirements in Option 3 is forecast to prevent a significant proportion of button battery incidents during the forecast period.

Incident category	Incidents prevented			
	Secure battery compartment requirements	Child-resistant packaging requirements	Warning and information requirements	Total (Option 3)
Fatalities	2	0	0-1	3-4
Severe injuries	63-205	10-25	14-66	87-295
Non-admitted presentations	3916-5338	641	855-1710	5412-7689
Forecast benefits (2020-2029)	\$9.6 m-\$32.1 m	\$1.6 m-\$3.8 m	\$2.3 m-\$10.3 m	\$13.5 m-\$46.2 m

Table 19: Incidents prevented and economic benefits—all options

It was not possible to determine the economic costs to industry associated with each button battery safety requirement option. While many products on the market use button batteries, the per-unit cost increase associated with each of the proposed options is small. Costs to government are expected to be minimal in respect of implementing each option.

Questions for response

- 10. What are the likely costs of implementing each of the requirements (design changes, child-resistant packaging, labelling), and what is the likely effect on sales and pricing to consumers?
- 11. Do you think that all potential costs to business have been considered? Can you provide any further information about likely costs/impacts of each of the options?

7. Recommended approach

7.1 Preliminary position

The ACCC recommends **Option 3** based on the available information as it is expected to prevent more deaths and severe injuries to children and reduce the burden on the health system to a greater extent than all of the other options. It also best addresses information asymmetry by improving consumer awareness of the hazard and providing information so that appropriate action can be taken if an incident occurs.

Over time, adoption of this preferred option is expected to reduce the number and rate of button battery injuries among children and reduce the overall burden of button battery injuries on Australian society.

As part of a holistic approach to mitigate the safety risks associated with button batteries, the ACCC notes that additional risk mitigation measures should be considered by relevant agencies such as national awareness-raising campaigns and further development of secure containers for the safe disposal of button batteries.

The ACCC considers that Australia could have a leading role in the development of button battery requirements globally, such as through the adoption of international standards. In recent years, the ACCC has led global product safety campaigns facilitated by the OECD. In the event that a mandatory standard for button batteries is introduced in Australia, the ACCC would propose to collaborate with the OECD and international standards bodies on the development of button battery requirements that can be adopted in other jurisdictions.

7.2 Implementation and review

Transition period

The ACCC considers that any new mandatory safety and/or information standard for button batteries and consumer goods that use button batteries be subject to a 12-month transition period from the date of commencement.

This transition period is expected to allow industry to implement any manufacturing and design changes to products and packaging and undertake any testing necessary to ensure compliance with a new mandatory safety and information standard. This transition period will also provide a period of time for industry to exit non-complying stock or source new stock that is compliant.

This transition period is considered a reasonable period of time given the wide range of consumer goods likely to be affected and noting that products that currently comply with the industry code would largely meet the requirements of the proposed mandatory safety and information standard.

Review of standard

The ACCC considers that a formal review of the operation of any new mandatory safety and/or information standard should be conducted at the end of five full years from the date of commencement.

Any review should consider levels of compliance with mandatory standards, changes in battery/product design and changes in the prevalence of button battery injuries and deaths.

Accessibility of requirements in a mandatory safety standard

Mandatory safety and information standards are often based on, or reference, voluntary national and international standards. Of the standards the ACCC administers, 25 of 40 mandatory safety standards, and one of three information standards are based on a voluntary standard developed or approved by Standards Australia, the national standards-setting body.

Copyright protections prevented the content of voluntary standards being replicated in relevant legislative instruments or in associated explanatory materials. At the same time, Australian Government policy encourages the use of Australian standards for regulatory purposes where such standards represent a minimum effective solution to the problem being addressed.

Because of copyright protections that exist for voluntary standards, the legislative instrument or associated explanatory materials for a mandatory safety standard are prevented from replicating the full text of requirements as contained in voluntary standards. Rather, the relevant clauses of voluntary standards incorporated into a mandatory safety standard are only referenced in the legislative instrument.

The ACCC continues to advocate for free and unfiltered access to voluntary standards that are referenced in legislated instruments. The ACCC considers that the text of a referenced clause from a voluntary standard should be replicated in relevant legislated instruments.⁹⁶

As a mandatory safety standard applicable to consumer goods that use button batteries would apply to a wide range of products, the ACCC proposes that a principles-based approach to the regulation of button batteries should be adopted. This approach would involve a mandatory standard that details a set of principles related to each requirement that can be applied across relevant product types.

This approach to a mandatory safety standard would seek to minimise referencing existing voluntary standards in a legislative instrument so that details of requirements are more readily accessible to manufacturers and retailers. This would also reduce the financial burden associated with the need to purchase voluntary standards referenced in any mandatory standard.

The ACCC's preliminary view is that a mandatory safety standard applicable to consumer goods that use button batteries should reference certain compliance tests contained in national and international voluntary standards. This is to ensure an acceptable level of safety flows from requirements for secure battery compartments and child-resistant packaging.

The ACCC would issue administrative guidance (or alternatively such guidance could be included in an Explanatory Memorandum) for any mandatory standard for button batteries which would provide further details on the interpretation of the principles related to each requirement and which would outline the relevant clauses of voluntary standards that are deemed to comply with each requirement.

Standards Australia's development of a horizontal standard on button batteries

In September 2019, following release of the Issues Paper, Standards Australia proposed to facilitate the development of a horizontal national standard for button batteries covering all products with button batteries.

A national standard facilitated by Standards Australia would be voluntary only and could potentially form a basis for an international standard in future.

While the ACCC supports the development of a horizontal standard for button batteries by Standards Australia, the ACCC will separately and independently continue its expedited regulatory impact assessment process to address the issue of button battery safety, as requested by the Minister.

⁹⁶ ACCC submission to Standards Australia's discussion paper on the Distribution and Licensing Policy Framework, 2019.

The ACCC will participate in the Technical Committee to be convened by Standards Australia to develop a voluntary horizontal standard. It is not clear that the requirements to be included in this voluntary horizontal standard will mirror the ACCC's recommended requirements to address button battery safety.

The ACCC considers that mandatory regulation is necessary to prevent deaths and severe injuries to children resulting from button batteries. The ACCC's recent evaluation of the impact of the National Strategy found that voluntary supplier self-regulation had not sufficiently reduced the risk of injury or death to children from exposure to button batteries.

Questions for response

- 12. Provide comment on the transition period for the proposed options.
- 13. Provide comment on the principles-based approach to a mandatory safety standard. A principles-based approach:
 - sets out safety principles that need to be met rather than specifying detailed standards
 - incorporates external instruments for compliance tests only
 - includes administrative guidance which provides examples of relevant clauses in external standards that are considered to comply with each requirement.

8. Next steps

This consultation paper identifies the policy options that the ACCC is reviewing to develop a Final Recommendation to the Minister.

A consolidated list of questions is included at the beginning of this consultation paper, and repeated in relevant sections. The ACCC encourages you to respond to any or all of the questions and to raise any additional issues that you consider relevant.

Submissions will inform the ACCC's development of a Final Recommendation which will be provided to the Minister in 2020.

Question for response

14. Provide any additional information or data that you think may be useful to informing the ACCC's recommendation to the Minister.
Appendix A: Stakeholder submissions in response to ACCC Button Battery Issues Paper

- Australian Information Industry Association (AIIA)
- Australian Toy Association
- Baby Bunting Australia
- Battery Association of Japan
- Catch.com.au
- CHOICE
- Consumer Electronics Suppliers Association (CESA)
- Hearing Aid Manufacturers and Distributors Association of Australia (HAMADAA)
- Hearing Care Industry Association (HCIA)
- Infant & Nursery Products Alliance of Australia (INPAA)
- JB HiFI and The Good Guys
- Kmart
- Lighting Council of Australia
- National Electrical Manufacturers Association (NEMA)
- National Retailers Association (NRA)
- New South Wales Poisons Information Centre
- Precision Acoustics Victoria
- Product Safety Solutions
- Queensland Family & Child Commission
- Queensland Injury Surveillance Unit (Dr Ruth Barker with cosignatories)
- Sivantos
- South Australia Health, Biomedical Engineering
- South Australia Health, Department of Health & Wellbeing
- Super Retailer Group (SRG)
- Woolworths

Appendix B: International approaches and initiatives

United States

The United States has a record of button battery ingestion injuries in children dating back to at least 1977. Some of the prominent organisations involved in addressing the dangers of button batteries include the NCPC, the CPSC and the US Button Battery Taskforce.

The NCPC, based in Washington DC, has been at the forefront of addressing battery injury incidents since 1980 and has extensive button battery-related research, management and safety information available on its website.⁹⁷ NCPC data includes data from the NBIH, which was created to gather case data, create triage algorithms and identify methods to reduce the hazard. The NBIH also provides the public and healthcare providers with guidance on suspected battery ingestion cases. Management of the NBIH moved from the NCPC to the Rocky Mountain Poison & Drug Safety organisation in 2018.

The CPSC is an independent government agency responsible for regulating product safety in the US. The CPSC is heavily involved in promoting awareness of the dangers of button batteries. The CPSC collaborates with the US Button Battery Taskforce on initiatives to address the issue including the development of voluntary industry standards, research, education and awareness activities.

In 2011, a Button Cell Battery Safety Bill was introduced to Congress. The Bill included requirements for secure battery compartments and warnings on the packaging of button batteries and on products powered by button batteries. The Bill did not pass Congress.

The US Button Battery Taskforce was then established in 2012 as a collaborative effort of representatives from relevant organisations in industry, medicine, public health and government to develop, coordinate and implement strategies to reduce the incidence of button battery injuries in children. The US Button Battery Taskforce includes members of at least five American medical associations, and representatives from industry, government, poison control and public health. The US Button Battery Taskforce is open to anyone around the world to participate.

The US Button Battery Taskforce has conducted a range of research activities and collected injury and incident data from hospitals to build an evidence base to inform government and influence change in both the battery industry and medical practice.

The US Button Battery Taskforce has successfully worked with industry representatives and manufacturers to develop voluntary industry standards that include requirements for button batteries of lithium technology.

In 2017, the CPSC voted to approve the ASTM F963-17: Standard Consumer Safety Specification for Toy Safety (table 6) as a mandatory toy safety standard. The standard requires toys designed for children under 14 years of age to have warnings on packaging and instructions to alert consumers on the hazard of button batteries. The standard also includes new testing requirements for button batteries of 1.5 volts or more.

⁹⁷ NCPC 2019, Washington DC, <u>www.poison.org/</u>.

United Kingdom

The European Union has a General Product Safety Directive 2001/95/EC, which obliges suppliers to place only safe consumer goods into the market.⁹⁸ The General Product Safety Directive complements sector-specific legislation such as specific rules that apply to toys, electrical and electronic goods, cosmetics, chemicals and other specific product groups.

In the United Kingdom a number of young children have swallowed or choked on small button batteries and at least two children have died from button battery injuries.⁹⁹

In the UK, batteries in children's toys are covered by toy safety regulations and are required to be contained within secure battery compartments. Similar to Australia, a range of existing voluntary British Standards include requirements for button batteries for specific product types including electric toys, audio/video equipment and household and electrical appliances.

The Department for Business, Energy & Industrial Strategy and the UK Office for Product Safety and Standards are currently working with the British Standards Institute to develop a publicly available specification (PAS) that will include guidance to stakeholders on safe packaging, labelling, product design, use and disposal of button batteries. A PAS is similar to a voluntary standard in Australia. It is estimated that the PAS will take around 12 months to develop and may be adopted as a national standard following a two-year review.¹⁰⁰

New Zealand

In New Zealand, the government, industry and the medical profession are involved in dealing with the button battery hazard. The New Zealand Minister of Commerce and Consumer Affairs issued a product safety policy statement on button batteries in February 2018.¹⁰¹

The policy statement was developed to highlight the risks associated with button batteries in household goods and provide guidance to suppliers on how these risks can be mitigated. Suppliers are encouraged to voluntarily adopt the recommendations in the policy statement. The recommendations include that products containing button batteries, or supplied with button batteries, should:

- have a secure battery compartment
- be subject to use an abuse testing, and
- include warnings on packaging.

The statement also recommends that button batteries available for sale should be supplied in packaging that is child-resistant, and marked with warnings to alert consumers to the hazards of button batteries to children.

The safety criteria included in the policy statement are similar to those included in the industry code in Australia.

⁹⁸ European Commission, ec.europa.eu/info/general-product-safety-directive_en, viewed 29 January 2020.

⁹⁹ Child Accident Prevention Trust www.capt.org.uk/button-batteries, viewed 29 January 2020.

¹⁰⁰ Healthcare Safety Investigation Branch, Undetected button battery ingestion in children, <u>https://www.hsib.org.uk/</u> investigations-cases/undetected-button-battery-ingestion-children/, viewed 10 February 2020.

¹⁰¹ Ministry for Business Innovation and Employment 2018, NZ Government, Wellington, <u>www.consumerprotection.govt.nz/</u> assets/PDFs/Product-safety-policy-statement-Button-batteries-safer-products-and-packaging-FINAL-as-published-onwebsite-2018-02-02.pdf, viewed 29 January 2020.

Appendix C: Relevant standards considered

Standards considered

Secure battery requirements

AS/NZS 60335.1:2011 Household and similar electrical appliances

AS/NZS 3100:2017 General requirements for electrical equipment

AS/NZS 62115:2018 Electric toys—Safety

AS/NZS 60065:2018 Audio, video and similar electronic apparatus

ASTM F963-17 Standard Consumer Safety Specification for Toy Safety

AS/NSZ 60598.1:2017 Luminaires Part 1: General requirements and tests

IEC 62368-1:2018 Audio/video, information and communication technology equipment—Part 1: Safety requirements

IEC 60086-4:2019 Primary batteries—Part 4: Safety of lithium batteries

UL4200A:2015 Standard for Safety-Products Incorporating Button or Coin Cell Batteries of Lithium Technologies

Child Resistant Packaging

IEC 60086- 4:2019 Primary Batteries—Part 4: Safety of lithium batteries

USA:16 CFR §1700 Poison Prevention Packaging

EN 862: 2016 Packaging—Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products

AS5808: 2009 Child-resistant packing—Requirements and testing procedure for non-reclosable packages for non-pharmaceutical products

Warnings and Labelling

IEC 60086- 4:2019 Primary Batteries—Part 4: Safety of lithium batteries

AS/NZS 62115:2018 Electric toys—Safety

ASTM F963-17 Standard Consumer Safety Specification for Toy Safety

UL4200A:2015 Standard for Safety—Products Incorporating Button or Coin Cell Batteries of Lithium Technologies

AS/NZS 60065 Audio, video and similar electronic apparatus

IEC 62368-1:2018 Audio/video, information and communication technology equipment—Part 1: Safety requirements

AS/NSZ 60598.1:2017 Luminaires Part 1: General requirements and tests

Appendix D: Cost-benefit analysis methodology

This annexure sets out the methodology used to conduct the cost-benefit analysis referred to in section 6: Impacts of the options.

General notes and assumptions

Affected stakeholders

The main affected stakeholder groups are:

- manufacturers, distributors and retailers of button batteries
- manufacturers, distributors and retailers of products that use button/coin cell batteries
- health professionals and the healthcare system
- families and children exposed to button/coin cell batteries.

General assumptions

- The base year of the cost-benefit analysis is 2020 and the assessment is conducted over a 10-year period.
- Sensitivity analysis, using discount rates of 3 and 10 per cent¹⁰², have been used to forecast a range of possible costs associated with each option.
- Costs are in 2019 dollars except where another year is specified.
- 2019 is the base year for discounting.

Data availability

It was not possible to obtain data that allows for a quantitative analysis of all costs and benefits associated with each of the proposed regulatory options to address the hazard of button batteries.

Where possible, data from Australian sources has been used to determine costs associated with button battery exposures. The ACCC obtained data from a number of organisations tracking button battery ingestions and insertions. These organisations collect data from hospital emergency departments, medical specialists or calls to Poisons Information Centres. As there is no standardised dataset for button battery injuries, these organisations have collected different types and ranges of data.

Table D1: Data obtained from organisations tracking button battery exposures and injuries in Australia

Organisation	Time period the data covers	Coverage
Australian Paediatric Surveillance Unit (APSU)	Dec 2017-Jan 2019	National
Victorian Injury Surveillance Unit (VISU)	1999 to 2011	Victoria
	2013 to 2018	
Queensland Injury Surveillance Unit (QISU)	1999 to 2017	Queensland
Poisons Information Centres	2015 to 2018	National
Centre for Epidemiology and Evidence, NSW Ministry of Health (NSW Health)	2014 to 2018	New South Wales

¹⁰² Three per cent and 10 per cent are the lowest and highest discount rates recommended by OBPR to account for the uncertainty of future costs.

Australian sources provide a significant amount of information about button battery exposures. However, the two fatalities recorded in Australia do not provide data that allows for the calculation of expected future fatality rates. Fatality rates available in data from the United States are used in this analysis.

The United States NBIH statistics¹⁰³ provide the best insight into button battery injury and fatality rates of any available dataset. These statistics were compiled from calls to the hotline and through extensive follow-up with health professionals. The National Battery Ingestion Hotline dataset provides rates of ingestion, injury and fatality per capita from 1985 to 2017.¹⁰⁴ Given lifestyle and demographic similarities between Australia and the United States, the fatality rates published in this dataset are good proxies for those ratios in the Australian data.

The NBIH records information in relation to button battery ingestions but not insertions. Australian Poisons Information Centres record information in relation to ingestions and insertions. NBIH data has been applied in the Australian context despite this difference as it is likely to provide the most accurate fatality rates given the large sample size used to quantify the number of fatalities.

Estimating the cost of button battery incidents

Cost categories

Button battery incidents can cause a wide range of complications, and in extreme cases they can be fatal. Not all button battery ingestions and insertions result in complications, however diagnostic imaging is required for most incidents. The ACCC divided button battery incidents into three categories, as shown in table D2, to account for the degree of variability between cases. Costs are calculated separately for each category.

Costing category	Description	Sources	
Fatalities	Button battery ingestion or insertion incidents that result in a fatality.	NCPC, NSW PIC, ABS, PM&C.	
Severe injuries	Any child under 16 years of age with newly diagnosed injury related to disc or button battery ingestion or insertion that required procedural intervention either to remove the battery or to assess or repair damage related to the battery.	APSU, ABS	
Emergency presentations	Where a person presents at a hospital emergency department because of a button battery ingestion or insertion incident but is not admitted to hospital.	NSW Health, VISU, QISU, ABS, IHPA.	

Table D2: Button incident categories

Forecasting fatalities in Australia

Fatality rates from the United States NBIH were used to estimate fatality rates in Australia.

During the period of 2015-2017, an average of 3274 button battery ingestions were reported to the NBIH each year.¹⁰⁵ This equates to 0.001019 fatalities per reported incident.

¹⁰³ NCPC, Button Battery Ingestion Statistics.

¹⁰⁴ The NCPC advised the ACCC that it ceased operating the NBIH in mid-2018 and that information relating to button battery injuries on its website is complete only to the end of 2017.

¹⁰⁵ NCPC, Button Battery Ingestion Statistics.

During a similar three-year period (November 2015–October 2018), an average of 344 unintentional button battery incidents per year were reported to Australian Poisons Information Centres¹⁰⁶—a similar service to the NBIH.¹⁰⁷ This equates to 1.3985 reported incidents per 100 000 population annually.¹⁰⁸ Assuming the rate of fatalities to reported incidents is the same in Australia as it is in the United States, 0.0014251 fatalities per 100 000 population are expected to occur in Australia each year. Taking projected population into account, four button battery fatalities are expected to occur in Australia during the forecast period.

Year	Projected population	Fatalities per 100 000 population	Forecast fatalities
2020	25 936 500	0.001425	0.37
2021	26 402 046	0.001425	0.38
2022	26 873 947	0.001425	0.38
2023	27 349 900	0.001425	0.39
2024	27 829 520	0.001425	0.40
2025	28 311 405	0.001425	0.40
2026	28 796 151	0.001425	0.41
2027	29 283 507	0.001425	0.42
2028	29 773 492	0.001425	0.42
2029	30 264 147	0.001425	0.43
Total			4.00

Table D3:	Forecast Australian fatalities based on calls to Australian PICs and US fatality rates
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Source: NCPC, ABS, NSW Poisons Information Centre.

Cost of fatalities

The Office of Best Practice Regulation (OBPR) estimates the value of a statistical life (VSL) to be \$4.9 million in 2019 dollars.¹⁰⁹ This estimate is based on Abelson's willingness-to-pay calculations and assume a healthy person living for another 40 years.¹¹⁰

The age at death is known for 63 fatal button battery ingestions globally; the average age at death is 1.9 years.¹¹¹ For the period 2016–2018, life expectancy at birth was 80.73 years for males and 84.87 for females in Australia.¹¹² Using averages weighted by sex, 81.1 years of life are lost per button battery fatality.

¹⁰⁶ R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, 'Button battery exposures in Australia, November 2017—October 2018, prepared for the ACCC by NSW Poisons Information Centre.

¹⁰⁷ The NBIH records ingestion incidents only, whereas Australian Poisons Information Centres record ingestion and insertion incidents. Despite this difference, it is reasonable to apply NBIH injury rates in the Australian context given both incident types cause injury.

¹⁰⁸ Australian Bureau of Statistics, 2018, *Quarterly Population Estimates (ERP), by State/Territory, Sex and Age*, ABS.Stat Dataset, cat. no. 3101.0, <u>stat.data.abs.gov.au/Index.aspx?DatasetCode=POP_PROJ_2011#</u>, viewed 28 November 2019.

¹⁰⁹ Department of Prime Minister and Cabinet, Office of Best Practice Regulation, *Guidance note: Value of statistical life*, 2016, Canberra, <u>www.pmc.gov.au/sites/default/files/publications/value-of-statistical-life-guidance-note_0_0.pdf</u>, viewed 26 February 2020.

¹¹⁰ Abelson P., *Establishing a monetary value for lives saved: issues and controversies*. Canberra: Office of Best Practice Regulation, Department of Finance and Deregulation. Abgerufen am. 2008;5:2012.a.

¹¹¹ Labadie M, O'Mahony E, Capaldo L, Courtois A, Lamireau T, Nisse P, Blanc-Brisset I, Puskarczyk E. Severity of button batteries ingestions: data from French Poison Control Centres between 1999 and 2015. European journal of emergency medicine. 2018 Aug 1;25(4):e1-8.; National Capital Poison Center 2019. NCPC, Button Battery Ingestion Statistics.

¹¹² Australian Bureau of Statistics, 2019, *Life Tables*, States, Territories and Australia, 2016–2018, Data Cube, Table 1: Life tables, States, Territories and Australia - 2016-2018, cat. no. 3101.0, <u>www.abs.gov.au/AUSSTATS/abs@.nsf/</u> DetailsPage/3302.0.55.0012016-2018?OpenDocument, viewed 28 November 2019.

Given that the average number of years lost is more than twice that accounted for in the standard VSL calculation, it is reasonable to assume that costs associated with button battery fatalities may be higher than \$4.9 million per statistical life. An adjusted VSL was calculated to account for the very young age of children that have lost their life following ingestion of button batteries. The adjusted VSL, along with the standard VSL calculation, are used to demonstrate the range of possible costs associated with button battery fatalities.

The adjusted VSL was calculated using Abelson's VSL (\$3.5 million) and VLY (\$151 000) in 2007 dollars.¹¹³ A constant VLY was set and a discount rate of 3 per cent per year applied.¹¹⁴ Given an average of 81 years lost, the adjusted VSL equates to \$4.6 million (2007) or \$5.9 million (2019).¹¹⁵

Costs were discounted using the upper and lower rates recommended by the OBPR (3 per cent and 10 per cent) to account for uncertainty in future costs.¹¹⁶ As shown in table D4, costs associated with button battery fatalities are expected to be between \$11.9 million and \$20.4 million during the forecast period. The figures presented here are in 2019 dollars, which is the base year for discounting.

Calendar year	Cost of fatalities (10% discount rate, standard VSL)	Cost of fatalities (3% discount rate, adjusted VSL)
2020	\$1 646 461	\$2 148 612
2021	\$1 523 649	\$2 123 474
2022	\$1 409 893	\$2 098 474
2023	\$1 304 421	\$2 073 436
2024	\$1 206 633	\$2 048 347
2025	\$1 115 933	\$2 023 122
2026	\$1 031 854	\$1 997 826
2027	\$953 925	\$1 972 464
2028	\$881 715	\$1 947 057
2029	\$814 769	\$1 921 499
Total	\$11 889 253	\$20 354 312

Table D4: Forecast cost of fatalities in Australia

Source: NCPC, ABS, Department of Prime Minister and Cabinet, NSW Poisons Information Centre.

Forecasting severe injuries in Australia

The Australian Paediatric Surveillance Unit began its study, Severe Injury Related to Disc Battery (SIRDB), in December 2017. The study aims to develop a body of knowledge that will assist in formulating recommendations for the prevention of severe injuries related to button batteries. Among its objectives is to estimate the incidence of severe injuries related to button batteries in Australian children aged under 16 years. Severe injury cases are those involving a:

'disc or button battery ingestion or insertion that required procedural intervention either to remove the battery or to assess or repair damage related to the battery'.¹¹⁷

The study's Principal Investigator and Director of the QISU, Dr Ruth Barker, provided updates to the ACCC on the study's findings thus far (26 months of data). The rates of severe injury recorded in this study are used as the basis for estimating the rates of severe injury during the forecast period.

¹¹³ Abelson, 2008.

¹¹⁴ ibid.

¹¹⁵ Abelson, 2008; ABS *Consumer Price Index*; Australian Bureau of Statistics, 2018, Consumer Price Index, Australia, Sep 2019, 'TABLES 1 and 2. CPI: All Groups, Index Numbers and Percentage Changes ' time series spreadsheet, cat. no. 6401.0, <u>www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6401.0Sep%202019?OpenDocument</u>, viewed 19 November 2019.

¹¹⁶ Department of Prime Minister and Cabinet, *Guidance note*.

¹¹⁷ Australian Paediatric Surveillance Unit, *Study Protocol: Severe Injury Related to Disc Battery (SIRDB)*, 2017, Sydney, <u>www.apsu.org.au/assets/new-studies/SIRDB-APSU-Protocol-FINAL-V5.1.pdf</u>, viewed 26 February 2020.

The reported rate of severe injury is significantly higher in Queensland than in other jurisdictions. This is likely because Dr Barker ensures that all Queensland cases are reported to the study, whereas cases from other jurisdictions may not be reported. Dr Barker advised the ACCC that, in her view, the rate of severe injury recorded in Queensland is likely to be close to the actual rate of severe injury nationally.

Given the uncertainty with respect to the rate at which severe injuries occur in Australia, this analysis will test two possible severe injury rates: the national average rate as reported to the SIRDB study and the Queensland rate reported to the SIRDB study, extrapolated to the national population.

During the 26-month period the study covered, a total of 27 severe injuries have been reported from six jurisdictions. The number of severe injuries per 100 000 population was calculated using July 2019 population estimates.¹¹⁸

State	Severe injuries	Severe injuries per year	Population	Severe injuries per 100 000 population
Queensland	13	6.00	5 095 100	0.11776
New South Wales	6	2.77	8 089 526	0.034232
Victoria	4	1.85	6 594 804	0.027994
South Australia	2	0.92	1 751 693	0.052696
Australian Capital Territory	1	0.46	426 709	0.108162
Tasmania	1	0.46	534 281	0.086385
Northern Territory	0	0.00	245 869	0
Western Australia	0	0.00	2 621 680	0
National average				0.049139

Table D5:	Severe injuries per 100 000 population (Dec 2017-Jan 2019)
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Source: APSU, ABS Population Estimates.

Upper and lower estimates of the incidence of severe injuries during the forecast period were calculated by applying the rate of severe injury per 100 000 population to the projected national population¹¹⁹ for each year of the forecast period. Between 138 and 331 severe injuries are expected to occur during the forecast period.

¹¹⁸ July 2019 population estimate. See: Australian Bureau of Statistics, *Quarterly Population Estimates (ERP), by State/ Territory, Sex and Age.*

¹¹⁹ Australian Bureau of Statistics, 2018, *Projected population*, Australia, 2017-2066, ABS.Stat Dataset, cat. no. 3222.0, stat. data.abs.gov.au/Index.aspx?DatasetCode=POP_PROJ_2011, viewed 19 November 2019.

Year	Projected population	Severe injuries per 100 000 population	Forecast severe injuries (national rate)	Severe injuries per 100 000 population (Qld rate)	Forecast severe injuries (Qld rate)
2020	25936500	0.04914	12.74	0.11776	30.54
2021	26402046	0.04914	12.97	0.11776	31.09
2022	26873947	0.04914	13.21	0.11776	31.65
2023	27349900	0.04914	13.44	0.11776	32.21
2024	27829520	0.04914	13.68	0.11776	32.77
2025	28311405	0.04914	13.91	0.11776	33.34
2026	28796151	0.04914	14.15	0.11776	33.91
2027	29283507	0.04914	14.39	0.11776	34.48
2028	29773492	0.04914	14.63	0.11776	35.06
2029	30264147	0.04914	14.87	0.11776	35.64
Total			137.99		330.69

Table D6: Forecast severe injuries in Australia 2020-2029

Source: APSU, ABS Population Projections.

Cost of severe injuries

De-identified health cost information was made available to the ACCC in relation to 11 Queensland severe injury cases for the 2017-18 and 2018-19 financial years. The data provided represents direct costs related to severe button battery injuries and include surgical costs, admission costs, social work and child and youth mental health service support. Not all severe button battery injury cases are the same. Depending on a number of factors, one case may be more complex than another or require more frequent or intensive interventions. The costings provided to the ACCC represent a range of case types within the severe injury category of incident, allowing for average cost per incident to be calculated.

Table D7: Average cost per severe injury

APSU Case number	Battery location	Treatment cost
1	Oesophagus	\$85 364
2	Oesophagus	\$134 598
6	Oesophagus	\$267 723
8	Ear	\$15 108
9	Oesophagus	\$54 342
13	Oesophagus	\$38 432
17	Oesophagus	\$55 366
21	Oesophagus	\$123 522
23	Stomach	\$3 566
24	Oesophagus	\$20 135
31	Oesophagus	\$76 294
Average		\$79 495

In cases of severe button battery injury, significant health costs are incurred soon after the incident. However, health costs continue to accrue years after an incident. Dr Barker advised the ACCC that because of the nature of the injuries sustained in cases of severe button battery injury, ongoing observation and treatment is often required until adulthood. Of the 11 cases for which health cost data has been provided to the ACCC, five incidents occurred during the 2017-2018 financial year—two years of health cost data is available for those cases. To identify the proportion of costs which are likely to continue to accrue, treatment costs were grouped by date for each case as follows:

- Group 1: costs incurred with one year of an incident occurring
- Group 2: costs incurred more than one year, and within two years of an incident occurring.

On average, 94.2 per cent of health costs are incurred during the first year after an incident occurs and 5.79 per cent are incurred in the second year.¹²⁰

Given the proportion of costs incurred in the first and second years after an incident occurs and the overall average cost per severe injury, first-year health costs are estimated to be \$74 893 per severe injury. Allowing for uncertainty as to future costs and rates of injury, costs associated with severe injuries are estimated to total between \$6.3 million and \$21 million during the forecast period.

Calendar year	Cost per severe injury (2019\$)	Cost of severe injuries (national rate) (10% discount)	Cost of severe injuries (national rate) (3% discount)	Cost of severe injuries (Qld rate) (10% discount)	Cost of severe injuries (Qld rate) (3% discount)
2020	\$74 893	\$867 730	\$926 702	\$2 079 486	\$2 220 810
2021	\$74 893	\$803 004	\$915 860	\$1 924 374	\$2 194 827
2022	\$74 893	\$743 052	\$905 077	\$1 780 700	\$2 168 987
2023	\$74 893	\$687 465	\$894 278	\$1 647 488	\$2 143 108
2024	\$74 893	\$635 928	\$883 457	\$1 523 981	\$2 117 175
2025	\$74 893	\$588 127	\$872 577	\$1 409 427	\$2 091 102
2026	\$74 893	\$543 815	\$861 667	\$1 303 235	\$2 064 957
2027	\$74 893	\$502 745	\$850 729	\$1 204 811	\$2 038 743
2028	\$74 893	\$464 688	\$839 770	\$1 113 609	\$2 012 482
2029	\$74 893	\$429 405	\$828 747	\$1 029 056	\$1 986 065
Total		\$6 265 959	\$8 778 863	\$15 016 166	\$21 038 258

Table D8:	Forecast first	vear cost of se	wara injurias	2020-2020
Table Do.	Forecast first	year cost of se	evere injuries	2020-2029

Source: APSU, ABS Population Estimates, ABS Population Projections.

Severe injuries—ongoing costs

In addition to the expected \$74 893 first-year cost, a cost of \$4603 (in 2019 dollars) is expected to be incurred for each severe injury in the second year after the incident occurs and each subsequent year of the forecast period.

The average age at the time of injury in the SIRDB study is 3.04 years. Given Dr Barker's advice that severe injury patients require ongoing treatment until adulthood, this analysis assumes that first year costs are incurred in the fourth year of life. In each case, a cost of \$4603 is incurred in each of the fifth to eighteenth years of life (14 years). The rate of severe injury per 100 000 population is assumed to be constant in the 14 years preceding 2019 and during the 10 year forecast period. The number of severe injuries occurring in each year is calculated using annual estimated historical population or projected future population as appropriate. The number of cases incurring ongoing costs in a year is calculated from the cumulative number of severe injuries in the preceding 14 years.

¹²⁰ The five cases for which data is available from the 2017-18 and 2018-19 financial years occurred partway through the 2017-18 financial year. The proportion of costs incurred in the second year after an incident is likely to be understated because cost information is not available for a full second year for any case.

Year	Population	Severe injuries per 100 000 population	Severe injuries per year	Cumulative severe injuries requiring treatment (National rate)	Severe injuries per 100 000 population (Qld rate)	Severe injuries per year (QLD rate)	Cumulative severe injuries requiring treatment (QLD Rate)
2005	20 174 463	0.0491	9.91		0.1178	23.76	
2006	20 448 587	0.0491	10.05		0.1178	24.08	
2007	20 825 108	0.0491	10.23		0.1178	24.52	
2008	21 246 516	0.0491	10.44		0.1178	25.02	
2009	21 688 777	0.0491	10.66		0.1178	25.54	
2010	22 028 695	0.0491	10.82		0.1178	25.94	
2011	22 336 907	0.0491	10.98		0.1178	26.30	
2012	22 730 432	0.0491	11.17		0.1178	26.77	
2013	23 125 167	0.0491	11.36		0.1178	27.23	
2014	23 472 790	0.0491	11.53		0.1178	27.64	
2015	23 813 144	0.0491	11.70		0.1178	28.04	
2016	24 186 299	0.0491	11.88		0.1178	28.48	
2017	24 597 239	0.0491	12.09		0.1178	28.97	
2018	24 978 054	0.0491	12.27		0.1178	29.41	
2019	25 359 662	0.0491	12.46	155.11	0.1178	29.86	371.71
2020	25 936 500	0.0491	12.74	161.89	0.1178	30.54	377.82
2021	26 402 046	0.0491	12.97	169.23	0.1178	31.09	384.60
2022	26 873 947	0.0491	13.21	176.79	0.1178	31.65	391.61
2023	27 349 900	0.0491	13.44	184.48	0.1178	32.21	398.74
2024	27 829 520	0.0491	13.68	192.23	0.1178	32.77	405.92
2025	28 311 405	0.0491	13.91	200.03	0.1178	33.34	413.16
2026	28 796 151	0.0491	14.15	208.00	0.1178	33.91	420.55
2027	29 283 507	0.0491	14.39	216.18	0.1178	34.48	428.16
2028	29 773 492	0.0491	14.63	224.47	0.1178	35.06	435.88
2029	30 264 147	0.0491	14.87	232.88	0.1178	35.64	443.71

Table D9: Severe injury cases requiring ongoing treatment by year

Source: APSU, ABS Population Estimates, ABS Population Projections.

Allowing for uncertainty as to future costs and rates of injury, ongoing costs associated with severe injuries are estimated to be between \$4.8 million and \$16 million during the forecast period.

Year	Ongoing annual cost per severe injury (2019\$)	Ongoing cost of severe injuries (national rate) (10% discount)	Ongoing cost of severe injuries (national rate) (3% discount)	Ongoing cost of severe injuries (Qld rate) (10% discount)	Ongoing cost of severe injuries (Qld rate) (3% discount)
2020	\$4 603	\$659 690	\$704 523	\$1 580 924	\$1 688 366
2021	\$4 603	\$609 976	\$695 703	\$1 461 787	\$1 667 228
2022	\$4 603	\$564 000	\$686 983	\$1 351 608	\$1 646 332
2023	\$4 603	\$521 421	\$678 282	\$1 249 568	\$1 625 481
2024	\$4 603	\$481 969	\$669 571	\$1 155 024	\$1 604 606
2025	\$4 603	\$445 560	\$661 057	\$1 067 770	\$1 584 202
2026	\$4 603	\$411 989	\$652 790	\$987 318	\$1 564 390
2027	\$4 603	\$380 935	\$644 607	\$912 899	\$1 544 779
2028	\$4 603	\$352 212	\$636 507	\$844 065	\$1 525 369
2029	\$4 603	\$325 687	\$628 572	\$780 498	\$1 506 352
Total		\$4 753 439	\$6 658 595	\$11 391 462	\$15 957 104

Table D10: Forecast ongoing costs associated with severe injuries 2020-2029

Source: APSU, ABS Population Estimates, ABS Population Projections.

While every effort has been made to forecast the cost of severe injuries, we expect the figures outlined above to underestimate the actual cost associated with severe injuries. An example of costs not accounted for in this analysis is the cost of emergency transport for a patient to a hospital that has appropriate facilities to treat a serious button battery incident. While the ACCC had insufficient data to forecast emergency transport costs, we are aware of one case where transporting a child from a remote location cost in excess of \$38,000 and two cases where transport costs were about \$10,000.

Forecasting emergency presentations in Australia

New South Wales Health, the VISU and the QISU provided the ACCC with data relating to button battery emergency department presentations. The most recent data available from each of these jurisdictions is for 2017.

Records are stored and queried differently in each jurisdiction. The relevant agency in each jurisdiction queried a database of emergency department records drawn from participating public hospitals as follows:

- New South Wales: 66 public hospitals accounting for about 85 per cent of state-wide emergency department activity
- Victoria: all 38 public hospitals with 24-hour emergency departments
- Queensland: nine Hospital and Health Service areas (including metropolitan and regional areas) representing 20–25 per cent of state-wide emergency department activity.

On this basis, the ACCC assumed that the following proportions of incidents are accounted for in the data provided and extrapolated accordingly to estimate the number of presentations in each jurisdiction:

- New South Wales: 85 per cent
- Victoria: 100 per cent
- Queensland: 25 per cent.

Cases where an emergency presentation is admitted to hospital are excluded from this category of the analysis because those costs are considered to be accounted for in the severe injuries category. The proportion of non-admitted emergency presentations by jurisdiction is as follows:

- New South Wales: 91 per cent
- Victoria: 86 per cent
- Queensland: 80 per cent.

Table D11: Non-admitted emergency presentations per 100 000 population (2017)

State	Population	Presentations	Proportion of ED activity represented	Proportion not admitted	Estimated Non-admitted presentations	Estimated non-admitted presentations per 100 000 population
New South Wales	7 86 7936	263	0.85	0.91	281.56	3.58
Queensland	4 927 629	51	0.25	0.80	162.63	3.30
Victoria	6 321 606	165	1	0.86	141.90	2.24
Total	19 117 171				586.09	3.07

Assuming that the rate of emergency presentations to population remains constant, 8609 non-admitted emergency presentations are expected to occur during the forecast period.

Year	Projected population	Forecast non-admitted per 100 000	Forecast number of ED presentations
2020	25936500	3.07	795
2021	26402046	3.07	809
2022	26873947	3.07	824
2023	27349900	3.07	838
2024	27829520	3.07	853
2025	28311405	3.07	868
2026	28796151	3.07	883
2027	29283507	3.07	898
2028	29773492	3.07	913
2029	30264147	3.07	928
Total			8609

Table D12: Forecast emergency presentations in Australia 2020-2029

Source: Queensland Injury Surveillance Unit, Victorian Injury Surveillance Unit, NSW Health, ABS Population Projections.

Cost of emergency presentations

In 2017, non-admitted emergency presentations cost \$553 on average.¹²¹ Independent Hospital Pricing Authority reports indicate that the cost per non-admitted emergency presentation rose consistently between 2009 and 2017.¹²² While the cost per presentation is unlikely to continue to grow indefinitely, this analysis assumes that cost per presentation will continue to grow at the rate of 3 per cent per year during the forecast period.

Discounting to account for the uncertainty of future costs, non-admitted button battery-related emergency presentations are estimated to cost between \$3.5 million and \$5 million during the forecast period.

Year	Forecast cost per non-admitted presentation	Cost of ED presentations (10% discount)	Cost of ED presentations (3% discount)
2020	\$604	\$436 279	\$465 929
2021	\$621	\$415 107	\$473 446
2022	\$638	\$394 636	\$480 688
2023	\$655	\$374 848	\$487 615
2024	\$672	\$355 751	\$494 224
2025	\$689	\$337 338	\$500 493
2026	\$706	\$319 622	\$506 436
2027	\$723	\$302 601	\$512 053
2028	\$740	\$286 275	\$517 348
2029	\$757	\$270 619	\$522 291
Total		\$3 493 075	\$4 960 522

Source: ABS Population estimates, NSW Health, VISU, QISU, IHPA.

Poisons Information Centre costs

Poisons Information Centres provide specialist information and advice in the event of a button battery incident. The New South Wales Poisons Information Centre advised the ACCC that a cost of \$100-\$120 is incurred for each button battery-related contact.

Poisons Information Centres handle about 200 000 contacts per year from healthcare professionals and the public.¹²³ An average of 344 unintentional button battery incidents per year were reported to Australian Poisons Information Centres between November 2017 and October 2018.¹²⁴ Thus the cost from button battery incidents to the Poisons Information Centre is relatively low in comparison to the total costs of such incidents. Moreover, there is some uncertainty about the incremental cost of button battery-related contacts, as opposed to the average cost.

Due to the comparatively low costs associated with Poisons Information Centre contacts and uncertainty with respect to calculating the effect of regulation on those costs, Poisons Information Centre costs are not quantified in the cost-benefit analysis.

¹²¹ IHPA, National Hospital Cost Data Collection Report, Public Sector, Round 21 (Financial year 2016-17) Appendix Tables, www.ihpa.gov.au/sites/default/files/publications/national_hospital_cost_data_collection_australian_public_hospitals_ cost_report_round_21_2016-17_-appendix_tables.xlsx.

IHPA, National Hospital Cost Data Collection Report, Public Sector, Round 16 (Financial year 2011-12) Appendix Table, www.ihpa.gov.au/sites/default/files/publications/chapter-4-tables.xlsx.
 IHPA, National Hospital Cost Data Collection Report, Public Sector, Round 18 (Financial year 2013-14) Appendix Tables, www.ihpa.gov.au/sites/default/files/publications/2_round_18_cost_report_appendix.xlsx.
 IHPA, Round 21.

¹²³ R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, *Button battery exposures in Australia, November 2017—May 2017*, prepared for NSW Fair Trading by NSW Poisons Information Centre.

¹²⁴ R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, *Button battery exposures in Australia, November 2017—October 2018*, prepared for the ACCC by NSW Poisons Information Centre.

Total cost of button battery incidents

The total health system costs associated with button battery incidents is calculated by adding the costs of each incident category (fatalities, severe injuries and emergency presentations).

Overall, button battery incidents are estimated to cost between \$26.4 million and \$62.3 million during the forecast period.

Lower estimate based on:

- Standard VSL
- National severe injury rate
- 10% discount rate

Upper estimate based on:

- Adjusted VSL
- Qld severe injury rate
- 3% discount rate

Table D14: Cost associated with button battery incidents if status quo remains, 2020-2029

Incident type	Lower estimate	Upper estimate
Emergency Presentations	\$3 493 075	\$4 960 522
Fatalities	\$11 889 253	\$20 354 312
Ongoing Severe Injury Costs	\$4 753 439	\$15 957 104
Severe Injuries	\$6 265 959	\$21 038 258
Total	\$26 401 727	\$62 310 196

Source: NCPC, APSU, ABS Population estimates, NSW Health, VISU, QISU, ABS Consumer Price Index, IHPA, Abelson.

Estimating the impact of regulation

Each of the proposed options to address the hazard of button batteries—secure battery compartments, child-resistant packaging and warnings and information—will have different impacts on the costs and benefits associated with button battery incidents. The economic impact of each proposed regulation is calculated separately.

Given uncertainty with respect to future costs and button battery incidence, upper and lower estimates have been calculated to demonstrate the range of possible incidents prevented and economic benefits for each proposed requirement. Ongoing costs related to severe injuries that occurred before 2020 will not be affected by the introduction of safety requirements. The upper and lower estimates make the following assumptions (where relevant for each category).

Lower estimate:

- 10% discount rate
- Standard VSL
- 'National' severe injury rate

3% discount rate

Upper estimate:

- Adjusted VSL
- Qld severe injury rate
- Warnings prevent 1/3 of applicable incidents
 Warnings prevent 2/3 applicable incidents

Secure battery compartments

The economic benefits associated with introducing a requirement for secure battery compartments on products that use button batteries will begin to accrue once products that do not have button batteries secured in a battery compartment are replaced with products in which batteries are secured. These benefits will accrue in relation to products manufactured in the forecast period and to products manufactured after the forecast period.

A broad range of products use button batteries. Some are low value and have a very short lifetime, while others are high-value products (or accessories to high-value products, such as remote controls) and not replaced as often. Data is not available to accurately calculate the number of consumer goods that use button batteries in homes or the rate at which they will be replaced.

Given the uncertainty with respect to how quickly benefits will begin to accrue after the introduction of a requirement for secure battery compartments, two different methods have been used to forecast the range of possible benefits: the 'product lifetime' method and the 'simple' method.

Simple method

This method makes the simple assumption that all products are compliant with the proposed secure battery compartment requirement at the beginning of the forecast period.

Product lifetime method

Research conducted for the European Parliament identifies the expected lifetime for various categories of consumer goods.¹²⁵ Products identified as the source of a button battery exposure in NBIH data were grouped according to the categories presented in the European Parliament study.¹²⁶ This allowed for the calculation of product replacement rates.

Table D15 shows the rate at which consumer goods that use button batteries are likely to be replaced. More than 90 per cent of button battery products are estimated to be replaced within four years of the introduction of a requirement for secure battery compartments coming into effect.

Table D15: Product replacement rates

Year	Proportion Replaced
2020	0%
2021	48%
2022	48%
2023	94%
2024	94%
2025	94%
2026	94%
2027	94%
2028	94%
2029	95%

Source: Montalvo et al, NCPC.

Incidents prevented and forecast benefits

Button batteries were accessed directly from a product in 62 per cent of incidents reported to the NBIH.¹²⁷ Assuming that the source of the battery is the same for incidents in Australia, a requirement for secure battery compartments will impact 62 per cent of incidents. Table D16 shows the number of incidents likely to be prevented by the introduction of a requirement for secure battery compartments.

Table D16: Secure battery compartment, incidents prevented, 2020-2029

Incident type	Lower estimate	Upper estimate
Emergency presentations	3916	5338
Fatalities	2	2
Severe injuries	63	205

Source: NCPC, ABS Population Estimates, NSW PIC, NSW Health, QISU, VISU, Litovitz et al, Montalvo et al.

As shown in Table D17, the introduction of a secure battery compartment requirement is estimated to provide an economic benefit of between \$9.6 million and \$32 million during the forecast period.

¹²⁵ Montalvo C, Peck D, Rietveld E. *A longer lifetime for products: benefits for consumers and companies*, European Parliament, Directorate General for Internal Policies, 2016.

¹²⁶ NCPC, Button Battery Ingestion Statistics.

¹²⁷ Litovitz T, Preventing Battery Ingestions.

Table D17: Economic benefits of secure compartment, upper and lower estimates, 2020-2029

Incident type	Lower estimate	Upper estimate
Emergency Presentations	\$1 465 492	\$3 075 523
Fatalities	\$4 825 286	\$12 619 674
Ongoing Severe Injury Costs	\$762 841	\$3 314 546
Severe Injuries	\$156 292	\$717 024
Total	\$9 596 675	\$32 053 463

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 21, ABS Consumer Price Index, IHPA Round 18, Abelson 2008, Montalvo et al., ABS Population projections, ABS Life Tables, Litovitz et al.

Child-resistant packaging

Button batteries obtained from packaging account for approximately 8 per cent of incidents reported to the NBIH.¹²⁸ Data is not available to determine how long batteries are stored in packaging in homes. This analysis assumes that all packaging of button batteries in homes would be child-resistant within one year of a child-resistant packaging requirement taking effect.

Incidents prevented and forecast benefits

No reduction in incidents was applied to the first year of the forecast period. An 8 per cent reduction in incidents is expected in each of the subsequent years. Table D18 shows the number of incidents estimated to be prevented by the introduction of a requirement for button batteries to be supplied in child-resistant packaging on that basis.

Table D18: Child-resistant packaging, incidents prevented, 2020-2029

Incident type	Lower estimate	Upper estimate
Emergency presentations	641	641
Fatalities	0.3	0.3
Severe injuries	10	25

Source: NCPC, ABS Population Estimates, NSW PIC, NSW Health, QISU, VISU, Litovitz et al, Montalvo et al.

The introduction of a requirement that button batteries be supplied in child-resistant packaging is estimated to provide an economic benefit of between \$1.6 million and \$3.8 million.

Table D19: Economic benefits of child-resistant packaging, upper and lower estimates, 2020-2029

Incident type	Lower estimate	Upper estimate
Emergency Presentations	\$250 657	\$368 557
Fatalities	\$839 909	\$1 492 867
Ongoing Severe Injury Costs	\$114 979	\$438 375
Severe Injuries	\$442 655	\$1 543 031
Total	\$1 648 200	\$3 842 830

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 21, ABS Consumer Price Index, IHPA Round 18, Abelson 2008, Montalvo et al., ABS Population projections, ABS Life Tables, Litovitz et al.

¹²⁸ Litovitz T, Preventing Battery Ingestions.

Warnings and information

Warnings and information on button/cell batteries sold separately and products that use button batteries will increase consumer awareness of the risks associated with these batteries and direct them to contact the PIC hotline in the event of a suspected button battery incident. Increased awareness is likely to reduce the number of incidents associated with loose batteries.

A key aspect of the proposed warnings and information requirement is publication of the PIC hotline number. PIC staff members provide expert advice and promptly direct callers to the best course of action in the event of a button battery incident, resulting in reduced button battery injury severity.

Loose batteries accounted for 30 per cent of incidents reported to the NBIH. Data is not available to calculate the number of incidents that would be prevented following the introduction of a requirement for warnings and information. A range of possible outcomes (between one-third and two-thirds of incidents prevented) have been calculated to demonstrate the possible range of economic benefits resulting from the introduction of a requirement for warnings and information.

Incidents prevented and forecast benefits

The upper estimate shown in table E20 is based on the assumption that warnings and information will prevent two-thirds of loose button battery incidents. The lower estimate assumes the prevention of one-third of incidents involving loose batteries.

Table D20: Warnings and information, incidents prevented, 2020-2029

Incident type	Lower estimate	Upper estimate
Emergency presentations	855	1710
Fatalities	0.4	0.80
Severe injuries	14	66

Source: NCPC, ABS Population Estimates, NSW PIC, NSW Health, QISU, VISU, Litovitz et al, Montalvo et al.

Table D14 shows the range of possible economic benefits resulting from a requirement for warnings and information on button batteries sold separately and products that use button batteries.

Table D21: Economic benefits of warnings, upper and lower estimates, 2020-2029

Incident type	Lower estimate	Upper estimate
Emergency Presentations	\$346 979	\$985 490
Fatalities	\$1 180 999	\$4 043 723
Ongoing Severe Injury Costs	\$32 956	\$229 756
Severe Injuries	\$622 419	\$4 179 601
Total	\$2 289 680	\$10 270 895

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 21, ABS Consumer Price Index, IHPA Round 18, Abelson 2008, Montalvo et al., ABS Population projections, ABS Life Tables, Litovitz et al.

