Child Safety – Button or Coin Batteries

Ingestion risks and preventative measures

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Agenda

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1. About button cells and batteries

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Cells and batteries terms

- A **cell** is the basic device that converts chemical energy into electrical energy[1]
- A **battery** consists of one or more component cells connected together, possibly including protective devices, in a form that is ready for use[1]
- Where there is only one cell, often the above terms are used interchangeably[1]
- **Primary** batteries are not intended to be recharged[1]. These are the most common button batteries available
- **Secondary** batteries are intended to be recharged
- **Button or coin cell or battery** is a cell or battery which is round, and where the diameter is greater than the height[1]

Button or coin batteries

- Many standard sizes available, with diameters ranging from less than 5 mm to more than 40 mm
- Many different cell chemistries available, but mostly divided into Voltage Range 1 (1.4V range) and Voltage Range 2 (3.2 V range - lithium) [1]

Where to find coin / button cells

Any household device requiring a small & portable electrical power source. Some examples:

- Remote controls (TV/audio)
- Garage door openers
- Bathroom scales
- Toys
- Cameras
- Watches
- Calculators
- Hearing aids
- Electronic greeting cards
- Digital thermometers, clocks
- Talking books

- Handheld electronic games
- Flash lights and pen lights
- Flashing shoes, balls, scooter wheels
- Wireless keyboards & mice
- Keychain devices
- Kitchen scales
- Car keys
- Clothing or fashion novelties
- Birthday candles
- Novelty drink glasses
- Pet tech items

All these use lithium CR2032 cells

Decoding "CR2032": C=lithium negative electrode with organic electrolyte, R=round shape, 20=diameter in mm, 32=thickness in tenths of a mm[1]

Diabetes glucose meters

Portable weighing scales

Activity tracker

Dog glitter collars

2. Hazards, harm and risk principles

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Hazards, harm and risk principles

- **Harm** is an injury or damage to health of people, or damage to property or the environment [5]
- **Hazard** is a potential source of harm [5]
- **Risk** is the combination of the probability of occurrence of harm and the severity of that harm [5]
- **Safety** is freedom from risk that is not tolerable (in a given context based on the values of society)[5]
- **To prevent harm**, risk assessment and risk reduction measures must be applied to identify and eliminate the hazards, or control the hazards to a "tolerable" level of residual risk[5]

- **Objective of this paper**: to better understand the risks and to prevent harm to children from button batteries

3. Child behaviour and battery risks

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Object ingestion and insertion risk

- Younger children have an instinctive behaviour to put non-food items into the mouth
- We need to determine whether this could cause injury, how serious, how frequently, and of what nature
- Sometimes objects are inserted into other places: the nose or ears, for example, and these have caused injuries too[31]
- Not just batteries are inserted or ingested, but any object the child can grasp by hand or mouth



Ingestion/swallowing risks

- Batteries 32 mm and larger won't pass through the Toy Standard **small parts cylinder**[2] (31.7 mm dia.), so children are unlikely to swallow them
- If the battery is greater than 12 mm, it may become stuck in the child's oesophagus[13]
- If the battery passes through the oesophagus, it rarely needs to be retrieved, unless there are signs of GI tract injury, or a larger battery has not passed from the stomach to the intestine[6]
- If the battery is smaller, it usually passes through and usually this does not cause injury[25]

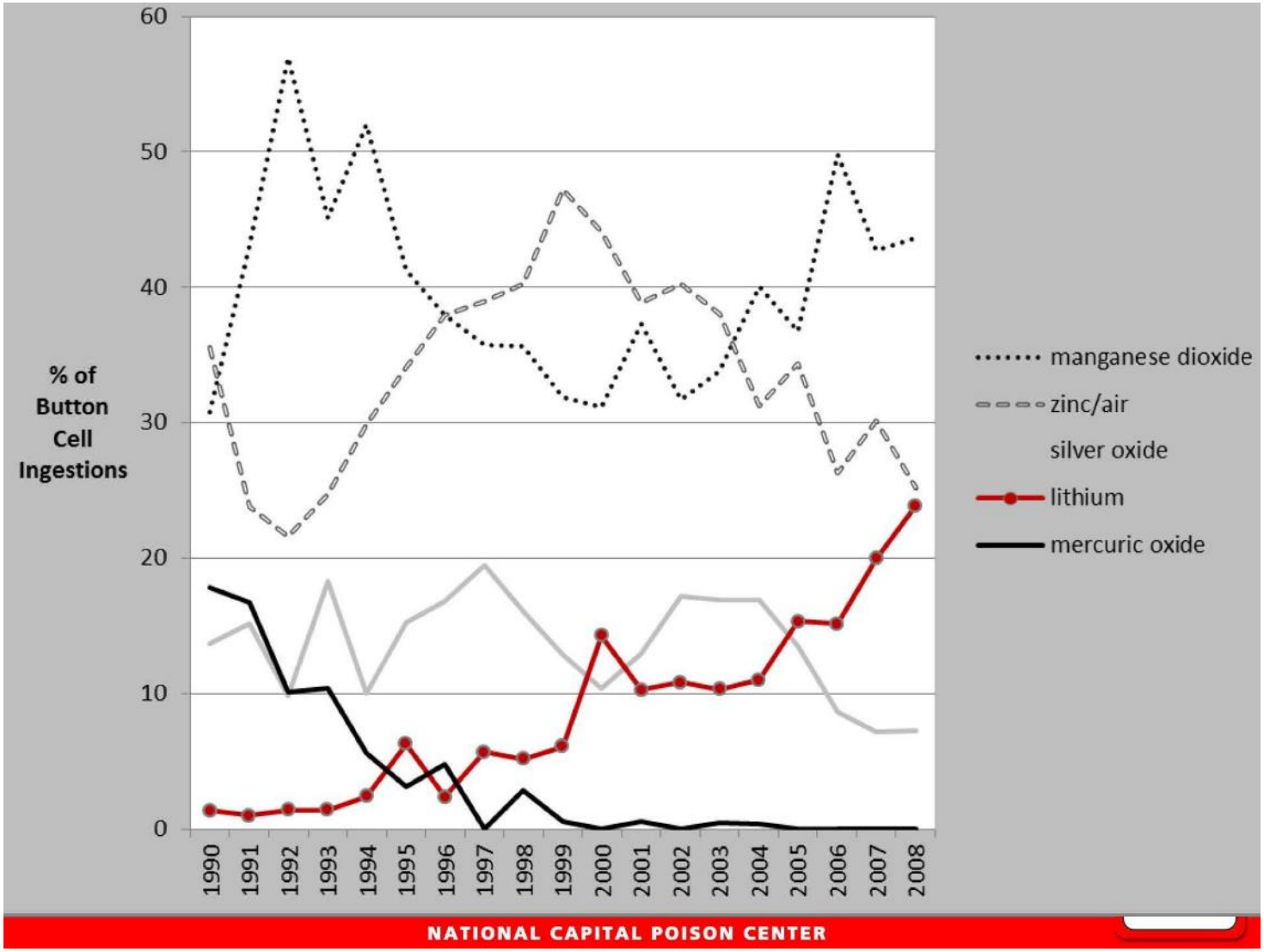
How children get coin batteries[25]

- USA National Battery Ingestion Hotline (NBIH) shows:
  - 61.8% of ingested batteries were obtained directly from the product by the child
  - 29.8% were loose
  - 8.2% were obtained from battery packaging
- Products from which 20 mm lithium batteries were obtained:
  - Remote control devices = 36.2% of cases
  - Games & toys = 13.1%
  - Watches & Stopwatches = 8.5%
  - Flameless candles = 7.7%
  - Bathroom & kitchen scales = 3.8%
  - Key fobs = 3.1%
  - Other products = remainder 27.6%

Injury mechanisms

- Four possible injury mechanisms include:
  - The moist adjacent tissue completes a circuit for the battery to produce current, creating hydroxide at the negative pole. This is the most significant injury mechanism[25]
  - Leakage of electrolyte may occur (but the electrolyte in lithium cells is only a mildly irritating organic electrolyte, thus not a source of injuries for lithium cells[25])
  - Direct pressure may cause ischemic necrosis (not a major injury source[25])
  - Choking and aspiration hazard (but usually with specific symptoms)
- The above conditions can block breathing and/or burn and damage soft human tissue, which worsens if the battery remains stationary

Cell type % of Ingestions[4]



Severity

- Nearly all severe-injury ingestion cases involve lithium batteries[25]
  - The few exceptions involved children < 1 year[25]
- 66% of button battery ingestions are in children < 6 years[25]
- All fatalities are in children < 4 years[25]
- 12.6% of child ingestions of 20 mm batteries in children younger than 6 years experienced a major effect[25]
- Significant nasal and ear injuries from alkaline batteries have also been presented to surgeries[31]

4. Medical triage challenges

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Triage challenges

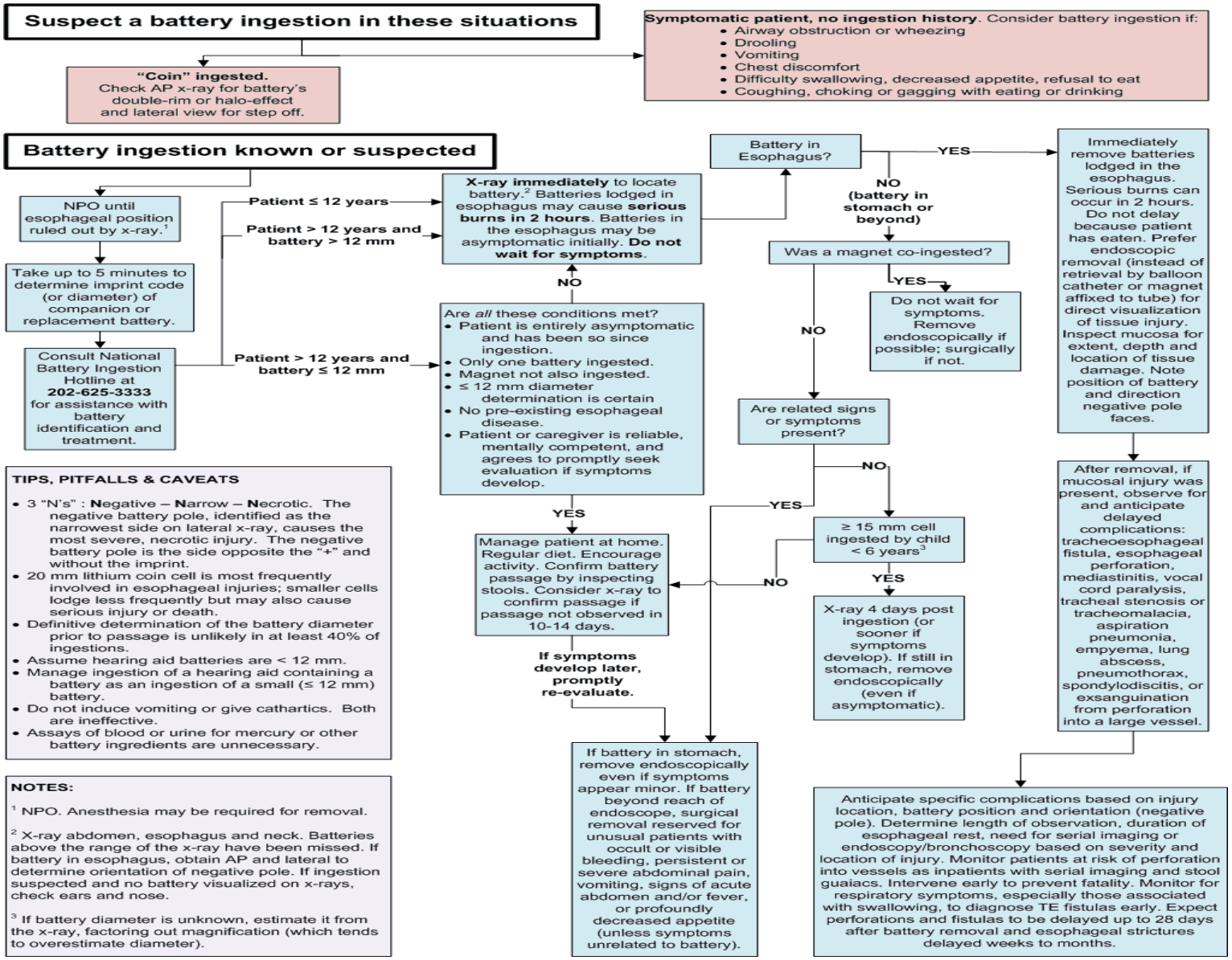
- Children might not be willing or able to say they swallowed a battery or gave one to a sibling
- Delays in treatment may lead to serious complications & death
- Serious oesophageal burns can occur in a relatively short period (2 h) when a lithium coin cell is lodged there[12][31], thus there are frequent recommendations to remove the battery within that 2 h window
- Perforation has been reported to occur as rapidly as 5 hours after ingestion[31]
- 3V lithium batteries generate more current than other types, which produces hydroxide 1 000 times more rapidly than 1.5 V cells[26]. Depleted lithium cells are still a risk
- Injury can continue after endoscopic battery removal for days to weeks due to residual alkali or weakened tissues[25]

Medical response

- Rapid medical response is essential, but diagnosis is a challenge[25]:
  - Button battery ingestions are not witnessed in
    - 92% of fatal outcomes, and
    - 56% of major complications
  - 36% of patients with oesophageal batteries have no symptoms
  - If symptoms do occur, they are non-specific
  - 12.6% of children under 6 years who swallow a 20 mm lithium battery suffer severe or fatal injuries
- NBIH Button Battery Ingestion Triage and Treatment Guideline[13]
  - See next slide (from http://www.poison.org/battery/guideline.asp)

NBIH Button Battery Ingestion Triage and Treatment[13]

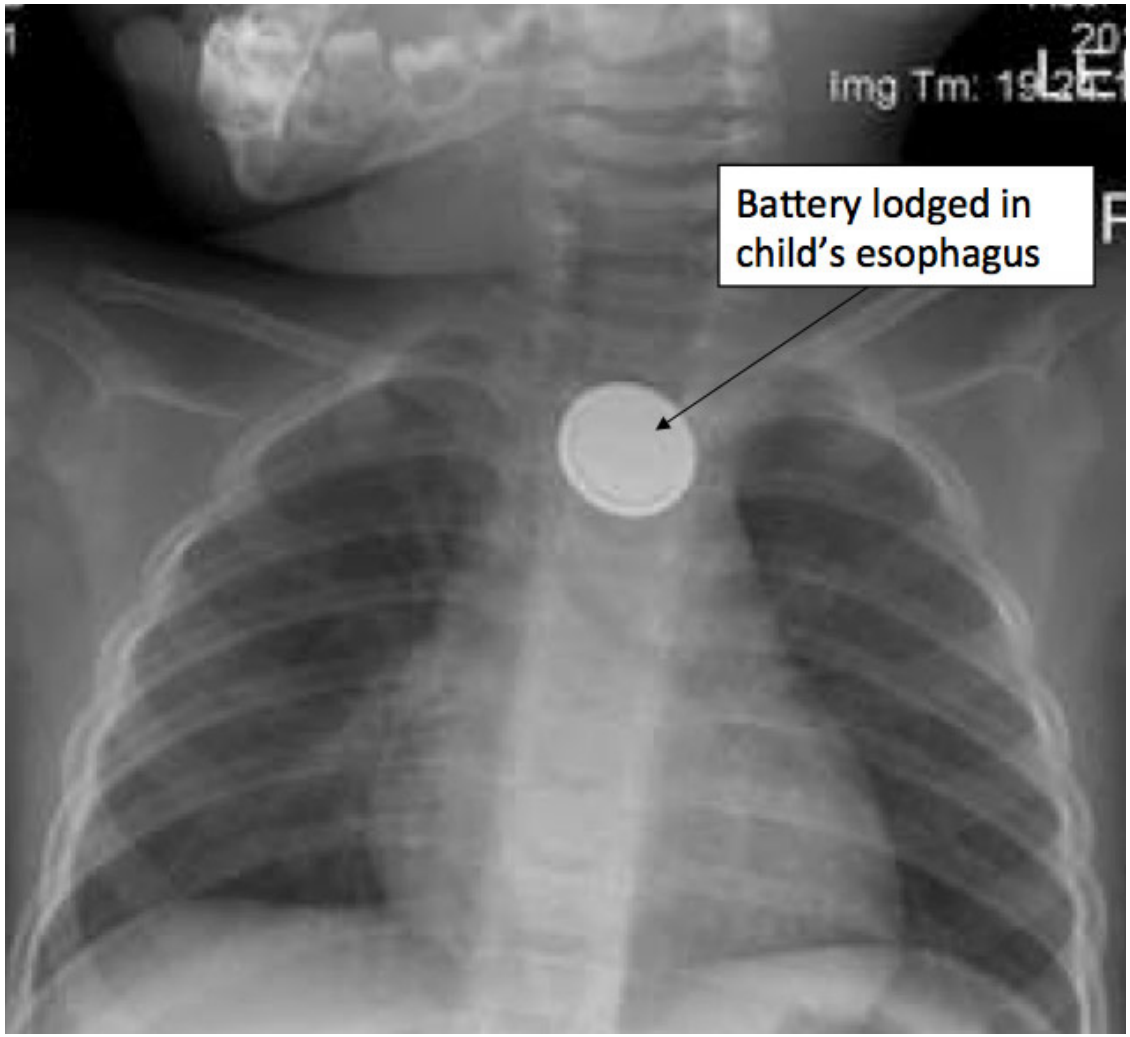
(NBIH: US National Battery Ingestion hotline http://www.poison.org/battery/)



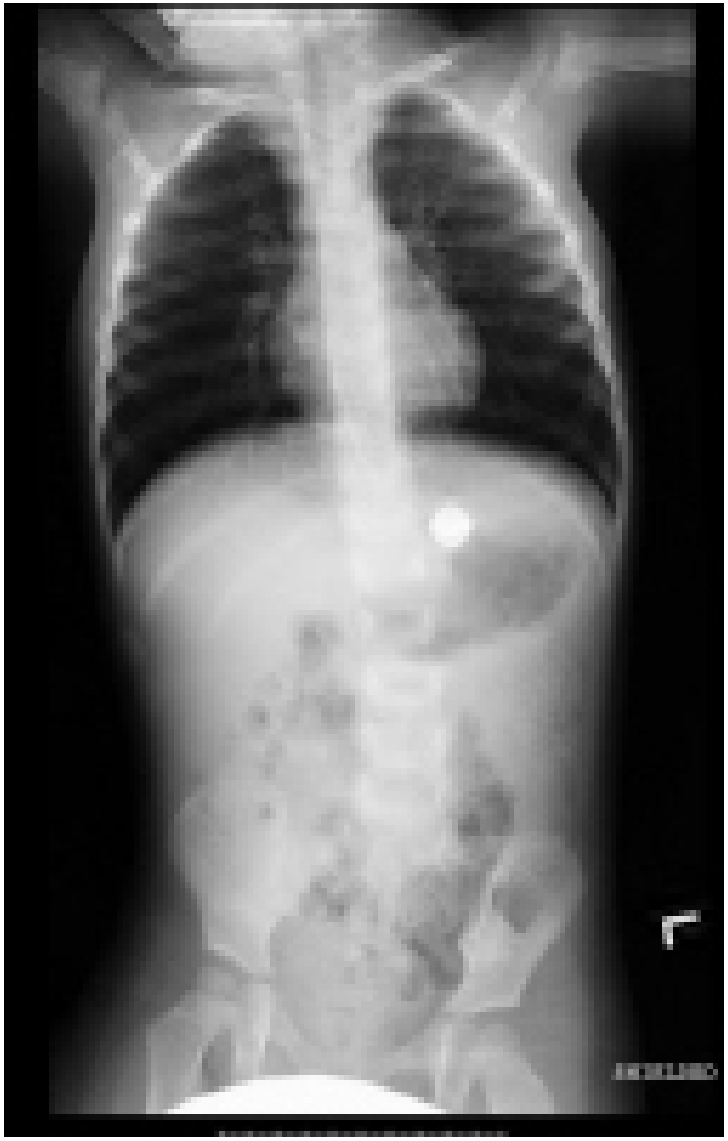
Other medical notes

- Do not induce vomiting for patients with a battery in the stomach
  - it could cause the battery to become lodged in the oesophagus by retrograde movement[5]
- Batteries which pass to the stomach usually pass through the remainder of the GI tract without incident[25]
  - Confirm battery passage by inspecting stools (4 to 10 days) and consider repeat x-rays if not observed[13]

X-Ray: battery in the oesophagus



Battery in the stomach of an 18 months old[6]



5. Worldwide frequency and extent

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Frequency of occurrence (OECD[7])

Country	Numbers	Period	Comment
USA	3500 ingestions	Per year	Numbers increasing: from 1900 in 2008 to 4800 in 2010[12] Most were treated & released without treatment; approx. 10% required hospitalization
	35 deaths	Not stated	
National Poison Data System[33]	**3,366 ingestions**, 2.6144% moderate-major injury or death	2013	Children <6 years = 66% of ingestions, 6 to 9 years = 15% of ingestions
Canada	65 emergency room visits	Per year	70% ingestion, 16% ear/nose insertion. 70% < 4 y old
France	248 accidents in 10 hospitals	2005-2012	Extrapolated globally to 1240 accidents/yr
Korea	254 ingestions (>half < 1 y old)	The last 4 years	= 64 per year
Japan	93 confirmed or possible ingestions	Not stated	Most often for 1-4 year age group
New Zealand	175 calls to poisons centre	2011-2013	= 58 per year

Frequency of occurrence[7] (cont)

Country	Numbers	Period	Comment
Australia	5/week treated	Not stated	= 270 per year
	One death		
Croatia	25 hospitalisations children < 7 y old and 1 adult	2011-2013	= 8 per year
Austria	14 reported hospitalisations	2005-2011	= 2 per year
Brazil	4 media reports	Not stated	No further info
Latvia	1 death 1 y old	Not stated	No further info
United Kingdom	1 death (13 months old)	2013	No further info
	1 severe case	2014	

6. Risk controls

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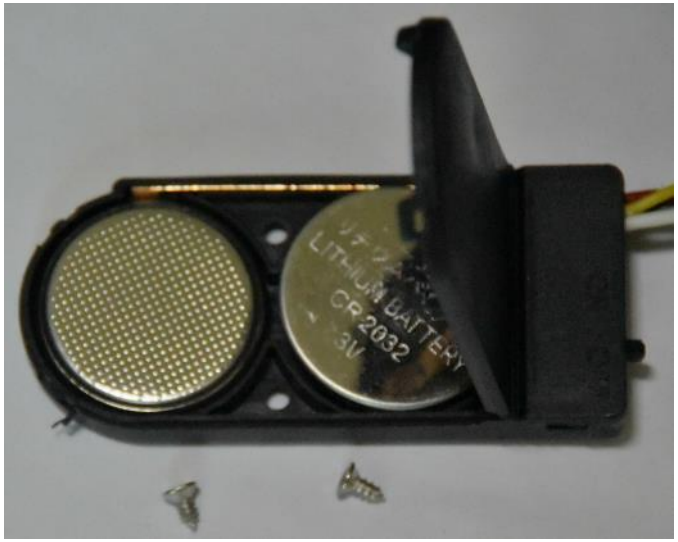
Risk control overview

- **Keep batteries away from children**, but it's not always so simple in today's distracting world, where consumers assume products are intrinsically safe
- **Engineering solutions** exist to reduce the likelihood of child-access to batteries inside products, e.g. child-resistant closures for lithium button batteries
- **Hazard warning instructions** can be applied to equipment, the packaging, and user instructions to advise adults of the risks of ingestions
- **Retail packaging for spare lithium batteries** can be dimensioned to prevent ingestion, made child-resistant, have relevant warnings, and be kept out of reach of children
- **Regulatory oversight:** to enforce standards compliance, mandate incident reports of significant harm or death, conduct recalls for potentially hazardous products
- **Consumer safety information** and education campaigns

International Standards

- **IEC 62368-1 Ed. 2, 2014**[8] covers **A/V & ICT** equipment containing lithium button batteries; where **accessible to children** and has **lithium** coin/button cells below 32 mm dia.
  - **Instructional safeguards** (safety labelling and instructions)
  - **A tool, or two hand movements** independent & simultaneous, used to open battery compartment door or cover
  - **Stress relief tests** (heat plastics to at least 70 Deg C)
  - **Battery replacement test** (repeated opening and closing)
  - **Drop test** (3 drops of 1 m or 10 drops for remote controls)
  - **Impact test** (2 Joules impact force perpendicular to cover)
  - **Crush test** (hand held remote control devices at 330 N)
  - **Test hook test** (20 N) for button battery cover or door
- No battery cover fastener retention (per IEC 60086-1)
- Revisions under consideration

Opening with tool examples



International Standards (cont …)

- Primary batteries, covering size, electrical, classifications, marking, packaging and general safety instructions etc[1]:
  - **IEC 60086-1** Primary batteries Part 1 General
    - IEC 60086-1 (draft) says cautions for “swallowable batteries” shall be given. There are recommendations in Annex B for equipment designs. These are similar to requirements in IEC 62368-1 (plus battery enclosure fastener retention)
  - **IEC 60086-2** Primary batteries Part 2 Physical and electrical specifications (under revision)
  - **IEC 60086-4** Primary batteries Part 4 Safety of lithium batteries, has equipment recommendations including:
    - Battery compartments should be designed so they cannot be opened by children
    - Precautions for proper handling of batteries should be given
- Does not contain recommendations for child-resistant packaging, or ear and nose insertion prevention/warnings

International Standards (cont …)

- The Safety of Toys standard, ISO 8124-1:2014[2]
  - Specifies requirements for toys intended for use by children in various age groups
  - Covers toys designed for children, not other products
  - For coin batteries, it's concerned with a potential choking or aspiration risk, as it treats coin batteries as "small parts" to be assessed by the small parts cylinder that's designed to assess ingestion or inhalation risks
  - Has a drop test, torque test, tension test, & compression test, but inconsistent with IEC 62368-1. Does not seem to have battery door cycling test, stress relief test, impact test & test hook test of IEC 62368-1, or the captive fasteners of IEC 60086-1

International Standards (cont …)

- **IEC 60065**[9] Audio, video and similar electronic apparatus—Safety requirements
  - Contains battery compartment design requirements for lithium button batteries, safety marking, and instructions similar to IEC 62368-1
- **IEC 60950-1**[10] Safety of information technology equipment
  - does not cover button battery ingestion
- **IEC 62368-1** is intended to replace the above standards

USA Response

- The USA CPSC sets safety standards for toys[12]
  - **Consumer Product Safety Improvement Act** 2008 Section 106 as follows:
    - **ASTM F963-11**[18] requires batteries to be inaccessible
      - Toys for children <3 years (secure compartments with screws)
      - Toys for <12 year olds where batteries fit the ingestion gauge
    - **ASTM F2923-14**[19] for children's **jewellery** to prevent button battery access by children
  - **Other legislation:** Button Battery Safety Act of 2011[14], was under consideration by Congress, but not enacted
- **ANSI C18.1M Part 2**[23] and **C18.3M Part 2**[24] contain information about battery compartment protection

USA Response (cont …)

- **UL 60065 Ed. 7**[16] has lithium cell child-access safety requirements for equipment (Annex I). Effective 2014-01-02
  - includes safety instructions, conditioning (mold stress relief and door/cover cycling) and mechanical abuse tests (drop, impact and crush) with an assessment of battery compartment door/cover functionality and battery accessibility after testing
- **UL 4200A**[22] Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies
  (Feb 10, 2015: UL is now in the final stages of adoption)
  - Very similar technical requirements to IEC 62368-1
  - Extends the lithium cell requirements of UL 60065 to other products
  - Includes lithium button/coin cell batteries <=32 mm diameter based on limits in the Toy Safety specification, ASTM F963, for ingestion of small parts.
  - Excludes professional or commercial use products not intended to be used where children will be present

Parents & Community

- The USA CPSC recommends the following steps to prevent unintentional battery ingestion[15]:
  - Do not allow children to play with or be in contact with coin cell batteries
  - Caution hearing aid users to keep hearing aids and batteries out of the reach of children
  - Never put batteries in your mouth for any reason because they are easily swallowed accidentally
  - Always check medications before ingesting them. Adults have swallowed button batteries mistaking them for pills or tablets
  - Keep remotes and other electronics out of your child's reach if the battery compartments do not have a screw to secure them. Use tape to help secure the battery compartment
  - If a button battery is ingested, seek medical attention immediately. The National Battery Ingestion and Poison Help Hotlines are available 24 hours a day
  - Discard button batteries carefully

Australian response

- The Australian Competition and Consumer Commission (ACCC) is consulting with industry on requirements
  - ACCC has also published consumer and supplier facts
- Standards Australia has published draft button battery safety requirements for its national adoptions of IEC 60065 and IEC 60950-1, based on IEC 62368-1 with national differences to cover[11]:
  - all button batteries below 32 mm diameter, not just lithium, and
  - small tubular batteries designated R1 in IEC 60086-2 (10.9 to 12.0 mm dia. x 30.2 mm long), as these fit in the small parts cylinder
- Published as DR AS/NZS 60065:2012 Amd 1:2014, and DR AS/NZS 60950-1:2014[11]
  - DR AS/NZS 60065:2012 is based on an older version of IEC 60065
  - Was open for public comment until 5 Feb 2015

Australian Response (cont…)

- The Australian Consumer Law (ACL) requires suppliers to report safety incidents involving products to the ACCC where it involves hospitalization or death relating to product use:

  "Suppliers must notify the Commonwealth minister within 48 hours of becoming aware that a person suffered serious injury, illness or death associated with a consumer good or product-related service they supplied – either in Australia or overseas. This applies even if the consumer goods or product-related services were misused" [20]

- The ACCC may request a voluntary recall of unsafe products, or may impose mandatory recalls if it believes necessary
- Having requirements in Australian standards will allow the ACCC to reference those technical requirements in regulations as it sees necessary
- Electrical regulators can also reference the safety standards for product compliance approvals

Australian Response (cont…)

- Adopted ISO 8124-1:2012 (Toy standard) [29] as voluntary, but now ISO 8124-1:2014[2] is current internationally, however:
  - Australia's Mandatory Standard for toys[27] (for children up to 36 months) calls up AS/NZS 8124:2002[30], an Australian modified version of ISO 8124:2000 – now 14 years out of date, AND
  - The Mandatory Standard for toys[27] further modifies AS/NZS 8124:2002 including the following:
    - Deletes the sentence in Annex A.2.3 that restricts access to batteries
    - Excludes balloons (battery-powered illuminated balloons do exist)
    - Does not include "goods supplied wholly or partially unassembled for assembly by an adult after supply, provided that, when assembled in accordance with instructions supplied in writing with the goods, the goods comply with the specified standards" [27]
  - So: if a button battery is not supplied inside the toy but an adult has to install/assemble it, these may not be covered by the Mandatory Standard. No mention of childproof battery packaging
  - *Note:* even if toys are labelled and/or marketed for older children, the Mandatory Standard may apply if the toys are commonly recognised as being intended or suitable for children under 36 months of age[28]

Special cases

- Packaging and labelling of spare button batteries for replacement use
- Hearing aid batteries
  - for children's hearing aids[21]
    - Special battery safety measures are required for hearing aids for children less than three years of age
    - Battery safety features can also be requested if the child wearing an aid has a sibling less than three years of age
  - for aged people and other "diverse users" [32]
    - For example button cells may be mistaken for medical pills
- Button battery equipment only used where children are unlikely to access them are not subject to requirements

Diverse users (ISO/IEC Guide 71:2014)[32]

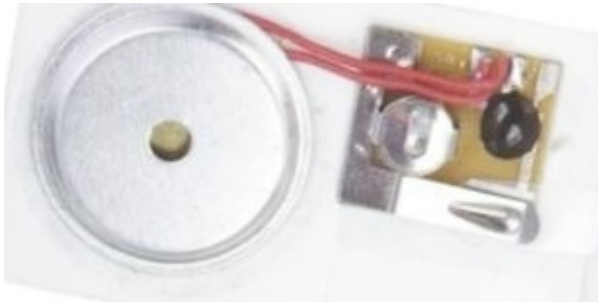
- **Diverse users** are individuals with differing characteristics or user accessibility needs
  - Includes age, gender, size, health condition, impairment, training and experience
- **Impairments** are problems in body function or structure relating to a significant deviation or loss
  - May be temporary or permanent, static or intermittent
- The user accessibility needs of some users might conflict with the user accessibility needs of other users

It is important to ensure that the user accessibility needs of diverse users are accommodated in diverse ways

- Some of the human ability impairments to consider:
  - Vision
  - Touch
  - Fine hand use abilities
  - Voice & speech
  - Hearing
  - Taste
  - Muscle power & endurance
  - Cognitive abilities

Special Cases (cont…)

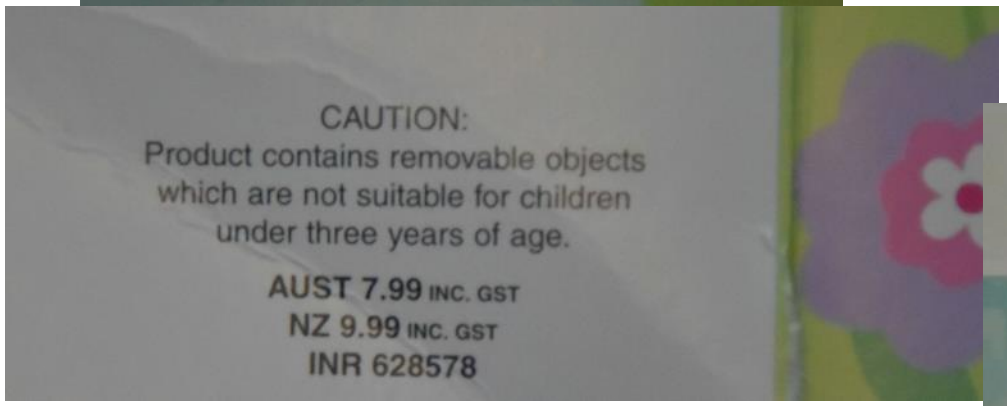
- Button batteries used in greeting cards…

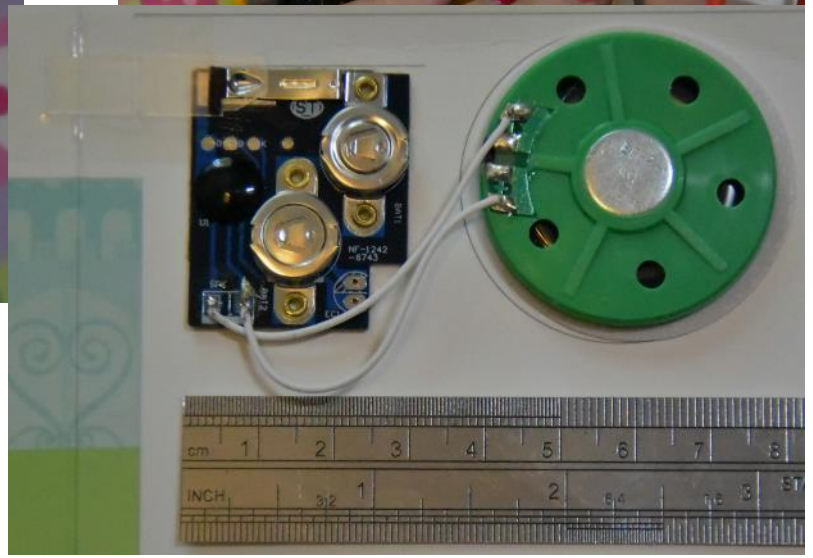


  - Often aimed at very young children, but are not toys
  - Children can tear the cards to access the electronic module for curiosity and play
  - Some of the modules may fit in the small parts cylinder, complete with batteries and electronics
    - Ensure the module can't be fully enclosed by the small parts cylinder of the safety of toys standard
    - Ensure the battery cannot be separated from the module (e.g. by permanently fixing in a holder or by using an enclosure

Special Cases (cont…)

- Two alkaline cells in series = 3 V in modules

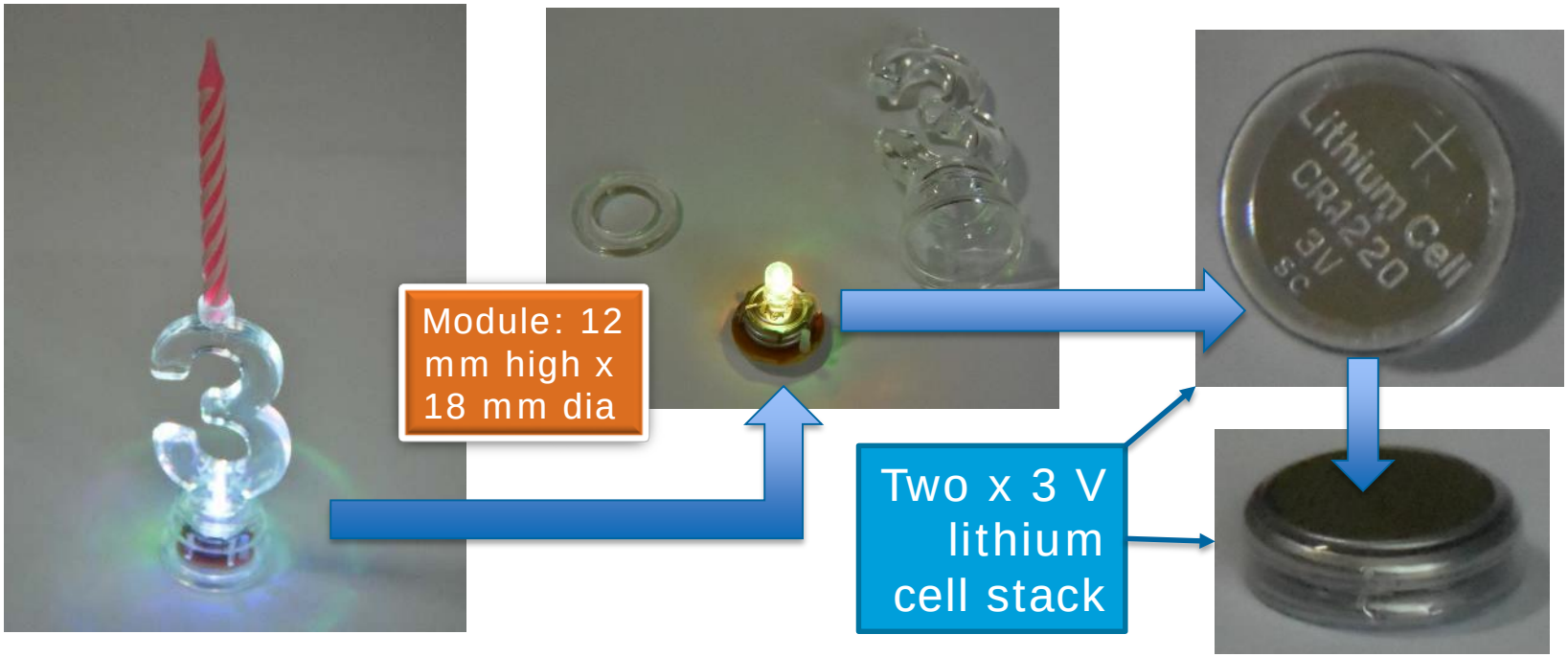




  - Need to check for module ingestion risk if accessible

Special Cases (cont…)

- Birthday candle: Multi-cell lithium battery = 6 V



  - Check if this module or 6 V multi-cell coin battery is child-accessible and ingestible (in this case a tool was needed)
  - Other tests: crush, impact, stress relief, test hook etc.?
  - This is not a toy, and not A/V or ICT[8]. It needs to be covered by a generic standard but none published yet

Special Cases (cont…)

- Store presentation issues

Price sticker covers warnings

Are the warnings prominent & legible?

Store displays: Non-childproof packaged button cells displayed at 1+years-old child-accessible height – these kids are learning to walk, and grab anything shiny/colourful

Special Cases (cont…)

- Is it a toy or not?
  - Never let a child play with this!

- Light-up party balloons containing batteries

7. Conclusions & recommendations

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Conclusions & Recommendations

Conclusion	Recommendation
1. Child ingestion and insertion risks and harm from button cells below 32 mm are very significant	1. Protection of children via good product design must be improved for button battery products
2. Child incidents are common, widespread & on the rise, with the growing availability of smaller, cheaper products	2. Raise community awareness via product safety instructions, advertising, social media, regulators and other channels
3. Adverse child health events can be quick & serious, including major injuries and death	3. Educate community to urgently seek medical help for child button cell ingestion or insertion events
4. Lithium button batteries below 32 mm have by far the greatest harm outcomes	4. Limit access to lithium cells by childproof compartments and packaging, & user instructions
5. Solutions exist to reduce and prevent injuries, but not applied consistently or across all lithium button battery-using products	5. Better coordination and consistency of requirements needed in a multi-disciplinary end-user application environment

Conclusions & Recommendations…

Conclusion	Recommendation
6. For multi-cell batteries or child-accessible modules with multiple batteries, the voltage is additive, increasing the risk	6. Check the whole module for child accessibility, then check with the small parts cylinder, and also check multi-cell button batteries
7. Risks are not entirely limited to lithium cells, as there are injury reports from other button cell types	7. Provide prominent child ingestion & insertion warnings with non-lithium button cell products
8. Adopting child-protection requirements for all coin cell types may cause other concerns with diverse users	8. Consider button cell access issues for diverse users with differing accessibility needs
9. Global incident reporting data is fragmentary, inconsistent and incomplete	9. Incident reporting needs to be more pervasive and granular, so the true scope can be analysed. Consider NPDS data system as a model[33], plus battery type info

Conclusions & Recommendations…

Conclusion	Recommendation
10. Treatment response must be urgent and assume ingestion of a lithium button battery	10. Medical facilities should triage patients similarly to US National Battery Ingestion Hotline guides
11. Public awareness of the risk is not pervasive, leading to poor and child-risky handling of products	11. Involve manufacturers, suppliers, regulators and medical teams in raising public awareness
12. Store display systems increase the risk of child access to lithium button battery spares during shopping excursions	12. Lithium button batteries in retail displays should be in childproof packaging, or kept out of reach of children
13. Store labelling can cover hazard warnings	13. Educate stores not to cover product safety warnings

Conclusions & Recommendations…

Conclusion	Recommendation
14. Some products with button cells that are not toys are attractive for children's play (e.g. pet products, jewellery, hand held device with button cells)	14. If it contains a button battery and it's readily accessible to children, it must be safe for children, taking into account diverse users needs
15. Current standards and regulations are mostly product based, dealing with niche lithium button battery applications	15. Supplement standards and regulations with an issues based approach, similar to the UL 4200A model[22] and consider how to include non-lithium batteries
16. Some older standards are being retrofitted with modified button battery requirements, and some regulations refer to old and modified requirements as well	16. Use the newest version of the international safety standards, as these contain the most up to date child protections, and other new safety requirements as well

Question time

Thanks for your attention

8. Bibliography & Notices

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