chi+med
making medical devices safer

EPSRC Programme Grant EP/G059063/1

Public Paper no. 168

Hearing Aid Battery Ingestion: Medical Error or Poor Design?

Chitra Acharya, Vinaya K. C. Manchaiah,
Alexis Lewis & Harold Thimbleby

Acharya, C., Manchaiah, V. K. C., Lewis, A., & Thimbleby, H. (2014). Hearing aid battery ingestion: Medical error or poor design? *BAA Magazine*, Summer 2014, 27–28. British Academy of Audiology.

PP release date: 28 June 2015

file: WP168.pdf

UCL UCLIC Swansea University Prifysgol Abertawe FIT LAB Queen Mary University of London CITY UNIVERSITY LONDON EPSRC Engineering and Physical Sciences Research Council

Hearing Aid Battery Ingestion: Medical error or poor design?




CHITRA ACHARYA[1], VINAYA K. C. MANCHAIAH[2,3], ALEXIS LEWIS[4] & HAROLD THIMBLEBY[1]
1. College of Science, Swansea University, United Kingdom
2. Department of Vision and Hearing Sciences, Anglia Ruskin University, United Kingdom
3. Linnaeus Centre HEAD, The Swedish Institute of Disability Research, Linköping University, Sweden
4. College of Medicine, Swansea University, United Kingdom

Background

Medical errors can result from a variety of activities. With equipment these include; faulty medical device design, and poor catheter and feeding tube management. Medical errors also arise from oral medication errors, intravenous infusion errors, protocol compliance failures and handover issues, all of these are responsible for causing patient injuries. A leading cause of death and injury in the United States of America to patients receiving care is caused by preventable adverse events from medical management and error.[1] There is also disturbingly high occurrence of preventable adverse events occurring in health organisations across the United Kingdom. In 2000 the UK National Health Service issued the report '*An organisation with a memory*', which emphasized the disturbingly high occurrence of preventable adverse events.[2] Healthcare organisations are not effectively dealing with errors; errors in healthcare are under reported and under recognised despite the prominence of patient safety in healthcare.[3]

Medical errors can result from a variety of activities including; faulty medical device design, oral medication and intravenous infusion errors, poor catheter and tube feeding management, patient injuries, protocol compliance failure, and handover issues. It is also suggested that medical errors are ten times more common than previously estimated.[4] This figure could be because reporting evidences inadequacy in healthcare professionals and service delivery. As a consequence often the responsibility of reporting passes to the patient or family/carer.

Audiology is a profession with relatively low risk in terms of life threatening or fatal medical errors when compared to other healthcare professionals (e.g., cardiac physiologists). However, there are examples where mistakes can be fatal. In this short report we present one such instance in audiology, discuss the reasons why such issues may not be taken seriously (and hence nothing learnt), and also present some insight into how such incidents might be eliminated.

Case Study

A two-year old child with a moderate degree of hearing loss was fitted with hearing aids. The device did not have a tamper proof battery compartment and was without a battery lock. The A13 type 1.4V zinc air battery can fall out easily.

On a visit to a General Practice surgery, the child pulled out the hearing aid and the parent found the battery compartment open and that the battery had fallen out. The parent and practice nurse were unable to find the battery and suspected it might have been swallowed by the child. The child was taken to accident and emergency where examination of the child's ears and nose and a chest and abdomen X-ray failed to locate the battery. On this occasion it was a near miss incident.

The doctor advised the parent that, "hearing aids without childproof battery compartments are dangerous. Batteries are a choking hazard and are also easily swallowed. You must complain to the designers!"

The following day the incident was narrated to the paediatric audiologist, with a request that a tamper proof battery compartment be inserted. The audiologist changed the battery compartment to a junior model with a battery lock. The parent expressed concern that this incident had not been recorded in the patient's notes.

It appears from this case that audiologists are aware of such incidents but continue to fit young children with hearing aids without battery locks. Moreover, it appears that little effort is made to report instances to hearing instrument manufacturers and to request improved designs.

What is the problem?

The use of small batteries (button size) has increased significantly in the past two decades as a result of the miniaturisation of electronic devices. Recent studies at the National Capital Poison Centre (NCPC) suggest that button battery related incidents

causing severe injuries and fatalities have increased seven-fold since 1985.[5-7] These reports concern mainly small batteries (about 20mm diameter) which can be swallowed and pass into the digestive system. Commonly they become lodged in the throat or intestine generating hydroxides resulting in chemical burns. Adverse effects can occur within two hours of swallowing the battery.[8] Other issues and examples can be seen on the NCPC website.[9]

Litovitz et al. analysed 8,648 cases of battery ingestion reported to the National Battery Ingestion Hotline.[6] In children most cases of battery ingestion are the result of removal of batteries from the product (61.8%), loose or discarded batteries (29.8%), or batteries obtained directly from product packaging (8.9%). In adults, most ingested batteries were loose, sitting out or discarded (80.8%). In some cases adults mistook batteries for a pill. A common intended use of batteries that had been ingested were from hearing aids and/or cochlear implants, 36.3% of the reported cases. In most fatal cases the ingestion was not witnessed.[7]

In another study, Sharpe et al. sampled US emergency department (ED) battery-related incidents for patients less than 18 years old over the period 1990–2010.[10] The average annual battery-related ED visit rate was 4.6 visits per 100,000 children, mean age 3.9 years, 60.2% boys. Sharpe et al. note an increasing rate of incidents over time.[10] This work also suggests that the instances of medical errors related to button batteries are more widespread than reported, and that there is some carelessness in taking responsibility and a lack of a learning culture. For example, in audiology, clinicians may think it is the responsibility of parents to make sure the children do not open the battery compartment and swallow them by keeping close watch. However, the parents may blame clinicians for not highlighting this as an important factor during counseling and the hearing aid manufacturers for poor design. The problem of near miss cases and under-reporting raises concerns about the learning culture amongst professionals and the organisations in which they work. The data implies it is important to have a secure battery compartment.

What needs to change and what can and should be done?

The handling of this near miss incident shows that at many levels the 'system' does not allow learning, and hence improvement. Since obviously improving the system is a long term prospect, we start with some long-term suggestions, working back to more immediate concerns.

Such issues can only be solved by involving all stakeholders. Encouraging near miss incident reporting and ensuring learning opportunities through propagation of such information could significantly reduce medical errors and save lives. If cultural changes are needed, then new standard procedures are unlikely to achieve change; instead, points of leverage might be identified in clinical educational requirements — this could lead to more effective solutions, albeit a generation late.

However, the best long-term solution, certainly in this example, can only be found through better design and there is a need for improved communications with hearing aid manufacturers to develop better designs. The problem should be 'designed out'. And, if designed out, there would be no need for specific 'loose battery' educational requirements, though we would argue that human factors, incident reporting, and so forth, need better embedding in the clinical culture.

Parents should be advised about such possibilities while counseling about their child's hearing aids and be advised to keep close watch. It is important for clinicians to take such reports from parents seriously in recording such reports and reporting them to appropriate venues (e.g., media, professional and academic journals, conferences, professional meetings, etc).

Conclusions

It appears that hearing aid battery ingestion is a common occurrence that may have been under reported. Considering the possible fatal consequences of ingested batteries it is important to take preventive measures, which may include: audiologists choosing appropriate hearing aids with a safety lock for children, audiologists counseling adult patients and the parents of children with hearing loss about these risks, and parents keeping close watch on children. More importantly, hearing aid manufacturers should encourage feedback from users and professional groups and involve them in device design.

Acknowledgements

Authors would like to acknowledge Dr Chris Wigham for his helpful comments on previous version of the manuscript.

References

1. Kohn, L., Corrigan, J. & Donaldon, M. (2000). To Err is Human: Building a Safer Health System., Washington DC, National Academy Press.
2. Department of Health (2000). An organisation with a memory. DOH, London.
3. Murphey, M. F. & Kay, J. D. S. (2004). Patient identification: problems and potential solutions. Vox Sanguinis, 87, s197–s202.
4. Classen, D.C., Resar, R., Griffin, F., Federico, F., Frankel, T., Kimmel, N., Whittington, J.C., Frankel, A., Seger, A. & James, B.C. (2011). 'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured. Health Affairs, 30(4), 581-589.
5. Consumer Product Safety Commission. (2011). CPSC Warns: As Button Battery Use Increases, So Do Battery-Related Injuries and Deaths: Toddlers and Seniors Most Often Injured in Battery-Swallowing Incidents. Accessed on 02.08.2012, from: http://www.cpsc.gov/cpscpub/prerel/prhtml11/11181.html
6. Litovitz, T., Whitaker, N. & Clark, L. (2010). Preventing Battery Ingestions: An Analysis of 8648 Cases. Pediatrics, 1178–1183.
7. Litovitz, T., Whitaker, N., Clark, L., White, N.C. & Marsolek, M. (2010). Emerging Battery-Ingestion Hazard: Clinical Implications. Pediatrics, 1168–1177.
8. Medical News Today. (2010). Swallowing Button Batteries Causing More Severe Injuries, Deaths In American Children. Accessed on 02.08.2012, from: http://www.medicalnewstoday.com/articles/189863.php
9. National Capital Poison Centre. (2012). Swallowed or ingested a button battery?. Accessed on 02.08.2012, from: http://www.poison.org/battery/inthenews.asp
10. Sharpe, S.J., Rochette, L.M. & Smith, G.A. (2012). Pediatric Battery-Related Emergency Department Visits in the United States, 1990–2009, Pediatrics, 129(6):1111–1117.