Letter: Difficulty in Tracing Manufacturer and Brand Names on Ventriculoperitoneal Shunt Catheters and Valves

To the Editor:

Ventriculoperitoneal shunt (VPS) implantation, including revision surgeries and reprogramming of adjustable shunt valves, is the most common procedure performed by pediatric neurosurgeons, costing an estimated US$100 million each year in the United States alone.[1-5] In the United States, shunt-related procedures rank 10th among the procedures with the highest readmission rates.[6] Mandatory shunt revision surgeries after VPS malfunctions, especially in children, are challenging for neurosurgeons and may cause long-term painful situations for patients and their families.[1,5,7] Before VPS revision surgery, the surgeon's knowledge of the brand name, type, and pressure setting of the VPS that had been implanted in the patient can provide safer and more practical surgical solutions to the problem. However, many times, it is almost impossible to know the trademark, model, year of manufacturing, and pressure setting of the VPS previously inserted in the patient.

Such a problem may not arise when the records of the patient's previous surgery can be accessed or if the patient has an implant card. However, there may be problems in the archive of hospital records. The patient's family may have lost the implant card over the years or the patient may be about to have surgery in a different hospital or country than the hospital where the previous surgery was performed. Thus, more often than not, the surgeon should detect the brand and type of implanted VPS by examining the shape of the valve/reservoir on plain skull graphs. Moreover, visual inspection of the VPS during surgery does not usually reveal any identifying information about the implant. In many cases, none of the ventricular, the peritoneal catheters, or the valve/reservoir is marked with the brand name of the company and the model of the shunt, pressure setting record, and year of manufacturing. Sometimes, some numbers/letters can be noticed on the valve/reservoir, but it is impossible to trace the actual product identity using them.

Clinical ethics in the use of VPS should be respected. Through a global secure network, attending neurosurgeons anywhere in the world should be able to access past information about the patient with a VPS implanted; of course, caring for data protection rules. Unfortunately, health information technology is focused on revenue optimization through support for billing documents for devices rather than monitoring the health of patients with implanted devices.[8-11] Sharing clinical information about these patients among neurosurgeons is not a priority of profit-driven public management systems and associated information technology. Thus, physicians cannot easily obtain information regarding the medical device implanted and must apply to authorized portals, often in vain.[12]

High-risk devices need to be subject to stricter premarket and postmarket controls to better protect public health and patient safety. In some countries, data on all pediatric neurosurgery units are uploaded to a central database monthly or annually.[1,2,5] However, these centralized data covering a particular country or narrow region also have several limitations and are costly.[2,5,13] For example, infants younger than 1 year who did not have a social security number could not be tracked over time, or there were errors related to the records.[5] Various laws have been enacted in both the United States and the European Union to overcome barriers to data sharing.[12,14-16] The Food and Drug Administration of the United States actively supports postmarket scrutiny of pediatric medical devices in the gathering of pertinent data.[17] The European Union is creating a comprehensive database called European Database on Medical Devices (EUDAMED) with a vivid picture of the life cycle of all medical devices and implants available on the EU market. It is hoped that easier traceability of medical devices will be possible.[15] However, it is impossible to obtain and analyze postmarketing reports if the implanted VPSs cannot be identified.

Today, people migrate massively for various socioeconomic reasons, including wars, or they frequently move for vacation or work by getting faster and more comfortable transport facilities. Therefore, citizens of any country may urgently need shunt revisions outside of their home country, where they are registered. It is quite obvious that children with VPSs will pass into adulthood with their implants.[18] It will not be surprising that many people with VPSs from any country may need to be treated surgically for VPS malfunction outside their home country; at the very least, reprogramming of an adjustable shunt valve may suddenly be necessary anywhere.

In addition to data sharing, it should be ensured that the companies clearly indicate their identification mark, their brand name or badge, the shunt model, pressure setting record, and the production year of the VPS, just as most electrical and electronic equipment sold in the United States and European Union must bear a certain mark. These inscriptions printed on the shunt parts must be permanent, clearly visible, and legible, preferably equipped with radiopaque identifying marks. It is also not appropriate to print only barcodes or numbers that are not easy to decipher. Detailed information must be present on both the valve/reservoir and catheters. In this way, feedback can be provided to the company and authorized portals when a problem related to the VPS is encountered during revision surgery. Unfortunately, there is no standardization in this regard today, and this might result in patient suffering.

Ethical Issues

The ethical issues for this study have been carefully considered in line with the Declaration of Helsinki and its amendments.

Funding

This study did not receive any funding or financial support.

Disclosures

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

Huseyin Akdemir, MD
Fatih Calis, MD
Abdullah Talha Simsek, MD
Naci Balak, MD
Department of Neurosurgery, Istanbul Medeniyet University, Göztepe Prof. Dr. Süleyman Yalçın City Hospital, Istanbul, Turkey

REFERENCES

1. Al-Tamimi YZ, Sinha P, Chumas PD, et al. Ventriculoperitoneal shunt 30-day failure rate: a retrospective international cohort study. *Neurosurgery.* 2014;74(1):29-34.
2. Patwardhan RV, Nanda A. Implanted ventricular shunts in the United States: the billion-dollar-a-year cost of hydrocephalus treatment. *Neurosurgery.* 2005;56(1):139-145; discussion 144-145.
3. Rymarczuk GN, Keating RF, Coughlin DJ, et al. A comparison of ventriculoperitoneal and ventriculoatrial shunts in a population of 544 consecutive pediatric patients. *Neurosurgery.* 2020;87(1):80-85.
4. Sikorski CW, Rosen DS, Frim DM. Adjustable shunt valve reprogramming at home: safety and feasibility. *Neurosurgery.* 2007;60(2):333-337; discussion 336-337.
5. Wu Y, Green NL, Wrensch MR, Zhao S, Gupta N. Ventriculoperitoneal shunt complications in California: 1990 to 2000. *Neurosurgery.* 2007;61(3):557-563; discussion 562-563.
6. Sribnick EA, Sklar FH, Wrubel DM. A novel technique for distal shunt revision: retrospective analysis of guidewire-assisted distal catheter replacement. *Oper Neurosurg.* 2015;11(3):367-370; discussion 370.
7. Balak N, Sandvik U, Honeybul S. Paediatric neurosurgery. In: Honeybul S, ed. *Ethics in Neurosurgical Practice*. Cambridge University Press; 2020:154-167.
8. Balak N, Broekman MLD, Mathiesen T. Ethics in contemporary health care management and medical education. *J Eval Clin Pract.* 2020;26(3):699-706.
9. Balak N, Tisell M. Healthcare economics. In: Honeybul S, ed. *Ethics in Neurosurgical Practice*. Cambridge University Press; 2020:73-84.
10. Castlen JP, Cote DJ, Moojen WA, et al. The changing health care landscape and implications of organizational ethics on modern medical practice. *World Neurosurg.* 2017;102:420-424.
11. Eijkholt M, Broekman M, Balak N, Mathiesen T. Three pitfalls of accountable healthcare rationing. *J Med Ethics.* 2021;47(12):e22.
12. Reforming America's healthcare system through choice and competition. *Vol 2022: The U.S. Secretaries of Health and Human Services, Treasury, and Labor*. U.S. Department of Health & Human Services; 2018. Accessed September 3, 2022. https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.
13. Steinbok P, Milner R, Agrawal D, et al. A multicenter multinational registry for assessing ventriculoperitoneal shunt infections for hydrocephalus. *Neurosurgery.* 2010;67(5):1303-1310.
14. Kramer DB, Xu S, Kesselheim AS. Regulation of medical devices in the United States and European Union. *N Engl J Med.* 2012;366(9):848-855.
15. *New EU Rules to Ensure Safety of Medical Devices*. European Commission the Directorate-General for Health and Food Safety. 2018. Accessed September 3, 2022. https://health.ec.europa.eu/system/files/2020-07/md_generic_fs_en_0.pdf.
16. Muskens IS, Gupta S, Hulsbergen A, Moojen WA, Broekman MLD. Introduction of novel medical devices in surgery: ethical challenges of current oversight and regulation. *J Am Coll Surgeons.* 2017;225(4):558-565.
17. *Pediatric Medical Devices*. The Food and Drug Administration; 2022. Accessed September 3, 2022. https://www.fda.gov/medical-devices/products-and-medical-procedures/pediatric-medical-devices.
18. Reddy GK, Bollam P, Caldito G, Guthikonda B, Nanda A. Ventriculoperitoneal shunt surgery outcome in adult transition patients with pediatric-onset hydrocephalus. *Neurosurgery.* 2012;70(2):380-389; discussion 388-389.

10.1227/neu.0000000000002238