REGULATION OF ORTHOPAEDIC IMPLANTS IN KENYA

A majority of orthopaedic surgery will require the use of implants. The implants will be a major contributor of the success (or failure) of the surgery. It is also important that the implants used in a particular region are compatible with the anatomical variations of the specific region. The study by Lakati and Ndeleva (1) identified a mismatch between some of the locally available implants for TKR and the dimensions of the proximal tibia in the local population.

Aside from this finding, something else that was observed when conducting this study was that a large number of the implants used locally are supplied by persons who lack detailed understanding of the implants as well as the appropriate instrumentation. For instance, some of the suppliers did not have the product monographs and even when given time to get this, they were unable to do so. This was the same in a previous study on the dimensions of the distal femur in comparison to widely used total knee arthroplasty implants (2).

This problem is not unique to implants used for arthroplasty but afflicts implants used for trauma care as well. In a previous study on the anterior curve of the femur in the local population and comparison to available femoral nails, product monographs for some implants were not available and the investigators had to measure the radius of curvature of some of the femoral nails themselves as they could not get this information from the local suppliers as the products documentation was unavailable (3).

This brings to the fore gaps in the regulatory framework in the local orthopaedic implant industry. It is expected that suppliers of any medical device or implant would have all the requisite documentation for their products. As per the National Guidelines for the registration of medical devices, this should include product specifications, instructions on its use, batch numbers and manufacturers contacts (4). Information on product specifications and instructions on their use ensures that the products are used correctly. Product batch numbers and manufacturers' details enable product tracing should the need arise as occurs when serious defects or adverse events are noted occasioning a recall. Trends are heading toward the use of human and machine readable Unique Device Identifiers (UDI) for this (5,6).

After products have been approved for use locally by the Pharmacy and Poisons Board, random checks should be conducted to ensure that requisite standards are maintained.

Additionally, we need a framework that allows for feedback on non-compliance on the part of the distributors as well as the performance of approved implants. This is important because the approval of devices is sometimes based on limited desktop evaluation or trials in small populations and the only true test of their efficacy and safety is their function once applied to a large number of patients (7,8). In other jurisdictions, post-market surveillance is in-part the manufacturers' responsibility with mandatory reports expected whenever any device related deaths or serious malfunction of the devices is identified (9,10).

Medical practitioners also have an important role in this. They are expected to report any un-toward events such as implant failure or any other adverse events (9-11).

For arthroplasty, reports on implant survival are also important. Registries would be of great use in this regard. Integration of registries with post-market surveillance systems further enriches the post-market surveillance systems. For instance, it is the report from the National Joint Registry of England and Wales that indicated that the DePuy's ASR acetabular implant was replaced or removed 29% of the times after six years that ultimately led to the recall of this implant (12-15). Similarly, a large proportion of the 578 recalls of total hip replacement implants that occurred between 2002 and 2013 were occasioned by information derived from joint registries (12).

The registration of implants locally is a function of the Pharmacy and Poisons Board. Neither orthopaedic surgeons nor their representatives (such as the Kenya Orthopaedic Association) are involved in this process. The capacity of the Pharmacy and Poisons Board to evaluate suitability of orthopaedic implants would be greatly enhanced by involving orthopaedic surgeons as well. This is the case in other jurisdictions. For instance, in the USA, the Food and Drug Administration (FDA) which is tasked with the responsibility of licencing orthopaedic implants involves orthopaedic surgeons in the evaluation of implants before they are approved for use (10).

All other conditions not withstanding, the Kenyan orthopaedic fraternity should be actively involved in all aspects of regulation of orthopaedic implants used locally as they bear ultimate responsibility for whatever happens to their patients after the use of these implants (15,16).

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REFERENCES

1. Lakati, C. K. and Ndeleva, B.M. Anthropometry of the proximal tibia in a Kenyan population and its correlation with total knee replacement implants. *East Afr Orthop J.* 2018;**12**(1): 3-8.
2. Lakati, C.K., Ndeleva, B.M., Kibet, C.K., *et al.* Anthropometry of the distal femur in a Kenyan population and its correlation with total knee replacement implants. *East Afr Orthop J.* 2017;**11**(2):67-72.
3. Lakati, C.K. and Ndeleva, B.M. The anterior curve of the adult femur in a Kenyan population and its mismatch with available intramedullary nails. *East Afr Orthop J.* 2016;**10**(2):51-54.
4. Ministry of Health, Pharmacy and Poisons Board. Guidelines on Submission of Documentation for Registration of Medical Devices. August 2017. www.pharmacyboardkenya.org/files/?file=Medical_Devices_Guideline_2017.pdf
5. Proposed rule: unique device identification system. Silver Spring, MD: Food and Drug Administration, July 2012.
6. Gross, T.P. and Crowley, J. Unique device identification in the service of public health. *N Engl J Med.* 2012; **367**:1583-1585.
7. Mohamed, N.N., Syed, K., Sledge, C.B., *et al.* Improving the postmarket surveillance of total joint artthroplasty devices. *Open Rheumatol J.* 2008; **2**:7-12.
8. Resnic, F.S. and Normand, S.T. Post marketing surveillance of medical devices – filling in the gaps. *N Engl J Med.* 2012; **366**:875-877.
9. US Food and Drug Administration. Overview of Device Regulation. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ Overview/default.htm. Accessed April 27, 2018.
10. Kirtkpatrick, J.S. and Stevens, T. The fda process for the evaluation and approval of orthopaedic devices. *J Am Acad Orthop Surg.* 2008; **16**(5):260-267.
11. Maisel, W.H. Medical device regulation: an introduction for the practicing physician. *Ann Inter Med.* 2004; **140**(4):296-302.
12. Major Hip Recalls. Available from: www.drugwatch.com/hip-replacement/recalls. Accessed on 5th May 2018.
13. DePuy ASR Hip Lawsuit Trial: John- son & Johnson Analysis Showed DePuy ASR Hips Could Fail in Nearly 40% of Patients, Bernsetin Leibhard LLP Reports. January 30, 2013; Available from: http://www.prweb.com/releases/depuy- asr-hip-lawsuits/depuy-asr-hip-recall. Accessed on 5th May 2018.
14. Johnson, C.H. and Johnson. Hip Flop. January 31, 2013; Available from: http://www.economist.com/blogs/schumpeter/2013/01/johnson-johnson. Accessed on 5th May 2018
15. Racine, J. Orthopaedic Medical devices: ethical questions, implant recalls and responsibility. *Rhode Is Med J.* 2013; **96**(6):16-19.
16. Meier, B. Doctors Who Don't Speak Out. NY Times, Sunday Review, The Opinion Pages. February 19, 2013; Available from: http://www.nytimes.com/2013/02/17/sunday-review/the-hip-replacement-case-shows-why-doctors-often-remain-silent.html. Accessed on 5th May 2018