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The official podcast of SMVMCH

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TRANSCRIPT

Hello Everyone….. This is Dr. Nitya and Dr. Suja , talking about "Awareness on Materiovigilance". Hope you find our conversation useful!

Good morning, ma'am.

We are reporting ADRs regularly, but now you have asked us to report adverse events related to medical devices. Can you elaborate more on this?

Good morning Dr. Suja .PVPI recommends us to report adverse events related to medical devices and it is called as materiovigilance program of India or MVPI. It is to ensure the quality and promote the safe use of medical devices.

Ma'am, what is the importance of reporting?

Medical devices have been associated with several adverse effects and at times fatal harmful effects to the patients. So as a stakeholder, it is the responsibility to provide adverse events associated with the use of medical devices and safeguard the health of the public.

Ma'am, what all to be reported under this?

According to article 10 of European Medical Devices Directive, the incidents that must be notified are

- Any modification or deterioration in the characteristics or performance of a medical device
- Any inaccuracy in the labelling
- Any inaccuracy in the instruction for use, which have lead or could lead to death or serious deterioration in the state of health of a patient or end user.

Ma`am, it is good that we get to report these too. However, I am curious to know how it all started?

That is a long story, Dr. Suja. In December 2008, a three days old was killed after incubator got fire in a hospital at Ahmedabad. In the following year, November 16, 2009, few new-borns, treated for jaundice at Government Hospital in Northern India died as a fire broke out in its phototherapy unit. Do u know that even a similar occurrence happened in Pondicherry on March 9, 2017 .There was an eight minute power cut at a premium hospital resulting in loss of three lives. After several similar incidents, Ministry of Health and Family Welfare, Government of India approved Materiovigilance Program of India to ensure safe use of medical devices which was launched by DCGI on July 6, 2015

That`s really sad to hear. I am happy that they have launched this program.

Who all can report there?

Under MVPI clinicians, biomedical engineers, clinical engineers, Hospital technology manager, pharmacist, nurses and even technician can report medical devices related adverse events. Not only that even medical device manufacturers, CDSCO notified medical device manufacturers or medical device importer or Trader also can report such reactions to us.

Ma'am, Can you be more precise on what all to be reported?

You can report all types of adverse events related to medical devices, irrespective of whether they are known or unknown, serious or non-serious, frequent or not.

Oh that's great Ma'am .who are we supposed to report this to?

You can simply call the extension number 2081 in our college and report it.

Alternatively, we have medical device adverse event reporting form which is available in the website www.ipc.gov.in or you can report to their research associates from medical device adverse event monitoring centre. After filling this form, it is submitted to National Coordinating Centre.

Thank you so much, ma'am. That was very useful.

Thank you, Dr. Suja.

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