Guidance Document
Materiovigilance Programme of India (MvPI)
(Reporting Medical Device Adverse Event)
(Version 1.1)
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Introduction

The word vigilance as per Oxford dictionary means — the action or state of keeping careful watch for possible danger or difficulties. All Medical Device carry certain level of risk. Materiovigilance envisage close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which is capable of identifying, collecting, reporting with estimate of undesirable occurrences and reacting to them with field safety corrective actions or device recall during post-marketing phase of a Medical Device.

(a) Programme objective:

To improve the protection of the health and safety of patients, healthcare professionals and others by reducing the likelihood reoccurrence of an adverse event associated with the use of Medical Devices.

(b) Definition of medical device:

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information by means of in-vitro examination of specimens derived from the human body
- aids for persons with disabilities
- devices incorporating animal and/or human tissues
- devices for in-vitro fertilization or assisted reproduction technologies
- disinfection substances;
and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

(c) Background:

After several horrific cases associated with malfunctioning of medical devices like infants burnt to death due to short circuits in incubators, or hip implants causing blood poisoning, the Ministry of Health and Family Welfare (MoHFW), Government of India have approved Materiovigilance Programme in an effort to address potential adverse events related to Medical Devices. In addition to creating database on medical device adverse event, Materiovigilance programme will give insight to reduce likelihood reoccurrence of adverse events related to Medical Device elsewhere, thereby improving medical device quality by and large. Materiovigilance programme of India was launched by DCG (I) on 6th July 2015 at Indian Pharmacopoeia Commission, Ghaziabad. For Materiovigilance Programme of India (MvPI), Indian Pharmacopoeia Commission functions as National Coordination Centre (NCC). Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram shall act as National Collaborating Centre, National Health System Resource Centre (NHSRC), New Delhi, shall act as Technical support partner and Central Drugs Standards Control Organisation (CDSCO), New Delhi, shall support MvPI with experience of functioning as National regulator.

Materiovigilance Programme of India (MvPI) aims to collect data on Medical Device related adverse events systematically and scientifically analyse them to aid in regulatory decisions and recommendations on safe use of medical devices being made using data generated from India. The programme is meant to monitor medical device-associated adverse events (MDAE), create awareness among healthcare professionals about the importance of MDAE reporting in India and to monitor the benefit-risk profile of medical devices. It is also meant to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders.

National Coordination Centre:

Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health and Family Welfare, Govt of India, and functions as National Coordination Centre for Materiovigilance Programme of India. The main responsibility of NCC is to monitor all adverse events of medical devices being observed in Indian population. NCC operates under the supervision of a steering committee and a working group which recommend procedures and guidelines for regulatory interventions. IPC also sets standards for drugs that are
Materiovigilance Programme of India

manufactured, sold and consumed in India. It also publishes Indian Pharmacopoeia and National Formulary of India to improve quality of medicine and promotes rational use of medicine.

**National Collaborating Centre:**

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) functions as National Collaborating Centre for Materiovigilance Programme of India. SCTIMST metamorphosed into an Institute of National Importance with the status of a University in 1980 under the Department of Science and Technology, Govt. of India, by an Act of Parliament. The joint culture of medicine and technology that the Institute pioneered more than three decades ago has come of age and gained unprecedented acceptance in India. The Institute focuses on patient care of high quality, technology development of industrial significance and health research studies of social relevance. The emphasis is on development of facilities less readily available elsewhere in the country such as interventional radiology, cardiac electrophysiology, pre-surgical evaluation and surgery for epilepsy, microsurgery and deep brain stimulation for movement disorders, new biomedical devices and products, evaluation of medical devices to global specifications, new academic programmes and global public health networks.

The Biomedical Technology Wing (BMT Wing) located at the Satelmond Palace in Poojappura, Thiruvananthapuram. The broad areas of activities of the wing include Medical devices, Biomaterials, Biocompatibility, Tissue Engineering, Product incubation and commercialization. Technical research centre for Biomedical Devices (approved by the DST, Govt of India) is a nodal centre undertaking Five Programmes for Mission Mode Industrial R&D in areas of Cardiovascular devices, Neuro-prosthetic devices, Hard tissue devices, In-vitro diagnostics and Biological and combinational products.

**Technical Support and Resource Centre:**

Technical support for the programme will be sought from institutions that have established technical capacity in the field of Medical Devices. To begin with, technical support will be taken from National Health System Resource Centre (NHSRC) which has been set up under the National Health Mission (NHM), Ministry of Health & Family Welfare, Government of India. The Healthcare Technology Division of NHSRC is a World Health Organization Collaborating Centre for Priority Medical Devices & Health Technology Policy. This division shall act as a technical support and resource centre for the Materiovigilance Program of India In future, additional technical support centre may be added to provide technical support on specific issues identified by competent authority as and when required.

**(d) Scope of Guidance Document**

The document intends to act as an information guide to all stakeholders to have general
Materiovigilance Programme of India

Following are some of the key stakeholders under MvPI:

- Professional staff at IPC, SCTIMST, NHSRC, CDSCO and whole citizens of India would serve as stakeholders of the programme

- Representatives of Medical Device Monitoring Centre across the country

- Policy makers at all levels of healthcare, particularly those concerned with Medical Device policy

- Under MvPI Staff of clinical establishments like clinicians, biomedical engineers/clinical engineers, hospital technology managers, pharmacists, nurses, technicians can report medical device adverse events. Medical device manufactures/CDSCO-notified medical device manufactures/medical devices’ importers-traders can also report adverse events specific to their product to the National Coordinating Centre

- Medical Technologists and Medical devices Innovators associated with Research and Development
Chapter 1: Materiovigilance Programme of India

1.0 Mission

Safeguard the health of Indian population by ensuring that the benefits of use of Medical Devices outweigh the risks associated with its use.

1.1 Vision

To improve patient safety and welfare of Indian population by monitoring adverse events related to Medical devices and thereby reducing the risk associated with use of Medical Devices.

1.2 Scope and Objectives

- To create a nation-wide system for vigilance on Medical Device related adverse event. Active system provide forum for encouraging adverse event reporting, proactive investigation, collecting risk-based information from global regulators and conducting reactive investigation. The database would enable data analysis in multiple ways.

- To capture and record suspected medical device associated adverse events like death or serious deterioration in state of health, serious injuries and disability.

- To identify and analyse new signal from the reported cases both via active as well as passive surveillance.

- To analyse the benefit-risk ratio/risk analysis/causality assessment of Medical Devices

- To generate evidence-based information on safety of Medical Devices and generate medical device alert to regulator/healthcare professional.

- To support regulatory agencies in the decision-making process on use of Medical Devices.

- To communicate the safety information on use of Medical Devices to various stakeholders with an aim to minimise the risk.

- To emerge as a national centre of excellence for Materiovigilance activities.
To collaborate with other national centres for the exchange of information and data management.

To create awareness among healthcare professionals about the significance of MDAE reporting.

To provide training and consultancy support to other national Materiovigilance centres across the globe.

**1.2.1 Short-term goals’**

To develop and implement Materiovigilance system in India.

To enrol, initially 10 medical colleges in the programme covering north, south, east and west of India.

To encourage clinicians, biomedical engineers/clinical engineers, hospital technology managers, pharmacists, nurses, technicians, medical-device manufacturers for reporting adverse events related to medical devices.

Compile adverse events reports, analyse and issue medical device reports to medical device regulator

Suo motu analysis and prepare reports on medical device adverse events.

Voluntary registration of medical device manufacturers to:

a) Report adverse events to IPC-NCC.

b) Undertake root cause analysis for deterioration or failure on any of their Medical Device and report to IPC-NCC.

c) Report corrective or preventive action taken in regards to potential adverse events/near miss incidents/adverse events/recalls related to Medical Devices.
1.2.2 Long-term goals

- To expand the Materiovigilance programme to all hospitals (Govt & private) and centres of public health programmes located across India.

- To develop and implement electronic reporting system (e-reporting).

- To nurture reporting culture among healthcare professionals, biomedical engineers, Medical device manufacturers etc.

- To provide feedbacks and issue progress or status report to all individuals reporting adverse events using MvPI MDAE form.

- Issue medical device alert to general public or a healthcare professional via email or text message.

- Monitor corrective action taken by the manufacturer in response to report submitted by Materiovigilance programme centre

- To support health system where in procurement of Medical device is only undertaken after studying adverse events associated with Medical Device intended for procurement.

- To make Materiovigilance reporting mandatory for medical-device manufacturers or their authorised representatives for marketing or sale of medical devices in India

- To make adverse event reporting of medical devices mandatory for all healthcare providers under Clinical Establishment Act

1.3 Committees under NCC

The following committees and panels have been constituted by MoHFW, Government of India, to give proper direction for efficient functioning of the programme.

MvPI Steering Committee

MvPI is administered and monitored by a Steering Committee for supervising and giving proper direction to the programme.
MvPI Working Group

It has been constituted to approve major technical issues related to establishment and implementation of programme and giving technical inputs to CDSCO for regulatory intervention of medical devices. Working group may designate core technical committee for quality, technical, training and adverse event signal-related issues.

Communication under MvPI

An effective communication channel is a key to successful functioning of MvPI. The following chart depicts the movement of information between the key stakeholders, ensuring continuous transfer of data, information and knowledge.
Chapter 2: Responsibilities of Stakeholders under MvPI

2.0 Personnel at Medical Device Monitoring Centre (MDMC)

Each MDMC under MvPI is assigned with a coordinator and a Research Associate responsible for its functioning. Their roles and responsibilities are:

- The designated coordinator is responsible for proper functioning of the respective MDMC. In absence of the coordinator, the designated deputy coordinator is responsible for the smooth functioning of the centre. Standard operating procedure (SOP) for MDMC, Coordinator, MDMC-RA to be strictly adhered.

- Other important responsibilities of the coordinator include checking completeness of a valid case, failure mode effect analysis, causality assessment and scrutinizing the MDAE reports as per SOPs. Time to time Coordinator should call for committee in MDMC after initial analysis for further deliberation with experts (expert may be selected on ad hoc basis depending upon the knowledge on medical device associated with adverse event) in MDMC centre.

- The Research Associate is responsible for collection and follow-up of MDAEs. All scrutinized and signed MDAE reports have to be sent for central assessment to National Collaborating Centre. MDAE report has to be submitted immediately after report preparation.

- The coordinator is responsible for sending the consolidated monthly reports of its MDMC to NCC.

- In addition to reactive investigation or report preparation done by MDMC, proactive investigation and risk-based information from global regulators has to be reported as and when it’s noticed.

- The centre coordinator is also responsible for sensitization/encouragement of clinicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses, technicians of the hospital for Medical Device Adverse Event reporting by various modes (e.g. lectures on ADE reporting, emails, telephone communication, publication of pamphlets and newsletters).
Feedback to all healthcare professionals involved in reporting is to be sent by the MDMC coordinator

2.1 Personnel at National Collaborating Centre (SCTIMST)
Collaborating centre is responsible for:

- Receiving and collating all Adverse Events reported from MDMC (The MvPI staff at MDMC shall be responsible for monitoring of serious and non-serious Adverse Events due to use of medical devices in public and private hospitals of their region and reporting to National Collaborating Center i.e. SCTIMST).

- Coordinating with the respective MDMC for further follow-up/analysis in case of a serious Adverse Event.

- Data collection, collation, analysis, signal detection, baseline study and its outcome to be communicated to NCC (IPC).

- Organizing continuous, professional development education programmes on Materiovigilance at various zone.

- Conducting periodic training and workshops for all enrolled MDMCs.

- Database and updating custodian for MvPI.

2.2 Personnel at National Coordination Centre (IPC)

- The main responsibility of NCC is to coordinate with all partners of the programme. Organising steering committee and working group meetings.

- Recognition of new Medical Device Adverse Event Monitoring Centres (MDMCs) of public and private hospitals across the country.

- Recruitment of manpower and appointed MvPI staff shall work under the administrative control of IPC-NCC.

- Any adverse event due to use of a medical device received directly at SCTIMST-NCC shall be immediately communicated to the nearest MDMC for processing.
Formulate data received from SCTIMST and recommend to CDSCO for appropriate regulatory action.

Publication and dissemination of standard operating procedures, guidance documents, newsletters, training manuals, etc with technical support from NHSRC and SCTIMST.

Providing financial support to SCTIMST and NHSRC for procurement of technical document.

Providing assistance to NHSRC for organizing MvPI awareness programme among medical device manufacturers/healthcare organisations.

2.3 Personnel at Regulatory authority (CDSCO HQ)

The CDSCO HQ is responsible for:

- Taking appropriate regulatory decisions and action on the basis of recommendations made by IPC-NCC.

- Joining international medical device regulators' forum (IMDRF) and Asian Harmonization Working Party (AHWP) and other forums organised by regulatory body of other countries for exchange of post-market safety information globally via NCAR (National Competent Authority Report) form exchange programme.

- Regular meetings with the NCC-MvPI, SCTIMST & NHSRC for continuing monitoring of medical device safety.

- Auditing/inspecting MDMCs and National Collaboration Centre with IPC-NCC officials providing administrative support to run MvPI.

2.4 Personnel at Technical support and resource centre (NHSRC)

- To provide technical support/guidance for preparation of standard operating procedures, guidance documents, newsletters, training manuals, etc.

- Support in Identification of new MDMC and intimating the same to IPC.

- Technical support for National Collaboration Centre and National Coordination Centre activities, including training.
To draft terms of reference for various positions under MvPI. Explore possibility of integrating data mining/data analytics to adverse event reports. Technical advice on setting up of online adverse events data collection and release of medical device alerts via Email/SMS, etc.

Awareness programme among medical device manufacturers/healthcare organizations.
Chapter 3: Post-Market Surveillance

The vigilance on use of medical devices, including collection of information on the quality, safety or performance of medical devices after the medical device is placed in market is termed as Post-Market Surveillance Programme. Another term for the same process is —Medical device Post-marketing surveillance or —medical device vigilance. Injury or death may not be necessarily be the final effect in a medical device associated adverse event. Final effect could be miss diagnosis or error in diagnosis, need of timely intervention from healthcare professional to prevent an adverse event that may lead to any harm/ injury to patient.

The objective of an adverse-event reporting system and its subsequent evaluation is to improve protection of health and safety of patients, and users of the medical device, reducing the likelihood of the same type of adverse incident being repeated in different places at different times. This will be achieved by the evaluation of reported incidents, and wherever appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such repetitions.

3.1 The Vigilance in Medical Devices is useful for:

Ministry of Health and family welfare, Governments of India initiative on setting up a system to record and analyze Medical Devices related adverse events is a huge milestone in terms of providing secured, sensible and responsible healthcare to citizens in India.

The importance of an efficient system for dealing with medical devices safety risks and crises has become increasingly evident in recent years. Medical device safety issues tend rapidly to take on international significance. The speed with which information spreads in the modern world means that medical device safety concerns are no longer confined to individual countries. Often the media and general public are informed at the same time as, or even before, the national regulatory authority. When crises arise, whether they are real or perceived, local safety issues or concerns arising abroad, regulatory authorities are expected to meet them openly, efficiently, thoroughly and rapidly.

Following are some of the key specific benefits to its stakeholders like Health system of India (Public & Private), National Regulator (CDSCO), Medical Device Manufactures, Healthcare Professionals and Citizens of India.

1. Potential for huge reduction in direct cost (from Indian healthcare budget) related to preventable adverse events related to medical devices.
2. Possible to contribute in optimization of Medical device to maximum without compromising patient safety.

3. To contribute in establishing a system in India for Systematic, scientific and practical means of screening large Medical device adverse events datasets at national level.

4. Positive contributions to public health by identifying potential safety issues more quickly and/or more accurately than conventional passive responding to information on Newspaper.

5. To improve performance and promote patient safety through the identification of incidents that resulted in, or could have resulted in, patient harm. Subsequent investigation and analysis of the incidents, including their severity, type, frequency, and probable cause, are intended to provide organizations with the necessary information to implement interventions that will limit recurrence of such events and mitigate their impact if they do recur.

6. Medical device manufactures could put products in market with as sense of ethical business, analyze and improve design and performance of products.

7. Better decision support for the Medical Device industry and National Regulators (CDSCO).

8. Would result in establishing a open database system for healthcare professionals, healthcare procurement experts across country to procure medical devices with maximum value and weed out spurious products entering Indian Health systems.

9. Adopting good Materiovigilance practice in clinical establishments and having an aptitude to utilize the advantages Materiovigilance solutions can provide key to unlock the power to maximize clinical safety returns in an evolving Medical Device technology.

10. To provide supportive data to improvise product standards developed by ISO/BIS.

A large number of adverse events occur due to the manufacturing defects in medical devices. There are various standards for testing the safety of medical devices, e.g. IEC 60601-1, first published in 1977 (referred to as IEC 601), addresses electrical, mechanical, temperature and fire-related hazards in medical devices. IEC 60601-1 has been further developed into Collateral & Particular Standards such as (IEC 60601-2-X) which are standards addressing unique safety concerns for specific technologies used in medical devices, e.g. IEC 60601-1-3 for X-ray
equipment. Some standards are device-specific such as IEC 60601-1-1 which address safety-related issues with only particular devices, e.g. IEC 60601-2-27 for ECG-monitoring devices.


The adverse events include but are not limited to:

1. Non-compliance or incomplete compliance to safety testing. Safety testing means proactive collection of information about the quality performance of medical device before placed in market. Post market surveillance requires safety testing for proactive collection or information about the quality and performance of medical device when they initially placed on market. E.g. Lot testing verification, its aim to identify any catastrophic product failure and to determine variation from lot to next lot.

2. Non-declaration of sufficient warning/labeling even after testing based on objective standards labelling here refers in the use manual/instruction for users. E.g. a sterilizer sterilise the instruments at certain label temp. 120°C as per user manual or instruction manual, if temperature falls above given temp i.e. 135°C than it leads to higher rate of adverse events.

3. A higher rate of adverse events than what was declared in labelling after testing based on objective standards.

4. Due to clinical application error: An act of commission or omission by the user or operator of a medical device which is not in accordance with the directions by the manufacturer.

5. An unintended use of medical device/equipment/instrument.

6. A malfunction or deterioration in characteristics or performance. For IVDs where there is a risk that an erroneous result would either (1) lead to a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or to the individual’s offspring, or (2) cause death or severe disability to the individual or foetus being tested, or to the individual’s offspring, all false positive or false negative test results shall be considered as events.
7. Unanticipated adverse reaction or unanticipated side-effect.

8. Undesired interactions (electromagnetic interference, biocompatibility etc) with other substances or products.

9. Inappropriate delivery of therapy.

10. Degradation/destruction of the device (e.g. fire).

Examples of Reportable Adverse Events are:

a) While taking an X-ray view of during patient examination, the C-arm had uncontrolled motion. The patient was hit by the image intensifier and his nose was broken. The system was installed, maintained, and used according to manufacturer’s instructions.

b) It was reported that a monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke off. Nobody was injured in the surgical theatre at that time but a report is necessary (near miss incident). The system was installed, maintained, and used according to manufacturer’s instructions.

c) Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator did not show up in due time although it should have as per device specification.

d) Sterile single-use device packaging is labelled with the caution 'do not use if package is opened or damaged'. The label is placed by incorrect design on inner packaging. Outer package is torn and device is not used during procedure as device is stored with inner packaging does not offer sufficient sterile barrier.

e) A batch of out-of-specification blood glucose test strips is released by manufacturer. Patient uses strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycaemic shock and hospitalization.

f) Premature revision of an orthopaedic implant due to loosening. No cause yet determined.
Chapter 4: Baseline studies

Baseline studies could be conducted through a questionnaire(s) to capture data on potential medical devices adverse events based on Recalls/Filed safety correction notice issued by medical device regulators across the globe (E.g.: FDA, CE, Swiss medic, TPA-Australia etc). Though it is difficult to collect medical device-associated adverse events for all categories of devices, a beginning could be made by collecting those resulting due to medical devices categories that are put on alert by other international regulatory agencies. Baseline studies are essential as Materiovigilance programme of India is in its initial stage and there are equipments in Indian market which are recalled by regulators across the globe but continue to be in use in India for want of materiovigilance enforcement. A sample questionnaire is given below for conducting initial studies. This sample questionnaire should be applied to all medical devices in the identified centres listed in Annexure

Sample Questionnaire

1. Health Facility demographics

2. Medical device information:
   a) Type of Device
   b) Control/Lot/Serial #
   c) Age of Device/Date of manufacture: (Indicates the number of years since the manufacturing date of the device)
   d) How long was the device in use here: (Indicates how long the device was used)?
   e) Packing condition sterile / Non sterile
   f) Was the device tested during sale/installation?
   g) If the device is meant for reuse: Is proper cleaning/maintenance done?

3. Description of incident:
   a) Date of Incident
   b) Patient Consequences: (Includes information on the effect of the event on patient, user or any other person(s) involved)
   c) Details of Incident: (Includes description of device(s), equipment, or drug-device combination involved in the incident, and a detailed description of what happened in the incident)

4. Medical Records Tagging: Data would be collected from medical records also to find more details of the incident and to triangulate the findings and increase validity of the data.
5. Baseline Causality: The research team would evaluate whether the event had any temporal relationship with the device, using different causality assessment criteria. This may include qualitative findings also like:

(a) Action taken by the manufacturer with a copy of the final report.
(b) Does manufacture stick to the timeframe mentioned in the recall notice or field safety corrective notice?
(c) Medical device or equipment of different serial number or model number may also be observed to anticipate probable adverse events.

Baseline studies also include documenting the correlation between the devices that are recalled by regulators in any country across the globe and the same model or type or category of medical device is sold in India, which could have the potential of causing an adverse event or a near-miss incident to Indian citizen.

**Timeframe and submission of report:** The study has to be initiated when IPC – NCC or any other MDMC centre alerts about the recall or field safety corrective action notice issued by any medical device regulator across the globe. The study has to be completed within 30 days from date of intimation and completed report has to be submitted to IPC-NCC.
Chapter 5: Reporting of Medical Device Adverse Events

In the pilot phase, reporting by a prescribed form would be done by only research associates deputed at 10 Medical Device Event Monitoring Centres or voluntary medical device manufactures. The two-page format of the form is given at the end of chapter 5.

5.1 Scenario where an event or incident is noticed by manufacturer or healthcare service-provider or MDMC.

5.1.1 When an event or incident is noticed by medical device manufacturer
Currently the incident or event reporting is to be taken as a voluntary initiative by medical device manufactures in India. When the manufacturer is aware of information regarding an event which has occurred with their device, manufacturers are advised to initiate investigation root cause for failure and intimate IPC-NCC. IPC-NCC would send this information to research associates at MDMC located nearest to location of event or incident. The information obtained by performing device testing by the manufacturer, user or other party may include:

a) A malfunction or deterioration in the characteristics or performance of the Medical Device
b) An incorrect or out-of-specification test result
c) The discovery of a design flaw during design review
d) An inaccuracy in labelling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users
e) The discovery of a serious public health threat. This may include an event that is of significant and unexpected nature and is a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD).
f) Increase in user error or application error with the medical device
g) Any other information (Recall or field corrective notice) made available by medical device regulators in other countries for the same product
h) Information available by way of literature, scientific documentation, or increase in complaint trend.

It is possible that the manufacturer may not have enough information to decide definitively on the reporting of an event. In such a case, the manufacturer should make reasonable efforts to obtain additional information to decide upon reporting. Wherever appropriate, the manufacturer should consult the medical practitioner or healthcare professional involved, and try their utmost to retrieve the device concerned. As a general principle, there should be a predisposition to report rather than not to report in case of doubt on the reporting of an event.

5.1.2 When an event or incident noticed by Healthcare service-provider
The healthcare service-provider is aware of information regarding an event, which has occurred with their medical device. This information will be sent to research associates at the medical device event monitoring centres. The information may include:

a) A malfunction or deterioration in the characteristics or performance of the medical device

b) An incorrect or out-of-specification test result

c) An inaccuracy in labelling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users

d) The discovery of a serious public health threat. This may include an event that is of significant and unexpected nature and is a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD).

e) Increase in user error or application error with the medical device

f) Any other information made available by medical device regulators in other countries for the same product.

g) Information by way of literature, scientific documentation, or increase in complaint trend.

5.2 Assessing medical device associated with an event or incident
In assessing the link between the device and the event, the following parameters be followed:

- Opinion based on information made available by a healthcare professional
- Failure mode-effect and non-destructive root-cause analyses on the medical device
Information concerning similar events in the past

Complaint trends

Other information made available by the manufacturer

A Committee may be formed at MDMC or at manufacture, as the case may be and then deliberate the initial findings on root cause of event. The committee formed at MDMC may have experts like research associate (prepared initial report and positioned at MDMC), MDMC coordinator, Biomedical/Clinical engineers, Administration/Quality official of hospital, Healthcare professional and/or technician handling medical device (added on ad hoc basis based on event or incident and medical device) associated with the use of medical devices.

However, to make the correct assessment it may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device was associated with the event is minimally influenced by effect of drugs.

5.3 Event or Incident not to be reported

When the only root cause for the adverse event was that the device exceeded its service-life or shelf-life as specified by the manufacturer, and the failure mode is not unusual, the adverse event need not be reported.

Reporting under Medical device vigilance systems is not usually required:

1. When deficiency of a medical device found by the user prior to its use:

Regardless of the existence of provisions in the instructions for use provided by the manufacturer, deficiencies of devices that are always detected (that could not go undetected) by the healthcare professional or end user, prior to its use do not need to be reported under the vigilance system.

This is without prejudice to the fact that the user should inform the manufacture of any deficiency identified prior to the use of a medical device.
Examples:

❖ The packaging of a sterile single use device is labelled with the caution 'do not use if the packaging is opened or damaged'. Prior to use, obvious damage to the packaging was observed, and the device was not used.

❖ Intravenous administration set tip protector has fallen off the set during distribution resulting in a non-sterile fluid pathway. The intravenous administration set was not used.

❖ A vaginal speculum has multiple fractures. Upon activating the handle, the device fell apart. The device was not used.

❖ In an IVD testing kit a bottle labelled lyophilised is found to be fluid, this is discovered by the user or healthcare professional prior to use.

2. When event is caused by patient conditions:

When the MDMC or manufacturer has information that the root cause of the event is due to patient condition, the event does not need to be reported. These conditions could be pre-existing or occurring during device use.

To justify no report, the MDMC or manufacturer should have information available to conclude that the device performed as intended and did not cause or contribute to death or serious deterioration in state of health. Moreover, a person qualified to make a medical judgement would accept the same conclusion.

It is recommended that the MDMC or Manufacturer involves a clinician in the specific domain (related to clinical specialist and medical device) in making the decision.

Examples:

❖ Early revision of an orthopaedic implant due to loosening caused by the patient developing osteolysis, which is not considered a direct consequence of the implant failure. This conclusion would need to be supported by the opinion of a medical expert.

❖ A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure, the MDMC or manufactures investigations revealed the device to be functioning as claimed and the event was not attributed to the device.
3. When service life or shelf life of the medical device exceeded:

When the only cause for the event was that the device exceeded its service life or shelf-life as specified by the manufacturer and the failure mode is not unusual, the event does not need to be reported.

The service life or shelf-life must be specified by the device manufacturer and included in the master record [technical file] and, where appropriate, the instructions for use (IFU) or labelling, respectively. Service life or shelf-life can include e.g.: the time or usage that a device is intended to remain functional after it is manufactured, put into service, and maintained as specified. Reporting assessment shall be based on the information in the master record or in the IFU.

Examples:

- Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator has shown up in due time according to device specification. Surgical explanation of pacemaker required.

- Insufficient contact of the defibrillator pads to the patient was observed. The patient could not be defibrillated due to insufficient contact to the chest. The shelf life of the pads was labelled but exceeded.

- A patient is admitted to hospital with hypoglycaemia based on an incorrect insulin dosage following a blood glucose result. The investigation found that the test strip was used beyond the expiry date specified by the manufacturer.

4. When an inbuilt protection mechanism in medical device functioned correctly:

Events which did not lead to serious deterioration in state of health or death, because a design feature protected against a fault becoming a hazard (in accordance with relevant standards or documented design inputs), do not need to be reported. As a precondition, there must be no danger for the patient to justify not reporting. If an alarm system is used, the concept of this system should be generally acknowledged for that type of product.

Examples:

- An infusion pump stops, due to a malfunction, but gives an appropriate alarm (e.g. in compliance with relevant standards) and there was no injury to the patient.
Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm. (e.g., in compliance with relevant standards) and there was no deterioration in state of health of the patient.

During radiation treatment, the automatic exposure control is engaged. Treatment stops. Although patient receives less than optimal dose, patient is not exposed to excess radiation. A laboratory analyser stops during analysis due to a malfunction of the sample pipetting module, but the appropriate error message was provided for the healthcare professional or end user. An intervention by the user or an immediate remote intervention by the manufacturer allowed the analyser to resume the analysis, resulting in correct results.

5. In case of an expected and foreseeable side effect associated with medical device:

Cases which meet all the following criteria:

a) clearly identified in the manufactures labelling;
b) clinically well known (Scientifically/Clinically/ Technically identified or declared during clinical trial or clinical practices) as being foreseeable and having a certain qualitative (Condition that lead to side effect cannot be numerically predicted) and quantitative predictability when the device is used and performs as intended;
c) documented in the device master record, with an appropriate risk assessment, prior to the occurrence of the event, and
d) Clinically acceptable in terms of the individual patient benefit are ordinarily not reportable.

If the MDMC or Manufacturer detects a change in the risk-benefit-ratio (e.g. an increase of frequency and/or severity) based on reports of expected and foreseeable side effects that led or might lead to death or serious deterioration of state of health, this must be considered as deterioration in the characteristics of the performance of the device. A trend report must be submitted to the NCC (IPC) where the manufacturer or its representative has his registered place of business.

Examples:

- A patient who is known to suffer from claustrophobia experiences severe anxiety in the confined space of a MRI machine which subsequently led to the patient being injured. Potential for claustrophobia is known and documented in the device product information.
A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within range specified in the device master record.

A patient has an undesirable tissue reaction (e.g. nickel allergy) previously known and documented in the device product information.

Patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died. Risk assessment documents that endocarditis at this stage is clinically acceptable in view of patient benefit and the instructions for use warn of this potential side effect.

Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.

6. In case of negligible likelihood of occurrence of death or serious deterioration of health due to event:

Where the risk of a death or serious deterioration in state of health has been quantified and found to be negligibly small need not be reported if no death or serious deterioration in state of health occurred and the risk has been characterised and documented as acceptable within a full risk assessment.

If an event resulting in death or serious deterioration in state of health has happened, the event is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains negligibly small compared to previous events of the same type, then there is no need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented. Changes in the trend, usually an increase, of these non-serious outcomes must be reported.

Example:

Manufacturer of a pacemaker released on the market identified a software bug and quantified the probability of occurrence of a serious deterioration in state of health with a particular setting to be negligible. No patients experienced adverse health effects.
5.4 Severity of an adverse event can be broadly classified into three categories:

1. Death of a patient, user of the device or other person

2. Serious injury to a patient, user or other person

   **Serious Injury** (also known as serious deterioration in state of health) is either a life-threatening illness or injury, permanent impairment of a body function, cause congenital abnormality or permanent damage to a body structure -- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure. The interpretation of the term “serious” is not easy and should be made in consultation with a medical practitioner whenever appropriate.

   The term —"permanent or prolonged impairment“ means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage. Medical intervention is not in itself a serious injury. It is the reason necessitating medical intervention that should be used to assess the reporting of an event.

3. No Death or Serious Injury occurred but the event might lead to death or serious injury of a patient, user or other person, if the Event recurs or not addressed or prevented within adequate time by healthcare professional. They are also termed as "Near Miss event".

   All events do not lead to death or a serious injury. The non-occurrence of such a result might have been due to circumstances or to the timely intervention of healthcare personnel.

5.5 Who can Report?

   All healthcare clinicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses and technicians can report medical device adverse events (MDAEs). Medical device manufactures could voluntarily send adverse events specific to their product to IPC-NCC

5.6 Why to Report?

   As a healthcare professional or ethical medical device manufacturer, it is one’s moral responsibility to report adverse events associated with use of Medical Devices, hence safeguard the health of public.
5.7 What to Report?

To foster the habit of reporting, MvPI encourages reporting of all types of adverse events related to Medical Devices irrespective of whether they are known or unknown, serious or non-serious, frequent or rare though Materiovigilance is primarily concerned with adverse events associated with Medical Devices used in India.

5.8 How and Whom to Report?

Use the Medical Device Adverse Event Reporting Form which is available on the official website of IPC (www.ipc.gov.in) to report any adverse event. Reporters from MDMCs after filling the above mentioned MDAE reporting form can submit it to the coordinator or Research Associate of the respective MDMC. A reporter who is not part of MDMC can submit the filled MDAE reporting form to the nearest MDMC or directly to the National Collaborating Centre. Reporter can also mail the scanned form at mvpi@sctimst.ac.in and copy to mvpi.ipcindia@gmail.com.

NCC-PvPI has also created a helpline number 1800-180-3024 to report adverse events associated with medical devices and medicines. A reporter can also call on this number to report MDAEs.

5.9 Timeframe for reporting an event or Incident

<table>
<thead>
<tr>
<th>REPORTER</th>
<th>WHAT TO REPORT</th>
<th>TO WHOM</th>
<th>WHEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturers</td>
<td>Initial reports for an event on MDAE reporting form with remedial action to</td>
<td>MvPI</td>
<td>Within 5 work days of becoming</td>
</tr>
<tr>
<td></td>
<td>prevent an unreasonable risk of substantial harm to public health. Adverse</td>
<td></td>
<td>aware of an event</td>
</tr>
<tr>
<td></td>
<td>event or incident resulting in death or of serious public health threat should</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>submit initial report</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturers</td>
<td>Medical device adverse event (MDAE) or incident on MDAE-reporting form with</td>
<td>MvPI</td>
<td>Within 30 calendar days of becoming</td>
</tr>
<tr>
<td></td>
<td>causality assessment report and future preventive or corrective steps that would</td>
<td></td>
<td>aware of an event</td>
</tr>
<tr>
<td></td>
<td>be taken in a defined timeframe</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5.10 General Instruction to fill MDAE reporting Form

**General information section:**

**Type of report:** Report can be submitted as initial or final report. Initial report has to be submitted within timeframe as mentioned in section 5.9.

**Report Number:** This is intended for IPC-NCC to fill. MDMC or manufacturer may maintain report identification code at their end for future reference. Report number for MDMC/Manufacturer of medical device company should be filled in the format of: Centre name/month/year/report number (e.g. AIIMS/Jan-2017/01)

**Section A. Patient Information**

This section captures basic information about patient:

A.1) Patients Hospital ID- To be filled by the reporter, in case patient was not directly involved during the event this section may be left blank.

A.2) Sex - To be filled by the reporter (Tick the respective gender)

A.3) Age at the time of Event or Date of birth- Fill the age of patient at the time of event (if patient is directly involved)

A.4) Weight (kg) - To be filled by the reporter (Mention the weight of the patient)

All data collected under section A by IPC-NCC or MDMC or Manufacturer will have to be maintained confidentially and privacy to be protected.
For Section B. Event Details

This section is intended for capturing information on Medical device adverse event:

B.1 Event Description: Describe the event based on initial technical analysis how, when, why and where it took place
Reason for event: Mention the reason lead to adverse event (e.g. event took place due to application error (due to lack of user knowledge) then choose clinical application error). If multiple reasons are suspected tick all applicable
B.2 Severity of the Event: Choose how serious the event or incident from the given options, use “Other” option to detail
B.3 Date of the event: Fill date on which adverse event taken place
B.4 Location of event: Mention where incident taken place eg: OPD, IPD or other e.g. home, ambulance etc.
B.5 Device Category: It is divided into three. First is based on purpose of medical device i.e. therapeutic, diagnostic or both. Second is nature of location of medical device in relation with the end user i.e. Implantable or Non Implantable. Third category is based on the nature of use instructed by manufacturer i.e. single use, reusable, reuse of medical device marked as single use only.
B.6 Date of last preventive maintenance and calibration: This is reserved for medical devices that are subject to preventive maintenance or calibration to be undertaken periodically by user as per manufacturer instructions.
B.7 Location of device after the incident or event: Mention the location of device after the incident or event.
B.8 Is device in use after incident?: Mention whether the device is continued to put in use neglecting the adverse event or before identifying the root cause of adverse event.
B.9. A) Is same model device available in organisation: Choose whether multiple model or serial number of medical device is located at other department with in healthcare facility
B.9.B) Organization: Choose option place where event took place or identified i.e. hospital / clinical facility, or at manufacturers site

For Section C. Medical Device details:

This section is intended for capturing information on Medical device caused adverse event:

In C.1, C.2, C.3, C.4, C.5, C.6, C.7, C.8, C.9 ;Mention name of medical device , Medical device manufactures name, brand Name, model number, serial number, batch/lot no, Catalogue no, date of installation and list of accessories respectively.
Under C.10 Mention action taken immediately after Incident: - Describe what action had been taken after the incident taken place eg: initial assessment, equipment withdrawn from use, intimated the manufacturer, issued notice to check other similar equipments etc. 

Under C.11. A) Specify whether other medical device used at the same time with above device, if yes please specify what are the other medical devices simultaneously used during the incident or event. Also mention other adverse event that had taken place with the same device i.e. same serial number/model/ catalogue number, in the past under C11. B)

For Section D. Regulatory Details:

This section is intended for capturing regulatory details of Medical device caused adverse event:

(Under D.1) Mention manufacturer’s name, the name of regulator and regulatory status in the country of origin i.e. recall issued, regulatory body withdrawn approval. In D.2) if manufacturer is not the legal entity registered for sale in India, then mention legal entity name with full address

D.3) If the regulatory body across the globe granted permission via inspecting using a notified body please mention the name of notified body eg. In Europe CE is marked on high risk medical device after inspecting product using regulator notified bodies. If the manufacturer is of Indian origin has got licence from notified body on inspection, please mention name of notified body (eg EU- BIS , TUV, UL) In Europe Notified body for medical device is can be found on the EU certificate issued for concerned device.

For Section E. Reporter Details of MvPI Centre:

This section is intended for capturing basic details of reporter, this may be RA of MDMC, representative of manufacturer or Healthcare professional. Reports can be submitted without this detail, if reporter wishes to be anonymous.

Under E. Detail the name of reporter with complete address, designation and signature with date.

For section F. Causality Assessment:
Mention here the status of causality assessment i.e. completed root cause analysis or root cause analysis in progress or not initiated root cause analysis as team is waiting for further information on event or incident.
Additional information: 
This section is intended to submit relevant additional details as annexure eg: Minutes of clinical establishment on medical device adverse event reporting committee, Photos/Videos of incidents, base line study, root cause analysis, failure mode effect analysis or any other supporting documents.
MEDICAL DEVICE ADVERSE EVENT REPORTING FORM
Materiovigilance Programme of India

FOR MDMC/NCC USE ONLY

<table>
<thead>
<tr>
<th>Type of report</th>
<th>Initial</th>
<th>Follow-up</th>
<th>Report No.</th>
</tr>
</thead>
</table>

A. PATIENT DETAILS

1. Patient Hospital ID __________
2. Sex: M ☐ F ☐
3. Age at time of Event or Date of Birth __________
4. Weight (Kg) __________

B. EVENT DETAILS

1. Event description:

| Reason for the Event | Yes ☐ No ☐ | a) Electrical ☐ b) Mechanical ☐ c) Electronic ☐ d) Biocompatibility ☐ e) Clinical application error ☐ |

2. Severity of the event: (Yes ☐ No ☐) if yes please specify following
   □ Death (…………….) □ Cause congenital anomaly □ Life threatening □ Required intervention to prevent death or impairment of body function
   □ Hospitalization/Prolonged impairment/damage □ Disability □ Other (specify) __________________________________________________________________________
3. Date of event: -(dd/mm/yyyy) _______________________________________________________________________
4. Location of the event: ODI ☐ IPD ☐ Others(Please specify) _______________________________________________________________________
5. Device category: (A) Therapeutic ☐ Diagnostics ☐ Both ☐ (B) Implantable device ☐ Non Implantable device ☐
   (C) Single use device ☐ Reusable device ☐ Reuse of manufacture marked single use device ☐

6. Date:
   Last preventive maintenance: __________
   Last calibration: __________

7. Location of device after the incident:
   Place of use ☐ Place of reporter ☐ Place of Manufacture/vendor ☐ With patient or end user ☐

8. Is device in use after incident: Yes ☐ No ☐
9. (A) Is same model device available in organisation? Yes ☐ No ☐ If yes, Quantity __________
   (B) Organization: Healthcare facility ☐ Manufacturer ☐

C. MEDICAL DEVICE(S) DETAIL

<table>
<thead>
<tr>
<th>Name of Medical Device</th>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Model No.</th>
<th>Serial No.</th>
<th>Batch No./Lot No.</th>
<th>Catalogue No.</th>
<th>Date of installation/implantation/explantation</th>
<th>List of Accessories</th>
</tr>
</thead>
</table>

10. Actions taken immediately after incident

11. A. Whether other medical devices were being used at same time with above device for therapeutic or diagnostic service? If yes, please specify: __________________________________________________________________________
11. B. Any history of adverse event(s) from device with same serial/model/catalogue number. If yes please specify: __________________________________________________________________________
<table>
<thead>
<tr>
<th>D. REGULATORY DETAILS</th>
<th>E. REPORTER DETAILS OF MVPI CENTRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer name:</td>
<td>Name and Professional Address:</td>
</tr>
<tr>
<td>Register in Country of</td>
<td>E-mail: ________________________</td>
</tr>
<tr>
<td>origin:</td>
<td>Tel. No. (with STD code)________</td>
</tr>
<tr>
<td>Regulatory status in</td>
<td>Designation: ___________________</td>
</tr>
<tr>
<td>origin country:</td>
<td>Signature: _____________________</td>
</tr>
</tbody>
</table>

F. Causality Assessment Details  
- Completed [ ]  
- In Progress [ ]  
- Awaited [ ]

Additional information:

Confidentiality: The patient’s identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter’s identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.

National Collaborating Centre-Materiovigilance Programme of India,

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) under the Department of Science & Technology, Government of India. Biomedical Technology Wing, Poojappura, Thiruvananthapuram 695012, Kerala. Phone: 91-471-234011, Fax: 91-471-2341614, Email: head-bmtw@sctimst.ac.in.

National Coordination Centre-Materiovigilance Programme of India,

Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-201002, Tel.: 0120-2783400, 2783401, and 2783392, FAX: 0120-2783311, Email: ipclab@svnil, pvp.ipcindia@gmail.com

Technical support and Resource Centre- Materiovigilance Programme of India,

National Health System Resource Centre (NHSRC), NHFW campus Baba Ganganath marg, Munirka, New Delhi-110067, Phones: 011-16108962 / 03 / 04 / 02 / 03, Fax: 011-26108939 Email: nhsr.india@gmail.com.

Where to report

- Duly filled Medical Device Adverse Event Reporting Form can be send to Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), National Collaboration Centre-Materiovigilance Programme of India, Biomedical Technology Wing, Poojappura, Thiruvananthapuram 695012, Kerala, India.
- Or can directly email the duly filled form to mvpi@sctimst.ac.in.
- Call on Helpline no. 1800 180 3024 to report Adverse event.

Event description Details of adverse event including description of device (deficiency or malfunction), clarification of hazards associated with device and the associated risk of patient, user or person any possible risk to patient associated with previous use.

Additional Information Other relevant information related to treatment should be provided.
Chapter 7: Causality Assessment

7.1 Causality assessment measures the relationship between the use of a medical device and the occurrence of any adverse event and their categorization. Causality being the association of a medical device with a suspected adverse event, the expression of the strength of this association in a standardized, transparent and rational manner, in a qualitative or quantitative method is defined as assessment of causality or causality assessment.

The causality assessment helps as follows:

a) It decreases disagreement between assessors by establishing a standardized approach.

b) It will classify likelihood of relationship.

c) It will mark individual case reports.

d) It helps in improvement of scientific and educational evaluation.

However, the process of causality assessment may have the following limitations:

a) It cannot give a very accurate quantitative measurement of likelihood of relationship.

b) It cannot always distinguish valid from invalid cases.

c) It cannot change uncertainty into certainty.

d) It cannot quantify the contribution of device to the development/occurrence of event.

Since assessment of causality is undertaken for reported events, it is necessary to ensure a standardized report that meets certain pre-specified quality and content assurance criteria. The following serves as themes to capture the important criteria within an adverse event reports:

a) Quality check for completeness of a reported case.

b) Validity of the case.

c) Follow up a case, if necessary.
d) Causality assessment.

This level of causality assessment has to be done by research associates deputed at deputed at 10 Medical Device Event-Monitoring Centres (MDMCs) in collaboration with the National Collaborating Centre, SCTIMST and IPC-NCC.

7.2 Overview of causality assessment procedure

The causality assessment activity has to be a combination of clinical investigation, risk-management analysis and failure-analysis including, but not limited to, Material, Mechanical, Electrical, Electronic, Biocompatibility software, etc. Causality assessment based on clinical investigation will be conducted on the basis of ISO 14155. Risk-management analysis will be done as per ISO 14971 and similarly failure mode-effect analysis.

An adverse event can be related to both procedures and the investigational device. Complications of procedure are considered 'not related', had the said procedures been applied to patients in the absence of investigational device use/application. In some particular cases the event may not be adequately assessed because information is insufficient or contradictory and/or the data cannot be verified or supplemented. The investigators will put in the maximum effort to define and categorize the event and avoid such complications.

Research associates and MDMC coordinators during their scheduled training will be taught the detailed procedure for conducting failure mode-effect analysis on medical devices. Similarly, the techniques used for root-cause analysis on the failure of medical devices and the necessary details need to be incorporated in the final causality assessment report by the MDMC.
Chapter 8: Signal detection

There is a striking difference in signal detection as practised in drugs and as suggested for devices. The reason: most pharmaceutical products have a single or at the most a dual Active Pharmaceutical Ingredient (API). A single device could, however, have hundreds of components, each working on a distinct technological pathway. Signal detection in medical devices could make root-cause analysis more elaborate.

Signal detection involves identifying patterns of adverse events associated with a particular device that warrant further investigation.

A medical device safety signal may arise from:

- a previously unrecognized safety issue
- a change in frequency or severity of a known safety issue
- identification of a new at-risk group
- use of a device other than one intended by the manufacturer

Based on the completed root cause analysis report, events/incidents would be classified as per above mentioned signals or classification of signals after discussion in technical core committee of MvPI. Signals would be used as markers for trend analysis.

Once a safety signal has been detected it is assessed to determine the nature, magnitude and significance of the concern, and the impact on the overall benefit-risk profile of the device. The complete analysis of the signals detected has to be initiated after getting enough adverse events reports.
Chapter 9: Regulatory action and action outcome on medical device ecosystem.

The regulatory structure has an established licensing component, a proactive inspection component and a responsive compliance/investigation component. The licensing component plays a major role in pre-market approval and device registration. Post-market surveillance, including a responsive investigational component, is in a nascent stage in India. Support of clinical engineering apart from other sciences within medical faculty could play a significant role in regulating medical devices by post-market surveillance.

9.1 Timeframe for recall: The speed with which the various elements of the recall are to be accomplished have to be clearly addressed in the recall strategy. Where the initial communication is not the corrective action, a detailed plan including estimated timeframes for accomplishing the corrective action needs to be included in the recall strategy. This has to be based on the rationale which takes into account factors such as complexity of the fix, number and geographic location of customers, the risk associated with the affected device, validation requirements, and continuous availability of essential products.

9.2 Severity associated with the device intended for recall:

Severity associated with recall has to be classified on the basis of the health hazard. Health hazard may be classified as:

Type I: A situation in which there is a reasonable probability that the use of, or exposure to, a recalled device will cause serious adverse health consequences or may even result in death.

Type II: A situation in which the use of, or exposure to, a recalled device may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

Type III: A situation in which the use of, or exposure to, a recalled device is not likely to cause any adverse health consequences. Such hazard-based classification systems can be formulated in countries intending to initiate a Post-Market Surveillance Programme.
9.3 Effectiveness checks by the recalling Manufacturer.

The purpose of effectiveness checks is to verify that all organisations (Manufacturer/import-trader/distributor, etc) specified in the regulatory strategy has received notification about the recall and has taken appropriate action. The method for contacting may be accomplished by personal visits, telephone calls, letters, or a combination thereof. The recalling firm is responsible for conducting effectiveness checks.

Records generally include:
- Dates of attempted contact.
- Response received at each attempt.
- Name and title of person contacted.
- Means of contact, including telephone or fax number, email or mailing address.
- Details of communications once contact is successful.
- Conclusion as to whether recall instructions were understood and carried out.

A recall progress report should normally contain the following:

i. Number of organisations (Manufacturer/import-trader/distributor, etc) notified of the recall and date and method of notification
ii. Number of respondents and quantity of affected device(s) in possession of each
iii. Number of non-respondents
iv. Number of devices returned or corrected and the quantity of devices accounted for
v. Number and results of effectiveness checks
vi. Estimated timeframe for completion if revised from the original

9.4 Design Considerations to reduce recall/corrective action:

The complexity and diversity of medical devices used simultaneously contribute to human factor/error. A key objective of human factor in medical device design is to enhance the likelihood of good performance under less-than-ideal conditions. To minimize human factor/error, devices should be designed according to users' needs, abilities, limitations, and work environment. This includes the design of the device’s user-interface, which includes controls, displays, software, labels, and instructions — anything the user may need to operate and maintain a device.
Good design should include:
❖ operation that's intuitive and doesn't require frequent reference to an instruction manual.
❖ Easy-to-read displays.
❖ Easy-to-use controls.
❖ Appropriate connections of device-to-device and device-to-outlet for safe use.
❖ Effective alarms.
❖ Easy repair and maintenance.

9.5 Significance of training to reduce recall/corrective action:

It is important that anyone using a device has received training for operating it. Then consider a less obvious factor, the user's expectations of how the device works. Whether a user is a healthcare professional or a patient, he/she may expect a device to work like another device that looks similar. For example, based on his/her experience, he/she may expect a device to deliver the same prescribed treatment or dose as a similar device, or expect the alarms to be in a specific sequence or pattern of sounds.

Many intra-venous (IV) fluid pump programming errors were reported when the actual device function wasn’t what the user expected. It is important that healthcare providers, manufacturers, importers and distributors are also trained according to regulations covering the adverse event reporting system.

9.6 Appropriate Communications/awareness to reduce adverse events:

Monitoring, evaluating and communicating device safety is a public health activity with profound implications for the public at large. Consumers, health professionals, clinical engineers/biomedical engineers, researchers, academia, media, pharmaceutical industry, device regulators, governments and international organizations need to work in tandem to achieve the objective of safety of health for all. Scientific, ethical and professional standards bound by a moral code would govern this activity. The inherent uncertainty of risks and benefits of devices needs to be acknowledged and explained. Decisions and actions that are based on this uncertainty should be informed by scientific and clinical considerations and should take into account social realities and circumstances
(Adapted from Preamble of the Erice Declaration Effective Communications in Pharmacovigilance 1997)
Conclusion:

Given that many countries do not have a Post-Market surveillance/vigilance programme; it is desirable that a beginning is made. Although a complex science in itself, requiring support of many domains including clinical medicine as well as clinical engineering/biomedical engineering, capacities exist in countries to promote safe and safer use of medical devices for the maximum health benefit of patients as well as care providers.
GLOSSARY

Abnormal use/manoeuvre: Due to lack of experience and training, there may exist act/manoeuvre of omission of warning, provided from manufacturer against ―“instructions of use‖. User error is, therefore, an act of commission or omission that has a result different to one intended by the manufacturer or expected by the operator. User error includes slips, lapses, mistakes and reasonably foreseeable misuse.

Active & Passive Surveillance: In passive surveillance, criteria are established for reporting diseases, risk factors or health-related events. Health practitioners are notified of the requirements and they report events as they come to their attention. This is the more common type of surveillance. Active surveillance, criteria are established for reporting disease (or its absence), risk factors or health events, but those maintaining the surveillance system active to initiate reporting. Active surveillance is used when there is an indication that something unusual is occurring.

Adverse Event: An adverse event (AE) is any untoward medical or technical occurrence with a medical device during operation with or without patient.

API: Active pharmaceutical ingredient (API) is any substance or combination of substances used in a finished pharmaceutical product, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

ASTM: ASTM International is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. ASTM standards on medical device and implant (These apparatuses are used in surgical procedures that involve the placement of such devices to specified parts and structures of the body (both humans and animals) for the purpose of enhancement or as an aid in a disability. ) are instrumental in specifying and evaluating the design and performance requirements of a number of biomedical materials, tools, and equipments.

Authorised Representation: The India Authorized agent/representative is a person/company that granted Power of Attorney by the foreign manufacturer who wants to register/Sale their medical device in India. Foreign manufacturers of medical devices who want approval and distribute their medical device (regulated devices) in India must appoint an Indian Authorized Agent. Also called as importer-trader.

Baseline Studies: The purpose of a baseline study is to provide an information base against which to monitor and assess an activity's progress and effectiveness during implementation.
and after the activity is completed. In MvPI, it helps to understand manufactures compliance with global regulators action/advice.

**BIS:** The Bureau of Indian Standards is the National standards body of India working under the aegis of Ministry of Consumer Affairs, Food & Public Distribution, Government of India. They represent medical devices in ISO and formulate Medical device standards in India.

**CDSCO:** The Central Drugs Standard Control Organization is the National regulatory body for Indian pharmaceuticals and medical devices, and serves parallel function to the European Medicines Agency (CE Marking) and US FDA.

**Clinical Establishment Act:** The Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.

**Corrective Action and Preventive Action:** Corrective and preventive action (CAPA, also called corrective action / preventive action, or simply corrective action) are improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations.

**Distributor:** A medical device distributor can be an authorised representative of medical device manufacturer who has no direct presence in India or representative of a legally registered manufacturer in India.

**Intended purpose:** The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use/user manual and/or in promotional materials.

**ISO:** ISO is an independent, non-governmental international organization with a membership of 162 national standards bodies who creates standards for products but not limited to medical device.

**IVD:** A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

**Malfunction or deterioration:** Failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer’s instructions.

**Manufacturer:** For the purpose of this document, the term "manufacturer" must be understood to include the manufacturer, its authorized representative or any other person who is responsible for placing the device in the Indian market.
Materiovigilance Programme of India

MDAE: Medical device adverse event means patients/consumers, healthcare professionals and manufacturer who found an unanticipated event or incident related to a medical device.

Medical Device Alerts: Medical Devices Alerts (MDA’s) are the prime means of communicating safety information to clinical establishments on medical devices.

Near Miss Event: A Near miss event is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so.

Post Market Surveillance: Post marketing surveillance (PMS) (also post market surveillance) is the practice of monitoring the safety of a medical device after it has been released on the market.

Recall: A product recall is a request to return a product after the discovery of safety issues or product defects that might endanger the consumer or put the maker/seller at risk of legal action.

Root Cause Analysis: It is a method of problem solving used for identifying the root causes of faults or problems.

Serious public health threat: Any event type which poses an imminent or potential threat to life, or may result in death, serious injury and/or illness that requires prompt remedial action.

Seriousness of event: (also known as serious deterioration in state of health) is either a life-threatening illness or injury, permanent impairment of a body function, cause congenital abnormality or permanent damage to a body structure -- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

Service-life or shelf-life: The time for which a device is intended to remain functional after it is manufactured, put to use, and maintained as specified.

Signal Detection: Signal detection means identifying patterns of adverse events associated with a particular medical device that warrant further investigation.

Suo motu Analysis: Suo motu, meaning "on its own motion," is a Latin legal term, approximately equivalent to the term sua sponte. For example, it is used where a government agency acts on its own cognizance.

Unanticipated death or unanticipated serious injury: A death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device. There must be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level.
Annexure 1

Collaborating with MvPI: List of Hospitals & Technical support centre

1. Department of Biomedical Engineering, PGIMER, Chandigarh
2. Department of Biomedical Engineering, CMC, Vellore
3. Department of Biomedical Engineering, AIIMS Trauma Centre, New Delhi
4. National Health System Resource Centre, NHSRC, New Delhi
5. Biomedical Technology Wing, SCTIMST, Kerala
6. Department of Biomedical Engineering, Glocal Group of Hospitals, Kolkata
7. Department of Biomedical Engineering, DMCH, Ludhiana
8. Department of Biomedical Engineering, JIPMER, Puducherry
9. Department of Biomedical Engineering, Bankura Sammilani Medical College, Bankura
10. Department of Biomedical Engineering, Narayna Hrudalaya Hospital, Karnataka
11. Department of Biomedical Engineering, Sanjay Gandhi Post Graduate Institute of Medical Collage, Lucknow
12. Department of Biomedical Engineering, NIMHANS, Bengaluru
13. Mysore Medical college and research institute, Mysore, Karnataka
14. Department of Clinical Pharmacology, Shree Ramakrishna Hospital, Coimbatore, Tamilnadu
15. Department of Quality Systems, Royal Care Hospital, Tamilnadu
Collaborating with MvPI: List of Medical device industry association

1. AIMED
2. CII
3. FICCI
4. PHD chamber of commerce
5. AMCHAM