Diagnostic Errors
The Next Frontier for Patient Safety

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9 Moments of Patient Safety

01. **Medication Safety**
Ensuring correct medication is given at the right dose and time.

02. **Surgical Safety**
Following protocols to prevent errors during surgery.

03. **Infection Control**:
Implement measures to prevent HAI

04. **Diagnostic Accuracy**
Ensuring accurate and timely diagnosis.

05. **Patient Identification**
Correctly identifying patients to avoid mix-ups.

06. **Communication**
Clear communication among healthcare providers and with patients..

07. **Patient Falls**
Measures to prevent falls in healthcare settings.

08. **Pressure Ulcers**
Preventing and managing pressure ulcers.

09. **Blood Transfusion Safety**
Ensuring safe blood transfusion practices.

DIAGNOSTIC ERRORS

Definition:

- A diagnostic error emerges when a diagnosis is **missed**, **inappropriately delayed** or is **wrong**. There may be overlaps in these classifications.

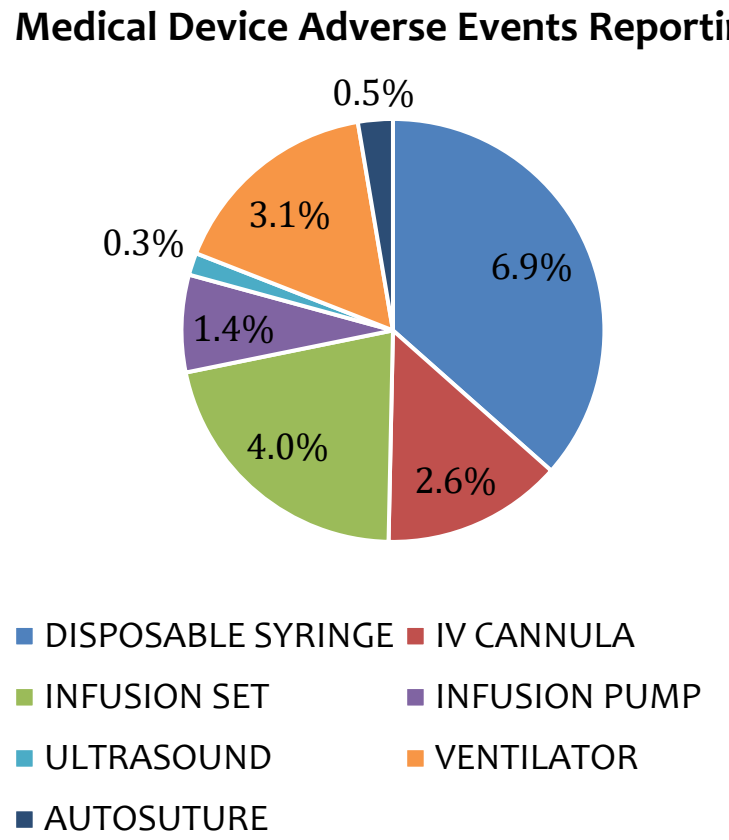
- Diagnosis often occur over time, rather than at one point in time, including initial assessment, performing and interpreting diagnostic tests, follow-up and tracking of diagnostic information, referral-related communication and coordination, and patient behaviour, adherence and engagement.

- Diagnostic errors can occur at each of these points.

- Diagnosis is a high risk area for errors in primary care. Primary care providers are faced with potential difficult clinical presentations as they have limited experience with uncommon diseases and varying access to diagnostic tests.

BURDEN OF DIAGNOSTIC ERRORS

- Lack of culture of reporting and recording medical errors precise data are not available regarding the diagnostic medical errors
- As per a study, it is estimated that around 5.2 million injuries occur due to medical errors, resulting in around 3 million preventable deaths every year. For every 100 hospitalizations, an average of 12.7 adverse events occur
- Delays in diagnosing cancer are common. Lack of continuum of care and communication to patient of abnormal test results lead to delay in diagnostic errors.
- Medical Device Adverse Events database under the National Materiovigilance Programme (MvPI) acts as a repository of adverse events reported voluntary by MDMCs



Data taken from (2018-Mar, 2023) covering 14, 221 MDAE Reports

DIAGNOSTIC ERROR- TERMS

Diagnostic error can lead to Sentinel/ Adverse or Near Miss Event

NEAR MISS EVENT	ADVERSE EVENT	SENTINEL EVENT
Could have caused damage, but didn't	Caused damage that was not serious/ lasting	Caused death or major enduring, loss of function lasting at least 02 weeks
Examples		
Fungus in IV bottle detected just in time	Medication error causing minor allergy	Wrong detection of the cancer
Sudden equipment failure but no damage	Slip/ Fall from patient bed causing injury	Wrong site/ wrong patient/ wrong surgery

COMMON DIAGNOSTIC ERRORS

Delayed Diagnosis

Failure to Diagnose an Unrelated Disease

Failure to Diagnose Related Diseases

Missed Diagnosis

Failure to Recognize Complications

Misdiagnosis

COMMON DIAGNOSTIC ERRORS

Delayed diagnosis- When a doctor eventually makes the correct diagnosis, but it takes a significant period of time.

Failure to diagnose an unrelated disease- When a medical professional accurately diagnoses a specific disease but fails to diagnose another unrelated disease that was also present.

Failure to diagnose related diseases- When a doctor correctly diagnoses one disease but doesn't diagnose another related disease.

Failure to recognize complication- when doctors make the correct diagnosis for a patient but fail to identify certain complications or other factors that may change or aggravate the condition.

Missed diagnosis- when a doctor gives a patient a clean bill of health in cases where that patient is actually suffering from a disease or illness.

Misdiagnosis- A misdiagnosis occurs when a doctor diagnoses a patient with the wrong illness.

FACTORS CONTRIBUTING TO DIAGNOSTIC ERRORS

- All aspects of the diagnostic process are vulnerable to error
- **Cognitive Errors** – Failure to synthesize the available evidence correctly or failure to use physical examination or test data appropriately
- **System Flaws –** Problems with communication or coordination of care, availability of correct medical record, insufficient access to specialists
- **Process breakdown** – A study undertaken in a developed country finds that Patient-Doctor clinical encounter breakdowns like inadequate history taking, missing signs & symptoms, asking diagnostic tests for further work-up etc. (79%), Referral problems (20%), Patient related factors (16%), Follow-up and tracking of diagnostic information (15%), performance and interpretation of diagnostic tests (14%)
- **Lack of communication** – Both patient-doctor and doctor-healthcare providing team

FACTORS CONTRIBUTING TO DIAGNOSTIC ERRORS IN PRIMARY CARE SETTING

Factors	Possible issues contributing to error
Access to high quality treatment	Limited access due to lack of money, remoteness, illiteracy, travel constraints or a limited number of health care facilities.
Availability of healthcare professionals	Lack of sufficient, competent health care professionals, for example, due to lack of training, outward migration or a poor employment situation.
Team-work	Poor teamwork, lack of learning and feedback when errors occur.
Availability of diagnostic tests	Diagnostic tests limited in scope, availability or quality.
Communication	Little or no sharing of medical information.
Care Coordination	Consultations delayed or test results lost or a lack of health records documenting care.
Follow-up	Limited follow-up reduces the ability for diagnostic impressions to evolve.

FACTORS CONTRIBUTING TO DIAGNOSTIC ERRORS IN PRIMARY CARE SETTING

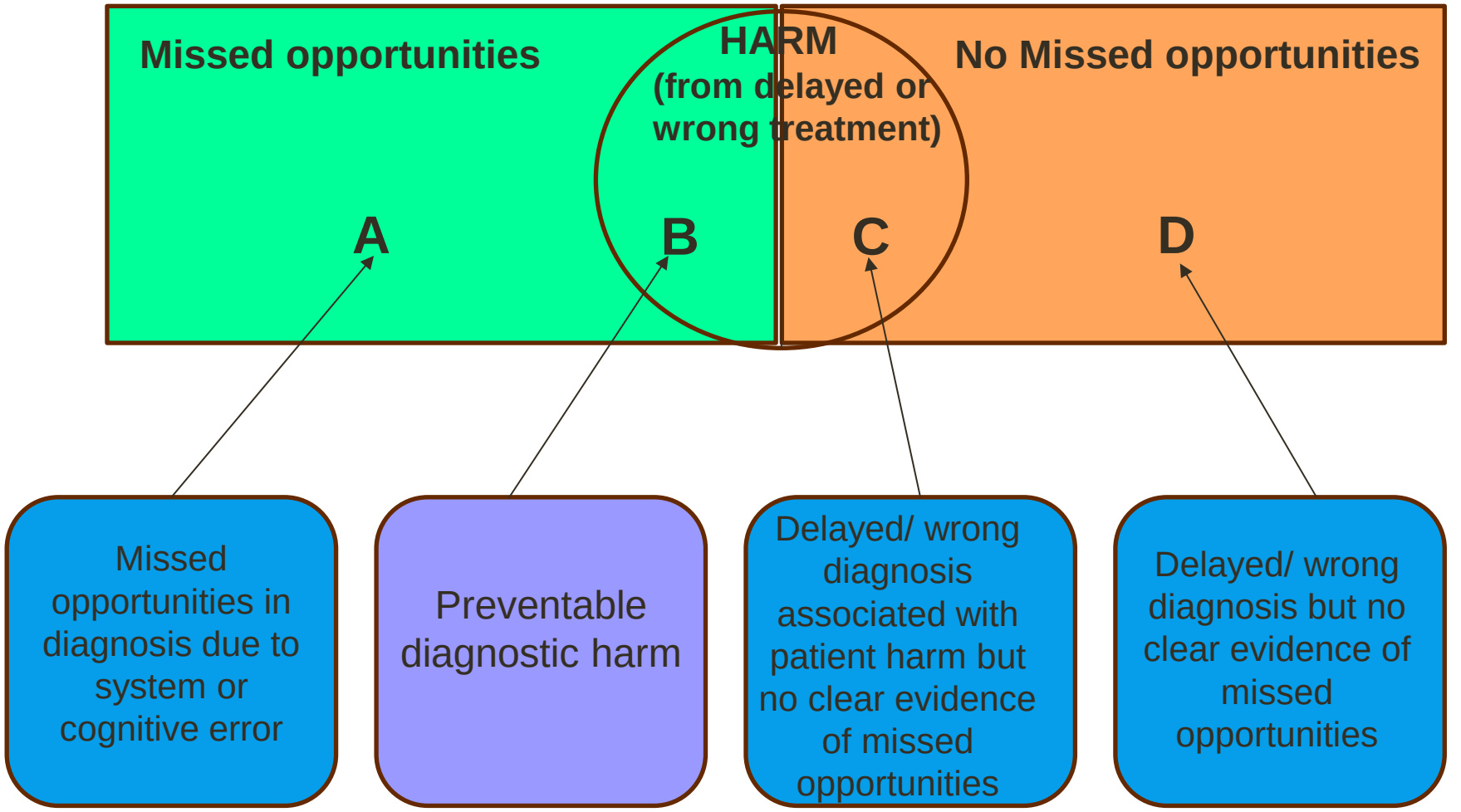
Factors	Possible issues contributing to error
Affordability of care	Care unaffordable or compromises other basic needs such as food or housing.
Training of healthcare providers	Training is suboptimal, in particular lack of training for clinical reasoning; certification and licensure requirements are deficient.
Availability of health informatics resources	Health informatics resources, including internet access, may not be available, especially in remote areas; unaffordable subscription or download fees for medical information.
Culture	Some cultures may be punitive, which discourage sharing and inhibit learning; physician-centric systems limit the value of the team.
Human factors and Cognitive issues	The work environment and systems may be subject to distractions, interruptions and a lack of organization of information.

CONDITIONS INVOLVED IN DIAGNOSTIC ERROR IN PRIMARY HEALTHCARE SETTING

High-risk areas	Disease	Additional considerations
Infections	Viral Infections	Often misdiagnosed as bacterial and result in unnecessary antibiotics.
	Malaria	Key presenting features like fever not specific.
	TB	Lack of careful use of basic diagnostics result in almost 10% being misdiagnosed.
	Pneumonia, dehydration from diarrhea and malaria	Diagnoses of children often suboptimal, particularly with less well-trained healthcare workers.
Cardiovascular Disease	Myocardial infarction, stroke	Errors may occur when subtle premonitory symptoms are missed or disregarded in primary healthcare setting
Cancer	Several types of cancer	Cancer diagnosis presents with nonspecific symptoms to primary healthcare providers
Paediatrics	Meningitis, gastroenteritis, pneumonia, appendicitis, sepsis and malignancy	Misdiagnoses may contribute to the nearly million children who die each year, largely from preventable causes

Reference: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5502242/

CONCEPTUAL MODELS OF MISSED OPPORTUNITIES IN THE DIAGNOSIS



Relationships between diagnostic errors, missed opportunities and patient harm

Materiovigilance Program of India (MvPI)

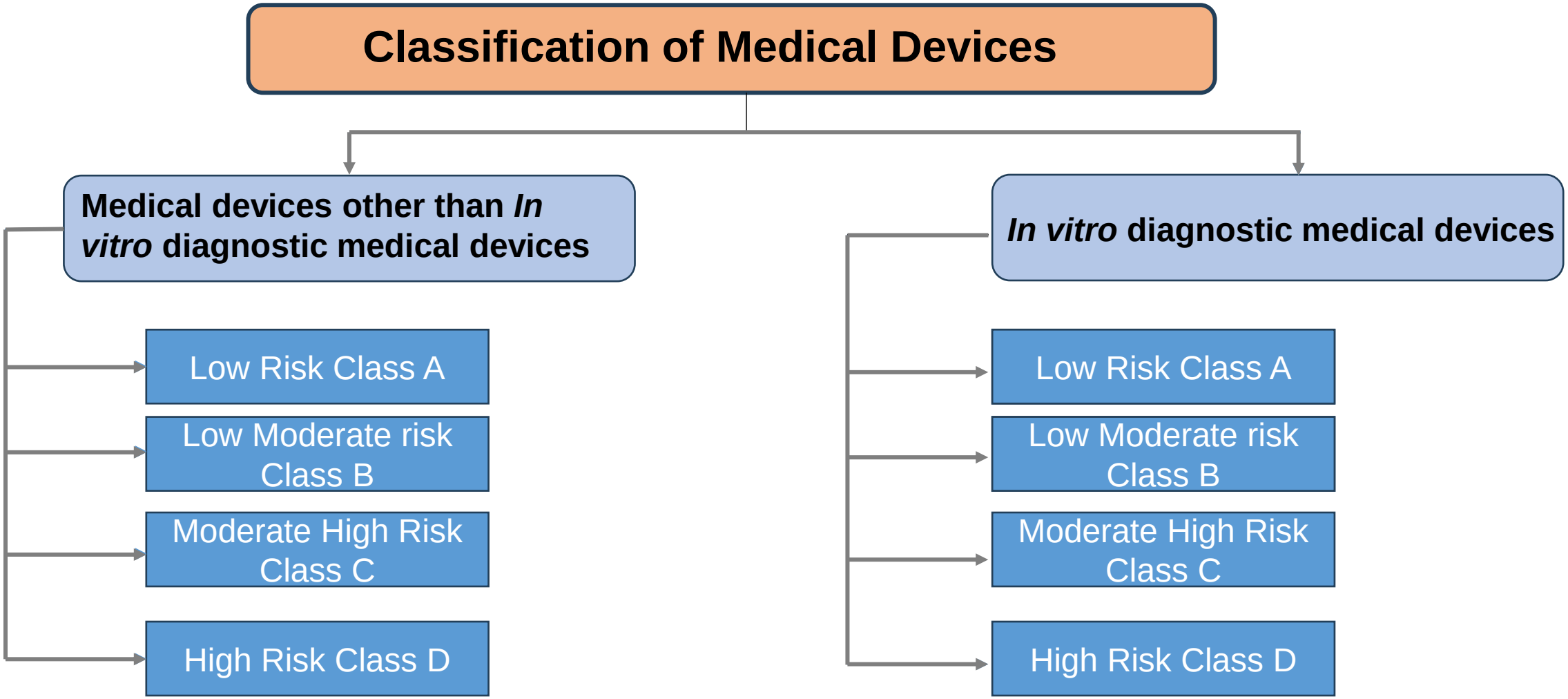
Materiovigilance Program of India (MvPI) was launched by DCG (I) on 6th July 2015 at Indian Pharmacopoeia Commission (IPC) Ghaziabad.

IPC Ghaziabad functions as National Coordination Centre

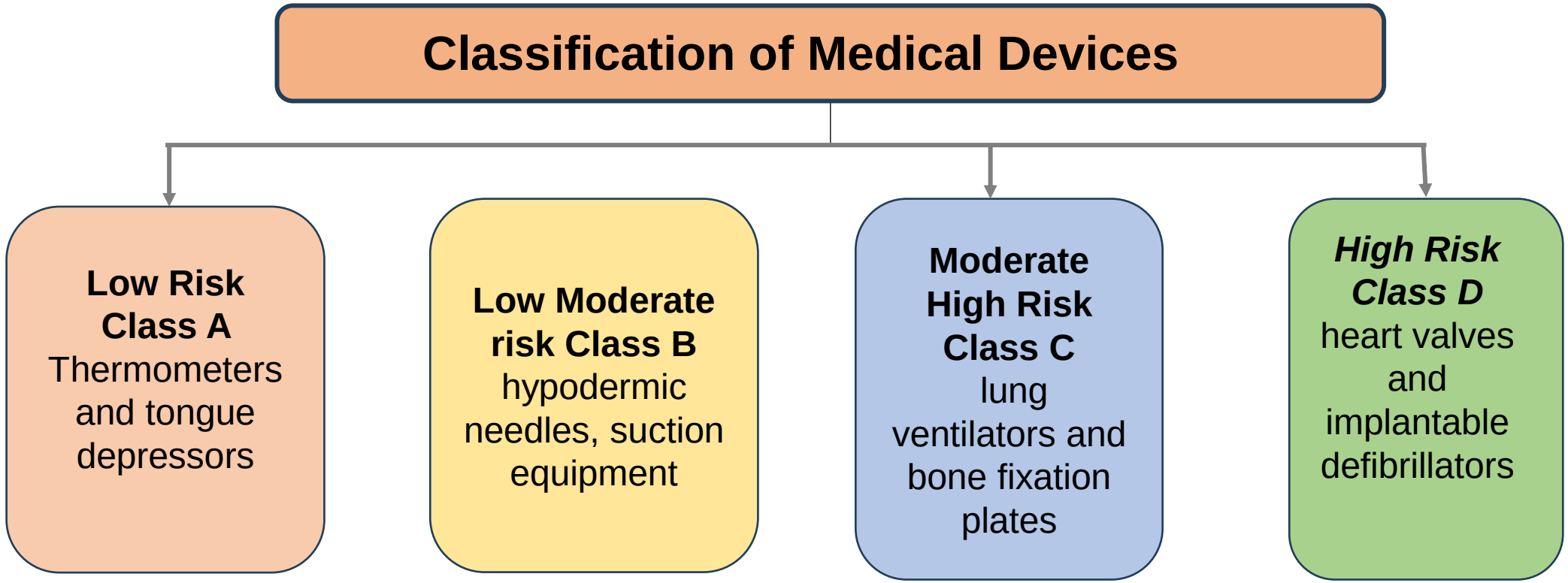
Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, functions as National Collaborating Centre

National Health System Resource Centre (NHSRC) functions as Technical support & Resource Centre

CHAPTER- II CLASSIFICATION OF MD, GROUPING OF MD, ESSENTIALS PRINCIPLES (Rule 4-7) (MDR-2017)



CLASSIFICATION OF MEDICAL DEVICES



SUMMARY OF MDAE CASES FROM MARCH- MAY 2024

Sr. No.	Device Name	Adverse Event	Nature of Case	Source of Data	No. of cases
1	Ventilator Circuit	Water is Entering the patient's Trachea/ Probable Chances of Ventilator Associated Pneumonia	Serious	MDMC	24
2	Intravenous Infusion Set	Surplus Quality/Blockage/Leakage/Irregular Flow	Non-Serious	MDMC	176
3	Intravenous Infusion Set	Outpouring/Obstructed & Irregular Flow	Non-Serious	MDMC	134
4	Spinal Implant (Spinal Fixation System)	Implant Breakage	Serious	MDMC	133
5	Surgical Gloves	Severe Rashes/Contact Dermatitis/Poor Quality	Non-Serious	MAH	24
6	Hypodermic Syringe	Leakage/Breakage & Blockage of Piston	Non-Serious	MDMC	257

SUMMARY OF MDAE CASES FROM JUNE- JULY 2024

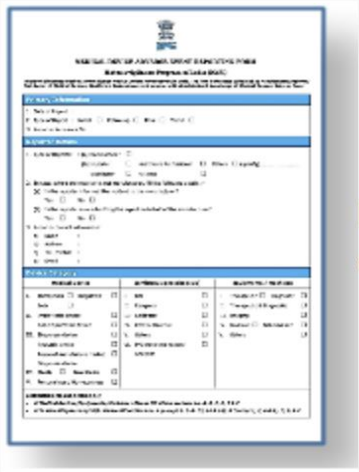
Sr. No.	Device Name	Adverse Event	Nature of Case	Source of Data	No. of cases
1	Blood Transfusion Set	Chamber leakage & blockage, uncontrolled regulator causing free flowing of blood	Serious	MDMC	121
2	Adhesive Surgical Tape	Poor adhesive property, insufficient adhesion	Non-Serious	MDMC	152
3	Voice Prosthesis	Prosthesis leakage	Serious	MAH	01
4	Excimer Laser & Femtosecond Laser	Blurry vision/ Hyperopia/ Corneal haze/ uncut area on eye/ formation of white spot	Serious	MAH	21
5	Hypodermic Auto Disposable Syringe	Blockage/ Leakage/ Piston & plunger breakage	Non-Serious	MDMC	264
6	Intravenous Infusion Set	Non-functioning of regulator/ uncontrolled medication delivery/ leakage/ slipping of Leur Connector	Non-Serious	MDMC	102

POST MARKET SURVEILLANCE

- Post Market Surveillance is the practice of monitoring the safety of a medical device after it has been released in the market
- The goal is to continually ensure the safety, effectiveness and quality of marketed medical devices with reasonable risk/benefit profiles
- The Periodic Safety Update Report for medical devices (PSUR) is a periodic report required by the Medical Device Regulation for all devices of Class IIa and above.
- It compiles information relating to the security and performance of the device, identified during the Post Market Surveillance activities and submitted the manufacturer to the licensing authority (CDSCO)

REPORTING OF MEDICAL DEVICE ADVERSE EVENT

1. Medical Device Adverse Event (MDAE) Reporting Form-



MvPIMDAE reporting form is available on the official website of IPC (www.ipc@gov.in).

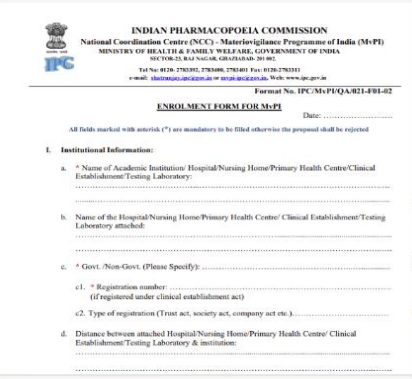
2. Mobile Application-

PvPI mobile applicationis freely available on google play store.

3. Number- Helpline-

NCC-MvPI, IPChelpline facility (1800-180-3024)available between (Monday to Friday from 09:00 AM to 5:30 PM)

4. Enrollment Form-



INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre (NCC) - Materiovigilance Programme of India (MvPI)
MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA

Format No. IPC/MvPI/QA/021-F01-02

ENROLMENT FORM FOR MvPI

Date: .....

All fields marked with asterisk (*) are mandatory to be filled otherwise the proposal shall be rejected

I. Institutional Information:

a. * Name of Academic Institution/ Hospital/Nursing Home/Primary Health Centre/Clinical Establishment/Testing Laboratory:

b. Name of the Hospital/Nursing Home/Primary Health Centre/ Clinical Establishment/Testing Laboratory attached:

c. * Govt./Non-Govt. (Please Specify):

c1. * Registration number: (if registered under clinical establishment act)

c2. Type of registration (Trust act, society act, company act etc.).....

d. Distance between attached Hospital/Nursing Home/Primary Health Centre/ Clinical Establishment/Testing Laboratory & institution:

The filled MDMC Enrollment Form has to be sent to IPC- Dr Shatrunajay Shukla, MvPI co-ordinator (E-Mail Id: mvpi-ipc@gov.in).

OPTIONS WITH REGULATORY AGENCY

CDSCO

01 Notify manufacturer to take appropriate action

02 Product correction
Sales restriction
Market withdrawal

03 Audit inspection
Sample testing

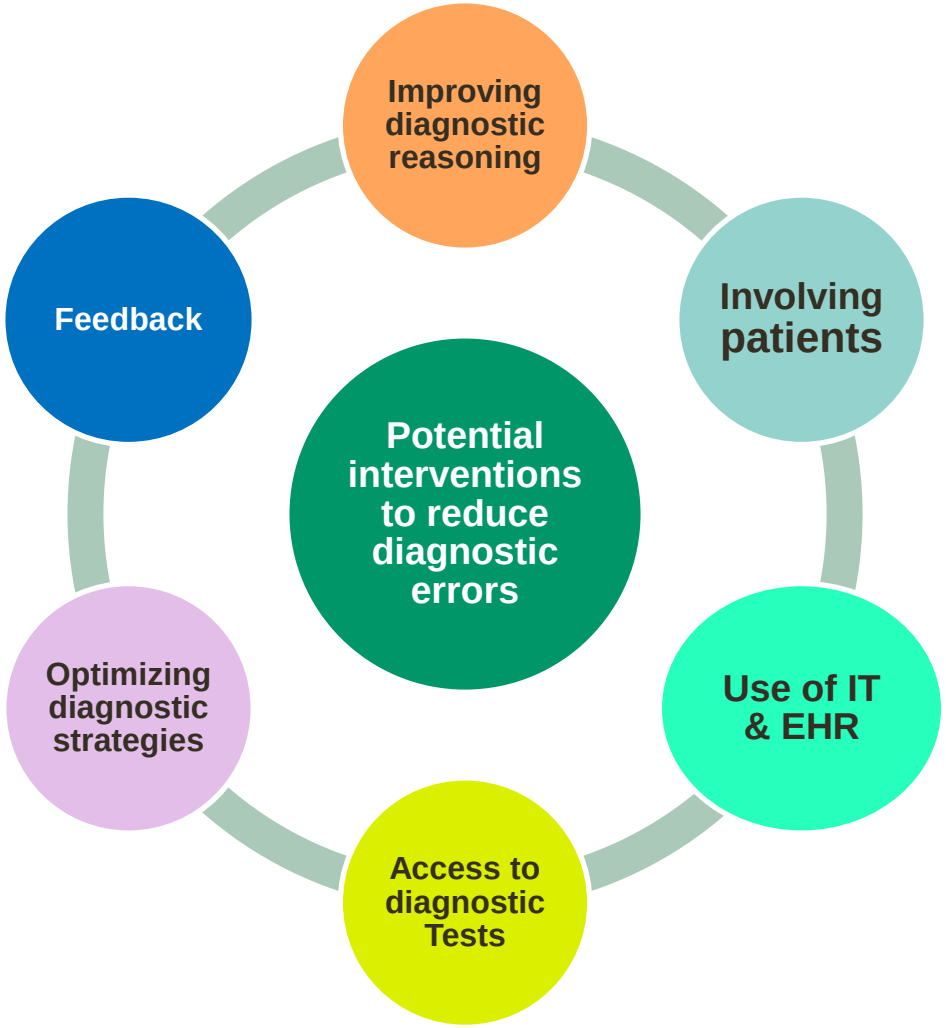
04 Issue a public announcement
Safety alert/Recall

05 Inform targeted healthcare providers

06 Escalate safety monitoring

POTENTIAL INTERVENTIONS TO REDUCE BURDEN OF DIAGNOSTIC ERRORS

- Training & Skilling – Capacity building
- Empowering patients – Improving communication
- Strengthening Health Systems
- Robust referral and follow-up mechanism at the primary healthcare settings
- Use of IT and EMR for recording all transactions – Tele-consultations, Tele-radiology, Tele-pathology etc
- Improving access to diagnostics – EDL, Mini Diagnostic Hubs at Block CHC level
- Encouraging a culture of self-reporting of diagnostic errors, near miss event and adverse event



WAY FORWARD

- Training & Capacity building.
- Improve patient communication & coordination
- Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance
- Develop a reporting environment and create awareness regarding reporting of medical devices related adverse events (MDAE) to IPC
- Patient should be able to use MERA- ASPATAL application for sharing their feedback and reporting.

Patient Safety Solutions

- Look-alike, sound-alike medication names
- Patient Identification
- Communication during patient hand-overs
- Performance of correct procedure at correct body site
- Control of concentrated electrolyte solutions
- Assuring medication accuracy at transitions in care
- Avoiding catheter & tubing's misconnections
- Single use of Injection devices
- Improved hand hygiene

Thank You