Innovative Process Improvement Initiative

To ensure Safety of Chemo Drug Management Process

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Project Introduction

- Administering medication with infusion pumps carries specific risks, which **lead to incidents that affect patient safety.**
- We found that **wrong rate errors** led to medication being **infused at a faster rate** than intended.
- Our study helped us identify areas to target for **risk mitigation** related to medication errors and the use of infusion pumps.
- Fortunately, medication errors did not cause patient harm or death at Max Vaishali.

Why we took this Project ?

WHY ?

Patients undergoing Chemotherapy in Max Vaishali, were touching 900 Chemo therapy in a month ……. SUDDEN SWING IN ONE YEAR

The Incidences of error during Chemo Drug Administration were happening frequently.

We had Incidents like "5 FU Chemo Drug got finished four and half hours before the desired time".

It became difficult to explain the patient and attendant about the early finish of Chemo Medicine. We all were concerned about the Incidents.

Better synchronization between Nursing, clinicians, paramedics and other support staff was needed.

Though most of the Incidences were such that there was no impact on the patient, keeping in mind the patient's and provider's safety we decided to start this project.

Aim and Objectives

Aim of the Quality Improvement Project

- To ensure the safe administration of Chemotherapeutics Drugs through Infusion Pump at the prescribed rate
- To lay down a mechanism for identifying, monitoring and reporting adverse incidents of medication administration
- To target for risk mitigation related to medication errors with the use of infusion pumps

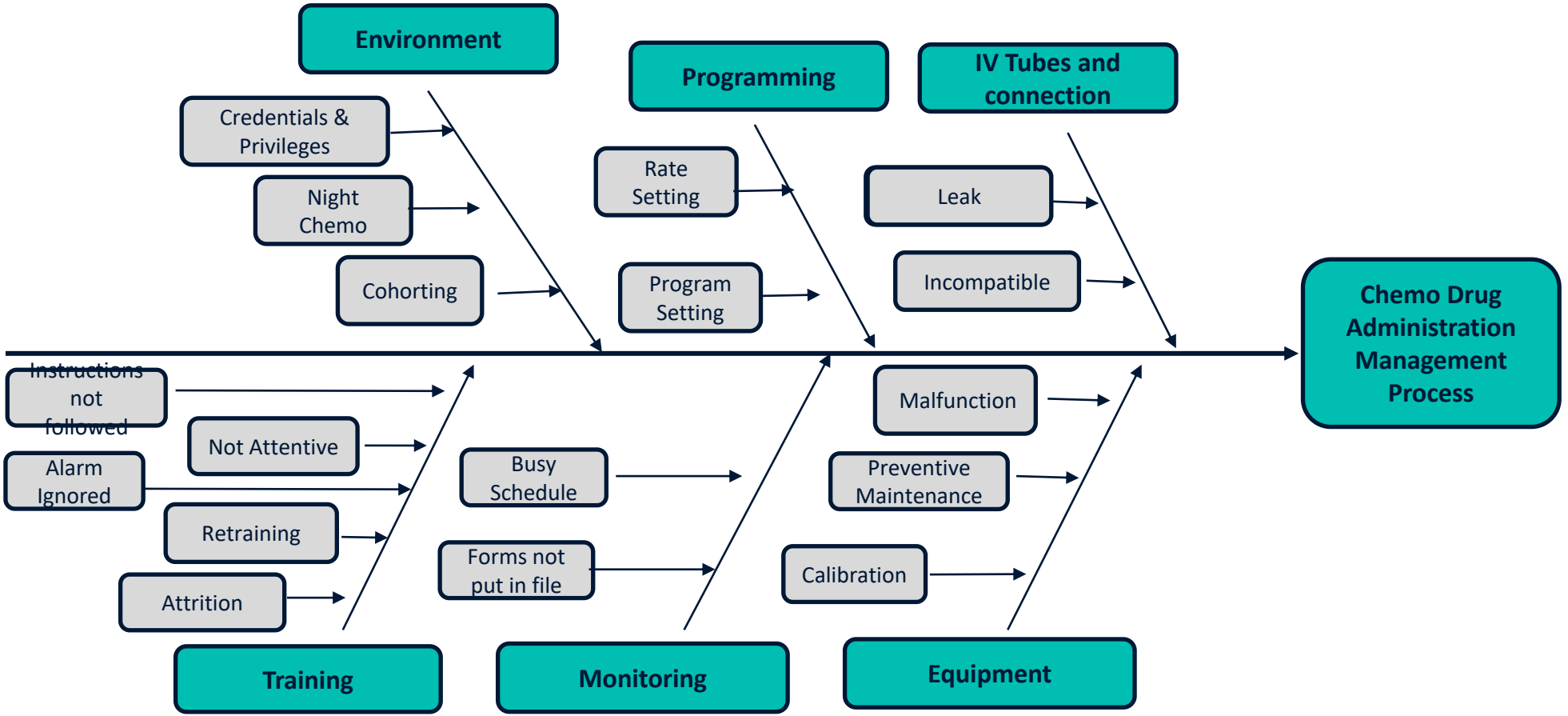
Objectives

- Patient's **Safety**
- **Provider's Safety from litigation.**

Study Methodology and Inclusion Criteria

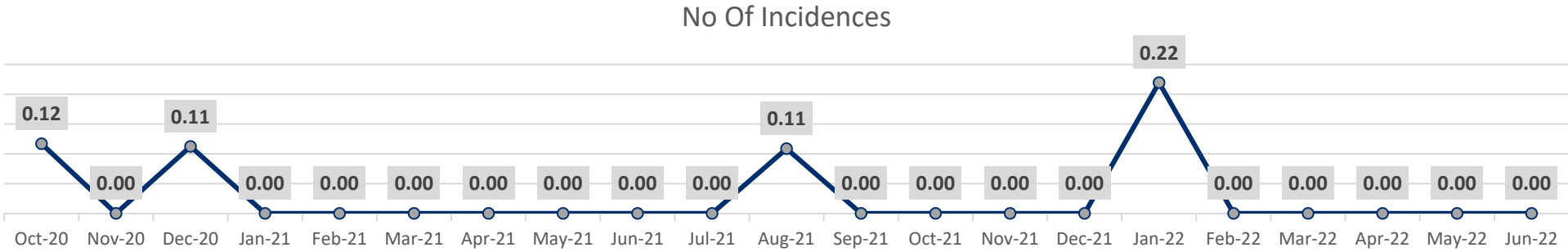
- We selected the cases in which Incident of **Medication Error was reported** in Max Vaishali after Chemo Medication was prescribed and which involved the **usage of Infusion Pumps for administration.**
- All the errors reached to the patient and all the incidents were with **5 FU Chemotherapy drug.**
- 100% Incidents were identified as **Medication Error** but none of them were Sentinel Event causing serious harm to the patient.
- We conducted a **before-and-after observational study**. A value stream map or a **detailed process was studied** to identify important underlying causes of medication errors. These causes were discussed by the Medical Quality, Nursing and Biomedical Team resulting in **small improvement cycles and measures.**
- **Contributing Factors for the Rate Errors** Identified during the Projects are as follows-
  - Tubing and Connections Error
  - Programming Error
  - Malfunction due to Device Maintenance
  - Monitoring Error
  - Training Issue

Fish Bone Analysis of Chemo Drug Administration Process



Incidence of Chemo Drug Administration

-	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22
No Of Incidences	1	0	1	0	0	0	0	0	0	0	1	0	0	0	0	2	0	0	0	0	0
Number of Chemo Infusion	855	798	890	871	798	954	812	679	801	929	920	974	1035	951	1044	911	985	1055	980	1108	983
Rate of Incidences	0.12	0.00	0.11	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.11	0.00	0.10	0.00	0.00	0.22	0.00	0.00	0.00	0.00	0.00



Factors contributing to rate error

- Tubing and Connections
- Programming Error
- Malfunction due to Device Maintenance
- Monitoring Error
- Training Issue

Challenges that we faced at the initial phase of the Project.

Consumables	• The IV Sets provided by the store were not compatible with our Infusion Pump. Instead of B Braun IV Sets, Rompson IV Sets were given by the Store. After speaking to the vendor we came to the conclusion that only B Braun IV Sets are to be used with the B Braun Infusion Pump as the Rompson sets are not compatible with B Barun Infusion Pump.
Nursing	• Awareness regarding the infusion pump setting and the awareness regarding the impact of Chemo Drug Administration Error was lacking. Monitoring was not very efficient.
BME	• Getting Calibration of Infusion Pumps was time consuming as the pumps were being sent to Mumbai for Calibration.

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HFMEA Risk Scoring and HFMEA Risk Analysis
Chemo Drug Management Safety
Risk Probability Number = Severity X Probability X Detection

Severity		
1	None	Would not effect an individual or system
2	Minor	Minor injury to patient or minor effect on system
3	Moderate	Moderate injury to patient or moderate effect on system
4	Major	Major injury to patient or major effect on system
5	Catastrophic	Death of Individual or complete system failure

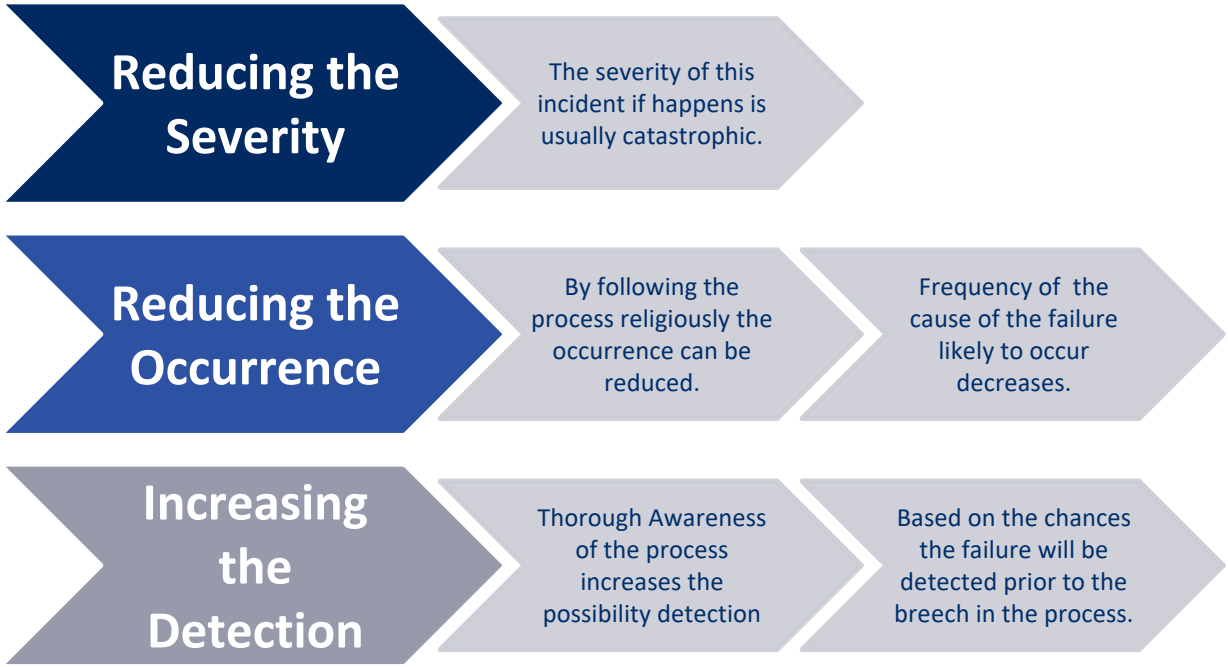
Probability		
1	Remote- Failure unlikely	One occurrence every 2 years
2	Low – Few Failure	One Occurrence every 1 year
3	Moderate- occasional failure	One Occurrence every three months
4	High – Repeated Failures	One occurrence per month
5	Very High-Failure is inevitable	More than one occurrence per week

Detection		
1	Almost Certain	Control will detect potential cause & subsequent failure mode
2	High	High Chance that Control will detect potential cause & subsequent failure mode
3	Moderate	Moderate Chance that Control will detect potential cause & subsequent failure mode
4	Low	Low Chance that Control will detect potential cause & subsequent failure mode
5	Remote	Remote Chance that Control will detect potential cause & subsequent failure mode

		Severity of Effect			
		Catastrophic	Major	Moderate	Minor
Probability	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

Reducing the Risk Priority Number (RPN) – Severity X Occurrence X Detection

HFMEA Risk Scoring and HFMEA Risk Analysis Chemo Drug Management Safety



Improvement Initiated

Administrative Decisions….

As a team Medical Quality, Nursing and BME started **analysing each and every incident** in detail. The incidences were discussed in **Incident Reporting Forum** chaired by the Unit Head.

The entire **Process flow of Chemo Drug Administration** was studied again.

Patients planned for Chemotherapy were **cohorted** on a dedicated floor.

Credentials and Privileges of nurses taking care of patients on Chemotherapy was ensured.

Chemotherapy **Infusions at night** were avoided

It was made mandatory that for the Chemo Infusions only the **compatible Set of Tubing** will be used as per the **manufacturer's instructions.**

Improvement Initiated

Tubing and Connections	Utmost care was taken to ensure that the **chemo drug was administered via infusion pump only** and not by IV tube directly.
	Ensuring Chemo Drugs are connected through **the Infusion Pump Tubing only and not** the **tubing meant for IV Fluid**
	Power Cord of the Infusion Pump must be **fixed tightly.** **Machine** must be fixed on IV pole tightly.
	Infusion tube should be fixed in air bubble detector properly
	Ensure **Changing the position of IV tube** which is placed between the peristaltic pump, **every 4-6 hours.**
	The staff was sensitized to **check the patient positioning and line positioning** to ensure there is no leak from air vent of IV Set

Proper Programming of the Infusion Pump

The Rate of Chemo Drug Infusion (ml of Chemo drug to be administered per hour) must be **set accurately as per the prescription of the doctor** keeping in consideration the weight of the patient

Before setting the rate, **the prescribed duration of Chemo Drug Infusion is counter checked** to prevent administration of drug in lesser or longer time than prescribed for

The desired rate of chemo drug to be administered through Infusion Pump to be set only by the Medication Nurse, Team Leader or Supervisor on duty. After setting the Infusion Pump at a set rate the snap shot is taken by the staff nurse and to be sent to Team Leader or the Supervisor for check and documentation purpose.

It must be ensured to set the Infusion Pump and the rate of flow correctly**. Miscalculation** due to **incorrect patient weight** or **choosing incorrect units of measure** when calculating rate, (e.g., ml/hr vs. mg/kg/hr), failure to adjust rate post-bolus, **entering too few or too many digits** (e.g., entered 0.2 instead of 0.02 or 488 instead of 48), or failing to start pump after entering

With **B Braun infusion set** user must select the B Braun **Setting** only while programming the infusion pump and not the **JMS or any other setting** which can cause the variation in the rate of drug delivery to the patient

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Improvement Initiated

Infusion Pumps and their Maintenance

Ensured Sufficient **quantity of infusion pumps** dedicated for chemo **patients**

Time display on the Infusion pumps was set with the actual time

Pre Printed Preventive Maintenance and Calibration Registers was provided to the nurses. The parameters mentioned on the register are Date, Name of the Equipment, Equipment Number, Remark (PM, Breakdown, Calibration), Date of receiving by Bio Medical Engineering Team, Sign of Nursing Team Leader and Bio Medical Engineering staff, Date of return by Bio Medical Engineering Team and Sign of Nursing staff

The Preventive Maintenance and Service Report was **signed by the Supervisor or Team Leader**

Department wise Preventive Maintenance and Calibration tracker was shared with the user end by the BME team, so that the user end can remind BME for PM and Calibration in case it is missed by BME Team

Instead of sending the infusion Pump to Vendor, **Calibration was started in house by the vendor**

Improvement Initiated

Monitoring after the start of Chemo infusion

Documented hourly monitoring of the Chemo Drug Volume administered and Remaining Chemo Drug Volume was done by Team Leader and Supervisor through a Checklist

Close monitoring by Medication staff and Night supervisors for all Chemo on flow patients for dose calculations and fluid administration was done

Regular 2 hourly round was carried out by the Supervisor to check the Chemo Flow Rate and Balance Drug

Change in Infusion flow rate if needed was done along with the **Medication Nurse or TL** and **double check** was done by both the staff.

~~After changing the rate Nursing Team leader or supervisor is informed~~

Verbal instructions by doctors for changing the Chemo Drug Flow rate **was not followed**

Nurses were empowered to escalate the matter to seniors in case they find something odd

Improvement Initiated

Training of the Nurses

Importance of Alarm and Lights on the infusion Pump was emphasized

Hands on practice sessions for Infusion Pumps was done by BME Team through the vendor or BME Team for the new joinees and all the staff quarterly

Aware ness regarding the **rate of medication flow calculation** as per the prescribed rate and time was addressed

Instructions and precautions regarding **infusion pump handling** was addressed

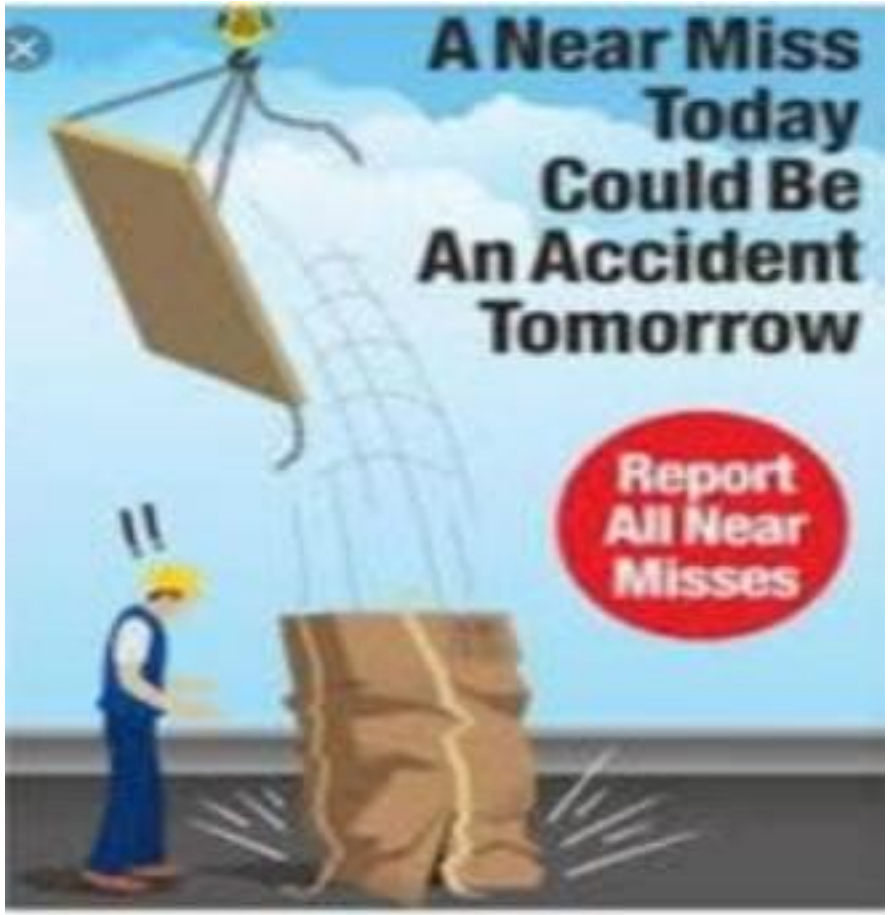
Conclusion

- Despite **recent advances** in infusion pump technology, hospitals continue to experience **medication errors while using infusion pumps**. The current study provides insight into the frequency of **events during administration**, types of medication administration errors, and contributing factors.

- The findings show that **Tubing and Connections, Programming Error, Device Maintenance,Monitoring Error and Training Issue are the factors contributing** to medication errors with infusion pumps. At times **Insufficient Information** did not lead us to any conclusion

- In an effort **to mitigate risk of safety-related events**, we urge to foster **a strong culture of event reporting**, including near miss events. With that information, a safety program can proactively identify problems and subsequently develop solutions.

- As we have highlighted, there are many **potential solutions to mitigating risk** of medication errors with infusion pumps. We must carefully consider all possible solutions.



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Success factors

- Fostering the Culture of Safety
- Patients Safety and Providers Safety without extra cost to the organisation

Chemo Infusion Monitoring Sheet

Date	Name of the Chemo Drug	Total Time for which Infusion advised	Rate of Flow advised	Infusion Start Time	Time of Monitoring	Chemo Drug left in the Bag	Hours/ Min Left	Remarks

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Thank You