FMEA (FAILURE MODE AND EFFETS ANALYSIS) APPLICATION TO PARENTERAL NUTRITION BAGS MANUFACTURING PROCESS: ROLE OF HOSPITAL PHARMACIST

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BACKGROUND AND IMPORTANCE

Correct identification of unexpected/unwanted processes variability allows us studying solutions for increasing any system reliability. FMEA (Failure Mode and Effects Analysis) is an inductive method that provides a "bottom up" approach; starting from activities process analysis, it reaches identification of possible inconveniences (failure mode) and effects on an entire system.

AIM AND OBJECTIVES

Our purpose was detecting the most critical phases of Parenteral Nutrition bags (PNB) compounding process through an audit consisting of Hospital Pharmacists, Doctors, Nutritionists and Nurses.

MATERIALS AND METHODS

PROCESS IN 4 PHASES

- PRESCRIPTION
- FORMULATION
- COMPOUNDING
- QUALITY-CONTROLL

IRC'S ESTIMATE = D x O x S

- D — DETECTION (RILEVABILITY)
- O — OCCURRANCE (FREQUENCY)
- S — SEVERITY (GRAVITY)

RESULTS

Phases	Details of the phase	Failure Mode	Failure Causes	Failure effects	Detection	Occurran-ce	Severity	IPR
PRESCRIPTION	The pharmacist on the search engine selects the patient for whom to make the bag	The pharmacist selects the wrong patient to make the bag	The data on the prescription does not correspond to the patient (cases of homonymy)	Fitting of bag for patient not requiring NP	7	3	8	168
	The pharmacist checks the accuracy and completeness of the data on the prescription	Medical prescription not complete in all parts	The doctor forgets to include all the constituents necessary for the patient's nutrition	Failure to prescribe micro-nutrients necessary for the patient's needs	5	6	5	150
FORMULATION	The pharmacist checks the osmolarity of the bag	High osmolarity for peripheral mixtures	The doctor mistakenly biases the wrong access based on the osmolarity of the bag	Setting up bags that are too concentrated for a patient with peripheral and not central access	8	6	8	384
COMPOUNDING	Checking the correct assembly of the lines and the correct filling of the Siframix feeding machine	Confusion between electrolytes being accommodated in the wrong cradle	The nurse in charge mistakes correct electrolyte storage for distraction	Danger to the patient (in the event that the K is accommodated in the cradle of an electrolyte required in a larger quantity)	7	2	10	140
	The nurse in charge of setting up the bag selects the necessary components from the cabinet	The nurse in charge selects the wrong component from the cabinet to make the bag	Confusion by distraction of components with similar name and same container (look alike sound alike such as Inframini and Siframin/magnesium sulphate and sodium chloride)	Fabrication of a bag with a different set-up from the one required (inversion of nephropathic patient with hepatopathic)	9	2	8	144

CONCLUSIONI

Joint audit proposed solutions for each phase. For prescriptive one, it would be desirable to take advantage of a software that gives access to medical records in order to check that bag suited patient's needs. During formulation phase, it's necessary that Hospital Pharmacist(HP) performs a double check between worksheet drafting and label, verifying correspondence, completeness and overlapping with data indicated in prescription. HP have to control prescription feasibility and that volume is suitable for access provided for patient. For set-up phase, a double check should be carried out to make sure that each cradle contains corresponding nutrient; in addition, at least two people should be present to carry out the operations in duplicate.

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