Egyptian Drug Authority
Central Administration of Pharmaceutical Care
General Administration of Drug Utilization & Pharmacy Practice

هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
الإدارة العامة للممارسات الدوائية والصيدلية

EDA NEWSLETTER DECEMBER, 2021 – VOLUME 2, ISSUE 7

Medication Safety Newsletter
Close Overview of NOHARMe Reports
Medication During Covid-19 Pandemic

- General Administration of Drug Utilization & Pharmacy Practice is pleased to publish a new issue of its medication safety newsletter.
- Medication safety newsletters were launched to provide information on the safe and effective use of medications and to share knowledge on the patterns of medication errors and drug therapy problems reported to the NoHARMe system.
- In appreciation for their efforts, we would like to thank all clinical pharmacists who have been keen on documenting their interventions during the pandemic period.
- **NOHARMe "National Office For Handling And Reduction Of Medication Error"** is a national voluntary medication error and "near miss" reporting program founded for the purpose of sharing the lesson learned from medication errors.
- Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.
- **NOHARMe** system records two types of clinical pharmacy interventions related to pharmacotherapy:

Drug Therapy Problems and Medication Errors.

Drug Therapy Problems are problems discovered during appropriateness reviews conducted on patients' medical therapy; the reviewer decides there are problems with pharmacotherapy if, for example, it is not following the latest guidelines, or when they simply have a different opinion than the prescriber.

Medication errors are errors that occur while implementing a patient's therapeutic plan that has already been discussed and approved by clinicians. Medication errors are classified according to the stages of medication use, e.g. medication preparation, administration ... etc.; also, they are given severity ratings based on: whether they have reached a patient; whether they have caused harm; and the type of harm they caused. It takes clinical knowledge and drug use expertise to review a patient's therapeutic plan and discover Drug Therapy Problems; on the contrary, medication errors can be documented by anyone including patients.

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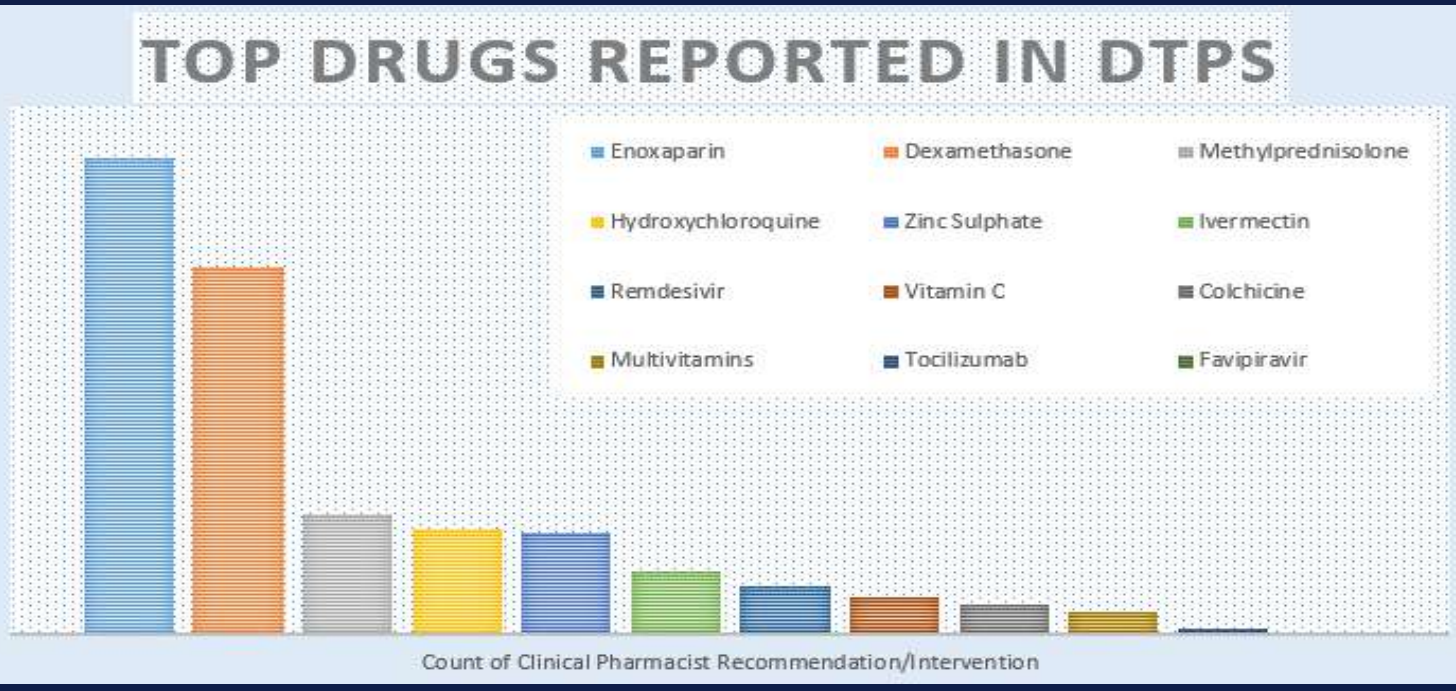
Inside this issue:

A quick look on the NOHARMe data generated in the period from March 2020 August 2021

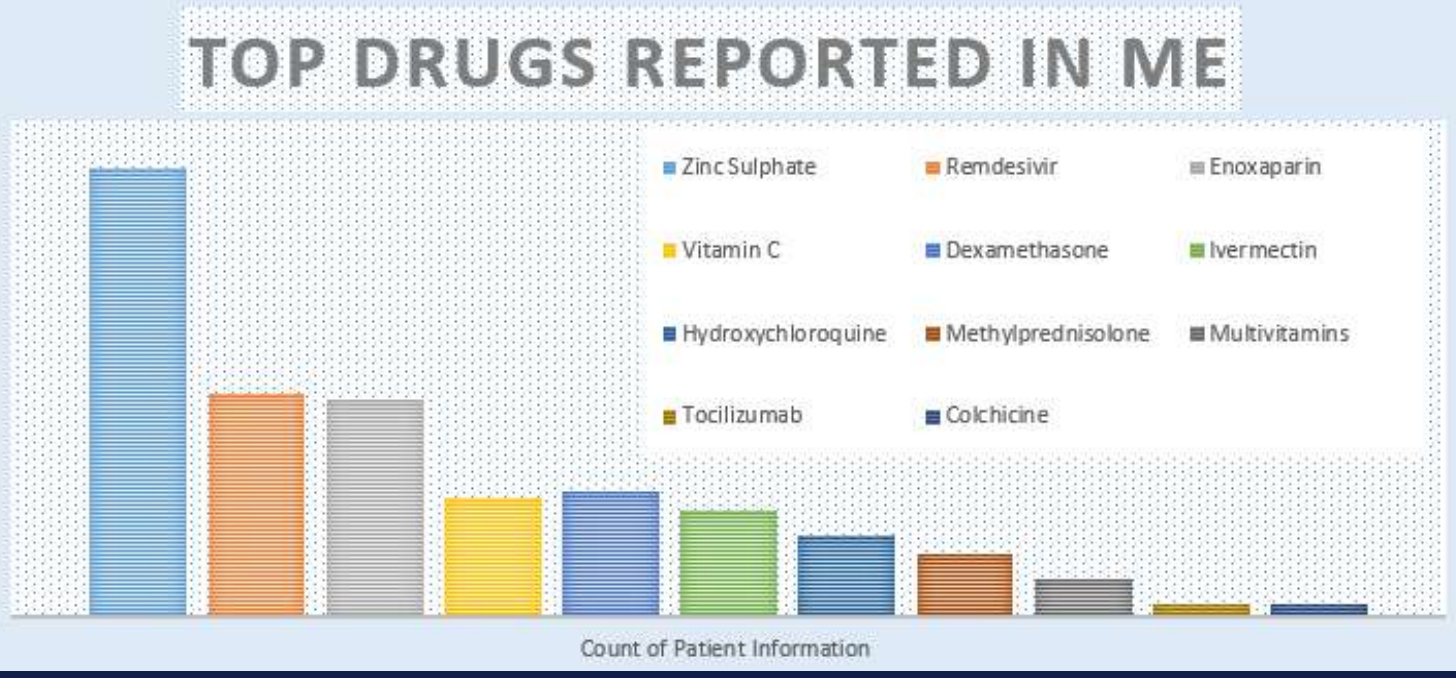
Overall Reports

- A total of 83,413 valid reports have been generated in this period, 42.1 % of which have been labeled as drug therapy problems "DTPs", 4.82 % have been labeled as medication errors "MEs", and 53.08 % have been labeled as drug therapy problems that are also medication errors.

Top drugs "used in COVID-19" in DTPs

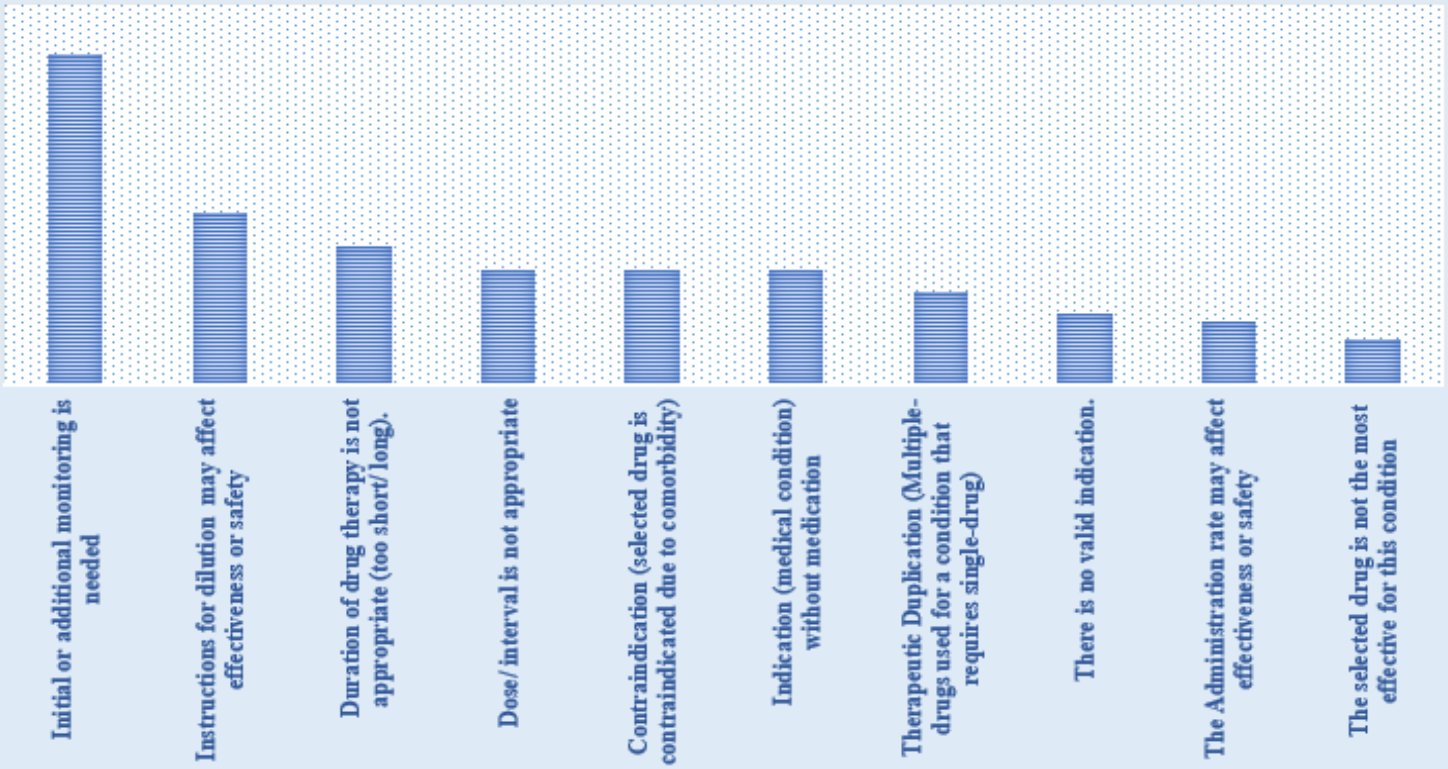


Top drugs "used in COVID-19" in ME

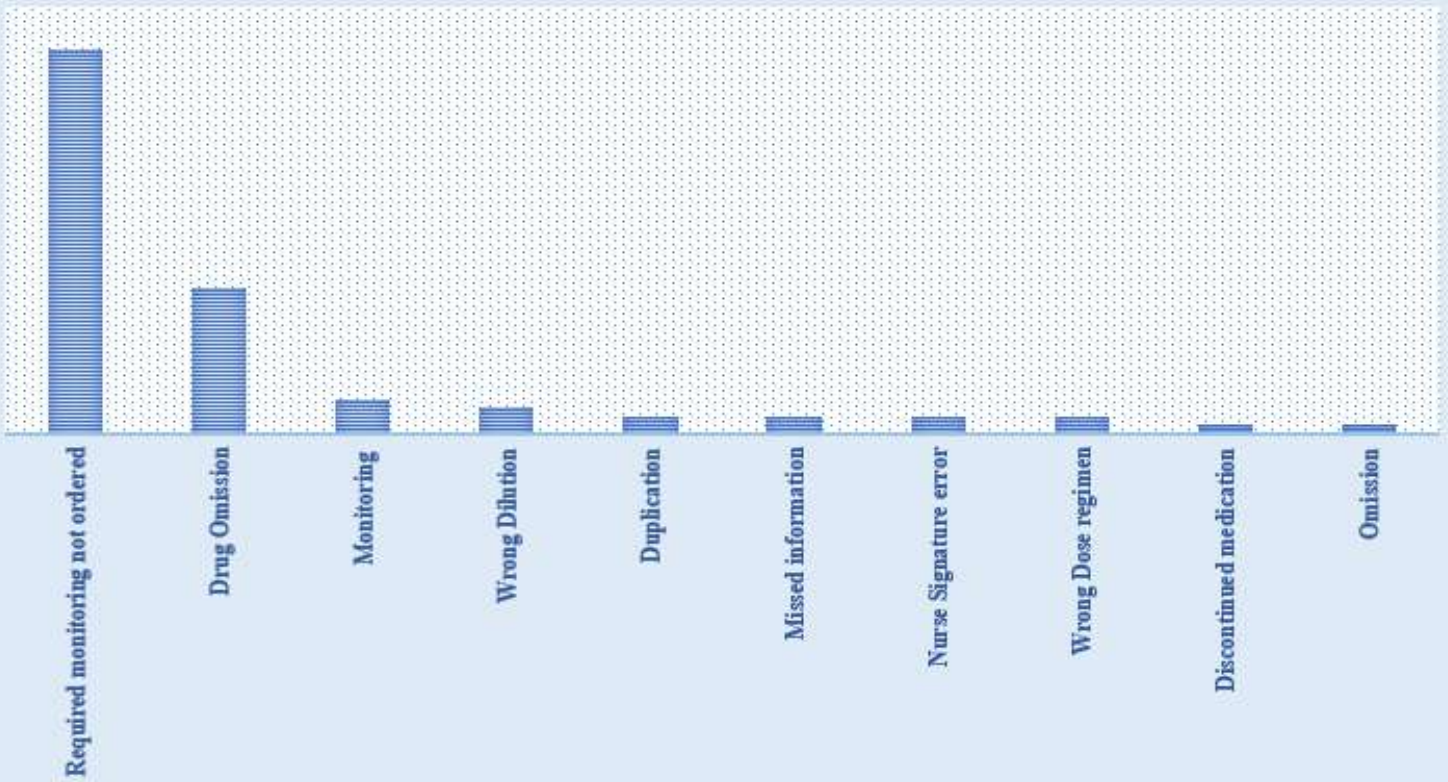


Remdesivir

Types of Drug Therapy Problems associated with Remdesivir "Top 10"



Types of the Medication Errors associated with Remdesivir " TOP 10"



Using Remdesivir Appropriately and Safely for COVID-19 Patients

How to prepare Remdesivir for administration?

Injection solution concentrate (5 mg/ml)	Lyophilized powder (100 mg)
1. Allow the vial to warm in room temperature prior to dilution.	1. Reconstitute vial with *19 ml SWFI*; shake for *30 seconds*.
2. Add either 40 ml ***(for a 200 mg dose)*** or 20 ml ***(for a 100 mg dose)*** to normal saline to reach final volume 250 ml.	**2.** Allow vial contents to settle for *2-3 minutes*; if not completely dissolved *repeat* the process as necessary until vial contents are completely dissolved.
3. Gently invert *20 times* to mix the solution; ***Do NOT Shake***	**3.** Reconstituted vial contains *100 mg per 20 ml (5mg/ml)*.
4. Discard the unused portion of the injection solution vial (If any).	**4.** Add vial content to normal saline to reach final volume *100 or 250 ml.* Gently invert *20 times* to mix the solution; ***Do NOT Shake***
Administer the IV infusion over 30-120 minutes	

What are the monitoring parameters for Remdesivir?

- Obtain baseline liver function tests and prothrombin time before Remdesivir initiation and during treatment as clinically indicated.
- **Consider discontinuing** Remdesivir if alanine transaminase (ALT) levels increase to > 10 times the upper normal limit
- **Discontinue** if elevation in ALT level accompanied by signs or symptoms of liver inflammation .
- Renal function tests, sign and symptoms of infusion reaction should also be monitored.

What is the optimum duration of treatment?

- Remdesivir is given as IV 200 mg as a single dose on day 1 followed by 100 mg once daily. Total duration is 5 days or until hospital discharge whichever first. The healthcare provider may extend duration up to 10 days in patients without substantial clinical improvement at day 5.

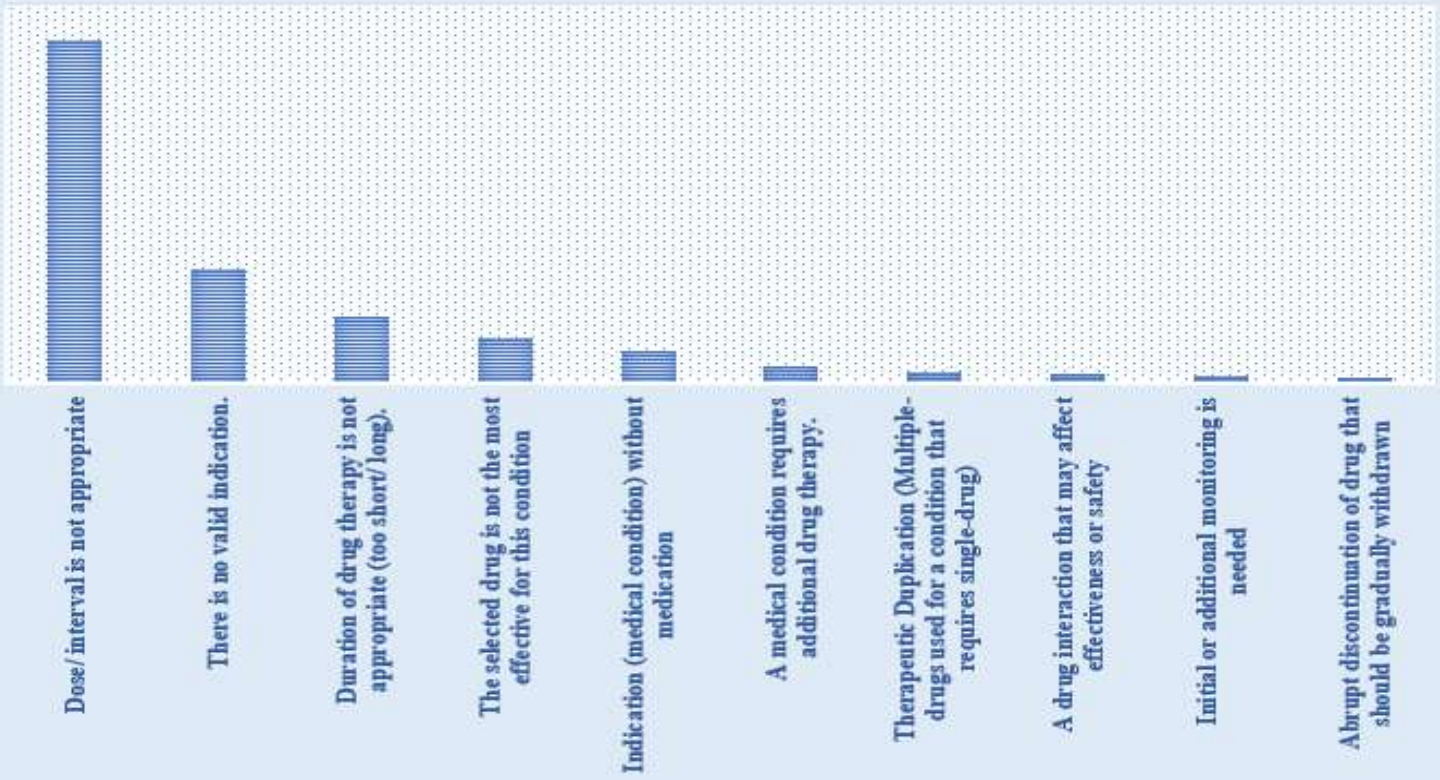
Considerations in special populations:

- Each 100 mg vial of remdesivir lyophilized powder contains 3 g of cyclodextrin or sulfobutylether beta-cyclodextrin sodium (SBECD), whereas each 100 mg/20 mL vial of remdesivir solution contains 6 g of SBECD. This may affect the selection of formulation in special populations as follows:

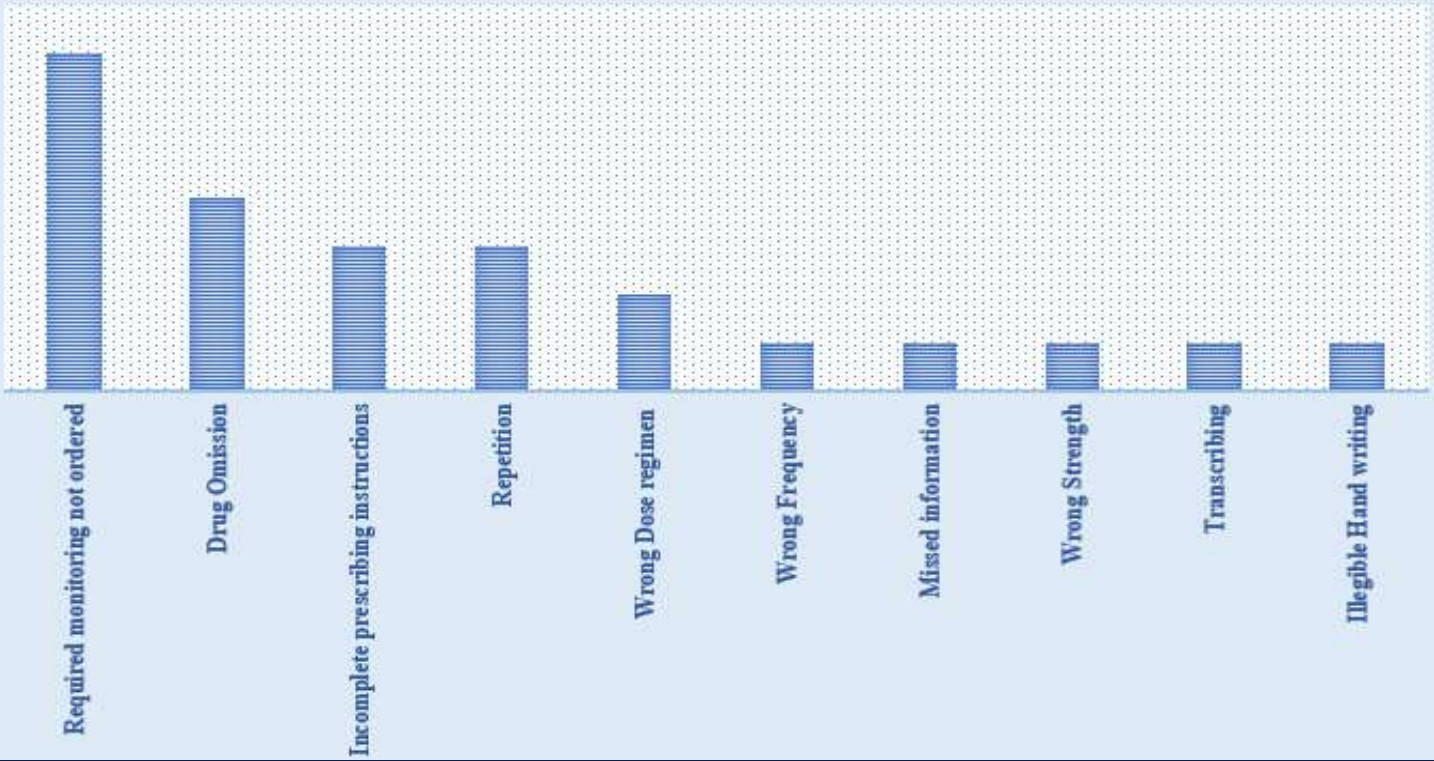
Patients with renal impairment	Pediatric patients
♦ **Lyophilized powder (which contains less SBECD) is preferred to avoid renal toxicities**	♦ **Use only lyophilized powder in pediatric patients <12 years of age or weighing <40 kg (*FDA 2020*)**

Dexamethasone

Types of Drug Therapy Problems associated with Dexamethasone "Top 10"



Types of the Medication Errors associated with Dexamethasone " TOP 10"



Using Dexamethasone Appropriately and Safely for COVID-19 Patients

When to use corticosteroids in COVID-19 treatment?

- It is recommended for patients with severe or critical COVID-19. The WHO classifies critical patients as those with ARDS, sepsis, septic shock, or other conditions that would normally require life-sustaining therapies; and severe patients with any of the following: oxygen saturation <90% on room air, RR > 30 bpm, signs of severe respiratory distress (IDSA & WHO).

What is the appropriate dose of Dexamethasone?

- Dose: 6 mg once daily for up to 10 days (or until discharge if sooner); may give as monotherapy or in combination with Remdesivir.
- If dexamethasone is not available, may use equivalent doses of other corticosteroids (e.g. Prednisone 40 mg, methyl prednisone 32 mg 1-2 divided doses, hydrocortisone 160 mg in 2-4 divided doses) .

What to monitor when using corticosteroids?

- Clinicians should closely monitor adverse effects (e.g., hyperglycemia, secondary infections, psychiatric effects, avascular necrosis).
- The use of systemic corticosteroids may increase the risk of opportunistic fungal infections (e.g., mucormycosis, aspergillosis) and reactivation of latent infections (e.g., hepatitis B virus and tuberculosis).

Enoxaparin: When and How to Use in COVID-19 Patients?

Enoxaparin in COVID-19: Therapeutic VS prophylactic dose

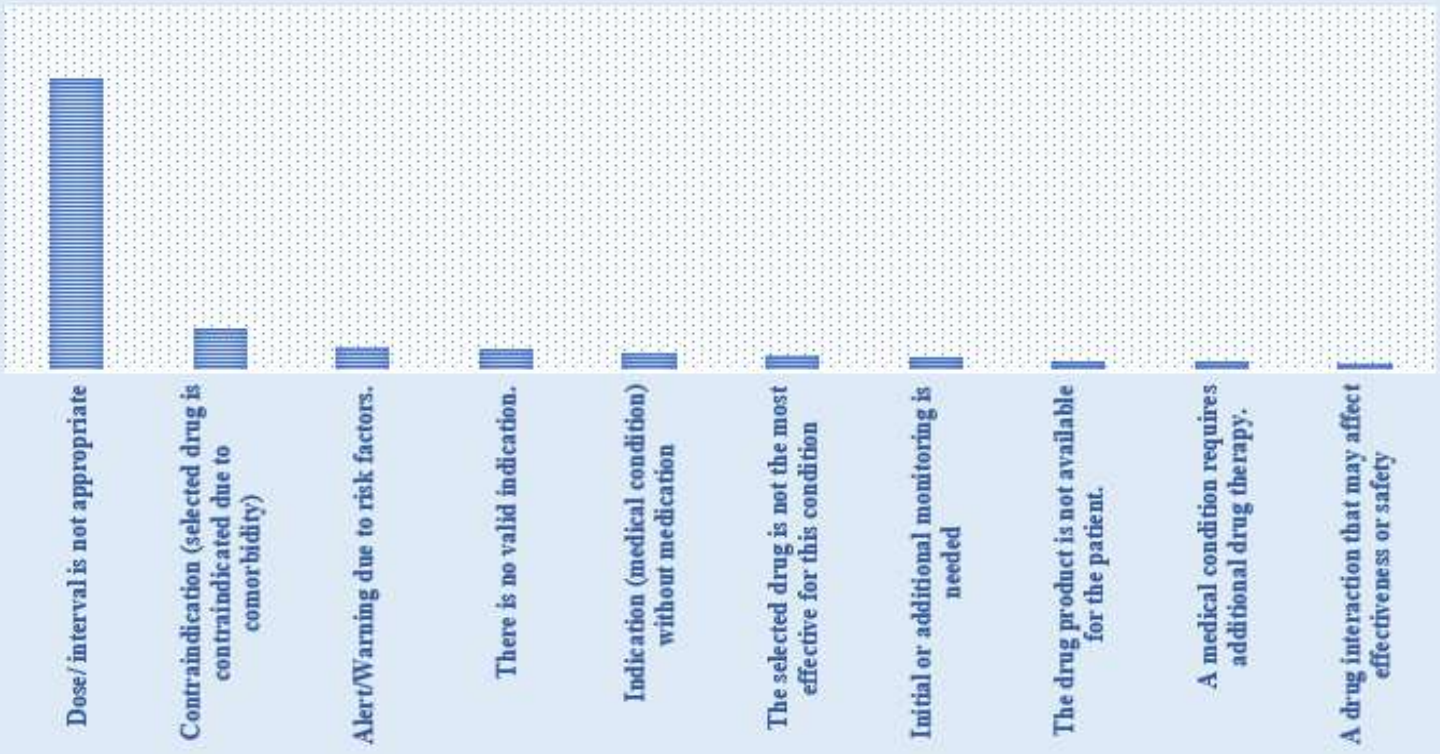
- **Only prophylactic dose of enoxaparin should be used, unless there is another underlying condition that requires treatment with therapeutic dose.**
- Patients should not routinely be discharged from the hospital while on VTE prophylaxis. Extending VTE prophylaxis after hospital discharge can be considered for patients at low risk for bleeding and high risk for VTE, as per protocol for patients without COVID-19.
- For hospitalized COVID-19 patients who experience rapid deterioration of pulmonary, cardiac, or neurological function, or of sudden localized loss of peripheral perfusion, the possibility of thrombo-embolic disease should be evaluated

Enoxaparin Contraindications

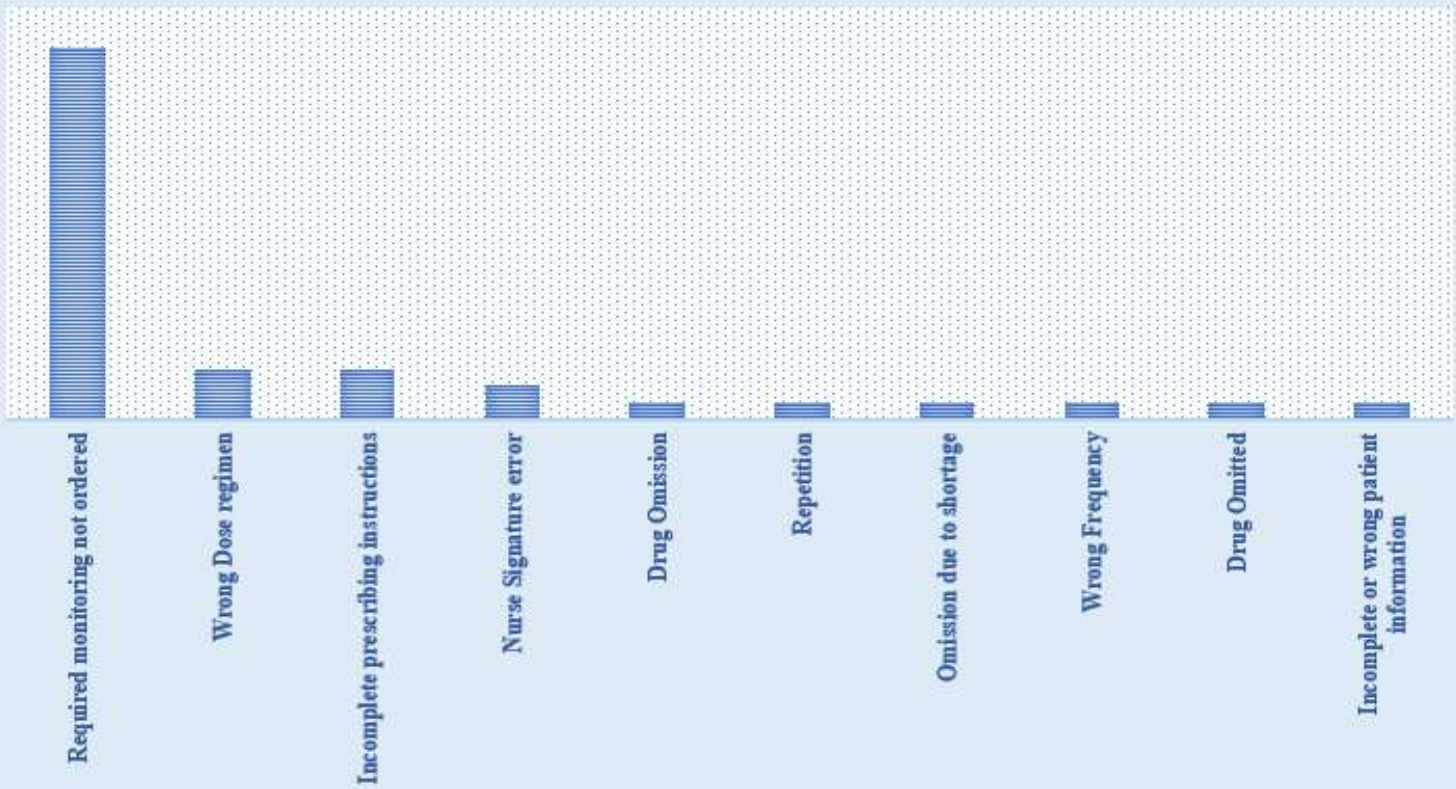
- Known hypersensitivity to enoxaparin.
- History of immune mediated Heparin-Induced-Thrombocytopenia (HIT) in the past 100 days
- Acute or subacute endocarditis.
- Any condition or disease involving an increased risk of hemorrhage; major blood clotting disorders, active GIT ulcers, severe uncontrolled hypertension, diabetic or hemorrhagic retinopathy.

Enoxaparin

Types of Drug Therapy Problems associated with Enoxaparin "Top 10"



Types of the Medication Errors associated with Enoxaparin " TOP 10"



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EGYPTIAN DRUG AUTHORITY

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