



PHARMACY BULLETIN

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- ◇ FDA Safety Communication: Statins use in pregnancy
- ◇ ADR Report

and much more.....

Second course of IVIG not beneficial for patients with severe Guillain-Barré syndrome

Ahad Sunny (Staff Pharmacist, Critical Care)

Guillain-Barré syndrome (GBS) is a rare, **autoimmune disorder** in which a person's own immune system damages the nerves, causing muscle weakness and sometimes paralysis. Weakness and tingling in extremities are usually the first symptoms. The exact cause of Guillain-Barre syndrome is unknown. But two-thirds of patients report symptoms of an infection in the six weeks preceding these include respiratory or a gastrointestinal infection or Zika virus.

Neurology practice changing updates:

For patients with severe Guillain-Barré syndrome (GBS) whose symptoms worsen or fail to improve after a course of **IV immune globulin** (IVIG), a repeat course has sometimes been given, despite uncertain benefit. In a randomized trial of 93 patients with GBS and a poor predicted outcome, those assigned to a **second course of IVIG** (given 2-4 days after completion of the first course) had similar disability but more adverse effects than those who were assigned to placebo; i.e. Serious adverse events (35% vs 16% in the first 30 days), including thromboembolic events. Four patients died in the intervention group (13-24 weeks after randomization). Based on these data, it is suggested **against** retreating with a second course of IVIG for patients with GBS

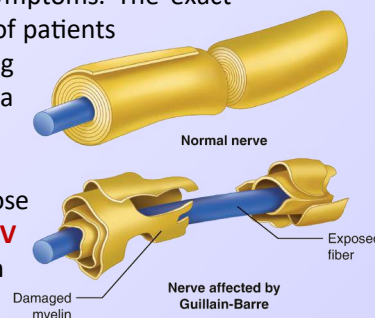
Grade 2C recommendation:

For patients with GBS treated initially with IVIG who show further deterioration or no improvement, we suggest **against retreating with IVIG** because it exposes patients to adverse risks without additional benefit.

A Grade 2C recommendation is a very weak recommendation; other alternatives may be equally reasonable. Low-quality evidence: Evidence from observational studies, unsystematic clinical observations, or from randomized trials with serious flaws. Weak recommendation: Benefits and risks closely balanced and/or uncertain.

Reference:

Second intravenous immunoglobulin dose in patients with Guillain-Barré syndrome with poor prognosis (SID-GBS): a double-blind, randomized, placebo-controlled trial. *Lancet Neurol.* 2021 Apr;20(4):275-283.



Join Us for Monthly Pharmacy CE session (Register at <https://forms.gle/4n23WUdB3Zynv2Y49>)

Month	Topic	Month	Topic
Jan	Management of Ambulatory Care Infections	Jul	A Pharmacist how to be a career oriented?
Feb	High Reliability Organizations (HROs) vs Healthcare Organizations (HCOs)	Aug	Ambulatory Care Pharmacy practice
Mar	Pharmacotherapy of Liver transplant	Oct	Supply chain and Medication Storage Monitoring
Apr	Pain management	Nov	Medication Safety Overview
May	Management of Neutropenic sepsis	Dec	Managing Complication of CKD
Jun	Importance of KPIs in improving Pharmacy practice	Knowledge is Power!	

Hospitalized but Does Not require Supplemental Oxygen

- The Panel recommend against the use of **Dexamethasone** (AIIa) or other **Corticosteroids** (AIII)
- There is sufficient evidence to recommend either for or against the routine use of Remdesivir. For patients at high risk of disease progression, Remdesivir may be appropriate.

Hospitalized and Requires Supplemental Oxygen

- Use one of the following options
 - Remdesivir^{b,c}** (for patient who require minimal supplemental oxygen) (**BIIa**)
 - Dexamethasone plus Remdesivir^{b,c}** (**BIIb**)
 - Dexamethasone** (**BI**)
- For patients on dexamethasone with rapidly increasing Oxygen needs and systemic inflammation, and a second immunomodulatory drug^d. (**baricitinib^e** or **tocilizumab^e**) (**CIIa**)

Hospitalized and Requires Oxygen through a High flow device or NIV

- Use one of the following options
 - Dexamethasone** (**AI**)
 - Dexamethasone plus Remdesivir^b** (**BIII**)
- For patients with rapidly increasing oxygen needs and systemic inflammation, add either **baricitinib^e** (**BIIa**) or **IV Tocilizumab^e** (**BIIa**) to one of the two options above.

Hospitalized and Requires MV Or ECMO

- Dexamethasone** (**AI**)^g
- For Patients who are within 24 hours of admission to the ICU.
- Dexamethasone plus IV Tocilizumab** (**BIIa**)
- If **IV tocilizumab** is not available or not feasible to use, **IV sarilumab** can be used (**BIIa**)

Rating of Recommendation: A= Strong, B= Moderate, C=Optional

Rating of Evidence: **I** = One or more randomized trials without major limitations; **IIa** = Other randomized trials or subgroup analyses of randomized trials; **IIb** = Nonrandomized trials or observational cohort studies; **III** = Expert opinion

- Corticosteroids** prescribed for underlying condition should be continued.
- If the patient progresses to requiring high flow oxygen, NIV, MV or ECMO, complete the full course of **Remdesivir** (Refer to Table)
- Evidence suggest that benefit of **Remdesivir** is greatest when the drug is given early in the course of COVID-19 (within 10 days of symptoms onset). Clinical trials have not demonstrated a mortality benefit for Remdesivir, but large placebo controlled trial showed that Remdesivir reduce time to clinical recovery in hospitalized patients.
- Drugs are listed alphabetically. There are no studies directly comparing **baricitinib and tocilizumab**, and there is sufficient evidence to recommend 1 drug of 1 class of drug (**JAK inhibitors, anti-IL-6 receptor mAbs**) over the other. Treatment decision should be based on local guidance, drug availability and patient comorbidities
- If **baricitinib and IV tocilizumab** are not available or not feasible to use, **Tofacitinib** can be used instead of **baricitinib** (**BIIa**) and **IV Sarilumab** can be used instead of **IV tocilizumab** (**BIIa**)
- The panel recommend against the use of **baricitinib in combination with tocilizumab** for the treatment of COVID-19, except in the clinical trial (**AIII**). Because both **baricitinib** and **tocilizumab** are immunosuppressants, there is a potential for additive risk of infection.
- The combination of **Dexamethasone plus Remdesivir** may be considered for patients who have recently been intubated (**CIII**). The panel recommend against the use of Remdesivir monotherapy in these patients (**AIIa**).

KEY: **ECMO** = Extracorporeal membrane oxygenation; **ICU** = Intensive Care Unit; **IL** = Interlukin; **JAK** = Janus Kinase; **mAb** = Monoclonal antibody; **MV** = Mechanical Ventilation; **NIV** = Non Invasive Ventilation; **The panel** = The COVID-19 treatment-Guidelines panel; **PO** = Per Oral

Reference: COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at <https://www.covid19treatmentguidelines.nih.gov/>. Accessed [3 January 2022]


Increasing the Medication Adherence

Sharon Floric (Point of Care pharmacist - Neurology Clinic)

Medication adherence may be defined as “the extent to which a patient acts in accordance with the prescribed interval, and dose of a dosing regimen”. Medication persistence refers to the duration of medication-taking, and defined as “the duration of time from initiation to discontinuation of therapy”. The World Health Organization recognizes two distinct categories of non-adherence, preventable (e.g., patient forgets, misunderstands) and non-preventable (e.g., life-threatening side effects), and recommends targeting tailored treatment interventions.



Common Barriers in Adherence

Barrier to Knowing	Clinical Strategy to Improve Adherence
Low health literacy (patient did not understand instructions)	<ul style="list-style-type: none"> Provide written and verbal information and use pictures or audiovisual format for better understanding Conduct medication use skills check (e.g., teach – demonstrate – repeat and playback methods) Offer patient to watch a short video on their medications and how to take them prior while waiting. Give instructions to a second person (spouse or significant other, or caregiver) Present 2-3 key points only; share complete list of medications
Poor communication (language barriers)	<ul style="list-style-type: none"> Seek support from translator or the person who can understand well. Engage and encourage patients to log concerns, side effects or symptom patterns related to their medicines (Tools that can be offered: e-health diaries, simple diaries, voice notes in mobile etc.) <p>AVOID the following:</p> <ol style="list-style-type: none"> Failing to assess patients’ understanding. Overwhelming the patient with too much information. Using jargon and technical terminology. Relying on words alone (not using pictures or visual aids) 
Negotiate agreement with the medication plan	<ul style="list-style-type: none"> Simplify the dosing regimen. Explore the patient’s activity and meal schedule, and preferences for dosing schedules. Altering the administration route as per their convenience Explore the patient’s beliefs about the medication and how it works for them.
Barrier to Doing	Clinical Strategy to Improve Adherence
No-fill of first pre-prescription identified	<ul style="list-style-type: none"> Dispense to the patient the first week of medications at discharge or in clinic. Discuss the patient’s desire/willingness to take the new medication.
Irregular refills obtained / forgetfulness	<ul style="list-style-type: none"> Choose drug available in a calendarized blister-packaging (if available). Enroll patient in a frequent follow-up program to receive reminder triggers from pharmacist Use multiple frequent reminder trigger systems with the patient, including cell phone . Include a caregiver in the communication for reminders.
Cost prohibitive for the patient	<ul style="list-style-type: none"> Select a different medication or a generic after consulting with prescriber. Identify a local low-cost drug program/patient access programs.
Serious mental illness (major depression, schizophrenia etc.)	<ul style="list-style-type: none"> Treat mental health first; then resume other adherence/interventions and monitoring. Using a long-acting formulation (patch etc.)
Side effects (e.g., diarrhea, weight gain, sleeplessness)	<ul style="list-style-type: none"> Attempt to confirm drug-effect relationship Change drug or drug class after consulting prescriber Modify dose (After consulting prescriber)
Serious complications (e.g., allergic reaction)	<ul style="list-style-type: none"> Discontinue; change drug choice (after consulting prescriber)

Cool Fact
Shifa Point of Care (PoC) pharmacist in Neurology clinic monitors adherence to therapy using **Morisky Med Adherence Scale**. Data depicts that **15%** patients have low/poor adherence, while **38%** patients have medium adherence scores. Pharmacists follow-up with these patients on monthly basis and strive to improve their adherence. Moreover PoC pharmacist also performs:

- Medication reconciliation
- Patient counseling
- ADRs Reporting
- Prescription review and
- Discussion with neurologists when therapy needs modification

Reference: Neiman AB, Ruppert T, Ho M, et al. CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities. *MMWR Morb Mortal Wkly Rep* 2017;66.

World Antibiotic Awareness Week 2021 At Shifa

World Antimicrobial Awareness Week (WAAW) is celebrated annually between 18-24th November. It aims to increasing awareness for global antimicrobial resistance and to encourage best practices among the general public, health workers and policy makers to avoid the further emergence and spread of drug-resistant infections.



Shifa Pharmacy department actively takes part in these activities to enhance rationale use of antibiotics. As a key stakeholder in antimicrobials stewardship (AS) program along with Infectious disease consultants, we have implemented many important core and supplementary AS strategies e.g. ID rounds, Auto-stop for antibiotics, no OTC sale of antibiotics, restricted use, prior approvals, drug utilization reviews and daily defined dose (DDD) review etc. Shifa arranged a walk to spread awareness among the community about antibiotic resistance where team interacted with healthcare staff, patients and their families. Pharmacists also counselled patients on rational

use of antibiotics at dedicated patient counters during the entire week. Shifa Pharmacists gave talks in seminars arranged by NIH Islamabad and Antibiotic awareness session at PIMS Islamabad.

USE ANTIBIOTICS WISLEY!

FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy; still advises most pregnant patients should stop taking statins.

Statins Use in Pregnancy

FDA Safety Communication



Breastfeeding not recommended in patients who require statins

The U.S. Food and Drug Administration (FDA) is requesting removal of its strongest warning against using cholesterol-lowering statin medicines in pregnant patients.

Patients should not breastfeed when taking a statin because the medicine may pass into breast milk and pose a risk to the baby. Many can stop statins temporarily until breastfeeding ends. However, patients requiring ongoing statin treatment should not breastfeed and instead use infant formula or other alternatives.

A contraindication is FDA's strongest warning and is only added when a medicine should not be used because the risk clearly outweighs any possible benefit. Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate. **FDA expects removing the contraindication will enable healthcare professionals and patients to make individual decisions about benefit and risk, especially for those at very high risk of heart attack or stroke. This includes patients with homozygous familial hypercholesterolemia and those who have previously had a heart attack or stroke.** Statins are safe to use in patients who are not pregnant but may become pregnant.

Patient taking statins should notify her healthcare professionals if she become pregnant or suspect a pregnancy. Health care professional will be able to advise whether to stop taking the medicine during pregnancy and to stop statin temporarily while breastfeeding. **Patients who are at high risk of heart attack or stroke who require statins after giving birth should not breastfeed and should use alternatives such as infant formula.**

Reference: FDA, Safety Communications 30th August 2021

Expressions :
When You Come to Know That



NOT ALL CAPSULES ARE FOR ORAL USE

The choice of routes of administration of medicines depends not only on the indication, convenience; but also on the drug's properties and pharmacokinetics.

Taking the drugs other than the prescribed route could lead to failure of therapy, toxicity and adverse drug reactions.

Some drugs are available in tablet or capsule forms that are routinely assumed to be taken orally. But actually tablets can be for vaginal or rectal use, or capsules for inhalation purpose and some injections for oral use etc.

So Never Assume that patient knows, Always Educate about the proper route of administration.

Ask Your Pharmacist!

Key facts

- Rabies is a vaccine-preventable viral disease which occurs in more than 150 countries and territories.
- Dogs are the main source of human rabies deaths, contributing up to 99% of all rabies transmissions to humans.
- Interrupting transmission is feasible through vaccination of dogs and prevention of dog bites.
- Infection causes tens of thousands of deaths every year, mainly in Asia and Africa.
- Immediate, thorough wound washing with soap and water after contact with a suspect rabid animal is crucial and can save lives.



Post-exposure prophylaxis (PEP) is the immediate treatment of a bite victim after rabies exposure

Vaccination Schedule for Pre and post exposure prophylaxis (PEP)

Post-exposure prophylaxis (PEP) is the immediate treatment of a bite victim after rabies exposure. This prevents virus entry into the central nervous system. PEP consists of:

- Extensive washing and local treatment of the bite wound or scratch as soon as possible after a suspected exposure;
- A course of potent and effective rabies vaccine that meets WHO standards; and

The administration of rabies immunoglobulin (RIG), if indicated.

Starting the treatment soon after an exposure to rabies virus can effectively prevent the onset of symptoms and death.

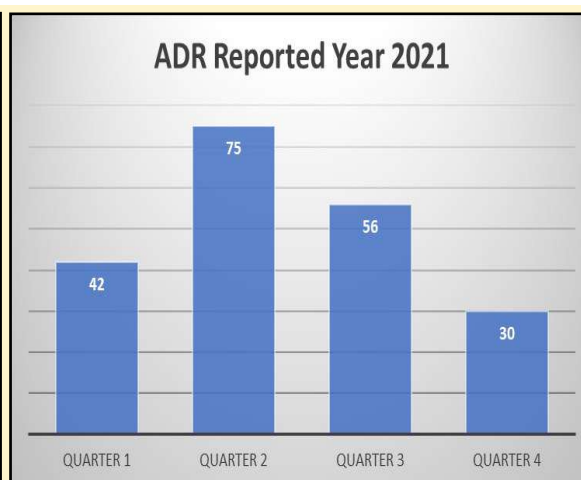
	<i>Pre-exposure Rabies Vaccination Schedule</i>	<i>Post-exposure Rabies Vaccination Schedule</i>	
	3 dose IM regimen: (1-0-1-0-1)	Non-immunized Individuals	Previously Immunized Individuals
1 st dose	Day 0	Day 0	Day 0
2 nd dose	Day 7	Day 3	Day 3
3 rd dose	Day 28	Day 7	
4 th dose	6 month to 1yr <i>booster dose</i>	Day 14	
5 th dose*		Day 28	

Categories of contact with suspect rabid animal	Post-exposure prophylaxis measures
Category I - touching or feeding animals, animal licks on intact skin (no exposure)	Washing of exposed skin surfaces, no PEP
Category II - nibbling of uncovered skin, minor scratches or abrasions without	Wound washing and immediate vaccination
Category III - single or multiple transdermal bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to	Wound washing, immediate vaccination and administration of rabies immunoglobulin

All category II and III exposures assessed as carrying a risk of developing rabies require PEP. *Recommended for immune compromised persons

Reference: CDC, WHO Guide for Rabies Pre and Post Exposure Prophylaxis in Humans, 2014

REPORT ADR
Adverse Drug Reaction
HOTLINE: 3977, 3492
Shifa Pharmacy
Reporting of ADR is duty of ALL
Report ADR to increase patient Safety



Key facts

- The majority of unintended, harmful reactions to medicines (known as adverse drug reactions) are preventable (in some instances as many as 60%).
- In some countries, ADR-related costs such as hospitalization, surgery and lost productivity exceed the cost of medications.
- No medicine is risk-free. Vigilant assessment of the risks and benefits of medicines promotes patient safety.

Proud to Share

Pharmacists in Department of Pharmacy Services, Shifa are committed to life-long learning and continuous professional development in order to serve our patients better. We are proud to share that this year 2 of our clinical pharmacists **Rehan Anjum** (Renal Transplant) and **Muhammad Hamid** (Liver Transplant) have cleared Board of Pharmacy Specialist exam (BCPS) in Pharmacotherapy. While 4 other pharmacists, **Ms. Naima Manzoor**, **Mr. Aziz Ullah Khan**, **Ms. Sundus Awan** and **Ms. Ammara Razi** have completed American Society of Health System Pharmacists® (ASHP) certifications in various domains (see details as under):

Congratulations

Rehan Anjum and M. Hamid for successfully achieving Board of Pharmacy Specialities certification.

Board of pharmacotherapy specialist (BCPS)





Rehan Anjum
Clinical Pharmacist



M. Hamid
Clinical Pharmacist

Board certification through the Board of Pharmacy Specialties® America, is the gold standard for determining which pharmacists are qualified to contribute at advanced practice levels. Through the rigorous examination standards mandated by the Board of Pharmacy Specialties®, the BPS board certified pharmacist is uniquely trained and educated to meet the continually expanding expectations of other healthcare team members and the specialized needs of the patients they serve.



Naima Manzoor

Principal Pharmacist, Emergency Pharmacy Shifa,
Is now a **Certified in Emergency Medicine From: ASHP USA**

The self-guided, online continuing education program is to equip pharmacists with the foundational knowledge and skills necessary for pharmacists to provide optimal patient care in the emergency department. The curriculum focus on the key roles and responsibilities of pharmacists practicing in emergency medicine.



Aziz Ullah Khan

Charge Pharmacist, Outpatient Pharmacy Shifa,
Is now a **Certified in Pharmacy Informatics From: ASHP USA**

Comprises of 7 modules designed to enhance the skills and resources for managing medication related information in electronic health records, pharmacy information systems and automated systems.



Ammara Razi Staff Pharmacist & **Sundus Awan** Principle Pharmacist - Compounding Pharmacy Shifa

are now a **Certified Pharmacist in Compounded Sterile Preparation From: ASHP USA**



The self-guided, online continuing education trains pharmacists in basic compounding techniques and advanced skills required to lead and manage safe and compliant sterile preparation in a clean room environment. It will also serve as the preparatory course for the pharmacists pursuing the BPS, Board Certified Sterile Compounding Pharmacists (BCSCP) certifications.

Formulary Updates (Visit Shifa Intranet Home Page—click Medication Updates for details)			
Brand	Generic	Class	Indications
Pegstim 6mg Injection	Peg-filgrastim	Colony Stimulating Factor	Prevention of chemotherapy-induced neutropenia
Fludrocortisone tablet 0.1mg	Fludrocortisone	Mineralocorticoid	Adrenocortical Insufficiency/ Addison Disease
C-Tax Tab 450mg	Valganciclovir	Antiviral	Prevention and treatment of cytomegalovirus

Looking for Your Valuable Feedback

We want to bring to you valuable, updated and interesting information via Pharmacy Newsletter, so please spare some time to provide your valuable feedback in the form of comments or suggestions. Its your newsletter and with your help we'll make it better!

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Thank you.



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