Indian Health Service
National Pharmacy and Therapeutics Committee
Quarterly Adverse Drug/Vaccine Event Report

This Quarterly Adverse Drug/Vaccine Event Report period includes adverse events submitted to the FDA MedWatch or FDA/CDC VAERS programs from January 1, 2020 through November 1, 2020.

Medication and Suspected Adverse Event	Comments
Chlorhexidine Mouthwash: Throat swelling and hives. Hives persisted for 2 months.	Hypersensitivity reactions, including anaphylaxis, have been reported.
Remdesivir: - 3 reports decreased renal function - 3 reports of increased LFTs - Severe leukopenia - Shivering during infusion - Increased O2 requirements followed by STEMI - Decreased Hgb - Hypotension and bradycardia 14h after 2nd dose	Anticipated adverse events include hyperglycemia, increased LFTs, renal failure, and fever. Hypersensitivity or infusion related reactions may include: hypotension, nausea, vomiting, diaphoresis, and shivering. From internal IHS remdesivir utilization surveillance, adverse events have included: - 8 reports of decreased renal function - 13 reports of increased LFTs - Leukopenia - Allergic reaction - Atrial Fibrillation - Infusion related reactions (5 reports of nausea, 3 reports of bradycardia, hypotension, & shivering)
Semaglutide: Hair loss	Causal relationship is unclear. Hair loss is not reported in the package insert but 11 cases of alopecia have been reported to the FDA MedWatch program. Hair loss is associated with uncontrolled diabetes and may be disease related rather than medication related.
Varenicline: Pain in multiple joints	Musculoskeletal pain has been observed in <1% of patients. Joint swelling, stiffness, range of motion, and dislocation have been reported to the FDA MedWatch program.
Verapamil: Bradycardia	Common adverse event consistent with pharmacologic action.

Report suspected Adverse Drug/Vaccine Events:

- Report suspected adverse drug events to MedWatch - Enter "IHS" in the reporter field
- Report suspected adverse vaccine events to VAERS - Enter "IHS" in the field for item #26

November 3, 2020