SOLA.CHEM.INF.1001 Therapeutic Drug Monitoring Guidelines 2022

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Location Laboratory Collection Manual

Organization South Louisiana

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	8/10/2022	1.0	Gregory Sossaman Gregory Sossaman, M.D.	
Approval	MD/PhD Lead, Chemistry Technical Work Group	6/16/2022	1.0	Qingli Wu PhD Qingli Wu	
Approval	Administrative Lead, Chemistry Technical Work Group	6/16/2022	1.0	Belinda Ourso, MT(ASCP) BELINDA G OURSO	

Signatures from prior revisions are not listed.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	6/15/2022	8/24/2022	Indefinite

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Therapeutic Drug Monitoring Guidelines

Name	When To Draw Sample	Steady State*	Additional Considerations
Amikacin	Traditional Dosing: **Peak:** 30 minutes after IV infusion, 60 minutes after IM infusion.**Trough:** 30 minutes before the next dose. Once daily dosing: **Trough**: 30 min before the next dose	10-15 hours or greater dependent on renal function.	Trough: Draw serum concentrations after 5 half-lives, usually around the third dose. Half-lives in patients with normal renal function are generally 2 to 3 hours No peak for once daily dosing.
Carbamazepine (Tegretol)	**Trough:** immediately prior to the next dose after steady-state concentration is achieved.	4-7 days	Half-life is about 35 hours (range 18 to 65 hours) Plasma levels should be monitored weekly during the first month of therapy, periodically thereafter.
Cyclosporine A	Trough: Immediately prior to the next dose **2 Hour Level:** drawn 2 hours after dosing.	2-3 days.	**2 Hour Level:** The therapeutical range is 700-1200ng/dL. **Trough:** > 500 ng/mL is associated with cyclosporine induced nephrotoxicity. The optimal therapeutic range for a given patient may differ from the suggested trough range based on the indication for therapy, treatment phase (initiation or maintenance), Use in combination with other drugs, time of specimen collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center
Digoxin	Draw levels: at least 4 hours after an IV dose or 6-8 hours (no earlier than 6 hours) after an oral dose.	IV, PO, Adults: 1-2 weeks.	**Peak:** *Oral:* after 2-8 hours *IV:* after 1-4 hours. Draw levels when compliance, effectiveness, or systemic availability is questioned or toxicity is suspected.
Ethanol	Dependent on time of exposure, test upon presentation to hospital		. MEDICAL USE ONLY. No micro collection.
Ethosuximide (Zarontin)	**Trough:** immediately prior to the next dose after steady-state concentration is achieved	Adults: 10-13 days Children: 6-7 days.	**Peak:** *Capsule*: 2-4 hours *Syrup:* <2-4 hours. Half-life is 17-56 hours (adult) and 30 hours (pediatric).

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Everolimus	Trough: immediately prior to the next dose.	Within 7 days.	The optimal therapeutic range for a given patient may differ from the suggested trough range based on the indication for therapy, treatment phase (initiation or maintenance), use in combination with other drugs, time of specimen collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center.
Gentamicin	Traditional dosing: **Peak:** 30 minutes after a 30 minute infusion. **Trough:** 30 minutes before the next dose. Once Daily Dosing: **Trough:** 30 minutes before the next dose.	10-15 hours or greater dependent on renal function.	The mean half-life after intravenous administration was 75 min (range, 26-230 min) No peak for once-daily dose
Lidocaine	**1)** 12 hours after initiating therapy for arrhythmia; then every 24 hours thereafter. **2)** Every 12 hours when evidence of cardiac or hepatic insufficiency exists. **3)** Whenever toxicity is suspected. Whenever ventricular arrhythmias occur despite lidocaine administration.	IV, Adults: immediate	Maximum serum levels achieved in 5-8 hours. Obtain periodic plasma levels once effective levels have been reached.
Methotrexate	Draw levels 24-72 hours after drug infusion. Will vary according to dosing protocol.	N/A	**Peak:** *Oral:* 1-2 hours *Parenteral:* 30-60 minutes Criteria for serum concentrations indicative of a potential for toxicity after single-bolus, high-dose therapy are as follows: -Methotrexate >10 mcmol/L 24 hours after dose -Methotrexate >1 mcmol/L 48 hours after dose -Methotrexate >0.1 mcmol/L 72 hours after dose

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Phenobarbital	Trough: just prior to the next dose (If infusion, ensure level drawn at least 1 hour after infusion.)	PO: 14-21 days for adults and adolescents. PO: 8-15 days for children and infants.	Peak plasma levels 1-3 hours after oral and IM route. Upper limits for phenobarbital dosing primarily determined by its sedative effects. Trough preferred for monitoring therapy. Dosage adjustments are made after 2 weeks of therapy to achieve steady-state blood levels.
Phenytoin	Trough: just prior to the next dose	Highly variable, about 1-5 weeks	Peak plasma levels 1-3 hours after oral dose. Peak 2-4 hours after IV loading dose. Dose should be adjusted to achieve steady-state total phenytoin concentrations within the therapeutical ranges
Primidone (Mysoline) Includes phenobarbital determination	Trough: just prior to the next dose	approximately 2 weeks	Peak plasma levels 1-3 hours after oral dose. Sample 2 weeks after initiation of therapy to allow concentrations to reach steady state.
Procainamide (Pronestyl) Includes NAPA	IV Administration: **1)** 2 hours after start of IV maintenance infusion **2)** 6-12 hours after start of IV maintenance. Oral therapy: just prior to the next dose	Steady state for oral therapy: 12-18 hours w/normal renal function. 48-72 hours w/renal impairment.	
Tobramycin	Traditional dosing: **Peak:** 30 minutes after IV infusion. **Trough:** 30 minutes before the next dose. Once daily dosing: **Trough:** 30 minutes before the next dose.	10-15 hours or greater dependent on renal function.	Trough: Draw serum concentrations after 5 half-lives, usually around the third dose. No peak with once daily dosing.

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Valproic Acid (Depakene)	Trough: just prior to the next dose.	*PO: Adults* 1-17 hours *PO: Child* <17 hours	Approximate peak plasma levels after oral dose: *Syrup:* 0.5-1 hour *Capsule:* 1-3 hours *Enteric coated tablet:* 2-6 hours Half-life is 10 to 14 hours in adults but is shorter in children. Monitor trough within 2-4 days of initiating treatment or changing dose. Because the concentration of valproic acid fluctuates considerably depending on the time from last dose, interpretation of the clinical significance of the valproic acid concentration must take into consideration the timing of the blood specimen. For this reason, 2 collections are sometimes made to assess the trough and peak concentrations.
Vancomycin	**Peak:** draw 1-2 hours after the end of infusion. For neonates and patients receiving Q 6hr dosing draw peak 1 hr after infusion. **Trough:** 30 min prior to the next dose.	24-36 hours	Vancomycin has a bi-phasic elimination half-life with its initial half-life being relatively quick and a terminal half-life of 4 to 6 hours in healthy adults with normal renal function. Trough concentrations are recommended for therapeutic monitoring of vancomycin, preferably acquired at steady-state (just before fourth dose). Peak concentrations do not correlate well to efficacy or nephrotoxicity, but may be useful for pharmacokinetic analyses (eg, area under the curve: AUC studies) or for select patients.
Quinidine	Trough: just prior to the next dose.	30-35 hours	Peak depends on preparation: Quinidine sulfate 1-2 hours after oral dose. Quinidine gluconate 4-6 hours after oral dose. Half-life is 6 to 8 hours
Salicylate	Draw steady state plasma levels, or immediately if suspect poisoning.	> one week	Peak plasma levels achieved 2 hours after PO dose. Draw plasma levels for high dose treatment or a change in dosage regimen. Dose-dependent serum half-life ranging from 3 to 20 hours.

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Theophylline	**IV Adminitration:** **1)** Prior to infusion (if patient has history of theophylline therapy). **2)** 4-8 hours after the start of infusion. **3)** Repeat as needed to ensure concentration is maintained within therapeutic range. **Oral Administration:** **Trough:** immediately prior to the next dose after steady-state concentration is achieved	**IV, PO, Adults:** about 2 days **IV, PO, Child:** 1-2 days PO, infants gradually decreases from newborn value to childhood level. **Neonates, prematures:** 150 hours	Peak plasma levels depend on oral preparation: **1)** Solution - one hour after oral dose. **2)** Solid with rapid dissolution characteristics - two hours after oral dose. **3)** Slow release formulations - 4-6 hours after oral dose. Theodur - 3 to 7 hours after oral dose. Theophylline has a half-life of approximately 4 hours in children and adult smokers, and 8.7 hours in nonsmoking adults.
Tacrolimus	Trough: immediately prior to the next dose.	2-3 days.	The optimal therapeutic range for a given patient may differ from the suggested trough range based on the indication for therapy, treatment phase (initiation or maintenance), Use in combination with other drugs, time of specimen collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center.
Sirolimus	Trough: immediately prior to the next dose.	5-7 days.	The optimal therapeutic range for a given patient may differ from the suggested trough range based on the indication for therapy, treatment phase (initiation or maintenance), use in combination with other drugs, time of specimen collection relative to prior dose, type of transplanted organ, and/or the therapeutic approach of the transplant center.

*: Steady state will be achieved after 5 half-lives. For a drug with a long half-life, using a high loading dose may achieve a target steady state level more quickly.

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THERAPEUTIC DRUG MONITORING GUIDELINES
Reference List

1. Fischback, Frances. A manual of Laboratory & Diagnostic Test 4th ed. J. B. Lippincott Co.: Philadelphia, 1992.
2. Henry, John Bernard. Clinical Diagnosis and Management by Laboratory Methods. W.B. Saunders Co.: Philadelphia, 1991.
3. Knoben, James E., et al. Handbook of Clinical Drug Data 7th ed. Drug Intelligence Publications: Hamilton, 1993.
4. Lacy, Charles, et al. Drug Information Handbook 4th ed. Lexi Comp Inc.: Hudson, 1996.
5. Leiken, Jarold B. Poisoning and Toxicology Handbook 2nd ed. Lexi Comp Inc.: Hudson, 1995.
6. Taylor, William. A Textbook for the Clinical Application of Therapeutic Drug Monitoring. Abbott Lab: Irving, 1996.
7. Winter Michael E., et al. Basic Clinical Pharmacokinetics. Applied Therapeutics, Inc. Vancouver, 1994.
8. Mayo clinic laboratories test catalog May, 2022