RISK REFERENCE SHEET

Failure to Perform/Communicate Therapeutic Drug Monitoring

Sector: LHIN/Home Health Funder, Homecare

Therapeutic drug monitoring (TDM) provides important information for tailoring the dosage of prescribed medication(s) to a patient. TDM uses blood serum concentrations of medications to optimize drug dosing to minimize toxicity and maximize treatment benefit. TDM is required when medications have a narrow therapeutic range (e.g. some antibiotics, antiarrhythmics, anticoagulants, anticonvulsants, post-transplant anti-rejection drugs) and there is a very small margin between effective therapy and under or overdosing. Some drugs also require time-specific laboratory work (e.g. two hours after the last dose) creating further monitoring and/or management considerations in non-acute settings. Failure to perform and/or communicate and act on therapeutic drug monitoring results can result in significant harm to the patient.

COMMON CLAIM THEMES

- Cumbersome, impractical and/or conflicting TDM protocols/ guidelines.
- Lack of clarity as to who is responsible for obtaining orders for serum levels, interpreting results and communicating results to the most responsible practitioner, including transfer of most responsible practitioner status after transition.
- Critical and/or toxic serum levels not communicated to the most responsible practitioner and/or the patient.
- Systems not in place to advise practitioners of the availability of testing in the community or hospital.
- Assumption that another practitioner will be monitoring therapeutic drug levels.
- Poor understanding/compliance of healthcare providers with TDM protocols/guidelines.
- Poor documentation practices (e.g. signs/symptoms of toxicology; communication of test results to the most responsible practitioner; patient education/training, etc.); particularly with charting by exception.
- Poor patient education and instructions regarding signs/symptoms of toxicity and requirements for blood work.
- Healthcare practitioners with little to no experience in TDM, including interpretation of results, and proper actions if levels are out of the desired range.
- Communication gaps between nursing, lab and clinical pharmacists related to the relay of/acting on TDM results during hospital stay and prior to discharge.
- Communication gaps with community providers related to the provision of results received after the patient has left the hospital.
- Inability to acquire time-specific lab tests due to blood technician availability or constraints of out of facility laboratories.

CASE STUDY 1

A patient with diabetes was admitted to hospital to undergo aggressive therapy for osteomyelitis of the foot, the result of a previous foot injury. The patient was discharged on antibiotic therapy. Community nurses monitored the patient's progress but failed to inform the patient of the signs and symptoms of hearing impairment related to drug toxicity despite a policy indicating it was necessary to do so. The patient ended up suffering from hearing loss. Experts were critical of the hospital healthcare providers, the most responsible physician and community nurses for the failure to provide appropriate education to the patient.

Canadian Case Example

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MITIGATION STRATEGIES

Note: The Mitigation Strategies are general risk management strategies, not a mandatory checklist.

Reliable Care Processes

- ☐ Ensure protocols/algorithms to guide decision making for medications requiring TDM (e.g. anticoagulants, aminoglycoside antibiotics, phenytoin, cyclosporine, digoxin, lithium) that consider:
  - Therapeutic and toxic drug levels/ranges and standardized nomograms for monitoring TDM levels where possible;
  - Individual responsible for obtaining levels and/or acting on results;
  - Best practices for the communication of critical test results to the most responsible/ordering practitioner, including alternative contacts for critical results.
  - Timing of blood samples;
  - Escalation steps and time thresholds if the levels are not available at the time of next dose;
  - Escalation steps and time thresholds if the levels are abnormal/critical/toxic;
  - The need to ask if the patient is experiencing side effects that could be early indicators of toxicity;
  - The availability and accessibility of laboratory services to a patient in the community.
- ☐ Consider, when purchasing or updating electronic systems, clinical decision supports/embedded algorithms to order lab tests and instruct users on how to promptly respond to/act on critical levels.
- ☐ Adopt a standardized process to ensure TDM requirements are included in discharge orders including therapeutic and toxic levels and the need for stringent compliance with obtaining and communicating TDM levels to the most responsible practitioner.
- ☐ Provide regular in-services/training to all nursing staff administering and/or monitoring patients with TDM requirements including therapeutic and toxic levels, signs/symptoms of toxicity, risk factors impacting metabolism and clearance of medications (e.g. age, disease, drug interactions, impaired renal failure) and the need for stringent compliance with obtaining and communicating TDM levels to the most responsible practitioner.

Patient & Family Centred Care

- ☐ Provide education/training to the patient/family, emphasizing the need for strict adherence/compliance with administration/testing/monitoring/schedule, possibility of repeat testing, signs/symptoms of toxicology, the need to report changes or untoward symptoms immediately to the most responsible practitioner.
- ☐ Encourage patients (and caregivers) to create a backup plan when they do not receive the feedback on drug levels as promised (e.g. if you do not hear from the physician by predetermined date, you need to urgently present to the Emergency Department to have your gentamycin or creatinine level assessed).

Documentation

- ☐ Ensure complete and timely documentation regarding TDM (including date/time):
  - When blood is drawn;
  - Upon delivery and receipt of TDM levels;
  - When communicating results to the most responsible practitioner including the name of the practitioner contacted and any resulting actions taken with respect to the information provided;
  - If laboratory results are pending and how these will be relayed to the most responsible physician used in the community.

Monitoring and Measurement

- ☐ Ensure laboratory services have a formal quality assurance process regarding adherence to drawing of blood samples and communication of critical/toxic levels to the most responsible practitioner. Ensure these services can perform time-specific blood tests if necessary and have a result reporting time within safe standards.
- ☐ Implement formal strategies to help ensure consistent adherence to TDM policies/practices (e.g. periodic chart/e-record audits, analysis of reported incident/events, learnings from medico-legal matters).