RISK REFERENCE SHEET

HIROC

Failure to Perform/Communicate Therapeutic Drug Monitoring

Therapeutic drug monitoring (TDM) is defined as the management of a patient's drug regimen based on the serum, plasma, or whole blood concentration of a drug (Dasgupta, 2016). There are several classes of drugs commonly monitored to ensure correct blood concentration, including, but not limited to the following: antiepileptics, antiarrythmics, antibiotics, antineoplastics, antimanics, bronchodilators, and immunosuppressives (Siemens, 2009). Therapeutic drug monitoring (TDM) provides important information for tailoring the dosage of prescribed medication(s) to an individual patient (Titrating). TDM uses blood serum concentrations of medications to optimize drug dosing to minimize toxicity and maximize treatment benefit. Not all medications require TDM; most drugs have a wide therapeutic range or "window" and can be prescribed based upon pre-established dose ranges and dosing regimens. When medications have a narrow therapeutic range, there is a very small margin between effective therapy and under or overdosing. In those cases, TDM is required to maintain the right concentration of those medications in the blood system. Failure to perform, communicate, or act on therapeutic drug monitoring results can result in significant harm to the patient.

COMMON CLAIM THEMES

System

- Cumbersome, impractical and/or conflicting TDM protocols and guidelines.
- Lack of clarity as to who is responsible for obtaining serum levels, interpreting results, and communicating results to the most responsible practitioner, patient, family member or caregiver.
- Systems not in place to advice practitioners of the availability of testing.

Knowledge and judgement

- Assumption that another practitioner will be monitoring therapeutic drug levels.
- Poor understanding or compliance with TDM protocols and guidelines.
- Healthcare practitioners with little to no experience in TDM.

Communication and documentation

- Critical and/or toxic serum levels not communicated to the most responsible practitioner and/or the patient.
- Inconsistent or poor documentation practices (e.g., signs or symptoms of toxicology;

CASE STUDY 1

A patient with diabetes was admitted to hospital to undergo aggressive therapy for osteomyelitis of the foot as a result of a foot injury. The patient was discharged on gentamicin therapy and followed by community nurses. Five weeks later, the patient was diagnosed with ototoxicity and vestibular dysfunction associated with gentamicin toxicity. Expert review of case was not supportive, noting that there was no indication for using gentamicin for such a prolonged period based on culture results taken while in hospital. The case was considered indefensible from a quality of care and causation perspective.

CASE STUDY 2

A patient with diagnoses of kidney disease, COPD, asthma, and type 2 diabetes, under the care of multiple physician-specialists, was prescribed a course of Methotrexate (MTX). The patient continued to receive MXT for approximately one month. Within 2 weeks following the suspension of MTX, the patient attended at the Emergency Department for internal bleeding. The patient's condition deteriorated and passed away: the autopsy revealed patient expired secondary to methotrexate toxicity. Expert review of the care and decisions was not supportive. Experts noted that the treatment was initiated despite concerns raised by the care team, as well as, a verbal order to hold treatment

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communication of test results to the most responsible practitioner, patient, family member, caregiver education, etc.); particularly with charting by exception.

- Inconsistent or poor patient, family member, or caregiver education and instructions regarding signs or symptoms of toxicity and requirements for blood work.
- Communication gaps between nursing, lab, and clinical pharmacists related to the relay of or 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.
- Discharge planning that lacks fulsome education for patients, family member, or caregiver and referral for continued TDM in the community.

by the primary care physician, both of which failed to be documented in the medical chart. During this period, symptoms consistent with MXT toxicity were observed, including skin ulcers, generalized erythema, facial edema, and gait issues. However, these symptoms were not communicated to the treating physician directly, despite requests to do so by multiple family members. Patient complexity, competing physician orders, poor charting practices, and lack of patient and family-centred care contributed to a delay in acting on patient symptoms.

Canadian Case Examples

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MITIGATION STRATEGIES

Reliable Care Processes

- Implement a standardized evidence based protocols or algorithms to guide decision making surrounding medications requiring TDM that consider (but not limited to):
  - Therapeutic and toxic drug levels or ranges;
  - Individual responsible for obtaining levels;
  - 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, or toxic;
  - The need to ask if the patient is experiencing side effects that could be early indicators of toxicity.
- Leverage technology where possible to assist with prevention (e.g., decrease omission errors) from a system level. When purchasing or updating electronic systems, consider clinical decision supports and embedded algorithms to order lab tests and instruct users on how to promptly respond to or act on critical levels.
- Adopt a standardized nomogram for monitoring TDM levels.
- Adopt best practices for the communication of critical test results to the most responsible practitioner, including alternative contacts for critical results.
- Adopt a standardized process to ensure TDM requirements are included in discharge orders, including (but not limited to) therapeutic and toxic levels and the need for stringent compliance with obtaining and communicating TDM levels to the most responsible practitioner.

Patient and Family-Centred Care

- Ensure that bloodwork is prescheduled (and that the patient is able to go to the appointments or have in-home bloodwork arranged) for patients transitioning from hospital to home.
- As part of the discharge planning, ensure the patient, family member, or caregiver understand:
  - Their role in TDM;
  - The importance of the required bloodwork.
- Educate patients and family regarding signs or symptoms of toxicology, the need to report changes, or untoward symptoms immediately to the most responsible practitioner.

Documentation

Strategies for healthcare practitioners

- Ensure complete and timely documentation (including date and 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 lab results are pending and how these will be relayed to the most responsible practitioner in the community;
  - Of education or training provided to the patient or family (e.g., the need for strict adherence and compliance with TDM surveillance protocol);
  - Signs or symptoms of toxicology and the communication of such to the most responsible practitioner.

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Education

- Implement formal multifaceted and targeted safety strategies to support and enhance TMD monitoring requirements (e.g., therapeutic and toxic levels, signs or symptoms of toxicity, risk factors impacting metabolism, and clearance of the need for stringent compliance with obtaining and communicating TDM levels to the most responsible practitioner).

Monitoring and Measurement

- Implement formal strategies to monitor and measure the effectiveness and efficiency of, and interdisciplinary adherence to TMD guidelines and protocols, including:
  - o Adoption of formal quality measure and indicators;
  - o Sharing of learnings from TMD harm incidents (e.g., learnings from chart audits or trigger tools, incident reports, team debriefs, critical incident, quality of care or quality improvement committee reviews, medical legal claims, and coroner reports or recommendations).

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