

90-Day Status Report Following the Lang Review of the Motherisk Drug Testing Laboratory (MDTL)

On December 17, 2015, the Honourable Susan Lang released the *Report of the Motherisk Hair Analysis Independent Review*. The report concluded hair-strand drug and alcohol testing used by the Motherisk Drug Testing Laboratory (MDTL) between 2005 and 2015 was inadequate and unreliable for use in child protection and criminal proceedings and the laboratory did not meet internationally recognized forensic standards.

Justice Lang found that SickKids failed to exercise meaningful oversight over MDTL; she also concluded she was confident that SickKids would reflect deeply on what went wrong at MDTL and in the broader institution. SickKids has and continues to reflect on what has been learned, and has taken and will continue to take appropriate action to ensure that the hospital and its staff meet the highest standards when interacting with the justice system.

This summary highlights the changes SickKids has implemented, as a result of Justice Lang's report and SickKids' own internal review, to enhance our oversight structure and mechanisms as well as quality control systems across the organization, to prevent similar events from ever occurring at SickKids again.

Understanding interactions with the judicial system

Interactions between SickKids physicians, staff and the legal system are inevitable and occur in a number of settings, as they do with staff in most children's hospitals. Such interactions occur when staff are asked under subpoena to provide testimony about care delivery and when they voluntarily provide expert testimony. They may participate in civil or criminal proceedings including child protection proceedings. Staff members have a professional responsibility to provide impartial testimony that reflects current medical science including any limitation or uncertainty.

The hospital has considered which programs are likely to provide 'forensic' testimony or evidence. Given the nature of highly specialized children's hospitals like SickKids, many clinical programs and services have the potential to interact with the judicial system in a number of ways. To ensure that staff are well aware of their professional responsibilities, and to track

interactions in order to enable better oversight, we have implemented a new policy. This policy allows interactions with the legal system to be monitored, and mandates education for staff who provide testimony for legal proceedings.

1. Monitoring interactions with the legal system

All staff interacting with the legal system will be required to notify the organization. In most circumstances, the hospital recognizes that it cannot restrict staff and physicians from interacting with the legal system and cannot prevent staff from fulfilling requirements under summons or subpoena. We do not intend to restrict activities but rather to be able to monitor the types and frequency of interactions with the legal system and to ensure that staff are properly trained to fulfill their professional obligations.

By adopting a new policy, SickKids now requires all staff and physicians who accept service of a summons or subpoena to register a copy of the summons or subpoena with SickKids' legal department. Additionally, all staff and physicians acting as an expert witness in legal proceedings or who provide written opinion for medical/legal matters must notify their supervisor, and provide a brief explanation of the circumstances to SickKids' legal department. This notification triggers mandatory education and training.

2. Training for staff that interact with the legal system

SickKids has implemented mandatory training for staff and physicians prior to testifying or submitting opinions to the legal system. Upon completion of the training, staff must provide written affirmation that they understand their role and responsibilities. Prior to deciding whether to provide expert testimony, staff members are encouraged to seek advice from SickKids' legal department and/or the Canadian Medical Protective Association so that they fully understand their proposed role.

Clinical and research laboratory oversight

As an innovative, academic teaching hospital with a world-renowned Research Institute, we recognize that many discoveries in our research laboratories are translated to clinical application. Many new clinical tests originate in research laboratories as part of clinical research studies. When new tests are found to be useful, they are often adopted for clinical use and possibly forensic use. As tests become used for clinical decision-making, it is important that the laboratories performing those tests are in compliance with *Laboratory and Specimen Collection Centre Licensing Act* ("the Act").

In an effort to strengthen clinical laboratory oversight, and to ensure that research labs that develop useful tests and then wish to transition those tests from research to clinical settings are compliant with the Act, SickKids implemented a new policy in December 2015. This policy requires that any laboratory at SickKids that meets the definition of a clinical laboratory must identify the associated testing on the Department of Paediatric Laboratory Medicine (DPLM) laboratory license and arrange for testing to be placed under the clinical, operational and quality management control of DPLM.

SickKids does not currently perform tests that are predominately used for forensic purposes and does not operate a laboratory that is accredited as a forensic laboratory. We recognize that results from our clinical laboratory could be admitted as evidence or otherwise be used in legal proceedings. By the end of March 2016, more than 95% of our laboratory reports will be modified with a disclaimer to ensure that results are not mis-represented as coming from a forensic laboratory. The remainder of the reports will be modified as new information systems go-live in the next 2-3 months.

Conflict of interest management

SickKids has reflected deeply on concerns raised about perceptions of conflicts of interest arising from research funding by private industry or by deriving revenue from other activities.

We believe that relationships with industry including financial support of research are vital to an effective and productive academic research environment. However, we acknowledge that when funding is received by a hospital or scientist from private industry, disclosures must occur and the potential for conflict of interest and/or bias must be managed.

Concerns about conflicts of interest arise in many walks of life whenever a person's self-interest can be perceived to be at odds with those in whose best interests they are supposed to acting. For example, when a scientist's interests in preserving funding is at odds with their responsibility to act scientifically in a way that best serves the public's interests. Ethical behaviour is the first line of defense in ensuring potential conflicts doesn't bias an individual's actions. While potential conflicts may be inevitable, the hospital must take a more active role in ensuring that conflicts don't influence physicians, scientists, or other staff and that the public understands when conflicts might exist. SickKids has long had a policy requiring staff to disclose potential conflicts to their supervisor. However, to allow the hospital to evaluate and better manage potential conflicts, we have established a Conflict of Interest Committee to evaluate

potential conflicts and to prescribe appropriate management strategies including, when necessary, avoiding conflicts altogether. The committee is currently working on harmonizing conflict of interest policies across SickKids, and will develop a standard process for managing conflicts of interest across SickKids. A compliance officer will be hired to provide leadership to support the Conflict of Interest Committee.

Ongoing clinical research oversight

SickKids is committed to ensuring that all clinical research meets quality, regulatory, and research ethics standards. Over the past two years, SickKids has developed educational workshops on Good Clinical Practice for researchers and their teams on topics such as staff training, study documentation, medical oversight, and adverse event reporting. In addition, a mandatory process was implemented for all new investigator-initiated/sponsored clinical trials that must be completed prior to starting any new study to ensure that all relevant processes, training, and oversight mechanisms are in place.

Access to data on electronic systems is governed by privacy legislation as well as by research ethics. All research staff must complete mandatory online learning modules that teach regulations and expectations regarding privacy and confidentiality. In addition, the Chief of Research and the Chair of the Research Ethics Board have communicated to all research staff that, in accordance with existing policies, any electronic system with personal health information must have appropriate controls and any research use of the data must be fully authorized by the Research Ethics Board. An annual privacy audit plan, including self-audit by research teams, has been implemented to monitor and ensure research compliance with privacy standards and legislation.

Organizational Oversight and Accountability

To ensure that key learnings are applied broadly across the organization and that people leaders fully understand their responsibilities to provide appropriate oversight, SickKids President and CEO Dr. Michael Apkon and the executive team have conducted a series of mandatory meetings with all clinical and research leaders in the organization to introduce these new policies. Leaders will continue to be held accountable for being familiar with activities of their teams and for relevant regulations governing those activities.

Justice Judith Beaman Commission

On January 15, 2016 the Province of Ontario launched an independent commission to assist families who may have been affected by results generated by the MDTL. Commissioner Judith C. Beaman is leading the review and will provide support to individuals in Ontario whose cases involved the use of MDTL hair tests between 1990 and 2015.

SickKids will cooperate fully with Commissioner Beaman during her team's review. At this time, it is our understanding that this review will only consider cases that involved the Ontario legal system. The hospital has sent letters to other provinces and territories that used MDTL results to call their attention to the findings in the Lang review and to notify them that there are clients who used the MDTL services in their province. We have offered to work collaboratively with them to ensure they have whatever information they need from the hospital.

Summary

SickKids deeply regrets that it fell short in terms oversight and responsibility of the MDTL. We are resolved to learn from these events and are committed to applying lessons learned broadly with safe, high quality and effective practices being our highest priority. In the wake of the Lang review and SickKids' own internal review, we have amplified and reinforced our commitment to robust oversight.

In particular, we have introduced new policies and structures regarding:

- Defining interactions of staff and physicians with the judicial system
 - Formal notification to leadership when such interactions occur
 - Formal training in roles and responsibilities of giving legal testimony
- Clinical and research laboratory oversight to ensure compliance
- Conflict of interest management to facilitate disclosure and enhance management of conflicts
 - COI policy
 - Oversight committee

Over the past two years, SickKids has been working to more deeply adopt principles and behaviours associated with high reliability organizations. We recognize that, within all systems, failure may be ultimately inevitable. However, high performing organizations seek to learn from

their failures as well as to work to ensure that such failures are increasingly less likely and more easily intercepted.

As a high reliability organization, we are also committed to resilience – to being able to recover from errors that have occurred and learn from them as quickly as possible. We also recognize that all SickKids leaders have a shared responsibility to nurture an exceptional community with well-defined oversight and accountability. Our intent is not to stifle innovation or prevent society from benefiting from new tests developed by our talented staff or their expertise. Rather we wish to promote high quality and safe practices throughout our organization. We will continue to examine our practices and to cultivate and adhere to principles of high reliability.

We are confident that we are addressing the recommendation contained in Justice Lang’s report while implementing appropriate and effective measures to prevent the need for another review or inquiry into how SickKids, its professional staff, or its programs interact with the justice system. The majority of these measures have been implemented. It is our intention to provide a subsequent report later in the fall to provide an update on our progress and ensure that our learnings as an organization are shared broadly.

Once again, we deeply regret the events that have occurred in this particular laboratory and the impacts that children and their families may have experienced.