Background
Alemtuzumab is an effective treatment for MS, but pathology monitoring for late adverse effects is difficult to implement. In the real world, patients may miss tests, and pathology reports might not be received or reviewed. Risk management theory suggests that in addition to education and training of staff and patients to improve human factors, safety can also be improved by adding organisational layers of defense, with distinct characteristics that have different non-overlapping points of weakness (Reason, 2000). We proposed that a computerised monitoring clinical decision support system (CDSS) would have different strengths and weaknesses to traditional human-based clinical care and would complement safety as an additional layer.

Aims
To improve the benefit:risk ratio of alemtuzumab for MS by developing:
• an efficient automated CDSS to prompt and track pathology
• providing customisable alerts for abnormalities in identified risks
• an app based education module
• a systematic approach to pre-screening.

Table 1: The Brain and Mind Centre, The University of Sydney, Sydney, Australia; 2: Concord Repatriation Hospital, Sydney, Australia; 3: Norwest Medical Imaging, Sydney, Australia; 4: Royal Melbourne Hospital, Melbourne, Australia; 5: Medical Safety Systems, Sydney, Australia; 6: Converged IT, Sydney, Australia.

Methods
Ten patients with active MS treated with alemtuzumab and followed for 2 years served as beta-testing patients for the CDSS. Pathology monitoring was performed by a networked pathology provider and hardcopy reports reviewed. Electronic results in HL7 format were also sent to CDSS project software (RiskMx™), once operational. We developed automated alerts for abnormal results and patient reminders that were sent as required to neurologists, their teams, and/or to patients. Compliance to receipt, time to receipt, time to alerting, and clinical consequences of alerts were evaluated.

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Results
The study successfully met the combined endpoint of design and implementation of the monitoring CDSS, educational app and prescreening tool. Other results are as follows:
• Compliance with monthly monitoring 96.7% (146/151 test groups).
• HL7 results received by RiskMx = 151 (all), hardcopy 143 (8 lost).
• Final HL7 receipt 1.10 days +/-1.57 (0-15), final hardcopy = 15.08 days +/- 15.99 (0-106), p<0.001.
• Alerts when abnormal were sent in 0.87 days +/-0.45 (0-2).

The study was powered to test the accuracy and speed of electronic versus hardcopy transmission of results, but few actual autoimmune adverse effects of alemtuzumab were anticipated given the study size and duration. Nevertheless, three patients had autoimmune conditions: 2 with hyperthyroidism only, 1 with ITP, neutropenia and hyperthyroidism. All were alerted correctly by RiskMx prior to hardcopy receipt.

The ACR recommends a diagnostic work-up if ITP, neutropenia and hyperthyroidism is present. The alert was associated with increased awareness of these conditions in early management.

The study demonstrated the feasibility of developing an automated CDSS and implementing it for clinical practice. The case studies support further validation in a larger, more diverse setting.

Conclusions
The RiskMx platform effectively supported the risk management plan implementation, demonstrated impressive compliance with monitoring, and timely receipt of abnormalities, without requiring extra clinical staff. Not surprisingly, the AMS3 study also demonstrated significantly faster review of pathology results by electronic means than standard practice.

The largely automated service was delivered nationally in Australia with >99% uptake and excellent ongoing compliance with laboratory monitoring for the risk management program. The RiskMx platform, customised to specification, has potential value in supporting many medical therapies that require pathology monitoring, both in MS and in other clinical settings.

RiskMx

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