COMparing Potential and Actual harms of Recorded medication Errors (The COMPARE Trial)

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Background

- British Columbia uses the Patient Safety Learning System (PSLS) to report medication errors using a 5 point likert scale (1 = no harm, 5 = death)
  - Subjective tool that assigns a harm score based on actual harm[1]
- Reporting only actual harm, and not potential harm, could fail to identify errors that could cause severe harm if they reoccurred[2]
- The Harm Associated with Medication Error Classification (HAMEC) potential harm tool[3] provides a potential harm classification

Primary Objectives

- Apply the HAMEC potential harm tool to score the potential harm severity of medication errors reported to the PSLS
- Compare potential versus actual harm severity as scored by the HAMEC tool and the documented PSLS severity score respectively

Secondary Objectives

- Describe medications associated with incidents that have the potential to cause severe harm
- Determine the inter-rater reliability of the HAMEC tool for 2 and 3 reviewers through calculation of a Kappa coefficient

Potential Harm	Score	Potential Harm Description
No Harm	0	No potential for harm/change in monitoring, level or length of care.
Minor Harm	1	Minor, non-life threatening, temporary harm that may or may not require efforts to assess for a change in patients' condition.
	2	Minor non-life-threatening temporary harm that would require efforts to assess for a change in a patient's condition or change in level or length of care
Severe Harm	3	Major, non-life threatening, temporary harm, or minor permanent harm that would require a high level of care.
	4	Life-threatening or mortal harm, or major permanent harm that would require a high level of care.

Table 1: Summary of the HAMEC Potential Harm Tool. Potential Harm categorization determined by reviewers and the description of the HAMEC tool is briefly summarized.

Methods

Design: Retrospective review of PSLS charts obtained from British Columbia Children's Hospital (BCCH).

Study Population: First 108 medication incidents that met below criteria

Inclusion criteria:

- Reports for <18 yo patients obtained in reverse chronological order starting Aug 2020
- Determined to be a medication problem by the reporter of the incident
- Report listed as a "Patient Safety Event"
- PSLS score assigned in the incident report

Exclusion criteria:

- Near miss reports/ narcotic drug discrepancies
- No identifiable information about medications related to events

Statistics: Descriptive statistics and kappa coefficient score

Results

Table 2: PSLS Severity Score Compared to HAMEC Potential Harm Score for Medication Error Incidents

PSLS Severity Score		HAMEC Score: No Harm 0	Minor Harm 1	Minor Harm 2	Severe Harm 3	Severe Harm 4
No Harm (N = 98)	1	19 (18.8%)	46 (45.5%)	23 (22.8%)	8 (7.9%)	2 (2.0%)
Minor Harm (N = 6)	2	0 (0.0%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	1 (14.3%)

Discrepancy*: N = 4

*All three reviewers assigned a different HAMEC Potential Harm score to the medication error incident. These incidents were not included in the above analysis.
No reports had a PSLS severity score of 3,4, or 5.

Table 3: Potential for Severe Harm or Death Based on PSLS Reports Compared to HAMEC Potential Harm Scores

Potential For Severe Harm or Death per PSLS Report	HAMEC Score: 0	1	2	3	4
No (N = 45)	11 (24.4%)	26 (57.8%)	6 (13.3%)	2 (4.4%)	0 (0.0%)
Yes (N = 21)	2 (9.5%)	2 (9.5%)	6 (28.6%)	5 (23.8%)	3 (14.3%)
Unknown (N = 42)	6 (14.3%)	20 (47.6%)	13 (30.9%)	2 (4.8%)	0 (0.0%)

Figure 1: Harm Associated with PSLS Medication Error Incidents

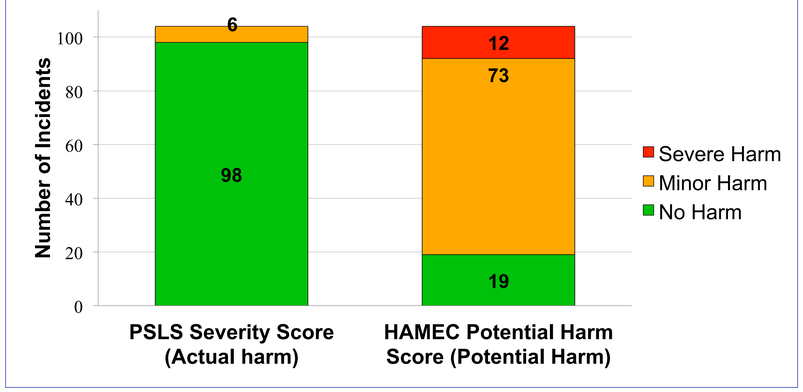

Figure 2: Description of Medications Involved in Medication Error Incidents with the Potential to Cause Severe Harm

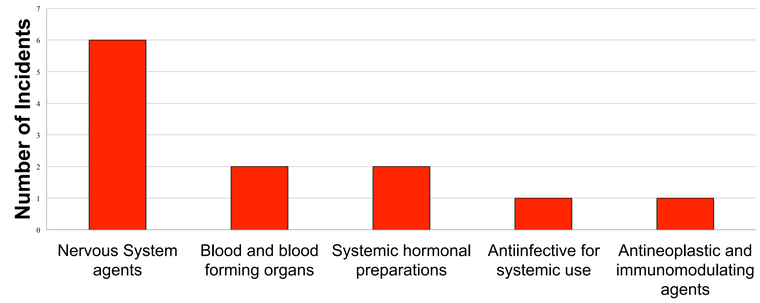

Table 4: Inter-Rater Reliability Score of 2 and 3 Reviewers for the HAMEC Tool Based on Different Potential Harm Categorizations

	Score of 0 to 4		No Harm vs. Minor Harm vs. Severe Harm		Minor Harm vs. Severe Harm	
	Kappa (κ)	Std. Error	Kappa (κ)	Std. Error	Kappa (κ)	Std. Error
Reviewer 1 vs. Reviewer 2	0.476	0.061	0.514	0.084	0.586	0.112
Reviewer 1 vs. Reviewer 3	0.269	0.065	0.424	0.079	0.56	0.113
Reviewer 2 vs. Reviewer 3	0.196	0.055	0.298	0.077	0.403	0.126
3 Reviewers	0.294	0.033	0.398	0.042	0.519	0.056

Reviewer 1: Hospital pharmacy resident; **Reviewer 2:** Practicing pharmacist specialized in medication safety practices; **Reviewer 3:** Practicing pharmacist specialized in pediatric care.
Definition of "No harm vs Minor Harm vs. Severe Harm": No harm equivalent to HAMEC score = 0; Minor harm equivalent to HAMEC score=1,2; Severe harm equivalent to HAMEC score = 3,4.
Definition of "Minor Harm vs Severe Harm": Minor harm equivalent to HAMEC score = 0,1,2; Severe harm equivalent to HAMEC score = 3,4.
For 3 reviewers a fleiss kappa score was calculated. All scores were calculated using SPSS.

Conclusions

- 12 incidents caused no or minor actual harm, but had the potential to cause severe harm of which 6 incidents were associated with nervous system agents (opioids).
- The HAMEC tool had moderate inter-rater reliability for 3 reviewers if harm was categorized into minor vs. severe harm (kappa coefficient of 0.519).
- Scoring potential harm identifies more medication error incidents that would benefit from review of policies or procedures to reduce future patient harm.

References:
1.BC Patient Safety & Learning System (PSLS) [Internet]. [cited 2020 Aug 20]. Available from: http://bcpslscentral.ca/
2.Bates DW, Boyle DL, Vliet MBV, Schneider J, Leape L. Relationship between medication errors and adverse drug events. J Gen Intern Med. 1995;10(4):199–205.
3.Gates PJ, Baysari MT, Mumford V, Raban MZ, Westbrook JI. Standardizing the Classification of Harm Associated with Medication Errors: The Harm Associated with Medication Error Classification (HAMEC). Drug Saf [Internet]. 2019;42(8):931–9. Available from: https://doi.org/10.1007/s40264-019-00823-4