

ONLINE SUPPLEMENTARY MATERIALS

Appendix 1: Medico-legal case types

Appendix 2: Data capture methods at the CMPA

Appendix 3: Included codes with rationale

Appendix 4: Derived variables

Appendix 5: Adaptation of the DEER (Diagnostic Error Evaluation and Research) taxonomy

Appendix 6: Provider contributing factors by specialty

Appendix 7: Patient characteristics in CMPA medico-legal cases (closed 2011-2020) with peer expert criticism of a diagnostic issue linked to sepsis or a relevant infection, n = 162 patients (Appendix 7)

Appendix 1: Medico-legal case types

In the current study, each closed case represented a civil legal, College, or hospital matter defined as follows:

- *Civil legal action*: A physician was served or received a claim from the plaintiff or third party claimant or a defence was filed on their behalf.
- *Civil legal threat*: The CMPA referred a physician to legal counsel because there was a probability that civil litigation would be advanced against the physician.
- *College complaint*: A complaint was lodged against a physician to a medical licensing (regulatory) authority.
- *College disciplinary matter*: The matter was considered by a committee of a medical licensing (regulatory) authority whose function it was to discipline.
- *College preliminary matter*: An investigation, peer assessment, professional inspection, or request for personal information was commenced by a medical licensing (regulatory) authority. (These matters were distinct from those undertaken by a fitness committee, complaints committee, or discipline committee.)
- *Hospital complaint*: A complaint lodged against a physician to a hospital or health authority.

If multiple case types reflected the same physician complaint, then we included only the most serious case type (legal > College > hospital, in order of decreasing severity).

Appendix 2: Data capture methods at the CMPA

The methods for routine medical coding of closed cases at the CMPA are described below and in Supplemental Figure 1. The CMPA deems a case to be **closed** when the court, College, or hospital determines a final medico-legal outcome or when there is mutual agreement between the parties to resolve the action.

For all closed CMPA cases that are eligible for medical coding (e.g., must have involved a patient and other criteria), CMPA nurse-analysts review the medico-legal record and write a concise summary of the case including the medico-legal findings and outcomes for the physician(s) who were implicated in the case. **Implicated** physicians are the named physicians who the CMPA deems to be most involved in the issue that was central to the medico-legal case. Nurse-analysts code clinical details that are pertinent to the case by using the Canadian Classification of Health Interventions and the Canadian version of the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10-CA), ¶ as well as the CMPA's classification of patient harm (see patient harm table below) and contributing factors framework. § **Peer experts** are individuals retained by a party in the case to review and interpret the issues and quality of care associated with an alleged patient complaint; most are physicians with similar training and experience as the physician named in the case. To reduce misclassification, CMPA nurse-analysts routinely conduct quality assurance reviews of medical coding, electronically and as a group.

The table below outlines the CMPA's definitions of **patient harm** of relevance to this study. Definitions were adapted from the American Society for Healthcare Risk Management's *Healthcare Associated Preventable Harm Classification Tool* * unless otherwise indicated.

Term	Description
Patient safety incident **	An event or circumstance that could have resulted, or did result, in unnecessary harm to the patient.
Healthcare-related harm **	Harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.

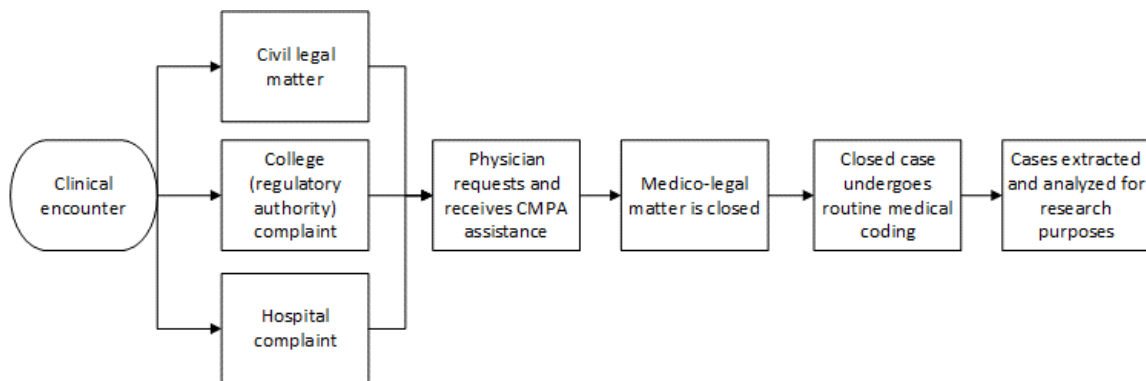
Term	Description
No harm (Asymptomatic)	Patient safety event or patient safety incident that reached the patient but the patient reports no symptoms and no treatment is required.
Mild harm	Patient harm is symptomatic, symptoms are mild, loss of function or harm is minimal (permanent or temporary), and minimal or no intervention is required (e.g., extra observation, investigation, review, or minor treatment).
Moderate harm	Patient harm is symptomatic, requiring intervention (e.g., additional moderate or minor operative procedure, additional therapeutic treatment), or an increased length of stay, or causing permanent or temporary harm, or loss of function.
Severe harm	Patient harm is symptomatic, requiring life-saving intervention or major medical/surgical intervention, or resulting in a shortening life expectancy, or causing major permanent or temporary harm or loss of function.
Death	Healthcare-related death

* Hoppes M, Mitchell J. Serious safety events: A focus on Harm Classification: Deviation in care as link. *Getting to Zero™ White Paper Series* Edition No. 2 ed. Chicago, Illinois: American Society for Healthcare Risk Management, 2014.

** World Health Organization. *More than Words: Conceptual Framework for the International Classification for Patient Safety - Final Technical Report*. World Health Organization; 2009.

¶ Canadian Institute for Health Information. Canadian Coding Standards for Version 2018 ICD-10-CA and CCI. Ottawa, ON: Canadian Institute for Health Information; 2018

|| McCleery A, Devenny K, Ogilby C, et al. Using medicolegal data to support safe medical care: A contributing factor coding framework. *J Healthc Risk Manag* 2019;**38**(4):11-8.



Supplemental Figure 1: Schematic depicting the acquisition, coding, and analysis of CMPA case data.

Appendix 3: Included codes and rationale

a) *Inclusions based on clinical condition*

We included eligible cases with the sepsis-related ICD-10-CA codes [¶] listed below.

Notably, four relevant infections were eligible for inclusion—endocarditis, *C. difficile*, *S. aureus*, and pneumonia—as these are severe infections that may lead to sepsis and death and physicians generally view them as sepsis risk factors. Our aim by including these infections was to capture as many early-recognition scenarios as possible. See “*Noteworthy exclusions based on clinical condition*” below for the exceptions to this list.

Included

<u>Code</u>	<u>Description</u>
A23.9	<i>Brucellosis</i>
A40.0	<i>Sepsis due to streptococcus, group A</i>
A40.1	<i>Sepsis due to streptococcus, group B</i>
A41.0	<i>Sepsis due to Staphylococcus aureus</i>
A41.1	<i>Sepsis due to other specified staphylococcus; includes sepsis due to coagulase-negative staphylococcus</i>
A41.2	<i>Sepsis due to unspecified staphylococcus</i>
A41.3	<i>Sepsis due to Haemophilus influenzae</i>
A41.4	<i>Sepsis due to anaerobes</i>
A41.5	<i>Sepsis due to other Gram-negative organisms</i>
A41.50	<i>Sepsis due to Escherichia coli [E.coli]</i>
A41.51	<i>Sepsis due to Pseudomonas; includes Pseudomonas aeruginosa</i>
A41.52	<i>Sepsis due to Serratia</i>
A41.58	<i>Sepsis due to other gram-negative organisms; includes gram-negative sepsis not otherwise specified</i>
A41.8	<i>Other specified sepsis</i>
A41.9	<i>Sepsis, unspecified; includes septicaemia</i>
A48.3	<i>Toxic shock syndrome</i>
A49.9	<i>Bacteremia</i>
A02.1	<i>Salmonella sepsis</i>
A20.7	<i>Yersinia pestis / Septicaemic plague</i>
A21.7	<i>Tularaemia</i>
A22.7	<i>Bacillus anthracis / Anthrax sepsis</i>
A24.1	<i>Melioidosis sepsis</i>
A26.7	<i>Erysipelothrix sepsis</i>
A27	<i>Leptospirosis</i>
A28.0	<i>Pasteurella multocida</i>
A28.2	<i>extraintestinal yersiniosis</i>
A32.7	<i>Listeria monocytogenes sepsis</i>
A33	<i>Tetanus</i>
A39.4	<i>Meningococcaemia</i>

Diagnostic delays in sepsis

A39.2	<i>Acute meningococcaemia</i>
A39.3	<i>Chronic meningococcaemia</i>
A42.7	<i>Actinomycotic sepsis</i>
A54.86	<i>Gonococcal sepsis</i>
B00.7	<i>Herpesviral sepsis</i>
B37.7	<i>Candidal sepsis</i>
B37.5	<i>Candidal meningitis</i>
G00*	<i>Bacterial meningitis, not elsewhere classified</i>
G01*	<i>Meningitis in bacterial diseases classified elsewhere</i>
G02*	<i>Meningitis in viral diseases classified elsewhere</i>
G04*	<i>Encephalitis, myelitis and encephalomyelitis</i>
I74.9	<i>Embolism and thrombosis of unspecified; includes septic embolism</i>
R57.2	<i>Septic shock</i>
R65.0	<i>Systemic inflammatory response syndrome of infectious origin without organ failure</i>
R65.1	<i>Systemic inflammatory response syndrome of infectious origin with acute organ failure</i>
J189	<i>Pneumonia, unspecified</i>
A04.7	<i>Enterocolitis due to Clostridium difficile</i>
I33*	<i>Acute and subacute endocarditis</i>
I38*	<i>Endocarditis, valve unspecified</i>
I39*	<i>Endocarditis and heart valve disorders in diseases classified elsewhere</i>
I09.1	<i>Rheumatic diseases of endocardium, valve unspecified</i>
I01.1	<i>Acute rheumatic endocarditis</i>
B95.6	<i>Staphylococcus aureus as the cause of diseases classified to other chapters</i>

* includes all codes in the alpha-numeric block

b) *Noteworthy exclusions based on clinical condition*

For all cases involving endocarditis, *C. difficile*, *S. aureus*, or pneumonia, a nurse-researcher (P.J.F.) reviewed the CMPA's summary of the case and, based on the clinical details, excluded the case if sepsis was unlikely. Examples of the latter were non-sepsis pneumonia with no ICU admission, a relevant infection with no positive blood culture, and a relevant local infection with no positive blood culture.

We did not include cases with ICD-10-CA codes related to perinatal infections, neonatal infections, or puerperal sepsis because we suspected that the diagnostic issues in those matters would not generalize to most sepsis patients.

c) *Inclusions based on contributing factors*

We included eligible cases with peer expert criticism of a physician and a diagnosis contributing-factor code signifying a diagnostic delay, diagnostic failure, or wrong diagnosis.[¶] Moreover, this code must have been electronically linked (**Appendix 2**) to an ICD-10-CA code for sepsis or a relevant infection, either through direct or indirect linkages. As well throughout the study, a nurse-researcher (P.J.F.) confirmed this relation manually when reading the CMPA summary of each case.

[¶] Canadian Institute for Health Information. Canadian Coding Standards for Version 2018 ICD-10-CA and CCI. Ottawa, ON: Canadian Institute for Health Information; 2018

^{||} McCleery A, Devenny K, Ogilby C, et al. Using medicolegal data to support safe medical care: A contributing factor coding framework. *J Healthc Risk Manag* 2019;**38**(4):11-8.

Appendix 4: Derived variables

a) *Years of CMPA membership*

We derived each physician's total years of CMPA membership by the year of the clinical encounter that featured in the medico-legal case. Since an estimated 95% or more of physicians in Canada are CMPA members, we considered this variable to be a surrogate measure of physician years in practice since graduating from a medical degree (MD).

b) *Number of outpatient visits before recognizing sepsis*

A nurse-researcher (P.J.F.) reviewed the CMPA's summary of each case and identified the number of discrete visits made to a family doctor's office, emergency department, or walk-in-clinic for the same health issue, prior to a sepsis-related condition being recognized or the patient being admitted to hospital. Phone consultations with a healthcare provider were not included in the count. A nurse-clinical-coding specialist (C.O.) verified the number of visits.

c) *Recent surgery or procedure prior to sepsis*

A nurse-researcher (P.J.F.) reviewed the CMPA's summary of each case and identified whether the case involved a surgery or invasive procedure (e.g., scopes) prior to sepsis. A nurse-clinical-coding specialist (C.O.) verified this identification. Although efforts were made to abstract only the surgeries or procedures that contributed to sepsis, a causal relation was difficult to establish. We therefore identified only the presence or absence of these events, not causal relations.

d) *Geographic location*

Geographic location was the location of the physician who administered the healthcare intervention(s) described in the medico-legal record (e.g., city of occurrence). We abstracted only the geographic location of the implicated CMPA physician-members. A statistical data

analyst (R.L.) classified each location according to Statistics Canada’s 2016 definitions of population centres and rural areas [†] by using population sizes and densities from the 2016 Canadian Census.[‡] The Statistics Canada definitions were as follows:

- *Population centre*: An area with a population of at least 1,000 and a density of 400 or more people per square kilometer.
- *Large urban population centre*: A population centre with a population of 100,000 or more people.
- *Medium population centre*: A population centre with a population between 30,000 and 99,999 people.
- *Small population centre*: A population centre with a population between 1,000 and 29,999 people.
- *Rural area*: An area outside of a population centre.

For analysis purposes, we combined rural areas with small population centres since these areas likely had similar healthcare resources and possibly more-limited expertise for assessing sepsis patients. We distinguished large urban population centres because these areas would likely contain tertiary care centres and therefore have unique system factors contributing to early detection of sepsis.

e) *Physician specialty*

We categorized the specialty areas of the physician(s) implicated in each medico-legal case. Physicians had previously self-reported their sub-specialty for administrative purposes when obtaining CMPA membership. After reviewing sub-specialties, we collapsed them into five specialty groups as follows.

Specialty group	Self-reported sub-specialty (in alphabetical order)
Family medicine	Family medicine or General practice

Diagnostic delays in sepsis

Emergency medicine	Emergency medicine
Surgical	Anaesthesiology, General surgery, Gynecology, Obstetrics and gynecology, Orthopedic surgery, Plastic surgery, Urology
Medical	Cardiology, Critical care medicine, Diagnostic radiology, Gastroenterology, Infectious diseases, Internal medicine, Medical microbiology, Nephrology, Neurology, Oncology, Pediatrics / Neonatal-Perinatal, Physical medicine and rehabilitation, Psychiatry, Respiriology
Trainees	Residency / Postgraduate training

† Population Centre and Rural Area Classification Ottawa: Statistics Canada; 2016 [Available from: <https://www.statcan.gc.ca/en/subjects/standard/pcrac/2016/introduction>].

‡ Population and Dwelling Count Highlight Tables, 2016 Census Ottawa: Statistics Canada; 2016 [Available from: <https://www12.statcan.gc.ca/census-recensement/2016/dp-pd/hlt-fst/pd-pl/Table.cfm?Lang=Eng&T=703&S=87&O=A>].

Appendix 5: Adaptation of the DEER (Diagnostic Error Evaluation and Research) taxonomy

Phase of diagnostic process	Definition adapted from Schiff <i>et al.</i> [§]	Study-specific interpretation
1. Access/presentation	<ul style="list-style-type: none"> • Failure/delay in accessing care 	<ul style="list-style-type: none"> • Patient-focused. Included scenarios in which the patient did not have access to care (e.g., to a hospital or doctor's office). Excluded physician failures/delays to attend.
2. History	<ul style="list-style-type: none"> • Failure/delay in eliciting critical piece of history data • Inaccurate/misinterpretation 	<ul style="list-style-type: none"> • None
3. Physical exam	<ul style="list-style-type: none"> • Failure/delay in eliciting a critical physical exam finding • Inaccurate/misinterpretation • Failure/delay in following up on a critical physical exam finding 	<ul style="list-style-type: none"> • None
4. Tests (Lab/Radiology)	<ul style="list-style-type: none"> • Failure/delay in ordering needed test(s) • Failure/delay in following up on (abnormal) test result • Error in clinician interpretation of test result 	<ul style="list-style-type: none"> • Excluded generic criticism in the medico-legal record of a "work up", "investigation", or "sepsis protocol" as these terms may overlap with other phases of the diagnostic process.
5. Assessment	<ul style="list-style-type: none"> • Failure/delay in considering the diagnosis • Suboptimal weighing/prioritizing of potential diagnoses • Failure/delay in recognizing/weighing urgency or complication(s) 	<ul style="list-style-type: none"> • Excluded generic criticism in the medico-legal record of the "assessment" or "reassessment" as these terms may overlap with other phases of the diagnostic process.
6. Referral/Consultation	<ul style="list-style-type: none"> • Failure/delay in ordering referral • Suboptimal diagnostic consultation performance • Failure/delay in communicating/following up on consultation 	<ul style="list-style-type: none"> • Included transfers of a patient to another hospital.
7. Follow-up	<ul style="list-style-type: none"> • Failure/delay in timely follow-up/rechecking of patient 	<ul style="list-style-type: none"> • Included failures/delays that followed the patient care episode, after the patient had left. Excluded reassessments during the patient care episode.

[§] Schiff GD, Hasan O, Kim S, Abrams R, Cosby K, Lambert BL, Elstein AS, Hasler S, Kabongo ML, Krosnjar N, Odwazny R, Wisniewski MF, McNutt RA. Diagnostic error in medicine: analysis of 583 physician-reported errors. *Arch Intern Med.* 2009 Nov 9;169(20):1881-7

Appendix 6: Provider contributing factors ^a by specialty

Contributing factor ^a	Specialty	Proportion (%) of physicians in specialty group with the contributing factor
Deficient assessment	Family Medicine	51/63 (81.0)
	In emergency department	12/15 (80.0)
	Not in emergency department	39/48 (81.3)
	Emergency medicine	36/59 (61.0)
	Surgical	27/47 (57.4)
	Medical	27/39 (69.2)
	Residency / Postgraduate	5/10 (50.0)
Failure to perform a test/intervention or administer medication	Family Medicine	26/63 (41.3)
	In emergency department	10/15 (66.7)
	Not in emergency department	16/48 (33.3)
	Emergency medicine	31/59 (52.5)
	Surgical	25/47 (53.2)
	Medical	10/39 (25.6)
	Residency / Postgraduate	5/10 (50.0)
Inadequate monitoring or follow-up	Family Medicine	12/63 (19.0)
	In emergency department	2/15 (13.3)
	Not in emergency department	10/48 (20.8)
	Emergency medicine	10/59 (17.0)
	Surgical	12/47 (25.5)
	Medical	9/39 (23.1)
	Residency / Postgraduate	3/10 (30.0)

^a Peer expert criticisms documented in the medico-legal case.

Appendix 7: Patient characteristics in CMPA medico-legal cases (closed 2011-2020) with peer expert criticism of a diagnostic issue linked to sepsis or a relevant infection, n = 162 patients ^a

Characteristics	No. (%) ^b of patients
Demographic	
Age (yr), median (IQR) ^c	53 (34-66)
Age (yr)	
< 2	7 (4.3)
≥ 2 to 17	14 (8.6)
≥ 18 to 29	8 (4.9)
≥ 30 to 64	83 (51.2)
≥ 65 to 79	37 (22.8)
≥ 80	9 (5.6)
Unknown	4 (2.5)
Gender	
Male	80 (49.4)
Female	79 (48.8)
Unknown	3 (1.9)
Pertinent risk factors ^d	
Recent surgery or procedure	41 (25.3)
Immunocompromised or immune deficiency ^e	23 (14.2)
Cardiac disease	19 (11.7)
Diabetes	19 (11.7)
Hypertension	12 (7.4)
Obesity	7 (4.3)
Chronic obstructive pulmonary disease	5 (3.1)
Cancer	5 (3.1)
Other ^f	5 (3.1)
Disease	
Level of harm ^g	
None (asymptomatic)	6 (3.7)
Mild	17 (10.5)
Moderate	11 (6.8)
Severe	49 (30.2)

Diagnostic delays in sepsis

Characteristics	No. (%) ^b of patients
Death, any age	79/162 (48.8)
Age < 2	3/7 (42.9)
Age ≥ 2 to 17	8/14 (57.1)
Age ≥ 18 to 29	4/8 (50.0)
Age ≥ 30 to 64	29/83 (34.9)
Age ≥ 65 to 79	24/37 (64.9)
Age ≥ 80	8/9 (88.9)
Age unknown	3/4 (75.0)
Reason for physician visit, according to patient ^h	
Fever	42 (25.9)
Nausea and vomiting	27 (16.7)
Abdominal/pelvic pain	22 (13.6)
Cough/cold	20 (12.3)
Back/neck pain	17 (10.5)
Malaise and fatigue	17 (10.5)
Neurologic symptoms ⁱ	16 (9.9)
Joint/muscle pain	15 (9.3)
Headache	14 (8.6)
Circulatory symptoms ^j	12 (7.4)
Shortness of breath	12 (7.4)
Diarrhea	11 (6.8)
Setting	
Multiple outpatient visits (family physician, walk-in clinic, emergency department) ^d	80 (49.4)
Admitted to intensive care unit ^d	63 (38.9)

^a One patient made 2 claims; therefore, the number of patients is less than the number of cases.

^b For death, the denominators represent the total number of patients in each age category.

^c Based on 158 patients with known age.

^d According to details in the medico-legal record that were pertinent to the case; may be undercounted since medico-legal records may not provide all clinical details.

^e Current or recent chemotherapy or radiotherapy, immunosuppressant medications, autoimmune disease, splenectomy, sickle cell disease.

^f Comprises pre-existing renal insufficiency or dialysis, alcoholism, HIV.

^g Based on the CMPA's classification of patient harm (**Appendix 2**). Harm is the healthcare-related harm arising from (or associated with) the plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.⁴⁸

^h Refers to the pertinent signs or symptoms that prompted the patient to seek medical care at the earliest point in the medico-legal case. Only frequencies ≥ 10 are shown.

Diagnostic delays in sepsis

- i Disorientation, confusion, dizziness, giddiness, hallucinations, abnormalities of gait or mobility, dysphasia or aphasia, speech disturbances, convulsions.
- j Chest pain, tachycardia, palpitations, syncope and collapse.