

Diagnostic Delays in Sepsis: Lessons Learned From a Retrospective Study of Canadian Medico-Legal Claims

IMPORTANCE: Although rapid treatment improves outcomes for patients presenting with sepsis, early detection can be difficult, especially in otherwise healthy adults.

OBJECTIVES: Using medico-legal data, we aimed to identify areas of focus to assist with early recognition of sepsis.

DESIGN, SETTING, AND PARTICIPANTS: Retrospective descriptive design. We analyzed closed medico-legal cases involving physicians from a national database repository at the Canadian Medical Protective Association. The study included cases closed between 2011 and 2020 that had documented peer expert criticism of a diagnostic issue related to sepsis or relevant infections.

MAIN OUTCOMES AND MEASURES: We used univariate statistics to describe patients and physicians and applied published frameworks to classify contributing factors (provider, team, system) and diagnostic pitfalls based on peer expert criticisms.

RESULTS: Of 162 involved patients, the median age was 53 years (interquartile range [IQR], 34–66 yr) and mortality was 49%. Of 218 implicated physicians, 169 (78%) were from family medicine, emergency medicine, or surgical specialties. Eighty patients (49%) made multiple visits to outpatient care leading up to sepsis recognition/hospitalization (median = two visits; IQR, 2–4). Almost 40% of patients were admitted to the ICU. Deficient assessments, such as failing to consider sepsis or not reassessing the patient prior to discharge, contributed to the majority of cases (81%).

CONCLUSIONS AND RELEVANCE: Sepsis continues to be a challenging diagnosis for clinicians. Multiple visits to outpatient care may be an early warning sign requiring vigilance in the patient assessment.

KEY WORDS: Canada; delayed diagnosis; infections; malpractice; sepsis

Sepsis is organ dysfunction caused by a dysregulated host response to infection and is life-threatening (1), with greater risks for people under 1 year old or in higher age groups (2, 3). There were an estimated 11 million sepsis-related deaths worldwide in 2017 (4), and for septic shock, in particular, the mortality rate has decreased very little in recent decades despite advances in sepsis management (5, 6).

Outcomes for patients with sepsis can be improved through the early recognition of sepsis and appropriate management, which may include prompt consultation and admission to ICU (7). Yet early detection can be difficult. Of patients who experience sepsis, the estimated proportion with a missed or delayed diagnosis ranges between 8.2% and 20.8% (8, 9). In an effort to help with early detection, researchers have redefined sepsis (10) and validated criteria for identifying high-risk patients. Other studies have analyzed sepsis care

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KEY POINTS

Question: Using medico-legal data, what patient characteristics and elements of healthcare contributed to diagnostic delay of sepsis? What potential warning signs for patients at risk of developing severe sepsis could be identified?

Findings: Findings include a relatively high mortality rate (49%). Deficient assessments, including failure to include sepsis in the differential diagnosis, contributed to the majority of cases in our study. Almost half of the patients had multiple visits to outpatient care prior to recognition of sepsis.

Meaning: Medico-legal data may help to identify clues that are overlooked early in the patient course that may result in delayed diagnosis of sepsis.

retrospectively to learn from suboptimal outcomes, but their use of billing data (11) or medical charts from a single hospital (12) may have overlooked contextual factors that challenge early detection.

In this study, we analyzed cases featuring diagnostic delays with sepsis or relevant infections from a repository of medico-legal data. Each case had previously undergone independent peer-reviewed scrutiny of the care provided, offering unique insights into physicians' cognitive processes, personal interactions with teams and patients, and system factors. Our study objectives were to describe the patient characteristics and elements of healthcare associated with diagnostic delays and suggest opportunities for improvement.

MATERIALS AND METHODS

We conducted a retrospective descriptive study of medico-legal cases supported by the Canadian Medical Protective Association (CMPA). Ethical approval for the conduct of this study was provided by the Advarra Institutional Review Board (Approval number: MOD01230759; approval date: February 18, 2022; study title: "The Canadian Medico-legal Landscape: A Mixed Methods Study." Study procedures followed the regional ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975). The Reporting

of studies Conducted using Observational Routinely-collected Data (RECORD) statement (13) guided report writing.

Setting

The CMPA offers medico-legal support, advice, and education to physicians and engages in safe medical care research using medico-legal data. The CMPA has over 105,000 physician members who can contact the Association for advice or support for medico-legal matters.

In this study, each case represented a complaint against a physician in a civil legal, medical regulatory authority (College, equivalent to a state medical board), or hospital matter (defined in **Appendix 1**, <http://links.lww.com/CCX/B128>). All cases had been closed by the CMPA between January 1, 2011, and December 31, 2020. Cases were de-identified and reported in aggregate to ensure confidentiality for both patients and healthcare providers.

Data Source

For all closed cases with sufficient information, experienced CMPA nurse-analysts routinely summarize each case file—including the case information, peer expert opinions, and the ruling or final decision—and apply medical coding. These codes represent patient demographic information, health conditions (14), peer expert opinions classified using the CMPA's published contributing factors framework (15), and patient harm classified using an in-house classification of harms (**Appendix 2**, <http://links.lww.com/CCX/B128>). To reduce misclassification, nurse-analysts conduct regular quality assurance reviews of coding electronically and as a group.

Study Population

For study inclusion, cases must have been closed by the CMPA between 2011 and 2020 and involved sepsis or relevant infections (defined in **Appendix 3**, <http://links.lww.com/CCX/B128>) that were associated with an identified diagnostic delay/failure or wrong diagnosis and had documented peer expert criticism of a provider, team, or system. We identified these cases using *International Classification of Diseases*, 10th Revision, Canada (ICD-10-CA) codes

from the literature (16) and the clinical judgment of coauthors (P.J.F., E.J.B., G.E.G.). Perinatal infections, neonatal infections, and puerperal sepsis were not included. Specific other infections were included (endocarditis, *Clostridioides difficile*, *Staphylococcus aureus*, pneumonia) as they may progress to sepsis and addressed our interest in early recognition. For those infections, a nurse-researcher (P.J.F.) reviewed CMPA case summaries and excluded the case if sepsis was unlikely (explained in Appendix 3, <http://links.lww.com/CCX/B128>). We excluded cases with clinical encounters pre-2000, the approximate year of change in sepsis standard of care (Fig. 1 for study flow chart).

Variables

Variables of interest were patient characteristics, location, and specialty of implicated physicians (defined in Appendix 2, <http://links.lww.com/CCX/B128>) and documented peer expert criticisms (contributing factors). We abstracted the following variables directly from the repository: case type, date of clinical encounter, physician subspecialty, patient gender implied from the medico-legal documentation, patient date of birth, risk factors, harm (Appendix 2, <http://links.lww.com/CCX/B128>), patient-reported reason for visiting a physician (presenting complaint), and CMPA contributing factors as previously described. We derived the

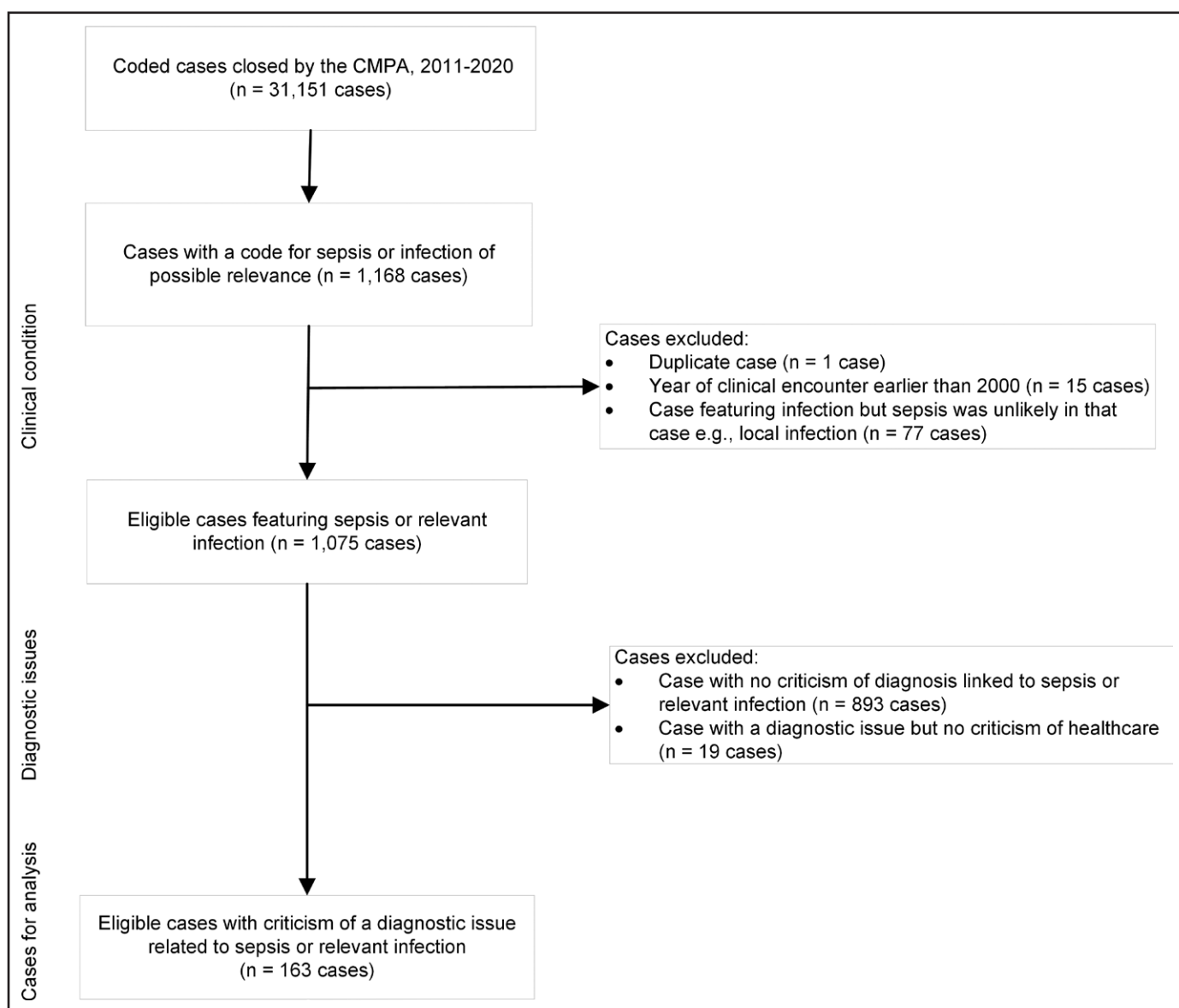


Figure 1. Study flow chart. See Appendix 3 (<http://links.lww.com/CCX/B128>) for list of eligible *International Classification of Diseases*, 10th Revision, Canada codes for sepsis and relevant infections. CMPA = Canadian Medical Protective Association.

following variables (described in **Appendix 4**, <http://links.lww.com/CCX/B128>): number of outpatient visits for the same condition (to a family doctor, emergency department, or walk-in clinic) before sepsis was recognized or patient was admitted to hospital; recent surgery or invasive procedure; geographic location (17, 18); and physician specialty.

Analysis

We calculated frequencies, proportions, and univariate statistics for variables of interest. For brevity, we reported only the most frequent (≥ 10) reasons for visiting physicians and the three most frequent contributing factors attributed to providers, teams, and systems, respectively. We described patient-physician communication breakdowns as in the literature (19). In post hoc analyses, we mapped criticisms of physicians to the Diagnosis Error Evaluation and Research (DEER) taxonomy (20) (**Appendix 5**, <http://links.lww.com/CCX/B128>). To apply the DEER taxonomy, a nurse-researcher (P.J.F.) and emergency department physician (E.J.B.) independently reviewed medico-legal case summaries and categorized peer expert criticisms into phases of the diagnostic process. A nurse-clinical-coding specialist (C.M.O.) verified categorizations and discrepancies were resolved by consensus. We used SAS Version 9.4 (SAS Institute Inc., Cary, NC), Microsoft Excel (Microsoft Corporation, Redmond, WA), and a custom data analysis tool in Microsoft Access (Microsoft Corporation) for statistical analyses.

RESULTS

One-hundred sixty-three cases met eligibility criteria: 81 civil legal matters (50%), 75 College matters (46%), and seven hospital matters (4%). These cases involved 162 patients (one patient made two claims). Most clinical encounters happened in large urban population centers (99/163 cases, 61%) (**Table 1**). Clinical encounters occurred between 2000 and 2020 as civil legal cases may take years to proceed to closure.

While patients spanned all ages (range, 0–90 yr), many (83/162, 51%) were 30–64 years old. The mortality rate of 49% (79/162) varied by age group and was highest among elderly patients (65% for patients 65–79 yr old, 89% for patients ≥ 80 yr; see **Appendix 7**, <http://links.lww.com/CCX/B128>). Thirty percent of patients (49/162) experienced severe harm, such

TABLE 1.
Physician Characteristics in Canadian Medical Protective Association Medico-Legal Cases (Closed 2011–2020) With Peer Expert Criticism of a Diagnostic Issue Linked to Sepsis or a Relevant Infection, $n = 163$ Cases

Characteristics	<i>n</i> (%)
Healthcare	
Geographic location ^a	
Large urban population center	99 (60.7)
Medium population center	19 (11.7)
Small population center or rural area	45 (27.6)
Physicians, $n = 218$	
Specialty ^{b,c}	
Family medicine or general practice	63 (28.9)
Subgroup that provided care in the emergency department	15 (6.9)
Emergency medicine	59 (27.1)
Surgical	47 (21.6)
Medical	39 (17.9)
Residency or postgraduate training	10 (4.6)

^aLocation of the implicated physician(s) (defined in **Appendix 2**, <http://links.lww.com/CCX/B128>) when administering healthcare described in the medico-legal record. Geographic locations are defined using Statistics Canada categories (21, 22) and methods described in **Appendix 5** (<http://links.lww.com/CCX/B128>).

^bSee **Appendix 7** (<http://links.lww.com/CCX/B128>) for physician specialty definitions.

^cPercent was calculated for 218 implicated physicians (defined in **Appendix 2**, <http://links.lww.com/CCX/B128>); 42 of 163 cases (25.8%) involved more than one of these physicians.

as limb amputation due to gangrene or brain damage. Fever was a documented presenting complaint for just 26% of patients (**Appendix 4**, <http://links.lww.com/CCX/B128>). Several patients had recent surgeries/invasive procedures (41/162, 25%), of which most were abdominal (31/41, 76%). Almost 40% of patients (63/162) required ICU care during their hospitalization. More detailed patient characteristics can be found in **Appendix 7** (<http://links.lww.com/CCX/B128>).

Nearly half of patients (80 of 162, 49%) made multiple visits to a family physician, walk-in clinic, or emergency department in the time leading up to sepsis recognition/hospitalization. Of those, 75% (60/80) made more than one visit within 72 hours of recognition/hospitalization (e.g., signs or symptoms normalized but later returned). The median number of visits

was 2 (interquartile range, 2–4 visits); 13 patients made five or more visits. Among 41 patients with recent surgeries/invasive procedures, a subset was discharged from hospital and later assessed in hospital emergency departments (11 patients) or sought care multiple times (2–4 visits) from family physicians or specialists (nine patients).

A total of 218 physicians were involved in these cases. While the implicated physicians spanned all specialties, the majority (169/218 physicians, 78%) specialized in family medicine, emergency medicine, or surgery (Table 1). Within the surgical group, 30 of 47 physicians (64%) were general surgeons.

Deficient assessment was the top contributing factor attributed to providers, suggesting problems with information-gathering or considering diagnoses. For example, some physicians failed to reassess symptomatic high-risk patients before discharging from emergency departments (Fig. 2). Also common were physicians failing to perform tests or interventions (e.g., bloodwork) or inadequately monitoring patients. Other notable contributing factors identified in our cases included delays in physicians attending to patients (e.g., not assessing patients in person in a timely manner after handover or consultation) and poor coordination of care that led to delays in diagnostic testing.

The DEER taxonomy classified 76% of physician pitfalls (123/163 cases; Table 2) in the assessment phase of diagnosis (defined in Appendix 5, <http://links.lww.com/CCX/B128>), suggesting failures/delays to consider diagnoses, failures/delays to consider or recognize patient urgency or complications, or suboptimal prioritization of diagnoses.

The top contributing factors attributed to teams were inadequate documentation and communication breakdowns, either between healthcare professionals or between physicians and patients/caregivers (Fig. 2). In the latter scenario (24 cases), peer experts were critical of physicians' communication: delayed, absent, or incorrect (e.g., communicating diagnostic test results); being disrespectful (e.g., end-of-life communication with family); or not eliciting key information (e.g., from parents of pediatric patients). Peer experts also noted issues with transitions in care, including failures to document detailed patient information when transferring patients to another institution, or failures to provide clear monitoring instructions to nurses (Fig. 2).

The top contributing factors attributed to systems were insufficient/unavailable resources (e.g., pediatric specialist) and extended wait times in emergency departments or patient transfers (Fig. 1).

DISCUSSION

We analyzed 163 closed cases involving physicians and sepsis-related diagnostic issues. We observed a relatively low proportion of known sepsis risk factors such as chronic illness, immune compromising conditions, and extreme age in our population. Of note, just 25% of patients presented with fever. Most physicians implicated in these cases specialized in family medicine, emergency medicine, and surgery. The top factor contributing to sepsis-related diagnostic issues was deficient assessment.

Epidemiological studies suggest that the incidence of severe sepsis is greatest for patients age less than 1 year (5/1,000 patients) or greater than or equal to 85 years (26/1,000 patients) (3). In our dataset, however, 51% of patients were age 30–64 years, which is more consistent with large studies of medical malpractice data (24). The 49% mortality rate in our study exceeded average mortality associated with septic shock (30–40%) (5, 6) and was comparable to 5-year mortality for severe sepsis (55%) (21).

Our findings of frequent deficient assessments, issues with verbal and written communication, and insufficient resources (in the provider, team, system domains, respectively) align with other studies of diagnostic error (20, 22, 25), sepsis care (23,26,27), and medico-legal risk (24). A deficient assessment, the most common contributing factor overall, may reflect cognitive bias—a form of systematic error due to subconscious, intuitive clinical reasoning or mental shortcuts (28). Early screening tools such as quick Sequential Organ Failure Assessment scores (29) have potential to mitigate bias but in order for physicians to apply them, infections need to be in the differential diagnosis. Physicians might also consider cognitive debiasing strategies (30, 31), such as deliberately reflecting (31), using decision support systems (32), and drawing collective intelligence from teams (33) to improve patient assessments.

Multiple visits to outpatient care may be an early warning sign for patients at risk of developing sepsis (11, 34). Studies suggest that multiple outpatient

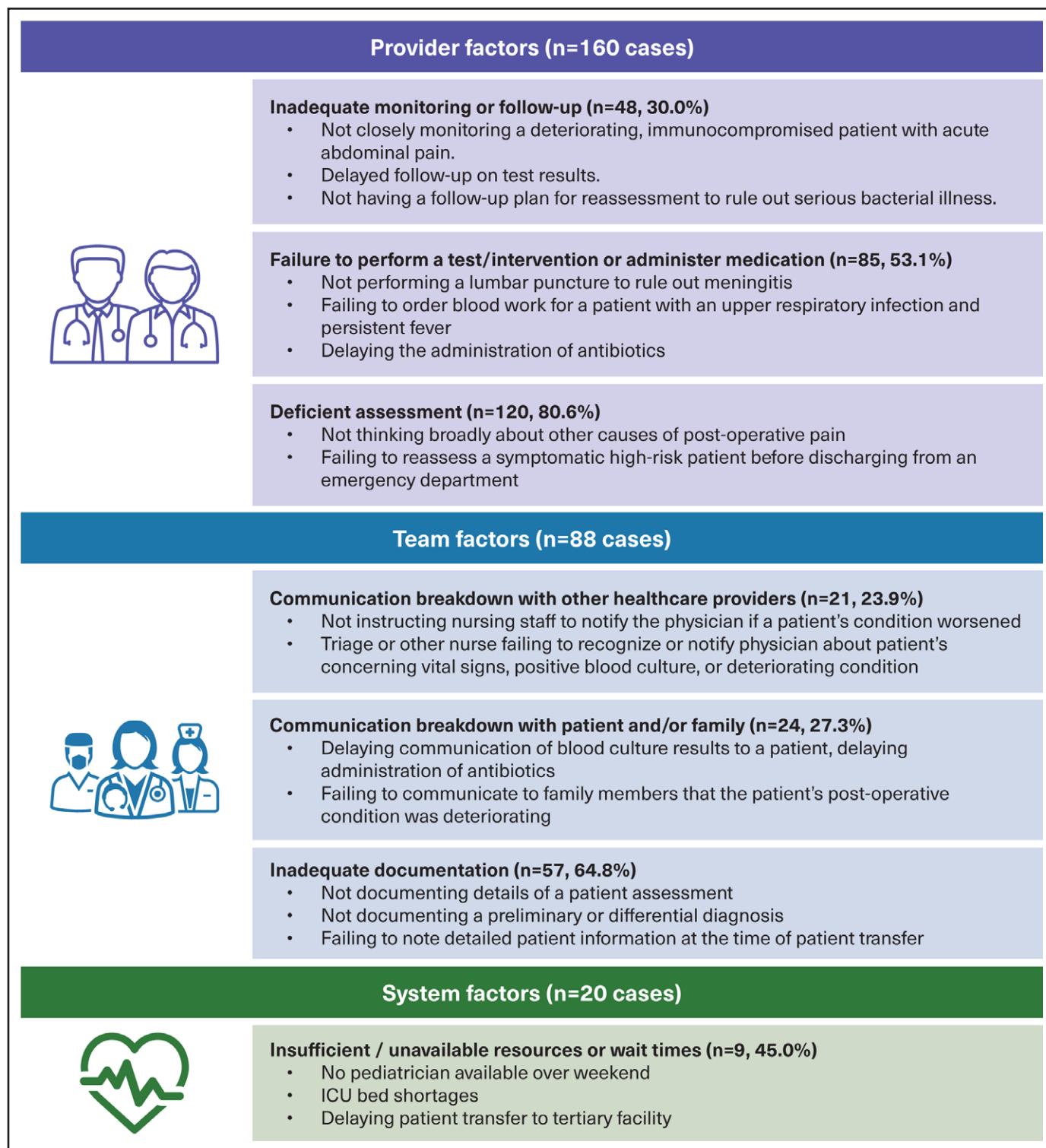


Figure 2. Top factors contributing to 163 medico-legal cases involving physicians; Canadian Medical Protective Association cases closed 2011–2020.

visits are common in the 2 to 3 days (11, 34) or 5 to 7 days (35–37) leading up to sepsis hospitalization. This is consistent with our study, in which half of the patients in our dataset had multiple outpatient visits prior to the diagnosis of sepsis. The literature in

this area has been limited to studies without control groups and further research is required, but multiple visits to outpatient care may represent an opportunity for physicians to consider sepsis in an evolving differential diagnosis.

TABLE 2.**Physician-Related Pitfalls in the Diagnostic Process^a in 163 Medico-Legal Cases Involving Physicians; Canadian Medical Protective Association Cases Closed 2011–2020**

Phase of Diagnostic Process	n (%)	Example From Cases
Access and presentation	0 (0)	None
History	31 (19.0)	Failing to question patients in detail about risk factors for infection Not reviewing a medical chart that included abnormal findings by a previous physician
Physical examination	66 (40.5)	Not listening to the patient's chest at any repeat visit for the same health issue Conducting a suboptimal (superficial) examination on a deteriorating patient with concerning vital signs
Testing	80 (49.1)	Not conducting a full septic work-up when indicated for a patient under 12 mo old Misinterpreting a postoperative CT image showing the source of infection Delaying to follow-up on a positive blood culture after discharging a patient from the emergency department
Assessment	123 (75.5)	Wrongly attributing signs or symptoms in adult patients to illicit drugs or prescription medications Not recognizing the signs and symptoms of septic shock thereby delaying treatment Failing to consider an alternative diagnosis when the treatment response was not sustained or a patient was deteriorating
Referral or consultation	48 (29.4)	Delaying or not requesting a second opinion when the diagnosis was unclear Delaying transfer of a patient with significant signs and symptoms to a tertiary hospital
Follow-up	7 (4.3)	Performing no further investigations after the clinical encounter to confirm or rule out a diagnosis

^aEach pitfall represents documented peer expert criticisms of a physician's care in the medico-legal record. A single case may have had multiple pitfalls.

^bUsing the Diagnosis Error Evaluation and Research taxonomy (23) defined in **Appendix 6** (<http://links.lww.com/CCX/B128>).

Almost 40% of patients in our series were admitted to the ICU during their hospitalization, and mortality rate was high in this group. Criticism of the care received in the ICU or provided by critical care physicians, however, was uncommon. This underscores the importance of early diagnosis and also suggests that diagnostic issues related to sepsis occur prior to admission to ICU. Despite this, our data offer some potential considerations for critical care specialists. In several of our cases, peer experts were critical of the timeliness of physicians directly assessing patients after handover or consultation. Providers should consider the importance of prompt, in-person assessments of patients to reduce potential delays in ordering appropriate tests or supporting the diagnostic process. Critical care physicians might also consider how best to coordinate the

care of patients at increased risk of sepsis with their surgical, emergency department and hospitalist colleagues, as appropriate care and prompt admission to ICU may improve outcomes (7).

Our study has several limitations. Lack of a control or comparator group prevented comparisons that might have generated further insights and context. The ICD-10-CA codes for identifying sepsis conditions (Appendix 3, <http://links.lww.com/CCX/B128>) differ from those used in other studies (16), which could impact comparisons with other reports. Our list was appropriate, however, given our inclusion of both clinical and microbiological indications of relevance to early sepsis recognition and case-by-case verification by a nurse-researcher. Our results reflect only diagnostic issues reported to the CMPA. To our knowledge, CMPA physician-members

seek assistance for nearly all civil legal cases to the CMPA but do not always seek assistance for College and hospital matters. Despite rigorous quality assurance processes in place to assess the quality of the medical coding of our cases, we do not calculate and thus cannot report formal measures of inter-coder reliability, such as a Kappa statistic. We also acknowledge the selective nature of peer expert opinions in civil legal cases and potential for biases (38); some contributing factors were likely undocumented. Finally, our data may underrepresent patient risk factors and outpatient visits since the CMPA's medical coding generally only captures details of medico-legal relevance.

CONCLUSIONS

This study describes a cohort of medico-legal claims pertaining to patients with missed or delayed diagnoses of sepsis. Adults 30–64 years old were overrepresented in our data, and patient outcomes were severe. Over half of the patients in our sample had multiple visits to outpatient care in the days leading up to their diagnosis with sepsis. Our descriptive analysis of a unique medico-legal dataset suggests that there are challenges remain in recognizing sepsis-related conditions in patients of any age, with or without specific complaints or comorbidities.

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