NOTICE OF PUBLICATION BAN

In the College of Physicians and Surgeons of Ontario and Dr. Stephen Rose James, this is notice that the Discipline Committee ordered that no person shall publish or broadcast the names or any information that could disclose the identity of the patients referred to orally or in the exhibits filed at the hearing under subsection 45(3) of the Health Professions Procedural Code (the "Code"), which is Schedule 2 to the *Regulated Health Professions Act, 1991*, S.O. 1991, c. 18, as amended.

Subsection 93(1) of the Code, which is concerned with failure to comply with these orders, reads:

> Every person who contravenes an order made under … section 45 or 47… is guilty of an offence and on conviction is liable,
>
> > (a) in the case of an individual to a fine of not more than $25,000 for a first offence and not more than $50,000 for a second or subsequent offence; or
> >
> > (b) in the case of a corporation to a fine of not more than $50,000 for a first offence and not more than $200,000 for a second or subsequent offence.

Indexed as: **Ontario (College of Physicians and Surgeons of Ontario) v. James, 2016 ONCPSD 6**

THE DISCIPLINE COMMITTEE OF THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

IN THE MATTER OF a Hearing directed
by the Inquiries, Complaints and Reports Committee of
the College of Physicians and Surgeons of Ontario
pursuant to Section 26(1) of the **Health Professions Procedural Code**
being Schedule 2 of the ***Regulated Health Professions Act***, ***1991***,
S.O. 1991, c. 18, as amended.

B E T W E E N:

THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

- and -

DR. STEPHEN ROSE JAMES

PANEL MEMBERS:

DR. M. GABEL (CHAIR)
MAJ. KHALIFA
DR. P. CHART
P. PIELSTICKER
DR. P. GARFINKEL

Hearing Date:	November 16, 2015
Hearing Date on Penalty:	December 15, 2015
Decision Date:	March 16, 2016
Release of Written Reasons:	March 16, 2016

PUBLICATION BAN

DECISION AND REASONS FOR DECISION

The Discipline Committee (the "Committee") of the College of Physicians and Surgeons of Ontario heard this matter at Toronto on November 16, 2015. At the conclusion of the hearing, the Committee stated its finding that the member committed an act of professional misconduct and that the member is incompetent. On December 15, 2015, the Committee heard submissions on penalty and delivered its penalty and costs order with written reasons to follow.

THE ALLEGATIONS

The Notice of Hearing alleged that Dr. James committed an act of professional misconduct:

1. under paragraph 1(1)2 of Ontario Regulation 856/93 made under the *Medicine Act, 1991* ("O. Reg. 856/93"), in that he has failed to maintain the standard of practice of the profession; and

2. under paragraph 1(1)33 of O. Reg. 856/93, in that he has engaged in conduct or an act or omission relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional.

The Notice of Hearing also alleged that Dr. James is incompetent as defined by subsection 52(1) of the Code.

RESPONSE TO THE ALLEGATIONS

Dr. James did not contest the allegations in the Notice of Hearing that he has committed an act of professional misconduct in that: he has failed to maintain the standard of practice of the profession: and, that he has engaged in conduct or an act or omission relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional. He also did not contest the allegation that he is incompetent.

THE FACTS

The following facts were set out in a Statement of Facts and Plea of No Contest that was filed as an exhibit and presented to the Committee:

PART I: FACTS

1. Dr. Stephen Rose James ("Dr. James") is an anaesthesiologist practising in pain management. Dr. James graduated from the Universidad Iberonamericana in the Dominican Republic in 2001. After graduation, he practised in the United States. He became a member of the College of Physicians and Surgeons of Ontario ("the College") on September 10, 2009. From September 10, 2009 he has had a certificate of registration restricted to practicing anaesthesiology limited to pain management. He was recognized as a specialist in anaesthesiology by the College in September, 2009. His practice at the time relevant to these proceedings was at a clinic in Ontario ("the Clinic").

2. On October 8, 2014, after allegations had been referred to the Discipline Committee and in lieu of a s. 37 order, Dr. James executed an undertaking with the College agreeing to co-operate with specific infection control guidelines provided to him and to submit to unannounced inspections by the College to ensure his infection control practices were acceptable.

3. The case before the Committee involves a s. 75(1)(a) investigation as well as six patient complaints.

The Section 75(1)(a) Investigation

4. On about November 30, 2012 and December 10, 2012, the College received information from Toronto Public Health ("Public Health") relating to a suspected meningitis outbreak connected to Dr. James at the Clinic.

5. On the basis of that information, the Inquiries, Complaints and Reports

Committee ("ICRC") approved the appointment of investigators under s. 75(1)(a) of the Health Professions Procedural Code to conduct an investigation into Dr. James' practice.

(a) Public Health Investigation

6. The genesis of the public health involvement is as follows:

(i) In November 2012, the Public Health Unit in an Ontario city ("Public Health") received information from a public health unit elsewhere in Ontario that a patient who had received epidural steroid injections from Dr. James at the Clinic had been hospitalized and had a cerebrospinal fluid culture positive for staphylococcus aureus ("staph aureus"). This patient (Patient T) was also diagnosed with an abscess at the site of the epidural steroid injection.

(ii) Later in November, 2012, Public Health learned that a second patient, this time in another part of Ontario, had received epidural injections from Dr. James at the Clinic and had been hospitalized and diagnosed with meningitis (Patient A, a complainant in this proceeding).

(iii) On a later date in November, 2012, Public Health was notified that another Ontario patient (Patient U) had a cerebrospinal fluid culture positive for staph aureus.

(iv) Dr. BB, Associate Medical Officer of Health for a city in Ontario's Health Unit, was concerned about what might be causing the infections, noting that there were three cases related to injections by Dr. James at the Clinic, a substantially greater number than the expected risk of complications from epidural steroid injections. Public Health determined that on Friday, November 30, 2012, Dr. BB and Ms. CC, Communicable Disease Manager, Public Health, would attend the Clinic to speak with Dr. James.

(v) Ms. CC and Dr. BB attended the clinic on the afternoon of Friday, November 30th. At that time, Dr. BB made a verbal order requiring that Dr. James not perform any procedures and that no one change or touch anything in Room 11 or use it in any way. (Room 11 was Dr. James' procedure room. All of his non-X-ray guided procedures were performed in that room; no other doctor used that room).

(vi) On Monday December 3, 2012, Ms. CC re-attended at the Clinic to continue the Public Health investigation.

(vii) On Tuesday, December 4, 2012 Dr. James was served with a written order to immediately cease performing any medical procedures that involve penetration of an instrument into a sterile site, and that he not enter Room 11. The order made by Dr. BB on December 4, 2012 is attached at Tab 1 [to the Statement of Facts and Plea of No Contest] (the "Section 13 Order"). The Section 13 Order provides reasons, which include the following:

7. The occurrence of three patients with complications of meningitis and abscess following the same procedure, performed by the same physician in the same clinic room, within the described time frame, is substantially greater than the expected risk of such complications from epidural steroid injections.

I am of the opinion on reasonable and probable grounds that:

1. a health hazard exists in the health unit served by me; and

2. the requirements specified in the order are necessary in order to decrease the effect of or to eliminate the health hazard.

(viii) As a result of their visits to the Clinic, Public Health noted the following:

- The patient's sterile field was not covered;
- A non-sterile gauze was used after a procedure to wipe the ooze from the patient's back;
- Dr. James' gloves were too big;
- Dr. James used a mask but the nose was not pinched;
- Dr. James did not always allow the Betadine, the antiseptic used to wipe the patients' skin, to dry for long enough before he started a procedure;
- After Dr. James used an alcohol-based hand rub ("ABHR") (Purell), and prior to donning sterile gloves, he touched many surfaces
- Dr. James opened sterile items onto a non-sterile field into a sterile container; and
- Dr. James' wedding band was not removed during the procedure.

7. On December 7, 2012, at the request of Public Health, the province's public health office attended the Clinic with a representative from Public Health to conduct a review of Infection Prevention and Control (IPAC) practices within the Clinic. At that visit, Dr. James offered to provide a mock demonstration of a typical epidural procedure. The audit team observed the following issues that required immediate attention:

- Dr. James applied and removed his mask without performing hand hygiene;
- Dr. James' hand hygiene ABHR lasted less than 5 seconds;
- Dr. James stated that he does not wait for the skin prep to dry before inserting the needle;
- Abundant supplies (including unwrapped gauze pads) stored on the counter are subject to contamination; and
- Dr. James' mask was not adjusted at the bridge of his nose.

8. The initial investigation conducted by Public Health revealed a total of nine (9) patients infected by Dr. James: 3 confirmed cases of meningitis, 5 cases of epidural abscess and 1 case of bacteraemia linked to the cluster. The nine (9) patients include: two complainants in this proceeding, Patient A and Patient B, and 7 others: Patients T, U, V, W, X, Y and Z.

9. All nine (9) patients received lumbar steroid injections from Dr. James at the Clinic during the period of August 20 to November 25, 2012. All of the patients required hospitalization. Eight of the 9 cases tested positive for Methicillin Sensitive Staphylococcus aureus (MSSA or staph aureus). However, in the remaining case, an isolate was not available for testing. Of the 8 cases that tested positive for MSSA, 6 had isolates available for further testing and were interpreted as being the same strain of MSSA (the "Outbreak Strain").

10. Specimens collected from Dr. James (through nasal and perianal swabs, as well as swabs of Dr. James' wedding ring) and swabs taken from Dr. James' procedure room (Room 11), tested positive for MSSA. PFGE testing confirmed a match to the Outbreak Strain. Samples taken from 18 staff members who work at the Clinic were either negative for staph aureus or, if positive, did not match the Outbreak Strain.

11. In addition to Patient A and Patient B, (complainants in this proceeding whose experiences are described in further detail below), the patients revealed in the Public Health investigation suffered serious complications. Parts of their disease courses are described here:

    (a) **Patient T**: Patient T received lumbar injections from Dr. James commencing in 2012. She had previously been a recipient of a kidney transplant and sought assurances that Dr. James' plan of treatment would not affect her kidney. Following her last injection in October 2012, Patient T was admitted to a hospital in a city in Ontario, vomiting and incoherent. She was diagnosed with bacterial

meningitis. After a 5-6 day hospital admission she was discharged home with a PICC line.

(b) **Patient U:** Patient U received lumbar injections from Dr. James commencing in 2011. In October 2012, she received 3 lumbar/thoracic epidural injections. In late October or early November, Patient U began suffering from headaches, nausea, vomiting, confusion, blurred vision, tremors. On a day in November 2012, she notified the Clinic that she was suffering persistent headaches. By later that month, she was admitted to hospital and diagnosed with meningitis. In December 2012, Patient U was discharged from hospital to a rehabilitation center, where she stayed until about mid-January 2013. She uses a walker and continues to suffer from incontinence.

(c) **Patient V**: Patient V received lumbar injections from Dr. James commencing in 2010. Following a lumbar injection in July 2012, she developed fever and sought attention at the Emergency Department of a hospital of a city in Ontario. She was discharged with negative blood and urine cultures. She subsequently sought treatment from her family physician complaining of pain, fever and difficulty urinating. She received additional injections from Dr. James on two occasions in August of 2012. In September 2012, she suffered a stroke and on investigation, it was discovered that many sites on her spine were infected with abscesses requiring hospitalisation and the insertion of a PICC line.

(d) **Patient W:** Patient W received lumbar injections from Dr. James in September and October 2012. Later in October 2012, Patient W was experiencing back pain and fever and went to a hospital in a city in Ontario, but an MRI revealed no abscesses. In November 2012 he was admitted to hospital with on-going fever and increasing weakness. A lumbar epidural abscess was found and he was transferred to another hospital where an emergency laminectomy was performed. He was transferred back to the first hospital, and ultimately discharged with a PICC line for 6 weeks. He underwent physical and occupational therapy.

(e) **Patient X:** Patient X received lumbar injections from Dr. James commencing in 2012. Following his last injection in November 2012, Patient X developed a fever and was hallucinating. He was admitted to hospital where he was diagnosed with an epidural abscess and staph aureus infection requiring evacuation and spinal decompression. Patient X required further surgical intervention.

(f) **Patient Z:** Patient Z received lumbar injections from Dr. James commencing in 2012. After her third injection in September 2012, Patient Z experienced increasing back pain. She developed a fever. She attended a hospital in a city in Ontario and was admitted with two epidural abscesses and sepsis. She required medical management of the infection and was discharged with a PICC line, to be followed by a neurosurgeon.

12. Public Health advised Dr. James that in order to satisfy the conditions of the Section 13 Order, Dr. James must:

1. Receive decolonization therapy for MSSA and provide evidence of one set of negative screening samples or MSSA following completion of therapy;

2. Review and comply with the following Infection Prevention and Control Practices documents

i. Provincial Infections Diseases Advisory Committee (PIDAC) document Best Practices for Hand Hygiene in All Health Care Settings

ii. PIDAC document Routine Practices and Additional Precautions in All Health Care Setting

iii. Centres for Disease Control and Prevention (CDC) Clinical Reminder: Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis

3. Public Health Staff observe your infection prevention and control practices during your demonstration of a mock epidural steroid procedure

13. Public Health confirmed that the above noted conditions were met on December 31, 2012, and the Section 13 Order was lifted, permitting Dr. James to recommence performing injections.

(b) Public Health Look Back and Conclusion

14. Public Health initiated a patient look-back to include all patients who received epidural injections in Dr. James' procedure room (Room 11) between August 2012 and December 2012, as well as patients who received any invasive procedure two weeks prior to December 2012.

15. A total of 272 patients were contacted. The investigation did not reveal any additional cases linked to the cluster.

16. Based on the information obtained by Public Health, and a review of the literature regarding complications following epidural steroid injections, Public Health concluded that 9 patients developed serious infections after receiving an epidural steroid injection performed by Dr. James at the Clinic. Public Health's view regarding the cause of these infections is that Dr. James was colonized with staph aureus, and due to breaches in IPAC, transmission of staph aureus occurred from Dr. James to his patients.

(c) Evidence of Dr. James' IPAC Practices obtained from Clinic Staff

17. As part of the section 75(1)(a) Investigation, College Investigators interviewed nursing staff who assisted Dr. James in the performance of epidural injections. Certain nurses indicated:

- Dr. James' use of masks while performing epidural injections was inconsistent: in some cases, he would wear a mask, in other cases he would not;

- Dr. James did not always use sterile gloves when performing epidural injections; he sometimes used "clean" gloves.

18. Following the Public Health investigation, Dr. James conducted all lumbar epidural injections in a fluoroscopy suite, using x-ray guidance, and employing sterile procedures. However, Dr. James employed "clean" rather than "sterile" technique for caudal injections, until February 2013 when the College was coming to interview nurses.

(d) Dr. EE's Opinion

19. The College retained Dr. EE, Medical Director of IPAC at a hospital and professor of medicine at an Ontario university, to provide an opinion regarding Dr. James' infection control procedures.

20. Dr. EE was asked to opine on Dr. James' practices prior to Public Health's intervention largely on the basis of the information gathered by Public Health. In a report dated December 20, 2013, attached at Tab 2 [to the Statement of Facts and Plea of No Contest], he opined:

> …Dr. James practices prior to their revision fell below the standard of infection control practice expected of a physician performing such procedures. I base this opinion on several significant practice breaches that were identified by Public Health personnel:
>
> 1. He did not perform a surgical scrub with appropriate agents prior to performing an invasive procedure;

2. He did not consistently and appropriately perform hand hygiene;
3. His surgical mask was improperly worn and sterile gown was not used;
4. Multiple episodes of hand contamination were observed during the procedure
5. Instruments were not properly placed on a sterile drape but rather onto an open glove wrapper.

In addition, while it is impossible to determine which of these breaches led to an outbreak of invasive *Staphylococcus aureus* infections involving 8 patients of Dr. James, the fact remains that the outbreak occurred and that the strains all genetically matched each other and a strain found to be colonizing Dr. James. This epidemiologic linkage means that Dr. James' flora was very likely the source of the outbreak as any other explanation is highly improbable. To be clear, any of the aforementioned breaches could have on their own caused wound contamination, which could result in infection.

I conclude that these breaches were of a major nature and resulted in an uncommon serious outbreak, hence the standard of practice was not met.

21. Dr. James is incompetent and failed to maintain the standard of practice of the profession in in his care and treatment of the patients identified by Public Health, as set out above.

(e) Disgraceful Dishonourable and Unprofessional Conduct – Interview Prep Sheet

22. In the course of the College's Investigation, the College arranged to interview a number of nurses and staff who worked with Dr. James at the Clinic. Interviews with individual nurses were scheduled to take place at the Clinic during the week of February 6, 2013.

23. In the course of these interviews, the College obtained a document entitled "Interview Prep" a copy of which is attached at Tab 3 [to the Statement of Facts and Plea of No Contest]. The Interview Prep document itemized Dr. James' aseptic technique with respect to infection control post-Public Health investigation and itemized major differences in his technique before and after the Public Health investigation, for example, that since the Public Health investigation he removes his wedding band, and applies ABHR immediately prior to donning sterile gloves. The Interview Prep document implies that Dr. James always wore a mask and always wore sterile gloves prior to Public Health involvement.

24. The College learned that Dr. James had distributed the document to various nurses he works with very shortly before the College interviews were scheduled to take place, and left the document in the recovery room and the nurses' station so that it would available to all nurses who were to be interviewed by the College.

25. Dr. James advised the College that he prepared the "Interview Prep" document to help the nurses prepare for their College interviews, in response to the specific request of certain individual nurses. He suggested that he was approached by junior nurses who were apprehensive about being interviewed by College investigators. He stated that he recently changed his technique with respect to caudal injections (from administering caudal injections under "clean" conditions to administering caudal injections under sterile conditions), and that this change was causing his staff some stress. He claimed that in an effort to support their learning and to further allay their anxiety, he prepared the document as a reference aid.

26. Contrary to Dr. James' explanation, nurses interviewed by College investigators reported that, while they were stressed and anxious about the College interviews, they did not request any such assistance from Dr. James. The nurses' interviews

also do not support Dr. James' statements that he always wore a sterile mask and gloves for procedures in the fall of 2012.

27. Dr. James provided the Interview Prep document to nursing staff at the Clinic in order to influence their responses to the College Investigation. His actions in doing so, and in misrepresenting the purpose of the Interview Prep Document to the College, constitute disgraceful, dishonourable and unprofessional conduct.

Patient A

28. Patient A was referred to Dr. James by a pain specialist who was treating her with trigger point injections. She first saw Dr. James in August 2012, at which time he administered a lumbar steroid injection for her chronic pain.

29. Patient A attended Dr. James again in September and October 2012, at which appointments she again received lumbar steroid injections.

30. At the October 2012 appointment, Patient A states that she noticed that Dr. James did not wear sterile gloves or a mask; and stated that she did not have iodine put on her back like previous times; her procedure felt rushed to her. Dr. James' records of his care and treatment of Patient A are attached at Tab 4 [to the Statement of Facts and Plea of No Contest].

31. Patient A started to feel unwell soon after the October 2012 appointment. By November 2012, Patient A felt extremely confused, weak, and lethargic, and had a fever. Her spouse called 911, and an ambulance took her to a hospital in a city in Ontario (Hospital Z).

32. Patient A was admitted to hospital and found to have a staph aureus infection. She was diagnosed with meningitis and an epidural abscess precisely where the injection had taken place. She underwent an MRI of her brain and spine in November 2012, at which time the abscess was found. During the course of her

illness she lost control of her bowel and bladder and was unable to walk unassisted. Neurosurgeons at another Ontario hospital, Hospital Y, were consulted later in November 2012, and Patient A was transferred to that hospital in November 2012.

33. In November 2012, Dr. James was contacted by physicians at Hospital Z and advised of Patient A's staph aureus infection. In November 2012 at Hospital Y, Patient A was taken urgently to the OR where she underwent a laminectomy and evacuation and drainage of spinal epidural abscess. Cultures from the OR were positive for staph aureus. She experienced urinary retention, and saddle anesthesia.

34. Dr. James advised the College that, on a later date in November 2012, he again spoke with Patient A's attending physician who confirmed that she had an epidural abscess. Dr. James wrote: "I encouraged him to obtain a neurological consultation or have her transferred to a Toronto hospital for surgical decompression and drainage. He agreed and arranged for her immediate transfer to Hospital Y to be placed under the care of a neurosurgeon." In fact, Patient A had already been transferred to Hospital Y, without any input from Dr. James. In a July, 2014 response to the College, Dr. James stated: "Importantly, once the epidural abscess had been diagnosed, I was the one who recommended that Dr. LL obtain a neurological consultation or have her transferred to a large city's hospital for surgical decompression and drainage." This was not accurate.

35. Patient A was hospitalized until December 2012, at which time she was discharged home with a PICC line and a catheter, and required home care.

36. In March 2013, Patient A attended to speak with Dr. James about what had happened to her. Dr. James explained that there may have been no brown spot on her skin in October 2012 from the Betadine because a clear solution may have been used. However, nursing staff confirmed that Betadine, not chlorhexadine

(the clear solution), was routinely used prior to Public Health involvement. Patient A's pre-printed chart from October 2012 refers to the use of Betadine.

37. Dr. James also told the patient at the March 2013 meeting that Public Health came in and performed a full audit, and that everything was within the normal standard of care. He did advise Patient A that he was found to be positive for staph aureus around his mouth and nose, and put on antibiotics.

38. The College retained Dr. FF, an anesthesiologist who practices interventional chronic pain and who is the chronic pain fellowship director at a hospital in a city in Ontario, to provide an opinion, attached at Tab 5 [to the Statement of Facts and Plea of No Contest]. With respect to the care and treatment provided by Dr. James in respect of Patient A and Patient B, Dr. FF opined:

> I would agree that based on the IPAC review, that Dr. James' practice did not maintain aseptic technique for the procedures provided and that this failure to maintain a sterile environment, failure to perform sterile procedures with appropriate sterile technique was the causative factor in the outbreak of infections. This would certainly fall below the standard of practice and did lead to significant patient harm. …
>
> In summary, it is my opinion that Dr. James has demonstrated a lack of knowledge, lack of judgment and lack of skill in providing care to [Patient B] and [Patient A]…. His non adherence to appropriate aseptic technique in the invasive procedures provided has led to significant complications and morbidity.

39. Dr. James was incompetent and failed to maintain the standard of practice of the profession in his care and treatment of Patient A.

40. In addition, as set out in paragraphs 33-36 above, Dr. James engaged in

disgraceful, dishonourable and unprofessional conduct.

Patient B

41. Patient B was referred to Dr. James by her family physician in May 2012 due to debilitating back pain. Her first consultation and treatment with Dr. James occurred in June 2012. Dr. James indicates that his general practice at that time was to tell patients, before treating them with epidural steroid injections, that there is a less than one percent risk of backache, headache (1/300), bleeding (1/100,00) or infection (1/10,000) associated with epidural injections. Dr. James proceeded to administer a lumbar steroid injection to Patient B that day.

42. Dr. James performed lumbar steroid injections on Patient B again in July 2012 and August 2012. Dr. James' records from his care and treatment of Patient B are attached at Tab 6 [to the Statement of Facts and Plea of No Contest].

43. In September 2012, Patient B, whose hometown is about 25 km from Hospital X, was taken there by her husband, with fever, confusion and lower back pain. Patient B spent several days in the Emergency Room, and was ultimately admitted to Hospital X as an in-patient.

44. In September 2012, the Emergency Room physician at Hospital X spoke with Dr. James, and advised him that Patient B's blood cultures demonstrate gram-positive cocci likely secondary to staph aureus and that she had been started on IV antibiotics. Her vital signs were stable and she did not exhibit any bowel or bladder dysfunction. Dr. James told the Emergency Room physician that without any focal neurological symptoms, nothing urgent needed to be done. However, in Dr. James' response to the College investigation, he told the College that:

> I notified the attending physician that this was a potential neurosurgical emergency I stressed that it was imperative that an epidural abscess be ruled out immediately because if one was

> present and not treated in a timely manner, the long term effects could be serious. I advised that she needed to immediately order a neurosurg consult and MRI of Patient B's lumbar spine to investigate for the presence of an abscess. If one was detected, she needed to consider surgical decompression and/or drainage. I emphasized that there was a 24 hour window in which to treat Patient B in order to prevent progression of the disease process and limit any long term side effects such as new focal deficits, paralysis or bowel/bladder dysfunction. These are standard emergency protocols.
>
> The attending physician advised that the hospital did not have neurosurgical services. She also advised that an urgent MRI would not be possible and that the earliest it could be done was four days later in Sept 2012. I stated that such a delay was unacceptable and that she needed to arrange for Patient B's immediate transfer to Hospital Y or another hospital.
>
> … The next day I spoke with an ER physician. I urged him to obtain an infectious disease consult.

45. This was not an accurate account of his interactions with Hospital X; those interactions are accurately set out in the first three sentences of paragraph 44 above.

46. As of September 2012, Hospital X's working diagnosis in respect of Patient B was an epidural abscess secondary to direct skin infection from the epidural injections.

47. The next day in September 2012, it was confirmed that Patient B had a positive blood culture for staph aureus. An MRI was performed, which showed that she did not have an abscess; rather, Patient B had arachnoiditis.

48. Patient B remained hospitalized until November 2012, at which time she was discharged; she suffered saddle anaesthesia and bowel and bladder incontinence, and could only walk with the aid of a walker. Those conditions persist to this day.

49. As stated above, the College retained Dr. FF to provide an opinion in respect of the care and treatment provided by Dr. James to Patients A and B, which is attached at Tab 5 [to the Statement of Facts and Plea of No Contest]. Dr. FF opined:

> I would agree that based on the IPAC review, that Dr. James' practice did not maintain aseptic technique for the procedures provided and that this failure to maintain a sterile environment, failure to perform sterile procedures with appropriate sterile technique was the causative factor in the outbreak of infections. This would certainly fall below the standard of practice and did lead to significant patient harm. …
>
> In summary, it is my opinion that Dr. James has demonstrated a lack of knowledge, lack of judgment and lack of skill in providing care to [Patient B] and [Patient A]…. His non adherence to appropriate aseptic technique in the invasive procedures provided has led to significant complications and morbidity.

50. Dr. James was incompetent and failed to maintain the standard of practice of the profession in his care and treatment of Patient B.

51. In addition, as set out in paragraphs 44-45 above, Dr. James engaged in disgraceful, dishonourable and unprofessional conduct.

Patient C

52. Patient C was referred to Dr. James in April 2012 for management of lower back pain. She was treated by Dr. James seven times between April and August 2012.

53. In May 2012, Dr. James administered an epidural steroid injection to Patient C. She returned for further epidural steroid injections on June 2012 and July 2012. Dr. James' records of his care and treatment of Patient Care attached at Tab 7 [to the Statement of Facts and Plea of No Contest].

54. In or around July 2012, after having received a number of injections from Dr. James, Patient C started to experience increasing pain and decreasing stability on her feet. She reported these concerns to Dr. James, and on two occasions sought treatment at the Emergency Department at Hospital W.

55. Hospital W Records from her ER visit in July 2012 indicate that Patient C had complaints of urinary burning, numbness in her buttocks and perineum and increased numbness in her leg after receiving injections. Records from her August 2012 visit indicate she complained again of increased lower back pain since treatment by Dr. James and fecal/urinary incontinence since July.

56. A CT scan dated August 2012 revealed a small collection of soft tissue close to the right sacral foramen at the level of S1/S2, and increased paraspinal soft tissue density.

57. Patient C continued to see Dr. James throughout that summer. After the epidural injections failed to alleviate Patient C's pain, Dr. James administered bilateral diagnostic lumbar facet blocks in July 2012. Following this, in August 2012, he performed left rhizotomy on Patient C.

58. At her next appointment, later in August 2012, Patient C provided Dr. James with a copy of the CT scan report obtained from her August visit to Hospital W. At that appointment, Dr. James performed a right rhizotomy. He provided Patient C with

a note to take to her family doctor recommending a neurosurgery consult and recommending that her family physician request an MRI. He engaged in no further follow up with Patient C.

59. Ultimately, Patient C obtained an MRI and was diagnosed with a serious spinal infection. She required a surgical debridement of her spine (requiring a 4 day hospital admission) and was discharged with a PICC line to receive a lengthy course of antibiotic treatment. A sensitive strain of staph aureus was recovered from the surgical specimen and the infection was believed to be the direct result of steroid injections.

60. The College retained Dr. FF to provide an opinion, attached at Tab 8 [to the Statement of Facts and Plea of No Contest], with respect to the care and treatment provided by Dr. James to Patient C. Dr. FF opined:

> …although this patient did not present with all of the most typical signs and symptoms of epidural infection, I find that the treatment of this patient was below the standard of care. Dr. James failed to appreciate the patient's progressive symptoms, failed to realize that the symptoms could be signs of an infection in a high risk patient. He also failed to adequately document the patients progressive symptoms, failed to correctly diagnosis/work up possible complications of treatments he provided, failed to adequately inquire about the patients ER visits and failed to organize appropriate timely work up of the patient's symptoms.
>
> …Dr. James has shown a lack of judgment/act(s) of omission, in the care of this patient. There are documented poor responses to the provided large number of injections and yet the injections are repeated on several further visits.

61. In his report dated June 22, 2015, attached at Tab 5 [to the Statement of Facts and

Plea of No Contest], Dr. FF opined:

> I would agree that based on the IPAC review, that Dr. James' practice did not maintain aseptic technique for the procedures provided and that this failure to maintain a sterile environment, failure to perform sterile procedures with appropriate sterile technique was the causative factor in the outbreak of infections. This would certainly fall below the standard of practice and did lead to significant patient harm.
> …This is true in regards to all three patients I have reviewed (..i.e. [Patient, A, Patient B and Patient C])

62. Dr. James was incompetent and failed to maintain the standard of practice of the profession in his care and treatment of Patient C.

Patient D

63. Patient D was referred to Dr. James in June 2010 for treatment of chronic back pain arising from a car accident in the previous year.

64. Commencing in 2010, Patient D was seen by Dr. James for injections on a regular basis. In October 2011, Dr. James administered a lumbar epidural injection. A copy of Patient D's patient records are attached at Tab 9 [to the Statement of Facts and Plea of No Contest].

65. Less than two weeks after receiving the epidural injection, Patient D began to experience symptoms of fever, increasing confusion, neck pain, nausea, vomiting and occipital headaches. She was admitted to Hospital V. The suspected etiology was an infection secondary to epidural injections received from Dr. James. CSF demonstrated bacterial meningitis and she was discharged with conservative treatment of IV antibiotics.

66. Patient D was readmitted to Hospital V in November 2011 for a 12 day period. Her headache, nausea and vomiting continued. She had photophobia, diplopia

phonophobia, and neck stiffness. An MRI taken in November 2011 demonstrated an epidural fluid collection with a diagnosis of a likely enlarging epidural abscess. Patient D required extensive surgical laminectomies. Cultures from the surgical decompression demonstrated staph aureus sensitive to ancef. She remained in the Hospital until December 2011 when she was ultimately discharged with a plan to continue IV antibiotics.

67. Dr. James was consulted by Patient D's family, and treating physicians while Patient D was hospitalized.

68. The College retained Dr. FF to review the care and treatment provided by Dr. James to Patient D. A copy of his report is attached at Tab 10 [to the Statement of Facts and Plea of No Contest]. Dr. FF opined that:

> …it appears that the patient has suffered a severe life threatening infection after an epidural injection by Dr. James. This infection was most likely caused by instillation of skin flora into the patients epidural and intrathecal spaces during the epidural injection in October 2011.
>
> … I would conclude that Dr. James poor infection control practices were below standard of care and would result in significantly increased risk of infectious complications, such as that suffered by this patient.
>
> Dr. James has therefore not met the standard of care in treating this patient. There are many issues in the notes in relation to the details of procedures performed, the aseptic technique, repeating procedures that gave less than expected pain relief/shorter duration of effectiveness as compared to the published literature, questionable procedure injection technique and the use of consents that are at times over vague… There appears to be a lack of knowledge in regards to proper sterile technique.

69. Dr. James was incompetent and failed to maintain the standard of practice of the profession in his care and treatment of Patient D.

Patient E

70. Dr. James treated Patient E for pain in her right elbow. In January 2012, Dr. James injected her elbow with cortisone. He performed a caudal epidural injection on Patient E the same day. Dr. James' medical chart for Patient E from January 2012 forward is attached at Tab 11 [to the Statement of Facts and Plea of No Contest].

71. Soon after the injection, Patient E's right arm became painful and red. She began calling the Clinic to get an appointment with Dr. James so that he could look at her arm. In February 2012, she spoke with a nurse, telling her there was a toonie-sized swelling on her elbow, that the area was red and hot to the touch, and that she was worried about infection. She advised the nurse that she had no fever. The nurse advised Patient E that it did not seem like an infection, but if her condition worsened she should seek medical attention.

72. Patient E telephoned the Clinic again later in February 2012, in response to a call she received from the nurse manager. She attended the clinic that day and saw Dr. James and the nurse-manager, whose note from the visit states:

> There was a red area covering her elbow that was about 5cm in diameter with a slight swelling. After speaking with Dr. James, the patient was advised to get an over the counter triple antibiotic cream…and to use the cream three times a day for 10 days and to call if area became worse or to go the local emergency department if after clinic hours.

73. Patient E again called the Clinic on a further date in February 2012 and advised a

nurse that although the swelling had previously gone down somewhat, it had now returned – the injection site was again red, painful, swollen and hot. The nurse told Patient E she would speak with Dr. James and call her back. The nurse's note states:

> 9:50 – writer spoke [with] Dr. James. He stated there is no infection. Patient doesn't have a fever. Patient to apply ice, take Benadryl [] an anti-inflammatory. Dr. James stated he will not be able to see patient, it is his x-ray day. If patient has any concerns she should go to emerg.

74. Later in February 2012, Patient E attended at the clinic, and asked that someone look at her red and swollen elbow. She was told she would have to wait, as the clinic was not a walk-in clinic, and agreed to wait, as she wanted answers as to why it has remained red and swollen. After she waited for about an hour and a half, Dr. James saw her, told her it was likely nothing – perhaps the preservatives in the cortisone - but gave her a prescription for antibiotics "just in case", and told her to follow up in two weeks.

75. During and after the course of antibiotics Dr. James had prescribed, Patient E's arm remained very painful, swollen and red. When she returned to the Clinic in March 2012, and was seen by Dr. James, he immediately sent her to the Emergency Department at Hospital U.

76. At Hospital U, a large lump at her elbow, which was painful and hot, was noted. Patient E was found to have a post-injection abscess and a heavy growth of staph aureus and was referred for both orthopedic and plastic surgery consults. The infection site was drained, then later cut open, drained, cleaned, packed, taped and bandaged. Patient E required home care and further antibiotic therapy.

77. Patient E telephoned the Clinic so that Dr. James would be aware of her infection, and how it was treated. Dr. James left her a message later that evening and the nurse manager spoke with her on one occasion.

78. The College retained Dr. FF to provide an opinion on Dr. James' care in this case, attached at Tab 12 [to the Statement of Facts and Plea of No Contest]. Dr. FF opined, among other things, as follows:

> There is [an] incorrect assumption made here by Dr. James that since the patient has no fever, she must not have an infection…. It is an incorrect assumption that Dr. James can tell if the elbow or soft tissue is infected based on the information given to him through these phone conversations without seeing the area personally and considering further investigations if warranted (ie CBC, blood cultures, local tissue/ fluid aspiration/ ultrasound of the area). It is below standard of care to not offer urgent follow up for a potential infection after a procedure, there is a lack of knowledge displayed by Dr. James as he assumes that sine the patient does not display a fever, that she must not have an infection.
>
> …
>
> There is no noted follow up plan, no differential diagnosis offered to explain what Dr. James believes is happening or what the planned follow up should be? Prescribing keflex would imply that he believes there may be an infection, whereas steroids would be detrimental to an infection and used along with Benadryl for a irritation/inflammatory reaction (there is no note of itchiness, hives, which would be more common with an inflammatory reaction). I believe there should be a planned short term follow up if there is a potential infection and advice to go to a local ER if the symptoms do not significantly improve after 2-3 days of antibiotics.
>
> …

> The patient states that Dr. James barely looks at her elbow and states that it is a reaction to the preservative and explains who to use cortisone cream to treat it. If Dr. James did not actually take the time to palpate the area, assess that skin temperature, examine for possible fluid collection /abscess, check the patient's range of motion and palpation of the joint; it would be below standard of care (this is in discordance with Dr. James notes that describe palpation of the area and that the area is hard/indurated).

79. Further, on the basis of the IPAC information provided to Dr. FF and referred to in paragraphs 6 (viii) - 7 above, Dr. FF concluded:

> It is possible that someone can have this type of infection even with appropriate sterile technique, but this should be a rare event for a low risk patient (which this patient is, since she has very few medical co-morbidities and none that would increase infection risk). It is also possible that this bacteria came from Dr. James if he had not adhered to appropriate aseptic technique. From the IPAC review, in relation to the soft tissue infection, there are significant breaches in technique that would significantly increase risk of infection.

80. Dr. James was incompetent and failed to maintain the standard of practice of the profession in his care and treatment of Patient E.

81. In addition, as set out in paragraphs 71-73 above, Dr. James engaged in disgraceful, dishonourable and unprofessional conduct.

Patient F

82. Patient F was referred to Dr. James for lumbar epidural injections in April 2012 for lower back pain. In May 2012, Patient F received a lumbar epidural injection from Dr. James at the Clinic. A copy of his patient records is attached at Tab 13

[to the Statement of Facts and Plea of No Contest].

83. Less than two weeks later, while in the U.S., Patient F developed a high fever, delirium and increasing back pain. In May 2012, Patient F was admitted to a hospital in an American city, critically ill. He was found to have an epidural abscess and sepsis (staph aureus bacteremia), requiring ICU admission, intubation and neurosurgical evacuation together with hemi laminectomies. The likely etiology of the epidural abscess was believed to be the epidural injection.

84. In May 2012, Patient F was transferred from the American hospital to a hospital in Ontario for post epidural abscess care. While in hospital, he experienced complications including significant urinary retention, and subsequently a bladder infection resulting from the insertion of a catheter.

85. The College retained Dr. FF to review the care and treatment provided by Dr. James to Patient F. A copy of his report is attached at Tab 14 [to the Statement of Facts and Plea of No Contest]. Dr. FF opined that:

> …If Dr. James had used the same sterile technique as that observed during the IPAC review then he would not have maintained standard of care. This lack of proper aseptic technique would be expected to result in increased infections and severe complications such as that occurred with this patient.
>
> The patient suffered an epidural abscess with Staph Aureus, which is a common bacteria found on normal skin flora… The timeline for developing signs of infection- approximately 10-12 days after an injection would certainly indicate that the infection was likely secondary to bacteria introduced into the epidural space at the time of the epidural steroid injection. This is why appropriate sterile technique must be adhered to during these types of invasive

procedures.

…If Dr. James had not followed appropriate ascetic technique during this injection (as was observed in the IPAC review), then it is more probable than not that this lack of adherence to standard of care was the cause of this patient's epidural abscess….

86. Dr. James was incompetent and failed to maintain the standard of practice of the profession in his care and treatment of Patient F.

PART II: PLEA OF NO CONTEST

87. Dr. James pleads no contest to the facts set out in paragraphs 1-86 above, and does not contest, for the purposes of College proceedings, that:

(a) He failed to maintain the standard of practice of the profession and is incompetent in his care and treatment, including in his infection control practices, of: Patient A, Patient B, Patient C, Patient D, Patient E, Patient F as well as the additional seven (Patients T, U, V, W, X, Y, Z) identified by Public Health.

(b) He engaged in disgraceful, dishonourable and unprofessional conduct including by:

i. Providing the Interview Prep document to nursing staff at the Clinic in order to influence the nurses' responses to the College Investigation.
ii. Misrepresenting the purpose of the Interview Prep Document to the College
iii. Misstating the steps he took when learning of Patient A and Patient B's complications caused by his inadequate IPAC procedures.

iv. Failing to make himself available, and communicating inappropriately through his nursing staff, when Patient E suffered complications.

FINDINGS

Certain legal consequences flow from the Rules of the Discipline Committee when a physician pleads no contest to an allegation of professional misconduct or incompetence. Rule 3.02 of the Discipline Committee's Rules of Procedure provides:

> 3.02(1) Where a member enters a plea of no contest to an allegation, the member consents to the following:
>
> a) that the Discipline Committee can accept as correct the facts alleged against the member on that allegation for the purposes of the proceeding only;
> b) that the Discipline Committee can accept that those facts constitute professional misconduct or incompetence or both for the purposes of the proceeding only; and
> c) that the Discipline Committee can dispose of the issue of what finding ought to be made without hearing evidence.

As a result of Dr. James' plea of no contest, the Committee accepted as correct the uncontested facts in the Statement of Facts and Plea of No Contest and found that:

- Dr. James committed an act of professional misconduct in that.
    - he has failed to maintain the standard of practice of the profession; and
    - he engaged in conduct or an act or omission relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional.

- Dr. James is incompetent under subsection 52(1) of the Code, in that his care of patients displayed a lack of knowledge, skill or judgment of a nature or to an

extent that demonstrates that he is unfit to continue to practise, or that his practice should be restricted.

FACTS ON PENALTY

The following facts were set out in an Agreed Statement of Facts for Penalty and were accepted by the Committee:

1. Dr. James was co-operative with the Toronto Public Health investigation, as well as the look-back process.

2. The College retained Dr. EE, Medical Director of Infection Prevention and Control at an Ontario hospital, and associate professor of medicine at an Ontario university, to provide an opinion regarding Dr. James' infection control procedures. Dr. EE conducted an inspection and observation of Dr. James in January 2013. Dr. EE had a few recommendations for further improvement but concluded: " Dr. James meets the standard of practice of the profession with respect to infection control procedures. …Dr. James does not display a lack of knowledge, skill or judgment. … Dr. James' clinical practice, behaviour or conduct do not expose or are likely to expose his patients to harm or injury."

3. Dr. James retained Dr. GG, an expert in anaesthesiology and chronic pain, to review the care and treatment that Dr. James provided to Patients A, B and C. Separate and apart from the issues of aseptic technique and infection control, Dr. GG was supportive of the care and treatment that Dr. James provided to Patients A, B and C and delivered expert reports outlining his opinions in that regard. Given the timing of the referrals to discipline of Patients D, E and F, Dr. James did not receive and provide to the College expert reports in respect of the care he provided to them.

4. On April 1, 2014, the Inquiries Complaints and Reports Committee approved an appointment of investigators to conduct a broad investigation into Dr. James' clinical practice in interventional pain management. The College retained Dr. JJ, FRCPC, Anesthesiology, to review 25 patient charts, observe Dr. James in practice (performing 10 procedures) and conduct an interview. Three of the charts reviewed were Patient X, W and Z, revealed in the Toronto Public Health investigation as having contracted staph aureus. In respect of each of the remaining 22 cases reviewed, and in respect of each of the ten procedures observed, Dr. JJ concluded that Dr. James' care and treatment met the standard of practice of the profession. Dr. James did not display any deficiencies in knowledge, skill or judgment, nor did his practice, behaviour or conduct expose or likely expose his patients to harm or injury. Dr. JJ concluded Dr. James to be a knowledgeable, skilled and competent physician, practicing to a high standard.

5. On May 22, 2015, Dr. James completed a series of on-line infection control courses offered by Public Health Ontario. The certificates of completion are attached at Tab A [to the Agreed Statement of Facts for Penalty].

6. Dr. James advised the College of his intention to perform procedures at a new clinic. Prior to the opening of that clinic, the Associate Director of Infection Prevention and Control at a hospital network in Ontario was sent by the College to review the clinic's physical layout, as well as its policies and procedures. The assessment report made some recommendations about changes to the premises (for example, cupboards should be changed from being wall-mounted to being on the floor, sinks should be wall-mounted, certain configuration changes to the rooms should be made.) These changes were made and the premises received a pass with conditions on July 15, 2015. The Premises Inspection Committee will conduct a further inspection-assessment within 6 months of the new clinic becoming operational to observe procedures and review record-keeping documentation.

7. On September 21, 2015, a College-approved assessor, the Medical Director of Infection Prevention and Control at Hamilton Health Sciences, attended for an unannounced inspection of Dr. James' practice at the Rothbart Centre for Pain Care. The assessor reviewed the setting and observed Dr. James perform two procedures: an epidural steroid injection and a radiofrequency ablation of the L5 root. The assessor concluded that Dr. James "continues to meet the standard of practice of the profession in respect of infection prevention and control procedures. There was no evidence of lack of knowledge, skill or judgment, and there was no unnecessary risk of harm or injury".

In addition, the following facts accepted by the Committee were set out in a Supplementary Agreed Statement of Facts for Penalty:

1. On November 12, 2015, Dr. HH, the Associate Director of Infection Prevention and Control at a hospital network in Ontario, attended for an unannounced inspection at Dr. James' new clinic. She observed him perform two procedures, a lumbar epidural injection on one patient and a cervical epidural inspection on a second patient.

2. The College received Dr. HH's report on November 20, 2015. Dr. HH opined that Dr. James met the standard of practice of the profession with respect to infection prevention and control, and that he did not display a lack of knowledge, skill or judgment in respect to infection prevention and control. Dr. HH made some recommendations.

3. As a result of recommendations made by Dr. HH and others, Dr. James has entered into an undertaking with the College, formally setting out his agreement to follow the recommended infection control practices for specified procedures. That undertaking constitutes further terms, conditions and limitations on Dr. James' certificate of registration, and will be relied upon by the College in its compliance and monitoring activities.

4. The undertaking, including Appendix A thereof which sets out the infection control practices for specific procedures, is attached hereto as Tab 1 [to the Supplementary Agreed Statement of Facts for Penalty].

PENALTY AND REASONS FOR PENALTY

Counsel for the College together with counsel for Dr. James made a joint submission as to an appropriate penalty and costs order.

The Committee considered that protection of the public from further misconduct by Dr. James is of paramount importance in determining the appropriate penalty. The penalty must also provide specific and general deterrence; communicate the profession's disapproval of the behaviour; and take into account any aggravating and mitigating factors. Further, it is vital to maintain the public's confidence in the medical profession's ability to self-govern in the public interest.

The Committee recognized that the law requires that a joint submission must be accepted unless the joint submission is contrary to the public interest and its acceptance would bring the administration of justice into disrepute.

Initially, the jointly-proposed order included the following provisions:

- that Dr. James be prohibited from holding the position of medical director in any facility;

- that Dr. James be required to perform all injections in the presence of a regulated health professional who would observe each injection, as well as sign and date the patient record;

- that, if Dr. James were to become aware of a patient developing an infection following a procedure that he performed, he be required to report this infection to the College within seven days;

- that Dr. James would be subject to:

  - the reassessment of his practice, including his sterile technique, within six months of his return to practice; and

  - periodic assessments, both announced and unannounced, at the discretion of the College;

- that Dr. James be required to complete the next available medical record-keeping course approved by the College;

- that Dr. James be required to complete the next available course in communications approved by the College;

- that Dr. James be required to engage in a preceptor acceptable to the College regarding infection and treatment of infection in interventional pain medicine for a minimum of four hours; and

- that Dr. James' certificate of registration be suspended for a period of ten months, effective 30 days after the date of this order.

The Discipline Committee accepted the above penalty provisions as appropriate, but considered that an even more serious penalty was called for on the facts of this case by reason of the following:

- Dr. James' extremely poor antiseptic technique;

- the lack of self-scrutiny Dr. James exhibited in his practice, despite a number of his patients developing serious infections within a relatively brief period;

- Dr. James' breaches of ethical behaviour in his initial dealings with nurses in the clinic, his initial response to the College, and his response to the College investigation;

- Dr. James' inadequate communication with several patients harmed by his behaviour; and

- Dr. James' apparent lack of remorse for his misconduct and its consequences, as demonstrated by the record.

As a result, the Committee asked both the College and counsel for Dr. James to reconsider certain aspects of the proposed order in their joint submission on penalty. They did so, returning with a strengthened requirement for the monitoring/education program (a clinical supervisor, who will meet with Dr. James monthly for a year; reviewing patient charts and discussing infection control) and added a requirement that Dr. James complete an ethics program that will be individualized to his specific needs.

In considering the revised joint submission of the parties, the Committee had regard to the legally mandated penalty principles and considered the nature and the circumstances of Dr. James' misconduct. The Committee determined that the sanctions and measures of protection in the proposed penalty satisfy the basic principles underlying penalty orders – public protection, maintenance of the integrity of the profession, public confidence in the profession's ability to self-regulate in the public interest, specific and general deterrence, and rehabilitation of the member where possible. The Committee also took into account aggravating and mitigating factors, and penalties that have been imposed in similar cases. The Committee recognized that no two cases are identical, but that the Committee should consider like cases when considering whether a proposed penalty is appropriate.

Counsel presented the Committee with prior cases with similar, but not identical, facts to the present case.

Several of these cases (*Haines* 2014; *Huebel* 2015) resulted in reprimands, giving the panel an opportunity to express publicly its abhorrence for the misconduct, and deploy significant conditions of remediation with no period of suspension. Panels in other similar cases, which involved a more systemic pattern of poor patient care, revoked the member's certificate of registration (e.g., *Shum* 2013). In *Farazli* 2014, the member signed an undertaking to resign. In other cases, the penalty included three or six month suspensions (*Handy* 2010; *Wu* 2013).

The ten month suspension ordered in the present case is within the continuum of penalties imposed for similar misconduct and incompetence. It reflects the Committee's view that Dr. James' actions were very serious, involved poor ethical behaviour and caused severe harm to many patients and their families.

Aggravating Factors

Dr. James' poor antiseptic technique

Dr. James' clinical care was brought to the attention of the College after Toronto Public Health (Public Health) suspected a meningitis outbreak. Public Health examined a total of 272 patients who received epidural injections from Dr. James between August and December 2012. Nine patients were found to have serious infections. The College's enquiry found six patients, two of whom overlapped with the Public Health enquiry. In total, 13 patients became infected.

Public Health noted serious breaches of antiseptic technique during its visit to Dr. James' clinic, including: the patient's sterile field was not covered; Dr. James used a non-sterile gauze after a procedure; Dr. James' gloves were too large; he used a mask but its nose was not pinched; he did not often allow the betadine antiseptic to dry; he touched many surfaces after donning sterile gloves; and he wore his wedding band throughout the procedure.

Moreover, Dr. James did not wipe the multi-dose vials of local anesthetic with 70% alcohol prior to accessing with a syringe. This was also not done with single use vials. This practice would put patients at increased risk of infection. Reviewers also found needles left in partially-used vials, a practice that should never be followed because air contaminants in the room could easily enter the vials.

The Committee found that there were very serious breaches occurring over many months, and the consequences have been devastating. The breaches affected people's lives permanently, physically and emotionally, with significant effects for patients and their families. Dr. James' breaches also undermined his patients' trust in the medical

profession. Some patients have permanently lost the control of their bladders and bowels and cannot walk without canes or walkers.

The Committee heard several powerful victim impact statements. Those affected by Dr. James' misconduct said, *"This has not only affected me but our whole family… our mobile home sits empty…has not called us to discuss what happened…carelessly ruined our lives… no longer trust doctors. " "My trust in doctors has really been shattered."*

All of the impact statements strongly urged that action be taken so that this type of problem should never happen again. They expressed a sense of betrayal that their authors felt about the medical profession.

Lack of Self-Scrutiny and Response to Patients in Distress

Over a relatively brief period of time, many of Dr. James' patients became seriously ill. Although Dr. James was made aware of some of the patients' complaints, he tended to dismiss them as involving an allergy to the preservative. Dr. James was often too busy to see the patient, and at times he became annoyed with patients requesting such follow up. Had he clinically assessed these patients himself, and noted the frequency of these infections, Dr. James might have alerted himself and others to the problem much sooner.

The Committee does note that, since decolonization and corrective action, there has been no report of infections in almost three years in Dr. James' practice.

Communication with Patients

One patient (Patient E) commented that when she finally saw Dr. James about the abscess in her elbow, he was stern with her and told her that he was annoyed. He lectured her on her abusive attitude to two of his nurses, and told her that that this was not a walk-in clinic. When he looked at her elbow, he thought mistakenly that it was a reaction to the preservative and suggested the use of cortisone cream.

Breach of Ethics

The Committee was dismayed that Dr. James had sought to manipulate the nursing staff at his clinic into falsely describing his antiseptic technique when he knew he was under College investigation. In an effort to thwart the College, Dr. James attempted to influence how nurses would answer College investigators' questions by writing a false "prep sheet." The procedures described on the "prep sheet" did not correspond to the actual techniques Dr. James used.

Furthermore, Dr. James was dishonest with the CPSO investigators in describing what he did and the purpose of the "prep sheet." Importantly, Dr. James' medical records in several cases did not correspond with material written in hospital records when patients were referred.

Questionable Remorse

Counsel for Dr. James submitted to the Committee that Dr. James felt devastated by these infections and their consequences. At times, Dr. James did attempt to phone some of his patients after they had been ill, but this was not a consistent practice. Several patients commented in their victim impact statements that they never received any contact from Dr. James expressing regret for his actions.

Mitigating Factors

The Committee took into account that Dr. James has no previous disciplinary history. By pleading no contest to the allegations, he accepted the facts and allegations made against him. This spared the College the time and expense of a contested hearing and avoided causing the emotional turmoil that his patients would suffer if they were required to testify as witnesses. Also, Dr. James cooperated with Toronto Public Health during its investigation and look-back process, as well as with the decolonization procedure.

The evidence before the Committee is that there have been no further episodes of infection in the past three years since Dr. James returned to work. He has passed four further inspections between January 2013 and November 2015, two of which were unannounced.

Dr. James did not hide his status as a staph carrier; it is significant that he did not know he was one and he fully complied when he was informed of this. Dr. James has demonstrated insight. He has been amenable to remediation and has completed an online infection control course offered by Public Health Ontario in May 2015. In addition, Dr. James recently moved to a practice in a new clinic, and has received a pass on infection control since his relocation.

ACCEPTANCE OF THE JOINT SUBMISSION

The penalty as a whole upholds the principles governing penalty. It serves as a deterrent to the membership at large. The ten month suspension is consistent with past decisions; the duration of the suspension serves to express the repugnance of Dr. James' behaviour by the medical profession. By the reprimand, the Committee expresses publicly its abhorrence of the physician's misconduct.

In addition, the penalty permits remediation, which, in this case, involves the appointment of a clinical supervisor who meets monthly with Dr. James for a one year period, and a preceptor targeting treatment of infection in Interventional Pain Medicine. The various courses required – ethics, communications, record keeping, and infection control, are also imposed with the goal of remediation in mind. The ethics course and the communications course have no time limit, and can be tailored to Dr. James' specific needs over time.

The public is protected additionally by the requirement of the presence of a health care practitioner who observes every injection that is administered, and by Dr. James' obligation to report any patient infections within seven days. The public is further protected by the requirement of the preceptor and of the clinical supervisor; the ability to conduct announced and unannounced inspections; and the planned reassessment of the practice within six months after the end of the suspension. Dr. James' undertaking, which addresses infection control procedures, adds to public safety. The fact that Dr. James will not be able to hold the position of Medical Director in any facility ensures he will be under an ongoing degree of clinical supervision.

The penalty as a whole seeks to uphold the reputation of the profession and instills confidence in the public that the profession is capable of self-governance.

ORDER

In its written order of December 15, 2015, the Committee stated the finds of professional misconduct and incompetence. It also stated its penalty and costs ,date order effective on that the provisions of which were as follows:

3. Dr. James appear before the panel to be reprimanded.

4. the Registrar suspend Dr. James' certificate of registration for a period of ten (10) months, effective immediately.

5. the Registrar impose the following terms, conditions and limitations on Dr. James' certificate of registration:

    a. Dr. James be prohibited from holding the position of Medical Director in any facility;

    b. Dr. James shall perform all injections in the presence of a regulated health professional who observes each injection and who contemporaneously signs and dates the patient record confirming he/she has observed the injection. Dr. James shall provide the College with a list of regulated health professionals with whom he works and provide copies of their signatures within seven (7) days of the date of this Order, and within fourteen (14) days of employing any additional regulated health professional thereafter;

    c. If Dr. James becomes aware that a patient developed an infection following a procedure that he performed, Dr. James shall, within 7 days of date on which he became aware, report the infection to the College;

d. Dr. James shall complete the next available medical record keeping course approved by the College and provide proof of successful completion within three (3) weeks thereof;

e. Dr. James shall successfully complete individualized education in communication, approved by the College at the instructor's earliest availability and provide proof of successful completion within three (3) weeks thereof. The course will involve a series of one-on-one sessions with a College-approved instructor (the "Instructor"), incorporating principles of guided reflection, tailored feedback, and other modalities customized to the specific needs of Dr. James as assessed by the Instructor. The Instructor will make reports to the College regarding Dr. James' progress and compliance;

f. Dr. James shall successfully complete individualized instruction in ethics approved by the College at the instructor's earliest availability and provide proof of successful completion within three (3) weeks thereof. The instruction will involve a series of one-on-one sessions with a College-approved instructor (the "Instructor"), incorporating principles of guided reflection, tailored feedback, and other modalities customized to the specific needs of Dr. James as assessed by the Instructor. The Instructor will make reports to the College regarding Dr. James' progress and compliance;

g. Dr. James shall retain a clinical supervisor, approved by the College, who will sign an undertaking in the form attached hereto as Schedule "A" (the "Supervisor") no later than 30 days prior to Dr. James' return to practice after the suspension referred to in paragraph 4 above. Dr. James shall practice under the guidance of the Supervisor for a period of period of twelve (12) months. Dr. James shall meet with the supervisor monthly to discuss any concerns arising from patient care, including infection prevention, control and treatment.

h. Dr. James shall engage a preceptor acceptable to the College to provide education in the indications and treatment for infection in Interventional Pain Medicine for a minimum period of (4) four hours. The preceptorship shall be completed within (3) months of Dr. James' return to practice after the end of the suspension referred to in paragraph 4 above, and the preceptor shall confirm such completion in writing to the College;

i. Dr. James shall be subject to a reassessment of his practice including an observation of his sterile technique, within six (6) months of his return to practice after the end of the suspension referred to in paragraph 4 above, and shall be subject to periodic assessments (announced and/or unannounced) thereafter at the discretion of the College, including a reassessment following the completion of supervision described in paragraph g above. Dr. James shall abide by the recommendations of the assessors;

j. Dr. James shall cooperate with unannounced inspections of his practice and patient records by a College representative for the purposes of monitoring his compliance with the provisions of this Order and his infection control practices; and

k. Dr. James shall be solely responsible for payment of all fees, costs, charges, expenses, etc. arising from the implementation of any of the provisions of this Order.

6. Dr. James pay costs to the College in the amount of $4,460.00 within thirty (30) days of the date of this Order.

At the conclusion of the hearing, Dr. James waived his right to an appeal under subsection 70(1) of the Code and the Committee administered the public reprimand.

TEXT of PUBLIC REPRIMAND

Delivered December 15, 2016 in the case of the

COLLEGE OF PHYSICIANS and SURGEONS of ONTARIO

And

DR. STEPHEN ROSE JAMES

THE CHAIRPERSON: What we have heard today in the Statement of Facts about the patients in your care has deeply, deeply disturbed the Committee.

Your care – or, better said, lack of proper care – and procedures you performed on these patients is, and was, simply unacceptable. These cases present serious concerns about your ability to maintain the standards of the profession.

Your conduct during the investigation was, as noted in the decision of this Committee, disgraceful, dishonourable, and unprofessional. Or, put more simply, without ethical basis, and devious in method and intent.

We are reassured by the comments of your present supervisors and your apparent commitment to education. We take some comfort that, along with education and supervision, there will be reassessments over the extended period of time, to be sure that you maintain standards.

That being said, we do not know why you failed to comply with straightforward, well-understood protocols. It was, whatever the reasons – or lack of them – shameful behaviour, and hurtful to many. The results are something you will have to live with, and hopefully find some way to fully show your understanding of the pain and suffering you have caused.

Protection of the public is not just a College ideal, but the responsibility of every member of the profession. As well, upholding our ability to self-regulate in the public interest depends on every member of the College keeping protection and service of the public uppermost in our minds. And, that fully means you.

I would repeat, in your carelessness, you have truly caused pain and suffering. The principle of “first do no harm” is real. And you failed to apply simple, direct, and well-known procedures that would have protected your patients from a lifetime of suffering. The individuals you were so careless with suffered, the public suffers, and the profession suffers when one of our members becomes so inattentive to basic medical care and surgical technique.

We fully expect you to permanently change your method of practice, and to bring to bear full attention to detail in your care of patients and in your documenting of this care. We expect you will continue your education, and meet the expectations of the public, your supervisors, and colleagues.

We expect that exposure to learning in ethics and proper communication will have a lasting effect on you. We trust, as well, that we will never have reason to see you again in front of this Committee.