



**Juravinski Hospital
and Cancer Centre**

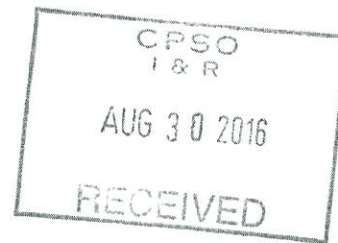
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Lisa Mueller
Investigator
Investigations and Resolutions
The College of Physicians and Surgeons of Ontario
80 College Street
Toronto Ontario
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File Number:



Dear Ms. Mueller:

Re: Dr. Akbar Nauman KHAN
CPSO: 65240

I am a Medical Oncologist in active practice since 1997. I have Full Hospital Privileges at Hamilton Health Sciences and have an appointment as an Associate Professor in the Department of Oncology at McMaster University. I am currently the Chief of the clinical Department of Oncology at Hamilton Health Sciences. Previously I was the Division Head of Medical Oncology. I am an Associate Professor in the Department of Oncology, Faculty of Health Sciences, McMaster University. My practice includes sarcoma, melanoma and breast cancer. I have been asked to review several cases under the care of Dr. Akhbar Khan. I have been informed of my duty to the Inquiries, Complaints and Reports (ICR) Committee and to the Discipline Committee of the College. I understand this duty.

I have been provided with:

1. Guidelines for the Assessor's Report
2. Section 36 of the Regulated Health Professions Act, 1991
3. Section 75(1) – 75(3) of the Health Professions Procedural Code
4. Privacy and Confidentiality Best Practices
5. Information of Breach Protocol
6. A copy of the Appointment of Investigators
7. Assessing Standard of Practice
8. CPSO Policy Statement #3 – 11 Complementary/Alternative Medicine
9. Patient Charts (21)
10. Patient imaging
11. Patient/Physician Email communication

The opinion provided in this report is based upon review of the charts provided, the imaging and the email communications. As per the CPSO Policy Statement #3 – 11, I was asked to review the charts in light of the three points listed below.

- i) Physicians must always act within the limits of their knowledge skill and judgment and never provide care that is beyond the scope of their clinical competence.
- ii) All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science.
- iii) Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

Introduction

Dr. Khan is a physician with family medicine training. He assesses and treats patients with various forms of cancer usually in late stage. It is unclear how patients are referred to him. Initial documentation includes a self administered questionnaire that reviews patient history, comorbid conditions, medications and also gives the opportunity for the patient to state which physicians he/she would like Dr. Khan to be in communication. Documentation does not include statements about what treatment options other than those prescribed by Dr. Khan might be available. Information about the side effects of drugs used are the information sheets that are used by Cancer Care Ontario.

Many of his patients are prescribed a drug called DCA (dichloroacetic acid) which has been studied in only five patients with glioblastoma as part of a Phase I Dose Finding trial. Its efficacy as a cancer treatment is unknown.

His other treatment option consists of a regimen called SAFE chemotherapy. This was developed by a family physician called Dr. Kenneth Matusumura in California with the claims that it cures 95% of patients with cancer and with no side effects. It consists of a standard chemotherapy drug called carboplatin which he administers at a dose between an AUC of 3 to 5 (typical regimens for cancers that are sensitive to carboplatin use a dose between an AUC of 4 to 6). In addition he uses an addition drug called MESNA that is typically used as a bladder protectant in chemotherapy regimens that use high doses of ifosfamide or cyclophosphamide. In some patients he will add an additional chemotherapy drug called gemcitabine. In Ontario, these drugs are funded by the Ministry of Health via Cancer Care Ontario when administered according to practice guidelines by appropriate practitioners. It appears that in this scenario, patients are paying for the drugs themselves and receiving them in a private infusion clinic.

Dr. Khan does prescribe some supportive drugs such as 5HT3 inhibitors and granulocyte colony stimulating factor. There are guidelines that help physicians determine their appropriate use. Routine blood work is collected prior to each cycle including complete blood count and basic biochemistry. Tumour markers do not appear to be routinely measured. Routine imaging to determine response is not routinely ordered. On some patients, blood is sent to a laboratory in Germany for assessment of circulating tumour cells.

It is not clear who else makes up Dr. Khan's team. There does appear to be a close relationship with a doctor of naturopathy. He does appear to seek advice from Dr. Kenneth Matsumura.

There is no documentation recording patient outcomes following the last treatment they received.

Patient YP DOB 07/05/1955

- i) Physicians must always act within the limits of their knowledge skill and judgment and never provide care that is beyond the scope of their clinical competence.

Cytotoxic chemotherapy is typically prescribed by physicians trained in medical oncology, malignant hematology or gynecology. In situations where chemotherapy is prescribed by non-oncologists (general practitioners oncology or family physicians in rural settings) this is done under the direct supervision of an oncologist. The prescription of carboplatin by an individual not specifically trained to do so is odd. Furthermore, although Mesna is a drug used to prevent cystitis caused by drugs such as ifosfamide or cyclophosphamide. It is unclear what its role given in combination with carboplatin would be.

- ii) All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science

There was a conventional diagnosis of metastatic liposarcoma and the statement that there were limited treatment options was correct. The patient had received a number of standard options and appears to have participated in and been considered for clinical trials. History appears to have been obtained by a self completion questionnaire but a physical examination appears to have been done.

Although blood work was ordered by Dr. Khan, there is no evidence that he ordered imaging. There is no specific laboratory measure such as a tumour marker to be used to determine response. As sarcomas typically are followed by either imaging or in some cases clinical examination, it would have been difficult to assess whether the treatments prescribed were efficacious or not. Furthermore, there is no clinical documentation by Dr. Khan as to whether the patient was tolerating the regime. The patient also indicated that he wished for communication between Dr. Khan and his oncologist and family physician. There is no evidence that this actually occurred.

- iii) Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

The consent appears to be valid with a list of potential side effects of treatment and a disclaimer about efficacy.

Patient TM DOB 30/05/1969

- i) Physicians must always act within the limits of their knowledge skill and judgment and never provide care that is beyond the scope of their clinical competence.

Comments stated above apply here.

- ii) All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science

The patient had received standard treatment for metastatic colorectal carcinoma. There had been evidence of progression of disease and further chemotherapy had been recommended by the patient's medical oncologist. It appears from the history that the patient had decided to pursue a course of naturopathy including mistletoe, hyperbaric oxygen, high dose vitamin C. The patient had a CT scan performed after six months of this treatment demonstrating significant progression. The patient was seen by Dr. Khan, who sent information to the patient.

There is no evidence that the patient had any radiologic investigations performed to determine treatment efficacy of the SAFE chemo. Nor were serial CEAs ordered.

- iii) Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

Dr. Khan's comment was that the patient had "limited options" but did not state what these options were and that these options were in fact evidence supported.

Patient FH DOB 16/07/1966

Patient FH was a 47 year old woman with a remote history of cervical cancer who presented with bilateral ovarian masses. She underwent resection of the disease and her case was discussed at a multidisciplinary case conference. Based on the pathology and the elevated CA125, a diagnosis of ovarian carcinoma was made.

- i) Physicians must always act within the limits of their knowledge skill and judgment and never provide care that is beyond the scope of their clinical competence.

Patients with ovarian cancer are typically managed in a multidisciplinary team consisting of gyne-oncologists, medical and radiation oncologists. It is not clear that the physician understands the management of chemotherapy side effects in that he actually was using Mesna to combat neutropenia. The means to combat neutropenia is either dose reduction or use of filgrastim.

- ii) All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science.

Dr. Khan consistently referred to the patient as having metastatic cervical cancer whereas the diagnosis was demonstrated to be metastatic ovarian cancer. Furthermore there was no discussion as to what the systemic treatment of a newly diagnosed patient with ovarian cancer is. Standard assessments of response to this cancer would be monitoring of CA125 and imaging (neither done). He did refer her appropriately when she developed a deep vein thrombosis.

- iii) Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

The consent states that the patient has been offered "generally accepted medical treatments of my cancer" but there is no documentation as to what was offered and what the patient refused. In the initial assessment there is the statement that the patient is looking for aggressive therapy that has potential for remission e.g. SAFE chemo." Aggressive therapy in the first line would typically consist of a taxane/platinum doublet. There is no evidence that this was discussed. The combination of carboplatin and gemcitabine is second line option. Typically a patient with metastatic ovarian cancer would have been followed by serial CA125 testing, but despite multiple laboratory testing this was not ordered. I assume the improvement in "markers" refers to the patient having response to treatment being assessed by measurement of circulating cancer cells which remains in the realm of experimental.

Patient JF DOB 29/08/1990

This is a patient with metastatic melanoma. The first note is from May 9, 2013 and I see no consultation note and can only infer that she had been treated with ipilimumab. Patient seemed to have issues with depression and body image. Patient was initially started on DCA.

- i) Physicians must always act within the limits of their knowledge skill and judgment and never provide care that is beyond the scope of their clinical competence

This patient was particularly complex with competing co-morbidities. Furthermore the patient had received treatment with ipilimumab which can have late onset toxicities. Such a patient would normally be managed in

an interdisciplinary fashion. One would worry about the use of interventions in a patient that appears to have depression and brain metastases that could have neuro-psychiatric effects such as DCA and medical marijuana. Patient was demonstrated to have bilateral ovarian metastases and yet there was a discussion about fertility preservation. Dr. Khan does not appear to have a realistic understanding of the prognosis of metastatic melanoma. Furthermore, were the patient to become pregnant, melanoma is one of two cancers that can cross the placenta and colonize the fetus.

- ii) All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science

Patient developed worsening nausea, vomiting and abdominal pain. The latter was attributed to "hunger pangs". Given history of peritoneal deposits of the melanoma, one would be more concerned about the risk of bowel dysmotility and obstruction. The physician also attributed these symptoms to the chemotherapy ("cerebral edema"). While anti-emetics such as granisetron can result in a headache, one would be concerned that progression of the known brain metastases would be far more likely explanation. The development of severe right flank pain was attributed to nephrolithiasis but progression of disease would have been a more likely diagnosis

- iii) Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

It is unclear as to whether the patient ever had a good understanding of her prognosis. Discussions about liposuction and fertility preservation in a patient with a poor prognosis seem unreasonable. Diagnoses related to changing symptoms never included the possibility of disease progression.

There does not appear to be an honest discussion as to whether Dr. Khan's treatments were working or not and in fact the patient discontinued treatment not because her disease had progressed because the treatments had failed but rather that she had exhausted her financial resources.

Patient LL DOB 02/07/1948

This is a 64 year old patient who had a triple negative breast cancer treated with lumpectomy and node dissection and chemotherapy (drugs not specified). She then had a local recurrence treated with completion mastectomy and then developed chest wall recurrence. The chemotherapy the patient received is not specified clearly.

- i) Physicians must always act within the limits of their knowledge skill and judgement and never provide care that is beyond the scope of their clinical competence

It is not clear what training this physician received with respect to the administration of chemotherapy. Dr. Khan states that the patient had limited treatment options, but given that he does not state what the patient had received in the past, it is not clear whether that statement is true.

- ii) All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science

The patient demonstrated progressive pancytopenia. This could be attributed to chemotherapy however alternate explanations must be entertained. With respect to the anemia, ongoing bleeding from the chest wall disease is certainly contributive. With the thrombocytopenia and neutropenia, bone marrow infiltration by the tumour also needs to be considered.

Cutaneous/chest wall metastases are notoriously difficult to assess in terms of treatment response. Alternative imaging and tumour markers studies might have been useful but were not ordered.

- iii) Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

There is no consistent record of what prior treatment the patient had received. There is also no discussion about what other alternative chemotherapy options might be available. Platinum-containing regimens do show efficacy in triple negative disease and would have been an option from her medical oncologist. She might have also been eligible for a clinical trial.

Patient AY DOB 31/08/1950

This is a sixty five year old male with non small cell lung cancer diagnosed in May 2013. The tumour consisted of a large mass in the left upper lobe and the patient received "natural therapy". He was seen by Dr. Khan in July of 2013 and received two cycles of DCA treatment. He then received SAFE chemotherapy (low dose carboplatin and Mesna) from September 2013 till April 2014 when gemcitabine was added. This combination continued until July 2014. He had two measurements of circulating tumour cells performed in December 2013 and February 2014 which were interpreted as showing a response. A CT scan requested by the patient's family physician in December 2013 demonstrated significant increase in the size of the left upper lobe lesion. On a subsequent requisition completed by Dr. Khan, it appears that he is doubtful of the veracity of the former report as he states that the patient is responding favorably to treatment and he puts the word growth in quotation marks. The report from this requested CT scan is missing.

The documentation is rather sparse. It is unclear why there was the decision to switch from DCA to SAFE Chemo and what led to the decision to add gemcitabine. In April 2014 there were requisitions for brain imaging sent to a number of institutions. It was finally performed in Guelph and demonstrated disease progression in the brain. A referral was also made to the Odette Cancer Centre in March 2014 for consideration of palliative radiation therapy. There is a notation of March 28, 2014 that Dr. Khan accompanied the patient to the appointment and that the patient had declined radiation therapy until it was "definitely required". Finally there is an undated note from Trillium in which the patient appears to now be on tarceva, dexamethasone and is being considered for a craniotomy as his condition is apparently deteriorating.

- i) Physicians must always act within the limits of their knowledge skill and judgment and never provide care that is beyond the scope of their clinical competence

The comments made in the previous assessments apply here. Typically the management of patients with lung cancer involve a team including thoracic surgeons, medical and radiation oncologists. A number of evidence supported treatments would have been available to the patient.

- ii) All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science.

There is no discussion of conventional treatment. Furthermore, the histology of lung cancer is crucial to treatment decision making. It is not mentioned whether this is squamous or non squamous lung cancer. Its EGFR/ALK mutational status is not described. It is not clear whether the patient had been seen by a medical oncologist or any cancer specialist at the outset. The use of patient imaging as an assessment tool is inconsistent. The physician's interpretation of imaging results appears to be at odds with the actual report. The use of circulating tumour cells as a means to determine response would be experimental at best. Most chemotherapy drugs (carboplatin and gemcitabine included) do not cross the blood brain barrier. Reliance on chemotherapy as a means to manage brain metastases is very risky (particularly when there is evidence that a lung primary was progressing on treatment).

- iii) Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

There is no evidence that there was a discussion of any therapeutic options other than DCA and SAFE chemo. There was evidence for a discussion around radiation therapy in one case.

Patient RPA DOB 2/12/1951

This is a patient with small cell lung cancer previously treated with chemotherapy and radiation. Although there is no notation of what the chemotherapy was, standard treatment would have been cisplatin/etoposide. The patient was initially started on DCA and TM. The patient received SAFE chemotherapy from December 2013 till February 2014. Interestingly there was no evidence of active disease seen on chest X-rays, CT scan or abdominal ultrasound at the time treatment was commenced. The response to treatment was a reduction in circulating tumour cells.

- i) Physicians must always act within the limits of their knowledge skill and judgment and never provide care that is beyond the scope of their clinical competence.

Previous comments apply here. He should have known what treatment the patient received.

- ii) All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science.

There was no disease seen on the ordered scans. Use of circulating tumour cells would not be an appropriate means of determining whether a patient was responding to treatment.

- iii) Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

This patient may have been cured by his initial treatment. He took an unconventional approach because of fear of recurrence. He would have received approximately 6 cycles of cisplatin before. Thus he was at significant risk of developing renal impairment. Appropriate management here would have been to watch and wait. The requisitions referred to this as an experimental treatment.

Patient AC DOB 20/02/1950

This patient presented with a squamous cell cancer of unknown origin in his left supraclavicular fossa. After multiple investigations including genotyping, the primary was felt to be a lung cancer. He initially received palliative chemotherapy with carboplatin/paclitaxel. He then had radiation therapy. He then saw Dr. Khan and was recommended a course of high dose vitamin C, Misteltoe, Coriolus versicoloured, therapy in, Vitamin D, melatonin. It is not clear what the patient actually did. He was being considered for SAFE chemo, but it didn't seem to matter that the patient had already been treated with carboplatin previously.

Patient AB DOB 28/11/1959

This is a woman with triple negative breast cancer metastatic to bone and lymph nodes. There is no discussion of what treatment this patient had received in Ireland, nor a discussion of what conventional treatments might have been. It is noted that when she was diagnosed in Ireland in October 2013, capecitabine had been offered by her oncologists. Requisitions again described this treatment as experimental and made a point to determine whether lesions were necrotic or viable. Imaging demonstrated progression of the liver in January 2014 and the

patient was switched over to high dose DCA. There does not appear to be a discussion of conventional treatment.

Patient GB DOB 11/11/1967

This was a patient with non-Hodgkin's lymphoma who had previously only been treated with radiation. He had issues with renal insufficiency and anemia. He was on several natural compounds. He was advised to consult with a naturopath given the multiplicity of things he was taken. There was no discussion around conventional chemotherapy. He was recommended a regimen including DCA.

Patient WP DOB 18/08/1959

This is a 57 year old male from Alberta with metastatic pancreatic cancer. This is an incurable malignancy with evidence of improved survival/quality of life with FOLFIRINOX chemotherapy and improved quality of life with gemcitabine. He appears to not have received either treatment and there is no evidence that Dr. Khan discussed these potential options with the patient. He was initially treated with DCA and then SAFE chemotherapy. The tumour marker CA19.9 is commonly followed in addition to imaging (usually CT) to gauge response. It should be pointed out that an out of province resident would be covered for hospitalization but not for home care services. The patient did not appear to tolerate treatment very well with intractable nausea and vomiting and was described as being dehydrated on a number of occasions. Anti-emetic guidelines appear to not have been followed.

There was no pathology or notes from a referring physician. Only chest X-rays and ultrasounds were ordered. The ultrasound comments of thickening of the pancreas and evidence of cirrhosis of the liver. It is not clear that the patient ever had metastatic pancreatic cancer given no pathology, confirmatory imaging, or an elevation in CA19.9. When the patient complained of increase pain, Dr. Khan's assumption was that it represented tumour response not progression (if in fact the patient had a pancreatic cancer). In February, a calf deep vein thrombosis was diagnosed on an ultrasound ordered by Dr. Khan. It is not clear whether this diagnosis was managed.

Patient RO DOB 01/06/1978

This is a 38 year old male from Saskatchewan with a non-Hodgkin's lymphoma. It appears that she had three lines of previous chemotherapy complicated with bowel perforation. He progressed following the third line and was no longer a candidate for allogeneic bone marrow transplant/high dose chemotherapy. He had exhausted treatment options and his oncologist gave him a prognosis of one month. He was prescribed DCA treatment but it is not clear whether he started or not as there is no documentation apart from the initial consultation.

Patient LN DOB 23/07/1961

This is a 55 year old woman with glioblastoma multiforme. The patient had received combined adjuvant temozolomide/radiation at Princess Margaret Hospital and was considering continuing with adjuvant temozolomide. Dr. Khan also prescribed DCA that was administered while the patient was on temozolomide. It would be worrisome to prescribe a drug with known neurotoxicity with a patient who has had a brain tumour, has had radiation given concurrently with a drug where interactions are unknown. Typically in this situation a dialog should have occurred between the oncologist and Dr. Khan to develop a plan to monitor this situation or to even determine whether or not this was safe. The oncologist appears to have only been aware that the patient was on DCA late in the treatment course when the patient herself told him. There is no evidence of any communication between Dr. Khan and the oncologist.

Patient ML DOB 31/10/1953

This is a 63 year old male patient from New Brunswick with a diagnosis of esophageal carcinoma with evidence of liver metastasis. It does not appear that he received any form of conventional treatment nor were such options discussed by Dr. Khan. He was commenced on SAFE chemotherapy and received approximately 10 cycles give. While undergoing treatment with SAFE chemotherapy, ultrasound investigations demonstrated a mixed response of the liver metastasis. Dr. Khan also ordered ultrasounds, but they were done in different institutions and not compared. Ascites were noted in the last ultrasound and would be consistent with progression as that had not been noted in the prior scan. Dr. Khan also put in orders for home care in New Brunswick, but he should have known that he has no license to practice medicine in that province. He again referred to his treatment as experimental. Of note the patient had an emergency room visit in Toronto in which investigations demonstrated that the patient was at high risk of developing esophageal obstruction. The only communication that Dr. Khan had about this was to CCAC in New Brunswick who would have been unable to act upon this. There was communication to one of the patient's physicians in January 2014 that was somewhat misleading about the patient's response to therapy and did not mention that the patient was at risk of obstruction. In a consultation note from a palliative care physician, there is the comment that Dr. Khan had told the patient and his wife that the metastases were responding. The palliative care physician had felt that at this point the patient would have benefitted from a CADD pump but given that the patient was travelling from New Brunswick to Toronto every two weeks, that would have been impossible. The patient ultimately had a stent inserted. A feeding tube was contemplated, but the patient's ascites prevented it.

Patient AK DOB 20/04/1945

This is a 71 year old woman with a diagnosis of recurrent transitional cell cancer of the bladder. The tumour was superficial and BCG had been recommended by her urologist. In this situation, Dr. Khan was supportive of the patient speaking with the urologist about BCG and suggested adding DCA. Although Dr. Khan attributes DCA as being the reason the cancer appears to have resolved, there is not enough documentation from her other physicians to determine whether this was true. He did note that the patient had neutropenia and attributed it to the other naturopathic medications that the patient had taken. In fact myelosuppression is a known side effect of DCA.

Patient MG DOB 18/10/1960

This is a 55 year old woman metastatic lung cancer to brain, bone and liver. There is a paucity of information. There are letters to Dr. Kis in which Dr. Khan is stating that carboplatin penetrates the blood brain barrier and with the MESNA can result in a significant immunological response and thus is worried that there could be temporary swelling. There is no evidence that carboplatin penetrates the blood brain barrier to any extent and there is no evidence that MESNA is protective of carboplatin side effects, nor has an immunological effect. My concern here is that if the patient were to develop symptoms of increased intracranial pressure most likely due to progression, the normal treatment which would be high dose steroids, is being dissuaded. There is evidence of ordering an ultrasound and chest X-Ray at the beginning of treatment. The patient was assessed in an emergency department in November (the patient was continuing to receive treatment in December) due to dyspnea. Her symptoms were attributed to extensive lung metastases. Interestingly, Dr. Khan acknowledges evidence of progression but decides to continue on with chemotherapy anyway.

Patient MH DOB 27/05/1946

This is a 70 year old woman diagnosed with a high grade ovarian cancer. She was initially treated with a TAH BSO and received six cycles of carboplatin/paclitaxel. She received treatment with cyclophosphamide, gemcitabine, vinorelbine, mitomycin and 5FU from another physician. Dr. Khan did see her and contemplated SAFE chemotherapy. Given the patient's histology (clear cell) and the fact that the patient had already received carboplatin previously with rapid recurrence, it is unlikely that this drug would have been effective.

Patient HP DOB 01/06/1971

This is a 41 year old patient with an osteogenic sarcoma of the sacrum. There is no documentation of pathology but there is an indication that he had received prior chemotherapy though it is not specified what. It is unlikely that in this location, surgery would have been possible. Standard chemotherapy would have been palliative cisplatin/doxorubicin. Imaging is from April 2013 and December 2014. He received SAFE Chemotherapy from September 2013 to January 2014. There is no documentation why treatment was ended. It is unlikely that an osteogenic sarcoma that had previously been treated with cisplatin would have responded to carboplatin.

Patient BR DOB 26/07/1957

This is a 59 year old female patient with melanoma. It appears to be early stage though no pathology or information from prior consults are available. Patient apparently had been offered adjuvant interferon (which has modest benefit in the adjuvant setting). The patient had blood sent for circulating tumour cells which resulted in no evidence of malignancy. Patient was offered chelation, vitamin C. There is no evidence for this approach in the adjuvant setting. Surveillance would have been the standard approach.

Patient RB DOB 24/06/1946

This is a 70 year old male with a locally advanced, metastatic prostate cancer. He was commenced on standard hormonal therapy with good response. He was offered aggressive experimental treatment with SAFE chemotherapy. He never commenced it.

Patient HS DOB 13/12/1962

This is a 54 year old woman with a locally advanced lung cancer. She received SAFE chemotherapy from July to August 2013. The issue here is that the patient developed worsening shortness of breath while on SAFE chemotherapy. She was referred to the hospital but a letter was sent describing the chemotherapy and that worsening symptoms could be a result of the rapid response of the cancer to the chemotherapy. Instead, imaging demonstrated extensive disease with complete pacification of her right lung. There was also a pulmonary embolus. She received SAFE chemotherapy up to October. There is no documentation of why the patient stopped. Furthermore, the letter that went with the patient appears to be designed to deflect the treating physicians from assuming that the patient's symptoms are from disease progression, rather due to the success of the treatment.

Review of Email communications

Several email communications were provided. It is clear that SAFE chemotherapy can be quite toxic given the issues around dose delays due to pancytopenias and ongoing nausea and vomiting. With respect to the latter, carboplatin has significant emetogenic potential. There are both ASCO and CCO guidelines about the management of chemotherapy-induced emesis. 5HT3 inhibitors (in combination with a corticosteroid) can be useful to prevent acute emesis. His patients seemed to have issues with delayed emesis in which a corticosteroid with or without an NK-1 inhibitor would have been appropriate. Dr. Khan did not seem to follow these guidelines.

There was on email communication in which Dr. Khan dissuaded a patient from communicating with his medical oncologist. This would be counter to the need of these patients to have access to a multidisciplinary team.

There were several references to treatment decisions ultimately being made by a Dr. Kenneth Matsumura. This is the individual who developed the chemotherapy regimen used by Dr. Khan. This individual appears to be a

family physician in the United States and it is not clear what his expertise in oncology is. There was no documentation on what information was exchanged with Dr. Matsumura.

Summary

- i) Physicians must always act within the limits of their knowledge skill and judgment and never provide care that is beyond the scope of their clinical competence

As stated previously, systemic anti-cancer therapy (which includes but is not limited to chemotherapy) should be administered and supervised by physicians with the appropriate training (medical oncologists, malignant hematologists, gyne-oncologists) or those physicians who work under their supervision. Dr. Khan does not seem to have a good understanding of the drugs that he prescribed, both in terms of indications or side effects. He overestimates the ability of chemotherapy to cross the blood brain barrier. He seems to receive direction from Dr. Matsumura, who appears to be a family medicine trained physician in the United States. There was a lack of adherence to well established, evidence based guidelines with respect to both cancer treatment and use of supportive treatments (growth factors, anti emetics). There was inconsistent use and interpretation of radiology and laboratory investigations.

- ii) All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science.

In the diagnosis and treatment of cancer, pathology is crucial. As we move closer to more individualized approaches to cancer therapy, knowledge as to whether specific molecular targets exist guides treatment options. In Dr. Khan's case, he has demonstrated to not have known the actual diagnosis in one patient and in others mentions the diagnosis in a most superficial way. Treatment has become more cancer site specific. There is no one size fits all in current cancer treatment as far as chemotherapy is concerned and certain drugs work better in some cancers than others. There is no chemotherapy drug that is useful across all sites, though immunotherapy through checkpoint inhibitors may be an exception (and even then we are learning that there are disease sites that do not respond such as most colorectal cancer, sarcoma etc.).

When patients develop new symptoms, oncologists need to rule out that they result from side effects of treatment and as importantly, that they do not represent disease progression and thus failure of the current treatment. In Dr. Khan's case there seemed to be a systematic avoidance of considering treatment failure and disease progression as a diagnosis (headaches implying worsening brain metastases, abdominal pain as a potential risk of bowel obstruction). There are certain situations where tumours may temporarily become bigger before becoming smaller (immunotherapies, some tyrosine kinase inhibitors) but this would not be the case with conventional chemotherapy drugs such as carboplatin and gemcitabine. There was the one patient with a letter that seemed to deflect physicians from making the diagnosis of progression. There were two instances when he dissuaded physicians from using steroids as they could negate the putative immunostimulatory action of his treatment.

His means to follow disease response was unclear. He would order chest X-rays on patients with no known thoracic pathology. Blood work ordered rarely included appropriate tumour markers. He frequently sent blood to Germany for analysis of circulating tumour cells. Interestingly the only FDA approved assay for circulating tumour cells is the Cellsearch system (the German system he used was Maintrac). At present its utility is primarily for prognosis. Even use of this system for monitoring treatment is still under scrutiny. With respect to Maintrac, it does show some promise for following treatment response however it has been studied only in breast cancer (two studied) and thus its applicability to other cancers is unknown. Dr. Khan also did not seem

to follow patient's symptoms as a means of determining clinical response, but rather always interpreted almost any symptom as representing a positive response.

There is no documentation as to patient outcomes following treatment. Given purported goal of cure or disease stabilization with these patients, notes about well follow up are conspicuously missing.

- iii) Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

Typically in discussions with treatment options with patients, efficacy (likelihood of response and what response may mean—longer survival, better quality of life) and potential side effects are discussed. Since this information is gleaned from clinical trials numerical data can be shared with patients as well as the important task of explaining what the clinical significance really means. There is no evidence in any of the material presented that these discussions occurred. Patients were given information about the side effects of the drugs used by Dr. Khan (using the CCO drug information sheets) but there is little discussion as to what the outcome was expected to be nor the evidence that would support it. I saw no evidence that Dr. Khan discussed any standard treatment options or referred/communicated with oncologists with the one exception of a radiation oncology referral.

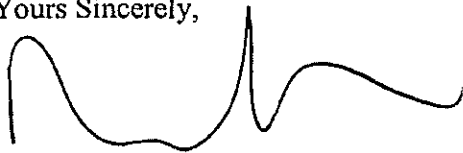
It is also interesting that Dr. Khan was using OHIP palliative care billing codes. There is little evidence that he presented his course of treatment to patients as being palliative. There was no evidence of end of life planning and there was inconsistent management of symptoms such as pain, dyspnea etc. It seems inconsistent that a physician who is treating patients with a regimen that he claims to have a high success rate for cure, would bill these encounters as palliative. Furthermore there was no obvious communication back to family physicians and others who would be responsible ultimately for these patients.

On many occasions he refers to his treatment as aggressive, experimental chemotherapy. If use of a treatment is deemed experimental, it must then be scrutinized very closely. There are very strict guidelines about human experimentation that fall under international guidelines. These are usually done in academic settings with physicians trained in clinical trials. Trials have to be submitted to research ethics boards for review. There are strict guidelines with respect to informed consent, record maintenance, patient monitoring etc. None of this seems to apply to Dr. Khan.

Thus with the information provided, Dr. Khan does not appear to be practicing in accordance to CPSO Policy Statement #3 – 11.

If you require any further information please feel free to contact me.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Richard Tozer', with a stylized, flowing script.

Dr. Richard Tozer BSc(Hon) PhD MD FRCPC
Chief of Oncology, Hamilton Health Sciences
Associate Professor, Department of Oncology, McMaster University
Medical Oncologist