Report

Inspectorate Public Health, Social Development and Labor

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INSPECTORATE REPORT

Dossiername and number: [redacted] - IVSA/02-2016

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Investigator(s): [redacted]

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Content

1. Introduction

2. Inspection Findings

3. Conclusions

4. Measures

5. Annexes
    1. Media articles
    2. Email request to SMMC and response
    3. Port- a- Cath procedure and X-ray report
    4. X-Thor – CT Thorax and ER notes
    5. Letters Dr. [redacted]
    6. Assistance request Inspectorate Curacao
    7. SEHOS Curacao: Radiology report – Letter Internal Medicine - Progress notes
    8. Result re-evaluation CT-scan July 25th 2016

1. Introduction

On October 20th 2016 an article was published online on SMN news.

EXCLUSIVE: Breast Cancer patient almost died at the hands of Dr. Luc Mercelina, place port catheter in patient lungs instead of heart.

This article refers to a patient who had been flown out urgently to Curacao due to complications caused by a mal positioned port-a-cath for chemotherapy. According to the article this catheter was placed by [redacted] and his competency was questioned after being out of practice for almost three years.

The Inspectorate considered this article a very serious matter not only because of the serious accusations made therein but also because of the possibility of medical errors committed that might have serious implications for the patient which had not been reported to the Inspectorate by the SMMC. The Inspectorate immediately requested the SMMC officially to provide more information on October 20th, 2016.

On October 21st, 2016, the SMMC sent out an official press release stating that [redacted] was not involved in the placement of the port-a-cath, that such a case is not known nor that any complaint has been filed *(Annex 1).*

The Inspectorate received an official response from the SMMC on the inquiry on October 21st, stating that [redacted] has never performed a port-a-cath procedure in the SMMC since his return and that it was unable to provide any detailed information as the article nor the inquiry mentioned the patient's name *(Annex 2)*.

The Inspectorate traced the name of the patient concerned through its contacts in Curacao and provided this information by e-mail to the SMMC on October 21st, 2016. In addition, it requested the complete patient file from the SMMC. The file was delivered on October 24th, 2016.

Relevant medical information was requested from Curacao as well and received on October 25th *(Annex 7)* and November 23rd, 2016.

In addition the Inspectorate requested a re-evaluation of the two [redacted] made in the SMMC on July 25th and August 12th by external radiologists *(Annex 8)*.

3. Conclusions

Summary

I. The port-a-cath procedure was not performed by [redacted], but by [redacted].
II. A malposition of the catheter is a known complication of this procedure. However this was never suspected nor recognised during the 2 months the patient visited the SMMC regularly with symptoms and was also admitted;
III. It can be concluded that the malposition of the port-a-cath due to a [redacted] [redacted] [redacted], has existed from the day the procedure was performed and was not established in the SMMC by any of the [redacted] on the many [redacted] and was also not recognized on the two more accurate and reliable [redacted] performed with contrast;
IV. From the patient dossier and correspondence it has become clear that from the onset of the symptoms the investigation into the possible cause thereof included [redacted]. However the diagnostic procedure and analysis to exclude this had not been completed by the treating physicians;
V. Based on the radiology reports it was concluded by the treating specialists in the SMMC that the catheter was in proper position, and it was decided to continue [redacted] therapy, although there was an evident relationship between the administration of [redacted] therapeutics and the symptoms;
VI. The leaking of the administered [redacted] therapeutics has caused a severe chemical [redacted] reaction of the right [redacted] and [redacted] for which extensive [redacted] and [redacted] was needed and performed in Curacao;
VII. Patient will continue to experience the consequences of this serious complication due to a restrictive [redacted];
VIII. Although not many port-a cath's are placed in the SMMC annually and very few patients are flown out afterwards due to complications, the SMMC claimed to be unable to determine the relevant patient based on the information provided in the media and didn't acknowledge the existence of this case when asked by the Inspectorate in first instance;
IX. This case with serious complications has not been reported to the Inspectorate by the SMMC.

4. Discussion – Measures

A port-a-cath is a medical device that is used to ease the administering of [redacted] with little risk of complications. Modern imaging allows for accurate and safe insertion of the port-a-cath. Known complications may be the result of allergic reactions by some patients to the imaging dyes. There may also be an allergic reaction to medications used during the procedure. However, allergic reactions are not common.

The most common port-a-cath complications are:

- Infection
- Excessive blood loss
- Damage to vein
- Bruising
- Hematoma
- Blockage (clot or tissue growth)
- Chemical (chemo drug) irritation

When having a port-a-cath inserted, it is important that whoever is performing the procedure has experience and that the right equipment, including real time ultrasound and fluoroscopy is available. Immediately after the insertion procedure a chest x-ray is ordered, which is the common method for verifying the catheter tip position, safety of the tip, pneumothorax and kinking. [1]

Warning signs of catheter or port problems are:

- The area becomes red, swollen, painful, bruised, or warm.
- There is a lot of bleeding
- Fever
- Leaking of any fluids
- Shortness of breath or dizziness
- The catheter tube outside the body gets longer
- The catheter or port cannot be flushed with liquid. It seems blocked.

In case of symptoms further investigation needs to be conducted into possible causes. It is known that chest X-rays do no accurately assess the tip of the catheter in relation to the superior vena cava (SVC) and right atrium.[2]

(1) *Practice Guidelines for Central Venous Access - A Report by the American Society of Anesthesiologists Task Force on Central Venous Access. Copyright © 2012, the American Society of Anesthesiologists, Inc. Lippincott Williams & Wilkins.* Anesthesiology 2012; 116:539–73.

(2) *Role of chest X-ray in citing central venous catheter tip: a few case reports with a brief review of the literature. Achutan Nair Venugopal, Rachel Cherian Koshy and Sumod M. Koshy – J. Anaesthesiology Clin Pharmacol. 2013 Jul –Sep; 29(3):397-400*

Measures

1. It remains unclear why the malposition was missed on the [redacted] [redacted], which were both evaluated by the radiologist [redacted] 6 days after insertion and 3 days after the first [redacted] administration on July 25th and on August 12th.
   - Further investigation in the competency of the radiologist with advanced imaging techniques such as CT and MRI scanning will be conducted;
2. The evident relationship between the administration of [redacted] therapeutics and the symptoms was enough reason not to continue the [redacted] therapy without properly establishing the cause of the symptoms and [redacted] pathology ;
3. Not adequately following up on intended pathological analysis of [redacted] [redacted] fluid can be considered a serious omission by the treating specialists. A negative result would have led at a much earlier stage to the conclusion that the catheter tip was malpositioned.
   - Proper communication between the two main treating specialists, [redacted] [redacted] and adequate communication with the nursing staff has been lacking in this case; warning signs and symptoms have been neglected.
   - Proper record keeping is lacking. There are various patient files from different departments ([redacted]). It is not clear whether interdisciplinary case discussion has taken place as there are no notes to be found on this in the patient records received.
   - The Inspectorate will submit a complaint against the responsible specialists, [redacted], with the Medical Disciplinary Board based on the demonstrated negligence a/o incompetence which resulted in serious damage to the patient.
4. SMMC never reported this case with serious complications after the procedure performed on July 19th to the Inspectorate as a calamity.
5. Although not many cases of this nature with necessity for medevac to Curacao exist, and SMMC therefore should have been able to determine the identity of the patient the news article referred to and the Inspectorate inquired about, SMMC chose not to honor the Inspectorates information request and to deny the existence of a calamity on October 21st.
6. SMMC has not conducted an investigation into this calamity. Patient will continue to experience the consequences of these serious complications due to a [redacted] [redacted].
   - As SMMC should have reported this case as a calamity and conducted an investigation, the Inspectorate will take further action against the SMMC in accordance with its decision from March 23rd, 2016 (IVSA 104/2016).