Operational Directive

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Subject: IMPLANTATION AND RETRIEVAL OF INFERIOR VENA CAVA FILTERS

Compliance with this Operational Directive is mandatory for all public hospitals and those private healthcare facilities contracted to provide services to public patients.

This Operational Directive describes the minimum policy and procedural requirements to be followed by Western Australian healthcare facilities for patients implanted with an inferior vena cava filter.

Rationale for retrieval of IVC filters

Inferior vena cava (IVC) filters are small cage-like filtration devices that are placed percutaneously, or less commonly, surgically, in the inferior vena cava to provide protection from pulmonary embolism. IVC filter placement is commonly indicated for patients with existing venous thromboembolism (VTE) for whom anticoagulant therapy has been ineffective or is contraindicated. Filters may also be placed to prevent pulmonary embolism in trauma patients, or in patients with a high risk of VTE from an existing medical condition or surgery.

IVC filters can be permanent devices. However, the use of a retrievable IVC filter allows a device to be placed as a permanent or temporary measure. For temporary devices, retrieval is generally recommended once the indication for insertion has subsided and the risk of pulmonary embolism is considered acceptably low.

Complications associated with IVC filters, albeit rare, include device migration, embolisation of device components, perforation of the IVC, and filter fracture. An increased rate of deep vein thrombosis after long term insertion of IVC filters has also been reported. There is international recognition that further studies and systematic follow up of IVC patients are necessary to conclusively determine the long-term safety and efficacy of IVC filters. For this reason, the following requirements will apply to the use of inferior vena cava implants for Western Australian public patients.

1 US Food and Drug Administration. Removing Retrievable Inferior Vena Cava Filters: Initial Communication, 09 August 2010
Requirements for patient follow up:

- Whenever possible and clinically appropriate, retrievable implanted IVC filters should be removed.
- The clinician performing a retrievable IVC filter implantation is responsible for follow up of the patient and liaison with the clinical team to arrange removal of the device when clinically indicated*.
- The clinical record-keeping system utilised for IVC filter patients must adequately allow for patient notification and follow up.
- Annual IVC filter implantation and retrieval data, as set out in Appendix 1, is to be provided to the Office of the Chief Medical Officer by 1 March of each year.

As set out in the Operational Directive 0398/12 and the related Policy for the Release of Human Tissue and Explanted Medical Devices, it is strongly recommended that explanted IVC filters are sent to the Biomaterials and Implant Technology Section of the Bioengineering Division, Royal Perth Hospital, for examination and where required, failure analysis.

*Individual clinical departments may wish to delegate this responsibility to specific individuals.

Dr D J Russell-Weisz
DIRECTOR GENERAL
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APPENDIX 1

Inferior vena cava filter placement –
Minimum Summary Data to be provided by medical practitioner. Report may be submitted on behalf of medical practitioners by the relevant Health Service department.

Please note that to better reflect IVC filter implantation and retrieval practices, the reporting period for IVC filters implanted in any given financial year covers the period from 01 July of the financial year to 31 December of the following financial year.

Data - Table 1

1. Health Service site and department (for insertion of IVC filter)
2. Name and contact details of person submitting report
3. Year (financial)
4. Number of patients who received IVC filters during year (01 July to 30 June)
5. Number of patients who received permanent IVC filters during year (01 July to 30 June)
6. Number of patients who received retrievable IVC filters during year (01 July to 30 June)
7. Indication for IVC filter implant (# patients)
   - Recurrent pulmonary embolism despite adequate anticoagulation
   - Recurrent deep vein thrombosis despite adequate anticoagulation
   - Pulmonary embolism with contraindication to anticoagulation
   - Deep vein thrombosis with contraindication to anticoagulation
   - Large pulmonary embolism
   - Filter placement during catheter-directed lysis of pulmonary embolism
   - Prophylaxis - major trauma
   - Prophylaxis - pre surgery
   - Prophylaxis - deep vein thrombosis
   - Prophylaxis - during endovascular treatment of deep vein thrombosis
   - Prophylaxis - post surgical embolectomy for massive pulmonary embolism
   - Other - please describe in report
8. Number of patients who received retrievable IVC filters during year (01 July to 30 June) with IVC filters removed by 31 December (of the following financial year)
   - with retrieval performed by reporting department within 90 days post-implantation
   - with retrieval performed by reporting department after 90 days post-implantation
   - with retrieval performed at another hospital
9. Number of patients with IVC filters removed by reporting department by 31 December (current reporting period) following implantation at another hospital*
10. Number of patients who received retrievable IVC filters during year (01 July to 30 June) with IVC filters *not* removed by 31 December (of the following financial year) as:

- IVC filters deemed permanent following consultation with referring clinician
- retrieval attempted but unsuccessful (filter left in place)
- non responsive/lost to follow up
- patient returned overseas
- patient died
- patient scheduled for follow up after 31 December of the following year

11. Further comments (optional)

**Data - Table 2**

1. Number of patients who received retrievable IVC filters during previous financial year (01 July to 30 June) scheduled for follow up after 31 December of the following year:

- with IVC filter retrieved by Dec 31 of following financial year’s reporting period
- with IVC filter retrieved at another hospital in subsequent reporting period
- with IVC filters deemed permanent following consultation with referring clinician
- with retrieval attempted but unsuccessful (filter left in place)
- non responsive/lost to follow up
- patient returned overseas
- patient died
- other – please specify

* Please ensure patients are only accounted for in a single reporting period

Summary data for the financial year should be sent by 1 March of the following year to:

The Office of the Chief Medical Officer
PO Box 8172
Perth Business Centre
Western Australia 6849

health.wa.gov.au
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