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ONCOLYTIC VIRUSES RISK AND CONTROL ASSESSMENT: TALIMOGENE LAHERPAREPVEC EXPERIENCE

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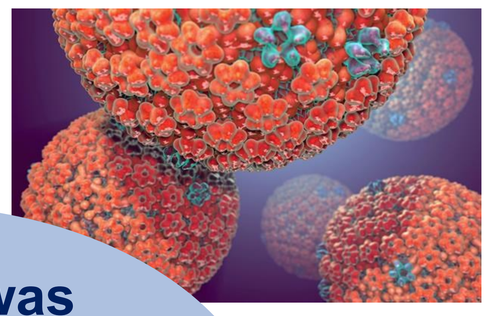
The Oncolytic virus (OV) **Talimogene Laherparepvec (T-VEC)** is a Microorganism Genetically Modified (MOGM), since it is genetically engineered to no longer be capable of causing infection or of spreading in normal cells.



Even if it was considered to have a minimal exposure risk, is there the need to take control measures?

Purpose:
Implementation of the **shared procedures**, already created for appropriate management of OV, for T-VEC management, in CT for **squamous-cell head-neck carcinoma (SCHN)**, between **Pharmacy Clinical Studies ward** and **Head-neck ward** in our Oncology Institute, and evaluation of the **risk of possible contamination** at every step of operation conducted following the procedures.

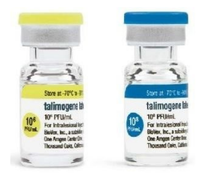
Material and method:
The Internal Hospital Procedure of IMP Management, study protocol, national and european law for MOGM-type-2 (conteniment-level-2) management and revision of literature were examined. For each category of personnel involved, with the specific roles established, was documented every step of operation conducted.

ACTIVITY LEVELS:

Results:

Pharmacy-Clinical Studies Unit

- Receipt and control
- storage (under-80°C) and use of individual protection devices (IPD)
- guidelines for preparation, operation control, instruction operation and decontamination (sodium hypochlorite)
- transport in specific box



INTERSECTION LEVEL

Head-neck carcinoma Unit-Clinical research nurses

- Product preparation: the operation was conducted separately from others in a specific vertical-flow biologic-safety-cabinet, always in double and documented (date, time, signature).
- Product administration: the operation was in a specific one-patient-room separated and before eventual concomitant therapy (pembrolizumab)

Hygiene Unit

- Management of residual vials, medical devices and IPD.
- These actions permitted to separate instruments used in previous steps and to avoid using the same autoclave available in hospital for sterilization.

None exposure of personnel and patients or contamination of other IV products, included chemotherapy, was detected with this procedure

Conclusion:
Handling OV as hazardous drugs in a coordinated method minimized the risk of exposure and therefore the risk of contamination. Furthermore being aware in the future of the symptoms associated with infection due to virus will help in monitoring for possible exposure.

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