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.

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 (containment-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.

Results:
• 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

• 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)
• 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.

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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