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Experts release new guidelines for studies into most effective treatments for HPV-positive throat cancer

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Heightened caution is needed when considering de-escalation trials for patients with Human papillomavirus (HPV)-positive oropharyngeal cancer (OPC), to ensure minimal harm to patients, new guidelines from a group of international head and neck cancer experts have suggested.

HPV-positive oropharyngeal cancer is a cancer of the throat caused by the human papillomavirus—a common, but symptomless group of sexually transmitted viruses. Instances of many throat and neck cancers have declined as smoking rates have fallen, whereas HPV-positive OPC has increased, largely affecting younger patients.

The standard course of treatment for this disease is a combination of cisplatin (a common chemotherapy drug) and radiotherapy. The younger age of the patient population, significantly improved prognosis, and relatively minimal morbidities caused by the standard treatment pathway have led to the popularisation of the concept of treatment de-escalation as a way to improve the quality of life of patients by reducing dosage or frequency of treatment.

These new recommendations, published today in the *Journal of Clinical Oncology* have been created by the Head and Neck Cancer International Group, a group of experts from nineteen countries, led by the University of Birmingham, UK. The guidelines have been prompted by the recent results of the first three randomised de-escalation trials which suggested

a clear detriment in survival when cisplatin is omitted or substituted to minimise side effects.

After a review of available HPV-positive OPC literature, the guidelines recommend an overall need for caution when considering de-escalation options, even in instances where there appears to be possible favourable disease outcomes. Experts also recommend a revised approach to how findings are evaluated during phase II studies to ensure that any potential risks to survival are identified and only if none are present should phase III trials follow.

The guidelines also recommend that de-escalation trials should only be considered for well-defined, very low risk groups and only when there is a strong rationale for investigating a particular treatment strategy. Additionally harm-minimisation techniques should be considered as an alternative. Importantly, treatments should not be implemented into clinical practice before high level evidence is available.

Corresponding author Professor Hisham Mehanna, Director, Institute of Head and Neck Studies and Education (InHANSE) at the University of Birmingham said: "Clinicians and researchers have to be careful when planning and undertaking de-escalation studies, as trials to date have that harm can befall patient. Very controlled and small strides need to be taken when evaluating a possible de-escalation strategy, especially one that removes cisplatin."

More information: Hisham Mehanna et al. De-Escalation After DE-ESCALATE and RTOG 1016: A Head and Neck Cancer InterGroup Framework for Future De-Escalation Studies, *Journal of Clinical Oncology* (2020). DOI: 10.1200/JCO.20.00056