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## Core Outcome Research Measures in Anal Cancer

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Dear Sir,

We would like to draw the readership to the problems associated with outcome heterogeneity in clinical trials, with particular reference to anal cancer. Outcome heterogeneity, and the related issue of reporting outcome bias, is a barrier to evidence synthesis [1] [2], particularly in rare diseases where few randomised trials are published. A recent review [3] of trials of chemoradiation for anal squamous cell carcinoma (ASCC) highlights the heterogeneity observed in reporting outcomes and calls for the development of a core set of outcomes.

A core outcome set (COS) is a standardised set of outcomes that should be measured and reported in all trials in a particular health area, the benefits of which are increasingly recognised by research funding bodies, regulators and journal editors, via the work of the COMET Initiative (Core Outcome Measures in Effectiveness Trials). The European Medicines Agency recommends COS use in asthma trials [4], and the UK National Institute for Health Research recommends inclusion of established COS in health technology assessment proposals.

A retrospective review of the outcomes used in phase III randomised trials in ASCC trials [3] is a first step towards developing a COS, but on its own fails to represent the priorities of all stakeholders, especially patients. The included trials were all designed over a decade ago and capture only sparse late effects and quality of life data. The focus in such retrospective reviews is often on how outcomes should be defined and measured. However, it is vital to additionally consider what should be measured, considering the priorities of all stakeholders. Having a clearly defined and reproducible outcome measure has limited value if the outcome in question is not important to patients.

COMET recommends that COS development utilises rigorous consensus methods involving relevant stakeholders. The CORMAC (Core Outcome Research Measures in Anal Cancer) project [5] has been set up to develop a COS for ASCC using the COMET methodological framework [6]. A primary information gathering phase will be followed by a consensus phase, with patients and

health care professionals involved at each stage. An up-to-date systematic review will identify all outcomes used in all trials, observational and qualitative studies published up to January 2016 [5]. This outcomes list will be supplemented by outcomes identified as important to patients through a series of semi-structured patient interviews. The complete outcome list will populate an international Delphi process involving patients, health care professionals and trialists. The final COS will be agreed at a consensus meeting in September 2017.

## References

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