Author's response to reviews

**Title**: Impact of Comprehensive Geriatric Assessment on Survival, Function, and Nutritional Status in Elderly Patients with Head and Neck Cancer: Protocol for a Multicentre Randomised Controlled Trial (EGeSOR)

**Authors:**
Lydia Brugel (lydia.brugel@chicreteil.fr)
Marie Laurent (marie.laurent@ach.aphp.fr)
Philippe Caillet (philippe.caillet@hmn.aphp.fr)
Anne Radenne (anne.radenne@hmn.aphp.fr)
Isabelle Durand-Zaleski (isabelle.durand-zaleski@hmn.aphp.fr)
Michel Martin (michel.martin@chicreteil.fr)
Melany Baron (melany.baron@chicreteil.fr)
Heloise DE Kermadec (eloise.dekermadec@chicreteil.fr)
Sylvie Bastuji-Garin (sylvie.bastuji-garin@hmn.aphp.fr)
Florence Canoui-Poitrine (florence.canoui-poitrine@hmn.aphp.fr)
Elena Paillaud (elena.paillaud@hmn.aphp.fr)

**Version:** 6  **Date:** 11 March 2014

**Author's response to reviews:** see over
Dear Editor,

Please find attached the manuscript “Impact of Comprehensive Geriatric Assessment on Survival, Function, and Nutritional Status in Elderly Patients with Head and Neck Cancer: Protocol for a Multicentre Randomised Controlled Trial (EGeSOR)”, which we are submitting for publication in *BMC Cancer*.

Survival is poorer in elderly patients with head and neck squamous cell carcinomas [HNSCCs] than in younger patients. Possible explanations include a contribution of co-morbidities to mortality, frequent refusal of standard therapy, and the use of suboptimal treatments due to concern about toxicities. The Comprehensive Geriatric Assessment [CGA] is a multidimensional assessment of general health that can help to customise treatment and follow-up plans. The CGA has been proven effective in several health settings but has not been evaluated in randomised studies of patients with cancer. The aim of this study protocol is to assess the impact of the CGA on overall survival, function, and nutritional status of elderly patients with HNSCC.

EGeSOR is an open-label, multicentre, randomised, controlled, parallel-group trial in patients aged 70 years or older and receiving standard care for HNSCC. The intervention includes four components: the CGA conducted by a geriatrician before cancer treatment, participation of the same geriatrician in cancer treatment selection, a standardised geriatric therapeutic intervention designed by the same geriatrician; and geriatric follow-up for 24 months.
We expect to demonstrate a direct clinical benefit of the CGA on outcomes of elderly patients with HNSCC. If such a benefit is found, the results of the EGeSOR trial may change the healthcare management model for elderly patients with cancer.

We confirm that we have forwarded the copies of all ethical approval and funding approval to BMCSeriesEditorial@biomedcentral.com. We have forwarded translated version endorsed and signed by Dr Christophe Bardin, head of Ethics Committee Ile de France I.

We have been awarded a grant for the study by the French National Cancer Institute (Institut National du Cancer INCa; grant INCa_6146). We confirm that the study protocol has undergone peer-review by the funding body. We confirm that the study is ongoing. This manuscript is not currently submitted for publication to any other journal. We declare no competing interests regarding this study.

Best regards,
Elena Paillaud

**Potential peer reviewers:**

Prof. Spano Philippe MD PhD : Medical Oncology Department, AP-HP, Salpêtrière Hospital, Paris VI University, 75013, Paris, France. Email: philippe.spano@psl.aphp.fr

Prof Dufour Xavier, MD PhD, Head and Neck Service, Department of Surgery, CHU de Poitiers, Poitiers cedex, France. Email: x.dufour@chu-poitiers.fr

Prof Shuman AN, Head and Neck Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, New York 10065, USA. Email: shumana@mskcc.org

Prof. Extermann Martine MD, PhD. H. Lee Moffitt Cancer Center, 12902 Magnolia Drive. MCC-SA Tampa, FL 33612, USA. Email: martine.extermann@moffitt.org