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# Applying the ESMO-Magnitude of Clinical Benefit Scale in real life

Fortunato Ciardiello,<sup>1</sup> Josep Tabernero<sup>2</sup>

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Our level of understanding of the biology of cancer at this point in time is amazing and continues to increase. Each year we know more and more about the fundamental mechanisms of tumour growth and progression of the disease.

Thanks to this improved knowledge we are able to evaluate new drugs that in some instances are very effective. We even have biomarkers that define a population of patients that may benefit more from the treatment. In some other patients we don't have such biomarkers and the benefit is only incremental. This does not mean that the treatment is not good, but the maximum effect can be considered very modest.

The European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS) offers an opportunity to grade the effect of these new drugs in each tumour and even in each indication. The tool enables us to gather important information on the real impact of any drug in the different settings in which a drug may be approved.

Using data from phase III clinical trials or meta-analyses, the tool uses a rational, structured and consistent approach to derive a relative ranking of the magnitude of benefit than can be anticipated from any new treatment. As the authors of the paper in *Annals of Oncology* in May 2015 concluded, "the ESMO-MCBS is an important first step to the major ongoing task of evaluating value in cancer care which is essential for appropriate uses of limited public and personal resources for affordable cancer care".<sup>1</sup>

Most countries determine reimbursement by considering the global effect of one particular drug in all the different tumour types and all the different indications in which the drug is approved.

The ESMO-MCBS provides real, important information on each of the indications that a drug may have in terms of efficacy and always looks for the primary endpoint which in most patients is survival, progression free survival, or disease free survival. It also balances

this information with the safety profile of the drug and the quality of life data we have from clinical trials.

The tool is currently applicable over a full range of solid tumours. ESMO's aim is to use this scale for grading any new anti-cancer drug that is approved by the European Medicines Agency (EMA) after 1 January 2016. This information will be published in *ESMO Open* and drugs with the highest scores will be incorporated into ESMO Clinical Practice Guidelines.

The American Society of Clinical Oncology (ASCO) is developing a framework for evaluating value in oncology through its Value in Cancer Care Task Force. While their work takes the cost of a drug into consideration, the ESMO-MCBS focuses on the magnitude of clinical benefit. Nevertheless, even though the cost-factor is not implemented in the scale, the ESMO-MCBS might also support decision-making within socioeconomic contexts.

The paper published in the current issue of *ESMO Open* by Kiesewetter *et al*<sup>2</sup> describes the first real life assessment of the ESMO-MCBS within a big comprehensive cancer centre. Medical University Vienna is one of the biggest and most important centres in Europe, and physicians in the Clinical Division of Oncology have applied the methodology to their daily clinical practice in treating patients.

The authors have evaluated, in an independent way, how the decisions the physicians take in Vienna correlate with the recommendations of the ESMO-MCBS. And actually they correlate very well. Interestingly, they have looked at different tumour types, namely metastatic/advanced breast cancer, lung cancer, colorectal cancer, gastric and oesophageal cancer, renal cell cancer, and prostate cancer.

Most of the decisions made by the physicians in Vienna to treat patients were those that had the best recommendation in the ESMO-MCBS. This exercise validates the use of the scale, since the decisions that were



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<sup>1</sup>Second University of Naples, Naples, Italy

<sup>2</sup>European Regulatory Affairs Unit, Italian Medicines Agency, Rome, Italy

#### Correspondence to

Dr Fortunato Ciardiello; Fortunato.CIARDIELLO@unina2.it

recommended in the scale were almost the same as the decisions the physicians took before having the scale.

The authors showed that the ESMO-MCBS is applicable in real life not only for decisions where we have predictive biomarkers, such as colorectal cancer and lung cancer, but also in decisions where we lack these predictive biomarkers like renal cell carcinoma and prostate cancer.

The medical oncologists in Vienna should be congratulated for putting this model into practice. The ESMO-MCBS is the first attempt to create a methodology that is not only qualitative but is mostly quantitative for determining the magnitude of benefit a new drug can add to a previous treatment. The study in Vienna is the first practical application of the tool and gives encouraging results. We hope that colleagues in other institutions in Europe and beyond will conduct similar analyses and share their findings and comments in ESMO Open, which as ESMO's new open access journal offers a platform for discussion and sharing.

The ESMO-MCBS is an evolving project. It will be adapted as novel therapies become available, new or more mature data emerge, and patient selection processes for targetable mutations improve. The Working Group is updating the tool to consider requirements for the evaluation of novel drugs, especially those with different mechanisms of action such as immunotherapy drugs. We have also made minor modifications thanks to the feedback we have received from cancer centres on how the scale deals with different drugs.

The ESMO-MCBS is not just an academic exercise, it is real life. The paper from Vienna shows that even treatments not listed in ESMO's field testing of the tool can be evaluated, and must be evaluated for appropriate clinical decision making. It shows the real relevance of a reproducible methodology that can be applied by everybody.

ESMO is committed to promoting the availability of cancer care to all patients and making the best use of limited healthcare resources. As stated in the ESMO

2020 Vision, the ESMO-MCBS "is a powerful tool to help clinicians choose the most effective anti-cancer medicines for their patients and to identify drugs with significant clinical benefit so they can be adopted rapidly across Europe".<sup>3</sup> The ESMO-MCBS scoring and proven reliability in this first 'real life' test bed will ultimately provide patients with more balanced information surrounding the relative benefit of the available therapeutic options.

ESMO's Public Policy Committee is evaluating models for offering the best treatment options to all patients. This task is being done by the newly created Cancer Medicine Working Group, which has two tracks. The first focuses on improving the worldwide availability of inexpensive but essential medicines. The second, which is a parallel project to the ESMO-MCBS, concentrates on expensive drugs. Here we are working on a position paper and tools to facilitate the discussion on reimbursement and payment based on value, adapted to different countries and regions.

**Competing interests** None declared.

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