

## Short communication

# Why patient recorded outcomes should be mandatory in and outside clinical trials to guide management of patients with metastatic breast cancer

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Although metastatic breast cancer (MBC) may be responsive to further treatment, it is incurable, and so improving the quality of life (QoL), not merely the length of life, is an important parameter of benefit. Patients need appropriate formal psychosocial assessment to enable identification of those who may require different forms of support in order to minimize the social and emotional impact of the diagnosis and effects of treatment. Between 31% and 57% of women with MBC will have a mood disorder that merits intervention [1,2], but oncologists are not very skilled at recognizing psychological distress and then referring patients for specialist help [3,4]. This means that patients' psychological needs may go unrecognized, underestimated and under-treated. Some countries may well have resource constraints that limit access to specialist supportive care provided by breast care nurses, trained counsellors, clinical psychologists, liaison psychiatrists and others, but a clear evidence base exists from at least five meta-analyses that demonstrates the efficacy of psychosocial interventions in adult cancer patients [5-9]. In MBC specifically, the benefits of interventions such as group support [10,11] and cognitive behaviour therapy [12] have been demonstrated. The UK and Australia have both produced national guidelines and guidance about the provision of supportive services [13,14].

Patient well being, length of life and QoL must always be the main factors that influence decisions about treatment; however, the accuracy and reliability of clinicians' assessments of well being and QoL in busy clinics is questionable. I have referred above to the difficulty oncologists have in detecting psychological morbidity; some might argue that they are trained in cancer medicine not psychiatry, but how reliable is their detection of other cancer treatment related problems that might influence a patient's well being? Studies show that monitoring of other troubling treatment-related side effects and symptoms is also rather poor when patient recorded outcomes are compared with those recorded by

physicians. Observation of oncologists working in busy clinics shows that the manner in which adverse events and side effects are recorded is not especially reliable. For example, even within the relatively tightly controlled setting of a clinical trial, the sensitivity and specificity of the detection of common chemotherapy side effects are unacceptably low [15]. Several other studies have examined the lack of congruence between patient and physician recording of side effects that have an impact on QoL; many are either underestimated or unrecognized altogether by clinicians [16-18]. This is serious because accurate recognition of bothersome side effects could influence the initiation, continuation, change, or termination of therapy, and may prompt timely instigation of other supportive and ameliorative interventions. Information from patient self-report questionnaires may provide a different viewpoint about tolerability and toxicity that is not always recognized as important by health care professionals, and accumulation and discussion of such information enables patients to make more informed choices regarding their treatment options. Some of the side-effects of treatment, especially vasomotor complaints, affect adherence to treatment even in women with advanced disease [19].

Despite the evidence supporting formal data collection, patient self-report assessments still fail to influence management decisions as much as traditional outcomes, such as tumour markers or other objective measures. This is curious given accumulating data from studies in metastatic melanoma, colorectal, lung and breast cancer that demonstrate the predictive and prognostic value of baseline QoL measurement [20]. This predictive information is independent of that derived from other orthodox measures [21]. Studies in patients with advanced breast cancer indicated that regular assessment revealed a decline in QoL scores when disease ceased to respond to chemotherapy, and again this occurred before any indications from other objective measures [22].

Collection of data from formal QoL instruments broadens the parameters of benefit beyond response and survival, and allows a more accurate determination of the supportive and ameliorative interventions that patients with MBC require. The challenge of how to convince clinicians of its value remains. Many worry about the practical difficulties of administering, scoring and interpreting QoL questionnaires, although some researchers have achieved this successfully in their own routine oncology practice [23]. Recently published recommendations from the European School of Oncology have stated the importance of thorough QoL assessment in MBC [24].

It is interesting that the practical and financial burdens associated with measuring tumour markers, despite the questionable utility of these in MBC, do not appear to have been subjected to the scepticism and scrutiny that is reserved for formal measurement of QoL variables.

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