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Development and implementation of the MammaPrint® Algorithm (MPA) to reduce chemotherapy overtreatment in South African patients with early stage breast cancer.

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Introduction: Compared to conventional risk assessment models, transcriptional profiling may reduce prescription of chemotherapy in patients with early-stage breast cancer by approximately one-third. This significant reduction prompted a South African medical insurer to subject the 70-gene MammaPrint® (MP) test to a Health Technology Assessment (HTA) in 2009. The HTA introduced a set of test eligibility criteria - the MammaPrint® Algorithm (MPA). This translational research study was undertaken to determine whether the MPA based partly on immunohistochemical Estrogen Receptor (ER) and HER2 status is appropriate for use in routine clinical practice.

Materials and Methods: The study population consisted of 72 early-stage South African breast cancer patients referred for the MP test, using a comprehensive computer-based clinical decision support system known as the Pathology Supported Genetic Testing (PSGT) service.

Results: When applying the HTA-derived MPA for determination of MP testing eligibility, 66 of the 72 patients enrolled in the study qualified. Sixty-two percent (41/66) of patients in this subgroup were classified as low risk using the MP test.

Conclusion: While the MP test classifies approximately 40% of early-stage breast cancer patients as low-risk compared to 15% using conventional criteria, application of the MPA identified more than 60% of patients subjected to the MP test as low risk. Assessment of clinico-pathological risk factors in conjunction with the MP test is an appropriate strategy to prevent overtreatment in early stage breast cancer.