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RISK SHARING IN CANCER CARE: AN ITALIAN CANCER CENTER EXPERIENCE

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Background: Economic sustainability of treatment is a problem for healthcare authorities and is linked to patients' rights to access treatment. The Italian Medicines Agency (AIFA), like other regulatory bodies, has developed reimbursement systems by Risk Sharing (RS) agreements with pharmaceutical companies.

Methods: This retrospective observational study evaluated anticancer drugs monitored by the AIFA RS program at the Cancer Institute of Romagna (I.R.S.T.) for renal cell carcinoma patients treated with sunitinib or sorafenib. The audit's aims were to measure concordance between I.R.S.T. computerized medical records and AIFA registers, to compare treated patient characteristics with those included in registry studies, and to evaluate the appropriateness of treatment prescription and disease re-evaluation timing on the basis of RS criteria. The RS program for the Italian National Health Service specified a 50% price reduction for the first 3 months of sunitinib and sorafenib, corresponding to 2 and 3 treatment cycles, respectively.

Results: 52 patients received sunitinib and 24 sorafenib. Full concordance was observed between I.R.S.T. electronic clinical forms and AIFA registers, in addition to high comparability between study populations, with the exception of a higher frequency of ECOG PS2 in I.R.S.T. patients. Disease re-evaluation was performed in 39 (75%) patients treated with sunitinib; the first was carried out as planned for 30 patients and was delayed for 3 or 4 cycles in 9 patients, 4 of whom showed progression. For 17 (71%) patients treated with sorafenib, disease re-evaluation was performed as planned with the exception of 2 patients who progressed. If the 6 patients whose treatment was delayed had been evaluated on time, the Italian NHS would probably not have had to pay the full cost of drug prescriptions.

Conclusions: The clinical audit performed was an effective tool to monitor both the prescription process and the timing of disease restaging. Such a method could help to optimize the high cost of new cancer drugs and to facilitate a more accurate selection of candidate populations.