J Health Serv Res Policy. 2006 Apr;11(2):89-93.

Managing the introduction of expensive medical procedures: use of a registry.

Grilli R, Taroni F.

OBJECTIVES: To explore how the adoption of medical innovations challenges tax-financed health systems, drawing from the case of sirolimus eluting stents, a promising and costly innovation for percutaneous coronary interventions.
METHODS: The coverage decisions for the new stents adopted in Emilia-Romagna, an Italian region, are described. The innovation was adopted through a process combining the development of clinical guidelines targeting their use to selected clinical indications, negotiation with the manufacturer for reducing price, and the organization of a registry for monitoring its patterns of utilization and assessing its effectiveness.
RESULTS: Overall, 17% of the 6276 patients included in the registry over a 12-month period had the new stent. Wide differences between published trials on sirolimus eluting stents and actual clinical practice emerged. The new stents were frequently (23%) used in combination with traditional bare metal stents, and for indications (acute myocardial infarction and multivessel coronary disease) never included in clinical experiments (25% and 8% of the cases, respectively). Patients' outcomes were also different, the overall rate of major adverse cardiac events being relatively higher (12%) than that shown in clinical trials.
CONCLUSIONS: The actions undertaken for the new stents allowed a timely, and at the same time targeted and monitored, adoption of the innovation. This experience highlights how policy decisions related to new medical products could benefit from the availability of clinical databases providing key information on how innovations are actually used and on their impact on clinical practice.