New Model for Rational Use of Medicines at Karolinska University Hospital.

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In 2012 a model for rational use of medicines (RUM) at the university hospital was suggested after many years of escalating drug expenditures, and this despite the recent drug budget devolution to hospital and clinic level. The model has since been stepwise implemented and has currently achieved budget control as well as initial steps of a structured introduction of new expensive medicines. The model, lead by the Hospital Medicines Council and implemented through a drug optimization work group operating in close collaboration with the hospital clinics, consist of several parts e.g. a) RUM at the clinic level to release resources for new drugs, b) allocating additional resources to new drugs through horizontal prioritization, and c) protocols for the controlled introduction process of new medicines. The Hospital Medicines Council and the drug optimization work group facilitate these processes and provide objective knowledge and decision support activities. These include academic detailing service to every hospital clinic with regular review and update of their drug expenditures and trends at both the in-hospital-use and prescription level. Here the focus is RUM, ie a dialogue aiming to identify savings opportunities aiding both budget control and funding of new medicines being introduced. In certain therapeutic areas, good examples of RUM are communicated through round table discussions and by comparison to peers. Strategic funds can, when available, be claimed for new drugs or indications through the Hospital Medicines Council that provides a recommendation to the Priority Council of the Hospital Board. Pivotal questions that need to be addressed in connection with these requests include type of indication, estimated number of patients, evidence for efficacy (symptoms , quality of life , survival, biomarker etc) and responder rate, cost per treated patient, and priority of the drug in national and international guidelines, by the pharmaceutical benefits agency, and by the Regional Drug and Therapeutics committee. Based on the above information, the Hospital Medicines Council review and propose horizontal prioritization of any strategic resources available to Priority Council to decide how these are keyed out on operations. Further, the prerequisites for structured introduction of new medicines include a description of the treatment decision process and follow up procedures and a treatment decision protocol including clinical criteria to fulfill for treatment. Inclusion and exclusion criteria are selected according to pivotal documentation for the approved indication, steps to avoid indication drift and uncontrolled introduction with unclear benefits/safety at an early stage. A protocol for each patient is completed, signed and sent to the Hospital Medicines Council for the go-ahead, and subsequent registration and monitoring of a continued rigorous implementation process.