

The importance of Integrated Care in the management of chronic disease. Patient Support Programs linked to drugs as tools for assistance and sources of pharmacovigilance data.

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The management of chronic diseases is a challenge for the Healthcare system of many Western Countries, due to their increase compared to acute disorders, the whole Healthcare System (HS) has taken care of for a long time. This is a consequence of increasing aging and survival of population. The management of chronic disease care is represented by both outpatient services and hospitals; this fragmentation usually causes uncertainties for the therapy patients have to comply with. The risk of a lack of therapeutic efficiency worsens the emerging problem of scarce coordination and integration of resources HS allocates. To avoid this, the model of Integrated Care is developing. It consists in the integrated management of diseases, through organized, multidisciplinary and proactive systems, focusing on patient's information and education in order to manage themselves the treatment, improving therapeutic adherence. Hence on top of new molecules, some pharmaceutical companies (PC) have developed supporting systems, especially for chronic patients, called Patient Support Program (PSP) in order to help them in their disease management. The main objective of PSP is to ensure therapeutic adherence, avoiding the treatment failure, through the involvement of health care professionals, who have to promote the patient empowerment. In addition, this support allows new sources of pharmacovigilance (PV) data because it increases the capacity of reporting any adverse events by health care professionals (HCP), who frequently keep in contact with the patients. In fact, according to good pharmacovigilance practices-Module VI, the PSP is considered as an organized system of PV data, which are actively sought by HCP and therefore are classified as solicited. At the same time, the data coming from PSP must be managed as a spontaneous report due to Italian Health Authorities requirements. This means that even if they are actively searched, only adverse drug reactions are entered into the National Pharmacovigilance Network by AIFA. The same PV data will appear in the Company database where there are all spontaneous reports that are daily forwarded to the PV department. The upload of the data coming from both PSPs and spontaneous sources in a unique database may cause some bias in the signal detection by the PV, due to the possible different completeness and medical content of the reported information. Therefore, it is important for the PV to develop an analytical approach for assessing data for a correct signals evaluation. We describe, as an example, the PSP Sanofi developed with a new long-acting insulin glargine 300 U/mL (Toujeo®), called TCoach. It has been adopted in two ongoing clinical studies in real life, investigating the efficacy and the safety of glargine 300/mL (Reach and Regain studies), in order to help patients with type 2 diabetes (T2DM) to optimize the treatment with glargine 300 U/mL, empowering them for an adequate insulin therapy initiation and long-term self-management. TCoach has been designed on the hypothesis that a support for T2DM patients should be tailored to each individual's needs and specific educational and behavioral requirements. Conclusions: Patient Supporting Programs linked to drugs are new solutions from pharma companies. They provide technological and innovative integrated services which can also improve the management

and reporting of PV data, by a recurring patient monitoring, in addition to their main objective that is to provide tailored support for improving patients care and therapeutic adherence. This could represent an example of synergy between HS and PC which can be useful not only for the individual patient, but also for public health.