Postmarketing safety of biologics and biological devices.

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Abstract:

Background context Regardless of study design, the approval process of biologics and biological devices cannot identify every possible safety concern. Postmarketing safety surveillance can provide information based on real-world use of medical products in heterogeneous populations and is critical for identifying potentially serious adverse events, events that are too rare to be detected during premarketing studies, late complications, and events involving individuals or uses that were not evaluated in clinical trials. Purpose To review why adverse event reporting is important and how the information is used, with emphasis on the points that are most applicable for surgeons and other spine professionals. Methods This is an overview of postmarketing safety surveillance. Results Review of adverse event reports has resulted in safety notifications, label changes, and publications regarding the safety of biologics and biological devices, such as the risk of airway compromise after the use of recombinant human bone morphogenetic protein in cervical spine fusion, the occurrence of a fatal air embolism after the use of a fibrin sealant that had been applied with a spray device, and infections after allograft transplantation of human tissues. Conclusions In light of the rapid development of new biologics, postmarketing surveillance is imperative for ensuring that these products are as safe as possible. By reporting adverse events, surgeons and other health care professionals play a key role in improving and refining our understanding of the safety of biologics.