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P-CHECK: A safety checklist for a chronic pain service

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The P-Check (Pain Checklist) is a patient safety tool used in our pain service for outpatient procedures. It has been created to decrease the incidence of human factors related adverse events for pain therapy procedures. It is composed by 12 items, 5 must be checked when the patient gets in the ambulatory, while 7 must be checked immediately before the procedure. The first 5 items to check are patient's identity, procedure scheduled and blood tests needed, availability of tools needed for the procedure and adverse events management, patient's awareness on the procedure, written informed consent. The last 7 items are injection site, allergy, anti-coagulation or platelet aggregation inhibitors use, hypertension or diabetes disease, correct position of the patient for the procedure, hands wash, and sterile procedure. We are going to record adverse and near misses events and compare their incidence with our data regarding these events before the P-Check use. Most of our procedures involve corticosteroid injection (i.e., facet joint or epidural), we will record the following adverse events: Abnormal hypertension (increase in blood pressure values with clinical symptoms), abnormal glycaemia (increase in glycaemia with need to change anti-diabetic therapy), bleeding during or after the injection, allergic reaction, infections in the injection site. The near misses events are: Injections performed without written informed consent, corticosteroid dose not reduced in patients suffering by diabetes or hypertension, injection in patient using anti coagulation or platelet aggregation inhibitors without the scheduled safety equipment (i.e., ultrasound machine), wrong injection site.

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Good manufacturing practices and globalization

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The term globalization was first used in 1940s. The political economist George Modelski reintroduced the term in 1972 to describe the impact of multinational cooperation on economic relations within and between countries. The concept of globalization means that countries and regions of the world come together toward policies and regulations. In other words, it is a global network where there is a better interconnection between different countries and regions. It dismantles the state barriers to trade, economic, social and politics to enhance their growth. Globalization of Good Manufacturing Practices (GMP) helps in removing the trade barriers, improve technical cooperation, improvise cost saving of testing & evaluation processes, support free market competition and information transformation. So, compliance with GMP is a necessary condition for marketing authorization because domestic and foreign producers of pharmaceutical companies cannot sell or market their drugs around the globe. While GMP compliance has not been universally adopted in the developing world, governments in less developed countries are under pressure to comply with GMP requirements when granting marketing authorizations to domestic companies and most of them have developed variety of strategies to ensure that developing countries adopt the rules. GMP requirements require major investment in upgrading manufacturing facilities and this has implications for local producers. An interesting empirical question is the impact of these changes on local markets, access to and affordability of medicines in developing countries. More importantly, pharmaceutical excipients are no longer inert materials but are effective and able to improve the characteristics of the product quality, stability, functionality, safety, solubility and acceptance of patients. Therefore, globalization of medicines supply, also enhance the importance of globalized good manufacturing practice (GMP) requirements for pharmaceutical excipients. Globalization of the medicine market motivates manufacturers especially in the developed countries to consider various pharmacopeia requirements to facilitate export of their products. In fact, globalization of the finished products supply chain elevated gradually even in the developed countries. Moreover, the current situation needs globalization of the excipients supply chain as well to improve the GMP compliance and appropriately counteract counterfeit and substandard ingredients besides lowering of the pharmaceutical excipients cost in addition to that traceability and contamination control are fundamental elements and should be revised by suppliers. Thus, Globalized Good Manufacturing Practice requirements for pharmaceutical industries are crucial to face the impact of globalized medicines supply. This study highlights the impact of globalization of good manufacturing practice (GMP) requirements for Pharmaceutical Companies.

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