

## Executive Summary

### Approaches to safe injection practice for the strengthening patient safety

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#### □ Study Background

Recently, infection and death accidents caused by the reuse of disposable syringes or the inadequateness of injection management become social problems. It commonly occurs in advanced countries such as the United States and Canada as well as Korea. In the United States, it was reported that sudden infection by hepatitis virus occurred 35 times or more for 10 years from 2000, and there were cases in which 751 patients were infected with encephalo-meningitis and 64 patients died owing to infection by steroid injections previously prepared. Moreover, in Canada, even if it was known that 70% or more of hepatitis C viral infections newly occurred are in users of injections, most doctors are not capable of providing a suitable treatment for it.

In particular, as the divided administration of injections and syringe reuse are mentioned as causes of mass infection accidents that have arisen recently in our country, it is required to figure out the current status relevant to the divided administration of injections and syringe reuse as well as the actual status of compliance with safety regulations for the administration of injections. With regard to the divided administration of injections, it can be conducted or not in accordance with injection types, such as ample and vial, as well as the maintenance of the sterile state, but the degree of education and the knowledge level of health care service providers for it are not

verified.

In addition, it is necessary to check whether safety management guidelines are fulfilled during the self-administration of patients carried out without any supervision of clinical experts. In case of self-administration, although a patient education guidebook for the use of insulin, growth hormone, and sex hormone medicines has been published, there is no guidebook for patients with rheumatoid arthritis. In case of biologics used by patients with rheumatoid arthritis as injections, as the storage and management method are difficult, and old-aged patients whose joint motion is not smooth due to the joint deformity, it is required to understand them and look into their self-administration experiences and needs in order to educate how to perform self-administration safely.

Therefore, this study was performed to give and information for the safe use of injections and management plans related to divided administration, reuse, and self-administration through exploring the current status of general evidence and perception of healthcare providers.

## **□ Study Objectives**

This study is aimed at providing information necessary to decrease adverse events caused by the use of injections, and detailed objectives are listed as follows.

- 1) Explore the existing domestic and foreign guidelines related to injections, and figure out the general guideline status for the safe use of injections.
- 2) Figure out the occurrence of adverse events related to domestic injections, and examine data resources that can be used for it.
- 3) Figure out the self-administration experiences of patients with rheumatoid arthritis.
- 4) Figure out the general management status and barriers of the safe use of injections.

## **□ Analytic Investigation of Domestic and Overseas Guidelines**

To investigate domestic and overseas guidelines, hand search that targets the Korean Medical Guideline Information Center, the Hospital Nurses Association, and the Guidelines International Network was conducted. As a result of the search, there is one guideline published by the Ministry of Food and Drug Safety and the one by Hospital Nurses Association, respectively in Korea. In case of overseas guidelines, there are two guidelines published by the World Health Organization, one by the Association for Professionals in Infection Control and Epidemiology, and one by the Centers for Disease Control and Prevention (CDC). A guideline recently published in the Ministry of Food and Drug Safety in Korea contained most comprehensively. Healthcare providers might experience confusion or be omitted from education as the range of contents differs according to each guideline. Thus, the development of guidelines adequate for domestic circumstances with regard to the safe use of injections and consistent update should be implemented, and information accessibility should be enhanced using checklists for noncompliance items.

## **□ Analytic Investigation of Reports for the Current Safety Status of Injections**

As a result of analyzing the “Complications by Injection” which were defined with the code of T80.0, T80.1, T80.2, T80.8, and T80.9 by the “Medical Statistical Information” of the Health Insurance Review and Assessment Service, there was an overall increase in the number of patients by year, the number of days of hospital visit, the number of claim cases, and the total amount of medical care expenses. In case of the number of days of hospital visit per head and medical care expenses per head as a personal unit, there was a variation in the difference according to the codes. It was shown that the Medical Statistical Information of the Health Insurance Review

and Assessment Service has a limit in figuring out causes on whether side effects are produced by the injections themselves or an error in administration.

As a result of analyzing the number of cases that report the side effects of heparin, insulin, Botox, influenza vaccine, and TNF- $\alpha$  antagonist, which are injections given through divided administration and self-administration reported in the KAERS (The Korea Adverse Event Reporting System) Database established by KIDS (Korea Institute of Drug Safety and Risk Management), the number of cases that report side effects increased annually. As a result of analyzing the occurrences of serious complications, 1,222 cases of death were also reported. Reporting case of TNF- $\alpha$  antagonist at 2013 and influenza vaccines at 2011 and 2015 dramatically increased, but their incident rate of adverse event could not be calculated as it is difficult to estimate the total number of injection use. Even if the KAERS database provide information with regard to a causal relationship with drugs and a severity of side effects, it was indicated that those have a limit in evaluating the incidence rate due to the under reports and a difficulty in figuring out errors that might result from the performance process or medication itself.

### **□ Investigation of the Qualitative Research for the Self-Administration Experiences of Patients with Rheumatoid Arthritis**

The qualitative research was conducted to look into the experiences of patients with rheumatoid arthritis about self-administration of biologics. Subjects are a total of five people, and the research involves a face-to-face in-depth interview using semi-structured questionnaire. The “PARANGSAE 2.0” of the qualitative data analysis system was used for content analysis.

The patients were experiencing difficulties in starting self-administration such as discomfort due to the joint deformity; fear of self-administration

behaviors; uncertainty with regard to the physical effects of injections, and anxiety for the accuracy of the self-administration method. Moreover, in actually performing self-administration, they experience the fear of side effects, the physical complication including pain, difficulty in managing schedule, the lack of knowledge on an infection prevention guideline, the helplessness of themselves, difficulty in discarding disused syringes, and maintaining continuous administration. Finally, they encountered a various difficult situations in conducting self-administration and concern discontinuity of treatment. With regard to such difficulties, the patients were seeking overcoming strategies such as putting up with them, asking for help themselves, changing hospital or medical team, and aggressively receiving medical service, and were considering prior education, continuous education and family education as supporting strategies, thus policy supports including prior and continuous education and family education are required.

#### Survey of healthcare providers

A survey was performed to figure out the current status related to the use of injections of experts in the clinical field and the barriers of the safe use of injection. Participants were a total of 1,000 experts working in the hospitals, and they were recruited online or off-line with the help of academic societies and associations. The questionnaire were composed of five domains, including general characteristics; practice for injections / syringes / injection needles, knowledge level of infection occurrence,; barriers for the safe use of injections; and the culture of patient safety.

As a result of the survey, 50% of participants reported that they had no education, and it was shown that the rate of incorrect answers among 9 of 13 questions for the knowledge regarding administration of injections and infection occurrence are over 30%. In addition, it was found that the absence of repetitive education and the lack of educational opportunity ranked highly

among barriers relevant to the safe injections. Furthermore, the more frequent receiving high scores in the culture of patient safety occurs, so did in the practice for the use of injections.

## **□ Management Plans for the Safe Use of Injections**

Based on this study, the following management plans were drawn. First, to secure the safety of divided administration, by reinforcing a domestically published guideline for multi-administration, it should be made more concrete and clarified, and the consistency of the administration guide and guideline should be obtained. Second, the development and dissemination of a guideline for the administration of injections, and the improvement of accessibility are required. Third, education on aseptic techniques and the intensification of reeducation should be realized. Fourth, the improvement of the patient safety culture for complying with aseptic techniques is required, and a boosting plan for the reporting learning system for the prevention of negligent accidents should be prepared. Fifth, a policy for disposing disused syringes and residual injections after use for the safe injection use of patients self-administering biological medicines for rheumatism should be prepared. Sixth, payment with regard to prior education, reeducation, and family education for self-administration should be taken into consideration.

## **□ Conclusion and Policy Proposals**

This study is significant in analyzing from various angles the current status of the safety problems of injections and the obstructive factors of safe use with various methodologies such as the analysis of claim materials and the materials for the drug side effect reporting system, the survey of target experts (doctors, nurses, practical nurses, and pharmacists), and an interview of patients. In particular, problems with regard to the safe use of injections in the domestic clinical field were extensively investigated with a survey of

experts in this study, thereby indicating that it can be a practical ground important to establish policies for the safe use of injections. Based on the results of this study, we desired to present the following policy proposals.

1. The systematic development of guidelines related to the administration of injections and the regular education of medical personnels should be made mandatory.
2. Consistent instructions and policy advertising in regard to items with a low compliance rate among the contents relevant to the administration of injections should be activated.
3. Personnel in charge with self-administration education, place and facilities standard, and payment expansion for educational programs according to subjects (personnel in charge, patients, patient family, etc.) should be reviewed.
4. Policies for the management of disused syringes after self-administration and injections to be discarded after divided administration should be established.
5. Activities for improving the patient safety culture are required, and plans that activate the reporting learning system for the prevention of negligent accidents related to the administration of injections should be prepared.

Key words: injections, patient safety, self-injection