

Full Length Research Paper

Establishment and standards for “high risk medicines” management system

Shiguang Sun¹, Xiaodi Sun¹, Qinggui Zhou⁶, Hui Yan^{1*}, Xiumin Li¹, Jie Cui², Jianfang Liu³,
Shujie Wang⁴, Lihua Li⁵ and Shoucheng Liu⁶

¹Department of Pharmacy, General Hospital of Beijing Military Region, BeiJing City, 100700, PR China.

²Information Section, General Hospital of Beijing Military Region, BeiJing City, PR China.

³Department of Pharmacy, Norman Bethune International Peace Hospital, ShiJiaZhuang City, PR China.

⁴Department of Pharmacy, 251 Hospital of PLA, ZhangJiaKou City, PR China.

⁵Department of Pharmacy, 264 Hospital of PLA, TaiYuan City, PR China.

⁶Department of Pharmacy, 266 Hospital of PLA, ChengDe City, PR China.

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The clinical, cost-effective and safe use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimizing potential harm. In this paper, we described “high risk medicines” management system designed by General Hospital of Beijing Military Region. This software has been applied in our hospital for two years, it effectively reduces risk and improves efficiency throughout the entire medication process. In short, the software is beneficial for management of some Chinese plant medicines with high side effect and toxicity.

Key words: “High risk medicines”, software, way, Chinese plant medicines.

INTRODUCTION

High risk medicines are medicines that are most likely to cause significant harm to the patient, even when used as intended (Peth, 2003; Winit-Watjana et al., 2008). The administration of medicines is an important aspect of the professional practice of persons whose names are on the Council’s register (Capleton et al., 2006). It is not solely a mechanistic task to be performed in strict compliance with the written prescription of a medical practitioner (can now also be an independent and supplementary prescriber). Herbal medicines are readily available in the market from health food stores without prescriptions and are widely used in India, China, USA and all over the world. Many commonly used herbal medicine in their irregular, high doses or with other medications in long term are toxic (Popat et al., 2001; Holmes et al., 2010; Khan et al., 2010; Özdemir et al., 2010; Ali et al., 2010). Toxic effects of herbal medicines range from allergic reactions to cardiovascular, hepatic, renal, neurological and dermatologic toxic effects. Some traditional plant medicines include radix aconite carmichaeli, curare,

Tripterygium wilfordii, *Caulis aristolochiae manshuriensis* etc (Zheng et al., 2007; Jordan et al., 2010; Chan and Ng, 1995). These plant medicines have high toxicity and side effects, and been listed in the range of “high risk medicine”. Because of careless and incorrect management of plant and chemical medicines with high toxicity, many medical negligences often occur every year. Since 1996, the Institute for Safe Medication Practices (ISMP) first put forward concept of “high risk medicine”, management is attracting the attention from people around the world (Doucette et al., 2005; Elliott, 2006). General Hospital of Beijing Military Region is building a well-developed set of “high risk medicines” system by consulting advanced experience and technology of other countries. In the article, we reported the management system.

METHODOLOGY

Establishment of “high risk medicines” management system

“High risk medicines” variety

Medicament section defines “high risk medicines” variety by consulting screening experience of “high risk medicines” at home

*Corresponding author. E-mail: yanhbdoc@sohu.com. Tel:/Fax: +86 10 66721268.

and abroad and our own hospital practical situation, and bring out and update “high risk medicines” variety through local area network of the hospital.

Propaganda and education

Hospital ensures all medical staff to learn the information regarding “high risk medicines” variety and to increase the sense of self-protection of using “high risk medicines” by some propagation channels, e.g. giving lecture and handing out data sheet which help in the following:

- (i) To encourage medical staff to put forward the suggestions of prevention of “high risk medicines”
- (ii) To establish regular and strict procurement procedure for “high risk medicines”
- (iii) To establish standardized management of storage and use of “high risk medicines”
- (iv) Information maintaining and updating, update information of “high risk medicines” in medicine management software.

Management of “high risk medicines”

Screening of “high risk medicines” variety

Consulting catalog of “high risk medicines” issued by ISMP and screening available medicines to determine “high risk medicines” variety and updating and regulating catalog of “high risk medicines” at all time.

Production of “high risk medicines” and management of the label of package

Making a mark on medicine to attract workers’ attention.

Use of “high risk medicines”

The introduction of new insulin formulations has resulted in potential risks in the care of diabetic patients. Errors may also occur from inadequate monitoring. Patients may not have blood glucose monitored at the correct frequency or before administration of insulin. Again, standardization of management may help to avoid incidents.

Storage

Registrants must ensure all medicinal products are stored in accordance with the patient information leaflet, summary of product characteristics document found in dispensed UK-licensed medication, and in accordance with any instruction on the label.

Induction and training

Medication errors are more likely to happen when new doctors arrive to work in hospitals. Only a small proportion of doctors surveyed felt that their induction dealt adequately with medicines management issues. Hospitals should therefore ensure that the induction and continuing training of all appropriate staff adequately covers prescribing practice, medicines administration and error-reporting arrangements.

Computer technology

Errors are mainly caused because the prescriber does not have

immediate access to accurate information either about the medicine or the patient. Handwritten prescriptions also contribute to errors as they may be illegible, incomplete and subject to transcription errors. Electronic prescribing reduces medicine errors significantly.

Inspection and supervision of “high risk medicines”

Doctors must know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications. For example, doctors may establish the supervision system of maximum safe dosage of medicine. When doctor dispenses a prescription to his patient, the system can automatically calculate the use dosage and frequency of medicines and make a warning when medicines exceed their safe dosage. Doctors must have considered the dosage, weight where appropriate, method of administration, route and timing you must administer or withhold in the context of the patient’s condition, (for example, Digoxin not usually to be given if pulse is below 60) and co-existing therapies, for example, physiotherapy.

Design of “high risk medicines” management software

On the basis of current medicine software and related database, high risk medicines” management software is designed. Overarching actions to reduce harm that are common to all high risk medicines and specific actions to reduce harm relating to individual medicines.

Establishment of rules

To build rules and regulations and normalize work procedure, and ensure internalization, normalization and standardization of “high risk medicines” management system. To establish the agency charged with supporting research designed to improve the quality of healthcare, reduce its cost, improve patient safety, decrease medical errors, and broaden access to essential services.

Noting development of “high risk medicines” management at home and abroad

Medical workers may pay attention to advance of “high risk medicines” management at home and abroad through internet and incorporate some useful information into science research work so as to offer effective help to science experiment.

RESULTS

Achievement of “high risk medicines” management

After executing “high risk medicines” management, medical workers’ knowledge and risk awareness about “high risk medicines” have been greatly enhanced and strengthened. As a result, disposal and prescription errors of “high risk medicines” have been greatly reduced.

Errors incidence and allocation errors incidences of “high risk medicines” are markedly ($p < 0.05$) lower than those prior to implement “high risk medicines” management. These effectively increase satisfaction rate of patients for the pharmacy service (Table 1).

Table 1. Statistic analysis between 2007 and 2009.

Item	2007	2008	2009
Errors incidence	5.4	1.8	0.0*
Allocation errors incidences	4.2	1.0	0.0*
Satisfaction rate	95.4	94.9	98.5

* $p < 0.05$, 2008, 2009 vs 2007.

Application of “high risk medicines” management software

“High risk medicines” management software is a complex system project which is jointly completed by nurse, pharmaceutical and health technology workers. “High risk medicines” management software designed by General Hospital of Beijing Military Region include dictionary service module and warehouse management module. The software may help section offices to clearly learn quantity and variety of “high risk medicines”, and nurse and health technology workers to reduce errors incidence during giving a prescription and patients to avoid taking wrong medicines during the self-administration of “high risk medicinal products”.

DISCUSSION

Since 2008, general hospital of Beijing Military Region initiate “high risk medicine” management project. “High risk medicine” management of our hospital obtains a great progress because of the project (Stuckey et al., 1994; Juarez et al., 2009). Our “high risk medicine” management software reduces risk and improves efficiency throughout the entire medication process. From the doctor prescribing, through clinical pharmacy review to medication administration by nurses, our software ensure clinical doctors prevent unnecessary patient suffering due to adverse drug events while enabling more efficient delivery of care as well as significant cost savings. Our software are underpinned by a sophisticated decision support engine that allows clinical staffs to implement their clinical business rules as an integral component of the medication management process. “High risk medicine” management still need to do a lot in the future. It need a joint effort from the whole society. For example, it needs the whole society to increase learning and understanding of “high risk medicine” and government to formulate guidance policy.

Drug manufacturers in China must be approved and issued a drug production license by the local provincial-level drug administration, and must register with SAIC by presenting the drug production license. All imported drugs must obtain a registration certificate from the State Drug Administration (SDA). Manufacturers of the imported drugs must meet the drug production and quality control

standards in the producing country as well as China’s GMP requirements (Zhao et al., 2011). There have been numerous studies in relation to the incidence of adverse drug reactions to children in hospitals (Impicciatore et al., 2001). The toxicity of certain herbal medications is well recognized on the basis of case reports (Daniels et al., 2002; Horowitz et al., 1993; Lai et al., 1990; Moore and Adler, 2000; Steenkamp et al., 2000). The incidence of toxicity in relation to herbal drug therapy, however, is unknown. A recent systematic review of the toxicity of CAM concluded that there were insufficient data to determine the incidence of toxicity of herbal medicines (Ernst, 2003). The ginkgo biloba is herbal medicine used mainly to sharpen mental focus and diabetes mellitus related circulatory disorders. The most adverse effects of ginkgo biloba are gastric irritability, headache, dizziness and spontaneous bleeding (Kobayashi et al., 2011). Ephedrine, phenylalanine are the prominent alkaloids of the ephedra plants; which contains pseudoephedrine, norephedrine, norpseudoephedrine, nmethylephedrine and phenylpropralamine. Toxic effects give signs and symptoms like hypertension, palpitation, tachycardia stroke and seizures (Gandhi and Yaqub, 2010; Satana, 2010). The dietary supplements that contain ephedra may pose serious health risk. In short, with continuous improvement of “high risk medicine” management project, medical malpractice (chemical and plant medicines) will be further decreased and people’s health will be greatly enhanced.

REFERENCES

- Ali F (2010). Use of vegetation for slope protection: Root mechanical properties of some tropical plants. *Int. J. Phys. Sci.*, 5(5): 496-506.
- Capleton AC, Courage C, Rumsby P, Holmes P, Stutt E, Boxall ABA, Levy LS (2006). Prioritising veterinary medicines according to their potential indirect human exposure and toxicity profile. *Toxicol. Lett.*, 163: 213-223.
- Chan WY, Ng TB (1995). Adverse effect of *Tripterygium wilfordii* extract on mouse embryonic development. *Contraception*, 51: 65-71.
- Daniels J, Shaw D, Atherton D (2002). Use of Wau Wa in dermatitis patients. *Lancet*, 360: 1025.
- Doucette WR, McDonough RP, Klepser D, McCarthy R (2005). Comprehensive Medication Therapy Management: Identifying and Resolving Drug-Related Issues in a Community Pharmacy. *Clin. Ther.*, 27: 1104-1111
- Elliott RA (2006). Problems with Medication Use in the Elderly: An Australian Perspective. *J. Pharm. Pract. Res.*, 36: 58-66.
- Ernst E (2003). Serious adverse effects of unconventional therapies for children and adolescents: a systematic review of recent evidence. *Eur. J. Pediatr.*, 162: 72-80.
- Gandhi M, Yaqub M (2010). 97: Energy Enhancement to Severe Toxicity Requiring a Transplant – A Case of Ephedra Toxicity. *Am. J. Kidney Dis.*, 55: B56.
- Holmes AM, Creton S, Chapman K (2010). Working in partnership to advance the 3Rs in toxicity testing. *Toxicology*, 267: 14-19.
- Horowitz RS, Dart RC, Gomez H (1993). Ji Bu Huan toxicity in children. *Colorado Morb. Mortal. Wkly. Rep.*, 42: 633-636.
- Impicciatore P, Choonara I, Clarkson A, Provasi D, Pandolfini C, Bonati M (2001). Incidence of adverse drug reactions in paediatric in/out-patients: a systemic review and metaanalysis of prospective studies. *Br. J. Clin. Pharmacol.*, 52: 77-83.
- Jordan SA, Cunningham DG, Marles RJ (2010). Assessment of herbal

- medicinal products: Challenges, and opportunities to increase the knowledge base for safety assessment. *Toxicol. Appl. Pharm.*, 243: 198-216.
- Juarez JM, Riestra T, Campos M, Morales A, Palma J, Marin R (2009). Medical knowledge management for specific hospital departments. *Expert Syst. Appl.*, 36: 12214-12224.
- Khan J, Farzand R, Ghumro PB (2010). Antibiotic sensitivity of human genital mycoplasmas. *Afr. J. Microbiol. Res.*, 4(9): 704-707.
- Kobayashi D, Yoshimura T, Johnno A, Sasaki K, Wada K (2011). Toxicity of 4'-O-methylpyridoxine-5'-glucoside in Ginkgo biloba seeds. *Food Chem.*, 126: 1198-1202.
- Lai SM, Lim KW, Wheng HG (1990). Margosa oil poisoning as a cause of toxic encephalopathy. *Singapore Med. J.*, 31: 463-465.
- Moore C, Adler R (2000). Herbal vitamins: lead toxicity and developmental delay. *Pediatrics*, 106: 600-602.
- Özdemir S, Yangilar F, Ozdemir C (2010). Determination of microbiological characteristics of Turkish Karin Kaymagi cheeses packaged in different materials. *Afr. J. Microbiol. Res.*, 4(9): 716-721.
- Peth Jr HA (2003). High-risk presentations in emergency medicine. *Emerg. Med. Clin. North Am.*, 21: 15-17.
- Popat A, Shear NH, Malkiewicz I, Stewart MJ, Steenkamp V, Thomson S, Neuman MG (2001). The toxicity of *Callilepis laureola*, a South African traditional herbal medicine. *Clin. Biochem.*, 34: 229-236.
- Satana D, (2010). Genc GE, Erturan Z. The antifungal susceptibilities of oral *Candida* spp. isolates from HIV-infected patients. *Afr. J. Microbiol. Res.*, 4(17): 1831-1835.
- Steenkamp V, Stewart MJ, Zuckerman M (2000). Clinical and analytical aspects of pyrrolizidine poisoning caused by South African traditional medicines. *Ther. Drug Monit.*, 22: 302-306.
- Stuckey B, Hounsell J (1994). Risk management in transfusion medicine: a hospital transfusion service perspective. *Transfus. Sci.*, 15: 27-35.
- Winit-Watjana W, Sakulrat P, Kespichayawattana J (2008). Criteria for high-risk medication use in Thai older patients. *Arch. Gerontol. Geriatr.*, 47: 35-51.
- Zhao L, Chen Z, Zhao Q, Wang DD, Hu R, You QD, Guo QL (2011). Developmental toxicity and genotoxicity studies of wogonin. *Regul. Toxicol. Pharmacol.*, 60: 212-217.
- Zheng FY, Li SX, Lin LX (2007). Assessment of bioavailability and risk of iron in phytomedicines *Aconitum carmichaeli* and *Paeonia lactiflora*. *J. Trace Elem. Med. Biol.*, 21: 77-83.