Quality of Cold Storage Drugs Transportation and Delivery to Thai Hospitals

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Background: *In Thailand there is no regulation and standard guideline to control the quality of drug transportation, including cold storage drugs.*
Objective: *To explore the condition of cold storage drugs transportation and delivery to general public hospitals, community hospitals and private hospitals.*
Material and Method: *This is a cross-sectional survey research. There were 301 questionnaires returned from 720 questionnaires sent (41.8% response rate)*
Results: *The serious problems of cold storage drugs on delivery were 1) Cold storage drugs (2℃-8℃) were delivered to the hospitals without controlled temperature boxes, was found in private, public and community hospitals at the rate of 46.7%, 48.3% and 72.9% respectively. 2) Cold storage drugs (-20℃,) i.e. polio vaccine came to the hospitals with a temperature higher than 8C or ice melting in the box, was found in private, public and community hospitals at the rate of 22.9%, 12.7% and 35.0% respectively*
Conclusion: *There are differences in quality of cold storage drug transportation and delivery among types of hospitals. It is highly recommended that Thai FDA should develop a standard and implement the control system for logistics management of cold storage drugs.*

Keywords: *Cold storage drugs, Logistics management, Drug delivery, Drug transportation, Problem*

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The cold storage drugs or temperature-sensitive products such as proteins, peptides, biologics, vaccines, enzymes, microorganisms, monoclonal antibodies have a short shelf life, high cumbersome storage, handling and distribution requirements, high shipping costs and need for cold storage environments[1]. Without an efficient cold chain management, many invaluable therapeutic products would be deteriorated. Logistics process of cold storage drugs was proposed by the logistic hand book and managing drug supply[2,3]. The process of logistics describes six activities of logistics process in drug management. These activities are product selection, purchasing and procurement, product receiving, inventory management, logistics management information systems, and customer service.

At every point in the chain, precautions should be taken to minimize the effect of adverse external conditions on the quality and stability of product[4]. There are many standard guidelines of cold chain management[5-11]. These various guidelines were composed of product selection, forecasting, receiving, inventory management, store management, distribution management, transport management, customer service, logistics management information services, personnel management and designing, implementing, and training programs.

In Thailand there is no regulation and standard guideline to control the quality of drug distribution and transportation, including distribution and transportation of cold storage drugs. The quality of cold chain management is under responsibility of each distributor. Problems found from a study by

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Rookkapan et al, which indicated that sub-standard deteriorated tuberculosis (TB) drugs are a serious problem for TB control. TB drugs examined in the study area were not managed properly[12].

The present research aimed to explore the condition of cold storage drugs transportation and delivery among Thai hospitals.

Objective

The present research aimed to explore the condition of cold storage drugs transportation and delivery to Thai general public hospitals, community hospitals and private hospitals.

Material and Method

This is a cross-sectional survey research. The data collection was done by a mailed questionnaire during February and April 2007. Pharmacists who were involved in receiving drugs at hospitals would respond the survey. All general hospitals with beds over 30 were included as the sample for this survey. There were 720 hospitals.

Two conditions[1,2] listed as the quality of cold storage drugs transportation condition and four the general problems[4-6] of cold storage drugs delivery claimed by hospital pharmacists were asked. They were;

Condition 1: Medicines were transported by vehicles controlling temperature in the storage compartments, < 25°C.

Condition 2: Proper amount of ice bags in the cool-box (six sides of the box).

Condition 3: Ice bags melt to water in the cool-box.

Condition 4: Cold storage drugs (2°C-8°C), *i.e.* chloramphenical eye drops, were delivered to the hospitals without controlled temperature boxes.

Condition 5: Cold storage drugs (-20°C, freezer compartment) *i.e.* polio vaccine, came to the hospitals with temperature higher than 8°C or ice melting in the box.

Condition 6: Drugs were delivered at out office hours (out of 8 am to 4 pm).

The condition 1 and 2 revealed the quality of cold storage drugs transportation condition which the expected answers should be *'Always happened'*; so other answers (sometimes and never happened) were considered problems of storage drugs transportation.

The condition 3, 4, 5, and 6 revealed the general problems of cold storage drugs delivery which the expected answers should be *'Never happened'*; other answers (sometimes and always happened) were considered problems of cold storage drugs delivery.

All questions were assessed for the content validity by experts and pre-tested by 20 pharmacists.

The data were analyzed by the application of the Statistical Package for the Social Sciences (SPSS) version 13.0. Chi-square and Fisher's Exact test were used to determine the differences among types of hospitals at p-value < 0.05.

Results

There were 301 questionnaires returned from 720 questionnaires sent, thus provided the response rate of 41.8%. It was found that 51.5% of respondents were from community hospitals (Table 1).

Overall picture of cold storage drug transportation and delivery to hospitals

Regarding the quality of cold storage drugs transportation;

1) Cold storage drugs were delivered by "Vehicles with controlled temperature (< 25°C) in the storage compartment" was "Always happened" at 43.2%, "Sometimes happened" at 33.9% and "Never happened" at 22.6%.

2) "The manufacturer or the distributors used a proper number of ice bags in cool-box, six sides of the box" when delivered cold storage drugs was reported as "Always happened". 39.5%, "Sometimes happened" at 49.2% and "Never happened" at 11.3%.

Table 1. Number of respondents classified by hospital type

Type of hospital	Number of sent questionnaire	Number of respondent	Response rate (%)
Private hospital	250	62	20.6
Public hospital	219	84	27.9
Community hospital	251	155	51.5
Total	720	301	100.0

Regarding the general problems of cold storage drugs delivery;

1) It was reported that "Ice bags melt to water in the cool-box when arrived at the hospital" as, "Always happened" at 4.7% and "Sometimes happened" at 62.8% but found only 32.6% as "Never happened".

2) It was reported that "Cold storage drugs (2°C-8°C), i.e. chloramphenical eye drops, were delivered to the hospitals without controlled temperature boxes" as "Always happened" at 26.6%, "Sometimes happened" at 35.9%, but "Never happened" only 37.2%.

3) Regarding the very important condition "Cold storage drugs (-20°C, freezer compartment) *i.e.* polio vaccine came to the hospitals with temperature higher than 8°C or ice melting in the box"; 2.7% of the respondents reported as 'Always happened 21.9% reported as 'Sometimes happened', while 65.1% reported as 'Never happened'.

4) The last situation "The cold storage drugs were delivered at out office hours (out of 8 am to 4 pm)" was reported as 'Always happened'2.3%, 'Sometimes happened' 76.1% and 'Never happened' only 21.6% (Fig. 1).

The magnitude of problems of cold storage drugs transported and delivered to different types of hospitals

Problems of cold storage drugs transportation and delivery condition among three types of Thai hospitals can be summarized as the following;

The problems of cold storage drugs transportation

1) Medicines were not transported by vehicles that controlled temperature in the storage compartments, < 25°C), was a problem in private hospitals, public hospitals and community hospitals at the rate of 43.5%, 55.0% and 61.7% respectively.

2) The manufacturer or the distributors did not use the proper amount of ice bags in cool-box, six sides of the box, was a problem in private hospitals, public hospitals and community hospitals at the rate of 69.4%, 56.4% and 59.4% respectively.

The problems of cold storage drugs delivery

3) Ice bags melt to water in the cool-box when arrived at the hospital, was a problem in private hospitals, public hospitals and community hospitals at the rate of 58.1%, 58.8% and 73.6% respectively.

4) Cold storage drugs (2°C-8°C), *i.e.* Chloramphenical eye drops, were delivered to the hospitals without controlled temperature boxes, was a problem in private hospitals, public hospitals and community hospitals at the rate of 46.7%, 48.3% and 72.9% respectively.

5) Cold storage drugs (-20°C, freezer compartment) *i.e.* polio vaccine came to the hospitals with a temperature higher than 8°C or ice melting in the box), was a problem in private hospitals, public hospitals and community hospitals at the rate of 22.9%, 12.7% and 35.0% respectively.

6) Cold storage drugs were delivered at out office hours (out of 8 am to 4 pm), was a problem in private hospitals, public hospitals and community hospitals at the rate of 77.4%, 64.6% and 83.2% respectively (Fig. 2).

Discussion

When looking at the overall picture on quality of cold storage drugs transportation, both the uncontrolled temperature vehicles and proper number of ice bags in the cool boxes were problems which will cause deterioration of drugs transported. This problem is lower among private hospitals but higher among public hospitals especially community hospitals. This is more serious because all the community hospitals

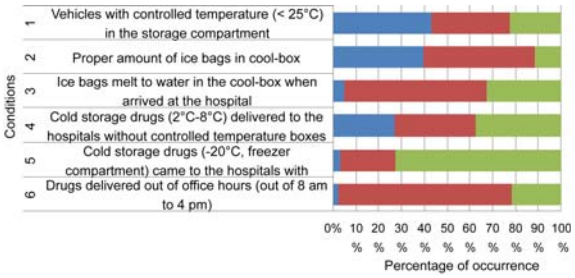

Fig. 1 Overall picture of cold storage drug transportation and delivery to hospitals

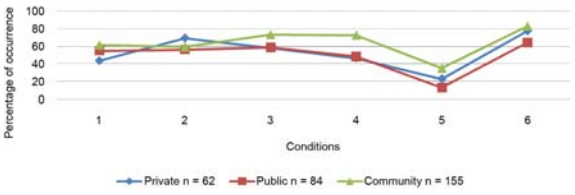

Fig. 2 Percentage of cold storage drug transportation and delivery problems classified by hospital type

are located far from cities and consume more travelling time; if the transportation condition is not well controlled, the quality of drugs will be at risk.

One problem found at delivery of cold storage drugs was ice bags melted to water in the cool-box on arrival at the hospitals, thus making the inside temperature higher than 8°C, which will cause deterioration. The potency of drug will be reduced. This statement was confirmed by the case of Chloramphenicol eye drops. The magnitude of the problem is higher than 70% among community hospitals, so the pharmacists should react to this problem.

When looking at the polio vaccine which needs a storage condition at -20°C[13], the condition on delivery was not proper. The range of problems found was 12.7%-35.0%, thus making the efficacy of this vaccine uncertain.

The differences in quality of cold storage drug delivery among types of hospitals reveal the fact that drug companies have less responsibility in logistics management. The company will put more concern for private and large hospitals. There should be an authorized organization to control the quality of cold storage drug transportation in order to assure the efficacy of drug utilization.

Conclusion and Suggestion

The present research shows serious problems of cold storage transportation; good practice guidelines were not consistency employed. It is highly recommended that Thai FDA put its effort to developing a standard and implement the control system to monitor on the quality for logistics management of cold storage drugs, as soon as possible

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คุณภาพของการขนส่งยาที่ต้องเก็บในที่เย็นและการจัดส่งยาไปสู่โรงพยาบาล

ชะอรสิน สุขศรีวงศ์, วรณัฐ บุษปฤกษ์

ภูมิหลัง: *ประเทศไทยยังไม่มีระเบียบและมาตรฐานที่ใช้ในการควบคุมคุณภาพของการขนส่งยาที่ต้องเก็บในที่เย็น*
วัตถุประสงค์: *เพื่อศึกษาสภาวะการขนส่งยาที่ต้องเก็บในที่เย็นและการจัดส่งยาไปยังโรงพยาบาลของรัฐ โรงพยาบาลชุมชน และโรงพยาบาลเอกชน*
วัสดุและวิธีการ: *เป็นการศึกษาแบบภาคตัดขวางโดยใช้แบบสำรวจเป็นเครื่องมือวิจัย จากแบบสำรวจทั้งหมด 720 ชุด คณะผู้นิพนธ์ได้รับกลับคืนมาทั้งหมด 301 ชุด (คิดเป็นอัตราการตอบกลับร้อยละ 41.8)*
ผลการศึกษา: *ปัญหาร้ายแรงของการจัดส่งยาที่ต้องเก็บในที่เย็นที่พบ คือ 1) ยาที่ต้องเก็บในที่เย็น (อุณหภูมิ 2-8°C) ถูกจัดส่งไปยังโรงพยาบาลโดยไม่มีการใช้กล่องควบคุมอุณหภูมิ โดยพบที่โรงพยาบาลเอกชนร้อยละ 46.7 โรงพยาบาลรัฐบาลร้อยละ 48.3 โรงพยาบาลชุมชนร้อยละ 72, 2) ยาที่ต้องเก็บในที่เย็น (อุณหภูมิ -20°C) เช่น วัคซีนโปลิโอ ถูกจัดส่งมาถึงโรงพยาบาลด้วยอุณหภูมิที่สูงกว่า 8°C หรือถูกจัดส่งมาในกล่องที่น้ำแข็งละลายแล้ว โดยพบที่โรงพยาบาลเอกชน ร้อยละ 22.9 โรงพยาบาลรัฐบาลร้อยละ 12.7 โรงพยาบาลชุมชนร้อยละ 35.0*
สรุป: *คุณภาพของการขนส่งยาที่ต้องเก็บในที่เย็นและการจัดส่งยาไปสู่โรงพยาบาลแต่ละประเภทมีความแตกต่างกัน ดังนั้นสำนักงานคณะกรรมการอาหารและยาควรอย่างยิ่งที่จะพัฒนามาตรฐาน และบังคับใช้ระบบการควบคุมการจัดการโลจิสติกส์ของยาที่ต้องเก็บในที่เย็น*