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Systems Thinking Approach to Visualize Problem Structure of Drug Ingestion Accidents by Infants

– Identifying its causal relationships and visualizing overall structure –

Naoshige AKITA*, Yoshitsugu MORITA* and Hisao SHIIZUKA**

** Kyushu University, 4-9-1 Shiobaru Minami-ku Fukuoka 815-8540, Japan*
akita@design.kyushu-u.ac.jp , morita@design.kyushu-u.ac.jp
*** Shiizuka Kansei Engineering Laboratory, Co., Ltd., 4-10-5 Sendagaya Shibuya-ku Tokyo 151-0051, Japan*
shiizuka@cc.kogakuin.ac.jp

Abstract: There has been no end to cases of infants opening drug containers meant for adults and accidentally ingesting them, and so it has become a social problem. The authors conducted experiments to evaluate child-resistant (CR) pill containers, which infants find difficult to open, and are also not difficult for ordinary people to use. In this paper, based on the findings of these experiments, we implemented systems thinking and interpreted human activities as an open-ended system, visualized the problem structure of drug ingestion accidents by infants, and were able to demonstrate modifications for preventing accidental ingestion by infants and matters requiring caution.

Keywords: *Systems Thinking, Visualization of Causal Relationships, Accidental Ingestion of Pharmaceutical Products, Visualization of Problem Structure, Child Resistant Pill Containers*

1. INTRODUCTION

In recent years, there has been no end to cases of infants opening drug containers meant for adults and accidentally ingesting them, and so it is a social problem. The Japan Poison Information Center collected information on accidental ingestion of medicine by children aged five years or younger between January and December 2012. Of these data, the Consumer Safety Investigation Commission conducted an analysis of 764 cases of accidental ingestion by the children themselves, including 549 cases of accidental ingestion by children aged between 1-2 years old, which accounted for 71.9% of all cases. The 871 accidentally ingested drugs included 442 tablets, which accounted for 50.7% of all accidentally ingested drugs. In addition, the types of packaging containers of the 558 drugs for which this could be confirmed were reported to be mostly Press Through Packages (PTP), accounting for 133 drugs (15.3%)[1].

Amid such circumstances, the authors have been conducting experiments considering methods for evaluating child resistant (CR) pill containers that infants find difficult to open and are also not difficult for ordinary people to use in order to develop and standardize them [2].

Firstly, the authors focused on the current state of packaging containers for preventing infants from accidentally ingesting medicine, and conducted an evaluation experiment (experiment 1) to assess the difficulty for infants to open child resistant (CR) pill containers filled with placebos that did not contain drug ingredients. A living space was recreated to identify the types of action that 15 children aged 12-36 months made while handling pill containers, and observations and analysis were performed to reveal whether the children could open the containers in order to identify the characteristics of their actions, which enabled them to open the containers based on their age [2].

Secondly, an impression evaluation experiment was conducted (experiment 2) with 15 parents of children aged 24-36 months as subjects, using various types of CR pill containers to assess their safety.

Three pharmacists and one medical writer conducted a hearing survey when defining the variables for evaluation. As a result, they were set as (i) the difficulty of extracting medicine from pill containers, (ii) the difficulty in understanding how to extract medicine from pill containers, (iii) the difficulty of the medicine coming out of the drug packaging if it is accidentally chewed, (iv) whether the drug package appears as a confectionary , (v) the likelihood of injury when handling the drug package, (vi) whether the size of the drug package is such that it would not fit into a child's mouth, (vii) the hardness of the

material so that it would be safe even if it is accidentally ingested, and (viii) overall safety.

The subjects provided scores for each assessment item on a 7-point scale and the data were processed based on these assessment results, and the level of importance and satisfaction were indicated for each evaluation variable. This was able to shed light on the subjective feelings of the parents. The variables with high importance and low satisfaction can be considered items requiring improvement [2].

Therefore, considering the findings from these experiments, the authors implemented systems thinking to provide an overview for and develop a discussion of the problem structure of accidental drug ingestion by infants in order to identify the causal relationship between accidental drug ingestion by infants and visualize the overall structure. What follows is a report on the process by which this causal relation was visualized.

2. METHODS OF VISUALIZING THE PROBLEM STRUCTURE OF ACCIDENTAL DRUG INGESTION BY INFANTS

2.1 The application of systems thinking

We live in a complicated world where a variety of elements are interrelated. Systems thinking interprets situations which cannot be completely grasped through reductionist concepts as systems, and focuses on the causal relation between the elements that constitute the system. Using this structure to understand the characteristics of how things behave and how the system is controlled, it attempts to solve issues. Systems thinking interprets all human activities as open systems, and it is characterized in considering that human behavior is constantly changing according to environmental influences [3] [4] [5].

Considering accidental drug ingestion by infants lead to the obvious finding that the overall problem cannot be completely grasped by simply making a reductionist analysis of the elements constituting the problem, analyzing each element, and understanding them.

This is because this problem occurs in a situation which is changing dynamically. The infants who are relevant individuals in this problem can be considered to accidentally ingest medicine as a result of effects from the people and environment surrounding them, by acting unwittingly amid changing circumstances. Therefore, the authors applied systems thinking to visualize this problem.

2.2 Method for creating a cause-effect digraph using systems thinking

The authors applied systems thinking using the following procedure to visualize the situation of accidental drug ingestion by infants. First, the observations in the authors' prior studies in the experiment evaluating the difficulty for infants to open the pill packaging and the impression evaluation experiment of pill packaging with parents as subjects were used to indicate elements thought to be factors relating to accidental drug ingestion accidents.

Second, the authors held a semi-structured interview of 15 parents of infants aged 24-36 months old, using question items such as (i) the things you were cautious about when your child was at an age where they would put anything in their mouth, (ii) the storage methods and places of medicine for adults, (iii) the circumstances of the infant's siblings' drug ingestion, (iv) the relationship between an infant's growth and drug ingestion. The authors identified the elements, which could be reasons for accidental drug ingestion, and then added them to a list of elements. The authors applied the KJ method to arrange these elements, and connected relationships of cause and effect among elements using arrows to create a graph (Figure 1): the KJ method is a method devised by professor Jiro Kawakita to summarize data, describing data on cards, grouping cards group by group, and so on..

When two elements connected by arrows point towards the same direction (such as when the level of one element increased and the level of the other element also increased), the relationship was indicated with a + sign. Meanwhile, when the level or quantity of two elements changed in opposite directions, this relationship was indicated with a – sign [4].

2.3 An examination of the problem structure of accidental drug ingestion by infants

Figure 1 visualizes the problem structure of accidental drug ingestion by infants using the method in 2.2. Here, the structure of the problem is explained starting from the number 1 in the figure.

(1) The parents or grandparents who are living with the infant(s) may place their own medicine somewhere that they can reach easily. (2) If the placement of the PTP becomes more accessible, the medicine will be easier to ingest in daily life for the person, and (3) the drugs will not be forgotten to be ingested. (4) If a person has less likelihood of leaving drugs without ingesting them, there is (5) less leftover medicine and PTPs are more easily organized. As a result, PTPs may be put in places which

are reachable for parents such as on top of dining tables, kitchen counters, and television tables.

Depending on where the PTPs are placed, (6) there is a higher risk for infants to reach PTPs, and (7) there are more chances for infants to open PTPs. (8) If an infant has seen a parent ingesting medicine, and (9) if the infant has had experience of eating soda pop flavored sweets (ramune), (10) the infant would recognize the content of the PTP as something edible. As a result, (11) the infant becomes more motivated to open the PTP in front of them.

Meanwhile, factors which suppress the motivation of infants also exist. For example, (12) when the infant grows up and has a better understanding of language, (13) there is better communication between the infant and parent, and (14) when the parent is highly cautious of their infant accidentally ingesting medicine, (15) the parent will explain more frequently to the infant not to touch the PTP, and (11) the infant's motivation to open PTPs may be suppressed.

(16) Infants who are highly motivated to open PTPs will attempt to open them. In such a case, (17) if an infant has already seen a parent opening a PTP, then (18) the infant may already know how to open the PTP. The infant may imitate the parent and (19) press the plastic parts of the PTP with their fingers, (20) press the aluminum sheet of the PTP, (21) bend the PTP with their fingers, and (22) press the aluminum sheet of the PTP using their fingernails. (24) These actions may sometimes be accidental, but if the infant has opened packaging for chocolate, which is structured the same way as PTPs, the infant will try to open the PTP using their previous experience.

In addition, (23) infants tend to put everything in their mouths from the age of about six months up to a certain age. If the infant chews the PTP during this age, they may open a hole in the aluminum sheet.

(25) When an infant attempts to open a PTP, the aluminum sheet of the PTP may tear (26) The PTP manufacturers sometimes strengthen the aluminum sheets to solve this problem, although (27) this could lead to the PTPs being difficult to open for ordinary people, such as the elderly people with weak hands, and (28) there is a risk of the medicine having less adherence. Therefore, (29) PTP manufacturers are developing various types of CR pill cases by taking measures such as creating complicated steps to open them.

If an infant opens a hole in the aluminum sheet, (30) he or she would pick at the hole so the chance of the PTP opening would increase, and (31) the risk of the infant accidentally ingesting the drug increases.

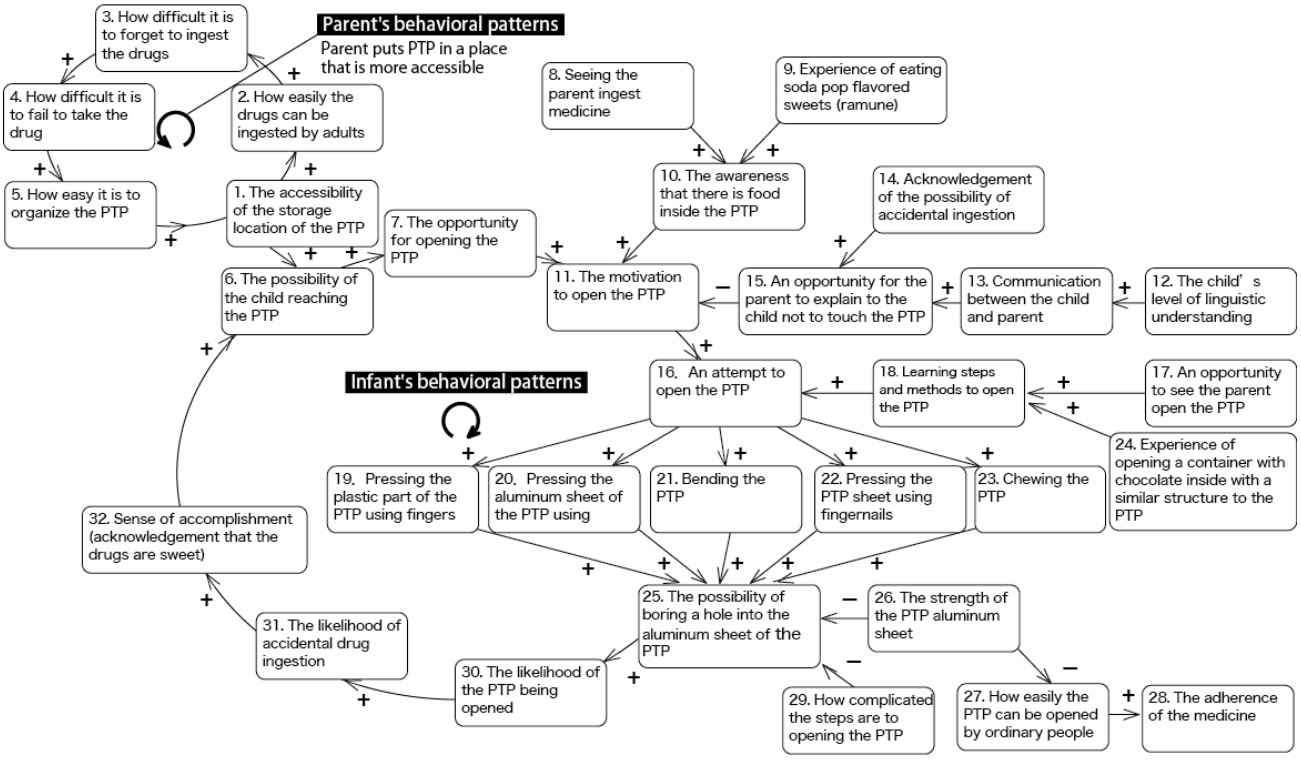

Figure 1: The problem structure of accidental drug ingestion by infants

If an infant accidentally ingests drugs, and (32) if the infant feels a sense of accomplishment and discovers the drugs taste sweet, the infant has a higher chance of reaching for the PTP again.

3. DISCUSSION AND SUMMARY

Two loop shapes can be found when observing Figure 1. The first loop figure illustrates the relation between the emotions and actions of the infant as a mental model structure. The loop indicates how the infant recognizes the situation, develops a reason to cause action, and the success in conducting this action leads to develop another reason. Therefore, this can be called a self-reinforcing feedback loop, which indicates the increasing input of feedback into the system. The other loop figure illustrates a self-reinforcing feedback loop to improve the easiness in managing PTPs. These feedback loops were confirmed to affect each other. Therefore, the parents taking precaution about where to store their PTPs is crucial in preventing accidental ingestion of their infants.

In addition, Figure 1 confirmed that various situations became factors which affected the previous feedback loop. In order to prevent accidental ingestion in particular, being cautious over the following matters are considered to be important: (i) to verbally explain to the infant not to touch PTPs, if the infant is old enough to understand words, (ii) to improve CR pill containers, (iii) not let the infant see the parent ingesting medicine, and (iv) refrain the infant from eating sweets with similar packaging to the PTP.

This paper used systems thinking to illustrate the causal relationship of elements which are related to accidental drug ingestion by infants, examine this relationship using concrete examples, and indicate measures that could be taken to prevent accidental ingestion by infants as well as precautions.

In the future, the authors hope to conduct more surveys to create a system graph capable of comprehending this issue from a broader perspective.

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