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A Discrete Event Systems Approach to Model Problem Structure of Drug Ingestion Accidents in Infants

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Abstract: There have been numerous incidents of infants opening drug packaging intended for adults and accidentally swallowing tablets, and this has become a social issue. The authors have previously carried out evaluation testing of child-resistant pill containers, which are difficult for infants to open but not difficult for ordinary people to use. Based on the findings from these tests, we have investigated the causes of the issue. In this paper, we modeled the problem structure of accidental drug ingestion by infants using the Petri Net Model approach, a discrete event system.
Keywords: *Discrete Event Systems, Petri net, Healthcare Design, Force of Object, Child Resistant Pill Containers*

1. INTRODUCTION

In Japan, there have been numerous incidents in recent years of infants opening drug packaging intended for adults and accidentally swallowing tablets, and this has become a social issue. 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 analyzed 764 cases of accidental ingestion by the children themselves. There were 549 cases of accidental ingestion by infants aged between 1-2 years old, accounting for 71.9% of all cases. In terms of the form of drugs accidentally ingested, 442 of the 871 cases involved tablets, accounting for 50.7% of all accidentally ingested drugs. In addition, of the 558 cases where the type of drug packaging could be confirmed, Press Through Packages (PTP) accounted for 133 drugs (15.3%) [1].

Given this situation, we have investigated evaluation methods and conducted experiments to evaluate child resistant (CR) pill containers, which are difficult for infants to open but not difficult for ordinary people to use, in order to support the development and standardization of such containers [2].

Firstly, focusing on the design of drug packaging to prevent accidental ingestion by infants, we conducted an evaluation experiment to assess how difficult it was for infants to open child resistant pill containers filled with placebos that did not contain drug ingredients (Experiment 1). We recreated a living space and observed 15 children aged 12-36 moths handling drug packaging. By observing and analyzing how they behaved and whether they were able to open the packaging as a result, we identified the characteristics of actions for each age group, and actions causing the packaging to be opened [2].

Secondly, an impression evaluation experiment was conducted with 15 parents of children aged 24-36 months as subjects, assessing their impressions of the safety of various types of CR pill containers (Experiment 2). By interviewing three pharmacists and one medical writer, the following evaluation items were defined: (i) how difficult it is to get the drug out of the container, (ii) how difficult it is to understand how to get the drug out of the container, (iii) how difficult it is for the drug to come out of the packaging if it is accidentally bitten or chewed, (iv) whether the package looks like 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 placed in the mouth, and (viii) overall safety. The subjects scored each evaluation item on a 7-point scale and the data were processed based on these evaluation results. By indicating the degree of importance and degree of satisfaction for each evaluation item, we were able to identify the parents' impressions. The items with high importance and low satisfaction can be considered as items requiring improvement [2].

Based on our findings from these experimental results, we identified the causal relationships involved in infants' accidental ingestion of drugs and modeled the overall structure using a Systems Thinking approach [3]. In this study, we model the problem structure of drug ingestion accidents by infants with reference to the Petri Net Model approach, a discrete event system. In this paper, we report on the process of this modeling.

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

2.1 Application of discrete event system approach to this research

A discrete event system refers to a system in which the occurrence of an event changes the state of the system, and this state drives the next event. Multiple instantaneous events may occur asynchronously in the system [4]. For example, when you come across a beautiful view on your travels, an event occurs: you press a button and take a photograph. Further events then occur: the photograph is saved on your smartphone, and if you have friends you want to share it with, you send the photograph to your friends.

In this way, certain conditions are satisfied at an arbitrary time, and as a result of these conditions being satisfied, a certain event occurs. If this event occurs, the state of the system changes; as a result, the previous conditions may no longer be satisfied, and different conditions may be satisfied. The Petri Net model was developed by German computer scientist Carl Adam Petri in 1962 as a way of modeling the interaction between such conditions and events. It has since been applied and developed by many researchers.

Drug ingestion incidents by infants are assumed to occur because the conditions causing the incident are satisfied as a result of a certain event occurring. The mechanism behind this may not be simple, but there may be a complex mechanism involving several conditions that must be satisfied discretely. We therefore decided to apply the Petri Net Model approach, a discrete event system, to model the problem structure of this issue.

2.2 Characteristics and basic structure of Petri Nets

The Petri Net is a graphic model useful for modeling systems that behave in a parallel and asynchronous manner. Unlike a static diagram like a flow chart, it is a dynamic model with black circles (●) called tokens that move around inside the relationship diagram [4].

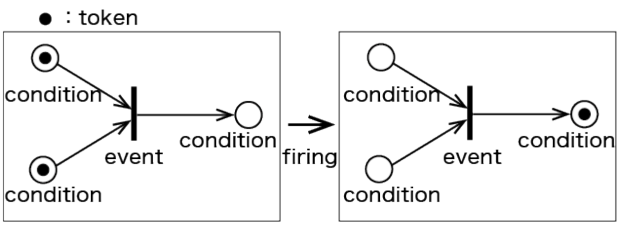

Figure 1: Basic components and firing rule of a Petri Net

Figure 1 shows the basic components of a Petri Net. Conditions are indicated by a circle, while events are indicated by a vertical bar; these two types of nodes are connected by arrows. When there is a token inside a circle indicating a condition, it means that the condition is satisfied. An event can only occur when all conditions leading to that event are satisfied. This is called firing. When an event is fired, the token moves to the next condition. This movement of tokens allows the model to express the state of the system at a certain point in time; that is, whether the system is in a state for the event to occur or not.

We will apply this Petri Net approach to model the problem structure of accidental drug ingestion by infants.

2.3 Modeling using the Petri Net approach

In our previous research, we used a systems thinking approach to propose a causal relationship diagram for the issue of accidental drug ingestion by infants. Firstly, we listed the causes of such incidents, taking into consideration the results of the studies "evaluation test on infants' difficulty of opening drug packaging" and "impression evaluation test of parents' impressions of drug packaging," reported in our previous research. Next, we conducted semi-structured interviews with 15 parents of children between 24 and 36 months old, asking questions such as "what were you cautious about when your child was at an age where they put everything in their mouth," "where and how do you store medicine for adults," "have the infant's siblings taken any medicines," and "the relationship between an infant's development and accidental drug ingestion." From the parents' responses, we identified further factors that could be causes of ingestion incidents and added these to the list of factors. We then arranged the factors using the KJ method and linked the cause and effect relationships between the factors with arrows to produce a causal relationship diagram.

In this study, based on this causal relationship diagram and leveraging our experiences observing infants' behavior in previous experiments, we modeled the process of accidental drug ingestion by infants with Press Through Packages (PTP), a common type of drug packaging, by applying the Petri Net approach (Figure 3. In this figure, conditions are indicated in green and blue, while events are indicated in black. A counter (like what is used in a board game) was used in place of a token, and the dynamic model was expressed by moving this counter.

3. DISCUSSION OF THE PROBLEM STRUCTURE OF ACCIDENTAL DRUG INGESTION BY INFANTS

3.1 System of human sensitivity (kansei) to the force of objects

In reference [5] we proposed the concept of the "force of objects." This includes the concept of affordance, proposed by perception psychologist James J. Gibson, but also has a wider meaning. Affordance refers to the "relationship between actions that exist between animals and objects," but the concept of "force of objects" also includes the relationship between the impressions a person gets from an object, such as "it is beautiful" or "it looks strong," even if no action is involved. In addition, it refers to the forces acting on the object itself because it exists even when it is not perceived by a person.

Figure 2shows the system of human sensitivity (kansei) to the force of objects, with reference to Shiizuka's diagram illustrating the modern interpretation of kansei [6]. This diagram is explained below.

Objects have forces. Humans access objects by performing various actions such as moving their limbs, moving their eyes, and breathing air, and they pick up on the forces of objects through their sensory organs. Meaning arises in the relationship between the force of the object and the person. This meaning is the meaning to that person, and it may have a different meaning for a different person. The person directly perceives the force of the object, and the result leads to the next action. Meaning is continuously generated as actions continue. Much of this meaning is unconsciously processed as information by the person. However, when the person becomes consciously aware of this meaning, the perceived information is compared against the memory and perceived linguistically or as an image. Recognition of this representamen is a thought process. Recognition is made up of perception and thought. In the thought process, perceived information is linked with memory, and deeper meaning is believed to arise through the individual's own interpretation.

3.2 Two types of conditions for events

As discussed in section 3.1, factors that cause an infant to feel something or to perform an action are believed to be "conditions concerning the force of objects" and "conditions concerning the infant's sensitivity." In other words, even if a certain force of an object is functioning, if the infant is not able to pick up on that force, the event will not occur. Therefore, in Figure 3 we have split the conditions into two types. Conditions concerning the environment or objects, such as the drug packaging, are indicated in green text, while conditions concerning the infant are indicated in blue text.

3.3 Problem structure of accidental drug ingestion by infants

Figure 3shows a model of our hypothesis of the problem structure of infants opening PTP and accidentally ingesting the tablets. (i) First, if the PTP has sufficient force to make the infant want to touch it, and the infant is old enough to be able to pick up on this force of the object and has both the physical and mental capacity to do so, then the infant will want to touch the PTP. (ii) If the PTP has sufficient force to make the infant want to open it and the infant is able to pick up on the force of the object, then the infant will want to open the PTP. (iii) If the PTP has

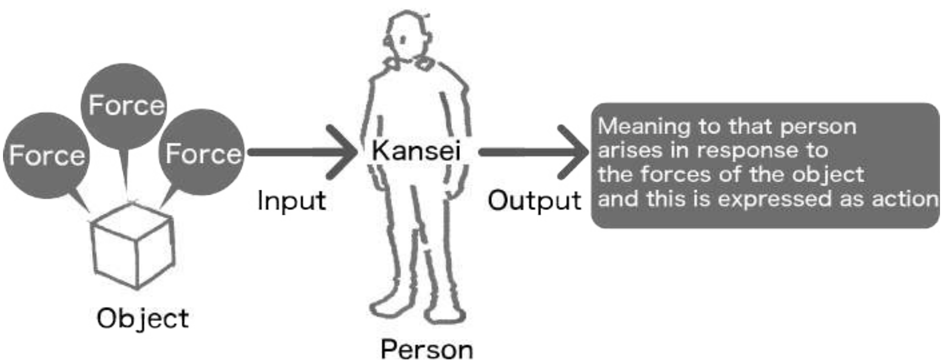

Figure 2: System of the force of an object and human sensitivity (kansei)

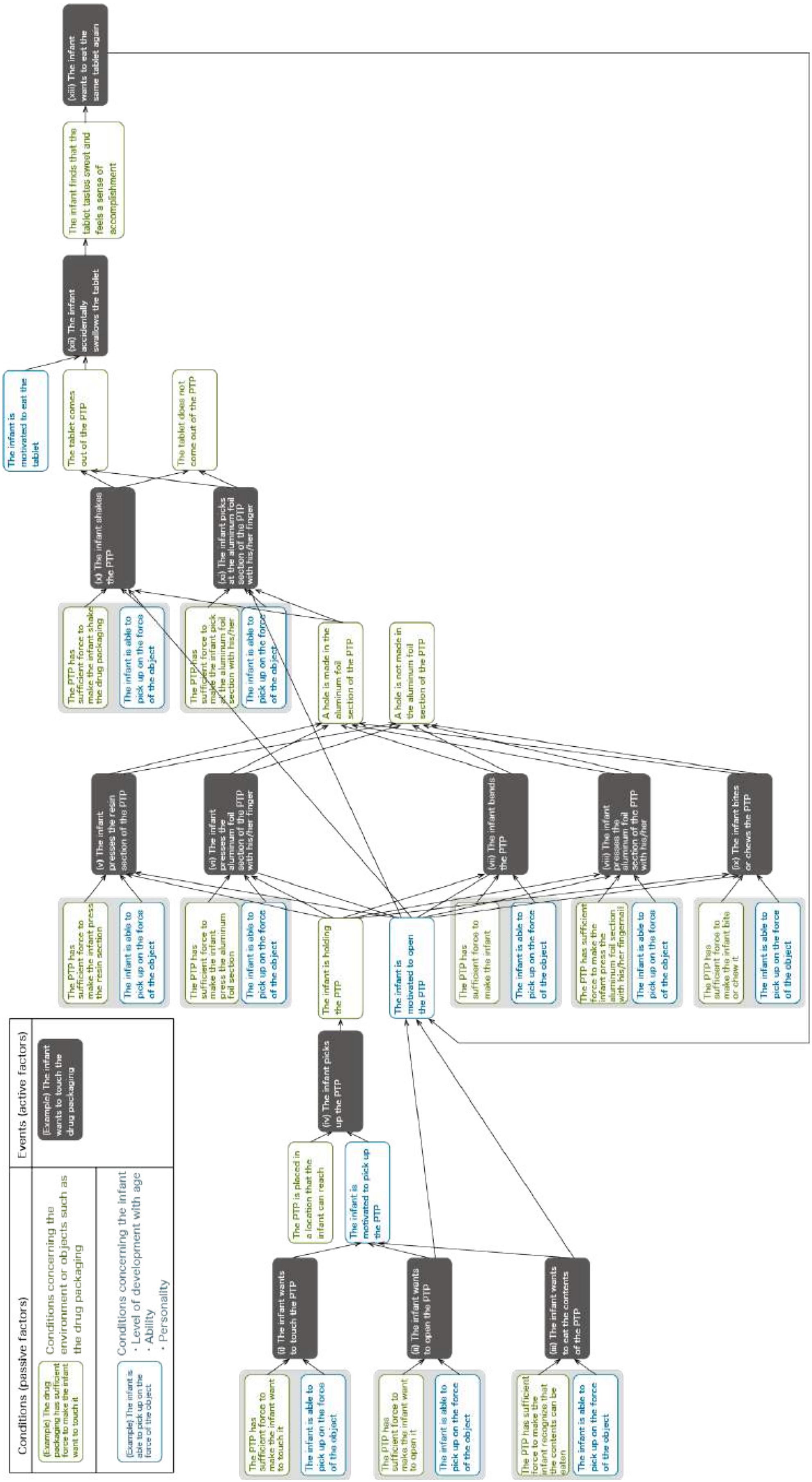

Figure 3: Petri Net model of the problem structure of accidental drug ingestion by infants

sufficient force to cause the infant to recognize that the contents can be eaten and the infant is able to pick up on the force of the object, then the infant will want to eat the contents of the PTP. If events (i), (ii), or (iii) are fired, then the infant has the motivation to pick up the PTP. (iv) If the PTP is placed in a location that the infant can reach, then the infant will pick up the PTP and be in a state of holding it in his/her hand. If either of events (ii) or (iii) are fired, then the infant has the motivation to open the PTP.

If the infant is in the state of holding the PTP in his/her hand, has the motivation to open the PTP, (v) is holding a PTP with a resin shape or material that encourages the infant to press it, and is able to pick up on the force of the object, then the infant will press the resin section. (vi) Also, if the aluminum foil section is made of a shape or material that makes the infant want to press it and the infant is able to pick up on the force of the object, then the infant will press the aluminum foil. (vii) If the main part of the PTP has a shape or material that makes the infant want to bend it, then the infant may bend the PTP. (viii) Or, if the PTP has the force to encourage the infant to press the aluminum foil area with his/her fingernail, then the infant may press this part with his/her fingernail. (ix) If the PTP has the force encouraging the infant to bite or chew it, and the infant is at an age where they put everything into their mouth, then the infant will bite or chew the PTP.

If events (v) to (ix) are fired, there are cases when a hole will or will not be made in the aluminum foil part of the PTP. In the former case, (x) if the PTP has enough force to encourage the infant to shake it and the infant is able to pick up on the force of the object, then the infant will open the PTP and shake it to get the tablet out of the hole. Also, (xi) if the PTP has the force encouraging the infant to pick at the aluminum foil with his/her finger and the infant is able to pick up on the force of the object, then the infant will pick at the hole in the aluminum foil with his/her finger to get the tablet out. As a result of (x) or (xi), there are cases when the tablet will or will not come out of the PTP.

If (xii) the tablet comes out of the PTP and the infant has the motivation to eat the tablet, then the infant will swallow the tablet. As a result, the infant will find that the tablet tastes sweet and will feel a sense of accomplishment. (xiii) The infant will want to eat the same tablet again, resulting in motivation to open the PTP again.

4. CONCLUSION

In this study, based on observations of children's behavior and interviews with parents, we applied the Petri Net Model approach, a discrete event system, to model the problem structure of infants opening PTP and accidentally ingesting the tablets inside. We intend to show this model to medical professionals such as pharmacists and specialists such as medical writers, followed by discussion their expert opinions on our hypotheses.

We hope to conduct further research and create a discrete event system model that can capture this issue from a broader perspective.

ACKNOWLEDGEMENTS

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