Proposal of Method to Consider Supporting Actions by Caregivers in Risk Evaluation of Robotic Devices for Nursing Care

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KEYWORDS: machinery safety, risk assessment, robotic devices for nursing care, caregiver's supporting action

ABSTRACT

This paper proposes a method for qualitatively evaluating the appropriateness of supporting actions required of accompanying caregivers in order to minimise the residual risks caused by the unexpected stoppage of robotic devices for nursing care, based on the concept of "controllability" in the risk analysis of safety-related parts of control systems (SRP/CS) for earth-moving machinery. Assuming some concrete examples, ways to reflect the results obtained from the risk assessment, safety design and supporting action specifications of the robotic devices are discussed. Furthermore, an alternative evaluation method is also proposed in which the achievability of the target supporting action is quantitatively judged based on the success rate of the action estimated from the result of human subject trials with reference to the controllability for SRP/CS of agricultural machinery.

1 INTRODUCTION

As the number of people in Japan in need of long-term nursing care increases, the utilisation of robotic technology in the nursing care industry has attracted increasing interest, and the Ministry of Health, Labour and Welfare is also promoting its development and dissemination [1]. The robotic devices proposed for this purpose thus far vary widely, including machines that reduce the burden on caregivers (e.g., nurses, nursing care helpers, physical therapists) who support the activities of daily living of care receivers, devices that facilitate independent behaviour among elderly or disabled persons, and systems that provide remote monitoring their health conditions and improve the efficiency of data collection and management in nursing care operations [2]. Among these, we consider only powered machines aimed at physically assisting the movements of care receivers (e.g., travelling, transferring, bathing) and refers to them collectively as "nursing care robotic devices (NCRDs)".

NCRDs can be roughly divided into two categories: devices that are operated by the user who needs its support functions, and those that always require a caregiver(s) to accompany the user while the NCRD is in operation (including NCRDs that are worn or operated by the caregiver). In the latter, the risks of harm that can occur after an unexpected stoppage of NCRD due to an overload, low battery or detection of any obstacles or abnormality, such as falling over or remaining in an unnatural posture, have generally been recognised as residual risks in the risk assessment conducted during the design and development stage. It is a commonly accepted to specify the measures for residual risks as appropriate actions or behaviours taken by the caregiver (hereafter, simply called "supporting actions") to prevent the accident or reduce the severity of that harm. However, the current situation is that the achievability and effectiveness of specified supporting actions are not always verified in detail and the risk assessments by designers are completed merely by describing the necessary actions in an instruction handbook.

To address this issue, this paper proposes a method for evaluating the appropriateness of supporting actions and for reflecting the obtained results in the risk assessment of NCRDs by referring to the evaluation of "controllability", which is stated in the functional safety standards of earth-moving machinery, agricultural machinery and road vehicles for the risk analysis of their safety-related parts of control systems (SRP/CS). Based on the concept of controllability for earth-moving machinery, "foreseeability of stoppage", "time until the start of action" and "caregiver restrictions" are considered to be factors that influence the successful implementation of supporting actions after the stoppage of NCRDs, and a method for qualitatively evaluating the appropriateness of supporting actions is proposed. Furthermore, an alternative method in which the achievability of supporting actions is quantitatively examined by replacing the above factors with the success rate estimated from the result of human subject trials is also discussed with reference to the controllability for SRP/CS of agricultural machinery.

2 RISKS ASSOCIATED WITH STOPPAGE OF NCRDs

One of the basic principles is that machines should be designed and constructed so that their stopped state can contribute to reducing risks, but for NCRDs, this may not always practicable. Stoppages that occur while using NCRDs are generally classified into planned stoppages, which are necessary to carry out some tasks (e.g., programmed or intentional stops by the operator), and unexpected stoppages, which can occur suddenly. Such

unexpected stoppages can be caused not only by failures or malfunctions in structural parts and mechanisms, in drive systems such as actuators and power supplies or in sensors and control systems, but also by unexpected behaviours of the care receiver which initiate a protective device or a safety function. The following possibilities of harm may arise as a result of such stoppages (due mainly to the influence of gravity):

- A care receiver falls or remains in an unnatural posture due to stoppage of a transfer-support robot while it is lifting their body.
- A mobility assist robot stops at a moment when its centre of gravity is unstable, and then falls over together with a care receiver whom it is assisting.

In the case of NCRDs that require the presence of a caregiver, the risks that arise after the NRCD stops are generally addressed by a supporting action taken by the caregiver, such helping the care receiver who has just fallen as in the above examples. However, the achievability and effectiveness of such actions have not always been verified in detail in risk assessments by designers. In addition, the risk assessments are completed with the expectation that, as long as the necessary supporting actions are described in accompanying documents, such as an instruction handbook or a reference manual, caregivers will learn the actions through training and education during the installation or commissioning of the NCRD and implement the actions when necessary without fail.

Concrete examples are explained using a risk assessment method that the authors proposed for designers of the robotic devices for nursing care [3]. This method has already been made publicly available as a specific risk evaluation method and criteria with template sheets that can be referenced as a documentation form. In this method, risk is considered to be a function of four parameters: the severity of harm S, the frequency or duration of exposure to that hazard F, the probability of occurrence of a hazardous event Ps and the possibility of avoiding or limiting that harm A. Then the estimated risk level R is derived by using Formula (1) based on the evaluation criteria shown in Tables 1 and 2.

$$R = S \times (F + Ps + A) \tag{1}$$

If the score of R is greater than 7, engineering measures are required to reduce the risk. If it is between 7 and 14 after all risk reduction measures have been implemented, the residual risk is considered to be "conditionally acceptable" only if its adequacy can be determined based on the state of the art. In this case, the management of the risks is entrusted to the NCRD users through the provision of warnings or instructions regarding the necessary training, the use of personal protective equipment and so on. The following examples show practical ways to minimise the residual risks mentioned above:

EXAMPLE 1: Assume a non-wearable transfer-support robot operated by a caregiver, as shown in Figure 1. Table 4 shows an example of risk assessment for this. The second row shows an accident scenario in which the transfer-support robot is lifting up a care receiver from the toilet seat and suddenly stops due to detection of an overload arising from a conflict between the motions of the care receiver and the robot which causes the care receiver to lose their grip on the handlebar, fall backward and hit their head on the toilet tank. The initial risk is assumed as follows, a possible harm is a moderate bruise to the head (S = 3), the robot is intended to be used about 10 times a day in a welfare facility (F = 3), there have been reports of people losing their grip while using similar machines (Ps = 2) and it is difficult for the care receivers to avoid harm by themselves (A = 3). To address this issue, the following two risk reduction measures are assumed to be implemented by the designer: covering the part of the toilet tank that the care receiver's head might hit using a cushioning material (S becomes 1) and changing the material of the handlebar to an anti-slipping material (Ps becomes 1). In our proposed method, after implementing the risk reduction measures, R is derived from the minimum value of each of the reduced S, F, Ps and A [3]. Thus, the final score of R in this scenario becomes 7, which means that

Table 1. *Criteria and scores of "S".*

Value	Foreseeable injury or health damage
4	It takes 1 week or more to heal completely.
3	Medical examination/care is required.
2	First-aid treatment is required.
1	No aid is needed (only temporary pain).

Table 2. *Criteria and scores of "F", "Ps" and "A".*

Value	*F*	*Ps*	*A*
4	Twice or more an hour, or more than 60 min per use	High	—
3	Once an hour, or 30 - 60 min per use	Likely	Difficult
2	10 times a day, or 10 - 30 min per use	Possible	—
1	Once a day, and 10 min or less per use	Rarely	Probable

Table 3. *Evaluation criteria of risk level "R".*

Score	Evaluation / Further action
15 or more	Risk is unacceptable.
7 to 14	Further risk reduction is required but it may be tolerable only if there is no reasonably practicable measure.
6 or less	Risk is acceptable or adequately reduced. No further risk reduction is required.

Figure 1. *An assumed non-wearable transfer-support robot operated by a caregiver.*

further measures are required. Some supporting action by the caregiver is therefore needed to prevent falls and/or mitigate the harm (e.g., the caregiver always places their hand on the body of the care receiver and supports them in the event that the care receiver's hand nearly slips). However, this requirement may be fulfilled simply by deciding that "the necessary supporting action of caregivers will be expressed clearly as an operating instruction", and the risk assessment is regarded as completed based on a prerequisite for using the robot that the accompanying caregiver must learn and appropriately carry out the supporting actions through education and training.

EXAMPLE 2: The third row of Table 4 presents another accident scenario where the robot suddenly stops due to a low battery while lifting a care receiver from their bed in order to transfer to a wheelchair and causes the care receiver's chest to be excessively compressed for a prolonged period of time. The initial risk is assumed as follows, a possible harm is temporary dyspnoea or congestion ($S = 2$), the robot is intended to be used about 10 times a day ($F = 3$), unfavourable stoppages due to low battery have been known to occur on similar machines ($Ps = 2$) and it is difficult for care receivers to avoid harm by themselves ($A = 3$). To address this, a battery monitoring function (*Ps* becomes 1) and a manually operated emergency lowering mechanism (*A* becomes 1) are assumed to be adopted. However, the final *R* remains at 10, and thus the caregiver's standing position and behaviour aimed at reducing the body-weight load on the care receiver need to be provided as the operating instructions.

***Table 4**. Excerpted results of risk assessment assumed in the use of a non-wearable transfer-support robot.*

Assumed accident scenario	Risk estimation (initial)					Technical risk reduction measures	Risk estimation (after)					Required measures for residual risks
	S	*F*	*Ps*	*A*	*R*		*S*	*F*	*Ps*	*A*	*R*	
Example 1: The robot suddenly stops due to an overload while lifting up a care receiver from the toilet seat and the care receiver loses their grip on the handlebar, falls backward and hits their head on the toilet tank.	3	3	2	3	24	Covering the toilet tank with shock-absorbing cushioning material.	1	3	2	3	7	Specifying instructions regarding the caregiver's actions aimed at preventing falls and containing them in the instruction handbook.
						Replacing the handlebar material with anti-slipping material.	3	3	1	3		
Example 2: The robot suddenly stops due to low battery, while lifting a care receiver from their bed in order to transfer to a wheelchair, causing the care receiver's chest to be excessively compressed for a long time.	2	3	2	3	16	Adding a battery monitoring function.	2	3	1	3	10	Specifying instructions regarding the caregiver's standing position and behaviour aimed at reducing the body-weight load on the care receiver.
						Equipping the robot with a manually operated emergency lowering mechanism.	2	3	2	1		

3 "Controllability" stated in functional safety standards of mobile machinery

The guidance of ISO 13849-1:2023 on risk analysis to determine the required performance level for SRP/CS introduced new factors, such as the possibility of recognition or awareness of the hazard and the complexity of operations, to make the evaluation of parameter *P* expressing the possibility of avoiding or limiting harm more precise. This revision intended to assess aspects of human behaviour in detail is interesting, but it seems insufficient to deal with the relationship between the supporting actions of caregivers and the risk reduction in NCRDs.

Meanwhile, in the field of functional safety for earth-moving machinery, agricultural machinery and road vehicles, operations and behaviours taken by the driver/operator or other involved persons to avoid accidents have already been considered in estimations of the required risk reduction to be provided by the targeted safety function, and a parameter named "controllability" has been defined as a criterion to evaluate their achievability [4, 5, 6]. If a failure or malfunction of SRP/CS can be easily addressed by the driver or the involved person as an incident and judged not to lead to an accident, a high level of ability to perform the

		AR0	AR1	AR2	AR3
AC0		C3	C3	C3	C3
	AW0	C3	C3	C3	C3
	AW1	C3	C3	C3	C2
AC1	AW2	C3	C3	C2	C1
	AW3	C3	C2	C1	C0

Controllability
C0: High controllability
C1: Medium controllability
C2: Low controllability
C3: No controllability

***Figure 2**. Controllability classification in ISO 19014-1:2018* [4].

***Table 5**. Factors to determine controllability* [4].

Alternative controls: AC
AC0 - No alternative controls or possible action
AC1 - One or more alternative control or possible action
Awareness of hazard: AW
AW0 - Not known at action of the function (e.g., a system one cannot see or one is not aware of), operating with an uncommand action
AW1 - Known at action of function, some of the time
AW2 - Known at action of function, all the time
AW3 - Known before action of function
Ability to react: AR
AR0 - Regardless of if there is another system to respond with, the operator or system is unable to respond in time to avoid the hazard
AR1 - Operator can react in time, unnatural response, e.g., operator grounds implement when brake fails
AR2 - Operator can react in time, natural response, operator has to move hand or foot to operate, e.g., operator applies park brake when brake fails
AR3 - Operator can react in time, natural response, operator has hand or foot on control, e.g., operator can steer around hazard when brake fails

safety function is not necessarily required for the SRP/CS.
As a method for evaluating the appropriateness of supporting actions specified by NCRD designers, we focused on this concept of controllability and, as a first step, specifically referred to ISO 19014-1 dealing with the SRP/CS of earth-moving machinery [4]. As stipulated in ISO 19014-1, controllability must be assessed while considering human reactions (e.g., panic, repeated commands of function) and the capacity for the operator to react to the hazard and provide a means to enter a safe state. When considering multiple alternative actions, each of these actions is independent of the others. In the determination of controllability, three factors, namely, alternative controls (AC), awareness of hazard (AW) and ability to react (AR) as shown in Table 5, are examined and combined in accordance with Figure 2. If AC0, AW0 or AR0 is applicable, then the result becomes C3: No controllability.

4 PROPOSAL OF A METHOD FOR EVALUATING THE APPROPRIATENESS OF SUPPORTING ACTIONS

Based on the concept of controllability in ISO 19014-1, a method is proposed for qualitatively evaluating the appropriateness of the caregiver's supporting actions. Its purpose is avoiding inappropriate expectations of risk reduction for the supporting actions and ensuring that designers examine any improvements in mechanisms, control functions and operating conditions of NCRDs to encourage the successful implementation of supporting actions in the risk assessment process. Ways to reflect obtained results into the design of NCRDs and supporting action specifications are described using concrete examples.

4.1 Evaluation factors and criteria for supporting actions

With reference to the three factors characterising controllability shown in Table 5, we considered the following three factors that may influence the achievement and effectiveness of supporting actions:

1. Foreseeability of stoppage: If the occurrence of stoppages could be known in advance, it would have a significant impact on managing the residual risk through supporting actions. For example, if an indicator or alarm is provided to warn the caregiver of a sudden stop, some behaviour can be taken to avoid the stoppage or prepare for the supporting action. Also, a stoppage due to the unnecessary activation of a safety function can be considered foreseeable if there is sufficient visibility and the caregiver can fully observe the behaviour of the care receiver.

2. Time until the start of action: The time required for a supporting action must be set appropriately according to the possible harm. It can take a certain amount of time for chest compression to cause harm, but bruising from a fall occurs nearly instantly. The time required to initiate a supporting action is also greatly affected by factors such as the operating state of the robot when the stoppage or a sign of impending stoppage is recognised, the caregiver's work being performed, the caregiver's posture, the distance from the care receiver, etc. Therefore, the time can be significantly reduced by modifying the operating conditions of the NCRD during the design stage.

3. Caregiver restrictions: If a supporting action is required, it must be set as a prerequisite that the involved caregivers have already been given the necessary education and training before starting to use the NCRD. However, in caring for elderly people, the parts of their body to which a force can be applied for support may differ depending on each individual's medical condition, and thus specific qualifications or experience may be required for the caregivers. In addition, there may be cases in which a certain level of physical ability, such as muscle strength, is required. When setting such caregiver restrictions, the first step should be to establish the supporting actions that any caregiver would be expected to perform, and then add specific conditions as needed.

The proposed criteria for evaluating the above factors are shown in Table 6. Each criterion has a score expressed as KF, KT or KR. Based on these combinations, the designers should be able to evaluate the appropriateness of

Table 6. *Proposed factors for assessing supporting actions specified to caregivers in terms of controllability.*

Foreseeability of stoppage
KF2 - Machine stoppage is not foreseeable.
KF1 - Machine stoppage is foreseeable. A sign can be recognised.
Time until the start of action
KT3 - The supporting action cannot be started before harm occurs.
KT2 - Depending on the situation, the action may not start immediately.
KT1 - The action can be started before harm occurs by natural response.
Caregiver restrictions
KR3 - Even a specified caregiver may not be able to perform the action, or any incident has experienced in the use of similar machines.
KR2 - A specified caregiver can perform the supporting action.
KR1 - All caregivers achieve the supporting action.

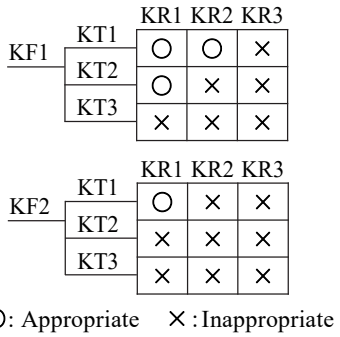

Figure 3. *Evaluation matrix of specified supporting actions.*

supporting actions designed or specified according to Figure 3. "○" indicates that the specified supporting action is appropriate and that the residual risks are expected to be managed in the intended manner, while "×" indicates that the supporting action is inappropriate and therefore the safety specification, design and/or operation conditions of the NCRD should be reconsidered. These analyses and evaluations are supposed to be implemented during the adequacy evaluation of the third step "information for use" in the three-step method of ISO 12100.
In addition, there are some cases for NCRDs in which such measures are taken to avoid or reduce harm by using hold-to-run control or an emergency stop device, but this study does not address them. Because, if appropriate operation by the caregivers can be assumed, the risk reduction effect of these devices would be reflected in the risk assessmentas *Ps* or *A* (in the above example shown in Table 4, the manual lowering mechanism itself was assumed to be used appropriately by the caregiver and *A* was reduced to 1 based on its effectiveness). Furthermore, some studies on the appropriate installation position and usability of these devices have already been reported [7].

4.2 Concrete examples of evaluation

EXAMPLE 1: Assume a non-wearable transfer-support robot operated by a caregiver as shown in Figure 1 and a supporting action to be specified that, when the robot stops suddenly due to an overload, the caregiver must support the care receiver to prevent them from falling when their hand slips. However, the conditions are also assumed that the caregiver can operate the robot by a handheld controller with one hand and an operating instruction that the caregiver must always place their hand on the care receiver's back during the lifting operation is stipulated. Under these assumptions, the factors for the specified supporting action can be evaluated as follows:
1. Foreseeability of stoppage, KF: If it is possible for every caregiver to sufficiently observe the care receiver's behaviour, then KF1 can be assigned. For this, the caregiver's position during operation must be appropriately considered so that the caregiver can carry out intended operations while observing the care receiver.
2. Time until the start of action, KT: Since it is stipulated as the operating instruction that the caregiver has to place their hand on the care receiver's back during the lifting operation, KT1 can be assigned.
3. Caregiver restrictions, KR: If the specified supporting action can be performed by every caregiver with one hand by grabbing hold of the care receiver's upper clothing, then KR1 can be assigned unconditionally.
Evaluation result: According to the evaluation matrix shown in Figure 3, even if KR2 is assigned, the specified supporting action can be evaluated as appropriate for managing the residual risk because both KF and KT are 1. Conversely, it is necessary to design the robot and plan the operation such that KF1 and KT1 are satisfied.

EXAMPLE 2: Assume a wearable transfer-support robotic device as shown in Figure 4 and an accident scenario in which the device suddenly stops due to a gear breakage and its power assistance is lost when a caregiver is transferring a care receiver to a wheelchair. In such a case, maintaining the caregiver's own balance while supporting the care receiver is required as the supporting action. Under these assumptions, the three factors can be evaluated as follows:
1. Foreseeability of stoppage, KF: Since it is obviously difficult for the caregivers to recognise a sudden stoppage due to a breakage or failure of components in advance (even if periodic inspections are implemented), KF2 has to be assigned.
2. Time until the start of action, KT: Based on the criterion shown in Table 6, for KT1 to be assigned, it needs to be stipulated as an operating instruction that the caregiver puts the care receiver's arm around their shoulder and carries out the transfer operation with a posture that supports the care receiver's waist or back, and the implementation of this must be ensured.
3. Caregiver restrictions, KR: For KR1 to be assigned, it is a precondition that the device is designed and constructed such that its drive mechanism cannot be locked and become a load on the caregiver. Furthermore, it needs to be stipulated that the care receiver is limited to someone whom the caregiver can hold up without using this device.

***Figure 4**. An assumed wearable transfer support robotic device.*

Evaluation result: According to the evaluation matrix shown in Figure 3, the specified supporting action can be evaluated as "appropriate" only if the conditions to assign KT1 and KR1 are satisfied by the design and the operational planning of the device.

4.3 Quantitative approach

Although the controllability in ISO 19014-1, which was referenced for the proposed method, is based on qualitative judgments, controllability in ISO 25119-2 for agricultural machinery and that in ISO 26262-3 for road vehicles are provided as quantitative evaluation results of success rates for the intended safe operation or a specified ability (a level of control) that are estimated through human subject trials. The former is shown in Table 7 as an example.

***Table** 7. Classification of a possible avoidance of harm (controllability) in ISO 25119-2:2019* [5].

C0	C1	C2	C3
Easily controllable The operator or bystander controls the situation, and harm is avoided.	Simply controllable More than 99% of people control the situation. In more than 99% of the occurrences, the situation does not result in harm.	Mostly controllable More than 90% of people control the situation. In more than 90% of the occurrences, the situation does not result in harm.	None The typical trained operator or bystander cannot generally avoid the harm.

By referencing this concept, an alternative evaluation method can be considered, in which the achievability of specified supporting actions is quantitatively judged by replacing the above qualitative three factors with the success rates of the supporting actions estimated from the result of human subject trials.
However, a statistical analysis procedure needs to be applied to obtain appropriate estimations of the success rates from experimental trials with a limited number of subjects. The probability distribution of the number of successful cases in a sequence of multiple independent trials in which each outcome is either "success" or "failure" (i.e., Bernoulli trials) is statistically given by a binomial distribution. Here, the lower limit of a confidence interval at the $(1-\alpha)$ level of confidence for the population proportion, which is represented as p, can be derived from the number of conducted trials n and the number of successful cases x by using Formula (2):

$$p = \frac{x}{(n-x+1) \times F_{\alpha}(2(n-x+1), 2n) + x} \tag{2}$$

where $F_{\alpha}(a, b)$ is the upper critical value of the F-distribution with a numerator degrees of freedom and b denominator degrees of freedom at a significance level of α. For instance, when a set of trials conducted with 20 subjects has 18 successful results, the sample success rate is 90% but p with 95% level of confidence (which is generally accepted for human factors tests) is estimated at 71.7%. In another case that all 20 obtained data comply with the predetermined pass-criteria for trials where 20 subjects participate, p (α = .05) of the success rate becomes 86.1%. For this quantitative evaluation method, we propose that a target supporting action could be regarded as "appropriate" only if a p (α = .05) of 95% or more was observed as its success rate, as long as the human subject trial for this action was conducted while taking into account all foreseeably unfavourable situations under the specified use limits of the NCRD under development, such as heavy care receivers, a wet floor surface and so on. The rationale for this proposal is the fact that ISO type-B1 standards dealing with ergonomic aspects generally cover anthropometric data for the 95th percentile or less (or 5th percentile or more) of the population. An experiment with 53 randomly selected participants that resulted in 53 successes can satisfy this acceptance condition.

5 CONCLUSIONS

This paper proposes methods for qualitatively and quantitatively evaluating the appropriateness of supporting actions required of the accompanying caregiver aimed at minimising residual risks due to the unexpected stoppage of NCRDs. Although concrete examples were given, this study is still in its early stages and thus the effectiveness of the proposed methods should be verified through actual applications. The relationship between persons and machines has become closer in various industries and it is becoming increasingly important to evaluate the adequacy and effectiveness of the contents specified by the designer as "information for use". We hope that our proposal provides a foundation for its consideration.

6 REFERENCES

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