A Formal Human Reliability Analysis of a Community Pharmacy Dispensing Procedure

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Medication errors in community pharmacies are a major threat to patient health and safety. Current experimental and observational studies are insufficient to address the medication error problem due to its complexity. Thus, we adapt a well-validated human reliability analyses (HRA) approach for use with the probabilistic model checking, to create and validate a formal approach that allows the analysts to predict medication error rates and explore interventions for different community pharmacy procedures. We use the method to analyze a common dispensing procedure of community pharmacies and compare our results to published error rates. Finally, we discuss our results and explore how our method could be further developed in the future.

INTRODUCTION

Approximately 1.7% of all prescriptions filled by community pharmacies have dispensing errors (Flynn, Barker, & Carnahan, 2003). This means that an average community pharmacy makes at least four medication errors a day and two clinically significant errors a week (Flynn et al., 2003). As such, medication errors originating from community pharmacies are a major threat to patient health and safety. While community pharmacists have a variety of tools to help them dispense prescriptions, these errors are overwhelming associated with human error (IOM, 2006). As such, the cognitive and environmental factors (sometimes referred to as sociotechnical factors (Phipps, Noyce, Parker, & Ashcroft, 2009)) that can influence the reliability of human work are deeply important for addressing medication errors in community pharmacies.

Community pharmacies are complex, dynamic environments where pharmacists are required to interact with patients and doctors and deal with insurance issues in addition to their dispensing responsibilities. As such, the medication error problem in community pharmacies is complex and can manifest in many different places. It is also a poorly understood problem. While reporting systems exist, errors are significantly underreported (Ashcroft, Morecroft, Parker, & Noyce, 2006). Further, pharmacies use different procedures, making it difficult to get comprehensive data. This problem is compounded by the fact that almost all community pharmacies are private organizations that are not required to share information about their procedures. Finally, observational and experimental studies are inherently limited in that they cannot account for all of the operational situations that can be encountered. These issues suggest that conventional reporting, observational techniques, and experimental methods are, on their own, insufficient to address the medication error problem. Thus, community pharmacy medication errors are a prime candidate for the application of model-based approaches like human reliability analysis (HRA).

HRAs allow analysts to estimate human error rates based on the sociotechnical factors that impact human performance (Hollnagel, 1998a; Swain & Guttmann, 1983). HRA has been used successfully in a number of safety-critical domains. However, it has not been used to evaluate medication errors in community pharmacies. Despite its successes, HRAs have shortcomings that can limit their usefulness. In particular, they are static and do not account for how system dynamics can impact error rates. They also fail to account for interactions between different errors.

In this paper, we present preliminary results for a new HRA approach we developed that will address the limitations of traditional HRAs and allow us to evaluate procedures used in community pharmacies. To do this, we build off of the basic Cognitive Reliability Error Analysis Method (CREAM) (a well-validated approach to HRA) to model the way a prescription moves through a pharmacy. In our new HRA, we account for system dynamics with PRISM probabilistic model checking. This novel, model-based approach is able to mathematically prove properties about the reliability of modeled procedures and explore interventions to improve performance.

Below we provide the background on the CREAM method and probabilistic model checking that is necessary for understanding our approach. We then detail the steps of our new formal approach. Further, we apply the method to a standard community pharmacy procedure to identify problems and recommend interventions that would improve reliability. Finally, we compare our results against published error rates and explore new avenues of future research.

BACKGROUND

HRA with CREAM

CREAM (Hollnagel, 1998a) is the leading second-generation HRA (Bell & Holroyd, 2009). First-generation HRAs [such as THERP (Swain & Guttmann, 1983), HEART (Williams, 1985), and HCR (Hannaman, Spurgin, & Lukic, 1984)] focus on inherent human error probabilities associated with individual human tasks but neglects other sources of error in a complex system.(Fujita & Hollnagel, 2004). CREAM improves on this by grounding its approach in the Contextual Control Model (COCOM) (Hollnagel, 1998b). This posits that human performance is determined more by the situation in which a task is performed than it is by inherent properties of the task itself. As such, CREAM, in its basic form, calculates ranges of human error probabilities based on assessed values of sociotechnical factors called Common Performance Criteria (CPCs; Table 1). These were chosen so that the minimal number of CPCs could adequately describe the criteria influencing human performance (Hollnagel, 1998a).

To use basic CREAM, analysts describe procedures as sequences of tasks. Then, CPCs are assessed by an expert who, for each task, rates whether the conditions associated with each CPC improve human task performance, reduce it, or are not significant. Two of the CPCs, Goals and Time of Day, have only two levels: not significant and reduced. Four of these CPCs (Conditions, Available Time, Goals, and Collaboration) are dependent on other CPCs and are thus adjusted based on assessed CPC values (Hollnagel, 1998a). Figure 1 describes this process.

After adjustments, the number of CPCs that are improved and the number that are reduced are counted. These counts map to one of four COCOM control modes, each with a range on probabilities of human error (Hollnagel, 1998a, 1998b) (Fig-

Table 1. *CREAM CPCs (Hollnagel, 1998a)*

CPC	Description
Organization	Relates to the roles and responsibilities of team members as well as the quality of additional support, communication systems, safety management systems, instructions, guidelines, and oversight.
Conditions	Relates to physical working conditions such as ambient lighting, screen glare, alarm noise, and interruptions.
Support	Relates to man-machine interfaces. This includes the information on control panels, computerized workstations, and operational support provided by decision aids.
Procedures	Relates to procedures, including operating and emergency procedures, familiar patterns of response heuristics, and routines.
Goals	Relates to the number of goals or tasks a person is required to pursue or attend to at the same time.
Available Time	Relates to the time available to carry out a task and corresponds to how well the task execution is synchronized to process dynamics.
Time of Day	Relates to the time of day; in particular, whether or not the person is adjusted to the current time.
Experience	Relates to the quality of operators' training and their level of operational experience.
Collaboration	Relates to the quality of the collaboration between crew.

ure 2). *Scrambled* control describes a situation where a human loses situation awareness (due to high task demands, unfamiliar situations, or unexpected events) and actions are chosen randomly with little or no thinking involved. *Opportunistic* control corresponds to situations where the human chooses actions inefficiently due to incomplete planning or a failure to anticipate events fully. This can occur because the time to perform the task is too constrained or because the human does not clearly understand the context under which a task is performed. *Tactical* control is characterized by situations where actions are chosen through planning that is based on following known procedures or rules. However, this planning will have a limited scope and the procedures and rules will not necessarily be appropriate in all situations. Finally, *Strategic* control encapsulates situations where a human plans and chooses actions after a full consideration of the situation. In cases with little control, such as in the scrambled and opportunistic modes, the probability of making a failure is high. Conversely, when the level of control increases, the likelihood of the human making an error goes down (Hollnagel, 1998a).

CREAM has proved to be useful in a number of different applications including nuclear power plants (Hollnagel, Kaarstad, & Lee, 1999), food manufacturing (Geng, Murè, Baldissone, Camuncoli, & Demichela, 2015), radiation therapy (Castiglia, Giardina, & Caravello, 2008), and hospital pharmacies (Rantanen, Deeter, Burke, & Wang, 2012). However, it has limitations inherent to all first- and second-generation HRAs. First, CREAM is static. Thus, it does not consider interactions between errors or how rates will change dynamically as a system operates. There have been attempts to develop third-generation HRAs to account for system dynamism (Bell & Holroyd, 2009; Kirwan et al., 2004). However, these are based on first-generation HRAs (like HEART) and thus lack the theoretical and cognitive grounding of CREAM. Further, all are simulation-based. This means that they can miss system conditions in their analyses and will only ever produce error rate estimates. Thus, we address this shortcoming by integrating HRAs with probabilistic model checking.

Formal methods and probabilistic model checking

Probabilistic model checking comes from the computer science field of formal methods. Formal methods are mathematical languages and techniques for the specification, modeling, and verification of systems (Wing, 1990). Specifications are formulated to rigorously describe desirable system properties, systems are modeled using mathematical languages, and verification mathematically proves whether or not the model satisfies the specification. Model checking (Clarke, Grumberg, & Peled, 1999), is an automated approach to formal verification, where specification properties (usually represented in a temporal logic) are checked against a state-machine based model of the system using efficient, exhaustive search algorithms.

A fair amount of research has gone into investigating how formal methods (and especially model checking) can be used to evaluate erroneous human behavior in complex systems (Bolton & Bass, 2013; Bolton, Bass, & Siminiceanu, 2012, 2013; Pan & Bolton, 2016). The vast majority of these analyses are concerned with finding specific unsafe system conditions. However, these methods use non-probabilistic models and are thus not suitable for assessing overall human reliability. Probabilistic model checking offers automated verifications techniques for analyzing stochastic systems using probabilistic models (e.g., variants of Markov chains) and probabilistic temporal logics (Kwiatkowska, Norman, & Parker, 2007). This enables analysts to both account for probabilistic behavior in their models and prove properties about the probabilities of system behaviors. PRISM (Kwiatkowska, Norman, & Parker, 2011) is currently the world's leading open-source software tool for probabilistic model checking. It allow analysts to definitively determine how likely different system behaviors and outcomes are while

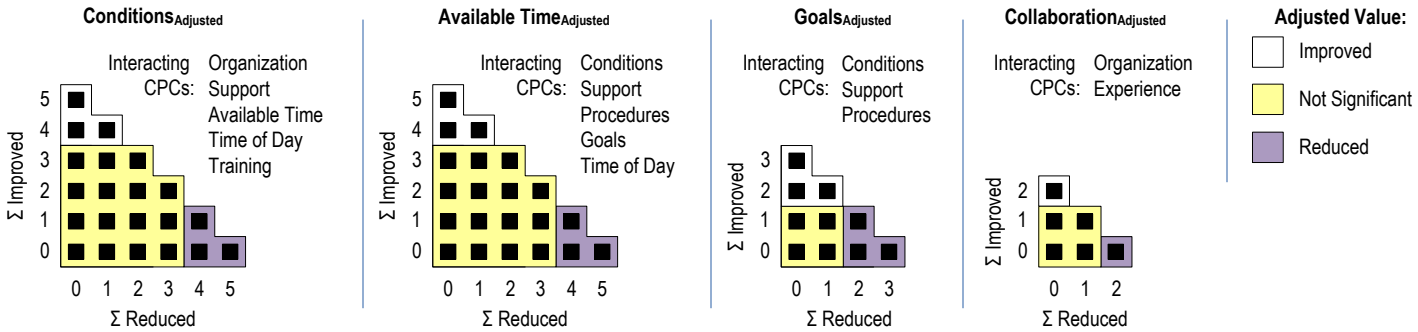

Figure 1. CREAM's method for adjusting CPC values to account for dependencies between CPCs (Hollnagel, 1998a). Each graph shows one of the four CPCs that are adjusted along with a list of the CPCs that it is dependent on (the interacting CPCs). Adjusted values are computed based on the number of the interacting CPCs that improve (Σ Improved) and reduce (Σ Reduced) human performance. These counts map to regions on the presented graphs that indicate whether an adjusted CPC is improved, reduced, or not significant.

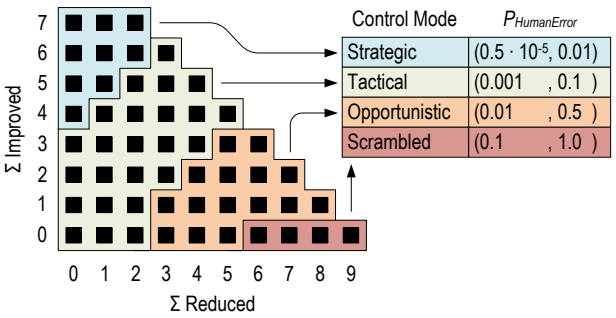

Figure 2. CREAM's method for converting CPC values into control modes. In this, the number of CPCs that improve (Σ Improved) and reduce (Σ Reduced) human performance are both counted. These values map (via the graph) to particular control modes that, in turn, map to ranges of human error probabilities ($P_{HumanError}$). Note that Σ Improved can only go up to 7 because there are two CPCs that can never improve human performance.

accounting for all of the different possible behaviors and system dynamics included in a system model. Probabilistic model checking has been used successfully in a number of applications, including systems that rely on human behavior (Feng, Humphrey, Lee, & Topcu, 2016; Feng, Wiltsche, Humphrey, & Topcu, 2016). It has never been used with HRA to account for human error. Despite this, probabilistic model checking is well suited for use with HRA. The discrete, logical nature of probabilistic model checking models is synergistic with the way that HRAs like CREAM compute human error rates. Further, probabilistic model checking can account for system dynamics and interactions between human errors and other types of system errors in a way not previously possible in HRAs.

A FORMAL APPROACH TO HRA

In this work, we develop a new approach to HRA that combines basic CREAM with probabilistic model checking using PRISM. In doing this, we are able to address the major shortcomings of HRA. Specifically, by using probabilistic model checking, our approach is able to account for interaction between errors and dynamic system behaviors while considering all of the possible paths through a modeled system.

The dispensing procedure used in community pharmacies is critical to whether or not a prescription is filled properly. It can thus have a profound impact on human health and safety. Thus, we apply our new approach to the dispensing procedure used in a community pharmacy.

Below we describe how we model a community pharmacy procedure along with our method's approach for predicting rates of human error formally. We then use our method to predict error rates both for the overall procedure and for individual tasks within it. To validate our findings, we compare our predicted results to rates from the community pharmacy literature. This is done in the discussion section.

Modeling

To demonstrate the feasibility and power of our new approach, we modeled and evaluated the dispensing portion of a common community pharmacy procedure (Figure 3). This particular procedure was chosen because it represents the critical part of a community pharmacy's dispensing activities. The project's subject matter expert (Dr. Daly, a practicing pharmacist and Clinical Assistant Professor in the University at Buffalo School of Pharmacy and Pharmaceutical Sciences) identified the individual tasks included.

This implementation works by modeling how a prescription moves through and is filled by the procedure in Figure 3. This

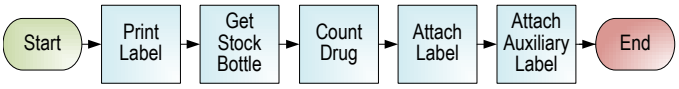

Figure 3. Flow diagram of the community pharmacy dispensing procedures analyzed with the developed approach. Individual processes/tasks are rectangles. Start and end events for the entire procedure are ovals.

model accounts for both normative dispensing and erroneous dispensing behaviors based on the human reliability predictions provided by basic CREAM, which are calculated based on assessed CPCs and system dynamics. Probabilistic model checking is then used to determine what the error rates are for the procedure in general (Figure 3) and for each individual task.

We developed a formal modeling architecture (Figure 4) that allowed us to formally model the pharmacy dispensing procedure as a discrete-time Markov chain using PRISM's input language. Models constructed using this architecture encapsulate four key concepts: the procedure used to fill a prescription, environmental dynamism, the prescription being filled, and CREAM's CPCs. The first three of these are sub-models that contain the transition logic of the system. The procedure is modeled as a single variable representing the state of the procedure being performed, where the procedure is modeled as if it is executed using the ordered steps shown in Figure 3. The environmental dynamism sub-model encapsulates dynamic factors that can influence CPCs that are not directly related to the human operator's task. In our model, this encapsulates the time of day at a community pharmacy, which can influence many sociotechnical factors related to time and human load (discussed subsequently). When the prescription procedure starts (Start in Figure 3), the environmental dynamism sub-model assigns a time of day to it probabilistically based on the distribution of prescriptions processed on average by a community pharmacy each hour (Boyd, Parker, & Yung, 1981) (see Figure 5). The filled prescription is represented by five variables, where each indicates if a part of the prescription has been dispensed properly: (1) was the correct label printed, (2) was the correct stock bottle (drug) selected, (3) was the correct amount (or count) of the drug dispensed into the vial, (4) was the correct label attached, and (5) was the correct auxiliary label attached. Each of these corresponds the respective task in Figure 3 and is only ever modified when the respective task in the procedure sub-model is being performed. When the procedure starts, the variables in the prescription are all set to "not applicable." Each task in the dispensing procedure can modify the corresponding variable in the prescription. However, whether or not a task transits the value to "incorrect" or "correct" is determined by the probabilities of human error as dictated by the values of the CPCs.

In our model, CPCs can be static or dynamic. Static CPCs have values associated with each task in the larger procedure (though value can differ between tasks). We treat all of the following CPCs as static: Organization, Conditions, Support, Procedures, Experience, and Collaboration. The values of these are determined by expert ratings. For the presented work, this was done by having our subject matter expert Dr. Daly answer a questionnaire assessing each of these CPCs for each of the tasks shown in Figure 3. In our formal model, functions map the state of the procedure (the specific task being executed) to the corresponding assessed CPC values (Figure 4).

Dynamic CPCs represent factors that can change dynamically in the environment. In our model, Goals, Available Time, and Time of Day are all treated as dynamic CPCs because they will vary based on when a prescription is being dispensed and the number of other tasks happening at the time. To represent

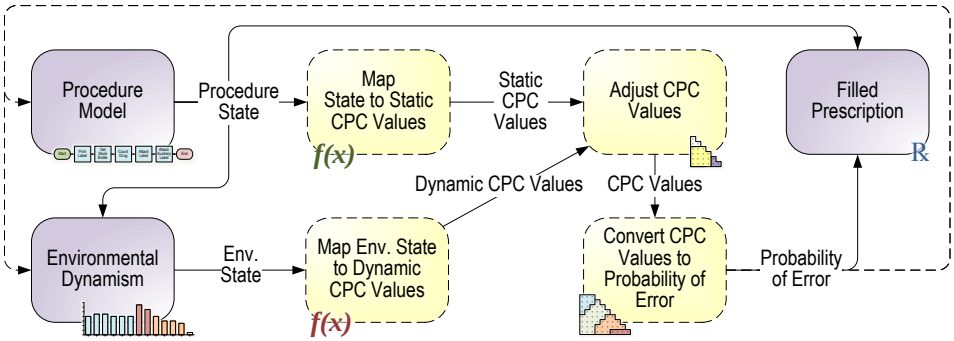

Figure 4. The formal modeling architecture used in our HRA method. Shapes with solid lines are formal sub-models. Shapes with dotted lines are functions. Arrows describe variables shared between sub-models and functions. Dotted arrows represent shared variables that are possible with the architecture, but currently not used in our model.

these CPCs in our formal model, functions map the time of day assigned to each prescription by the environmental dynamism sub-model to dynamic CPC values appropriate for that time of day. Specifically, based on the distribution of pharmacy prescriptions (Boyd et al., 1981), we identified four specific time zones (Figure 5). Then, we assessed each of the dynamic CPCs within these time zones and represented these in the functions that map the environment's state to CPC values (Figure 4).

Once the states of the environment and the procedure have been translated into CPC values, these must be adjusted. In our formal model (Figure 4), this is accomplished by functions that represent the adjustment operations shown in Figure 1. Finally, functions are used to convert the resulting CPC values to probabilities of human error using the CREAM algorithm from Figure 2. Because basic CREAM predicts a range of probabilities (Figure 2), predictions with our approach use two models. One uses the minimum probability from each control mode and the other uses the maximum. The log average method of probability estimation (Clemens & Simmons, 1998) can be used with predications from both models to produce point estimates.

Results

When we used PRISM to analyze the entire procedure, we found that medication error rates could range from 1.14% to 52.64%. Using the log average method of probability estimation (Clemens & Simmons, 1998), we obtained an average of 7.75%. We know that the analyzed procedure is incomplete in that it does not account for methods used to verify dispensed prescriptions (among other activities). If we accept that 20.9% of incorrect prescriptions fail to be caught during verification (Cina et al., 2006), we can apply this to our 7.75% prediction to find an average predicted medication error rate of 1.63%.

For each task in Figure 3, we also used PRISM to predict the lower and upper bounds on their error rates and the log average

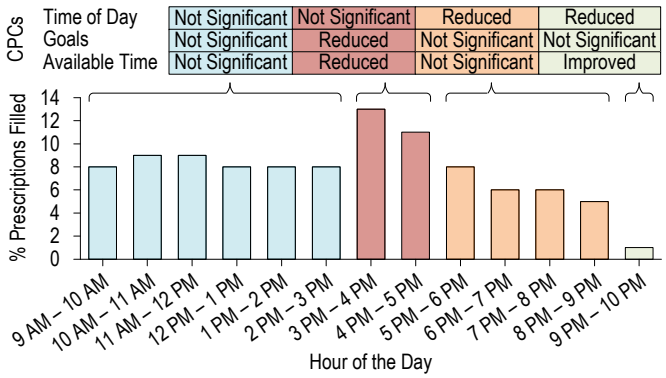

Figure 5. Graph showing how the distribution of prescriptions filled at an average community pharmacy each hour (Boyd et al., 1981) map to time zones and values of the dynamic CPCs.

method of probability estimation to obtain a mean. This revealed that, on average, (1) 1% of dispensed medications will have the wrong label printed, (2) 2.49% will have the wrong drug, (3) 2.49% will have the incorrect amount of the medication, (4) 2.49% will have the wrong or no label attached; and (5) 0.99% will have the wrong or no auxiliary label. These numbers need not add up to the observed 7.75% medication error rate from the overall analysis because there can be more than one error in any given filled prescription.

DISCUSSION AND FUTURE WORK

In this paper, we presented a new, formal approach to HRA for use in the analysis of community pharmacy procedures. By grounding this approach in CREAM (Hollnagel, 1998a) and the PRISM probabilistic model checker (Kwiatkowska et al., 2011), our method allows us to account for dynamic system conditions and compute accurate error rates at a level that was not previously possible in HRA. The 1.63% error rate predicted by our method is extremely close to the 1.7% rate reported by Flynn et al. (2003). This provides good evidence that the predictions of our method are accurate. The power of our approach is further found in the results we obtained from our analyses of each task in the procedure. Specifically, these show that, to have the most effect on medication errors, decision makers should focus on helping pharmacists select the right drug/stock bottle, count out the right number/amount of medications, and attach the correct label because these had the highest predicted error rates. Should an analyst choose to do so, our method should allow him or her to change the values of the CPCs to explore how different interventions could improve overall performance.

This work constitutes a major contribution to patient health and safety in that it provides analysts with a means of identifying which pharmacy procedures and which tasks within those procedures are the most error-prone. It also has the potential to allow analysts to compare procedures to determine which are safer and explore how interventions will reduce error rates. Because the approach is computational, it should allow analysts to reduce medication error rates (thus saving patient lives and improving health outcomes) in nearly any pharmacy without the need for observational and experimental studies.

Despite the success of our approach, our method has several deficiencies that limit its broader usefulness. Below, we describe how we hope to extend and improve our method.

Extended CREAM

Because the current approach uses basic CREAM, there may be situations where predicted error rates will be inaccurate due to the large ranges of probabilities associated with the different control modes (Figure 2). In Extended CREAM (Hollnagel, 1998a), a more precise error rates can be computed without the need for the averaging of ranges. Thus, in future research, we

will improve our method's prediction accuracy by making it compatible with Extended CREAM.

Extended Pharmacy Analyses

The presented results only relate to the dispensing portion of community pharmacy procedures. This procedure can vary between community pharmacies. Further, there are extended processes pharmacies use in full transcription and dispensing procedures. Thus, future work should attempt to extend our procedures to encompass all of these operations. This should encompass: prescriptions arriving at a pharmacy; the verification process that occurs prior to dispensing; the triage procedure for contacting prescribers and/or patients for addressing discovered issues; the dispensing procedure for filling the prescription (as shown in the presented results); the method for verifying a filled prescription; the triage procedure for addressing issues discovered in a filled prescription; and delivering medication to patients with counseling. In doing this, our method will need to account for additional sources of human error, including errors in human decision making as well as sources of error that are independent of pharmacist actions (such as a prescription arriving at the pharmacy with errors or errors from automated dispensing machines). We should also account for other sources of system dynamics that could influence CPCs such as distractions, interruptions, and the influence of human error on procedures and the environment (as shown in the dotted lines in Figure 4). Ultimately, we hope to make our method user-friendly so that any pharmacist will be able to model and analyze the procedures used in his or her community pharmacy.

Results Validation

As we continue to expand the scope of pharmacy procedures analyzed with our method, we will make every effort to validate our results. Wherever possible, we will compare the results we obtain with published results. For procedures without precedence or data in the literature, we will plan to validate predictions of our method with human subject experiments. Such efforts will be the subject of future research.

Generalizability

Human error is a problem in a number of safety critical domains beyond community pharmacies. These include other pharmacy environments, healthcare in general, aviation, automobile operation, unmanned vehicle control, and industrial environment prone to occupational accidents. The HRA approach presented here was designed specifically for use in analyzing community pharmacy procedures. However, it should be generalizable. Future research should investigate how our method can be used in other critical domains.

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