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## POTENTIALLY HAZARDOUS DRUGS: IDENTIFICATION OF RISKS AND ERROR PREVENTION BARRIERS IN INTENSIVE CARE<sup>1</sup>

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### ABSTRACT

**Objective:** to investigate the knowledge of nursing professionals and pharmacists in relation to the identification of potentially hazardous drugs, as well as the recognition of error prevention barriers in their use in hospital institutions.

**Method:** cross-sectional survey performed in intensive care units of four hospitals. A questionnaire constructed and validated based on the information provided by the Institute for Safe Practices in Drug Use was used for data collection. Statistical Package for Social Sciences, version 22.0 and the Kruskal-Wallis test were used to analyze the data between the professional categories. The significance level was set at 0.05.

**Results:** 126 professionals were included, among those eligible for participation. Of the 33 potentially hazardous drugs indicated in the instrument, none were identified as such by all respondents, although 17 were used by more than 95% of respondents. No statistically significant difference was observed in the responses of the different professional categories regarding the identification of these drugs. Regarding the measures of error prevention, nurses were the professional category that distinguished the existence of barriers at a higher rate.

**Conclusion:** this study pointed to important gaps in the recognition of potentially hazardous drugs and incipient adoption of barriers to prevent incidents, characterizing situations of fragility in hospitals because it implies the initial rupture of barriers, especially when the health professionals are inserted in high-complexity services.

**DESCRIPTORS:** Patient Safety. Medication Systems. Hospital Care. Nursing. Pharmacists. Risk Management. Pharmacovigilance. Critical Care.

## MEDICAMENTOS POTENCIALMENTE PERIGOSOS: IDENTIFICAÇÃO DE RISCOS E BARREIRAS DE PREVENÇÃO DE ERROS EM TERAPIA INTENSIVA

### RESUMO

**Objetivo:** investigar o conhecimento dos profissionais de enfermagem e farmacêuticos em relação à identificação de medicamentos potencialmente perigosos, bem como verificar o reconhecimento das barreiras de prevenção de erros nas instituições hospitalares.

**Método:** estudo transversal, tipo inquérito, realizado em Unidades de Terapia Intensiva de quatro hospitais. Um questionário construído e validado com base nas informações disponibilizadas pelo Instituto para Práticas Seguras no Uso de Medicamentos foi utilizado para coleta de dados. Para análise dos dados utilizou-se o *software Statistical Package for the Social Sciences*, versão 22.0 e o teste de Kruskal-Wallis para investigar diferença dos resultados entre as categorias profissionais. Adotou-se o nível significância de 0,05.

**Resultados:** foram incluídos 126 profissionais, entre os elegíveis para participação. Dentre os 33 medicamentos potencialmente perigosos indicados no instrumento, nenhum foi identificado como tal pela totalidade de respondentes, embora 17 fossem utilizados por mais de 95% dos entrevistados. Não foi observada diferença estatisticamente significativa nas respostas das diferentes categorias profissionais quanto à identificação desses medicamentos. Em relação às medidas de prevenção de erros, os enfermeiros constituíram a categoria profissional que distinguiu em maior número a existência de barreiras.

**Conclusão:** este estudo apontou importantes lacunas no reconhecimento dos medicamentos potencialmente perigosos e adoção incipiente de barreiras para prevenção de incidentes, caracterizando situações de fragilidade nos hospitais por implicar na ruptura inicial das barreiras, especialmente quando os profissionais de saúde estão inseridos em um ambiente de alta complexidade.

**DESCRIPTORIOS:** Segurança do paciente. Sistemas de medicação. Assistência hospitalar. Enfermagem. Farmacêuticos. Gestão de riscos. Farmacovigilância. Cuidados críticos.

# MEDICAMENTOS POTENCIALMENTE PELIGROSOS: IDENTIFICACIÓN DE RIESGOS Y BARRERAS DE PREVENCIÓN DE ERRORES EN TERAPIA INTENSIVA

## RESUMEN

**Objetivo:** investigar el conocimiento de los profesionales de enfermería y farmacéuticos en relación a la identificación de medicamentos potencialmente peligrosos, así como el reconocimiento de las barreras de prevención de errores en su uso en las instituciones hospitalarias.

**Método:** estudio transversal, tipo averiguación, realizado en las unidades de terapia intensiva de cuatro hospitales. Un cuestionario construido y validado en base a las informaciones ofrecidas por el Instituto para las Prácticas Seguras en el Uso de Medicamentos fue utilizado para la recolección de datos. Para el análisis de los datos se usó el *software Statistical Package for the Social Sciences*, versión 22.0 y el test de Kruskal-Wallis para investigar la diferencia de los resultados entre las categorías profesionales. Se adoptó el nivel significancia de 0,05.

**Resultados:** fueron incluidos 126 profesionales entre los elegibles para esa participación. Entre los 33 medicamentos potencialmente peligrosos indicados en el instrumento, ninguno de ellos fue identificado como tal por la totalidad de los respondientes, aunque 17 de ellos fueran utilizados por más del 95% de los entrevistados. No fue observada ninguna diferencia estadísticamente significativa en las respuestas de las diferentes categorías profesionales sobre la identificación de esos medicamentos. En relación a las medidas de prevención de errores, los enfermeros constituyeron la categoría profesional que distinguió en mayor número la existencia de barreras.

**Conclusión:** este estudio señaló importantes lagunas en el reconocimiento de los medicamentos potencialmente peligrosos y la adopción incipiente de barreras para la prevención de incidentes, caracterizando situaciones de fragilidad en los hospitales por implicar la ruptura inicial de las barreras, especialmente, cuando los profesionales de la salud están insertados en un ambiente de alta complejidad.

**DESCRIPORES:** Seguridad del paciente. Sistemas de medicación. Asistencia hospitalaria. Enfermería. Farmacéuticos. Gestión de riesgos. Farmacovigilancia. Cuidados críticos.

## INTRODUCTION

Drugs are a key topic in patient safety, given the high risk and frequency of adverse drug events (ADEs) deriving from their misuse. Medication errors figure among the most recurrent ADEs in health services and constitute an internationally acknowledged problem. The relevance of their early identification and monitoring is intended to reduce the number of events that lead to prolonged hospitalizations with a concomitant increase of the expenses for the institution.<sup>1</sup>

In view of the repercussion of cases involving medication errors, the World Health Organization (WHO) has published six international goals for patient safety, with emphasis on improving safety in the use of high alert medications.<sup>2</sup> These drugs, also called potentially hazardous drugs (PHD) or high-risk drugs, are more likely to cause significant harm to patients as a result of errors in the usage process.<sup>1,3</sup>

In this scenario, several internationally renowned organizations dedicated to promoting health care and patient safety improvement actions, such as the Institute for Healthcare Improvement (IHI) and the Institute for Safe Medication Practices (ISMP), recommend that health professionals know the risks of PHD and adopt measures to minimize the occurrence of errors involving this group of medicines.<sup>3-5</sup>

PHD are essential components of drug therapy, and it is imperative to establish educational processes for health professionals and to implement surveillance systems and barriers to prevent errors

and severe damage resulting from irregularities in their use.<sup>6-7</sup>

Regarding the implementation of specific measures for the safe use of PHD in a hospital setting, risk management is an important strategy aimed at improving the health care processes, also in the field of drug therapy.<sup>8</sup> In this context, nursing team professionals play a crucial role in hospital institutions, being responsible for several steps in the drug administration process, turning them into key components in the detection and prevention of errors involving PHD.<sup>1</sup>

The pharmacist's participation in the context of safe PHD use should also be emphasized, as this professional is able to identify and prevent risks related to concentration, physicochemical compatibility, drug interactions, dose, pharmaceutical form, route and schedules in medication administration.<sup>9</sup>

The objective of this study is to investigate the knowledge of nursing professionals and pharmacists about PHD by identifying these drugs as belonging to the group of potentially hazardous medication, as well as to verify the recognition of error prevention barriers involving such drugs in hospital institutions.

## METHOD

A cross-sectional survey was undertaken from August to December 2014, in which the data were collected through a structured questionnaire.<sup>10</sup>

The research was developed at four hospitals located in an interior city in the State of São Paulo,

being one public, two private for profit and one private non-for-profit. The participating institutions were intentionally selected to cover the various profiles and sizes of the hospital services existing in the city.

We chose to develop this study in the Intensive Care Unit (ICU) due to the fact that this scenario presents a significant number of factors predisposing to incidents, such as patient severity, use of highly complex technologies, diversity of drugs and treatments and invasive interventions.<sup>11-12</sup>

The data were collected through the elaboration, validation and application of a questionnaire with eight closed questions covering the participants' sociodemographic characteristics, the identification and use of PHD and the recognition of the existence and types of damage prevention measures related to these drugs in the institutions. This questionnaire was developed based on the information provided by the ISMP in its PHD list,<sup>5</sup> being a contemporary and globally acknowledged publication.

Aiming to ascertain the aspects of clear writing, applicability and consistency of the items, the questionnaire was subject to face and content validation by selecting and organizing an expert committee consisting of five specialists working in care, teaching and research on patient safety, who signed an Informed Consent Form.<sup>13</sup> A minimum interrater agreement of 80% was adopted to include the recommendations specified in the pre-final version of the questionnaire.<sup>14</sup> The items that required reformulations were reviewed, and the recommendations focused particularly on the clarity of the statements and the need for structural reorganization of the questionnaire to ensure its functionality.

Next, a pre-test was performed, in which the pre-final version of the questionnaire was applied in a sample of 15 nursing professionals from a pediatric and neonatal ICU of a private hospital in the interior of the State of São Paulo (Brazil) who signed the Informed Consent Form. The purpose was to stipulate the response time and ascertain the intelligibility, ease of completion and relevance of the items. The response time among the participants ranged from five to ten minutes, establishing a ten-minute interval to return the completed questionnaire and, without the need for new adjustments, the final version was defined.

The final version of the instrument was applied to the target population of the study, including all the pharmacists (nine), nurses (34), auxiliary

nurses and nursing technicians (122) working in the ICUs of the hospitals surveyed, totaling 165 professionals. Participants who were absent from the services for more than ten days during the data collection, as well as those admitted less than three months earlier, were excluded because it was deduced that these professionals did not have time to properly adapt to the processes that govern medication administration at the respective institutions.

The questionnaire was applied at the workplace, in a private environment, to those professionals who signed the Informed Consent Form. The guidelines regarding completion were provided on that occasion, individually, and no consultation material was allowed.

The obtained data were processed through double data entry and validated. The variables were analyzed descriptively by simple frequency and percentage, using Statistical Package for the Social Sciences (SPSS), version 22.0. The Kruskal-Wallis test was applied to investigate the existence of differences in PHD recognition among the professional categories surveyed. The level of significance was set at 0.05.

This study received Ethics Committee approval under CAAE process 30462914.2.0000.5393.

## RESULTS

Among the 165 professionals working in the study scenario, 126 (76.4%) made up the final sample. The smallest number of participants who agreed to take part in the survey, in relation to the total number of eligible professionals in the same group, came from the category of nursing technicians and auxiliary nurses, with 91 (75%) respondents, whereas the categories of pharmacists and nurses obtained effective participation percentages of 100% (9) and 77% (26), respectively.

Based on the analysis of the sociodemographic data, the profile of the participating professionals could be outlined. As far as gender was concerned, the higher presence of women was noted (70%) and, with regard to the age group, there were no respondents under the age of 21, being predominantly between 21 and 40 years (64%), while participants aged 51 or older accounted for 8% of the total.

As regards the variable time on the job, the percentage of respondents who informed two to five years of experience at the institutions stood out in comparison to the rest of the sample (36%). Nevertheless, it is noteworthy that 28% of the profes-

sionals surveyed had been admitted to the hospitals less than 12 months earlier. Regarding the variable total length of professional experience, the period of six to ten years (29%) was the most recurrent among the participants, accompanied by the interval of two to five years (23%).

Table 1 details the distribution of PHD identification and use percentages in drug therapy for

intensive care patients. It is important to highlight that all drugs included as response options in the questionnaire are considered PHD according to the official list,<sup>5</sup> but none of them were identified as PHD by all respondents in the sample (n=126). Regarding the use of these drugs, among the 33 PHD proposed in the instrument, 17 were used by more than 95% of the interviewees.

**Table 1 - Identification and usage percentages of Potentially Hazardous Drugs (PHD) at Intensive Care Units by professional categories. Ribeirão Preto, SP, Brazil, 2014. (n=126)**

Drug	Pharmacist (%)		Nurse (%)		Nursing technician (%)		Auxiliary nurse (%)		Total (%)	
	Use	PHD	Use	PHD	Use	PHD	Use	PHD	Use	PHD
Norepinephrine	100	89	100	100	100	100	100	93	100	98
Fentanyl	100	89	100	100	100	98	100	82	100	94
Potassium chloride	100	100	100	100	100	98	100	100	100	99
Enoxaparin	100	89	96	84	100	63	100	75	99	72
Epinephrine	100	89	100	100	98	95	100	96	99	96
Tramadol	100	56	100	50	98	44	100	46	99	46
Sodium chloride 20%	100	100	100	77	98	74	100	64	99	74
Sodium heparin	100	100	100	85	98	79	100	75	99	81
Midazolam	100	89	100	100	98	97	100	96	99	97
Amiodarone	100	89	100	92	100	95	96	85	99	92
Parenteral nutrition	100	89	100	73	98	53	100	57	99	61
Hypertonic glucose	100	100	100	73	98	65	100	64	99	69
Propofol	100	89	100	100	97	95	100	100	98	97
Morphine	100	100	92	92	100	86	100	96	98	90
Lidocaine	89	63	96	64	98	61	96	59	97	61
Subcutaneous insulin	100	100	96	76	95	73	100	75	97	76
Pancuronium	89	88	100	100	92	98	100	89	95	96
Suxamethonium	67	83	96	96	97	92	96	85	94	91
100 ml sterile water	89	63	92	17	84	32	100	14	90	27
Warfarin	100	89	77	85	90	81	93	88	89	84
Propranolol	78	29	85	50	89	57	86	50	87	52
Dexmedetomidine	78	86	85	77	78	90	89	84	82	85
Liposomal amphotericin B	89	75	69	39	65	63	82	57	71	58
Metformin	78	43	50	46	73	46	61	59	66	48
Milrinone	56	60	65	88	51	84	71	65	59	78
Glibenclamide	78	43	38	40	52	45	50	43	51	44
Alteplase	56	60	54	100	52	97	21	100	46	95
Potassium phosphate	33	100	31	75	37	87	75	67	44	78
Rocuronium	44	100	42	91	37	96	36	100	38	96
Phenylephrine	22	100	35	89	30	89	21	100	29	92
Vecuronium	33	67	35	100	29	100	14	100	27	97
Ketamine	56	80	23	83	21	69	25	71	25	74
Chloral hydrate	44	100	12	100	13	63	11	67	14	78



It is worth mentioning that 9.5% of the professionals claimed that all medication they used in the drug therapy of patients hospitalized in ICUs concurrently figured on the PHD reference list. In this perspective, when comparing the number of drugs not characterized as PHD among the professional categories surveyed, no statistically significant difference was observed among the groups (Kruskal-Wallis test:  $p=0.351$ ). Likewise, when the non-identified PHD were related among all nursing professionals (nurses, technicians and auxiliary nurses), there was no statistically significant difference in the level of recognition of these drugs in terms of professional training.

Another aspect investigated refers to the existence and identification of the error prevention measures, covering the PHD, previously established at the hospital services investigated. As shown in table 2, nurses constituted the professional category that most distinguished the existence of safety barriers (96%). On the opposite, pharmacists were the category that least demonstrated recognition of the surveillance strategies adopted at the institutions (78%).

**Table 2 - Percentage recognition of existence of error prevention measures involving Potentially Hazardous Drugs (PHD) at hospitals A (n=57), B (n=22), C (n=23) and D (n=24) by professional categories. Ribeirão Preto, SP, Brasil, 2014**

Professional category	Institution				Total (%)
	A (%)	B (%)	C (%)	D (%)	
Pharmacist	50	100	100	100	78
Nurse	93	100	100	100	96
Nursing technician	83	91	76	76	81
Auxiliary nurse	86	60	100	100	82
Total	84	82	83	83	84

In table 3, the percentage distribution is displayed for the error prevention measures related to PHD practiced at the ICUs of the places of study, according to the respondents.

**Table 3 - Error prevention measure percentages involving Potentially Hazardous Drugs (PHD) adopted by hospitals according to total sample. Ribeirão Preto, SP, Brazil, 2014. (n=126; multiple answers)**

Error prevention measures involving PHD	Respondents (%)
Restriction of access to PHD	79
Risk identification on packing	58
Verification of rights in medication therapy	56
Double checking	51
Alert labels	47
Training programs	38
Prohibition of verbal orders to administer PHD	35
Presence of PHD list	33
Alert system in electronic prescription	33
Colored packing for PHD	29
PHD administration by nurses only	22
Presence of lists containing maximum allowed doses	20
Alert system in checking/electronic consult	12
Others	2

## DISCUSSION

When asking about the use and recognition of PHD, lower recognition rates were noted for some drugs that can be considered as usual in ICUs. An example of this contrast is tramadol, a centrally acting opioid analgesic, used by 99% of the interviewees while only 46% assumed it as a PHD. Other relevant examples are 20% sodium chloride, hypertonic glucose, parenteral nutrition, lidocaine, enoxaparin and

subcutaneous insulin, used by most respondents but with limited identification. In line with these findings, in a review, opioids came out as the PHD class that is most often associated with errors.<sup>15</sup>

Like opioid analgesics, subcutaneous insulin is involved in a large part of the incidents with PHD, as the complexity of the dosage and the range of pharmaceutical presentations available in the market contribute to enhance the potential for errors and damages.<sup>16</sup> It is worth noting that, in this study, sub-

cutaneous insulin was routine medication for 97% of the participants and was named PHD by 76% of them.

Although there was no statistically significant relationship between the PHD recognition rates and the professional categories, the responses of the pharmacists and the nursing team contrasted, judging by the percentages found for 20% sodium chloride, hypertonic glucose, subcutaneous insulin and parenteral nutrition, with higher usage and identification rates for pharmacists compared to other professional categories. The proportion of PHD recognition by nurses stood out in comparison with the nursing technicians and auxiliary nurses, while the recognition percentages of the medication between nursing technicians and auxiliary nurses the categories of technicians and nursing auxiliaries were more converging.

Regarding the investigated categories, it is essential that each health professional knows the legal skills and specificities of their functions as, although they act as a multiprofessional team, they have quite different attributions, and are in charge of carrying out their activities in accordance with the highest quality standards and ethical principles, implying the promotion of safe care. It should be emphasized that the attributions of health professionals require knowledge of technical requirements and skills essential to the practice of the professions, as health care derives not only from the technical act, but also from the effective solution of the health problem.<sup>17</sup>

The divergent results regarding the particularities of the medication and the professional categories can mainly be attributed to the insufficient knowledge of these professionals regarding the use and identification of the drugs as, despite being widely used drugs in drug therapy, there is a gap in knowledge about their specificities.<sup>3,18</sup> Research has suggested that the knowledge deficit of health professionals plays a prominent role in the management of PHD, a fact that implies medication errors on a regular basis.<sup>3,15,19</sup>

In order to support this reflection, one study reported that the cognitive levels of a team consisting of doctors, nurses and pharmacists differed not only in terms of the profession but also in the degree of academic education. The research results indicated that the cognitive level associated with PHD should be improved, especially in the case of nurses, representing the final barrier between the drug administration and the patient.<sup>19</sup> In addition, the need to include the subject in the curricula of the

courses that prepare these professionals should be taken into account.

In the same research, it was verified that the nurses presented appropriate knowledge of the elements in the PHD administration, but the same knowledge was scarce when it came to the regulation of these medicines (storage, access and prescription). From this angle, in order to mitigate the deficiency evidenced in these professionals' knowledge, the researchers emphasized the importance of implementing the clinical pharmacist in hospitals, aiming to meet the knowledge demands of the team to assure the quality of care practice.<sup>19</sup>

In another study, a preliminary evaluation of pharmacists, nurses and physicians' knowledge about PHD was carried out at a hospital, aiming to implement interventions to improve the team's knowledge and, then, to carry out an evaluation similar to the initial one in order to verify if the interventions made were successful. Overall, 203 respondents completed the preliminary assessment, while 170 participated in the interventions and completed the final evaluation. Prior to the interventions, 42.9% of the respondents reported trusting their knowledge of the PHD applicable in the institution. After the interventions, this rate increased to 73.5% in the final evaluation, as a larger number of subjects correctly identified the PHD and recognized the relative safety procedures. Besides the better results in terms of team knowledge, the authors found that the evaluation of knowledge about these drugs makes it possible to include interventions and strategies specifically defined for the PHD adopted in each institution.<sup>3</sup>

In this context, a study on the teaching of PHD in nurses' education, in the perspective of nursing teachers and professionals, concluded that knowledge about such drugs is vital to competent nursing work, evidencing, however, dissatisfaction with their educational approach.<sup>6</sup> As pointed out in this and other studies, the insertion of contents on the theme PHD throughout vocational training and the creation of continuing and/or permanent education programs in health services are essential for these professionals to perform their functions in the administration stage of these drugs, even serving as an error prevention barrier.<sup>6-7</sup>

Although daily practice is the main source of experience for health professionals, in the context of the low level of knowledge about PHD, systematic, targeted and diversified training for health team members is an efficient improvement method.<sup>19</sup>

In a survey whose scope was to evaluate, through a questionnaire, the knowledge, experiences and perceptions of 786 health professionals from hospital organizations (physicians, nurses and pharmacists) about PHD, it was identified that: 29.3% of the participants reported their first experience involving PHD in their professional practice, without any background; 28% reported that PHD were a topic in the curricular structure of the undergraduate course; finally, 18.9% reported that the subject was partially addressed in the undergraduate course. It should be noted that 259 individuals (25%) mentioned that the safety of medication use, specifically PHD, was not part of the curricular structure of the undergraduate course and/or clinical practice. In view of these characteristics, the authors concluded that the teaching concerning PHD should be reinforced in hospital institutions rather than being introduced to professionals for the first time.<sup>18</sup>

When discussing the existence of error prevention measures encompassing PHD in hospital settings, the study participants' answers were consistent with the results outlined in other studies,<sup>1,3,18</sup> as 84% of the respondents mentioned prevention actions in their respective institutions. The category of pharmacists reported the existence of these barriers to a lesser extent, followed by the categories of nursing technicians and auxiliary nurses. The nurses were the category that most distinguished error prevention strategies. These disparities in the recognition of recommended error prevention actions point to the weaknesses associated with these institutions' risk management services, illustrated by the health professionals' limited engagement and the consequent difficulty to disseminate error interception practices.<sup>8,18</sup>

The barrier related to PHD use the respondents cited most was the restriction of the access to these drugs (79%) and, soon after, the risk identification on the drug bottle was predominant (58%), both being strongly recommended by international organizations on safe drug administration practices.<sup>4-5</sup> It should be emphasized that only 56% of the subjects considered the verification of the rights in drug therapy as a barrier to damage prevention and that, despite being a widely indicated resource, it has not been applied in clinical practice due to the trivialization of the routine tasks involved in medication use.<sup>18,20</sup>

Based on the findings in this study, we consider that the deficiency found in the distinction of

PHD and the professionals' omission in the dissemination of error prevention measures are elements that further the occurrence of errors. For this reason, it is proposed that institutions work together with risk management, discussing the singularities of their contexts with a view to mitigating errors and damages.<sup>8,12</sup>

It should be noted that the limitation in this study is due to the sample because, although PHD risk management requires multiprofessional commitment, only nursing professionals and pharmacists were included. It is therefore suggested that this research be replicated in other hospitals of different complexities, encompassing other professional categories to expand the knowledge about the risk management of the drugs under investigation.

## CONCLUSION

The study pointed out important shortcomings in the recognition of PHD and the incipient adoption of error prevention barriers. Errors in the recognition of PHD characterize situations of fragility in hospital institutions, as these circumstances imply an initial rupture of the error prevention barriers, especially when health professionals are inserted in a high-complexity environment like the ICU, with extremely vulnerable patients.

In summary, it is considered essential to carry out studies focused on reducing the negligence of preventive actions related to PHD and recommended by the risk management of hospital institutions. The dissemination of reports about the lack of knowledge on the use of PHD and the vulnerabilities deriving from this deficiency, observed in all professional categories studied, is aimed at instigating hospital institutions to propose ways of filling this gap in the training of their professionals. To do so, we suggest, for example, the implementation of ongoing and/or continuing education programs, robust risk management systems, evidence-based error prevention barriers and a policy to encourage the patient safety culture.

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