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Family Practice, XXXX, **XX**, 1–7
https://doi.org/10.1093/fampra/cmab156
Advance access publication 26 November 2021
Qualitative Research

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Abstract

Background: SARS-CoV-2 has been responsible for a pandemic since the beginning of 2020. Vaccine arrival brings a concrete solution to fight the virus. However, vaccine hesitancy is high. In France, the first available vaccine was Comirnaty from Pfizer-BioNTech. Shared decision-making, based on tools such as patient decision aids (PtDAs), can help patients make an informed choice about vaccination with Comirnaty.

Objective: The French College of Teachers in General Practice (CNGE) aimed to create a PtDA for people who have to decide whether they will receive the Comirnaty vaccine.

Methods: Development of the PtDA was performed according to the International Patient Decision Aids Standards (IPDAS). The initial design was based on a literature review and semistructured interviews with 17 patients to explore and clarify patients' expectations. A first draft of the PtDA was then alpha tested by a patient expert group and a physician expert group. The PtDA was finally beta tested in 14 prevaccine consultations. A steering group was consulted throughout the work. Patient support, community groups and the French National Authority for Health (HAS) were involved in the development process.

Results: A literature review identified one randomized trial on Comirnaty efficacy and safety. The first part of the PtDA allows patients to identify their own risk factors. The second part of the PtDA provides information on vaccination: benefits and risks, unknown data, and technical explanations about the mRNA vaccine.

Conclusions: We developed a PtDA to be used in primary care settings for shared decision-making regarding vaccination with Comirnaty.

Key words: consumer health informatics, health information, health literacy, patient adherence, primary care, public health

Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a highly infectious virus responsible for a pandemic since the beginning of 2020,[1] and it has had a major impact on various areas, including health, social interactions, and economics.[2,3] Although health authorities continue to expect treatment for patients in primary care,[4] a preventive approach remains the main way to fight the SARS-CoV-2 pandemic. Until late 2020, prevention was mainly based on social distancing measures, hand hygiene, and facemask use. On 21 December 2020, the European Union authorized the use of a vaccine from Pfizer-BioNTech Laboratories.[5] This vaccination has become central in most European national strategies against SARS-CoV-2.[6]

In France, the Comirnaty vaccine from Pfizer-BioNTech (BNT162b2) was the first to be available. According to international definitions,[7] French health authorities first recommended it for frail elderly patients, such as people living in retirement homes and people working in close contact with elders (over 65 or with comorbidities), and then for patients over 75 and caregivers or medico-social workers (over 50 or with comorbidities).[8]

As vaccination is not mandatory in France, population adherence is crucial for the success of such a public health policy. On the other hand, vaccine hesitancy is a major concern for the government, and 26% of the population reports that they do not want to be vaccinated.[9] Fake news and anti-vaccine content are frequently shared on social media, which has a negative impact on people's intention to vaccinate.[10] In total, a large proportion of French citizens report hesitancy towards SARS-CoV-2 vaccines.[11,12]

Shared decision-making could be a way to respond to vaccine hesitancy.[13,14] Patient decision aids (PtDAs) provide concise, clear, and trustworthy information to help patients

Key messages

- Adherence to COVID-19 vaccination is a major issue for health authorities.
- Shared decision-making might help to address vaccine hesitancy.
- In February 2021, we found no decision aid developed according to the IPDAS criteria.
- Decision aid for patients to decide whether they will receive the Comirnaty vaccination.
- Workgroup with patients, caregivers and French National Authority for Health.

clarify their values and make an informed choice.[15,16] PtDAs have demonstrated a positive effect on risk perception and the ability to choose; they decrease feelings of indecision and reduce decisional conflict related to a lack of information and passivity when people face a decision.[15] Therefore, the French College of Teachers in General Practice (CNGE) decided to create a PtDA for people who have to decide whether they will receive the Comirnaty vaccination.

The objective of this study was to develop a PtDA for people who have to decide whether they will receive the Pfizer-BioNTech Comirnaty vaccine.

Method

The development of the decision aid was based on the International Patient Decision Aids Standards (IPDAS) published in 2013.[17] We followed the related steps: design, alpha testing with patient and physician expert groups, beta testing (field testing) with patients and clinicians, and several steering group meetings (Fig. 1).

Design

Literature review

A narrative review was conducted in MEDLINE as well as the European Medicines Agency and US Food and Drug Administration reports, with the last update on 11 January 2021. Three researchers (RB, DP, and EF) analysed articles related to the Comirnaty Pfizer-BioNTech (BNT162b2) vaccine, with a specific focus on safety and efficacy. This information was selected and presented to privilege reliable and clear elements, and it was summarized in a "fact box" inspired by the *Harding Center for Risk Literacy* methods (Table 1).[18]

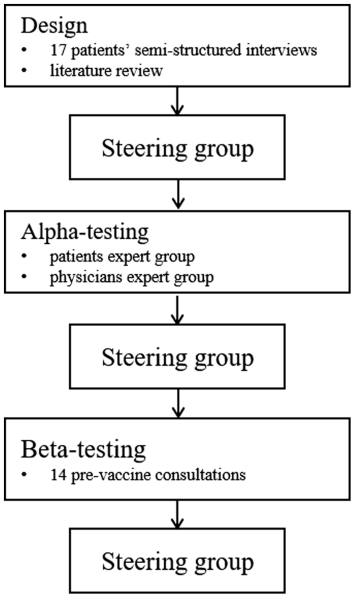

Fig. 1. Development process, adapted from the IPDAS.

Semistructured interviews

One researcher (YMV) experienced in qualitative research performed semistructured interviews to explore and clarify patients' expectations regarding the content of the PtDA. The inclusion criteria were an age of 18 or older and the ability to give consent without guardianship measures. Recruitment was carried out among 2 patient support and community groups. Seventeen patients were included from 22 December 2020 to 5 January 2021; no patients dropped out. The participants did not know the interviewer and were informed of the aim of the study before the interview. Each participant signed an informed consent agreement to participate in the study and returned it by email. Interviews were conducted via video calls due to the pandemic. Data, including age, gender, and socioprofessional status, were documented in field notes during the interviews without audio or video recording. The semistructured interview guide was based on the literature on vaccine hesitancy in the French context.[19,20] We conducted interviews until data saturation was reached, as defined in grounded theory[21] and considered by the interviewer when he conducted 2 consecutive interviews without the emergence of new codes. The interviews were analysed following an inductive content analysis approach by one data coder.[22]

First steering group meeting

Two general practitioners and 2 patient representatives met for the first steering group meeting. The patient representatives were members of the main French patient association, "France Assos Santé"; they were association specialists in shared decision-making and worked upstream with patients, both those in favour and not in favour of vaccination, on their perceptions of COVID-19 vaccines. The general practitioners were researchers on shared decision-making and decision aids; one of them was the interviewer from the qualitative part. They used data from both the "fact box," and the results of the interviews to elaborate specifications for the graphic designer. The specifications included precise sentences to use and graphic indications to present information deemed necessary by the patients from the elements available in the literature.

Alpha testing and second steering group meeting

A graphic designer elaborated a first draft of the PtDA. It was then alpha tested by 2 expert groups. The first group

Table 1. Extract of the "fact box" summarizing the data available in January 2021 about the safety and efficacy of the Comirnaty Pfizer-BioNTech SARS-CoV-2 vaccine.

Results of the Comirnaty vaccine for subjects over 16 years of age (N = 43,448) observed over a median of 2 months (2 doses, 21 days apart)			
Benefits	**Per 10,000 adults receiving the placebo**		**Per 10,000 adults receiving the Comirnaty vaccine**
How many adults will suffer from symptomatic COVID-19 after 2 doses?	89		*5*
Number of subjects to be vaccinated to avoid 1 symptomatic COVID-19 case		*120*	
How many adults will have severe COVID-19 after the first dose?	*5*		1
Number of subjects to be vaccinated to avoid 1 severe COVID-19 case after the first dose		*2,711*	
Risks			
How many people will experience at least one general side effect within 7 days and mostly of short duration (fatigue, fever, chills, headache, vomiting, diarrhoea, muscle pain, joint pain) after the 2nd dose?	3,380		6,990
Number of subjects to be vaccinated to cause 1 general adverse reaction		*3*	
How many people will experience moderate or severe fatigue within 7 days of the 2nd dose?	938		3,490
Number of subjects to be vaccinated to cause moderate or severe fatigue		*4*	
How many people will suffer from moderate (>38.4°) or severe (>38.9°) fever within 7 days?	19		*505*
Number of subjects to be vaccinated to cause moderate or severe fever		*21*	

Serious adverse events were rare, with no significant difference between the Comirnaty group (0.6%) and the placebo group (0.5%). The long-term side effects of this type of vaccine are still unknown. Some results are currently lacking, such as the impact of the vaccine on hospitalizations and deaths as well as the psycho-social and economic impact, but this does not mean that they will not be available later. The efficacy of the vaccine on transmission is still unknown, and it does not allow us to overcome barrier gestures. Last version of the tool can be found at: https://www.cnge.fr/media/docs/cnge_files/file_manager/marilyn_peronnet/FU_COVID19_Outil_Vaccination_Pfizer_26_mars.pdf. The last version of the fact box can be found at: https://www.cnge.fr/media/docs/cnge_site/cnge/210419_MAJ_Boite_decision_actualisation.pdf.

was composed of 21 patients and patient representatives from community groups, and the second group was composed of 6 general practitioners with experience in the research field.

After receiving the prototype, each group had to check that the information was well presented, clear, understandable, and loyal to the available data. The groups exchanged their comments and suggestions for modification via email. After 2 weeks, they synthesized their requests, remarks, and modification proposals and forwarded them to the investigator.

The same 2 general practitioners and 2 patient representatives met for the second steering group meeting. They discussed the expert group conclusions and chose modifications to be made to the PtDA. These modifications were transmitted to the graphic designer to update it in a beta-testing version.

Beta testing and third steering group meeting

Five general practitioners used the decision aid during dedicated prevaccine consultation with 14 patients and completed a short interview grid of 8 questions. They had to report information from both patients and physicians about the content of the decision aid and its graphic design, in addition to comments about the possibility of ensuring wide implementation.

The composition of the third steering group was the same as that of the first 2 groups, with the extra participation of 2 general practitioners from the expert group. The third steering group chose and submitted the last modifications to the graphic designer who created the final version of the decision aid.

This last version was presented by email to all experts who were involved in the design to obtain their approval of the final version.

Finalization with the French National Authority for Health

PtDAs are more efficient and have a better implementation if developed with national authorities.[23] In this study, the HAS agreed to provide its support. The research team consulted the HAS regarding specific requests, remarks, and modification proposals during the last steps of PtDA development (beta test and final version).

Results

Design

Literature review

The literature review identified 1 published trial related to Pfizer-BioNTech vaccine safety and efficacy,[24] an FDA briefing document,[25] and a report from the European Medical Agency.[5] Data about efficacy and safety were identified and summarized in a "fact box" (Fig. 1) as follows: efficacy to prevent symptomatic SARS-CoV-2, as well as efficacy against severe infection, was presented using a denominator of 10,000 instead of 36,523 to make the information easier to represent. Safety data were aggregated in a table in the following 3 categories, with the same 10,000 denominator: the first category was called "general side effects in the 7 days after the second dose," with a large amount of data detailing the minor side effects; the second category was called "moderate and

severe tiredness"; and the third category was called "moderate and severe fever," both for moderate and severe side effects. Serious adverse event data were presented in a separate sentence, with an explanation of the lack of difference between the placebo and vaccine groups. This "fact box" with contextual information on the French situation regarding vaccination[26] was made available to doctors giving vaccinations.[27]

Semistructured interviews

The recruited patients were aged 32–84, with an average age of 61. There were 5 men and 12 women. Ten patients were retired persons. The duration of the interviews ranged from 17 to 47 min. The participants reported many determinants of their choice on whether to be vaccinated against SARS-CoV-2.

Most of the participants had an opinion about vaccination, but few of them declared being sure of their choice: vaccine hesitancy seemed to be related to the loss of confidence in the media and the government. Some participants used other ways to obtain information: the youngest participants referred to uncertified websites or social media, whereas the oldest referred to friends working in the medical field. The participants asked for individual information based on their own risks and benefits regarding vaccination: none of them appeared clearly aware of their personal risk if they became infected.

Some participants with chronic diseases (such as diabetes) worried about vaccines due to possible adverse effects on their pathologies. The unusual rapid development of vaccines led to a feeling that "*it was probably botched*" (P11). Several participants were suspicious of the reliability and demonstrated efficacy of the vaccination. Other barriers related to vaccination hesitancy were a fear of immediate adverse effects and doubts related to long-term possible adverse effects, especially regarding the new mRNA technology. A few participants worried about the risk of multiple sclerosis, corresponding to a controversy previously related to the hepatitis B vaccine in France.

Most patients, even those most opposed to vaccination, felt a sense of social responsibility. They saw vaccination as a duty to help people with health issues, as well as those suffering from economic impacts, "*to get life back on track*" (P12).

First steering group meeting

The steering group met and adapted the information to obtain a 2-page document that was easily accessible to most patients. First, the group prioritized information according to the perceived importance by patients from interviews and from the field of experience of each expert. Then, the steering group selected several pieces of information and presented them in an understandable way. Finally, based on the experience of experts and PtDA models, the group defined the specifications (visual organization and use of figures) and precise sentences for the graphic designer.

The first page was about individual situations: after the title and a presentation of the aim of the decision aid, pictograms illustrated the risk factors for severe infection[28] to help patients identify their own situations regarding SARS-CoV-2 infection. The main contraindications were also stated: medical background of a severe allergic manifestation, pregnancy, and previous SARS-CoV-2 infection.

The second page presented specific information about the Comirnaty vaccine. Three key points were presented: that all the scientific steps of vaccine development had been followed, that it had fewer adjuvants than other vaccines and that the data presented had scientific proof.

The benefit of the vaccine was presented with the numbers of symptomatic COVID-19 and severe COVID-19 cases with the vaccine compared to the placebo. Risks were presented with probabilities of minor side effects and information about the absence of excess risk of serious adverse events.

The uncertain elements at the time of decision aid development were then presented: duration of protection, efficacy against transmission, long-term side effects, and impact of virus mutations on vaccine efficacy.

The sentences were specifically written to be easily understood, even for those with low health literacy.

Alpha testing and second steering group meeting

Alpha testing with patients made it possible to identify some omissions, such as the date of the last update of the decision aid, details regarding a severe allergic manifestation, and a precise list of COVID-19 symptoms. The patients asked to compare the probability of minor side effects to vaccines usually used in general practice and to clearly explain the differences between minor and serious side effects. The patients were asked to specify which uncertain elements could be clarified with further studies. Some modifications to the presentation, such as adding percentages to numbers and correcting some grammatical and syntax errors, were requested.

The general practitioner alpha test group was more concerned with the scientific content: they asked to add a positive test criterion to the question regarding a previous infection with COVID-19. On the second page of the introduction, they asked for information about adjuvants to be changed and for it to be explained that there are none. They asked that the decision aid state that the data were based on "a study on more than 35,000 people" instead of "scientific proof." Regarding benefits, they asked for information about patients over 75 for whom the results were extrapolated to be added.

The second steering group composition was the same as that of the first. The group considered the suggestions of both groups and decided to include all changes and transmit them to the graphic designer.

Beta testing and third steering group

Regarding the content of the decision aid, only a few remarks remained, mainly about the graphic presentation and grammatical or orthographic errors. Patients perceived the decision aid to be clear, serious, and reassuring. They found the expanded discussion to be helpful, even though some patients found the side effects part too short and expected more information. Some patients also had questions about the authors of the document. One patient clearly expressed that he learned new information from the tool but that it did not change his position regarding vaccination; another reported that it was good tool to be used in addition to discussion with practitioners but not enough to replace it.

Practitioners reported that the use of the decision aid was easy, that it was possible to adapt depending on the patient's knowledge and that it was helpful to drive discussion about vaccination. Some of the practitioners wondered about the clarity of information for patients. For some patients, more detailed information was required, leading the practitioners to use data provided in the "fact box."[26]

Finally, experts from the previous groups and from the HAS task force asked for minor modifications, including editing and minor modification of the pictogram graphic. The third steering group then discussed and validated most of these propositions, allowing the graphic designer to produce a final version of the decision aid (Fig. 2). This steering group was composed of the same experts as the first 2 steering groups, with the additional participation of 2 primary care researchers.

Discussion

We developed the first PtDA in the French language for people who have to decide whether they will receive the Comirnaty vaccination, in accordance with the IPDAS. Composed of 2 pages, it was designed for primary care consultations.

The development process of the decision aid reported in this study has many strengths; it was performed in accordance

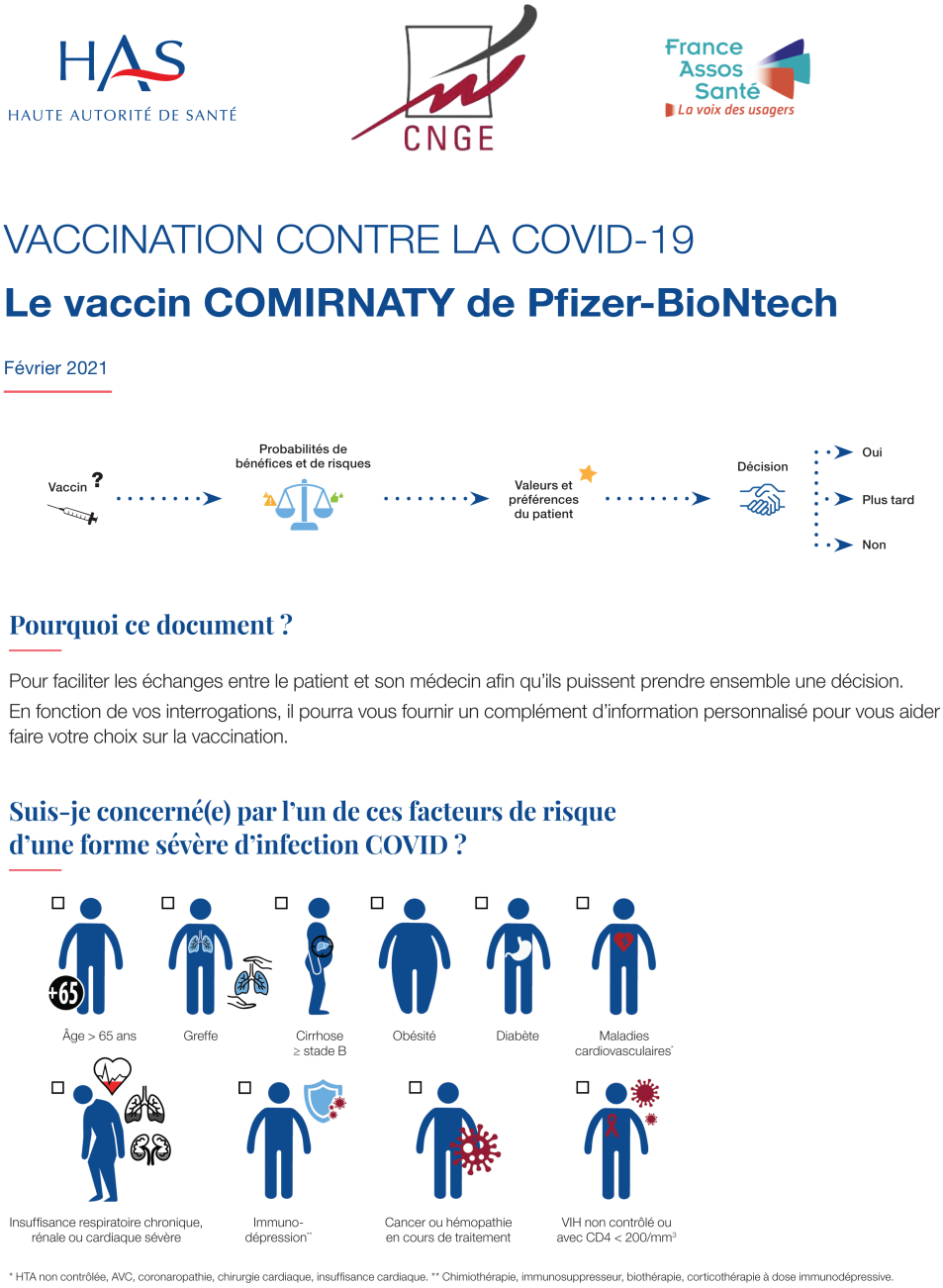

Fig. 2. (a, b) February 2021 version of the PtDA.

with the IPDAS, and it was rapidly developed, which was necessary in the French context of vaccine hesitancy. In May 2021, the IPDAS collaboration published an update about the development standards of PtDAs[29]; of note, our method included all 11 points from the updated IPDAS, as well as 7 of the 9 additional elements from this checklist.

The PtDA development involved 3 different partners that have a national audience in France: the CNGE, France Assos Santé, and the HAS. The CNGE provided expertise on the literature review and on PtDA development procedures. France Assos Santé, the major national patient support and community group in France, provided patient support, ensured patient involvement in community groups, and guaranteed respect for a patient-centred approach. The HAS provided technical support and participated in the PtDA finalization; they will also ensure national diffusion to health care providers and wide implementation.

The PtDA is an online file that can and will be updated, which is a crucial point in view of the rapid evolution of knowledge. The recent release of a study about the effect of mass vaccination in Israel[30] illustrated this fact, yielding significant results that will be incorporated into our PtDA.

Avoiding any jargon, this PtDA is supposed to be accessible for most patients, regardless of their health literacy. In the context of health inequities in the context of the pandemic and given the proven impact[31,32] of PtDAs on preventive behaviour and attitudes, our work could be part of a solution.[33] We noticed that no problems with understanding were reported during beta testing. The results also show that our PtDA could help clarify the patients' values without orienting their choice (which is consistent with shared decision-making principles).

The semistructured interview results regarding factors associated with decision-making about COVID-19 vaccination were consistent with the few published studies on the subject.[34]

Vaccination is usually associated with a collective choice for collective benefit, as with measles; this approach does not apply to COVID-19, for which vaccines have not yet been proven to reduce virus transmission. This situation also questions our usual approach to public health information about vaccines when they are not mandatory, with decision aids needing improvement.

This study also has limitations. To respect time constraints related to the specific context of the COVID-19 vaccination campaign, the interview analysis was based on only one round of coding to improve the flexibility, but this made our coding system less refined, with few perspectives and no disagreement discussion.[35] Beta testing was led only by 14 patients with various profiles who were or were not eligible for vaccination.

We note that our PtDA only refers to one vaccine. New vaccines are now regularly authorized in Europe,[36,37] and PtDAs should evolve so that patients can have similar decision aids for these vaccines. The question of a decision aid comparing different vaccines will arise when patients will have to choose between them.

Other PtDAs about COVID-19 vaccines, such as the EBSCO option grid[38] or the German internet website ShareToCare,[39] have been developed. No article has been published on this subject yet, so it is not possible to compare the methods. If we perform an operational comparison, our tool has some particularities: it has a large proportion of space allocated to the discussion and representation of patient situations, it is the only PtDA that has a large "uncertain elements" category, and the scientific data are presented in a way that is accessible to lay people to make it easier to understand than raw data. The design of the PtDA makes it clear that it is presenting the Comirnaty vaccine, whereas other tools could be confusing by presenting vaccination in a general way. This PtDA is the first released on this subject, designed via a collaboration of patient representatives, general practitioners, and members of a national institution.

We built this simple PtDA to be easily comprehensible; it is short and could be used during a consultation in accordance with shared decision-making principles. However, if some patients express the need to have more information or data, the physician can find this information in the "fact box."

Conclusion

We developed the first French PtDA for people who have to decide whether they will receive the Comirnaty vaccination. This 2-page PtDA was designed to be used in primary care consultations. This PtDA was conceived by a collaboration between the CNGE, France Assos Santé, and the HAS in accordance with the IPDAS.

Funding

There was no funding for this study.

Acknowledgments

We thank all the patients and physicians who were involved in this study. We also thank the members of France Assos Santé and Jacqueline Houdayer for their participation in the steering group. Finally, we would thank the French National Authority for Health, especially Joelle André-Vert, for their support.

Ethics

Our protocol was approved by the ethics committee of the French College of Teachers in General Practice (no. 170221265).

Conflict of interest

The authors declare that they have no conflicts of interest.

Data Availability

The data underlying the article are available upon contact with the authors.

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