

COMMENTARY

THE PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT: ITS CONTRIBUTIONS AND NEW POTENTIAL TO INCREASE PUBLIC HEALTH PREPAREDNESS

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APPROXIMATELY 6 YEARS AGO, then-President George W. Bush first signed the Pandemic and All-Hazards Preparedness Act (PAHPA) into law, reforming the nation's public health preparedness landscape. On March 14, 2013, President Barack Obama reauthorized the legislation, incorporating important lessons learned and setting the path for the next 5 years.¹

When the law was originally passed by the 109th Congress, policymakers were acting in response to Hurricane Katrina and the threat of a possible influenza pandemic.² Members of the 113th Congress have reauthorized PAHPA, seeking to enhance existing programs and authorities in light of recent public health emergencies. This article examines PAHPA, considers its impact on preparedness over the past 5 years, and describes the recently signed reauthorization legislation.

THE ROAD TO PAHPA

The terrorist attacks of September 11 and the subsequent anthrax attacks revealed a public health infrastructure that had suffered from political neglect, leaving the nation's health vulnerable to exotic diseases, bioterrorism, and other health threats.³ In response, Congress passed laws meant to strengthen the country's preparedness and response infrastructure and promote the development of medical countermeasures.

First, in the summer of 2002, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act") was signed into law.⁴ The Bioterrorism Act aimed to bolster the nation's ability to effectively respond to bioterrorism and other major public health emergencies by establishing a program of grants to states to prepare healthcare facilities for mass casualty events such as bioterrorism.⁵

Two years later, Congress passed the Project BioShield Act, answering President Bush's call during the 2003 State of the Union Address for Congress to "add to our future security with a major research and production effort to guard our people against bioterrorism."⁶ Project BioShield addressed concerns that the United States lacked vaccines and therapeutics against chemical, biological, radiological, and nuclear (CBRN) threats by creating a federal fund for procurement of CBRN countermeasures that otherwise lacked a viable commercial market, thus reducing market risk and providing economic incentives for development.⁷

In 2006, as funding for the Bioterrorism Act was set to expire, Congress began considering legislation meant to reauthorize funding for the Bioterrorism Act and to enhance existing programs based on lessons learned from the September 11 terrorist attacks, the threat of avian influenza (H5N1), and Hurricanes Katrina and Rita.⁸ The bill also sought to make adjustments to Project BioShield.⁹

Senator Richard Burr (R-NC) introduced the reauthorization legislation, called PAHPA. During a hearing held in

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New Orleans, discussing the response to Hurricane Katrina, Burr proclaimed that “the federal [government] must ensure that all state and local public health departments and health care facilities are prepared and have the tools they need to confront the unpredictable challenges that [lie] ahead—whether it’s a hurricane, a terrorist attack or a pandemic.”¹⁰ Indeed, the next 5 years would offer quite a few “unpredictable challenges,” providing invaluable insights into the successes and shortcomings of PAHPA during a range of emergencies.

PAHPA: 2007-2012

PAHPA passed out of a lame-duck Congress and was signed by President Bush just after Trust for America’s Health (TFAH) released its fourth annual assessment of the nation’s public health preparedness, finding that “five years after the September 11th and anthrax tragedies, emergency health preparedness [was] inadequate in America.”^{11(p2)} Six years later, despite cuts to federal and state budgets, PAHPA has helped usher in many meaningful improvements, some of which are described below.

Title I. National Preparedness and Response, Leadership, Organization, and Planning

Title I of the 2006 PAHPA legislation established the Secretary of Health and Human Services as the lead for all federal public health and medical response to public health emergencies and incidents covered by the National Response Framework.¹² Additionally, the Office of the Assistant Secretary for Preparedness and Response (ASPR) was established in HHS, replacing the Office of Public Health Emergency Preparedness.¹³ ASPR serves as the principal advisor to the secretary on matters related to federal public health and medical preparedness and response.

Federal response to the 2009 H1N1 pandemic is illustrative of ASPR’s role under PAHPA. During the H1N1 pandemic, ASPR organized efforts in HHS and throughout government. It coordinated interagency public health and medical response activities through a series of twice-weekly calls during which HHS regional public health administrators, regional emergency coordinators, and other federal interagency partners, such as the Department of Homeland Security (DHS), reported updates on their regions’ pandemic influenza preparedness and response activities.¹⁴ ASPR also conducted weekly calls with state health departments to identify needs and opportunities for federal assistance.

Beyond ASPR, the leadership role established for the secretary of HHS by Title I of PAHPA was also used during the H1N1 pandemic. Secretary Sebelius testified to Con-

gress that HHS worked “in close partnership with virtually every part of federal government under a national preparedness and response framework.”¹⁵ HHS characterized the new virus, disseminated information to researchers and public health officials, and developed and shipped to states a new test to diagnose infections. HHS also distributed antiviral drugs to the states from the Strategic National Stockpile (SNS). After working closely with manufacturers to prepare a virus strain for vaccine production, perform necessary clinical trials, and license multiple vaccines, HHS began a voluntary national vaccination program. Throughout the pandemic, HHS worked with state health officers and hospital administrators to monitor stress on the healthcare system.¹⁴

Additionally, Title I of PAHPA calls for HHS to integrate the needs of at-risk individuals at all levels of emergency planning.¹ Progress in addressing the needs of at-risk individuals was evidenced by HHS’s response to Hurricane Dean in 2007.¹⁶ During Hurricane Dean, states had adequate evacuation plans for at-risk individuals, and they used assessment strategies for sheltering at-risk individuals and were prepared for the rapid deployment of Federal Medical Station (FMS) units from locally pre-staged sites.

The first title of PAHPA also required that HHS submit a National Health Security Strategy to Congress every 4 years, beginning in 2009. HHS released the first strategy in December 2009, providing a blueprint for federal preparedness and response efforts.¹⁷

Title II. Public Health Security Preparedness

Title II of PAHPA primarily pertained to federal funding of state and local preparedness efforts and developing nationwide public health situational awareness.

PAHPA expanded the Center for Disease Control and Prevention’s (CDC’s) Public Health Emergency Preparedness (PHEP) cooperative agreement grant program to allow political subdivisions of states, or a consortium of states, to be eligible for funding.¹⁸ PHEP cooperative agreement grants have since provided support for state, local, and territorial health departments in demonstrating measurable progress toward achieving public health preparedness capabilities and other activities that promote resilient communities.¹⁹ These funds have been used to, among other things, strengthen biological laboratory capabilities and capacities in states and localities, allowing the rapid identification of certain disease-causing bacteria, as well as to enable states to prepare to receive, distribute, and dispense medical countermeasures from the SNS and rapidly staff state and local emergency operations centers.²⁰

CDC’s PHEP cooperative agreement has funded 62 state, local, and US insular area public health departments.²⁰ In 2009 alone, these funds helped state and local public health departments respond effectively to major

natural events, such as the H1N1 influenza pandemic, severe winter weather, flooding, and wildfires, and to biological incidents, such as outbreaks of salmonella, *E. coli*, and mumps, as well as an anthrax infection linked to animal hides in New Hampshire.²⁰

Additionally, PHEP cooperative agreement funding supports the Cities Readiness Initiative (CRI), which focuses on enhancing preparedness in US cities, where more than half of the population lives. In 2004, CRI funded only 21 cities; now, CRI funds important preparedness efforts in 72 cities and in all 50 states.²¹

Title II of the legislation also called on the secretary of HHS to establish a national real-time capability for obtaining situational awareness during public health emergencies.²² The law enabled the secretary to award grants to states to establish or operate disease surveillance networks. These grants have supported surveillance capabilities in states including Kansas, where, after the 2009 H1N1 influenza, HHS funding increased the number of sites in the Influenza-like Illness Surveillance Network statewide from 22 to 73 and supported the development of a hospital-based reporting system, a school absenteeism surveillance system, and weekly surveillance and epidemiology reports.²⁰

Title III. All-Hazards Medical Surge Capacity

With respect to medical surge capacity, Title III of PAHPA advanced work in healthcare preparedness through Hospital Preparedness Program (HPP) cooperative agreements and directed HHS to improve the use of medical volunteers in emergency response.²³

From 2002 to 2006, HPP funding enabled hospitals to make great strides in preparing to respond to emergencies. In 2006, under PAHPA, the HPP was transferred to ASPR, and the focus of the program shifted from individual hospital bioterrorism preparedness (ie, stockpiling and planning) to all-hazards capacity-building for responding to large public health emergencies and community-wide preparedness.²⁴ HPP funds have been used to strengthen the capabilities of hospitals to respond to events that require special resources, such as floods, tornadoes, wildfires, and infrastructure collapse. For example, preparedness building through HPP enhanced response to the Fort Hood, Texas, shooting in November 2009. Specifically, HPP funds helped facilitate communication among hospitals and emergency medical systems (EMS) during the incident.²⁵

Title III of PAHPA also directed HHS to improve programs for incorporating medical volunteers into emergency response. To ensure that medical volunteers are available to respond in mass casualty emergencies, HHS continued support for the Medical Reserve Corps (MRC). As of August 2011, the MRC program covered more than 90% of the US population through a force that exceeds 200,000 volunteers in more than 950 geographically based

units across the United States.²⁶ Likewise, Title III of PAHPA requires the secretary of HHS to link existing state verification systems for volunteers. Accordingly, ASPR manages the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), which is intended to help preregister and credential volunteer health professionals so that they can quickly plug into a disaster response without having to wait for registration approval. Now, every state and territory in the United States has a functioning ESAR-VHP system and a list of registered, credentialed volunteer health professionals.

This section of the law has also allowed the secretary to create additional positions in the Epidemic Intelligence Service (EIS) program. Officers in the EIS provide important public health assistance by conducting epidemiologic investigations, research, and public health surveillance. Since the passage of PAHPA, EIS officers have provided assistance throughout the country during incidents such as the 2009 H1N1 influenza pandemic, an extended disruption of drinking water service in Alabama, and an investigation of an outbreak of staph infections at a pain management clinic in West Virginia.²⁷

Title IV. Pandemic and Biodefense Vaccine and Drug Development

Title IV of PAHPA implemented steps to accelerate the development of medical countermeasures by making important modifications to Project BioShield and establishing the Biomedical Advanced Research and Development Authority (BARDA) in HHS.

The Project BioShield Act was signed into law in the summer of 2004.²⁸ This law was meant to both encourage the private sector to develop medical countermeasures to CBRN threat agents and to provide a novel mechanism for federal acquisition of these countermeasures for stockpiling.⁷ The law relaxed regulatory requirements for some CBRN terrorism-related spending, set up a federal market for CBRN medical countermeasures, and permitted emergency use of unlicensed countermeasures.⁷ Each of these authorities has since been used by HHS, including in the procurement of countermeasures against anthrax and smallpox and during the 2009 H1N1 influenza pandemic, when the emergency use authority was used several times.⁷

Industry participation during the early years of Project BioShield fell short of expectations, partially because BioShield was limited to late-stage procurement of countermeasures, leaving pharmaceutical companies to depend on unfavorable market forces for the period of expensive advanced development.⁹ PAHPA aimed to address this and other shortcomings by establishing BARDA. BARDA enabled HHS to use contracts and prizes to support development in advance of BioShield procurement, thus bridging the funding gap between early-stage development and product procurement by Project BioShield (sometimes

referred to as the “valley of death”). In addition to aiding in development, BARDA has also managed Project BioShield acquisition contracts. Thus, BARDA supports countermeasure development both in development and acquisition contracts under Project BioShield. Project BioShield provides one part of the bridge for the “valley of death” by providing dedicated funding through the Special Reserve Fund (SRF), which provides a market guarantee for industry partners who successfully develop and manufacture medical countermeasures (MCMs). Over the years, use of SRF funds for advanced development (rather than procurement) and in other sectors not devoted to threats posed by terrorism or rogue nations has generated controversy.²⁹ Despite that, SRF has been essential in developing and procuring critical countermeasures, including anthrax therapeutics and vaccines, heptavalent botulinum antitoxin, smallpox vaccine for immunocompromised people, smallpox antiviral drugs, and MCMs intended for use after radiological or nuclear events.³⁰

BARDA was also tasked through PAHPA with managing the Public Health Emergency Countermeasures Enterprise (PHEMCE), which has united diverse partners from across federal, state, and local governments, industry, and academia with the goal of improving coordination and efficiency to meet the country’s demand for an adequate supply of CBRN medical countermeasures.³¹

PAHPA: 2013–2018

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (HR 307) was first introduced to the 113th Congress in the House of Representatives by Congressman Mike J. Rogers (R-MI) and 5 cosponsors on January 18, 2013; it was passed by the House of Representatives on January 22, 2013. Championed by Senator Burr, the reauthorization legislation was passed by the Senate on February 27, 2013, paving the way for President Obama to sign the final legislation on March 14, 2013.

WHAT REAUTHORIZATION ACCOMPLISHES

Reauthorizes Important Programs

PAHPA reauthorization helps to preserve the gains in preparedness made since PAHPA was originally passed in 2006 by reauthorizing and proposing funding for critical preparedness and response initiatives. While funding levels suggested in this law are not guaranteed, they do offer a guideline for future appropriations considerations by Congress. These programs are the basis of our national medical and public health preparedness.

By reauthorizing CDC’s PHEP cooperative agreements, CDC’s Preparedness and Response Capabilities programs, and the HHS HPP grants, this bill ensures that public

health and medical systems will not revert to pre-2006 levels of preparedness. The funding proposed for these programs, while substantially lower than funding levels in 2006, ensures that these preparedness programs live on at the state and local levels.

Congress and the president have also guaranteed continued progress in medical countermeasures development, procurement, and distribution by reauthorizing BARDA and the BioShield Special Reserve Fund.

Funding for BARDA to continue leading development of critical medical countermeasures is proposed at \$415 million per year from FY2014 to FY2018, a higher funding level than any amount authorized for BARDA since FY2009.³² It remains to be seen if Congress will appropriate funds to BARDA at this requested level, as they have routinely funded this agency at lower-than-requested levels in the past and taken money from the BioShield SRF for use in BARDA instead of appropriating money directly to the authority.³²

The BioShield SRF is to be reauthorized and replenished with \$2.8 billion for use during FY2014 to FY2018, thus enabling the federal government to continue to purchase needed medical countermeasures against CBRN threats. In an attempt to limit underfunding of BARDA, and to limit the use of SRF funds for purposes other than the procurement of MCMs, Congress has restricted the amount of SRF monies that can be used by BARDA for countermeasures development (as opposed to procurement) to 50% and required HHS to report to Congress when the SRF drops below \$1.5 billion.

Finally, the law extends programs focused on recruiting and managing volunteer health professionals for disaster response. These programs provide the country with a way to harness medical volunteers as force multipliers to care for the sick and injured in disasters, and they will be particularly critical to enhancing our surge capacity should a large-scale or catastrophic disaster occur in the United States. The law reauthorizes and allows for some continued funding of ESAR-VHP, with suggested funding of \$5 million per year; reauthorizes the National Disaster Medical System (NDMS), with suggested funding at the highest level since the program moved to HHS in FY2006 (\$52.7 million per year); and reauthorizes the volunteer MRC at a funding level of \$11.2 million per year (approximately level with previous years).

Builds on Progress in Preparedness

In addition to reauthorizing important programs, this law also aims to make state and local public health and medical preparedness grant programs more efficient and effective.

ASPR is now required to coordinate HHS state and local grant program applications, guidance, and metrics in HHS and with sister programs in other departments (eg, DHS). This move toward greater grant coordination will help

federal agencies and state and local grant recipients alike by minimizing duplication of effort in the grant processes and ensuring more efficient use of funds between programs.

The law also permits state and local HPP and PHEP grant recipients more flexibility with unobligated grant funds by making grant money spendable over multiple fiscal years. This will provide an opportunity for health officials to pursue longer-term projects needed to protect the health and security of their constituents and will minimize loss of unspent funds and waste of funds on projects with little strategic importance.

The law provides continuity with prior preparedness efforts by emphasizing partnerships for local, state, and regional preparedness. These partnerships include health-care providers, public health agencies, emergency management organizations, and other participants working together to build surge capacity for all hazards but particularly for response to large disasters.

Finally, the law requires the secretary to update influenza plans and build on prior pandemic preparedness efforts. It authorizes a new program and \$30.8 million in funding for the development of a vaccine tracking and distribution system—a need identified following the 2009-10 H1N1 influenza pandemic. The law also requires the HHS secretary to periodically update pandemic planning criteria and present those criteria to the state agencies when appropriate. The updated criteria will be included in the benchmarks and standards for measuring progress in preparedness through the state and local public health emergency preparedness and hospital preparedness grants.

Requires Strategic and Regulatory MCM Planning

The main focus of this law is on medical countermeasure development, procurement, licensure, and use; it is intended to facilitate dispensing of appropriate MCMs to the people who need them as quickly as possible in an emergency.

PAHPA moves MCM development forward first by requiring that ASPR write and publicize a 5-year MCM budget plan that more explicitly identifies the public health threats that need to be addressed, the countermeasures needed to protect the US population against these threats, and an approach to developing and procuring needed countermeasures.

In addition, for procurement of MCMs under Project BioShield, the secretary now requires that any applicant or sponsor of an MCM seeking investigational new drug (IND) status will need to work with the Food and Drug Administration (FDA) to develop a Regulatory Management Plan. This addition to the law will engage FDA in helping companies navigate the regulatory process and will help ensure that needed MCMs are not held up excessively by unnecessary bureaucratic hurdles in regulatory approval.

Improves Regulatory MCM Management

This law expands the involvement of FDA in the processes of advanced MCM development in order to accelerate development, clearance and licensure, and procurement for the SNS. The law now ensures that FDA is integrally involved in the process of advanced development, so that companies and sponsors are better prepared to navigate the FDA regulatory process and bring MCM products to the market as quickly and efficiently as possible.

Integration of FDA into this process will include training of FDA personnel, better communication from ASPR about material threat information, and regular meetings among BARDA, FDA, and countermeasure sponsors and applicants.

Finally, ASPR will work with FDA to provide final guidance on the topic of animal models. The secretary will establish a procedure for discussing and evaluating proposed animal model procedures with each approved IND request and prior to initiation of animal model studies.

Focuses on MCMs for Children

Children are 25% of the US population, yet very few of the MCMs in the SNS or in the development pipeline are appropriate for pediatric use.³³ In order to address this gap in protection, this law specifically prioritizes children in MCM planning and development by requiring ASPR to address the need for pediatric MCM formulations. Under this law, ASPR and the secretary will work to consider the current gaps in pediatric MCMs, understand the need for additional MCM pediatric studies, and implement a plan to develop and stockpile medical countermeasures for the pediatric population. To do this, the secretary will establish a National Advisory Committee on Children and Disasters, which will provide guidance in this area and on other aspects of pediatric needs in disaster situations. Additionally, ASPR will seek guidance from the Pediatric Advisory Committee Regarding Countermeasures for Pediatric Populations.

Augments Federal Authorities for MCM Use

The law provides the HHS secretary with greater flexibility to decide what qualifies as “emergency use” of medical countermeasures. It expands the justification for authorization of emergency beyond an actual public health emergency to include a potential public health emergency, as well as identification by the secretary of a “material threat” to public health.

The secretary has the authority to waive or deviate from Good Manufacturing Practices (GMPs) to make needed countermeasures available to the public under the expanded

“emergency use” definition, even if the product has not yet been approved by the FDA or would be used in a way different from the original FDA-approved label.

In addition, the law gives authority to the secretary to extend the expiration dates of stockpiled countermeasures without resulting in the product’s being categorized as unapproved or mislabeled. This will prevent HHS from having to discard usable countermeasure products that can be extended and would avoid the long and costly process of seeking reapproval by the FDA for products that are still usable.

Aims to Improve Biosurveillance

This law requires HHS to conduct an updated review of its biosurveillance programs and prepare and submit to Congress a plan for improving information sharing and coordination of biosurveillance systems throughout the department. This mandate is a continuation of surveillance coordination efforts required under the original PAHPA law. It is a difficult problem to coordinate and harness all of the disparate biosurveillance efforts in HHS and across government, and it is a task that will benefit from continued support under PAHPA reauthorization.

Additionally, PAHPA now requires ASPR to consult with the Office of the National Coordinator (ONC) for Health Information Technology (HIT) on biosurveillance to find ways that HIT and biosurveillance systems can be of mutual benefit. Inclusion of the ONC in biosurveillance discussions will be critical to ensuring that the needs and requirements of public health are considered in the development of a national health information network and that public health is harnessing HIT to improve biosurveillance and thus response to public health emergencies.

WHAT IS MISSING FROM THE LAW

Increased Funding

The biggest hurdle to continuing advancement in preparedness and response capabilities is a lack of funding. In these times of fiscal constraint, it is important to recognize that the health and security of the nation rests on programs established in PAHPA. We are seeing a marked decline in state and local preparedness and response capacity because of budget cuts to HHS grant programs.³⁴ Funding cuts are resulting in a loss of institutional knowledge and expertise and technical capacity.³⁵ When epidemiologists are lost, laboratories are defunded, and hospitals can no longer afford to prepare for emergencies, we are putting ourselves at risk. These programs will require adequate funding to maintain gains in preparedness since 2006 and prevent public health and medical preparedness from backsliding to pre-2006 levels.

Focus on Public Engagement

One important area of focus that is largely missing from PAHPA reauthorization is community resilience and public engagement in preparation for and response to public health emergencies. The foundation of the National Health Security Strategy (NHSS), required by the original PAHPA and released in December 2009, is “informed, empowered individuals and communities.”^{17(p8)}

While community resilience and public engagement are clearly priorities for the Obama administration in the NHSS, this mandate has not been well supported, and little to no money or guidance has been issued for state and local initiatives to engage communities in preparedness activities and improve community resilience. With all of the competing priorities in public health, and continued cuts in public health funding at the state and local levels, if this is truly a federal priority, it should be accorded appropriate attention through program development and funds.³⁶

National Strategy for Volunteer Health Professionals

While medical volunteer programs such as the MRC and NDMS have been critical in building our volunteer capacity to respond to large-scale mass casualty disasters, in order to harness these volunteer health professionals appropriately, the federal government needs to consider strategically the issue of volunteer health professional integration into disaster response. ASPR should be charged with understanding how volunteers can best be used in a disaster setting, what different skills and knowledge volunteer health professionals have, the tasks they can perform, and how the various volunteer programs fit into the response structure. HHS has taken some initial steps to set strategy for the various medical volunteer programs, including the MRC and ESAR-VHP. However, an overall strategy for volunteer integration is needed to better understand how volunteer health professionals can be used most effectively and the barriers that still prevent their integration into preparedness and response.

Emergency Medical Services Integration

Currently, EMS, while an extremely important component of disaster medical response, has not been well integrated into the preparedness infrastructure at the federal level. EMS is instead still considered to be mainly a transportation asset, not a healthcare asset, and is located in the Department of Transportation. Preparedness and response components of EMS are currently located in both DHS in the Federal Emergency Management Agency (FEMA) and HHS in ASPR. These programs are not well coordinated. In fact, according to the federal Interagency Board, the

“absence of a single, unified ‘home’ for EMS at the Federal level contributes to an inconsistent operational doctrine for EMS response to daily emergencies and large scale disaster events.”^{37(p1)}

The consequences of this lack of a unified EMS at the federal level are that prehospital care is often overlooked in federal preparedness planning, EMS is not well integrated into response to large disasters, and EMS does not receive the same levels of federal grant support provided to improve hospital and public health preparedness and response. Thus, EMS does not have the resources and guidance to plan for and respond effectively to large disasters. In order for EMS to become an integral part of emergency preparedness and response, these programs need a much greater level of federal coordination and oversight.

CONCLUSIONS

PAHPA legislation has led to a fundamental and altogether positive transformation of the public health and medical preparedness and response landscape. The original PAHPA law helped to establish and fine tune key programs in public health preparedness, hospital preparedness, countermeasure development and stockpiling, and emergency response. The public health and medical communities are far better prepared today than they were in 2006, due in large part to PAHPA.

The reauthorized PAHPA bill now provides a roadmap for future preparedness that, if funded adequately, will build on preparedness from the last decade and may revolutionize areas of countermeasure development, surveillance, and public health and medical community preparedness. With PAHPA reauthorization, we can continue to build resilience to large disasters, respond more quickly and effectively, and reduce the impact of health events on the health and wellness of the country.

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