

THE NATIONAL VACCINE PROGRAM OFFICE

MID-COURSE REVIEW OF THE 2010 NATIONAL VACCINE PLAN

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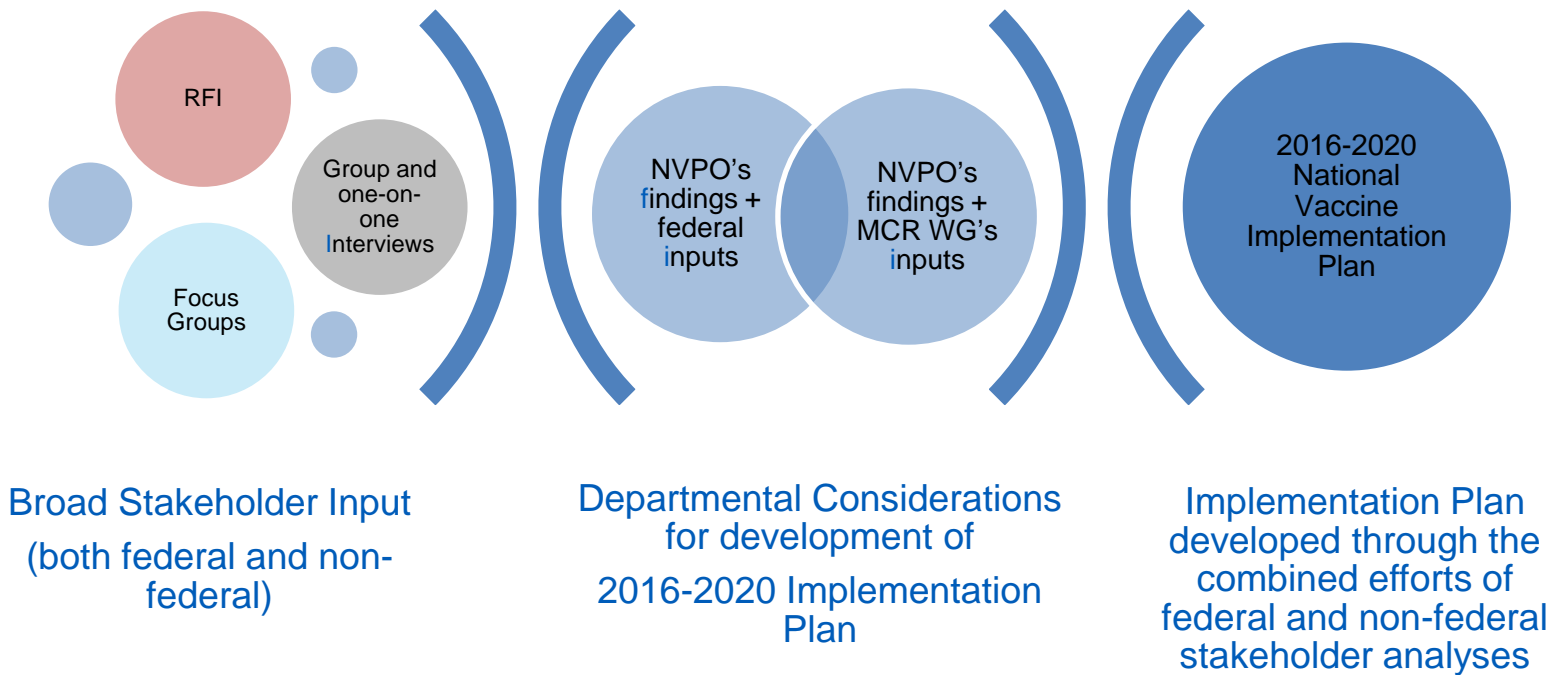


U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES

Overview of Presentation

- Purpose of the Mid-course Review
- Methodology
- Priority Opportunity Areas
- Indicators selected by federal partners
 - *Indicators selected by NVAC working group presented separately*
- Next Steps

Big Picture Overview of the Mid-course Review Process





Statutory Basis for the National Vaccine Plan: Title XXI of the Public Health Service Act (P.L. 99-660)

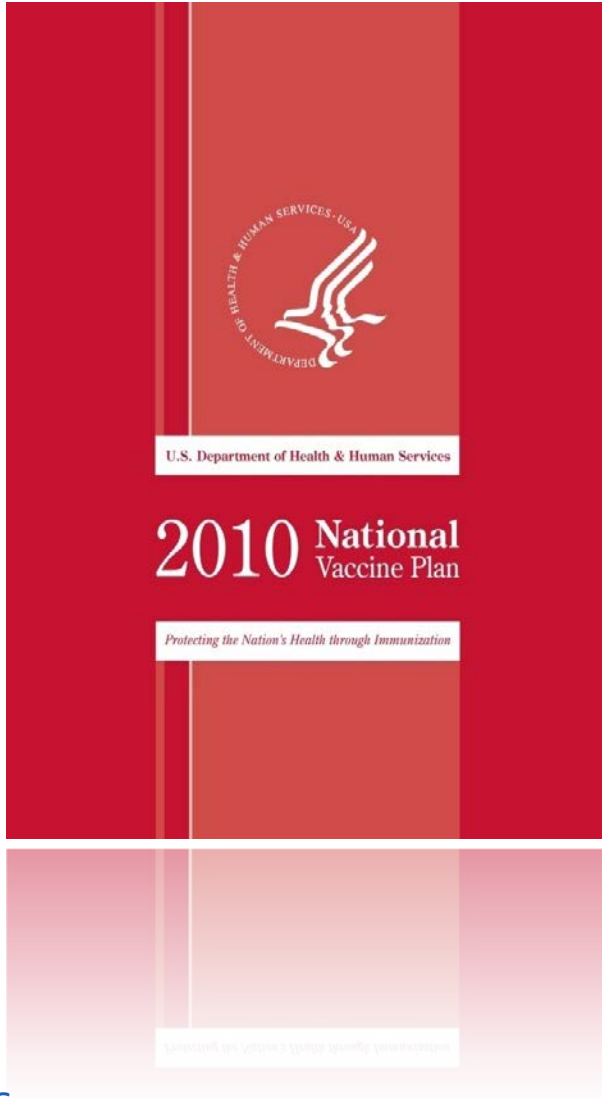
SEC. 2103. [300aa-3]

The Director of the program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 2102.

The plan shall

- Establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines;*
- Describe an optimal use of resources to carry out such priorities; and*
- Describe how each of the various departments and agencies will carry out their functions in consultation and coordination with the Program and in conformity with such priorities.*

2010 National Vaccine Plan



Goal 1: Develop new and improved vaccines



Goal 2: Enhance the vaccine safety system



Goal 3: Support communications to enhance informed vaccine decision-making



Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the United States

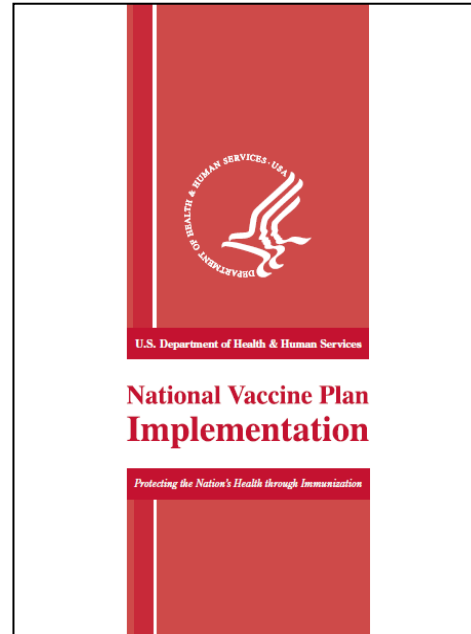


Goal 5: Increase global prevention of death and disease through safe and effective vaccination

The 2010-2015 National Vaccine Implementation Plan

National Vaccine Plan Priorities for Implementation

- | | |
|----|--|
| A. | Develop a catalogue of priority vaccine targets of domestic and global health importance (Goal 1). |
| B. | Strengthen the science base for the development and licensure of new vaccines (Goals 1 and 2). |
| C. | Enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda (Goal 2). |
| D. | Increase awareness of vaccines, vaccine-preventable diseases, and the benefits/risks of immunization among the public, providers, and other stakeholders (Goal 3). |
| E. | Use evidence-based science to enhance vaccine-preventable disease surveillance, measurement of vaccine coverage, and measurement of vaccine effectiveness (Goal 4). |
| F. | Eliminate financial barriers for providers and consumers to facilitate access to routinely recommended vaccines (Goal 4). |
| G. | Create an adequate and stable supply of routinely recommended vaccines and vaccines for public health preparedness (Goal 4). |
| H. | Increase and improve the use of interoperable health information technology and electronic health records (Goal 4). |
| I. | Improve global surveillance for vaccine-preventable diseases and strengthen global health information systems to monitor vaccine coverage, effectiveness, and safety (Goal 5). |
| J. | Support global introduction and availability of new and under-utilized vaccines to prevent diseases of public health importance (Goal 5). |



Priorities identified to guide federal immunization efforts across government agencies

Why Conduct a Mid-course Review?

2010 National Vaccine Plan:

“Recognizing these uncertainties, NVPO will coordinate a mid-course review of the Plan after five years allowing changes to be made which **respond to the reality of the environment**. Modified indicators, strategies, actions, and milestones will **guide subsequent annual evaluation through the overall ten-year horizon of the Plan.**”

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To guide development of 2016-2020 Implementation Plan

- outline near-term, actionable efforts based on areas where we have the greatest opportunity to move the program forward **by 2020**

To serve as a framework for building community consensus on priorities areas

- Where progress has been made, where it is needed, and what is possible by 2020

To serve as a roadmap for incoming political leaders

- Clearly-defined priorities laid out across the vaccine ecosystem can aid incoming political leaders in decisions that could impact resource allocation

Questions Framing the Mid-course Review

- Broadly speaking, is the Plan meeting its goals and objectives?
- Based on the current landscape, are we still going in the direction needed?
- How do we optimize implementation efforts going forward to better align with the current immunization landscape?
 - How will we ensure coordination with other vaccine and immunization-focused strategic plans across the Department?
- How will we measure our progress? How will we know that we accomplished our near-term goals (i.e., how will we define success)?

2010 NVP Mid-course Review Methodology

- NVPO/ Booz Allen Hamilton (BAH) to complete review and analysis
- Multi-pronged approach to solicit input from both federal and non-federal stakeholders
 - RFI from federal and non-federal stakeholders
 - One-on-one interviews (federal and non-federal partners)
 - Small group interviews
 - Focus groups (federal and non-federal partners)
 - Interagency calls for information sharing
- Building consensus and stakeholder support around the greatest areas of opportunity for accomplishing our NVP goals in the next five years
- Frequent engagement with federal partners to verify accomplishments, to gain further input on prioritized opportunity areas, and to identify metrics
 - One-on-one interviews with federal agencies
- All results also provided to the NVAC Working Group for deliberation and discussion– separate analysis and recommendations

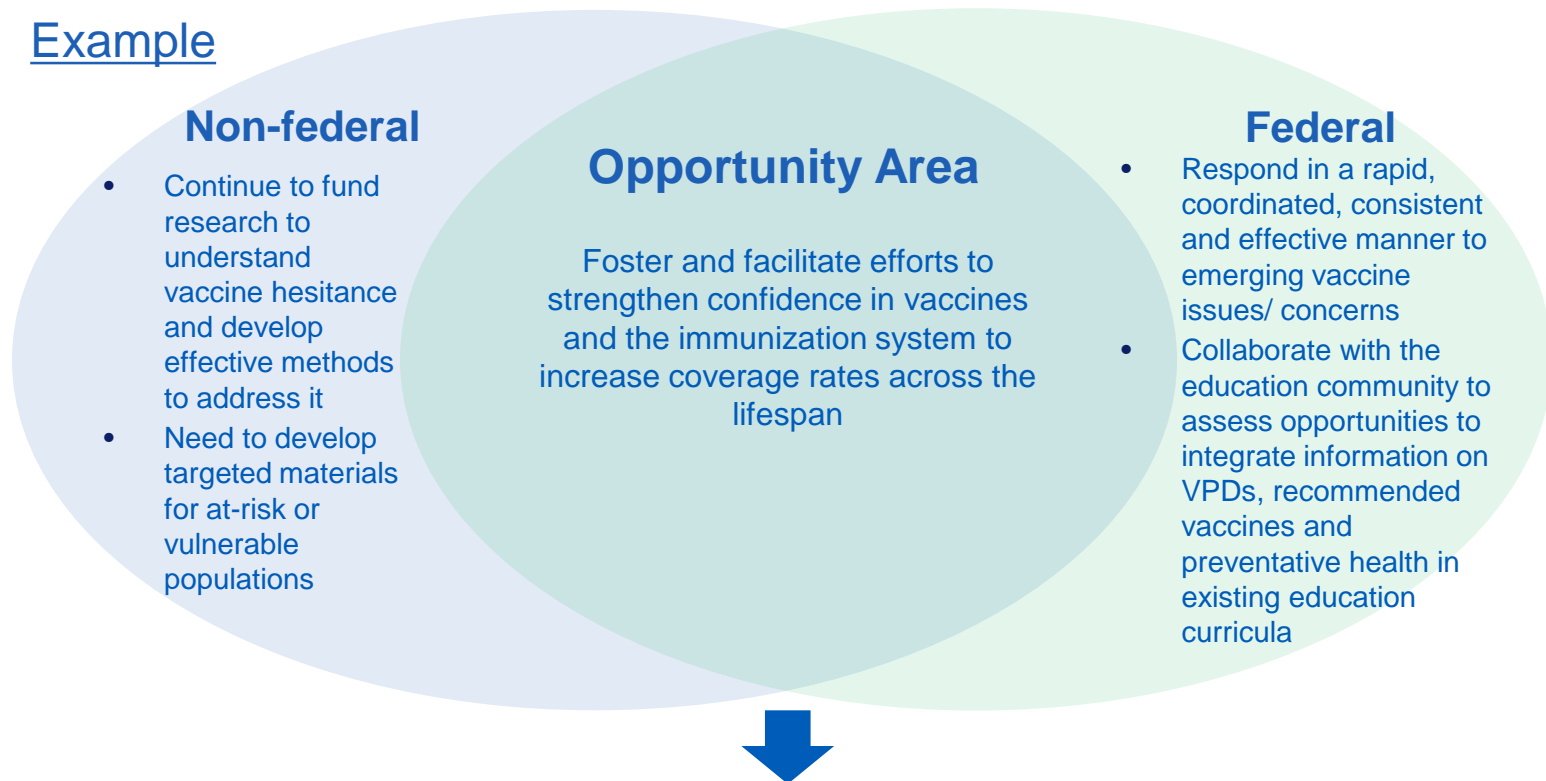
Combining Stakeholder Inputs to Develop Areas of Greatest Opportunity

- “Gaps” identified by both federal and non-federal stakeholders were evaluated and grouped into common themes
- Language crafted to broadly address the gaps
- When possible, language compared with previous priorities of the NVP and refined to best reflect the feedback from stakeholders

Combining Stakeholder Inputs to Develop Areas of Greatest Opportunity

Result – Areas identified by stakeholders as holding the greatest opportunity for moving the Program forward between 2016- 2020 (i.e. Opportunity Areas)

Example



Opportunity Areas for discussion and prioritization by stakeholder focus groups

Ranking of Proposed Opportunity Areas

- NVPO hosted three stakeholder focus groups to rank and identify Top 5 opportunity areas (OAs)
 - Many of the OAs were considered sub categories of other more broad OAs and so did not rise to top

| Opportunity Area |
|--|
| Strengthen health information and surveillance systems to track, analyze and visualize disease, immunization coverage and safety data, both domestically and globally. |
| Foster and facilitate efforts to strengthen confidence in vaccines and the immunization system to increase coverage rates across the lifespan. |
| Eliminate financial and systems barriers for providers and consumers to facilitate access to routinely recommended vaccines. |
| Strengthen the science base for the development and licensure of vaccines. |
| Identify and implement solutions to overcome vaccine development barriers. |
| Increase coordination, collaboration and knowledge sharing among related parties and disciplines. |
| Improve the transparency of the vaccine safety system and the entire vaccine enterprise to policy-makers, the public and providers. |
| Improve scientific knowledge about why and among whom vaccine adverse events occur. |
| Support the strengthening of immunization systems globally through policies, practices and partnerships. |

Resulting Top Ranked Opportunity Areas (2016-2020)

Top 5 from all three focus groups (aggregated and weighted rank as shown):

- 1) Strengthen health information and surveillance systems to track, analyze and visualize disease, immunization coverage and safety data, both domestically and globally
- 2) Foster and facilitate efforts to strengthen confidence in vaccines and the immunization system to increase coverage across the lifespan
- 3) Eliminate financial and systems barriers for providers and consumers to facilitate access to and administration of routinely recommended vaccines
- 4) Strengthen the science base for the development and licensure of new vaccines, especially our understanding of the host immune system and correlates of protection
- 5) Identify and implement solutions to overcome vaccine development barriers

Identification of Selected Indicators

- Federal partners and the NVAC working group both reviewed a proposed list of 59 relevant indicators from a number of existing immunization strategies and other relevant documents
 - Harmonizing with other strategic documents reduces duplicative efforts
 - Clear leads for implementation purposes and could be applied immediately

- HHS Strategic Plan, 2014-2018
- Healthy People 2020
- National Adult Immunization Plan, 2016-2020
- NIAID Strategic Plan, 2013
- FDA CBER Strategic Plan, FY12-FY16
- CDC's Strategic Framework for Global Immunization, 2016-2020
- PHEMCE Strategic Plan, 2015
- BARDA Strategic Plan, 2011-201
- GVAP 2011-2020
- PAHO, Regional Immunization Plan 2015-2020
- Vaccine Pipeline Analysis, 2015; Access to Medicine Foundation
- Access to Vaccines Index, Methods Report; Access to Medicine Foundation
- Pronker et al., 2013 (PLOS One): Risk in Vaccine Research and Development Quantified

Identification of Selected Indicators

- Federal partners weighed in on indicators found most appropriate for each OA
 - Indicators are not perfect but using existing indicators does not require additional resources or development time and can be applied to the 2016-2020 time horizon of the Implementation Plan
- Global indicators were incorporated into each OA to recognize both the domestic and global importance of the 5 OAs
- NVAC working group conducted an independent assessment of the proposed indicators (*presented by the working group*)

1) Strengthen health information and surveillance systems to track, analyze and visualize disease, immunization coverage and safety data, both domestically and globally

INDICATORS SELECTED BY FEDERAL PARTNERS

| Indicator | Currently Being Tracked by... |
|---|--|
| The number of Meaningful Use adopters that opt to fulfill the electronic reporting to IIS requirements to obtain Meaningful Use certification (domestic) | ONC 2020 Target: not defined Baseline: 73% of eligible U.S. hospitals able to report vaccination to their local IIS (2014) |
| Percent of adults age >19 with one or more immunizations recorded in an IIS (domestic) | NAIP 2020 Target: 50% Baseline: 25% (CDC, 2012) |
| Increase the percentage of children under age 6 years of age whose immunization records are in a fully operational, population-based IIS (domestic) | HP2020 2020 Target: 95% Baseline: 75% (2008) |
| Number of countries with case-based surveillance for vaccine-preventable diseases (global metric of surveillance) | GVAP SAGE 2020 Target: 75% of LMIC for hospital-based sentinel site surveillance for IBD and rotavirus Baseline: 67% Member States IBD; 52% Member States rotavirus (2013) |

2) Foster and facilitate efforts to strengthen confidence in vaccines and the immunization system to increase coverage rates across the lifespan

INDICATORS SELECTED BY FEDERAL PARTNERS

| Indicator | Currently Being Tracked by... |
|--|---|
| Decrease the percentage of children in the United States who receive 0 doses of recommended vaccines by age 19 to 35 months (domestic) | HP2020 2020 Target: not set (informational) Baseline 0.8% (2012) |
| Increase the vaccination coverage level of recommended number of doses human papillomavirus (HPV) vaccine for females by age 13 to 15 years (domestic) | HP2020 2020 Target: 80% Baseline: 28.1% (2012) |
| Increase the percentage of adults aged 18 and older who are vaccinated annually against seasonal influenza (domestic) | HP2020 2020 Target: 70% Baseline: 38.1% (2010-2011) |
| Percentage of pregnant women who report receiving influenza immunization during pregnancy (domestic) | CDC Internet Panel Survey 2020 Target: not set (developmental) Baseline: 52% (CDC, 2013) |
| The dropout rates between DPT3 and DPT1, globally (global metric of demand) | GVAP SAGE 2020 Target: decreasing trend Baseline: 18.6% Member States had dropout rates $\geq 10\%$ |

3) Eliminate financial and systems barriers for providers and consumers to facilitate access to routinely recommended vaccines

INDICATORS SELECTED BY FEDERAL PARTNERS

| Indicator | Currently Being Tracked by... |
|---|--|
| Percent of surveyed primary care providers who stock vaccines routinely recommended for adults (domestic) | NAIP 2020 Target: 60% Baseline: 20% Internists and 31% FP (CDC, 2012) |
| Percentage of states and territories that allow pharmacists to administer all routinely recommended vaccines for adults > 19 without a patient-specific prescription (domestic) | NAIP 2020 Target: 100% Baseline: 85% (APhA, 2013) |
| Percentage of state Medicaid programs that provide coverage of all ACIP/CDC-recommended vaccinations for adults and prohibit cost-sharing (domestic) | NAIP 2020 Target: 100% Baseline: 20% (CMS, 2012) |
| Increase the percentage of adults who are vaccinated against zoster (shingles) (domestic) | HP2020 2020 Target: 30% Baseline: 6.7% (2008) |
| Number of WHO regions achieving measles elimination by 2020 (global metric of access) | GVAP, SAGE 2020 Target: 5 WHO regions Baseline: 0/5 WHO regions (2010) |

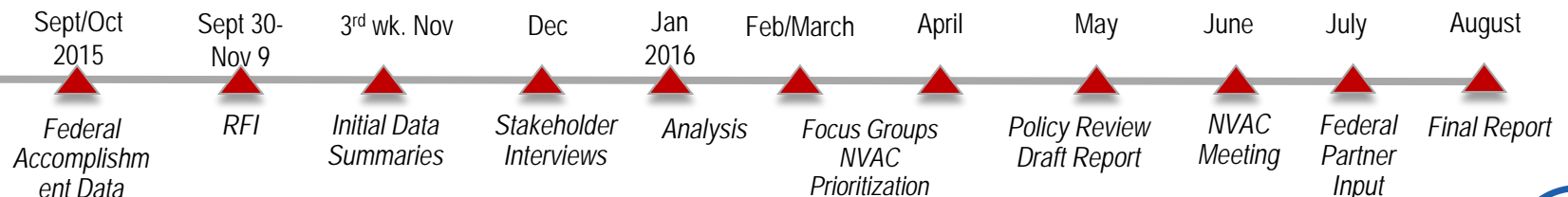
- 4) Strengthen the science base for the development and licensure of vaccines and identify**
- 5) implement solutions to overcome vaccine development barriers**

INDICATORS SELECTED BY FEDERAL PARTNERS

| Indicator | Currently Being Tracked by... |
|---|--|
| Average vaccine development timeline from the pre-clinical phase to regulatory submission (domestic and global) | To be identified |
| Number of vaccines in the pipeline for diseases where no vaccines are currently on the market and by developmental stage. The analysis will include the following infectious diseases: Chagas, dengue, HIV/AIDS, leishmaniasis, malaria and tuberculosis (global) | Access to Medicine Foundation |
| Licensure and launch of at least one platform delivery technology and/ or the number of vaccine deliver technologies (devices and equipment) that have received WHO pre-qualification against the 2010 baseline (global metric of innovation) | GVAP SAGE 2020 Target: 1 or more technologies |

Next Steps and Timeline

- Federal agencies will review findings from NVPO's analysis and provide further feedback on proposed indicators
- NVPO's Mid-course report finalized August 2016
- NVAC working group will continue their independent analyses with considerations from federal findings described here and in final report.
 - NVAC's report and recommendations presented at September NVAC
- All analyses (federal and NVAC) will help guide development of the 2016-2020 Implementation Plan for the National Vaccine Plan



THANK YOU!

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