SECTION-1: Ministry of Health Level

I. Vaccine Safety management and quality control

1. What is the overall mechanism to monitor vaccine safety and quality at the ministry level? (Probe: policy, strategies, coordination and collaboration with EFDA/EPSA and other agencies, supervision and monitoring system)
2. Now let us discuss Adverse Effects Following Immunization (AEFI). What is the role of MOH-E EPI in supervising and monitoring AEFI? How is the collaboration with EFDA? In what aspects of AEFI do you collaborate? The role of MOH-E in the process of AEFI case investigation and notification?
3. Let us turn our discussion to AEFI data utilization. How is the AEFI data analysis conducted and used for decision making (Ask on who analyzes it? How is a cause for the AEFI determined?)
4. How do you communicate AEFI risks? How do you decide whether or not to communicate the information, who is communicated? What are the challenges? (Ask on: How they manage media for post AEFI? How they deal with rumours and misinformation? challenges?

II. **Vaccine Preventable Disease Surveillance:** Let us discuss on the vaccine preventable disease surveillance in the country. What is your role in VPD surveillance? Can you tell me more about the VPD surveillance system in Ethiopia? (Probe: how VPDs are monitored continuously, the status of the VPD surveillance, laboratory system investigation of VPDs, zero reporting system, communication and information networks for notification of VPDs, etc.)

III. Immunization program M&E structure and Practice

1. Let us talk about the M&E of the immunization program. How are you providing the overall M&E of the program? (Probe: M&E platforms, agenda setting, collaboration with local academic institutions, planning, target setting and denominator calculation)
2. How the practice ensuring data quality, evidence generation and data is used to improve the immunization program? (Evidence synthesis, evidence-based interventions, routine data quality assurances…)

Challenges

1. What are the major and critical challenges related to the immunization program. Probe on:
    - Vaccine safety and quality, AEFI management, VPD surveillance

- Data quality, use, performance monitoring of immunization program

SECTION-2: Agencies and partner level

Ethiopia Food and Drug Administration (EFDA)

1. How do you describe the AEFI surveillance system in Ethiopia? Established system? Implementation strategies? Collaboration with national and sub-national actors and partners? The role of National AEFI Committee and the national pharmacovigilance center?
2. How is the role of EFDA in developing, updating, and distributing AEFI surveillance reporting tools and guidelines, ensuring accessibility of tools, providing training and supervision, and AEFI case investigation and notification process? What are the challenges?
3. Please elaborate how AEFI investigation and reporting runs?
   Probe: Overall procedure, Compensation scheme, awareness among providers, regional-level investigators, public awareness, etc.
4. How do you receive an AEFI report? How is data analyzed and interpreted? How is a cause for AEFI determined? How do you share information about AEFI? To whom do you normally share the data?
5. How do you conduct AEFI causality assessment? What are the level of assessment? How do you select cases for causality assessment? Who is responsible to conduct the causality assessment? What is the role of National AEFI Committee? What actions do you take after causality assessment? - Have you ever traveled to the location of the AEFI, or delegated responsibility to another trained person or team to do this? When? How? Why?
6. How do you communicate with health staff (e.g. treatment, information), parents and public (and media) and correct problems (based on the cause)? (May be related to training, supervision, distribution of vaccines/injection equipment?)
7. Would you tell us the challenges you have faced in the process of AEFI case detection, investigation, management, monitoring and reporting?
8. What do you suggest to improve the performance of managing and monitoring of AEFI at all FDA, MOH-E, Regional, Zonal, and facility levels?

Ethiopian Public Health Institute (EPHI)

1. For what purpose do you use VPD surveillance data in your institution? [Responses could be related to planning, performance progress review, reporting…etc.]

2. Are there systems for engaging other stakeholders in the surveillance system, in terms of reporting and response? (Probe: Voluntary health workers, private sector providers, NGOs, etc.)?
3. Tell me about any approaches to engage private sectors? How do see the reporting practices of private sectors on VPD surveillance?
4. In your opinion, how do you evaluate the adequacy and distribution of health staff to maintain the surveillance system?
5. What are the strengths and weaknesses of the laboratory system at national level for investigation of reported VPDs?
6. How do you assess the quality of VPD surveillance data? What mechanisms are in place) [Ask one question at a time]
7. How do you explain the overall VPD surveillance data flow in your institution? (probe: hierarchy of reporting, who compiles and send data, electronic and manual reports)
8. In your opinion, how do you see the communication and information networks for notification of VPDs?
9. What are the strengths and weaknesses of notification/ investigations of VPDs?
10. In your opinion, what are the strengths and weaknesses of the overall reporting system of VPDs? What about zero report system?
11. How is VPD surveillance data utilized for program improvement purposes at the field level?
12. In your understanding, how is the availability of VPD surveillance data recording and reporting tools? How does that affect the quality of VPD surveillance data?
13. In your opinion, how do you understand VPD surveillance data quality and when do you consider VPD surveillance data has good quality? [Responses could be related accuracy, completeness, and timeliness…etc. Do not read them]
14. In your opinion, how do you rate the quality of VPD surveillance data produced in your institution? [Probe: what is the level of data quality? Are the reports timely? Are the reports complete? Are the data accurate?
15. What is the role of PHEM in supporting the management of Adverse Effects Following Immunization (AEFI)? How do you monitor timely report? How do you collaborate with EPI officers and EFDA in sharing of AEFI related information, training materials and manuals? Lead handling and timely dissemination of well-organized information to the community on timely bases?

16. What do you suggest to improve the performance of AEFI monitoring and management at national and subnational level?
17. From your experience and knowledge, what are the strengths and weaknesses of the structure and function of VPD surveillance?
18. In your opinion, how can the overall quality of VPD surveillance system can be improved at all levels?
19. Overall what are the challenges for VPD surveillance performance in the sector?
20. Please tell me anything about vaccine advocacy and social mobilization for promotion of vaccine uptake in Ethiopia? Why? What are drivers of low vaccine uptake? Why?

SECTION-3: Regional Health Bureau Level

1. How do you evaluate the existing EPI human resource planning, capacity building, supervision, and performance monitoring?
2. How is the practice of managing and monitoring Adverse Effects Following Immunization (AEFI) (established system, designated unit/staff, training, communication, reporting, investigation, established compensation scheme, AEFI surveillance,
3. What are the practices of vaccine-preventable disease (VPD) surveillance? (probe on detail practices, data flow, notification, investigation, communication and information networks laboratory system, zero report system, interventions)
4. How do you see the VPD surveillance data quality (timelines, completeness, accuracy, e.tc.) and information use?
5. How is the EPI program monitored and evaluated (probe on the M&E structure, EPI data quality, and EPI data use)
6. How do you evaluate the management of new vaccine introduction in Ethiopia?
7. What are the challenges in the implementation of EPI programs in your region/Zone/District?

   Probe: challenges related to:

   - Vaccine quality, safety
   - VPD surveillance
   - EPI program M&E
8. What do you suggest to address the challenges of EPI program related to the above themes?

SECTION-4: Zonal Health Department/Woreda Health Office Level

1. How do you evaluate the existing EPI human resource planning, capacity building, supervision, and performance monitoring?
2. How is the practice of managing and monitoring Adverse Effects Following Immunization (AEFI) (established system, designated unit/staff, training, communication, reporting, investigation, established compensation scheme, AEFI surveillance)
3. How do you conduct AEFI investigation? What is the processes? What type of cases are investigated? Who did you engage in the process of investigation? What are the barriers? (for Woreda EPI-Focal)
4. How do you notify the AEFI cases to the higher levels, MOH-E and EFDA? Do you have a standard reporting format? Who do you engage? Ask about experts from MOH-E and EFDA during AEFI investigation
5. What is the practice of vaccine-preventable disease (VPD) surveillance at the zone and woreda level? (Probe: on detail practices, data flow, notification, investigation, communication and information networks laboratory system, zero report system, interventions)
6. How do you see the VPD surveillance data quality and use at the zone/woreda level?
7. How is the EPI program monitored and evaluated (probe on the M&E structure, EPI data quality, and EPI data use)
8. How do you evaluate the management of new vaccine introduction in Ethiopia?
9. What are the challenges in the implementation of EPI programs in your Zone/District?

   Probe:

   - Vaccine quality, safety
   - VPD surveillance
   - EPI program M&E

9. What do you suggest to address the challenges of EPI program related to the above themes?

SECTION-5: Service Delivery Levels

Hospital and Health Center

1) How an AEFI cases does investigated in your health facility? What should be investigated and when? Who do you involve in AEFI case investigation? Do you

engage woreda rapid response team (RRT)? To whom do you notify? How do you notify? What kind of data are collected and recorded?

2) How do you explain the overall VPD surveillance in your facility?(Probe: resource including HR, data source, data flow, data quality, data use)
3) Would you describe the M&E system in your institution? (*adequacy of the structure, tools, staffing, functionality, independence)*
4) How do you evaluate the quality of immunization data and its usage for planning and decision making?
5) How do you estimate immunization coverage at your institution?
6) What are challenges related to EPI program from the following perspectives?
    - VPD surveillance,
    - EPI M&E system/structure, practice, data quality and usage

Health Posts (Health Extension Workers)

1. How do you report cases with safety problems such as exacerbated side effects and complication? (Forms for reporting AEFI in the regular basis)? How do you investigate the AEFI?
2. What monitoring mechanism on vaccine safety is there in your woreda /health facility? (Quality control mechanism, Cold chain, administration, AEFI, surveillance)
3. What are possible solutions to the existing problems? (Ways forward, what must be done to maintain best immunization communication, safety, what expects from community plat form, HP, HC, and WoHo)
4. How do you evaluate the quality of immunization data and its usage for planning and decision making?

7) What are challenges related to EPI program from the following perspectives?
    - VPD surveillance,

    EPI M&E system/structure, practice, data quality and usage