5.2B ADVERSE EVENT REPORTING SOP

Z-CAN ADVERSE EVENT STANDARD OPERATING PROCEDURE (SOP)

EXAMPLES OF ADVERSE EVENTS

IUD perforation
Failed IUD insertion
Skin infection at implant site
Pregnancy at return visit
Product contamination
Ectopic pregnancy at return visit
IUD expulsion
Broken implant
Deep implant/need for alternative measures to remove implant
Pelvic inflammatory disease in IUD users
Venous thromboembolism (deep vein thrombosis, pulmonary embolism)
Hospitalization related to Z-CAN-provided contraceptive method

1. Z-CAN PROVIDERS
Management of adverse events

- Providers should follow any routine procedures they may have in place for adverse events.
- For consultation regarding the medical management of adverse events, Z-CAN physicians may call the Assigned Consultant to participating Z-CAN physicians. Consultation with the doctor will not establish a patient-physician relationship. Do not send patients to the doctor unless they personally accept patient for transfer of care.
- In an emergency, direct the patient to the closest available hospital or emergency room. Contact the administrative doctor.
  - Note: The role is exclusively administrative.
  - The administrative doctor will not offer consultation regarding the clinical management of any Z-CAN patient under any circumstances, including adverse events
- For the reimbursement of medical management for any adverse event related to contraceptive methods provided through the Z-CAN program, physicians should follow routine billing procedures, including collecting from health insurance plans. See Z-CAN Procedure Manual for policies regarding billing and insurance.

Z-CAN PROVIDER REPORTING OF ADVERSE EVENTS

1. Manage adverse event as appropriate

2. Complete Adverse Event Form

AND

Complete Initial Visit Patient Encounter Form
if the adverse event occurred during the initial visit

OR

Complete Return Visit Patient Encounter Form
if the adverse event occurred or was noted during a return visit

AND

Record information on other forms, as appropriate (e.g., IUD Procedure Note, Inventory Tracking Sheet, etc.)

3. Submit Adverse Event and Initial or Return Visit Forms <u>WITHIN 24 HOURS</u> to the Z-CAN Program.

AND for Severe Adverse Events, call the administrative doctor.

Reporting of adverse events by providers to the Z-CAN Program

- Providers should report all adverse events **<u>within 24 hours by</u>**:
  - Submitting all forms related to the adverse event (Adverse Event Form and Initial Visit or Return Visit Patient Encounter Form) to the Z-CAN Program
  - If it is a Severe Adverse Event, providers must also call the administrative doctor

2. Z-CAN PR Medical Director (The administrative doctor)
Reporting of adverse events to CDC and CDC Foundation

- The administrative doctor will receive Adverse Event Form, Initial Visit Form (even if adverse event was reported at a return visit) and Return Visit Patient Encounter Form(s), if applicable, from the Z-CAN Program.

- The administrative doctor will notify the Clinical Team at CDC by e-mail of any Severe Adverse Events within 24 hours of receiving a Severe Adverse Event report. This e-mail should also be copied to the CDC Foundation and CDC IMS Zika Virus Z-CAN Data..
  - Serious adverse events to be reported **within 24 hours** of receipt of report include:
  - Perforations
  - Hospitalizations related to Z-CAN-provided contraception
  - Pelvic inflammatory disease in IUD users
  - Venous thromboembolism (deep vein thrombosis, pulmonary embolism)
  - Ectopic pregnancy after initial visit

- The administrative doctor, with the assistance of others, will keep an active log of adverse events (**Z-CAN Adverse Event Log**), which includes:
  - Information on the event (patient's Z-CAN ID, date of event, date event reported to Z-CAN Program, and description)
  - Information on follow-up related to the event (whether follow-up is required, date of follow-up, outcome of follow-up, including corrective action if needed)

- The administrative doctor will submit the **Z-CAN Adverse Event Log** to CDC, CDC Foundation and CDC IMS Zika Virus Z-CAN Data monthly.

Follow-up related to adverse events

- The administrative doctor will follow up with individual physicians related to the adverse events below to discuss the event, resolve any problems, and provide refresher training as needed:
  - Perforations
  - Hospitalizations related to Z-CAN-provided contraception
  - Pelvic inflammatory disease in IUD users
  - Venous thromboembolism (deep vein thrombosis, pulmonary embolism)
  - Ectopic pregnancy after initial visit
  - Pregnancy with IUD in place
  - Skin infection around implant site
  - Deep implant/need for alternative measures to remove implant
  - Broken implants
  - Providers with ***repeated*** events of product contamination, failed IUD insertion, PID with IUD in place

- Follow-up related to adverse events should be recorded on the **Z-CAN Adverse Event Log**.