

Six-Step Plan: Responding to Announcements of Adverse Medical Events



Making Informed
Health Choices About
Hormonal Contraception

Provider Actions		Response to Patient Inquiries	
Step 1	<p>Acknowledgment</p> <ol style="list-style-type: none"> 1. Acknowledge concern. 2. Establish a trustworthy environment: listen to the patient’s concerns and answer appropriately in terms she can understand. Eliminate distractions (phone calls, interruptions) from the environment so you can give her your full attention. 3. Establish the source of information and patient’s understanding of it. 4. Remember that you cannot give evidence-based advice without doing homework. 5. Unless the initial information seems life-threatening, it’s important to let your patient know that you want to collect all the available facts and gather the opinion of experts in the field so you can give her solid advice and information about her current contraceptive method. First and foremost, you want her to prevent an unintended pregnancy by using a safe method of birth control. Patients will respect the limits of your role. 	Suggested Scripts	<ul style="list-style-type: none"> • “You sound concerned, and I take that very seriously.” • “I can understand why hearing something like that [on the news] would alarm you — let’s talk about it.” • “This information has just come to our attention. We need to evaluate how this research was done and what the outcomes may mean. We are investigating the study(ies) now and will get back to you ASAP. In the meantime, it’s important that you continue to protect yourself against unintended pregnancy. Our immediate advice is for you to continue with your current contraceptive method until we get back to you with more information. If you feel uncomfortable doing that, let’s talk about what other options are available for you – other methods of birth control you can use.” • “Your safety is our top priority, and we will not prescribe a method that carries an unsafe level of risk.” • “I’m curious where you heard this information. What exactly did they say? What does it mean to you?” • “I want to provide you with the information that you need. In order to do that, I need to consult with our medical experts so I can give you accurate information.”
Provider Actions			
Step 2	<p>Review</p> <ol style="list-style-type: none"> 1. Involve all the health care team members: administrators, communications experts, medical staff, public policy staff, and technical experts. 2. Access the study and make a quick safety judgment so you can respond to initial patient inquiries. 3. Assign staff to review the research. Consider: <ul style="list-style-type: none"> ○ Was the research on humans, or was it a preliminary study conducted on laboratory animals? ○ Did the breakthrough occur on a limited or a large number of people? ○ How rigorously was the study performed? Some trials have better control of factors that could bias the results. For example, a large randomized, double-blind trial is usually designed to account for biasing factors — more so than a study based on a small number of case reports. ○ Who sponsored the study? Is there a potential conflict of interest between the trial’s sponsors and the results? ○ Is the source reputable and trustworthy? Were the findings published in a professional peer-reviewed journal? ○ Is there additional research to support this perspective, or does this result from a single study? 		
Provider Actions			
Step 3	<p>Additional Input — Consult with Experts</p> <ol style="list-style-type: none"> 1. Discuss the research and your considerations with your medical director and other colleagues. 2. Adhere to any protocol your employer may have in place for evaluating research and making practice decisions. 3. Consult with professional organizations to see if they have issued position statements or guidance. 4. Research whether there have been other trials that looked at the same issue. If so, what were the findings? 		

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Step 4	<p>Recommendations</p> <ol style="list-style-type: none"> 1. Present internal and external findings to a multidisciplinary team (communications, medical affairs, public policy, etc.). 2. Establish a written medical protocol, based on the evidence and expert opinion. Also develop a comprehensive statement: <ul style="list-style-type: none"> o We consider the method safe to use and will continue without change in protocol. or o We are making the following changes in our protocol..... Note: Make sure you are specific when announcing changes in procedures or protocols. 	<ul style="list-style-type: none"> • Get back to the patient in a timely manner, or have her call you at a specified time. • Be open and honest with the patient. • Discuss your investigation and the credibility of your resources. <p>If possible, schedule a time for the patient to come in and discuss the results of your investigation. Let the patient know where you got the information and how the decision was made to continue without change or to modify the protocol. Then, together, decide if it is possible and in the patient's best interest to continue the method or if other options should be considered.</p>
Provider Actions		Response to Patient Inquiries
Step 5	<p>Rollout of Response to Clients and Community</p> <ol style="list-style-type: none"> 1. Circulate the new protocol and/or procedures to all staff. Make sure that consistent messages are given to patients. If the changes are significant, consider organizing a staff meeting to discuss the issue, how the information will be handled, what to say to patients and the public, and any questions that the staff may have. 2. Establish anticipatory guidance messages for patients. 3. Establish a script for the frontline personnel. 4. Discuss information with patient educators and sexuality educators. 5. Place the established message — or link to the message — in a prominent location on the main page of the organization's Web site. Also, make it available as a handout in the office. 6. Follow and/or develop a media response protocol. What general comments will you make regarding this issue? Who will be your spokesperson? 7. Consider reactions of external stakeholders and how to handle indirect effects, social amplification, or rippling effect (e.g., conservative groups often latch onto an adverse event story and reinforce their messages that contraception can result in adverse events. 	<p>Reinforce a patient's priority to prevent an unintended pregnancy — she should not stop her birth control method without a back-up plan in place. In addition, provide the patient with an advance supply of emergency contraception. Review the risks and benefits of the patient's contraceptive choice and go over the other options that may work for her.</p>
Provider Actions		Response to Patient Inquiries
Step 6	<p>Ongoing Evaluation</p> <ol style="list-style-type: none"> 1. Monitor ongoing research in order to react as soon as possible when new data become available. 2. Provide ongoing evaluation and leave future options open (to be decided as more information becomes known). 3. Whenever possible, anticipate potential "hot topics" that are likely to become media events and plan the way your health care team will handle the issue. 4. Consider developing a Risk Communication Process Protocol that will support a prompt, clearly-defined process for addressing any future frightening messages. 	<p>Maintain an ongoing dialogue with clients about their knowledge, feelings, and attitudes toward effective pregnancy prevention. Encourage questions and answers. Keep colleagues informed of any new information that relates to the issue.</p>

