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DOCTORS Rx

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Don't Get Stuck

WHAT TO DO WHEN PARENTS REFUSE TO VACCINATE THEIR CHILDREN

COULD IT HARM MY CHILD?

WILL IT ACTUALLY WORK?

SHOULD I VACCINATE?

WHAT ARE THE RISKS?

DOES MY CHILD REALLY NEED THIS VACCINE?

find out...

- Why parents can be hesitant about vaccines
- How to have a productive vaccine discussion
- What to do when a vaccine is refused

A LETTER FROM THE CHAIR OF THE BOARD

Dear Colleague:

Physicians are frequently tasked with the duty of educating parents on the effectiveness of their children's vaccines. Like most other conversations concerning treatment, communication and documentation are essential. In this issue of *Doctors RX*, we will discuss the recommended practices from the Centers for Disease Control and the American Academy of Pediatrics to assist you in your conversations with concerned parents.

George S. Malouf, Jr., M.D.
Chair of the Board
MEDICAL MUTUAL Liability Insurance Society of Maryland
Professionals Advocate Insurance Company

ISSUE HIGHLIGHTS

DOCTORS RX

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WHAT TO DO WHEN PARENTS REFUSE TO VACCINATE THEIR CHILDREN

The flu season is a demanding time for any medical practice, especially pediatricians and family practitioners. Not only are you dealing with a greater influx of sick patients, you are sometimes confronted with the task of educating your patients' parents on the efficacy of certain vaccines.

Consider the following scenario: A mother brings her daughter in for a well visit. You inform the mother that you would like to give her child this year's flu vaccine. Knowing how her child will react to the needle and after reading a number of publications online, the mother asks you a series of questions: "Does my child really need this vaccine? Will it actually work on this year's flu strain? I've heard there are chemicals in the vaccine that could harm my child. Is that true?"

The conversation that happens next may determine whether or not the parent consents to the vaccination. You are a concerned Physician; you want to do what is best for the child and you appreciate that the parent wants the same. As you know, being able to communicate effectively while listening to the parent's concerns is key to understanding her viewpoint and ensuring she receives the best clinical information to make her decision. Essentially, this conversation you have with the mother is a type of informed consent discussion. It is incumbent upon the Physician to explain the treatment to the patient (or parent) and to warn of any material risks or dangers inherent or collateral to the treatment – or *refusal* of treatment, in this case.

It is important to remember that whether or not the parent consents to having her child vaccinated, the discussion should be adequately reflected in the medical chart. From documenting that the parent received the required Vaccine Information Statement (VIS)[1], to placing a copy of a signed Refusal to Vaccinate form in the chart (if applicable), documentation is essential to defending your care.

THE ANTI-VACCINE POSITION

In recent years, a number of parents have reached the conclusion that the risks associated with vaccinating their child outweigh the benefits. A 2006 study by the American Academy of Pediatrics (AAP) found that within a 12-month period, 74% of pediatricians encountered a parent who refused or delayed one or more vaccines.[2] A follow-up survey conducted in 2013 revealed that the figure had increased to 87% of pediatricians.[3]

Despite some parents' reluctance to have their child vaccinated, national coverage remains fairly high. According to the Centers for Disease Control (CDC), during 2014-2015, the percentage of children who did not receive any vaccinations remained at less than 1%.[4] Target coverage of greater than 90% was met for the polio, hepatitis B, MMR (measles, mumps and rubella), and varicella vaccines. However, coverage fell below the 90% target for the four doses of DTaP (diphtheria, tetanus and whooping cough) (84.6%), the full series of Hib (haemophilus influenza type b) (82.7%),

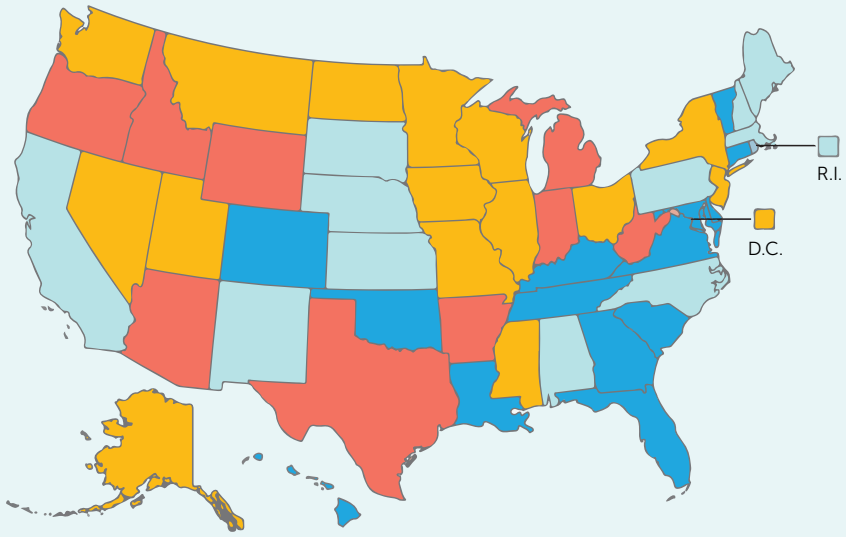
Michael Doll

The author of "Don't Get Stuck: What to Do When Parents Refuse to Vaccinate Their Children" is a Risk Management Specialist with MEDICAL MUTUAL. Prior to joining the Risk Management Department, Michael spent more than six years helping to defend Maryland and Virginia Doctors as a Claims Representative.

Vaccination Rates Among Children 19 to 35 Months

- 66% or less
- 67%-71.4%
- 71.8%-75%
- More than 75%

National Average: 71.6%



SOURCE: Centers for Disease Control and Prevention

Did you know?

In 2014, the United States saw the highest number of measles cases since it was declared eliminated in 2000.

and four doses of PCV (84.5%); below the 85% target for two doses of HepA (59.6%), and HepB birth dose (72.4%); and below the 80% target for rotavirus vaccination (73.2%), and the combined seven-vaccine series (72.2%).[5]

However, researchers believe that the recent anti-vaccine effort may partially be to blame for an increase in the number of measles cases. Studies have revealed that in 2014, the United States saw the highest number of measles cases since it was declared eliminated in 2000.[6]

Most parents want what is best for their child and tend to rely on their provider's skill and expertise on the subject. While conversations with parents can be confusing and frustrating at times, we will outline several sound principles and techniques that should help you navigate the minefield of a vaccine refusal.

AS WITH ANY INFORMED CONSENT DISCUSSION, COMMUNICATION AND DOCUMENTATION ARE VITAL

When parents have questions regarding their child and vaccines, it is the Physician they look to for scientifically-based and balanced information. Therefore, it is important to keep in mind that the parents must be fully informed of the material risks – both of the vaccine itself and of choosing not to vaccinate their child. Vaccine Information Statements, which are required (see the National Vaccine Childhood Injury Act - 42 U.S.C. § 300aa-26) and supplied by the CDC, are an appropriate way to help educate parents about the potential risks of the diseases their child is being vaccinated against, why the child should get vaccinated, and the risks associated with the vaccine itself. Vaccine Information Statements can be given to the parents in paper or electronic format.[7]

According to the AAP, there are a number of reasons why some parents may be vaccine hesitant. In one study, 44% of parents reported concern over the pain associated with their child receiving multiple vaccines during a single visit, 34% expressed concern over receiving too many vaccines at a single visit, 26% worried that vaccines contributed to the development of autism or other learning deficiencies, 13.5% were concerned that the vaccines could lead to chronic illnesses and 13.2% stated that the vaccines were not adequately tested prior to being brought to market.[8]

21 Million Hospitalizations

732,000 Child Deaths

ESTIMATED PREVENTED BY VACCINES AMONG CHILDREN BORN IN THE PAST 20 YEARS

SOURCE: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm

The CDC suggests that there are five key points to remember when talking to parents about vaccines:

1. Take time to listen
2. Be open to questions
3. Acknowledge the risks and benefits
4. Use science and stories to support your position
5. Make the entire experience a cooperative one between you and the parents[9]

Listen and Answer Questions

As indicated by the earlier scenario, parents may have already researched the vaccine(s) prior to you seeing their child. As a result, the parents may have many questions and concerns to discuss with you. According to the CDC, it is important to take time to listen to and address their questions and concerns. The CDC recommends that the Physician listen intently and allow the parents to speak uninterrupted. They advise Physicians to resist the urge to multi-task (e.g., making notes in the medical record, continuing with the well visit exam or talking to nurses or techs in the area). The CDC recognizes that understanding the parents' viewpoint on vaccination while maintaining your own can be a difficult balance. However, conveying your mutual interest in their child's health may assist the parents with their ultimate decision.[10]

Despite their perceived issues with vaccines, parents also may be reluctant to discuss the subject or ask questions. Therefore, the CDC believes it is important to maintain an open dialogue with parents by letting them know that you welcome *all* of their questions and you are more than willing to hear their concerns. Additionally, the CDC recommends that you try to understand *why* they are concerned and assure them that their child's health also is your top priority. This may open the door to more productive dialogue with the parents. According to the CDC, it also may be important to give short answers while addressing concerns so that more time is available for additional questions, if necessary.[11]

Acknowledge Risks and Benefits

While your opinion may be that the risks associated with vaccinations are low (81% of Physicians surveyed in 2011 agreed that vaccines are one of the safest forms of medicine ever developed[12]), it is important to clearly convey the possible side effects to the parents so they can make a truly informed decision. Also, indicate that while side effects *do* happen, they are rare. One possible example to share, according to the CDC, is that the risk of Guillain-Barre Syndrome (GBS – a serious complication involving the nervous system that is associated with the flu vaccine) has been estimated at one or two cases per million people vaccinated. It is important to advise parents that this occurrence is far lower than the risk of severe complications associated with actually getting the flu.[13] These complications can include: pneumonia, myocarditis, encephalitis, myositis, rhabdomyolysis and respiratory or kidney failure.[14] Additionally, if the child suffers from asthma, it is important to advise parents that asthma attacks may occur if their child is unvaccinated for the seasonal influenza virus.[15]

The AAP also recommends talking to parents about the long and tedious vaccine development process, which often takes many years and involves a number of public and private partnerships before the vaccine is approved for use by the FDA.[16]

Use Science and Stories

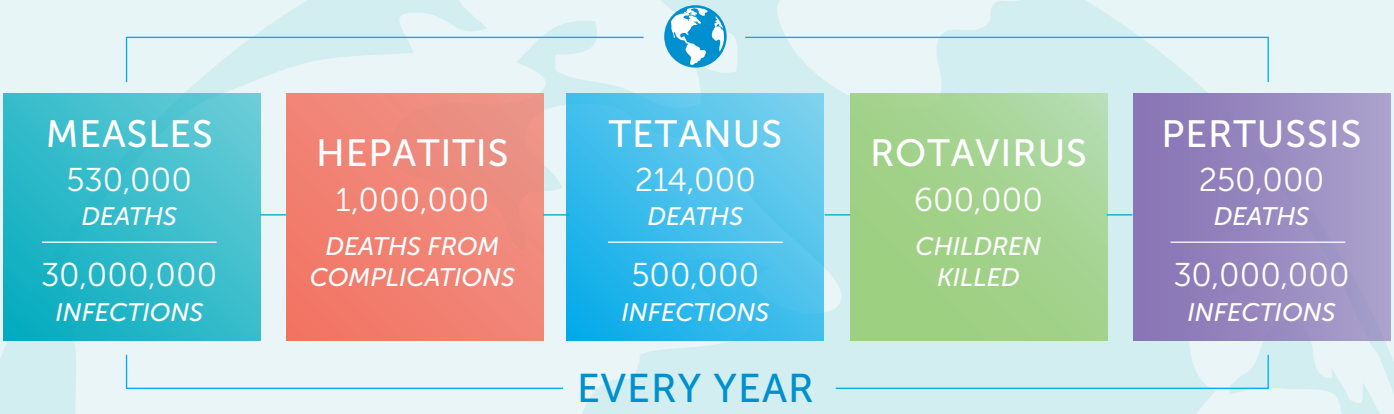
The CDC notes that anecdotal experiences or scientific studies (depending on the type of parents you are dealing with) may be helpful in these discussions. Some parents may prefer that you share prior experiences with them. An obvious example, without divulging any protected health information, would be a story about an unvaccinated child you know of who became infected with one of the illnesses that the vaccine is attempting to prevent. The CDC contends that it is important to share with parents the symptoms the child experienced, what treatment was involved and the outcome.

Having scientific studies available also may be helpful to parents. While anecdotal evidence is important, the CDC encourages Physicians to share clinical studies or surveys on the effects of vaccinations not only on the individual child, but on the population as a whole. The CDC

Common Ground

Conveying your mutual interest in their child's health may assist the parents with the decision to vaccinate.

Worldwide Illness Caused by Vaccine-Preventable Disease



SOURCE: https://teamvaccine.com/2013/08/16/top-10-vaccine-infographics/

A Broader Picture

The CDC believes it may be effective with some parents to give them a sense that they are doing what is best not only for their child, but for the community as well.

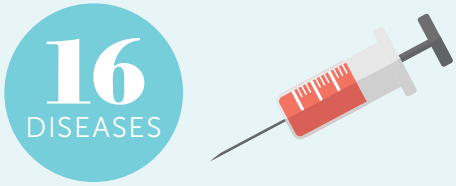
believes it may be effective with some parents to give them a sense that they are doing what is best not only for their child, but for the community as well.[17]

One possible story to share would be of a measles outbreak at Disneyland in Southern California in 2014. According to the CDC and the California Department of Public Health (CDPH), an 11-year-old was hospitalized for a suspicious rash after a visit to the Disneyland theme park. That same day, the CDPH reported four additional suspected measles cases in California and two in Utah residents, all of whom reported visiting Disneyland between Dec. 17-20, 2014. By Jan. 7, 2015, seven measles cases had been confirmed and by Feb. 11 a total of 125 measles cases had been confirmed. Among the California patients, 49 were unvaccinated; five had one dose of measles-containing vaccine; seven had two doses; one had three doses; and 47 had unknown or undocumented vaccination status. While 12 of the unvaccinated population were infants and too young for the vaccination, 28 were left unvaccinated because of personal beliefs. Among those unvaccinated due to personal beliefs, 18 were children.[18]

Closer to home, the Maryland Department of Health and Mental Hygiene, as well as the Health Departments of Prince George's County and the District of Columbia, issued a warning to local parents about a potential measles outbreak in early May 2017. According to a report, a patient was admitted to Children's National Medical Center on May 13, 2017, and was isolated for the majority of the visit due to measles. Officials warned that children who are not vaccinated would be the most susceptible to the disease.[19]

Make It a Cooperative Experience

The CDC believes it is important to try to make the vaccination experience cooperative rather than authoritative. While you are the "expert in the room," the CDC suggests that parents may find comfort in the fact that you also want to do what is best for their child. According to the CDC, using a phrase like "we both want what's best for your child," and stating that your goal is to keep the child "illness free" can be helpful. Additionally, the CDC recommends that, if you have children, you should explain that your children have received these same vaccines as well. The CDC acknowledges that for some parents, knowing that their Physician also chose to immunize and vaccinate his or her own children under the same recommended schedule could add some comfort to the process.[20]



CAN BE PREVENTED BY THE VACCINES RECOMMENDED FOR CHILDREN AND TEENS

SOURCE: https://www.cdc.gov/vaccines/parents/diseases/index.html

The AAP suggests that another potential strategy, specifically with parents who are concerned over the pain associated with receiving injections, is to take extra steps to minimize the amount of pain associated with receiving multiple vaccines at a single visit. The AAP recommends the following: "administering vaccines quickly without aspirating, holding the child upright, administering the most painful vaccine last, and providing tactile stimulation." Other options, according to the AAP, could include breastfeeding while the vaccines are administered, feeding the child sweet foods and applying topical anesthetics to reduce pain. Finally, distraction strategies also could be used, including pinwheels, deep breathing exercises and toys.[21]

The Discussion Must Be Documented in the Medical Chart

After each proposed vaccine, both the CDC and AAP suggest making a notation in the chart that the informed consent conversation occurred with the parents and they were given the VIS. They also suggest that it is important to note in the chart that all questions from the parents were addressed and answered.

WHAT IF THEY *STILL* REFUSE TO VACCINATE THEIR CHILD?

Although you ultimately may consider dismissing the child from your practice if the parents still refuse to vaccinate, the CDC recommends that you continue to engage the parents in the vaccine discussion. The goal should be to educate them on the risks of not getting their child vaccinated, what the potential symptoms are for the illness(es) they are choosing not to vaccinate their child against, and the fact that many of these diseases are highly contagious and potentially deadly.[22] Therefore, as suggested above, it is imperative to continuously utilize the VISs supplied by the CDC and document in the chart each time a vaccination is offered, each time a VIS is given to the parents for the particular vaccine being discussed and whether or not the vaccine is accepted or rejected by the parents.

The CDC also recommends providing the fact sheet, *If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities*, to parents who choose not to vaccinate. You can find a link to this fact sheet online at **mmlis.com/vaccinerefusal** or **proad.com/vaccinerefusal**

This information is important to the parents as it outlines what to do if their child *does* get sick, what to tell other health care professionals, the risks to their community and the additional burdens parents assume when they choose not to vaccinate their child (e.g., keeping the child home from school and out of organized activities during a prolonged illness).

Finally, the AAP recommends that providers have the parent sign the Refusal to Vaccinate form after each refused vaccination and include a signed copy in the medical record. This provides clear documentation that for each of the vaccinations attempted, the parent or guardian was made fully aware of the potential risks. You can download this form at **mmlis.com/vaccinerefusal** or **proad.com/vaccinerefusal**

Handling the Vaccine Discussion

1. Have an open discussion with the parent/guardian using the CDC's five key points
2. Provide supporting literature, including the VIS link (VISs are available at **mmlis.com/vaccinerefusal or proad.com/vaccinerefusal**)
3. Obtain the signed Refusal to Vaccinate form for **all** refused vaccines
4. Be sure to document the discussion and if the parent refuses to sign the Refusal to Vaccinate form

The AAP suggests that dismissal should only occur if the following conditions are met: the Physician has exhausted all avenues of education with the parents; the parents have been made aware of the office policy concerning dismissal of vaccine-hesitant families and patients; the geographic area is not in short supply of pediatric providers; and the practice can continue to provide health

Documentation

It is imperative to document in the chart each time a vaccination is offered, each time a VIS is given to the parents for the particular vaccine being discussed and whether or not the vaccine is accepted or rejected by the parents.

For Further Assistance

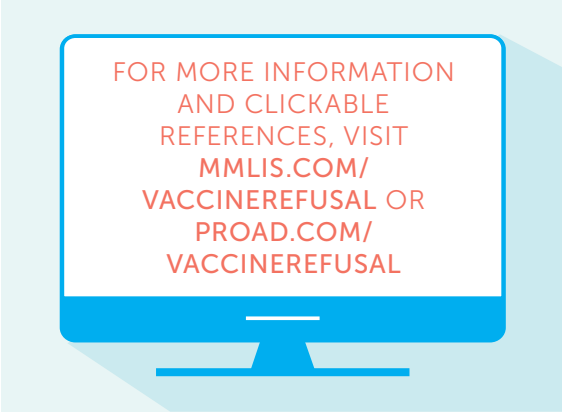
You can call the MEDICAL MUTUAL/ Professionals Advocate Risk Management Department for additional guidance.

care until the family finds another provider (usually for 30 days and for emergency visits only).[23]

CONCLUSION

The conversation you have with parents concerning the vaccination of their child is no different than any other informed consent or informed refusal discussion you have with a patient. Communication and documentation are critical aspects in avoiding any potential claim that the parents were not informed of the risks associated with not getting their child vaccinated. The recommended practice is to listen to the parents, allow them the time they need to ask questions, answer those questions, give examples of past experiences, inform them of the science behind vaccines, and make sure they know how important their child's health is to you as their Physician – all while appropriately documenting those conversations.

When all else fails, be sure to obtain a signed copy of the Refusal to Vaccinate form and include the signed copy in the medical chart. If the patient/guardian refuses to sign the vaccine refusal form, make sure that is reflected in the chart, even if you intend to dismiss the patient. This should be done after each vaccination offered. If it reaches the point where you feel as though you can no longer treat the child and discharge becomes necessary, follow the recommended discharge guidelines.



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[5] Id. The combined seven-vaccine series (4:3:1:3*:3:1:4) includes ≥4 doses of DTaP/diphtheria and tetanus toxoids vaccine/diphtheria, tetanus toxoids, and pertussis vaccine; ≥3 doses of poliovirus vaccine; ≥1 dose of measles-containing vaccine; ≥3 or ≥4 doses of Hib (depending upon product type of vaccine); ≥3 doses of HepB; ≥1 dose of varicella vaccine; and ≥4 doses of PCV.

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[10] Id

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CME TEST QUESTIONS

1. Religious objection is the only reason parents can refuse vaccines.

   A. True B. False

2. It is good practice for a Physician to provide scientific evidence to promote the use of vaccinations.

   A. True B. False

3. According to the Centers for Disease Control and Prevention (CDC), there are three key points to remember when speaking to parents about vaccines.

   A. True B. False

4. It is a good idea to interrupt parents with scientifically-based facts when they are discussing their concerns about vaccines in order to persuade them.

   A. True B. False

5. Multi-tasking while having conversations with parents about vaccinations is not recommended.

   A. True B. False

6. It is a good idea to make it known to the parents that as a Physician, their child's health is your top priority.

   A. True B. False

7. Since the risks associated with most vaccines are so low, you do not have to discuss them with the parents prior to administering the vaccines to the child.

   A. True B. False

8. In order to minimize the amount of pain during the administration of vaccines, one of the things the CDC recommends is to administer the most painful vaccine last.

   A. True B. False

9. After the parents have refused vaccines for their child, the CDC recommends discharging the child from your care.

   A. True B. False

10. It is good practice to have the parents sign the American Academy of Pediatrics' Refusal to Vaccinate form after each refused vaccination.

    A. True B. False

Instructions – to receive credit, please follow these steps:

Read the articles contained in the newsletter and then answer the test questions.

1. Mail or fax your completed answers for grading:
   Med•Lantic Management Services, Inc. | Fax: 410-785-2631
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   Attention: Risk Management Services Dept.
2. One of our goals is to assess the continuing educational needs of our readers so we may enhance the educational effectiveness of the *Doctors RX*. To achieve this goal, we need your help. You must complete the CME evaluation form to receive credit.
3. Completion Deadline: January 31, 2018
4. Upon completion of the test and evaluation form, a certificate of credit will be mailed to you.

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CME EVALUATION FORM

Statement of Educational Purpose

Doctors RX is a newsletter sent twice each year to the insured Physicians of MEDICAL MUTUAL/Professionals Advocate.®
Its mission and educational purpose is to identify current health care-related risk management issues and provide Physicians with educational information that will enable them to reduce their malpractice liability risk.

Readers of the newsletter should be able to obtain the following educational objectives:
1) Gain information on topics of particular importance to them as Physicians
2) Assess the newsletter's value to them as practicing Physicians
3) Assess how this information may influence their own practices

CME Objectives for "WHAT TO DO WHEN PARENTS REFUSE TO VACCINATE THEIR CHILDREN"

Educational Objectives: Upon completion of this enduring material, participants will be better able to:
1) Understand techniques in communicating with parents concerning their children's vaccines
2) Learn ways to properly provide informed consent to parents when they refuse vaccines for their child
3) Properly document your informed consent conversations in the medical chart

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	Strongly Agree				Strongly Disagree
Part 1. Educational Value:	5	4	3	2	1
I learned something new that was important.	❑	❑	❑	❑	❑
I verified some important information.	❑	❑	❑	❑	❑
I plan to seek more information on this topic.	❑	❑	❑	❑	❑
This information is likely to have an impact on my practice.	❑	❑	❑	❑	❑

Part 2. Commitment to Change: What change(s) (if any) do you plan to make in your practice as a result of reading this newsletter?

_____

_____

_____

Part 3. Statement of Completion: I attest to having completed the CME activity.

Signature:_____ Date:_____

Part 4. Identifying Information: Please PRINT legibly or type the following:

Name:_____ Telephone Number:_____

Address:_____

_____

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RISK MANAGEMENT NEWS CENTER

CYBER SECURITY HIGHLIGHT: MOBILE ELECTRONIC DEVICES

Doctors frequently hear about the need to secure, maintain and upgrade their computer networks to comply with HIPAA regulation. However, much less attention is given to securing the mobile devices that are constantly with us and have become valuable medical tools. Leaving the protected health information on these devices unsecured is a HIPAA violation that can have serious consequences.

The security risks

Smartphones and tablets present a host of new security issues, both in the storage and transmission of protected data. According to a report from Nokia, smartphone malware infections rose nearly 400% in 2016.* In addition to weak data protection, any data, such as a photo taken and stored on the phone, is pushed out of your secure network the moment it is transmitted over a public network or put in cloud storage.

What you can do

Following these steps can go a long way to securing your mobile electronic devices:

- Always require two-factor authentication to access protected information.
- When using a phone to send patient photos or other data for consults, use a secure app that was designed to be HIPAA-compliant.
- Enable encryption on the device. All protected health information sent over a public network must be encrypted.
- If possible, keep a work-only device that is separate from your personal mobile device. The work device should contain only the apps and programs needed for work. Many social media and other personal apps store information about the device and its contents that may violate HIPAA regulation.

For complete information on securing your electronic devices, visit the Department of Health and Human Services fact sheet, Your Mobile Device and Health Information Privacy and Security, available at **mmlis.com/vaccinerefusal** or **proad.com/vaccinerefusal**

*Nokia (2016). Nokia Threat Intelligence Report – 2H 2016. Pages.nokia.com

CALL OUR EXPERTS

When you have questions about HIPAA compliance or converting to EMR, you have a patient conflict or are considering discharging a patient, or you find yourself facing any other risk management concern, our experts are here to help you manage or significantly reduce your risk.

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MEDICAL MUTUAL and PROAD offer a variety of online tools and resources that are specially designed to help Doctors identify and address preventable issues before they escalate into potentially serious legal action.

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