Protect E-Mail to Minimize Medicolegal Liability

BY SHERRY BOSCHERT

San Francisco Bureau

SAN FRANCISCO — Give e-mail correspondence with patients the same care and attention you'd give to paper records, faxes, or phone calls in order to minimize medicolegal liability, advises Dr. Jeffrey L. Brown of the Cornell University Medical School in New York.

Physicians should be reasonably certain that the person requesting information by e-mail is authorized to receive it, just as would be done with phone calls, Dr. Brown said at the annual meeting of the American Academy of Pediatrics.

At a minimum, your e-mail system should include an automated response to any e-mails received from patients, acknowledging that an e-mail message has been received and saying that you will respond within a set period of time, such as 24 or 48 hours, said Dr. Brown, who is also in private practice in Rye Brook, N.Y. He has no association with companies that market e-mail systems or services.

The automated response should alert patients that confidentiality cannot always be ensured in e-mail correspondence, and that you cannot respond to urgent questions posed by e-mail. Patients should contact your office by phone for urgent matters.

The response also should inform patients that if they do not get a reply from you to any e-mail message within a reasonable period of time—"usually 48 hours," Dr. Brown said—the patient should call your office, because you may not have received the e-mail. If you are away from the office when patients e-mail, the automated response should let them know that, and give the date of your return.

In the other direction, e-mails sent by physicians must be compliant with the Health Insurance Portability and Accountability Act (HIPAA). As with faxes, conventional e-mails must protect the confidentiality of sensitive information such as Social Security numbers, medical identification numbers, laboratory results, diagnoses, medications, and more.

To ensure confidentiality in e-mails, use an encrypted message system, Dr. Brown advised. Solo practitioners or small practices may want to do an Internet search for the term "encrypting e-mail systems" to find a list of encryption providers, he said. Typically, an outgoing e-mail would be sent to the provider, encrypted, and returned to the physician's system before going out to a patient.

Or, physicians may want to look into the AAP's partnership with Medem (www.med em.com), he added. "They have a generic Web site that they will create for you. As part of that generic Web site, they will also encrypt e-mail and set you up with a professional e-mail service for not a lot of money on an annual basis," Dr. Brown said.

Confidential e-mail from physicians should contain a warning disclaimer similar to those used on fax transmissions, Dr. Brown suggested.

Treat e-mail messages like other patient correspondence, and file them appropriately, he added. Before erasing e-mail, save the patient's original e-mail and your response as hard copies in the patient's chart or electronically if you use electronic

Take precautions to protect confidential information on laptop computers and hard drives, as you would for other med-

Use encryption software or change passwords frequently to prevent unauthorized

Erase all confidential information from hard drives before disposing of them.

"Even if you do all the right things, there is still a possibility that you will be subject to suits," Dr. Brown said. "In the end, the best defense against legal action is practicing good medicine."

Immune system disorders: Hypersensitivity reactions (including anaphylactic reaction, facial edema and urticaria)

Nervous system disorders: Guillain-Barré syndrome, Bell's Palsy

Respiratory, thoracic and mediastinal disorders: Epistaxis Skin and subcutaneous tissue disorders: Rash

DRUG INTERACTIONS

Do not administer FluMist to children or adolescents who are receiving aspirin therapy or aspirin-containing therapy.

The concurrent use of FluMist with antiviral agents that are active against influenza A and/or B viruses has not been evaluated. However, based upon the potential for antiviral agents to reduce the effectiveness of FluMist, do not administer FluMist until 48 hours after the cessation of antiviral therapy and antiviral agents should not be administered until two weeks after administration of FluMist unless medically indicated. If antiviral agents and FluMist are administered concomitantly, revaccination should be considered when appropriate.

Concomitant Inactivated Vaccines

The safety and immunogenicity of FluMist when administered concurrently with inactivated vaccines have not been determined. Studies of FluMist excluded subjects who received any inactivated or subunit vaccine within two weeks of enrollment. Therefore, healthcare providers should consider the risks and benefits of concurrent administration of FluMist with inactivated vaccines.

Concomitant Live Vaccines

Concurrent administration of FluMist with the measles, mumps and rubella vaccine and the varicella vaccine was studied in 1245 children 12-15 months of age. Adverse events were similar to those see other clinical trials with FluMist. No evidence of interference with immune responses to measles, mur rubella, varicella and FluMist vaccines was observed. The safety and immunogenicity in children >15 months of age have not been studied.

Intranasal Products
There are no data regarding co-administration of FluMist with other intranasal preparations.

USE IN SPECIFIC POPULATIONS

Animal reproduction studies have not been conducted with FluMist. It is not known whether FluMist can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FluMist should be given to a pregnant woman only if clearly needed.

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The effect of the vaccine on embryo-fetal and pre-weaning development was evaluated in a developmental toxicity study using pregnant rats receiving the frozen formulation. Groups of animals were administered the vaccine either once (during the period of organogenesis on gestation day 6) or twice (prior to gestation and during the period of organogenesis on gestation day 6). Somet./rat/occasion (approximately 110-140 human dose equivalents based on TCllo₂), by intransaal instillation. No adverse effects on pregnancy, parturition, lactation, embryo-fetal or pre-weaning development were observed. There were no vaccine related fetal malformations or other evidence of teratogenesis noted in this study.

It is not known whether FluMist is excreted in human milk. Therefore, as some viruses are excreted in human milk and additionally, because of the possibility of shedding of vaccine virus and the close proximi of a nursing infant and mother, caution should be exercised if FluMist is administered to nursing mothers.

FluMist is not indicated for use in children <24 months of age. FluMist use in children <24 months has been associated with increased risk of hospitalization and wheezing in clinical trials.

Subjects with underlying high-risk medical conditions (n=200) were studied for safety. Compared to controls, FluMist recipients had a higher rate of sore throat.

FluMist is not indicated for use in individuals 50-64 years of age. In Study AV009, effectiveness was not demonstrated in individuals 50-64 years of age (n=641). Solicited adverse events were similar in type and frequency to those reported in younger adults.

PATIENT COUNSELING INFORMATION

Vaccine recipients or their parents/guardians should be informed by the health care provider of the potential benefits and risks of FluMist, and the need for two doses at least 1 month apart in children 2-8 years old who have not previously received influenza vaccine.

Asthma and Recurrent Wheezing

Ask the vaccinee or their parent/guardian if the vaccinee has asthma. For children <5 years of age, also ask if the vaccinee has recurrent wheezing since this may be an asthma equivalent in this age group.

Vaccine recipients or their parents/guardians should be informed by the health care provider that FluMist is an attenuated live virus vaccine and has the potential for transmission to immunocompromised household contacts.

Adverse Event Reporting

The vaccine recipient or the parent/guardian accompanying the vaccine recipient should be told to report any suspected adverse events to the physician or clinic where the vaccine was administered. FluMist® is a registered trademark of MedImmune Vaccines, Inc.

I i MedImmune

MedImmune Vaccines Inc.

Gaithersburg, MD 20878

For other product information regarding FluMist, call 1-877-FLUMIST (358-6478).

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E-Mail Don'ts

- ▶ Do not use your personal e-mail address to answer patient e-mails.
- ▶ Do not answer a new patient's emailed medical questions without first establishing a formal relationship. You have no idea who they are and what their problems are.
- ▶ Do not forward a patient's e-mail correspondence or address to a third party without first getting the patient's consent.
- ▶ Do not use an indiscreet topic in the heading of your response. Don't write, "Your pregnancy test is positive" in the subject line. Instead, use the same strategies you'd use when leaving a voice mail on a patient's answering machine. Say, "I have your lab work," or something like that.
- ▶ Do not leave e-mail messages on a computer screen where they can be read by others.

Source: Dr. Brown

