Informed Consent for Clinical Treatments and Procedures in VHA Medications with "Boxed Warnings"

What are "Boxed Warnings"?

The Food and Drug Administration (FDA) requires "Boxed Warnings," often referred to as "Black Box Warnings," for medications that may have serious adverse reactions for certain patients or that have been approved with restrictions. Per the FDA, "A Boxed Warning provides a brief, concise summary of the information that is critical for a prescriber to consider, including any restriction on distribution or use." Generally, the Boxed Warnings are not applied to a specific medication but to an entire class of drugs that work the same way in the body and so carry the same risk.

What are some examples of medications that have Boxed Warnings?

Many commonly prescribed medications, including some antidepressants, anticonvulsants, and antibiotics, and even some over-the-counter medications, carry Boxed Warnings.

How do VHA practitioners obtain informed consent for medications with a Boxed Warning?

VHA policy requires that practitioners conduct and document an informed consent discussion with the Veteran for every medication they prescribe. Just like all medications, the practitioner would review the risks and benefits of the medication as well as the alternatives to the medication, ensuring that the Veteran can make an informed, voluntary decision about whether to accept or refuse the practitioner's recommendation. For a medication with a Boxed Warning, the informed consent discussion would include review of the serious risk(s) that led to the FDA designation.

Do VHA practitioners look to see if the new medication they recommend for a Veteran is safe to prescribe with the medications the Veteran is already taking?

Yes. The VHA practitioner who prescribes the medication, as well as the pharmacist who fills the prescription, reviews the medications the Veteran is taking. The Veteran's medications are listed in the electronic health record (EHR) and include medications that are prescribed outside of VHA and that the patient purchases over the counter. Practitioners use computer drug interaction programs to identify any contraindications that might result from the combination of the new and old medications for the individual Veteran. Practitioners are required to review and respond to any alerts in the EHR that indicate there may be adverse drug interactions and explain their reasons for prescribing the new medication.

How does a VHA practitioner determine if the benefits outweigh the risks of a medication with a Boxed Warning?

The VHA practitioner has the training and experience to determine if the benefits of the medication outweigh the risks for the individual Veteran. They make an evidence-based decision about whether the Boxed Warning applies to the specific medical circumstances of the Veteran and to what extent the risk is of clinical concern for the Veteran. The practitioner then weighs this against the benefits of the medication for the Veteran as well as risks and benefits of alternative treatments. The practitioner explains their clinical reasoning to the Veteran during the informed consent discussion. The Veteran has the right to accept or refuse the practitioner's recommendation.

When a Veteran consents to a medication with a Boxed Warning, do they have to sign a consent form?

It depends on the medication. See Informed Consent for Clinical Treatments and Procedures in VHA: Veterans at the Center of Treatment Planning for information on documenting consent.

Podcast for Veterans:
Informed Consent Empowers Veterans

U.S. Department of Veterans Affairs
Veterans Health Administration
National Center for Ethics in Health Care

For more information visit
https://www.ethics.va.gov/policy.asp

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