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News Release

Panel evaluates continued use of QuikClot for the Marine Corps

BETHESDA, Md. – In response to safety concerns from the Marine Corps regarding the hemorrhage control agent QuikClot, a panel met at the Uniformed Services University of the Health Sciences here Feb. 21 to evaluate its continued use.

The panel was selected by the Marine Corps and consisted of 15 individuals – two Army and two Air Force members, two civilians and nine Navy and Marine Corps members. They found, according to their report completed Feb. 26, that the potential of tissue damage is offset by the opportunity to save a life in otherwise uncontrollable external hemorrhaging.

“We (USU) were asked by the Marine Expeditionary Medicine Warfighting Lab to review the risk-benefit ratio of this material for the Marine Corps, given a potential for burns,” said Army Col. David G. Burris, M.D., interim chairman of USU Department of Surgery who chaired the panel.

“The panel found that if QuikClot was used as defined by the FDA (Food and Drug Administration) -- for massive external hemorrhage that couldn't otherwise be controlled in standard ways -- that the benefit outweighed the potential for injury.

“The school does not have command oversight for any of the three services, we don't mandate policy for the three services,” Burris added. “The report was sent to the lab staff who will

forward it up to those in their chain of command for them to decide what policy to make from this review of the data.”

QuikClot, developed by Z-Medica, is a granulated mineral substance that rapidly adsorbs blood, promoting coagulation. The Office of Naval Research funded research to determine effectiveness of the product for use by the U.S. military in the battlefield. The team, led by Hasan Alam, M.D., a trauma surgeon on the USU faculty and research specialist in the area of battlefield casualties, tested it along with a number of other agents on a model for lethal combat injury. Alam, who is also on the staff of the Washington (DC) Hospital Center, said they found QuikClot to be the most effective and based on their research, it was approved by the FDA for clinical use in 2002.

“Their research suggested that QuikClot would be a good hemostatic agent for those who have massive hemorrhage on the battlefield,” said Burris. “Although it has been widely fielded,” he said, “there were reports of tissue damage associated with the exothermic reaction of this material. It was felt by some that it was too dangerous for continued use.”

Burris explained that it has been reported that some people have burned their hands using QuikClot, which produces heat when combined with water or blood.

“There are other hemostatic agents that are FDA approved, but some are not applicable to the battlefield due to the preparation time and complexity,” Burris explained. He added only few others are in full production, but the amount is not sufficient to meet the needs for combat distribution.

The report from the panel stated: “Hemostatic agents without this exothermic property will be available in the future and should be evaluated as a potential replacement. Until that time, *used carefully* in this *well-defined* population who are still bleeding despite all standard current therapy, it seems that the benefit of saving a life outweighs the risk.”

The panel also reinforced the FDA's recommendation for use by reporting that given tissue damage from this exothermic reaction may be a risk, this agent should only be used for life-threatening hemorrhaging.

They also reported that it should not be used in intra-cavitary wounds, but in external wounds only, after standard hemostatic techniques to control the bleeding have failed.

Another agreed-upon decision by the panel was that only personnel who are adequately trained to and demonstrate standard may be issued this agent. As stated in the report, "It is preferred that they (the users) be medical personnel such as corpsmen, but if the nature of the fighting unit does not allow medical personnel with each unit, others may be trained to standard."

Panel members also recommended that there be a unit accountability policy that requires reporting each time a packet is used; however, reporting method was not specified.

USU was established by Congress under the Department of Defense in 1972 and has the nation's only fully accredited federal school of medicine and graduate school of nursing. With its motto "Learning to Care for Those in Harm's Way," the university has a worldwide reputation as a center of excellence for military medical education and research.