

Development of Process to Address Ethical Issues and Altered Standards of Care in a Pandemic: Model for the Commonwealth of Virginia

1) CATEGORIES ADDRESSED:

- Emergency healthcare delivery
- Legal and regulatory policy
- Critical community infrastructure

2) COMMUNITY DESCRIPTION:

- This project is a collaborative effort of the Virginia Department of Health (VDH), the Virginia Hospital and Healthcare Association (VHHA), and Troutman Sanders LLP, legal consultant to both VDH and VHHA, with involvement of all hospitals and a large number of healthcare stakeholders from throughout Virginia. Virginia is relatively large geographically and has a population of over 7.5 million (2005) with significant diversity of both geographic area (urban, suburban and rural; coastal, piedmont and mountains) and ethnicity of population, including a large number of different nationalities speaking over 120 different languages.
- Virginia has a unified public health system. The Virginia Department of Health is directed by the Commissioner who serves as the State Health Official; the Commissioner reports to the Secretary of Health and Human Resources, a member of the Governor's Cabinet. There are four Deputy Commissioners, one of whom is responsible for Emergency Preparedness and Response (EP&R), including the Office of Emergency Medical Services. The Deputy Commissioner for EP&R is the Principal Investigator for both CDC and HRSA/HHS emergency preparedness cooperative agreements and responsible for coordinating all public health preparedness activities and assuring collaboration with healthcare providers. Thirty-five District Health Departments cover the entire state, with 33 of the 35 health districts part of the state public health system; 2 health districts are locally administered but function the same as the other 33 health districts under contract with the state health department. Health districts vary geographically from a single city to 10 counties, from highly urban to very rural, and also vary in ethnic and language diversity. Each Health District has a cooperative budget with both local and state funding and provides core public health services, including communicable disease control, environmental health and drinking water services and family health services including WIC. District Health Directors are all physicians and report to the Deputy Commissioner for Community Health Services. Each Health District now has an epidemiologist and planner funded with the CDC Emergency Preparedness and Response funds, who report directly to the District Health Director. The CDC Preparedness Grant also funds five regional teams of a physician consultant, planner, epidemiologist, public information officer and trainer; each team coordinates emergency planning and response activities for the Health Districts in the region.
- Virginia currently has 93 acute care facilities: 84 operated by the private sector, 2 state affiliated university health system hospitals, four operated by the Department of Defense and three operated by the Department of Veterans Affairs. These acute care facilities have a total of 14,706 staffed beds, including 1795 ICU beds. Of the 93 acute care facilities, about two thirds are part of multihospital health systems, of which there are 15 (including the Veterans Administration and the Dept of Defense). There are five Level I, three Level II and five Level III trauma centers. Virginia has three adult/pediatric burn centers that receive burn victim referrals based on referral criteria established by the American Burn Association (ABA), although none of the Virginia burn centers are currently accredited by the ABA. There are 274 long term care

facilities in the Commonwealth. There are approximately 150 mental health intake centers in the state, which include the 93 acute care facilities, five private and ten state operated behavioral health facilities, and the 40 Community Services Boards (CSBs). Community Services Boards are locally administered mental/behavioral health service providers, cover the entire state and provide outpatient mental health and substance abuse services as well as referrals for inpatient care. There are 3,543 psychiatric beds among all the acute care and behavioral health (private and state operated) facilities in the Commonwealth. Virginia has 3 medical schools, 1 school of osteopathic medicine, as well as schools of pharmacy, nursing, dentistry and allied health.

- The overall healthcare emergency planning effort in Virginia is a partnership between public health and the healthcare community. Since the beginning of the HRSA (now HHS) National Bioterrorism Hospital Preparedness Program (NBHPP) in 2002, NBHPP funds are awarded to VDH, which then contracts with VHHA to administer and monitor fund distribution and expenditures. At the state level, a Hospital Emergency Management Committee (HEMC), under the direction of the VHHA, makes state level policy decisions. HEMC provides direction for the implementation of the NBHPP and for development and implementation of an effective statewide hospital and healthcare emergency management program. The HEMC serves as the conduit between the hospital private sector and other professional associations and public agencies involved in Virginia's public health and healthcare emergency preparedness and response. Funding is allocated by HEMC to the six hospital planning regions with additional oversight from VHHA and VDH's EP&R Programs. The HEMC also determines overall funding priorities for cooperative agreement funds. This includes decisions for central expenditure of funds to benefit all hospitals and other funded entities, which has included: 1) purchase of a statewide internet based communications and bed and resource monitoring system, 2) training efforts to benefit all funded entities, 3) purchase of interoperable communications equipment, 4) funding for statewide poison control and mental health programs.
- Since 2002, overall emergency planning in the hospital and healthcare communities has been coordinated through 6 hospital planning regions, each with a Regional Hospital Coordinating Center (RHCC) and a Regional Hospital Coordinator. The RHCCs are all Level 1 Trauma Centers and key referral hospitals within their regions; the RHCC for the far Southwest Virginia planning region is located in Bristol, TN (Wellmont Health System), on the border with Virginia. The RHCCs are responsible for maintaining communications with all hospitals in that region during exercises and emergency events, as well as tracking bed utilization and other healthcare resources in the region. Each planning region has a regional hospital planning committee that includes representation from all acute care hospitals in the region, as well as representation from key healthcare provider groups and organizations in the region. The regional planning committees determine how NBHPP funds will be spent within the region, addressing needs specific to hospitals and other providers within that region; all expenditures meet the funding criteria for the HRSA/HHS Cooperative Agreement.
- Membership on the regional preparedness committees includes a representative from each hospital, local public health, EMS, and the Metropolitan Medical Response System, if applicable to the region, as well as mental health providers (CSBs), long term care facilities and Community Health Centers. Membership on the statewide HEMC includes representatives of each of the regional planning committees, the Virginia Department of Health, VHHA, the Dept of Mental Health, regional hospital coordinators, and professional organizations such as the Virginia Nurses Assn, Virginia APIC, and the Medical Society of Virginia.

3) PLANNING PROCESS FOR PANDEMIC INFLUENZA

- The planning process for pandemic influenza has used the planning system already in place for public health, hospital and health system emergency preparedness, to assure that pandemic flu planning is one component of all hazards planning. In addition, VDH established a Pandemic Influenza Advisory Committee in the spring of 2005, which meets quarterly to advise VDH and the healthcare system on pandemic flu planning issues. This Advisory Committee also works closely with the Virginia Department of Emergency Management and the Office of Commonwealth Preparedness, chief advisor to the Governor on homeland security issues, to assure that public health and healthcare planning is closely linked to overall, non-health state planning for pandemic influenza.
- The Pandemic Influenza Advisory Committee includes representation from all key healthcare provider groups and organizations (hospitals, academic health centers, physicians, nurses, pharmacists, long term care facilities, home health care, mental health providers, emergency medical services, community health centers, MMRS), state agencies (mental health, education, human resources, agriculture, game and inland fisheries, emergency management, homeland security, legal, social services, corrections), state and local public health (emergency preparedness, epidemiology, medical examiner, district health departments, school health, minority health, licensure and certification), first responders (law enforcement, fire, EMS), school superintendents, universities, researchers, faith communities, minority organizations, disability community, private business community, local government, ethicists. This Advisory Committee has been instrumental in providing input to state, local and health system plans and has engaged in exercises as well. Sub-groups of the Advisory Committee have been formed to address targeted planning issues, such as development of a state anti-viral distribution plan.
- Collaboration and coordination for all pandemic influenza planning activities for public health and healthcare, healthcare and non healthcare, public and private entities, local and state government, and government and community groups has been challenging. The history of public health and healthcare collaboration, including regional planning, has been instrumental in assuring coordination of pandemic influenza planning. One big challenge for both public health and the healthcare community is assuring involvement of the business private sector and non healthcare entities in both local and state planning activities. Other major challenges include engaging faith, disability and minority communities to assure services are available to everyone in the state during a pandemic. Pandemic influenza planning at the local level is coordinated by District Health Department planners, working closely with local government and the healthcare community, as well as all community partners. Without the previous 4-5 year history of collaborative regional planning, addressing the multitude of new issues related to an influenza pandemic would be much more difficult if not impossible. Pandemic influenza exercises now include all key partners at state, regional and local levels, both healthcare and non-healthcare, private and public sector.
- One major gap in pandemic influenza planning identified early in the planning process was lack of a process for addressing major resource shortages within healthcare and public health. A decision was made early in the planning process to address this issue using systems already established, especially systems to assure coordination and collaboration between public health and the healthcare community. Concerns included legal, ethical and logistic issues when providing healthcare and public health services when resources and personnel are in short supply.

4) NARRATIVE

The all-hazards collaborative model that Virginia has developed among public health, state hospitals, private sector hospitals and other health care providers has allowed us to work together to address and resolve many difficult issues that could otherwise thwart pandemic planning efforts. Perhaps the best example of the success of this approach is Virginia's work on "altered" standards of care.

Most experts, scholars and healthcare providers agree that during a disaster or emergency in which there are mass casualties, hospitals will not be able to maintain services in the same way or at the same level as they do in "normal" times. Instead, health care providers will be forced to implement "altered" standards of care as a way of dealing with shortages of personnel, equipment, supplies and time. While the term "altered" standards of care has not been defined, it is typically understood in the context of allocation of scarce resources.

Health care providers are not accustomed to having to allocate inadequate personnel, equipment and supplies on the scale they will confront in a pandemic. The prospects of allocation on this scale, understandably, cause profound concern within the health care community because such decisions are inextricably tied to liability. These providers understand that they have a duty to render care in accordance with the applicable standard of care or face liability for malpractice. "Altered" standards of care, which by definition do not meet the traditional standard of care, implicate and exacerbate these concerns.

Providers in Virginia, both hospitals and physicians, expressed concerns about this very issue to VHHA. These concerns were so strong that, at the extreme, some providers were contemplating closing their doors during a pandemic instead of providing care under "altered" standards unless they had some degree of liability protection.

VHHA recognized the gravity of the situation and, in coordination with VDH, engaged Troutman Sanders LLP to help it address this issue. Troutman Sanders is a large, international, full service law firm based in Atlanta, Georgia. Steven D. Gravely, head of the firm's Health Care Practice Group, and Erin S. Whaley, an associate in the Health Care Practice Group, have been extensively involved with disaster preparedness, response and recovery for several years. Gravely, with experience as both a first responder and hospital administrator, has over 20 years experience representing hospitals and other health care providers. Gravely and Whaley advise VDH and VHHA on a broad range of emergency preparedness issues including health care issues. Specifically they advise the HEMC and the Pandemic Influenza Advisory Committee on preparedness related legal issues. Because of their unique skill sets and knowledge of the health care industry, Gravely and Whaley were well positioned to address both the legal and pragmatic issues entangled in "altered" standards of care.

VDH, VHHA and Troutman Sanders (the "Core Team") recognized that there were substantial misconceptions and confusion among health care providers about their realistic liability exposure in relation to "altered" standards. The first step in developing a comprehensive strategy for addressing providers' concerns was for Troutman to evaluate the current law in this area to determine if any of the liability concerns were legitimate. This evaluation focused on application of the Virginia Emergency Services and Disaster Law, the Virginia Good Samaritan Law, the Virginia State Government Volunteers Act, the statutory standard of care in Virginia, Virginia's Model Jury Instructions for medical malpractice in relation to a potential "altered" standard of care case,

licensure and regulatory scope of practice restrictions. Troutman developed a White Paper summarizing its legal analysis that is available as a resource for all Virginia healthcare providers. This legal analysis confirmed that there is indeed a gap in liability protection that leaves healthcare providers vulnerable to potential claims of malpractice for care provided pursuant to “altered” standards during a disaster.

The Core Team, led by VHHA, convened a multi-disciplinary, state-wide work group to evaluate options to address the liability associated with altered standards of care (the “Work Group”). The Work Group was composed of individuals from across the state who represent various healthcare institutions, clinician groups, public health, emergency planning bodies and legislatures. The Core Team carefully selected members for the Work Group to assure that diverse perspectives were present without creating a group that was too large to be effective. VHHA hosted the Work Group sessions, which were facilitated by Troutman because of their extensive experience in representing both health providers and public health interests, which enabled them to understand the perspective of each stake holder.

The first Work Group session focused on a review of the legal issues white paper. This was important to dispel common misconceptions and assure that all members of the Work Group had the same basic background information. This helped the Work Group to realize that liability in an “altered standard of care” sense was a function of two separate but related components: existing law and the actual delivery of care. As a result of this realization, the Work Group decided to pursue a two-tiered approach to addressing the issue: suggesting legislative solutions and drafting practical guidance for hospitals to help them determine how to actually deliver care in the face of scarce resources.

The Work Group developed six potential legislative initiatives that would offer providers additional liability protections for care provided in the face of scarce resources during a disaster. These six options were discussed with various stakeholder and lobbying groups, including legislators and the Virginia Office of the Attorney General. As a result of these discussions, the Virginia General Assembly just passed a bill that will create a joint legislative subcommittee to study the feasibility of offering liability protections to health care providers rendering aid during a state or local emergency. The joint committee will present a report of its findings in late 2007, which will hopefully lead to specific legislation being introduced and passed in the 2008 General Assembly. Throughout this process, VHHA kept its members abreast of developments with accurate and timely information. This was crucial to the overall success of the effort.

Because these legislative solutions were neither immediate nor guaranteed, the Work Group pursued its second tier approach as well - providing a tool for hospitals to help them think and plan for “altered” standards. While a few others across the country had devised specific “altered” standard of care algorithms for the allocation of specific resources, like ventilators, the Work Group could find no “altered” standard of care planning guide on which to base its work. Instead, the Work Group undertook an ambitious project of creating such a guide from whole cloth (the “Planning Guide”).

To do this, the Work Group had to come to a consensus on various assumptions regarding “altered” standard of care planning. The three most basic assumptions are as follows:

1. When talking about “altered” standards, we are really talking about allocation of critical resources in times of shortage. Critical resources are those that are

required to sustain human life, prevent permanent disability, or stabilize a person experiencing a medical emergency.

2. While it is commonly recognized within the health care industry that “altered” standards of care will have to be employed during a disaster, the exact nature of those standards is far from understood. Each disaster situation is unique, as is each health care community. This makes it difficult to formulate “altered” standards of care in advance. Instead, it will be most beneficial to offer a *process* that providers can use to identify the content of such standards. That process can then be utilized to develop “altered” standards algorithms as the need arises.
3. Hospitals will allocate scarce resource in a way that does the greatest good for the greatest number, as determined by the provider.

These assumptions led the Work Group to create the “Critical Resource Shortage Planning Guide,” which provides a specific, detailed decision matrix that providers across the Commonwealth can use to anticipate and respond to shortages of critical resources during an event. The Planning Guide walks a provider step-by-step through the key stakeholders that should be involved in “altered” standards planning, the questions that need to be asked, the decisions that need to be made and the interdependencies that must be taken into account. The end product of the Planning Guide is the creation of an infrastructure that will allow providers to respond to resource shortages during disasters by creating their own treatment algorithms that will govern how these scarce resources should be allocated. Even with all of this specificity, the Guide is flexible enough to be used by a 900 bed academic medical center and a 15 bed critical access hospital.

Since finalizing a draft of the Planning Guide in late 2006, the Core Group has been rolling it out to various groups within Virginia and obtaining input from a variety of stakeholders who were not necessarily part of the Work Group. To this end, the Planning Guide was presented and discussed with HEMC, hospital ethics committee representatives from across the Commonwealth, regional groups of healthcare executives, and the Virginia Pandemic Influenza Advisory Committee. With each discussion, the Planning Guide is further refined as an effective and important tool for healthcare provider pandemic preparedness planning.

5) CONTACT INFORMATION

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