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Organizational Dynamics
3401 Walnut Street, Suite 328A
Philadelphia, PA 19104-6228
Tel 215.898.9185 Fax 215.898.8934
lstarr@sas.upenn.edu
www.organizationaldynamics.upenn.edu

Larry M. Starr, Ph.D.
Director, Graduate Studies

November 21, 2011

Lilly Fowler, *Fair Warning*
http://www.fairwarning.org/writer/lilly-fowler/

Dear Ms. Fowler,

We are responding to your recent *Fair Warning* report, "Defibrillator 'upgrade' apparently a dud." While one of us (L. Starr) is the author of "Automated External Defibrillation in the Occupational Setting" published by the American College of Occupational and Environmental Medicine (http://www.acoem.org/AED_OccupationalSetting.aspx), we all have special interest in AEDs and in your report. We feel you generally and correctly summarized most of the "story," but we believe there is a better explanation for the problem and outcomes. We would be very pleased to speak with you if you wish additional information.

We cannot address your comments on ethical concerns related to conflicts of interest associated with American Heart Association (AHA) editorial and writing committees. We do know, however, that the AHA has had a strict conflict of interest policy predating the 2000 Guidelines review process.

Your other questions, however, are compelling such as these: Was there inadequate clinical research? Do (new) AEDs placed in hospitals produce better outcomes than previous manual equipment? Is an AED that requires a less-skilled user more likely to be used than one requiring more skill? If AEDs seem to save lives in airports, can one put them a hospital and expect the same results? To what degree does AED manufacturer quality control affect survival? To what degree do "psychology and emotions" affect responders to cardiac emergencies in a hospital?

AHA CPR and ECC recommendations from 2000, 2005 and 2010 conferences and subsequent recommendations follow clear and defined science and review protocols, and are based on analytic, research-based scientific review and consensus. At the core of this decision-making is an assumption - the long-held "chain of survival" metaphor - that survival from this medical problem can be improved if one maximizes each of five independent and additive links - quickly accessing EMS + quickly performing CPR + quickly using an AED + quickly delivering advanced life support (ALS) procedures + (newly added) post-cardiac arrest care. This analytic model assumes that improving

each of the parts will de facto improve the whole problem. As an example, there are few who question that AEDs need to be widespread so that they can be quickly used with CPR until ALS can be provided.

However, we believe this assumption has limited – and even detrimental – outcome impact. We argue that sudden cardiac arrest survival is not "merely" a medical problem and cannot be solved using only analytic, research-based medical scientific thinking. The chain of survival – an additive/linear model – is a limiting and misleading metaphor.

We believe sudden cardiac arrest survival is a complex organizational system problem in which survival occurs due to the interaction and interdependency among many elements. Those identified in the "chain links" are important and account for some intermediate success, but there are many more elements that together account for survival. In your report, you described some of these elements and also identified some of the differences between an analytic medical and system organizational approach to this problem. Here are several important aspects of our perspective:

1. Altering elements within a system such as removing manual and replacing with automated external defibrillators requires people to change and also to transition, which is the process of coming to terms with the meaning of the change. For example, medical professionals may feel less personal control in decision making when using an automated device. Transitions are tricky because they require coping with loss of old ways of thinking and acting and replacing with new ways.

2. Optimizing or improving one part of an organizational system commonly leads to sub-optimization or failure in another part. Significantly increasing the number of AEDs in hospitals can co-produce failures and lead to unintended negative effects in other areas--and that can reduce overall effectiveness in the system. But even this can be confusing because, for example, an earlier paper found that relying only on an AED (no CPR) tripled survival rates (http://circ.ahajournals.org/content/106/9/1065). It seems absurd to argue that eliminating CPR and reducing the number of AEDs in hospitals can increase survival following sudden cardiac arrest, but when the focus is on improving individual elements as if each is independent in a "complex" system, confusion is common.

3. Success in one category of system or individual example of system (airports) rarely means success in another (hospitals), and this also applies to success in one community system compared to another. That is, applying a "best practice" from one system does not necessarily work well in another system. This is because each system is different and has unique interactions and elements.

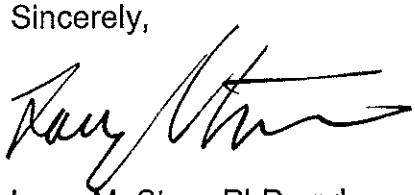
4. Quality control of AEDs seems to be one element of the sudden cardiac arrest organizational system problem. It likely interacts with the cost of a device, push for sales, and may influence the degree of training and service requirements considered important for devices. When quality is perceived to fail, it co-produces a failure in trust by users.

5. In organizational systems, people have individual purposes and feelings about their work and their actions. Ignoring these elements is naïve. That is, pretending they are "noise" in an otherwise clear set of medical protocols that is mechanically followed fails to recognize the complexity and effect of this significant system feature.

At the University of Pennsylvania, a multidisciplinary, multi-stakeholder "Special Task Force" has come together to challenge fundamental assumptions in order to better understand the sudden cardiac arrest survival problem. While we fully support the analytic, research activities for some aspects of the problem and for improving some outcomes, we feel this is insufficient. The approach of the Special Task Force is on use of systems and design thinking, some of which is described in the 5 points noted above, and on use of systems and design methodologies for solving (and dissolving) complex problems. Here is our website: http://www.organizationaldynamics.upenn.edu/survival

We expect to begin a comprehensive research project in the spring, pending adequate funding, that will define more specific information about the complete set of factors and their interactions that contribute to survival. Our project methodology will also allow for the derivation of an organizational system design to significantly improve outcomes.

Sincerely,



Larry M. Starr, PhD and
Allan Braslow, PhD (University of Pennsylvania)
Nicholas Bircher, MD (University of Pittsburgh)
John Field, MD (Pennsylvania State University)