Foundation assembles stakeholders to discuss medical device safety: Medical device technology is growing at an astounding rate, but effective standards and systems of checks and balances have not kept pace with that growth. The Foundation is helping solve this problem by encouraging communication and collaboration among all industry players. Dr. Yadin David, Foundation President Emirates and Director of Biomedical Engineering at Texas Children’s Hospital, together with Professor William Hyman of Texas A&M university and also a Foundation Board member, recently brought together a diverse group of some 65 stakeholders including biomedical engineers, risk managers, medical technology manufacturers, physicians, nursing leadership and industry regulators to discuss medical-device safety issues at the Responding to Medical Devices Failures Colloquium. The group met at the M. D. Anderson Cancer Center in Houston to hear about different reporting strategies and to develop an integrated action plan for improving patient safety through an effective -- and fair -- system for reporting device-related mishaps and failures. The one-day event was sponsored by the Foundation, Texas Children’s Hospital, Texas A&M University and the U.S. Food and Drug Administration (FDA) Medical Device Industry Coalition. "As an adviser to the FDA and an active member of the Clinical Engineering profession, I am called upon often to help interpret regulations and to investigate devices-related incidents," David said. "I was searching for a way I could help by promoting more open dialogue, a better-educated workforce and better-designed equipment. When I started talking to people in the industry, they encouraged me to bring together this colloquium to generate discussion and proposals."

Over the past 20 years, the average number of medical devices at the patient's bedside has increased on the average from just a few to over 20. Due in part to several high-profile recalls, the public is becoming increasingly concerned about device safety. In response, the FDA is moving rapidly to ramp up mechanisms for additional post market device monitoring. Achieving a higher safety level will require a concerted effort to bridge the gaps among manufacturers, regulators, maintainers, end-users and patients. All segments of the industry will have to share information in a way that will reduce problems and improve patient safety. In a 2006 editorial in an industry magazine, David set the wheels in motion for the colloquium by calling on leaders across industries and communities to join to improve device safety. “Unquestionably, consumer safety is diminished when there is limited communication among the engineers who design devices, the clinicians
who deploy them, the clinical engineers who support them, the regulators who monitor
them, and the patients and care givers who experience them," he wrote. At the
colloquium, David proposed a system to capture system data, and through review of this
data, to reduce errors that is similar to the "black box" method successfully used by
airlines. "If we are able to capture data at the point of care in the hospital, so we know
what conditions existed that allowed an error to be committed, or a device to fail, and
thereby learn how to avoid repetition, health care will be safer and better for our
patients."

Foundation Annual Meeting: The Board of Directors of the Foundation had a busy and
productive meeting in Houston immediately following the Colloquium. The focus of the
meeting was on sustaining and building the current momentum in fund raising and
project completion. Current projects include Clinical Alarms, the Shepherd Safety
Award, Patient and Public Education, and the new Clinical Engineering Excellence
Award. Newly elected to the Board are Dave Dickey, who served in an advisory capacity
over the past year, and Malcolm Ridgeway. Since the Foundation has no personnel other
than the directors, there is a great need for additional “doers” (as we have come to call
those who are active in our projects.) If there are Foundation activities that you have
interest in, please let us know.

Donations: As always, donations to the Foundation are welcome at any time, and they are
tax deductible.

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