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MEETING PROCEEDINGS

Insulin Pump Safety Meeting: Summary Report

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Abstract

Diabetes Technology Society convened a panel of insulin pump experts in Bethesda, Maryland, on November 12, 2008, at the request of the Food and Drug Administration. The group consisted of physicians, nurses, diabetes educators, and engineers from across the United States. The panel members (1) discussed safety features of insulin pump therapy and (2) recommended adjustments to current insulin pump design and use to enhance overall safety. Software and hardware features of insulin pumps were analyzed from engineering, medical, nursing, and pump-user perspectives. The meeting was divided into four sections: (1) Engineering Safety—Designing Software and Hardware for Insulin Pump Therapy; (2) Patient Safety—Selecting Patients and Clinical Settings for Insulin Pump Use; (3) Clinical Safety—Determining and Delivering Insulin Dosages Using Insulin Pump Therapy; and (4) Personal Experiences—A Panel Discussion about Insulin Pump Safety. Six aspects of insulin pump technology were noted to present potential safety problems: (1) software, (2) wireless communication, (3) hardware, (4) alarms, (5) human factors, and (6) bolus-dose calculation. There was consensus among meeting participants that insulin pump therapy is beneficial in patients of all ages and that insulin pump safety must be assured through careful regulation.

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Abbreviations: (BG) blood glucose, (CGM) continuous glucose monitor, (FDA) Food and Drug Administration

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