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TECHNOLOGY WORKS BEST WHEN IT IS ACCURATE

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San Mateo, California

ACCURACY IS THE MOST IMPORTANT FEATURE IN A DIABETES DEVICE

Disclosures: Consultant to Ascensia, Lifecare, Novo Onduo, Trividia, Voluntis
ACCURACY IS THE MOST IMPORTANT FEATURE IN A DIABETES DEVICE

GLUCOSE MONITORING
- INSULIN DELIVERY
- CYBERSECURITY

CORRECT DECISIONS REQUIRE ACCURATE INFORMATION

ACCURATE INFORMATION REQUIRES ACCURATE MONITORING DEVICES

AVOID ERRORS

ERROR

SAVE MONEY

FAVORABLE OUTCOMES

DIABETES THERAPY REQUIRES CORRECT DECISIONS

ACCURACY
MINIMUM ACCURACY CRITERIA FOR OTC BLOOD GLUCOSE MONITORS FROM THE 2016 FDA GUIDANCE

95% of glucose results must be within 15% of range

99% of glucose results must be within 20% of range

ANALYTICAL ACCURACY VS. CLINICAL ACCURACY

INACCURATE BG MONITORS ARE RISKY FOR MAKING TREATMENT DECISIONS OR CALIBRATING CGMS

MODELED SIMULATED PATIENT DATA

EMPIRICALLY COLLECTED PATIENT DATA
A BLOOD GLUCOSE MONITOR THAT HAS A HIGH BIAS WHEN CALIBRATING A CGM WILL RESULT IN UNDERREPORTING HYPOGLYCEMIA

CGM calibrated with BGM with positive bias underreports hypos

Green band is 5th-95th percentile of CGM readings

CGM calibrated with BGM with no bias accurately reports hypos

Teal band is 5th-95th percentile of CGM readings

HYPOLYCEMIA RISK AGAINST BGM INACCURACY

GLYCEMIC CONTROL AGAINST BGM INACCURACY

SMBG accuracy

SMBG accuracy

PROBABILITY OF FALING TO DETECT HYPOGLYCEMIA ACCORDING TO BGM INACCURACY

LIKELIHOOD (PERCENT)

0 5 10 15 20

BG MONITOR ACCURACY FOR 95% OF DATA POINTS +/- PERCENTAGE

Continuous Glucose Monitoring in Newborn Infants: How Do Errors in Calibration Measurements Affect Detected Hypoglycemia?

Felicity Thomas, BSc(Hons)1, Matthew Sigal, PhD2, Deborah L. Harris, PhD2,3, Philip J. Westen, MChB2,4, June E. Harding, DPhil1, Geoffrey M. Shaw, MChB2,5, and J. Geoffrey Chase, PhD2, on behalf of the CRYLD Study Group

Abstract

Hypoglycemia is common and can cause serious brain injury. Continuous glucose monitoring (CGM) could improve hypoglycemia detection, while reducing total glucose testing. Calibration algorithms use BG measurements to convert sensor signals into CGM data. Thus, inaccuracies in calibration BG measurements directly affect CGM values and any metrics calculated from them. The aim was to quantify the effect of timing delays and calibration BG measurement errors on hypoglycemia metrics in newborn infants. Data from 135 babies were used: Two strong and 1 I2 meter error models (Witten OptiGuard, Roche AccuCheck Inform & B. Metre) were reviewed using a longitudinal data. Chouf-Gabrielle algorithm and CGM calibrated with BGM were used to estimate strong varying measurement error added to BG measurements before CGM data was calibrated. The number of hypoglycemic events, duration of hypoglycemia, and hypoglycemic index were then calculated using the CGM data and compared to baseline values. Timing error alone had little effect on hypoglycemia metrics, but measurement error caused substantial variation. Abbott results underestimated the number of hypoglycemic events by up to 8 and Shisei overestimated by up to 4 while the original number reported was 3. No errors were created detected by the hypoglycemia metrics. Errors in glucose concentration measurements used for calibration of CGM devices are likely to cause substantial variation in hypoglycemia metrics. These metrics are going to be used for assessing hypoglycemia is important to understand the impact of these errors on CGM data.
The relationship between analytical accuracy of a BGM for calibration and both the A1C level as well as the frequency of severe hypoglycemia.

Error vs. A1C for three levels of CGM accuracy:
- MARD = 20%
- MARD = 13%
- MARD = 8%

Error vs. severe hypoglycemia frequency for three levels of CGM accuracy:
- Ratio of Areas: 3:2:1

Effect of BG monitor inaccuracy on mean glycemnic control:
- Inaccuracy of a BGM correlates with poor glycemnic control.

Effect of BG monitor inaccuracy on frequency of hypoglycemnic coma per 100 patient-yr:
- Positive bias of a BGM leads to excess Rx and correlates with hypoglycemnic coma.

BGM analytical inaccuracy:
- Incorrect insulin dosing
- More hypoglycemia
- Higher mean glucose
- Decreased CGM accuracy

Diabetes Technology & Therapeutics
Volume 17, Number 3, 2016
DOI: 10.1089/dtt.2015.0003

Original Article

Accuracy of Blood Glucose Meters for Self-Monitoring Affects Glucose Control and Hypoglycemia Rate in Children and Adolescents with Type 1 Diabetes
Claudia Boettcher, MD
Andreas Dost, MD
Stefan A. Wack, MD
Marion Flechner-Morsch, PhD
Martin Borkenstein, MD
Ralf Schel, MD
Dieter Weitzel, MD
Susanne Bechthold-Dalla Pozza, MD
Johannes Wolf, MD
and Reinhard W. Hoell, MD
for the German/Austrian Diabetes Prospective Documentation Initiative
9163 Type 1 pediatric patients from Germany & Austria

Abstract
Aims/hypothesis: This study investigated the accuracy of blood glucose meters for self-monitoring and its influence on glycated hemoglobin (HbA1C) levels and the frequency of hypoglycemic coma.

Inaccurate BGM leads to incorrect insulin dosing, more hypoglycemia, higher mean glucose, decreased CGM accuracy, and bad outcomes.
Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis

530,000 beneficiaries – 2009 through 2012

AFTER THE CBP BEGAN IN 2011 SMBG SUPPLY ACQUISITION WAS DISRUPTED. MIGRATION TO LESS FREQUENT OR NO SMBG WAS ASSOCIATED WITH INCREASED MORALITY, INPT ADMISSIONS, AND COSTS

THE CBP HAS LIMITED BENEFICIARIES’ PRODUCT CHOICES. AADE SURVEYED CMS MAIL ORDER SUPPLIERS IN NOV. 2016. 18 of 38 BRANDS AND 65 PRODUCTS ARE NOW UNAVAILABLE

DIABETES TECHNOLOGY SOCIETY SURVEILLANCE PROGRAM FOR CLEARED BGM SYSTEMS

Performance of Cleared Blood Glucose Monitors

David C. Klonoff, MD, FACP, FRCP (Edin), Fellow AIMBE1, and Priya Prahalad, MD, PhD2

Abstract

Cleared blood glucose monitor (BGM) systems do not always perform as accurately as users think they do become cleared. We performed a literature review of recent publications between 2010 and 2014 that present data about the frequency of inaccurate performance using ISO 15197:2003 and ISO 15197:2013 as target standards. We performed an additional literature review of publications that present data about the clinical and economic risks of inaccurate BGMs for making treatment decisions or calibrating continuous glucose monitors (CGMs). We found 11 publications describing performance of 16 unique BGM systems. 53 of these 98 (54%) systems met ISO 15197:2003 and 31 of the 98 (32%) tested systems met ISO 15197:2013 analytical accuracy standards in all studies in which they were evaluated. Of the tested systems, 33 were identified as FDA-cleared. Among these FDA-cleared BGM systems, 24 out of 33 (73%) met ISO 15197:2003 and 15 out of 33 (45%) met ISO 15197:2013 in all studies in which they were evaluated. It is more likely that a non-FDA-cleared BGM system, compared to a non-FDA-cleared BGM system, will perform according to ISO 15197:2003 (H = 4.2, d.f. = 3, p = 0.049) and ISO 15197:2013 (H = 11.4, d.f. = 3, p = 0.003). We identified 7 articles about clinical risks and 3 articles about economic risks of inaccurate BGMs. We conclude that a significant proportion of cleared BGMs do not perform at the level for which they were cleared or according to international standards of accuracy. Such poor performance leads to adverse clinical and economic consequences.

<table>
<thead>
<tr>
<th></th>
<th>ALL BGMs REPORTED</th>
<th>FDA CLEARED</th>
<th>NON-FDA-CLEARED</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL BGMs</td>
<td>n = 98</td>
<td>n = 33</td>
<td>n = 65</td>
</tr>
<tr>
<td>% ISO 15197:2003</td>
<td>54%</td>
<td>75%</td>
<td>45%</td>
</tr>
<tr>
<td>% ISO 15197:2013</td>
<td>32%</td>
<td>48%</td>
<td>23%</td>
</tr>
</tbody>
</table>


David C. Klonoff, MD, FACP, FRCP (Edin), Fellow AIMBE1, Courtney Linn, PhD, Stacey Beck, PhD2, Joan Lee Parkes, PhD3, Boris Kovatchev, PhD4, Robert A. Vigersky, MD, Guillermo Arreaza-Rubin, MD, Robert D. Burt, MD, Aaron Kowalski, PhD2, Randy Little, PhD, James Nichols, PhD, DABCC, FABC2, Matt Petersen, BA2, Kelly Rawlings, BA1, David B. Sacks, MD, CIB, FACP, FRCPath, PhD5, Eric Sampson, PhD5, Steve Scott, BS, Jane Jeffries, DNP, MPH, BC-ADM, CDE, CDC2, Robbert Slingerland, PhD1, and Hubert W. Vesper, PhD1

Abstract

Background: Inaccurate blood glucose monitoring systems (BGMs) can lead to adverse health effects. The Diabetes Technology Society (DTS) Surveillance Program for cleared BGMs is intended to protect patients from diabetes with diabetes from inaccurate, unreliable BGMs products that are currently on sale in the market. The United States. The Surveillance Program will provide an independent assessment of the as-applied performance of cleared BGMs.
PRESS RELEASE

www.diabetestechnology.org

Diabetes Technology Society Begins Surveillance Testing Study of Cleared BG Monitor Systems

June 8, 2016 – Burlingame, California - Diabetes Technology Society (DTS) is pleased to announce the commencement of testing for the DTS Surveillance Program for Cleared Blood Glucose Monitor systems (BGMS).

The results of the surveillance study represent how each product performed in a specific protocol and do not predict what a patient or other user can expect in the way of product performance in another setting. DTS makes no endorsements or predictions for future performance of the tested products.

PRESS RELEASE

www.diabetestechnology.org

Diabetes Technology Society Releases Results of Blood Glucose Monitor System Surveillance Testing

June 27, 2017 – Burlingame, California - The accuracy of 18 blood glucose monitoring systems (BGMSs) marketed in the USA was assessed in three studies each. A Seal of Approval was awarded to any product that passed all 3 of the 3 studies. The DTS Seal of Approval was awarded to ………

THE 18 BEST SELLING BGMs IN THE US
ALL EQUIPMENT PURCHASED BY DTS

TRIPLE BLINDED STUDY: CLINICAL SITES, REFERENCE LAB, AND SPONSOR

CLINICAL SITE  REFERENCE LAB  SPONSOR
TRIPLE BLINDED STUDY: CLINICAL SITES, REFERENCE LAB, AND SPONSOR

1035 SUBJECTS

CLINICAL SITE

REFERENCE LAB

SPONSOR

TRIPLE BLINDED STUDY: CLINICAL SITES, REFERENCE LAB, AND SPONSOR

1035 SUBJECTS

CLINICAL SITE

REFERENCE LAB

SPONSOR

TRIPLE BLINDED STUDY: CLINICAL SITES, REFERENCE LAB, AND SPONSOR

5584 DATA PAIRS

CLINICAL SITE

REFERENCE LAB

SPONSOR

FACTORS THAT CAN DECREASE BGM ACCURACY OVER TIME

- Scale-up issues
- Manufacturing errors
- Changes in components between lots
- Improper shipping
62% OF THE 2016 CMS MAIL ORDER MARKET WAS FOR BGMs THAT DID NOT PASS THE DTS SURVEILLANCE PROGRAM

FACTORS AFFECTING TREATMENT ACCURACY BESIDES BGM ACCURACY

- Incorrect estimation of carbohydrate content and glycemic index
- Inaccurate insulin dose delivery
- Variable absorption of insulin dose
- Residual effect of insulin on board
- Unpredictable effects of physical activity

GoCARB:
n=19 T1DM.
Mean error of carbohydrate estimation/day:
28 gm before vs. 12 gm after
(p =0.001)

Global Smart Insulin Pens Market Insights 2017-2023 - Explosion of Bluetooth Connected Insulin Pen & Rising Demand for Diabetes Management
Metrics for predicting glycemia during exercise

1 Heart rate
2 Heat flux
3 Skin temperature
4 Near-body temperature
5 Galvanic skin response
6 Acceleration
7 Energy expenditure

HOSPITAL BLOOD GLUCOSE MONITORING

OBTAINING A BLOOD GLUCOSE MONITOR TEST RESULT IS LIKE ORDERING A PIZZA

1 PREPARE: PREANALYTICAL ERROR
2 PERFORM: ANALYTICAL ERROR
3 DELIVER: POSTANALYTICAL ERROR

1 STRIPS HAVE NOT EXPIRED
2 STRIPS HAVE BEEN STORED PROPERLY
3 HANDS ARE CLEAN WITHOUT ANY NO FOOD RESIDUE
4 HANDS ARE DRY WITHOUT ANY ALCOHOL RESIDUE

INTERFERING SUBSTANCES:

1 PHYSICAL ENVIRONMENT (humidity, temp)
2 PHYSIOLOGY (pO2, edema)
3 MEDICATIONS (acetaminophen)

1 Hands are clean without any food residue
2 Hands are dry without any alcohol residue
3 Strips have not expired
4 Strips have been stored properly
5 Physical environment (humidity, temp)
6 Physiology (pO2, edema)
7 Medications (acetaminophen)
Sticking With Safety: Eliminating Bloodborne Pathogen risks during Blood Glucose Monitoring - May 3, 2010 Meeting Overview

“Critically ill patients should not be tested with a glucose meter because results may be inaccurate.”

2014 FDA Draft Guidance BGM Test Systems for Prescription POC Use. Page 31, lines 1113-1114
Rx DRUGS OFF LABEL
Rx DEVICES OFF LABEL

MINIMUM ACCURACY CRITERIA FOR PRESCRIPTION POINT-OF-CARE BLOOD GLUCOSE MONITORS FROM THE 2016 FDA GUIDANCE

95% of glucose results must be:
For glucose < 75 mg/dl – within 12 mg/dl of reference
For glucose ≥ 75 mg/dl – within 12% of reference

And 98% of glucose results must be:
For glucose < 75 mg/dl – within 15 mg/dl of reference
For glucose ≥ 75 mg/dl – within 15% of reference

Timely Hospital Glucose Measurement: Here Today, Gone Tomorrow?

David C. Konoff, MD, FACP, FACP (Edin), Fellow AIME; Robert A. Vigersky, MD, James H. Nichols, PhD, and Mark J. Rice, MD

Blood glucose meters (BGMs), first introduced in the US market in the 1970s, have revolutionized the care of patients with diabetes. Improved glucose control, enabled by frequent measurement, has greatly reduced long-term cardiovascular, renal, and ophthalmic complications. Although these devices were originally designed for and approved by the Food and Drug Administration (FDA) for “self-monitoring by persons,” they have obrigingly ignored standards of care for TGC.

In 2001, Van der Heijge et al, reported that TGC targeting a blood glucose level of 80 to 110 mg/dl (to convert to mmol/l, multiply by 0.0554) using intensive insulin therapy significantly decreased mortality and morbidity in critically ill surgical patients. This report led to increased adoption of POC BGMs in hospitals. Tighter glucose control was applied in various settings, including the intensive care unit (ICU), operating rooms, and neonatal units.

Memorandum Summary:

- “Off-Label Use” of BGMS. Many are marketed to the Food and Drug Administration (FDA) approved as “diabetes blood glucose meters, automated systems, and devices to measure the concentration of whole blood in the body.” “Off-label use” applies to all of these if the meter is used in a manner other than as intended, including in critically ill surgical patients. The Centers for Medicare and Medicaid Services (CMS) will ensure and follow-up by auditing the applicable regulations and guidelines.

Nina R. Shih, M.D., M.P.H.
Commissioner
January 13, 2014

Re: Off-label Use of Glucose Meters

Dear Laboratory Director:

As laboratory director, you are jointly and severally responsible with the owner for the maintenance and operation of the clinical laboratory (Article 5, Title V of New York State Public Health Law). This includes testing that is performed at the point-of-care (POCT) or as part of a health fair or other community screening event.

The US Food and Drug Administration (FDA) is responsible for approving medical devices, including glucose meters, based upon the performance characteristics established by the manufacturers (validation data) and submitted by the manufacturers to the FDA.


COMMENTARY

Department of Health & Human Services

Center for Clinical Standards & Quality/Survey & Certification Group

Ref: S&C: 15-11-CLIA

DATE: November 22, 2014

TO: State Survey Agency Directors

FROM: Director Survey and Certification Group

SUBJECT: Requirements on the Off-Label Modified Use of Waived Blood Glucose Monitoring Systems (BGMs)

Department of Health & Human Services

Center for Clinical Standards & Quality/Survey & Certification Group

Ref: Temporary Withdrawal S&C 15-11-CLIA

DATE: March 13, 2015

TO: State Survey Agency Directors

FROM: Director Survey and Certification Group

SUBJECT: Reissuance of S&C 15-11 As DRAFT ONLY – FOR COMMENT

Off-Label Modified Use of Waived Blood Glucose Monitoring Systems (BGMs)

We are temporarily withdrawing S&C Memorandum 15-11, which is previously issued on November 21, 2014, and resuming it in draft-only form in order to:
“Define subpopulations... that might be particularly vulnerable to ... health risks from meter inaccuracy.”

2016 FDA Guidance BGM Test Systems for Prescription POC Use. Page 15, lines 514-518
Table 2. CGM difference to YSI within YSI glucose ranges. Calibrating every 12 hours.

<table>
<thead>
<tr>
<th>Site Description</th>
<th>Overall Mean</th>
<th>Mean Difference (%)</th>
<th>Mean Absolute Difference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm (Glucose Sensor Recorder)</td>
<td>9.1%</td>
<td>9.4%</td>
<td></td>
</tr>
<tr>
<td>Abdomen (640 Insulin Pump)</td>
<td>10.4%</td>
<td>10.8%</td>
<td></td>
</tr>
<tr>
<td>Abdomen (Connect Mobile App)</td>
<td>9.6%</td>
<td>9.4%</td>
<td></td>
</tr>
</tbody>
</table>

GLUCOSE MONITORING

ACURATE INSULIN DOSING FROM AN INSULIN PUMP, INSULIN PEN, OR AN ARTIFICIAL PANCREAS

INSULIN DELIVERY

CYBERSECURITY

GUARDIAN SENSOR 3

The Performance and Usability of a Factory-Calibrated Flash Glucose Monitoring System

Timothy Bailey, MD, FACE, FACPE, Bruce W. Bodie, MD, FACE

Abstract

Introduction: The purpose of the study was to evaluate the performance and usability of the Flash glucose monitoring system (Guardian Diabetes Care, Alameda, CA) for patients with type 1 diabetes using the CGM-YSI difference. The study was a randomized, controlled, single-blind, multicenter trial. The primary endpoints were the CGM-YSI difference and the CGM-YSI difference in the past 7 days. The study was conducted at 20 centers in the United States.

Methods: The study enrolled 1000 participants with type 1 diabetes who were randomized to either the CGM-YSI or the CGM-YSI difference. The CGM-YSI difference was calculated by comparing the CGM-YSI difference to the YSI reference. The study was conducted over a period of 7 days. The primary endpoints were the CGM-YSI difference and the CGM-YSI difference in the past 7 days. The study was conducted at 20 centers in the United States.

Results: The CGM-YSI difference was significantly lower in the CGM-YSI group than in the CGM-YSI difference group. The CGM-YSI difference was also significantly lower in the CGM-YSI group than in the CGM-YSI difference group. The CGM-YSI difference was significantly lower in the CGM-YSI group than in the CGM-YSI difference group. The CGM-YSI difference was significantly lower in the CGM-YSI group than in the CGM-YSI difference group.

Conclusion: The CGM-YSI difference was significantly lower in the CGM-YSI group than in the CGM-YSI difference group. The CGM-YSI difference was also significantly lower in the CGM-YSI group than in the CGM-YSI difference group. The CGM-YSI difference was significantly lower in the CGM-YSI group than in the CGM-YSI difference group. The CGM-YSI difference was significantly lower in the CGM-YSI group than in the CGM-YSI difference group.
A STANDARD IS NEEDED TO DETERMINE THE MEASUREMENT METHOD, TEST CONDITIONS, AND TOLERANCE OF INSULIN PUMP DOSING

HOW ACCURATE MUST A PEN BOLUS BE ACCORDING TO ISO?

- Minimum bolus of 0-2 U, allowed deviation is up to ±1 U (= 50 mg/dl)
- Mid bolus of ~30-40 U, allowed deviation is up to ±5% (~ 1.5-2 U = 75-100 mg/dl)
- Max bolus of ~60-80 U, allowed deviation is up to ±5% (~ 3-4 U = 150-200 mg/dl)

OUTCOME MEASURES FOR ARTIFICIAL PANCREAS CLINICAL TRIALS

<table>
<thead>
<tr>
<th>Glycemic metric</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>Mean CGM glucose</td>
</tr>
<tr>
<td></td>
<td>% CGM time &lt;50 mg/dl (&lt;2.8 mmol/l)</td>
</tr>
<tr>
<td></td>
<td>% CGM time &lt;60 mg/dl (&lt;3.3 mmol/l)</td>
</tr>
<tr>
<td></td>
<td>% CGM time &lt;70 mg/dl (&lt;3.9 mmol/l)</td>
</tr>
<tr>
<td></td>
<td>% CGM time 70-140 mg/dl (3.9-7.8 mmol/l)</td>
</tr>
<tr>
<td></td>
<td>% CGM time 70-180 mg/dl (3.9-10.0 mmol/l)</td>
</tr>
<tr>
<td></td>
<td>% CGM time &gt;180 mg/dl (&gt;10.0 mmol/l)</td>
</tr>
<tr>
<td></td>
<td>% CGM time &gt;250 mg/dl (&gt;13.9 mmol/l)</td>
</tr>
<tr>
<td></td>
<td>% CGM time &gt;300 mg/dl (&gt;16.7 mmol/l)</td>
</tr>
<tr>
<td></td>
<td>SD and coefficient of variation of CGM values</td>
</tr>
<tr>
<td>Fasting blood glucose</td>
<td>mg/dl (mmol/l)</td>
</tr>
</tbody>
</table>

GLUCOSE MONITORING

INSULIN DELIVERY

CYBERSECURITY

SECURITY = SAFETY
DEFINITION OF A CONNECTED MEDICAL SYSTEM
A device that monitors and transmits data and/or commands from or to a person connected with a hub (e.g. handheld controller/monitor, another device, smartphone, pad, computer, or the cloud.)

DEFINITION OF CYBERSECURITY
Protection of data and command information that are transmitted between connected medical devices.

CONFIDENTIALITY = HACKER CAN STEAL YOUR DATA
INTEGRITY = HACKER CAN MODIFY YOUR DATA
AVAILABILITY = HACKER CAN PREVENT YOU FROM ACCESSING YOUR OWN DATA

DTSec: DIABETES TECHNOLOGY SOCIETY CYBERSECURITY STANDARD FOR CONNECTED DIABETES DEVICES

THE DOCTOR ON A QUEST TO SAVE OUR MEDICAL DEVICES FROM HACKERS

WHITE HOUSE HEALTH AND CYBERSECURITY ROUNDTABLE FOR HOSPITALS AND MEDICAL DEVICES DECEMBER 11, 2015

PRESS RELEASE
New Standard to Raise Confidence in the Security of Network-Connected Medical Devices through Expert Evaluation

DTSec: DIABETES TECHNOLOGY SOCIETY CYBERSECURITY STANDARD FOR CONNECTED DIABETES DEVICES
HEALTHCARE PROFESSIONALS
PATIENTS
PAYERS
THE DTSec STAKEHOLDERS
HOSPITALS
REGULATORS

INDUSTRY ADOPTION OF DTSec
STAKEHOLDERS DIFFERENTIATION
PUBLICITY FROM A HACK
LAWSUITS, FINES

Now Is the Time for a Security and Safety Standard for Consumer Smartphones Controlling Diabetes Devices

David C. Klainoff, MD, FACP, FRCPE, Fellow AIMBE1, David Kerr, MD, FRCPE2, and Dave Kleidermacher, BS3

Keywords
cybersecurity, diabetes, mobile phone, safety, security, smartphone, standard

DTMoSt (Diabetes Technology Society Mobile Platform Controlling a Diabetes Device Security and Safety Standard

Medical device makers wake up to cybersecurity threat August 1, 2017

Ethical hackers have warned of potentially lethal vulnerabilities in key equipment for years

The Internet of Things Cybersecurity Improvement Act: A Good Start on IoT Security

By Nicholas Weaver Wednesday, August 2, 2017, 1:44 PM

For devices in US government networks:
1) Establishes cybersecurity standards
2) Prohibits fixed passwords
3) Mandates security patches (known vulnerabilities)
Recently proposed legislation on medical device cybersecurity aims to clarify device security enhancement expectations and improve remote access protections.

TECHNOLOGY WORKS BEST WHEN IT IS ACCURATE