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EDITORIAL

Freedom of Speech and Science: Can Companies Force Us to Withdraw Data They Don't Like?

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In Europe, there are more than 100 blood glucose (BG) systems on the market. There is also fierce competition between a number of large companies (the "big four") and numerous smaller companies (>30). Although the market for self-monitoring of blood glucose (SMBG) still sees a constant increase in sales each and every year (but with steady declines in growth), the countermeasures by health insurance companies to reduce the cost burden/expenses for SMBG have started to bring down the margin of these companies.[1] An important marketing argument is the accuracy of the BG systems. We have recently seen a number of publications of mostly company-sponsored studies about this topic, after a period of many years where little was wrtitten about the tremendous importance of accuracy. It is not the aim of this editorial to discuss the appropriate performance of such accuracy studies, which are impressively complex to perform as outlined by Thorpe,[2] but to highlight a critical move recently made by a company in Europe.

Two excellent articles[3,4] by Freckmann and coauthors have been published in this journal, one about batch-to-batch differences in measurement performance (another widely ignored topic) and one in which his scientific institute evaluated the system accuracy of a number of BG systems with respect to their fulfillment of the system accuracy criteria indicated by the International Organization for Standardization (ISO 15197:2003).[5] The good news is, only ~20% of the systems tested do not fulfill the requirements of the ISO standard; however, the bad news is, ~47% do not fulfill the stricter requirements of the revised ISO standard,[6] which has been published this year. However, in Europe, companies have until December 2016 for their systems to fulfill the requirements of the revised standard.

Earlier this year, Freckmann's published study for system accuracy evaluation of BG monitoring systems[3] was attacked judicially by a European manufacturer and his resellers in various European countries because they do not agree with the results regarding their products tested in the study. They wanted to force Freckmann and the Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm (IDT) to withdraw the results of the evaluated system and to stop citing the published results of the study. They tried to prevail upon Freckmann and the IDT to publish a counterstatement that declares that the performance of the study was not adequate to show compliance with the system accuracy criteria of ISO 15197:2003, at least for their system.

It must be acknowledged that not all statements in the ISO standard are precise; they contain some ambiguity. In this study, only one batch was evaluated (the revised ISO standard asks for three batches), and it might have been an unfortunate coincidence for this company that a bad batch of their strips was tested. However, all materials used in this study were reported to have been purchased on the market. Now, if you start thinking about this for a second, it leads to the question, How good is the internal quality control of this company that they have released this batch

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Abbreviations: (BG) blood glucose, (IDT) Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose

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to the market? The much more important questions are, Does this batch represent a threat for patients with diabetes? Was this batch removed from the market in order to avoid any such risks?

Clinical trials are generally performed with volunteer subjects who expect that their risk, inconvenience, and/or discomfort will lead to a scientific advance. If the results are censored, then the subjects will have volunteered to be advancing science without the scientific community knowing about their contribution. The attempt to censor the results of Freckmann's studies would result in the efforts of his subjects going unnoticed by other scientists.

To our knowledge, the level at which European authorities check a company's internal quality control is suboptimal. There is no independent institution in Europe that objectively evaluates the performance of different batches of cleared test strips, at least at random.[7] There is also no such institution in the United States, but the need for post-clearance surveillance by the FDA is now being discussed.[8] It would be interesting to know how many batches the different manufacturers of test strips are discarding per year. It is clear that—depending on the quality of the test strip manufacturing—this is a costly move, as it means putting thousands of test strips into the garbage bin; however, the direct and considerable risk of patients being exposed to a bad batch also cannot be ignored.

And so, another question arises. Would it be possible for a European court to ask a U.S.-based scientific journal such as *Journal of Diabetes Science and Technology* to withdraw a manuscript not for any scientific reasons but for marketing reasons? From our very personal point of view as scientists, this would be an unbelievable (and stupid) move. Can any company that does not like the results of a study force authors or journals to withdraw published data? Why would a company not choose to respond by using the scientifically proven way of writing a letter and stating their concerns to start a scientific discussion? Or why would they not initiate another evaluation with other batches, according to ISO standards?

We strongly believe that no U.S. court or our journal would easily entertain such a request; however, our aim with this editorial is to initiate a public discussion about this action and the potential consequences this might imply. The data that Freckmann and his coauthors have published do not impose any crime or danger on patients themselves, and they are not a security threat. Just the opposite, they might very well help to prevent a dangerous situation for a patient. If the freedom of speech and science is challenged by attempts of companies to suppress "negative" information, then patients might be at risk.

Disclosures:

Lutz Heinemann advises various companies in the development of new diagnostic and therapeutic approaches to diabetes therapy. He is a shareholder and consultant at Profil Institute for Metabolic Research, Neuss, Germany, and Profil Institute for Clinical Research, San Diego, California. David Klonoff is an advisor for Google, InsuLine, and Sanofi.

References:

1. Heinemann L, Klonoff DC. Blood glucose meter market: this world is undergoing drastic changes. J Diabetes Sci Technol. 2013;7(3):584–6.
2. Thorpe GH. Assessing the quality of publications evaluating the accuracy of blood glucose monitoring systems. Diabetes Technol Ther. 2013;15(3):253–9.
3. Freckmann G, Schmid C, Baumstark A, Pleus S, Link M, Haug C. System accuracy evaluation of 43 blood glucose monitoring systems for self-monitoring of blood glucose according to DIN EN ISO 15197. J Diabetes Sci Technol. 2012;6(5):1060–75.
4. Baumstark A, Pleus S, Schmid C, Link M, Haug C, Freckmann G. Lot-to-lot variability of test strips and accuracy assessment of systems for self-monitoring of blood glucose according to ISO 15197. J Diabetes Sci Technol. 2012;6(5):1076–86.
5. International Organization for Standardization. ISO 15197:2003. In vitro diagnostic test systems -- requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Geneva: International Organization for Standardization; 2003.
6. International Organization for Standardization. ISO 15197:2013. In vitro diagnostic test systems -- requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Geneva: International Organization for Standardization; 2013.
7. Heinemann L, Freckmann G, Koschinsky T. Considerations for an institution for evaluation of diabetes technology devices to improve their quality in the European Union. J Diabetes Sci Technol. 2013;7(2):542–7.
8. Klonoff DC, Reyes JS. Do currently available blood glucose monitors meet regulatory standards? 1-day public meeting in Arlington, Virginia. J Diabetes Sci Technol. 2013;7(4):1071–83.