MALPRACTICE ISSUES IN THE USE OF BLOOD GLUCOSE METERS

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My topic this morning is malpractice issues for hospitals and health care practitioners in the use of blood glucose meters. I'd like to begin with a single-sentence, general statement of malpractice law: A hospital or practitioner is liable to a patient for malpractice if three conditions are met:

1. The hospital or practitioner owes a duty to the patient;
2. There was negligence in the performance of that duty; and
3. That negligence was the proximate cause of the injury to, or death of, the patient.

Here, the first and third conditions are straightforward. Hospitals and practitioners have a duty to patients to provide proper equipment and to utilize such equipment properly. Likewise, it is quite foreseeable that negligence in fulfilling this duty can be the proximate cause of severe injury and even death. A false high reading may mask significant hypoglycemia or may prompt excessive insulin administration -- leading to coma and even death. Conversely, a false low reading can delay the necessary administration of insulin – resulting in hyperglycemia and its consequences.

Thus, I'd like to focus my remarks this morning on the second element:

> What conduct, if any, with respect to the use of blood glucose meters by a hospital or health care practitioner might reasonably be characterized as negligent?

Preliminarily, however, I'd like to discuss how negligence is determined in malpractice cases generally. In essence, the trier of fact – the judge or the jury -- measures the challenged conduct

against the so-called "standard of care" – and decides whether the conduct satisfied the standard.

How is the standard of care determined? The approach varies somewhat from state to state. Basically, however, the trier of fact hears testimony from expert witnesses for both sides. It also considers other relevant authorities. These would include governing legal and regulatory requirements, pronouncements by government agencies such as FDA, statements of knowledgeable private organizations such as the American Diabetes Association, practice guidelines issued by professional societies such as the American Association of Clinical Endocrinologists, the manufacturer's package insert where a drug or medical device is concerned, and any other sources deemed by the court to be reliable and authoritative.

Where the conduct at issue directly violates a law or regulation, it is held in many jurisdictions to be negligence per se. In all other cases, the trier of fact evaluates all the relevant inputs and determines what a reasonable person or entity in the position of the defendant should have done. This determination constitutes the standard of care.

DISCUSSION

A. Use Of Blood Glucose Meters

With this general summary as background, let's move on to issues raised by use of point-of-care blood glucose meters. At the outset, use of such meters would, as a general matter, satisfy the standard of care. To be sure, results from meters may not be as precise as results from blood assayed by a clinical laboratory. But absolute precision is not generally required in the measurement of blood glucose. The FDA allows a 20% deviation when reference method glucose values are greater than 75 mg./dL. While this figure can be debated, deviation in the 10-15% range generally seems to pose little clinical problem. Moreover, bedside meters allow

frequent monitoring and rapid reporting, avoid multiple phlebotomies, and cost less. For this reason, their use is widely accepted.

Indeed, the 2010 "Standards of Medical Care in Diabetes," published by the American Diabetes Association and endorsed by the Joint Commission, note as follows (at S47):

> "Safe and rational glycemic management relies on the accuracy of blood glucose measurements using point-of-care blood glucose meters, which have several important limitations."

The Standards go on the state:

> "While laboratory measurement of BG has less variability and interference, multiple daily phlebotomies are not practical. The use of indwelling lines as the sample source also poses risks for infection."

Id. Given these statements and the wide acceptance of blood glucose meters, the use of such meters – without more – should not give rise to a malpractice action.

Nor do I believe that it is malpractice to use blood glucose meters in tight glycemic control situations -- even though these devices have not been cleared by FDA for this use – as long as such use has been clinically validated. The fact that a drug or device has not been cleared for a particular use means that the manufacturer cannot market – or otherwise promote it – for that use. But it does not mean that use of the drug or device for off-label purposes constitutes negligence.

In this connection, a 1982 FDA statement on "Use of Approved Drugs for Unlabeled Indications," 12 FDA Drug Bulletin 4 (April 1982) is relevant. There, the agency noted as follows:

> "The Food Drug and Cosmetic Act does not limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such 'unapproved' or, more precisely, 'unlabeled' uses may be appropriate and rational in certain circumstances and may, in fact, reflect approaches to

> drug therapy that have been extensively reported in medical literature."

Although this statement was made in the context of drugs, it applies equally to devices. Thus, use of meters in tight glycemic control situations should not be regarded as malpractice to the extent that the specific use is supported by peer-reviewed medical literature or by clinical validation by the practitioner.

2. Misuse Of Blood Glucose Meters

I want to go back to the statement of the American Diabetes Association to the effect that use of blood glucose meters has "several important limitations." It is the use of these devices without adequate regard for their limitations that can create malpractice liability. I have identified four such limitations:

1. The presence of interfering substances;
2. System limits;
3. Equipment malfunction; and
4. Patient misidentification

I'll address each of these limitations and consider their malpractice implications.

First, however, I must make an important point about blood glucose meters: To echo and distort the Declaration of Independence, all meters are not created equal. Depending on the chemistry and technology utilized, each brand of meter is subject to interference by different substances, has different system limits, and has other unique characteristics. Thus, the most basic advice that I would give to those responsible for use of blood glucose meters in a hospital is this: Know the limitations of the meters at your hospital and make adequate provision for those limitations. Let me turn now to specific applications of this general advice.

A. Interfering Substances

Probably the most serious of the limitations on blood glucose meters is the possibility of reporting significantly inaccurate glucose levels as a result of the presence of interfering substances. Of these substances, the most widely publicized is maltose -- and, to a lesser extent, xylose and galactose. FDA has issued numerous notices and safety alerts warning of problems caused by the presence of non-glucose sugars in the blood for meters and test strips based on glucose dehydrogenase piroloquinoline quinone – GDH-PQQ. The agency has warned of 13 patient deaths attributable to false readings from GDH-PQQ technology. These can be caused inter alia, by the presence of certain immunoglobulins, abatacept, and other sugar-creating substances – and in patients receiving peritoneal dialysis solutions containing icodextrin.

Notably, the blood glucose meters that have a problem with maltose, or other sugar, interference contain warnings to that effect in their labeling. Moreover, I understand that some manufacturers of these systems offer education for hospital personnel on the limitations of their devices. Thus, the issue of interference by non-glucose sugars should be well known to laboratory directors, clinicians, and hospital risk managers.

In light of the notices and safety alerts issued by FDA on sugar interference, the warnings in the package inserts of devices that are subject to such interference, and the programs of manufacturers to educate hospitals about such issues, it is highly likely that a death or serious injury attributable to maltose or other sugar interference would be regarded as the result of malpractice. Somewhat surprisingly, I have uncovered no case in which this issue has been considered or decided. But general principles of malpractice law strongly suggest that the exposure in this scenario is of major consequence.

The lesson is clear: It is essential to review the package insert of meters and test strips used at the hospital to determine whether they are GDH-PQQ based. If they are, hospital staff must be educated that the meters may not be used if the patient is on an immunoglobulin or other drug or biologic that produces maltose, is receiving abatacept therapy, is receiving a peritoneal dialysis solution containing icodextrin, suffers from galactosemia, or otherwise may have abnormal levels of non-glucose sugars in the blood. If there is any doubt, the lab director or hospital should contact the manufacturer, or otherwise resolve the issue, before permitting use of the system on a patient. The importance of this practice cannot be overstated.

FDA is, of course, performing a vitally important public health service in warning hospitals, practitioners, and patients of the risks of falsely elevated glucose results from GDH-PQQ test strips where non-glucose sugars may be present. But, given the significant implications of its statements, the agency also needs to take care to be precise. An example of a statement that I regard as overbroad appears in a Public Health Notification dated August 13, 2009. There, the agency made the following statement: "Avoid using GDH-PQQ glucose test strips in healthcare facilities." It then listed categories of patients for whom such strips should never be used, and it set forth steps that can be taken to address the risks posed by non-glucose sugar interference.

The listing of patients at risk and the recommendation of steps to address the risk are extremely valuable and important. Moreover, quite properly in my judgment, they increase the malpractice exposure of facilities and individuals who ignore them. But the advice to "avoid using GDH-PQQ glucose test strips in healthcare facilities" goes too far. It encourages facilities to discard meters in which they have made a substantial investment -- at significant cost, and it puts facilities at malpractice risk if an adverse event were to arise with such strips for reasons

unrelated to sugar interference. In my view, therefore, any Public Health Notification or similar alert should be worded as precisely as possible.

In this connection, I would note that there are other interfering substances that can skew results. These include acetaminophen, oxygen, uric acid, Vitamin C, and L-Dopa. As best I can determine, FDA has not issued any notices or safety alerts for these other interfering substances. This is probably because the deviation from accurate results is generally less with these substances than with maltose. Moreover, I am not aware of patient deaths associated with false readings from interference by other substances. Nevertheless, providers should be aware of interference by other substances – particularly for patients on tight glycemic control.

Manufacturers of blood glucose meters test for interference by a number of analytes. Any identified interfering substance should be warned of in the package insert. In light of these warnings, a hospital or practitioner that permits use of a meter in a situation warned against in a package insert risks malpractice liability to a patient who is injured or who dies as a result of incorrect therapy based on a faulty reading. To be sure, failure to follow the warnings in the package insert does not constitute malpractice per se. But in most jurisdictions, it will constitute strong evidence that the responsible practitioner and the hospital have failed to meet the standard of care. This fact underscores the need of laboratory personnel and hospital risk managers to be familiar with the package inserts of blood glucose meters and to take appropriate steps to guard against interference.

B. System Limits

A second important source of potential liability is use of a blood glucose meter outside of system limits. Although not as widely publicized as non-glucose sugar interference, this issue has received more attention recently. At the end of February, a manufacturer recalled 14,000 test

strips that led to false low readings in some circumstances. While no injuries were reported, the recall highlights the fact that this technology has limits.

System limits relate, among other things, to transient temperature, the humidity to which the strips are exposed, storage conditions, and strip expiration dates. Most, if not all, manufacturers build in so-called "fail safes" to lock out uses of the meter when the strip has been compromised or when conditions are otherwise beyond the system's limits. However, not every product has the same fail safe feature. Thus, it becomes important to understand the system's limits. These are generally set forth in the package insert.

No system guards against false readings due to all limits. For example, there can be a problem with open vials. Once a container of strips is opened, the strips remain good only for a certain period of time – which varies from manufacturer to manufacturer. Use of strips that have been exposed to the air for more than this period of time may result in erroneous readings. So it is important for hospitals to have policies in place against use of meters contrary to system limits and for practitioners to comply with these policies.

Another example of a system limit is the use of meters on patients with hematocrit values outside the manufacturer's specified range. In patients with a low hematocrit value, a meter may report false high glucose levels. Different systems have different capacities to guard against hematocrit distortion. Accordingly, steps should be taken to avoid use of the meters for patients with hematocrit values outside the range specified in the package insert.

C. Accuracy

Absent an interfering substance or a system limit issue, blood glucose meters generally report results that do not deviate more than 15% from the true value. However, it is a universal

truth that machines and systems sometimes malfunction. If a malfunction does occur and results in patient injury or death, it is quite likely that a malpractice suit will follow.

The best way to limit malpractice exposure in this area is to conduct QC in accordance with the manufacturer's instructions – or, in the absence of such instructions, on a daily basis. In making this recommendation, I recognize that, glucose testing is a waived test under CLIA. Thus, federal law does not mandate QC on glucose meters. However, both the Joint Commission and the College of American Pathologists, as part of their respective accreditation programs, require QC in this area.

If a hospital or practitioner were sued in this context, the Joint Commission and CAP standards are likely to be put into evidence. Likewise, the package insert will almost certainly be introduced. And there will be testimony on the importance of QC. Thus, despite the waived status of this test under CLIA, malpractice considerations counsel strongly in favor of performing appropriate QC.

D. Patient Misidentification

The final area of potential malpractice liability relates to patient misidentification. The Institute of Medicine Report "To Err Is Human" spoke about the incidence of adverse events due to human error. The Joint Commission has required that test results be noted in the patient's chart and associated with the correct patient. One can readily imagine the malpractice consequences if insulin administration to Patient A were based on Patient B's results.

Some manufacturers incorporate patient identification into their meters. Others do not. Many problems stemming from point-of-care testing are the result of human error – not instrument error. It is important, therefore, that a hospital which uses meters without a patient

identification feature make sure that it has a system in place to avoid patient misidentification errors.

CONCLUSION

Use of point-of-care blood glucose meters is well within the standard of care. However, each brand of these meters has limitations which should be understood and addressed if malpractice risks are to be minimized. Specifically, I would recommend the following ten steps to guard against malpractice liability from the use of blood glucose meters. Given the number, I shall refer to them as the Ten Commandments of Blood Glucose Meter Use:

1. For meters that use GDH-PQQ technology, educate staff and patients about the potential for falsely elevated glucose results in the presence of maltose or non-glucose sugars. Make sure that the meter is not used on patients who are having therapy, or who have a condition, that produces an interfering level of non-glucose sugars.

2. For all meters, be aware the manufacturer's instructions for proper use, storage, and handling of strips and meters – and have policies in place and enforced to follow those instructions.

3. Train all responsible personnel on proper use of the meters, document the training, and alert all such personnel to any relevant FDA pronouncements and any updates or notices issued by the manufacturer.

4. As the FDA has advised, consider using drug interaction alerts in computer order entry systems, patient profiles, and charts.

5. Know the hematocrit levels at which the meter functions effectively. Don't use the meter on patients whose hematocrit levels are outside the specified range.

6. Perform QC on each meter as recommended in the package insert – or at least once a day.

7. As the FDA has also counseled, consider periodic verification of glucose meter results with laboratory-based glucose assays – particularly in tight glycemic control situations.

8. Implement a system, either through a fail-safe mechanism on the meter or through general hospital protocols, to ensure that there are no patient misidentification errors.

9. If there is any issue regarding use of a particular meter for a particular patient, don't use the meter until you are satisfied that use on that patient is safe.

10. Most generally, know the limitations of any meter as set forth in the package insert. Make sure that use conforms to these limitations.

If you hearken diligently unto these commandments, patients will get the benefits of point-of-care blood glucose meters while the malpractice exposure of hospitals and health care practitioners should be substantially reduced.