**Bloody Glucose!**

**By Friso Jansen**[[1]](https://joxcsls.com/2015/10/28/socio-legal-objects/" \l "_edn1)

Sarah is worried: she has diabetes and her blood glucose readings are high.[[2]](https://joxcsls.com/2015/10/28/socio-legal-objects/" \l "_edn2)  She goes to see her general practitioner (GP) and asks her what she should do. Together they go through all the options: increasing the doses of her drug, adding a new drug to her current treatment, adopting changes in lifestyle and optimizing her measurement of blood glucose levels. They decide that it is best if another drug is added to her treatment so that her blood glucose levels would fall below the level they have agreed was appropriate for her.

This fictional exchange is a somewhat idealised form of patient-centred care and shared decision making that is currently seen as the hallmark of quality in medicine. Behind this mundane and routine exchange however is a fascinating world of socio-legal discovery. If we ask ourselves which tools and knowledge the parties need to be able to have in order to have this exchange, the answer may be found in the concept of evidence-based medicine.

**Evidence-based Medicine: the End of the Clinical Eye?**

This concept encapsulates a movement in medicine that started in the early nineties which aims to base treatment decisions on the best available objective scientific evidence: a move away from – in their eyes – from a time when clinical knowledge, the knowledge gathered trough experience with patients and watching other doctors perform medicine, was all important and scientific studies were not used in a systematic way to improve patient care. Due to the higher complexity of diseases, the great increase in treatment options and the increase in the volume of scientific literature it has become more complex to provide the right treatment. The evidence-based medicine movement called for medical treatment guidelines to help GPs and other healthcare professionals to make informed decisions based on the best available science, as they no longer could be expected to keep up with all the knowledge in the various medical fields. This has resulted in a great many evidence-based guidelines being developed, so that our GP can now refer to a guideline that advises him or her on the treatment for people with diabetes. These guidelines nominally only provide advice for the general population of people with diabetes and thus are not aimed at treating Sarah specifically; in practice, however, they are often followed in specific, discrete cases and thus deserve scrutiny. These guidelines can function as rules to follow in treating patients, so we need to understand how and by whom they are made.

**Medical Treatment Guidelines: Objectivity Under Pressure?**

This analysis shows that there are associations of doctors, sometimes in state sponsored centers, who develop these guidelines. However, the recommendations they make are not always based solely on scientific evidence; often clinical expertise dictates that a certain outcome be sought and compromises are therefore struck between the competing demands of scientific rigidity and clinical practice. One example is the level of fasting blood glucose that forms the threshold to determine whether someone has diabetes. The number associated with this level is relatively arbitrary and not dictated by science but rather and often the result of copying other guidelines on this topic that are made abroad, such as guidelines in the USA and Europe. It was originally chosen as ‘diabetes indicator’ because it designated the point at which an increase in one specific microvascular complication of diabetes would occur. The choice was then not questioned further. That number is far from innocent however, since it marks the dichotomy between normal and having an illness, such as in this example diabetes.

Where to draw the line is not only important for patients. It is also hugely important for drug companies: the earlier someone is considered diabetic, the bigger the market for their medication. In practice however the fact that there is no scientific base for some of the recommendations in a guideline does not preclude doctors from applying the recommendations as there is no other or better source of advice. Medicine in that sense is also a pragmatic profession, patients need to be treated and their symptoms alleviated. This approach does show however the limitations of ‘scientific evidence’ as a concept. This is an crucial realization:  a lot of the importance that is attached to guidelines in general by parties beyond the healthcare professional, such as governments, health care insurers and disciplinary tribunals, rest on their believing in the scientific validity of the recommendations.

A further example from the diabetes guideline environment further illustrates this point. Another important advice a guideline provides is the preferred order in prescribing medication to patients. Sarah, in our example, could be offered up to 6 different classes of drugs as a potential treatment. The guideline is there to help the GP choose and inform Sarah about the different choices that are available to her. The advice given on medication is not solely geared towards the most effective medication in providing glucose lowering with the least side-effects; as evidence-based medicine would suggest, those choices are also based on cost-effectiveness considerations.

The shift in the preferred treatment of diabetes may thus be based on the cost of a certain drug (whether it is patented or not for example) rather than on any evidence of superior effectiveness. The GP might not be aware of the fact that this ‘evidence-based’ advice is really rather a subjective struggle to achieve acceptable compromises. That compromises have to be made – some very expensive glucose lowering drugs should perhaps not be prescribed because their greater costs does not outweigh the limited added benefits they might have – is not unusual or wrong in a world were money is limited. That these decisions are made by medical professionals is however interesting, as they are themselves interested parties in the outcome of those kind of decisions. The use of centers like the National Institute for Care and Health Excellence in the UK to make those guidelines pushes part of the burden of making these rationing decisions away from politicians. In my eyes this is a deliberate move to depoliticize them and make them ‘unproblematic’ through the use of ‘scientific evidence’ as arbiter.

**Measurement of Blood Glucose: Adding Layers of Insecurity**

Sarah measures her blood glucose levels using a blood glucose meter. So the question is: does it provide an objective measurement to base her treatment on? Blood glucose meters are used by diabetes patients to measure the level of glucose in their blood and to help them manage their condition and help prevent blood glucose dropping too low or climbing too high. If we try to establish how accurate a blood glucose meter is, we discover however that there are several ISO[[3]](https://joxcsls.com/2015/10/28/socio-legal-objects/" \l "_edn3) standards that describe procedures for testing the meters and to set limits on the inaccuracy of the measurement of the level of blood glucose. The limit that has been set for the accuracy of blood glucose meters by ISO-committees is 15%, so if Sarah read a blood glucose level of say 7%, the true value of her blood glucose might be anywhere between 6.5-7.5%. This represents a relatively high tolerance of difference (between the actual value and the measured value of blood glucose) and thus diminishes the usefulness of measuring blood glucose. This also introduces a further element of insecurity in an already complex area of medicine. ISO committees do not deliberate in public – they work behind closed doors -, but their standards provide the basis on which regulators approve these medical devices. Even though these standards are highly technical, they are an essential part of a socio-legal regime that steers the way in which – in this case – medical devices are used by both patients and doctors.

**The Nature of the Disease**

On a more fundamental level, blood glucose meters are more than technical measurement: they are part of a knowledge regime. They provide a patient with knowledge about his or her glucose, so that the patient can manage his or her condition better, and they provide the medical professional with knowledge about the progression of the disease. But this knowledge brings a feeling of responsibility for the management of the disease for the patient and can give patients a sense of failure if the blood glucose values do not conform to target levels. This knowledge is neither totally objective nor totally value free. In fact it contributes to forming a narrative about ‘good patients’ and ‘bad patients’, about autonomy versus care and about disease control through technology. This then adds to the complexity of treating a patient with diabetes: the patient is not her disease, but rather a whole person with values and preferences, something that in the relationship between Sarah and her GP is vital. This ‘human’ dimension of the treatment of patients with diabetes can however collide and clash with a rigid interpretation of science as the only evidence to be valued in medicine.

**The multi-layered complexity of blood glucose meters**

Scientific evidence is constructed in a specific cultural environment and not as objective and unproblematic as the pundits of the evidence-based medicine movement would have us believe. As this article attempted to show, in reality the high-minded aims of evidence-based medicine to put science at the forefront of ‘doing medicine’, inevitably get diluted in the practice of creating guidelines and in implementing them. Medicine remains an art as much as a science and socio-legal enquiry brings out the often complex and convoluted relationship between the two. Only trough understanding this relationship can we value the role of medical practice guidelines as law in society where we see that sometimes they work and sometimes they fail. It also allows us to understand more of the context in which they develop and operate and discover that their role as ‘rules’, and  extent to which they can be said to be successful, depends to a great degree on forces outside of the remit of guidelines. Be it other rules that make it harder to achieve optimal results, such as the ISO-standards, or cost-effectiveness constraints imposed by governments that affects their content.  On a fundamental level it seems that guidelines are torn in different directions: they are asked to be general enough to be applied to the great majority of clinical situations but specific enough to provide assurances for individual cases. This tension that is inherent in the process plays out through the elements of scientific evidence, clinical knowledge and bargaining of guideline drafters and finds its way in a text that then tries to embody the holy grail of scientific objectivity.

Within the broad field of socio-legal studies, all these questions, and many more, can be asked about many such ‘simple and boring’ everyday objects like a blood glucose meter that bring out the multi-layered complexity this world exhibits and the often surprising links between law and society.

*Image by Uwe Hermann (*[*http://hermann-uwe.de/photoblog/sugar*](http://hermann-uwe.de/photoblog/sugar)*) [CC BY-SA 3.0 (*[*http://creativecommons.org/licenses/by-sa/3.0*](http://creativecommons.org/licenses/by-sa/3.0)*)%5D, via Wikimedia Commons.*

[[1]](https://joxcsls.com/2015/10/28/socio-legal-objects/" \l "_ednref1) Friso Jansen has been a DPhil student at the Centre for Socio-Legal Studies at the University of Oxford since 2013. His research focusses on the interaction between medical ethics and professional regulation of medical doctors in the UK and The Netherlands. He took his first degree in Law and Public Administration at the University of Groningen in The Netherlands. During his LL.M at the same University he specialised in sociology of law. He pursued his broader interest in rule-making during his MSc in regulation at the London School of Economics.  Before joining the Centre he worked for the University of Groningen and the Applied Science University of Amsterdam as a researcher on the ‘Crisis and Recovery Act’  and lecturer on public law, insolvency law and legal aid (friso.jansen@st-annes.ox.ac.uk).

[[2]](https://joxcsls.com/2015/10/28/socio-legal-objects/" \l "_ednref2) Controlling blood glucose levels is one of the ways of reducing the risks of complications from diabetes. People with diabetes have trouble with breaking down glucose due to the failure of the pancreas to produce sufficient insulin. A blood glucose meter is a way of measuring your blood glucose levels to enable appropriate control and react if the blood glucose level is too high.

[[3]](https://joxcsls.com/2015/10/28/socio-legal-objects/" \l "_ednref3) The International Organisation for Standardization, [www.iso.org](http://www.iso.org/). An independent non-governmental organisation that make international voluntary standards that govern specification for products to reduce barriers in international trade.