

depending on the disease area as well. The appropriate list of parameters relating to certain diseases and drug treatments, for example, cancer and infectious diseases and patient on NSAIDS, are disclosed herein.

In another aspect of this invention, the TI is calculated using information derived from the patient's biological sample and patient information that is non-drug related, the device input. For example, in an ambulatory setting, information relating to concentration of drug, metabolite and other biological markers can be detected in blood as described herein. The patient can also input many non-drug related personal parameters. This "patient input" can relate to the patient's personal information, for example, height, weight, gender, daily exercise status, food intake, etc. The patient input could also be provided by the patient's healthcare provider. An example of a patient input parameter and the input means is shown in FIG. 24.

In some embodiments the device input and patient input are used to compute the TI. A reference TI for the patient is already known using retrospective analysis of the data contained in the database. In formulating the TI using multiple regression analysis, the parameters such as those shown in Equation 6 are used. The same parameters are then used with the device input and patient input to compute the TI. Comparing the TI to the TI_{ref} , it is possible to determine the efficacy of the therapy. If the TI falls within a pre-determined range of TI_{ref} , then the treatment is considered to be efficacious. Values below that range indicate that the treatment is ineffective and values higher than the range are considered to be undesirable and could lead to adverse events.

Another example illustrates the implementation of this invention for studying the efficacy of therapy in diseases where it is difficult to make frequent measurements and the efficacy of the treatment is difficult to quantify. An example is determining the efficacy of drug therapy in children with autism. Frequent sampling and concomitant laboratory analysis is impractical for children. Abnormalities in blood concentrations of certain metals are implicated in autism. Hence, following the blood concentration of certain metals, for example, zinc, in autistic children might shed light on the efficacy of an intervention. However, it has been reported that lowered concentrations of Zn, for example, due to a treatment does not imply that the therapy is working. It is an indicator, but not a definitive surrogate for determining therapeutic efficacy. Computing a TI and comparing it to a reference level would better indicate the efficacy. This is illustrated in FIG. 25 by simulating the concentration of various pertinent markers and their change due to a drug intervention in an autistic child.

The program can involve monitoring subjects and matched control individuals over time for toxic metals, surrogate markers for metals (metallothionein, etc.), and other biochemical markers. Subjects are those prone to, or afflicted with autism; controls are situation-matched people. It is not mandatory that there be a situation-matched control. The scenario assumes that during the study a significant "event" occurs. Events could be movement into a more or less risky environment or initiation of therapy. Subjects could be frequently monitored for several parameters (device input) using the ambulatory system described herein. Additional laboratory assays that are not determinable in the ambulatory sys-

tem could be performed at a lower frequency using laboratory assays. Additional data such as patient information, local environment, use of drugs, diet, etc. would be logged (patient input). Of particular interest to this scenario is information such as exposure to lead, mercury etc.

The time course shown in FIG. 25 envisages an event (initiation of therapy) at 33 days. The subject who is exhibiting abnormal levels of CP and MT, gradually reverts to normal levels of markers. The TI captures the risk or safety level of the subject based on all information. The study will define the best inputs to determine TI.

As described above, TI can be used for determining the efficacy of drug treatment. A similar approach is also well suited for determining the efficacy of drugs during clinical trials. Additionally, this approach could be beneficially used to identify sub-groups of patients who respond well or poorly to a given treatment regimen. The ability to segregate responders from non-responders is an extremely valuable tool. The concept of using TI can be used not only during a therapeutic regimen, but for performing diagnostic tests to determine, for example, whether or not a patient is in need of a biopsy after a complete examination of prostate specific markers.

The invention claimed is:

1. A method of improving the accuracy of calibrating a fluidic system, comprising:

- a) providing a system for detecting an analyte in a bodily fluid from a subject comprising a fluidic device for providing said bodily fluid, said fluidic device having a calibration assembly and a reader assembly for detecting the presence of said analyte;
- b) measuring one or more parameters that are fitted to a calibration curve associated with said fluidic device;
- c) comparing said one or more parameters with predetermined parameters associated with said fluidic device;
- d) adjusting a signal output from the fluidic device by multiplying a ratio of said predetermined parameters to said one or more parameters, wherein the ratio is selected from the group consisting of: a ratio of maximum signal level during factory calibration to maximum signal level measured within the assay, and a ratio of minimum signal level during factory calibration to minimum signal level measured within an assay.

2. The method of claim 1, wherein subsequent to said measuring, said one or more parameters are used to calculate an assay signal as a function of an analyte concentration.

3. The method of claim 1, wherein subsequent to said measuring, said one or more parameters are used to calculate an analyte concentration as a function of an assay signal.

4. The method of claim 1 wherein said one or more parameters is selected from the group consisting of: a maximum signal, a maximum signal, a minimum signal level half way between the maximum signal and the minimum signal, and a shape parameter.

5. The method of claim 1 wherein said predetermined parameters are parameters determined at the time the fluidic device is manufactured.

6. The method of claim 5 wherein said calibration curve is used to scale a signal that is indicative of said analyte concentration.

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