

error process, and based largely on data gathered after observing the effect on the patient of the last-administered dosing regimen.

[0012] After administering the adjusted dosing regimen, the patient's response to the adjusted dosing regimen is evaluated, as shown at step 116. The physician then again determines whether to adjust the dosing regimen, as shown at 118, and the process repeats.

[0013] Such a trial-and-error based approach relying on generic indicated dosing regimens and patient-specific observed responses works reasonably well for medications with a fast onset of response. However, this approach is not optimal, and often not satisfactory, for drugs that take longer to manifest a desirable clinical response. Further, a protracted time to optimize dosing regimen puts the patient at risk for undesirable outcomes.

[0014] What is needed is system and method for predicting, proposing and/or evaluating suitable medication dosing regimens for a specific individual as a function of individual-specific characteristics that eliminates or reduces the trial-and-error aspect of conventional dosing regimen development, and that shortens the length of time to develop a satisfactory or optimal dosing regimen, and thus eliminates or reduces associated waste of medications, time or other resources and reduces the risk of undesirable outcomes.

SUMMARY

[0014a] In an aspect, the present disclosure provides a method for treating a patient with a personalized therapeutic dosing regimen, the method comprising: accessing a processor coupled to a memory; receiving by the processor a first model

stored in the memory, the first model being configured to indicate responses of patients in a population to a therapeutic administered to such patients based on a time course of exposure of the therapeutic in blood of the patients in the population; receiving by the processor first data indicative of an exposure of the therapeutic in the patient's blood after receiving a dose of the therapeutic, the exposure of the therapeutic being determined from a blood sample taken from the patient; receiving by the processor second data indicative of one or more characteristics specific to the patient, wherein the one or more characteristics are shared by patients in the population of the first model; the processor having third data indicative of a target exposure threshold of the therapeutic in the patient's blood; preparing a patient-specific model by performing, using the processor, a Bayesian update to the first model based on the first data and the second data, the patient-specific model providing a predicted time course of exposure profile of the therapeutic in the patient's blood that accounts for the patient's response to the first dose of the therapeutic; providing one or more proposed dosing regimens to achieve the target exposure of the therapeutic in the patient's blood, the one or more proposed dosing regimens based on the patient-specific model and the second data, wherein the memory further comprises a database coupled to the processor, and further comprising storing information indicative of the one or more proposed dosing regimens in the database; selecting, from among the one or more proposed dosing regimens, a patient-specific dosing regimen for the therapeutic; and administering the therapeutic to the patient according to the selected patient-specific dosing regimen.

[0015] The present ~~invention~~disclosure provides a system and method for providing patient-specific medication dosing as a function of mathematical models updated to

CLAIMS

1. A method for treating a patient with a personalized therapeutic dosing regimen, the method comprising:

accessing a processor coupled to a memory;

receiving by the processor a first model stored in the memory, the first model being configured to indicate responses of patients in a population to a therapeutic administered to such patients based on a time course of exposure of the therapeutic in blood of the patients in the population;

receiving by the processor first data indicative of an exposure of the therapeutic in the patient's blood after receiving a dose of the therapeutic, the exposure of the therapeutic being determined from a blood sample taken from the patient;

receiving by the processor second data indicative of one or more characteristics specific to the patient, wherein the one or more characteristics are shared by patients in the population of the first model; the processor having third data indicative of a target exposure threshold of the therapeutic in the patient's blood;

preparing a patient-specific model by performing, using the processor, a Bayesian update to the first model based on the first data and the second data, the patient-specific model providing a predicted time course of exposure profile of the therapeutic in the patient's blood that accounts for the patient's response to the first dose of the therapeutic;

providing one or more proposed dosing regimens to achieve the target exposure of the therapeutic in the patient's blood, the one or more proposed dosing regimens based on the patient-specific model and the second data, wherein the memory further

comprises a database coupled to the processor, and further comprising storing information indicative of the one or more proposed dosing regimens in the database;
selecting, from among the one or more proposed dosing regimens, a patient-specific dosing regimen for the therapeutic; and
administering the therapeutic to the patient according to the selected patient-specific dosing regimen.

2. The method of claim 1, wherein the time course of exposure of the therapeutic in the patient's blood is a concentration of the therapeutic in the patient's blood.

3. The method of claim 1, wherein parameters of the patient-specific model are stored in the memory.

4. The method of claim 3, wherein the one or more characteristics specific to the patient comprise at least one of: a body size indicator, gender, race, lab results, disease stage, disease status, prior therapy, concomitantly administered therapeutics, concomitant diseases, and demographic information.

5. The method of claim 4, further comprising outputting a subset of the one or more proposed dosing regimens as updated dosing regimens.

6. The method of claim 4, wherein the therapeutic is administered to the patient on a first day, and the method further comprising receiving by the processor fourth data

indicative of concentration of the therapeutic in the patient's blood in samples taken from the patient after the administration of the therapeutic.

7. The method of claim 6, wherein at least one sample providing the fourth data is taken from the patient's blood on the first day.

8. The method of claim 6, further comprising receiving an input signal indicative of the target exposure threshold of the therapeutic in the blood of the patient; and periodically updating the patient-specific model stored in the memory based on exposure of the therapeutic in one or more additional patient blood samples, until the target exposure threshold of the therapeutic in the blood of the patient is achieved.

9. The method of claim 8, comprising determining a revised dose based on whether the fourth data is above a predicted exposure level of the therapeutic in the blood of the patient.

10. The method of claim 8, comprising adjusting the dosing regimen after updating the patient-specific model by one or more of increasing dose and shortening dose interval.

11. The method of claim 8, comprising adjusting the dosing regimen after updating the patient-specific model by one or more of decreasing dose and lengthening dose interval.

12. The method of claim 11, wherein the first model and the patient-specific model include a PK model.

13. The method of claim 12, wherein the first model is a composite model prepared from a plurality of mathematical models derived from data obtained from the patients in the population.

14. The method of claim 13, further comprising preparing the composite model using Bayesian model averaging.

15. The method of claim 14, further comprising performing the Bayesian update on each of the plurality of mathematical models.

16. The method of claim 15, wherein performing the Bayesian analysis further comprises performing Bayesian forecasting to forecast a typical patient's response for each of the one or more proposed dosing regimens based on the patient-specific model and the second data.

17. The method of claim 8, comprising calculating an updated patient-specific dosing regimen of the therapeutic by selecting a dosing regimen corresponding to a minimum of an objective function.

18. The method claim 8, wherein the one or more proposed dosing regimens comprises a therapeutic-dosing interval of less than 4 weeks.

19. The method claim 8, wherein the one or more proposed dosing regimens comprises a therapeutic-dosing interval of 8 weeks.

20. The method of claim 19, wherein the therapeutic administered to the patient is infliximab, and wherein the first dose of infliximab is determined by a Bayesian composite model.

21. The method of claim 20, wherein the first dose of infliximab is 5-7 mg/kg and has a therapeutic-dosing interval of 8 weeks.

~~1. A method for preparing a patient-specific drug dosing regimen for treating a patient with a medication, using a computerized medication dosing regimen recommendation system, the system comprising a processor, the method comprising:~~

~~receiving data indicative of a first response of the patient to an administered dose of the medication, including medication concentration data measured in blood from the patient;~~

~~accessing, using the processor, a memory;~~

~~selecting, based on at least a portion of the received data, a first model stored in the memory;~~

~~forecasting, based on the selected first model and the medication concentration data measured from the blood of the patient, a patient-specific predicted concentration time profile of the medication, indicative of the patient response to the medication for a plurality of dosing regimens;~~

~~selecting from the plurality of dosing regimens, at least one patient-specific dosing regimen for the medication that achieves a treatment objective based on a desired concentration of the medication in the blood from the patient;~~

~~outputting at least one patient-specific dosing regimen for the medication for the patient,;~~

~~receiving data reflecting a response of the patient to the at least one patient-specific dosing regimen for the medication;~~

~~updating the first model, based on the received data reflecting the response of the specific patient to the at least one patient-specific dosing regimen for the medication;~~

~~calculating, based on the updated first model, at least one updated dosing regimen for the medication to reach the treatment objective for the patient; and~~

~~outputting the at least one updated dosing regimen for the medication for the patient to treat the disease of the patient.~~

~~2. The method of claim 1, wherein the method further comprises:~~

~~receiving a signal indicative of the treatment objective for the specific patient, wherein the first model is periodically updated until the treatment objective is achieved.~~

~~3. The method of claim 2, wherein the memory includes a database, and wherein the memory is stored in the computerized medication dosing regimen recommendation system further comprises the memory and a database stored in the memory.~~

~~4.—The method of claim 3, wherein the database stores the data indicative of characteristics of the specific patient, and wherein the processor connects to the memory through a bus.~~

~~5.—The method of claim 2, wherein the step of selecting the first model comprises:~~

~~comparing the received data indicative of a first response of the patient to an administered dose of the medication, including medication concentration data measured in blood from the patient to patient characteristics associated with a plurality of models;~~

~~selecting a model from the plurality of models with patient characteristics that~~

~~match the received data; and~~

~~outputting the determined model.~~

~~6.—The method of claim 2, wherein the treatment objective is a target profile representing a physiologic response of the specific patient to the at least one dosing regimen over time.~~

~~7.—The method of claim 2, wherein the treatment objective comprises maintaining a measurement above a therapeutic threshold for a period of time.~~

~~8.—The method of claim 7, wherein the treatment objective comprises maintaining the measurement below a second therapeutic threshold for the period of time.~~

~~9. The method of claim 7, wherein the therapeutic threshold is stored in the memory.~~

~~10. The method of claim 1, wherein the received data includes at least one of: a body size indicator, gender, race, disease stage, disease status, prior therapy, concomitantly administered drugs, concomitant diseases, demographic information, and laboratory test result information.~~

~~11. The method of claim 1, wherein the received data includes at least one of: a drug concentration level, a blood pressure reading, and a hematocrit level.~~

~~12. The method of claim 1, wherein the computerized medication dosing regimen recommendation system comprises a microprocessor communicatively coupled to the memory.~~

~~13. The method of claim 12, wherein the computerized medication dosing regimen recommendation system includes a database stored in the memory, the database being accessible by the microprocessor and storing information indicative of dosing regimens associated with the medication.~~

~~14. The method of claim 1, wherein updating the first model comprises:
adjusting the first model to fit the response data.~~

~~15. The method of claim 1, wherein the first model is one of: a pharmacokinetic (PK) model, a pharmacodynamic (PD) model, and an exposure/response model.~~

~~16. The method of claim 1, further comprising:~~

~~outputting a subset of the plurality of dosing regimens as updated dosing regimens.~~

~~17. The method of claim 1, wherein calculating the at least one updated dosing regimen comprises:~~

~~forecasting a patient response not specific to any particular patient for each of a first plurality of dosing regimens; and~~

~~selecting at least one dosing regimen of the first plurality of dosing regimens according to predefined logic,~~

~~wherein the predefined logic determines the selection of the at least one dosing regimen to find a minimum of a plurality of objective functions.~~

~~18. The method of claim 1, wherein calculating the at least one updated dosing regimen comprises:~~

~~selecting, based on the characteristics of the specific patient and predefined logic, at least one dosing regimen corresponding to a minimum of an objective function.~~

~~19. A method of treatment with a medication, using a computerized medication dosing regimen recommendation system, the system comprising a processor, the method comprising:~~

~~receiving a treatment objective for a specific patient;~~

~~receiving data indicative of characteristics of the specific patient;~~

~~accessing, using the processor, a memory;~~

~~selecting, based on at least a portion of the data indicative of the characteristics of the specific patient, a first model stored in the memory;~~

~~forecasting, based on the selected first model and medication concentration data measured from the blood of the specific patient, a patient-specific predicted concentration time profile of the medication, indicative of a response of the specific patient to the medication for a plurality of dosing regimens;~~

~~selecting from the plurality of dosing regimens, at least one patient-specific dosing regimen for the medication that achieves a treatment objective based on a desired concentration of the medication in the blood from the patient;~~

~~outputting at least one dosing regimen;~~

~~administering the at least one dosing regimen to the specific patient;~~

~~receiving data reflecting a response of the patient to the administered at least one dosing regimen;~~

~~updating the selected first model, based on the received data reflecting the response of the specific patient;~~

~~calculating, based on the updated first model, at least one updated dosing regimen to reach the treatment objective; and~~

~~outputting the at least one updated dosing regimen,~~

~~wherein the first model is periodically updated until the treatment objective is achieved.~~

~~20. A method for treating a specific patient with a medication, the method comprising:~~

~~setting a treatment objective for the specific patient;~~

~~using a computerized medication dosing regimen recommendation system to achieve the treatment objective for the specific patient, the computerized medication dosing regimen recommendation system configured to:~~

~~receive data indicative of a first response of the patient to an administered dose of the medication, including medication concentration data measured in blood from the patient;~~

~~access, using the processor, a memory;~~

~~select, based on at least a portion of the received data, a first model stored in the memory;~~

~~forecast, based on the selected first model and the medication concentration data measured from the blood of the patient, a patient-specific predicted concentration time profile of the medication, indicative of the patient response to the medication for a plurality of dosing regimens;~~

~~select from the plurality of dosing regimens, at least one patient-specific dosing regimen for the medication that achieves a treatment objective based on a desired concentration of the medication in the blood from the patient;~~

~~output at least one patient-specific dosing regimen for the medication for the patient;~~

~~receive data reflecting a response of the patient to the at least one patient-specific dosing regimen for the medication;~~

~~update the first model, based on the received data reflecting the response of the patient to the at least one patient-specific dosing regimen for the medication;~~

calculate, based on the updated first model, at least one updated dosing regimen for the medication to reach the treatment objective for the patient; and
output the at least one updated dosing regimen for the medication for the patient to treat the disease of the patient.