least one of entered patient weight or age. The example instructions also cause the machine to determine a dosing regime for the patient based upon the approximate pharmacokinetic profile of the patient, the dosing regime including a dosage and a dosage interval. The example instructions further cause the machine to modify the dosing regime in response to receiving another dosing interval for applying the dosage to the patient and enable the dosing regime and a time-varying therapeutic plasma protein level based on the dosing regime to be displayed to a user.

[0011] Aspects of the subject matter described herein may be useful alone or in combination with one or more other aspect described herein. Without limiting the foregoing description, in a first aspect of the present disclosure, a method for providing a therapeutic plasma protein dosing regime includes determining, via a processor, an estimated pharmacokinetic profile of a patient using a Bayesian model of pharmacokinetic profiles of sampled patients, the estimated pharmacokinetic profile based upon (i) at least one of a body weight or an age of the patient, (ii) pre-infusion patient samples, and (iii) three patient samples, each sample corresponding to a blood draw of the patient at one of three different times from an infusion treatment of the therapeutic plasma protein; determining, via the processor, a first dosing regime for a first specified dosing interval including (i) a first dosage and (ii) a first therapeutic plasma protein level in the patient over a time period based at least upon the pharmacokinetic profile, determining, via the processor, a second dosing regime for a second specified dosing interval including (i) a second dosage and (ii) a second therapeutic plasma protein level in the patient over the time period based at least upon the pharmacokinetic profile; determining for each of the first dosing regimen and the second dosing regimen amounts of time when each of the first therapeutic plasma protein level and the second therapeutic plasma protein level are above a first specified concentration level to identify an amount of time where the patient is fully protected or below a second specified concentration level to identify an amount of time the patient is likely to be left unprotected and susceptible to bleeds, wherein the first specified concentration level is greater than the second specified concentration level; displaying the first dosing regime and the second dosing regime on a client device such that the first dosing regime is displayed in conjunction with the second dosing regime.

[0012] In accordance with a second aspect of the present disclosure, which may be used in combination with the first aspect, the method further includes adjusting, via the processor, the estimated pharmacokinetic profile of the patient based upon previous treatments of the patient.

[0013] In accordance with a third aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the second specified dosing interval is longer than the first specified dosing interval.

[0014] In accordance with a fourth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the first specified dosing interval is 48 hours and the second specified dosing interval is 72 hours.

[0015] In accordance with a fifth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the first dosage is determined such that the first therapeutic plasma protein level in the patient over the time period does not fall below a minimum threshold level.

[0016] In accordance with a sixth aspect of the present disclosure, which may be used in combination with the first aspect, the minimum threshold level is less than 20%.

[0017] In accordance with a seventh aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the first therapeutic plasma protein level in the patient is based upon at least one of a minimum threshold level, the first dosage, or the first specified dosing interval, and the second therapeutic plasma protein level in the patient is based upon at least one of the minimum threshold level, the second dosage, or the second specified dosing interval.

[0018] In accordance with an eighth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the Bayesian model includes a two-compartment model having a first compartment corresponding to a time to metabolize the therapeutic plasma protein and a second compartment corresponding to a dose for achieving a certain amount of the therapeutic plasma protein within the patient.

[0019] In accordance with a ninth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, an apparatus for providing a therapeutic plasma protein dosing regime to a client device includes a model generator configured to create a Bayesian model of pharmacokinetic profiles of sampled patients, the Bayesian model including a (i) therapeutic plasma protein clearance and (ii) a volume of distribution relationship for a therapeutic plasma protein based upon at least one of patient age or body weight and a pharmacokinetic server configured to determine an approximate pharmacokinetic profile of a patient based upon (i) the Bayesian model and at least one of an age of the patient or a weight of the patient, (ii) pre-infusion patient samples, and (iii) three patient samples, each sample corresponding to a blood draw from the patient at one of three different times from an infusion treatment of the therapeutic plasma protein; determine the

therapeutic plasma protein dosing regime including a dosage and a therapeutic plasma protein level over a time period based upon the approximate pharmacokinetic profile of the patient; determine amounts of time when the therapeutic plasma protein level is above a first specified concentration level to identify an amount of time where the patient is fully protected or below a second specified concentration level to identify an amount of time the patient is likely to be left unprotected and susceptible to bleeds, wherein the first specified concentration level is greater than the second specified concentration level; modify the therapeutic plasma protein dosing regime in response to receiving a dosing interval for applying the dosage to the patient, and transmit the modified therapeutic plasma protein dosing regime to the client device.

[0020] In accordance with a tenth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the dosing interval is a two-day dosing interval, and wherein the pharmacokinetic server is configured to further modify the therapeutic plasma protein dosing regime in response to receiving a three-day dosing interval in place of the two-day dosing interval.

[0021] In accordance with an eleventh aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the pharmacokinetic server is configured to transmit a drug dosing tool to the client device, the drug dosing tool being configured to determine the therapeutic plasma protein dosing regime and the modified therapeutic plasma protein dosing regime.

[0022] In accordance with a twelfth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the pharmacokinetic server is further configured to modify the therapeutic plasma protein dosing regime based on daily activities of the patient.

[0023] In accordance with a thirteenth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the pharmacokinetic server is further configured to transmit the modified therapeutic plasma protein dosing regime to an infusion pump for administering the therapeutic plasma protein to the patient.

[0024] In accordance with a fourteenth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the approximate pharmacokinetic profile is a first approximate pharmacokinetic profile determined for a first therapeutic plasma protein treatment of the patient, and wherein the pharmacokinetic server is further configured to determine a second approximate pharmacokinetic profile for the patient

for a second therapeutic plasma protein treatment of the patient based on the modified therapeutic plasma protein dosing regime.

[0025] In accordance with a fifteenth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the volume of distribution relationship for the therapeutic plasma protein is a relationship for at least one of clotting factor VIII and modified forms of clotting factor VIII.

[0026] In accordance with a sixteenth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, a machine-accessible device has instructions stored thereon that are configured, when executed, to cause a machine to at least prompt a user to enter at least one of a patient weight or age, use a Bayesian model of pharmacokinetic profiles of sampled patients to determine an approximate pharmacokinetic profile of a patient based upon (i) the Bayesian model and the at least one of entered patient weight or age, (ii) pre-infusion patient samples, and (iii) three patient samples, each sample corresponding to a blood draw from the patient at one of three different times from an infusion treatment of the therapeutic plasma protein, the Bayesian model including (i) a therapeutic plasma protein clearance and (ii) a volume of distribution relationship for a therapeutic plasma protein based upon the at least one of entered patient weight or age, determine a dosing regime for the patient based upon the approximate pharmacokinetic profile of the patient, the dosing regime including a dosage and a dosage interval; determine amounts of time when the therapeutic plasma protein has a concentration level that is above a first specified concentration level to identify an amount of time where the patient is fully protected or below a second specified concentration level to identify an amount of time the patient is likely to be left unprotected and susceptible to bleeds, wherein the first specified concentration level is greater than the second specified concentration level; modify the dosing regime in response to receiving another dosing interval for applying the dosage to the patient, and enable the modified dosing regime to be displayed to a user.

[0027] In accordance with a seventeenth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the machine-accessible device further comprises instructions stored thereon that are configured when executed to cause the machine to determine a first dosing regime for a two-day dosing interval, determine a second dosing regime for a three-day dosing interval, and enable the display of the first dosing regime in conjunction with the second dosing regime.

[0028] In accordance with an eighteenth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the machine-

accessible device further comprises instructions stored thereon that are configured when executed to cause the machine to display a graphical representation of a time-varying amount of the therapeutic plasma protein within the patient, including at least one indication of a dose of the therapeutic plasma protein being provided to the patient.

[0029] In accordance with a nineteenth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the machine-accessible device further comprises instructions stored thereon that are configured when executed to cause the machine to display a graphical feature than enables a user to change at least one of (i) a minimum concentration threshold, (ii) the dosage interval, or (iii) the dosage of the therapeutic plasma protein.

[0030] In accordance with a twentieth aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the machine-accessible device further comprises instructions stored thereon that are configured when executed to cause the machine to modify the dosing regime in response to receiving a change of any one of the items (i), (ii), or (iii).

[0031] In accordance with a twenty-first aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the machine-accessible device further comprises instructions stored thereon that are configured when executed to cause the machine to display a graphical representation of a change in the amount of the therapeutic plasma protein within the patient over time based on the change of any one of the items (i), (ii), or (iii).

[0032] In accordance with a twenty-second aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the machine-accessible device further comprises instructions stored thereon that are configured when executed to cause the machine to receive a minimum concentration threshold and to display an amount of time the therapeutic plasma protein level is below the minimum concentration threshold.

[0033] In accordance with a twenty-third aspect of the present disclosure, which may be used in combination with any one or more of the preceding aspects, the machine-accessible device further comprises instructions stored thereon that are configured when executed to cause the machine to receive patient measurement blood laboratory data including a concentration of the therapeutic plasma protein within the patient after a time

from when the therapeutic plasma protein was administered to the patient and modify the approximate pharmacokinetic profile based on the patient measurement blood laboratory data.

[0034] In accordance with a twenty-fourth aspect of the present disclosure, any of the structure and functionality illustrated and described in connection with FIGS. 1 to 31 may be used in combination with any of the structure and functionality illustrated and described in connection with any of the other of FIGS. 1 to 31 and with any one or more of the preceding aspects.

BRIEF DESCRIPTION OF THE FIGURES

[0035] FIG. 1 shows a diagram of an example pharmacokinetic drug dosing environment, according to an example embodiment of the present disclosure.

[0036] FIG. 2 shows a diagram of patient sample data for a number of patients with hemophilia A, according to an example embodiment of the present disclosure.

[0037] FIGS. 3 to 13 show diagram that include example user interfaces provided by the drug dosing tool of FIG. 1 to determine a dosing recommendation and estimated pharmacokinetic profile for a specific patient, according to an example embodiment of the present disclosure.

[0038] FIGS. 14 to 18 show diagrams that include user interfaces provided by the drug dosing tool of FIG. 1 in a marketing tool embodiment, according to an example embodiment of the present disclosure.

CLAIMS

What is claimed is:

1. A method for providing a therapeutic plasma protein dosing regimen comprising:

determining, via a processor, an estimated pharmacokinetic profile of a patient using a Bayesian model of pharmacokinetic profiles of sampled patients, the estimated pharmacokinetic profile based upon (i) at least one of a body weight or an age of the patient, (ii) pre-infusion patient samples, and (iii) three patient samples, each sample corresponding to a blood draw of the patient at one of three different times from an infusion treatment of the therapeutic plasma protein;

determining, via the processor, a first dosing regimen for a first specified dosing interval including (i) a first dosage and (ii) a first therapeutic plasma protein level in the patient varying over time based at least upon the estimated pharmacokinetic profile;

determining, via the processor, a second dosing regimen for a second specified dosing interval including (i) a second dosage and (ii) a second therapeutic plasma protein level in the patient varying over time based at least upon the estimated pharmacokinetic profile;

determining for each of the first dosing regimen and the second dosing regimen amounts of time when each of the first therapeutic plasma protein level and the second therapeutic plasma protein level are above a first specified concentration level to identify an amount of time where the patient is fully protected or below a second specified concentration level to identify an amount of time the patient is likely to be left unprotected and susceptible to bleeds, wherein the first specified concentration level is greater than the second specified concentration level;

displaying the first dosing regimen and the second dosing regimen on a client device such that the first dosing regimen is displayed in conjunction with the second dosing regimen.

2. The method of Claim 1, further comprising adjusting, via the processor, the estimated pharmacokinetic profile of the patient upon previous treatments of the patient.

3. The method of Claim 1, wherein the second specified dosing interval is longer than the first specified dosing interval.

4. The method of Claim 1, wherein the first specified dosing interval is 48 hours and the second specified dosing interval is 72 hours.

5. The method of Claim 1, wherein the first dosage is determined such that the first time-varying therapeutic plasma protein level in the patient does not fall below a minimum threshold level.

6. The method of Claim 5, wherein the minimum threshold level is less than 20%.

7. The method of Claim 1, wherein the first therapeutic plasma protein level in the patient is based upon at least one of a minimum threshold level, the first dosage, or the first specified dosing interval, and the second therapeutic plasma protein level in the patient is based upon at least one of the minimum threshold level, the second dosage, or the second specified dosing interval.

8. The method of Claim 1, wherein the Bayesian model includes a two-compartment model having a first compartment corresponding to a time to metabolize the therapeutic plasma protein and a second compartment corresponding to a dose for achieving a certain amount of the therapeutic plasma protein within the patient.

9. An apparatus for providing a therapeutic plasma protein dosing regimen to a client device, the apparatus comprising:

a model generator configured to create a Bayesian model of pharmacokinetic profiles of sampled patients, the Bayesian model including a (i) therapeutic plasma protein clearance and (ii) a volume of distribution relationship for a therapeutic plasma protein based upon at least one of patient age or body weight; and

a pharmacokinetic server configured to:

determine an approximate pharmacokinetic profile of a patient based upon (i) the Bayesian model and at least one of an age of the patient or a weight of the patient, (ii) pre-infusion patient samples, and (iii) three patient samples, each sample corresponding to a blood draw from the patient at one of three different times from an infusion treatment of the therapeutic plasma protein;

determine the therapeutic plasma protein dosing regimen including a dosage and a therapeutic plasma protein level varying over time based upon the approximate pharmacokinetic profile of the patient;

determine amounts of time when the therapeutic plasma protein level is above a first specified concentration level to identify an amount of time where the patient is fully protected or below a second specified concentration level to identify an amount of time the patient is likely to be left unprotected and susceptible to bleeds, wherein the first specified concentration level is greater than the second specified concentration level;

modify the therapeutic plasma protein dosing regimen in response to receiving a dosing interval for applying the dosage to the patient; and

transmit the modified therapeutic plasma protein dosing regimen to the client device.

10. The apparatus of Claim 9, wherein the dosing interval is a two-day dosing interval, and wherein the pharmacokinetic server is configured to further modify the therapeutic plasma protein dosing regimen in response to receiving a three-day dosing interval in place of the two-day dosing interval.

11. The apparatus of Claim 9, wherein the pharmacokinetic server is configured to transmit a drug dosing tool to the client device, the drug dosing tool being configured to determine the therapeutic plasma protein dosing regimen and the modified therapeutic plasma protein dosing regimen.

12. The apparatus of Claim 9, wherein the pharmacokinetic server is further configured to modify the therapeutic plasma protein dosing regimen based on daily activities of the patient.

13. The apparatus of Claim 9, wherein the pharmacokinetic server is further configured to transmit the modified therapeutic plasma protein dosing regimen to an infusion pump for administering the therapeutic plasma protein to the patient.

14. The apparatus of Claim 9, wherein the approximate pharmacokinetic profile is a first approximate pharmacokinetic profile determined for a first therapeutic plasma protein treatment of the patient, and wherein the pharmacokinetic server is further configured to

determine a second approximate pharmacokinetic profile for the patient for a second therapeutic plasma protein treatment of the patient based on the modified therapeutic plasma protein dosing regimen.

15. The apparatus of Claim 9, wherein the volume of distribution relationship for the therapeutic plasma protein is a relationship for at least one of clotting factor VIII and modified forms of clotting factor VIII.

16. A machine-accessible device having instructions stored thereon that are configured, when executed, to cause a machine to at least:

prompt a user to enter at least one of a patient weight or age;

use a Bayesian model of pharmacokinetic profiles of sampled patients to determine an approximate pharmacokinetic profile of a patient based upon (i) the Bayesian model and the at least one of entered patient weight or age, (ii) pre-infusion patient samples, and (iii) three patient samples, each sample corresponding to a blood draw from the patient at one of three different times from an infusion treatment of the therapeutic plasma protein, the Bayesian model including (i) a therapeutic plasma protein clearance and (ii) a volume of distribution relationship for a therapeutic plasma protein based upon the at least one of entered patient weight or age;

determine a dosing regimen for the patient based upon the approximate pharmacokinetic profile of the patient, the dosing regimen including a dosage and a dosage interval;

determine amounts of time when the therapeutic plasma protein has a concentration level that is above a first specified concentration level to identify an amount of time where the patient is fully protected or below a second specified concentration level to identify an amount of time the patient is likely to be left unprotected and susceptible to bleeds, wherein the first specified concentration level is greater than the second specified concentration level;

modify the dosing regimen in response to receiving another dosing interval for applying the dosage to the patient; and

enable the modified dosing regimen to be displayed to a user.

17. The machine-accessible device of Claim 16, further comprising instructions stored thereon that are configured when executed to cause the machine to:

determine a first dosing regimen for a two-day dosing interval;

determine a second dosing regimen for a three-day dosing interval; and

enable the display of the first dosing regimen in conjunction with the second dosing regimen.

18. The machine-accessible device of Claim 16, further comprising instructions stored thereon that are configured when executed to cause the machine to display a graphical representation of a time-varying amount of the therapeutic plasma protein within the patient, including at least one indication of a dose of the therapeutic plasma protein being provided to the patient.

19. The machine-accessible device of Claim 16, further comprising instructions stored thereon that are configured when executed to cause the machine to display a graphical feature that enables a user to change at least one of:

(i) a minimum concentration threshold;

(ii) the dosage interval; or

(iii) the dosage of the therapeutic plasma protein.

20. The machine-accessible device of Claim 19, further comprising instructions stored thereon that are configured when executed to cause the machine to modify the dosing regimen in response to receiving a change of any one of the items (i), (ii), or (iii).

21. The machine-accessible device of Claim 20, further comprising instructions stored thereon that are configured when executed to cause the machine to display a graphical representation of a change in the amount of the therapeutic plasma protein within the patient over time based on the change of any one of the items (i), (ii), or (iii).

22. The machine-accessible device of Claim 20, further comprising instructions stored thereon that are configured when executed to cause the machine to receive a minimum concentration threshold and to display an amount of time the therapeutic plasma protein level is below the minimum concentration threshold.

23. The machine-accessible device of Claim 16, further comprising instructions stored thereon that are configured when executed to cause the machine to:

receive patient measurement blood laboratory data including a concentration of the therapeutic plasma protein within the patient after a time from when the therapeutic plasma protein was administered to the patient; and

modify the approximate pharmacokinetic profile based on the patient measurement blood laboratory data.