

injections according to the treatment regimen, having forgotten to perform the injection at all. Other patients may perform the injections, but then be unable to remember whether they performed the injections because they become distracted before they are able to record that they did so. Some patients may elect not to perform the injections because of misunderstandings or miscommunications of when or how the medication will affect the patient's disease or symptoms, especially where the effects are not felt by the patient until a considerable portion of the treatment regimen has been performed. Some patients may require support and/or encouragement from others (healthcare provider, caregiver, family member, etc.), which support and/or encouragement cannot be provided because the people that would provide that support and/or encouragement do not know if the patient has performed the treatment or if the treatment regimen has been followed correctly.

[0006] In addition, the condition and use of drug delivery devices is of importance to other parties, such as drug device manufacturers, pharmacies, health care providers and insurers. For instance, information regarding the condition of the drug delivery device along the supply chain may be relevant to whether the drug delivery device will be in good working order when it arrives for use with the patient. Information regarding the location of the drug delivery device along the supply chain may be relevant to the manufacturer and the pharmacy to ensure that adequate supplies are available for the pharmacy to delivery to the user. The compliance information mentioned above may be important to the healthcare providers and insurers, as well as to the patient, because compliance with a therapy regimen may have a direct impact on the success of the therapy.

[0007] As set forth in more detail below, the present disclosure sets forth an drug delivery system embodying advantageous alternatives to existing drug delivery devices and that may address one or more of the challenges or needs mentioned above.

Summary

[0008] According to an aspect of the disclosure, a drug delivery system includes a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a removable sterile barrier disposed about the distal end of the delivery cannula. The drug delivery system also includes one or more sensors coupled to the drug delivery device and configured to detect movement of the removable sterile barrier, a wireless transmitter, and a controller coupled to the one

or more sensors and the wireless transmitter. The controller may be configured to: use the one or more sensors to determine if the removable sterile barrier has been removed from the distal end of the delivery cannula, and control the wireless transmitter to wirelessly transmit, prior to delivery, a report representative of removal of the removable sterile barrier if the removable sterile barrier has been removed from the distal end of the delivery cannula.

[0009] According to another aspect of the disclosure, a drug delivery system includes a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a removable sterile barrier disposed about the distal end of the delivery cannula. The drug delivery system also includes a first sensor configured to detect movement of the removable sterile barrier, a wireless transmitter, and a controller coupled to the first sensor and the wireless transmitter. The controller may be configured to: use the first sensor to determine if the removable sterile barrier has been removed from the distal end of the delivery cannula, and control the wireless transmitter to wirelessly transmit a report representative of removal of the removable sterile barrier if the removable sterile barrier has been removed from the distal end of the delivery cannula.

[0010] According to another aspect of the disclosure, a drug delivery system includes a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and an actuator configured to trigger the drug delivery device. The drug delivery system also includes first sensor configured to detect movement of the actuator, a wireless transmitter, and a controller coupled to the first sensor and the wireless transmitter. The controller may be configured to: use the first sensor to determine if the actuator has been used to trigger the drug delivery device, and control the wireless transmitter to wirelessly transmit a report representative of triggering of the drug delivery device if the actuator has been used.

[0011] According to another aspect of the disclosure, a drug delivery system includes a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a needle shield moveable relative to the distal end of the delivery cannula. The drug delivery system also includes a first sensor configured to detect movement of the needle shield, a wireless transmitter, and a controller coupled to the

determine the charge level of the battery, and control the wireless transmitter to wirelessly transmit a report representative of the charge level of the battery.

[0021] According to a further aspect of the disclosure, a method is provided of using a drug delivery system comprising a reservoir, a drug contained in the reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a removable sterile barrier disposed about the distal end of the delivery cannula. The method includes determining if the removable sterile barrier has been removed from the distal end of the delivery cannula, and transmitting a report representative of the removal of the removable sterile barrier if the removable sterile barrier has been removed from the distal end of the delivery cannula; and after transmitting the report representative of the removal of the removable sterile barrier, delivering the drug from the reservoir to the patient.

Brief Description of the Drawings

[0022] It is believed that the disclosure will be more fully understood from the following description taken in conjunction with the accompanying drawings. Some of the figures may have been simplified by the omission of selected elements for the purpose of more clearly showing other elements. Such omissions of elements in some figures are not necessarily indicative of the presence or absence of particular elements in any of the exemplary embodiments, except as may be explicitly delineated in the corresponding written description. None of the drawings are necessarily to scale.

[0023] Fig. 1 is a schematic diagram of a drug delivery system according an embodiment of the disclosure in communication with one or more computing devices and one or more networks;

[0024] Fig. 2 is a block diagram of a method of operating the drug delivery system illustrated in Fig. 1 according to an embodiment of the disclosure;

[0025] Figs. 3A-3C is a block diagram of a method of operating the drug delivery system illustrated in Fig. 1 according to another embodiment of the disclosure;

[0026] Fig. 4 is a block diagram of a method of operating a computing device such as is illustrated in Fig. 1 according to an embodiment of the disclosure, the computing device in communication with a drug delivery system operating according to one of the methods disclosed herein, for example;

[0027] Fig. 5 is a block diagram of a method of operating a drug delivery system according to another embodiment of the disclosure;

[0028] Fig. 6 is a block diagram of a method of operating a drug delivery system according to a still further embodiment of the disclosure;

We claim:

1. A drug delivery system comprising:

a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a removable sterile barrier disposed about the distal end of the delivery cannula;

one or more sensors coupled to the drug delivery device and configured to detect movement of the removable sterile barrier;

a wireless transmitter; and

a controller coupled to the one or more sensors and the wireless transmitter, the controller being configured to:

use the one or more sensors to determine if the removable sterile barrier has been removed from the distal end of the delivery cannula, and

control the wireless transmitter to wirelessly transmit, prior to drug delivery, a report representative of removal of the removable sterile barrier if the removable sterile barrier has been removed from the distal end of the delivery cannula.

2. The drug delivery system of claim 1, the drug delivery device comprising:
a housing containing the reservoir and the delivery cannula; and
a removable sterile barrier disposed about a distal end of the housing, the removable sterile barrier having at least one roll inhibiting exterior side surface.

3. The drug delivery system of claim 2, at least a portion of the removable sterile barrier having a triangular cross section.

4. The drug delivery system of claim 2 or 3, the removable sterile barrier having a planar distal end surface, the at least one roll inhibiting exterior side surface being perpendicular to the planar distal end surface.

5. The drug delivery system of any one of claims 2 to 4, the removable sterile barrier including a cover member and a tubular member, the cover member covering an open end of the tubular member, and the tubular member including a plurality of outwardly protruding ribs to be gripped by the patient when removing the removable sterile barrier from the housing.

6. The drug delivery stem of any one of claims 2 to 5, the controller and the wireless transmitter being housed within the removable sterile barrier.

7. The drug delivery system of any one of claims 1 to 6, wherein the reservoir comprises a drug.

8. The drug delivery system of claim 7, the drug being selected from the group consisting of: TNF inhibitors, antibodies to the calcitonin gene-related peptide receptor, granulocyte colony stimulating factors, erythropoiesis stimulating agents, apelin receptor agonists, antibodies to proprotein convertase subtilisin/kexin Type 9 (PCSK9), and tissue inhibitors of metalloproteinases.

9. A drug delivery system comprising:

a drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a removable sterile barrier disposed about the distal end of the delivery cannula;

a first sensor configured to detect movement of the removable sterile barrier;

a wireless transmitter; and

a controller coupled to the first sensor and the wireless transmitter, the controller being configured to:

use the first sensor to determine if the removable sterile barrier has been removed from the distal end of the delivery cannula, and

control the wireless transmitter to wirelessly transmit, prior to drug delivery, a report representative of removal of the removable sterile barrier if the removable sterile barrier has been removed from the distal end of the delivery cannula.

10. The drug delivery system of claim 9, comprising:
the drug delivery device comprising an actuator configured to trigger the drug delivery device;
a second sensor configured to detect movement of the actuator; and
the controller being coupled to the second sensor and configured to:
use the second sensor to determine if the actuator has been used to trigger the drug delivery device, and
control the wireless transmitter to wirelessly transmit a report representative of the triggering the drug delivery device if the actuator has been used.

11. The drug delivery system of claim 10, comprising:
the drug delivery device comprising a needle shield moveable relative to the distal end of the delivery cannula between a proximal position and a distal position;
a third sensor and a fourth sensor each being configured to detect movement of the needle shield; and
the controller being coupled to the third sensor and configured to:
use the third sensor to determine if the needle shield has been moved relative to the distal end of the delivery cannula,
control the wireless transmitter to wirelessly transmit a report representative of insertion of the distal end of the delivery cannula into the patient if the needle shield has been moved relative to the distal end of the delivery cannula,
use the fourth sensor to determine if the needle shield is disposed about the distal end of the delivery cannula, and
control the wireless transmitter to wirelessly transmit a report representative of a completion of a delivery of a drug from the reservoir to the patient if the needle shield is disposed about the distal end of the delivery cannula after having been moved from the proximal position to the distal position.

12. The drug delivery system of claim 9, comprising:
the drug delivery device comprising a needle shield moveable relative to the distal end of the delivery cannula between a proximal position and a distal position;
a second sensor configured to detect movement of the needle shield; and
the controller being coupled to the second sensor and configured to:
use the second sensor to determine if the needle shield has been moved relative to the distal end of the delivery cannula, and

control the wireless transmitter to wirelessly transmit a report representative of insertion of the distal end of the delivery cannula into the patient if the needle shield has been moved relative to the distal end of the delivery cannula.

13. The drug delivery system of claim 9, comprising:

a needle shield moveable relative to the distal end of the delivery cannula between a proximal position and a distal position;

a second sensor configured to detect movement of the needle shield; and
the controller being coupled to the second sensor and configured to:

use the second sensor to determine if the needle shield is disposed about the distal end of the delivery cannula, and

control the wireless transmitter to wirelessly transmit a report representative of a completion of a delivery of a drug from the reservoir to the patient if the needle shield is disposed about the distal end of the delivery cannula after having been moved from the proximal position to the distal position.

14. The drug delivery system of claim 10, comprising:

the drug delivery device comprising a needle shield moveable relative to the distal end of the delivery cannula;

a third sensor configured to detect movement of the needle shield; and
the controller being coupled to the third sensor and configured to:

use the third sensor to determine if the needle shield has been moved relative to the distal end of the delivery cannula, and

control the wireless transmitter to wirelessly transmit a report representative of insertion of the distal end of the delivery cannula into the patient if the needle shield has been moved relative to the distal end of the delivery cannula.

15. The drug delivery system of claim 10, comprising:

the drug delivery device comprising a needle shield moveable relative to the distal end of the delivery cannula;

a third sensor configured to detect movement of the needle shield; and
the controller being coupled to the third sensor and configured to:

use the third sensor to determine if the needle shield is disposed about the distal end of the delivery cannula, and

control the wireless transmitter to wirelessly transmit a report representative of a completion of a delivery of a drug from the reservoir to the patient if the needle shield is disposed about the distal end of the delivery cannula.

16. The drug delivery system of claim 12, comprising:
the controller being configured to:

use the second sensor to determine if the needle shield is disposed about the distal end of the delivery cannula, and

control the wireless transmitter to wirelessly transmit a report representative of a completion of a delivery of a drug from the reservoir to the patient if the needle shield is disposed about the distal end of the delivery cannula after having been moved from the proximal position to the distal position.

17. The drug delivery system of any one of claims 9 to 16, wherein the first sensor, the wireless transmitter, and the controller are embedded in the removable sterile barrier.

18. The drug delivery system of any one of claims 9 to 17, wherein the controller is configured to limit delivery of a drug contained in the reservoir if it is determined that the removable sterile barrier has been prematurely removed.

19. The drug delivery system of claim 18, wherein the controller is configured to determine if the reservoir has been replaced if it is determined that the removable sterile barrier has been prematurely removed, and to permit delivery if it is determined that the reservoir has been replaced.

20. The drug delivery system of any one of claims 9 to 19, wherein the controller is configured to limit delivery of a drug contained in the reservoir unless it is determined that the removable sterile barrier has been properly removed.

21. The drug delivery system of any one of claims 9 to 20, wherein the controller is configured to use the sterility sensor to determine if the removable sterile barrier has been removed from the distal end of the delivery cannula and to determine if a time period has elapsed, and to control the wireless transmitter to transmit a report if the removable sterile barrier has been removed from the distal end of the delivery cannula and the time period has elapsed.

22. The drug delivery system of claim 21, wherein the drug delivery device comprises a lock and the controller is coupled to the lock, the controller being configured to actuate the lock if the removable sterile barrier has been removed from the distal end of the delivery cannula and the time period has elapsed.

23. The drug delivery system of any one of claims 9 to 22, wherein the reservoir comprises a drug.

24. The drug delivery system of claim 23, the drug being selected from the group consisting of: TNF inhibitors, antibodies to the calcitonin gene-related peptide receptor, granulocyte colony stimulating factors, erythropoiesis stimulating agents, apelin receptor agonists, antibodies to proprotein convertase subtilisin/kexin Type 9 (PCSK9), and tissue inhibitors of metalloproteinases.

25. A method for use with a drug delivery device comprising a reservoir, a drug contained in the reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, and a removable sterile barrier disposed about the distal end of the delivery cannula, the method comprising:

determining if the removable sterile barrier has been removed from the distal end of the delivery cannula;

transmitting a report representative of the removal of the removable sterile barrier if the removable sterile barrier has been removed from the distal end of the delivery cannula; and

after transmitting the report representative of the removal of the removable sterile barrier, delivering the drug from the reservoir to the patient.

26. The method of claim 25, further comprising:
receiving the report representative of the removal of the removable sterile barrier at a first computing device; and
transmitting the report from the first computing device to a second computing device.

27. The method of claim 25 or 26, further comprising:
limiting delivery of the drug contained in the reservoir if it is determined that the removable sterile barrier has been removed.

28. The method of claim 25 or 26, further comprising:

determining if the reservoir has been replaced if it is determined that the removable sterile barrier has been removed; and

permitting delivery of the drug contained in the reservoir if it is determined that the reservoir has been replaced.

29. The method of any one of claims 25 to 28, further comprising:
limiting delivery of the drug contained in the reservoir until it is determined that the removable sterile barrier has been removed.

30. The method of any one of claims 25 to 29, further comprising:
determining if a time period has elapsed following removal of the sterile barrier; and
transmitting a report if the removable sterile barrier has been removed from the distal end of the delivery cannula and the time period has elapsed.

31. The method of claim 30, further comprising:
locking the drug delivery device if the removable sterile barrier has been removed from the distal end of the delivery cannula and the time period has elapsed.

32. The method of claim of any one of claims 25 to 31, wherein the drug is selected from the group consisting of: TNF inhibitors, antibodies to the calcitonin gene-related peptide receptor, granulocyte colony stimulating factors, erythropoiesis stimulating agents, apelin receptor agonists, antibodies to proprotein convertase subtilisin/kexin Type 9 (PCSK9), and tissue inhibitors of metalloproteinases.