Two-Way Patient Monitoring in PD: Technical Description of Sharesource

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Abstract

The SHARESOURCE platform was designed to transform how clinicians approach dialysis by empowering them to focus on improving clinical decision making for their patients. Sharesource supports remote patient management through secure communication with Baxter's AMIA, HOMECHOICE CLARIA and KAGUYA peritoneal dialysis cyclers. Sharesource organizes and presents the treatment data to the clinician in a timely manner for assessment, allowing the clinician to review the treatment results, assess the therapy, and evaluate patient status and compliance. If the clinician determines that a change to the patient's therapy is required, Sharesource provides the clinician the ability to act on that assessment by updating the patient's device settings that can be communicated to the cycler in time for the patient's next treatment.

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Overview

The SHARESOURCE Medical Device Connectivity platform is a cloud-based global family of products that includes a medical device connectivity platform, a peritoneal dialysis (PD) adequacy calculator, and support for the ordering of PD therapy supplies. Sharesource is partitioned into 4 regions to support multiple products, languages, and geographies:

- Europe, Middle East, and Africa
- United States and Canada

Fig. 1. SHARESOURCE medical device connectivity platform.

- Asia Pacific
- Latin America

The SHARESOURCE platform securely communicates with Baxter’s AMIA, HOMECHOICE CLARIA, and KAGUYA automated PD cyclers and allows authorized users to remotely view and manage treatment information sent from a cycler [1–3]. Authorized users can also remotely program the therapy that will be performed by the cycler (Fig. 1).

Need for Sharesource

The SHARESOURCE platform was developed with 3 primary objectives: to improve clinician confidence to send dialysis patients home, to enable patients to extend their time on home dialysis therapy, and to generate operational savings.

The Sharesource features intended to improve clinician confidence include the organization and presentation of the treatment data to the clinician in a timely manner for assessment, allowing the clinician to review the treatment results, assess the therapy, and evaluate patient status and compliance. Sharesource also provides the clinician with the ability to remotely adjust the device settings as needed to maintain the appropriate therapy for their patients. While Sharesource supports the clinician, it is not intended to be a substitute for clinical practice, nor does it create decisions or treatment pathways.

The communications between the patient’s cycler and Sharesource is intended to support the patient by giving them assurance that there is an ongoing connection with their clinician. They know that their clinician is monitoring their status and that potential issues can be identified for proactive therapy management. Sharesource is also designed to reduce the burden on the patient by re-

placing manual record keeping with the automated data capture and transfer of their therapy information to their clinician. This can be beneficial when working with their clinician to troubleshoot issues or when preparing for their periodic clinic visits.

Sharesource is also designed to deliver operational savings by allowing clinicians to assess therapy success without relying on direct patient communications. The clinicians can review the patient's treatment data on their schedule from any location where they can access the internet through a browser. Because the treatment data are automatically transferred to Sharesource through a secure interface with the patient's cyclor, manual data entry and the potential associated errors are reduced. Finally, Sharesource may also reduce the amount of paperwork a clinic has to manage by digitizing the patient run sheets.

Indications for Use [1–3]

The SHARESOURCE portal is intended for use by healthcare professionals to remotely communicate new or modified treatment parameters with compatible dialysis instruments and transfer completed treatment data to a central database to aid in the review, analysis, and evaluation of patients' historical treatment results. This system is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

Sharesource Concepts

Treatment Files

The cyclers collect data while the treatment is being performed by the patient, and after the treatment is complete, the collected data are organized, and packaged into a treatment file which is then sent to the SHARESOURCE platform.

Device Settings

All the parameters required to configure a cyclor to provide a patient-specific PD treatment. Device Settings are comprised of Device Programs, Patient Settings, and System Settings.

Device Programs are used to enter the therapy parameters for a treatment (e.g., solution type and concentration, therapy volume, dwell time). Clinicians can configure some Device Program parameters to allow or prevent user adjustment [1–3]. For AMIA and KAGUYA, if user adjustment is allowed, clinicians

Fig. 2. Clinical treatment dashboard example for patients with HOMECHOICE CLARIA cyclers [2].

can either allow adjustment of the setting within the device default limits or restrict user adjustment to within a smaller range [1, 3].

Patient Settings are used to enter specific information that the patient should enter for a treatment (e.g., weight, blood pressure).

System Settings are used to configure device options (e.g., fluid temperature, language, date format).

Treatment Dashboard provides a 7-day window of up to 28 days of patients' treatment history at a high level for the clinic (Fig. 2). It is important to note that the overview only displays status for completed treatments. Treatment information is sent after the treatment has been completed, and not in real time. The Treatment Dashboard uses Patient Event icons to notify the clinician of treatment information and events that occurred during a patient's treatment. Patient Event icons show the following information:

- Treatment was completed without any flag events occurring
- Treatment had at least one flag event occurring
- No treatment data was received for a given day
- No communications have been received from the cycler for a given day.

The Patient Snapshot provides a numeric and graphical overview of the patient's treatment over a 7- or 30-day period. Specifically, Patient Event icons,

night ultrafiltration (UF), and patient survey question results (e.g., weight and blood pressure) are presented.

Treatment Summary provides the details for a specific treatment. Some of the primary information includes:

- Prescribed device program
- Actual treatment time
- Solutions used
- UF details
- Therapy details in a run sheet format
- Cycle profiles (Fig. 3)

Flag rules describe events and conditions that may occur during a patient's treatment that the clinician can configure Sharesource to notify them of, if they should occur. Flag rules assist with finding patient treatment results that match criteria defined in the flag rule settings (e.g., lost treatment time, lost dwell time).

Event flags will appear on the Treatment Dashboard, Patient Snapshot, and Treatment Summary. The event flags appear and are triggered based on the flag rule criteria that the clinic selects.

Sharesource User Roles

There are 5 Sharesource user roles that align with assignments commonly found in clinics, which allow access to the Sharesource feature(s) appropriate for that role:

- Clinic Administrator (ability to create and edit clinic user accounts)
- Patient Administrator (ability to create and edit patient records)
- Device Manager (ability to create and edit Device Settings)
- Clinic Settings Manager (ability to create and edit device settings templates and clinic flag rules)
- Basic Clinic Access (ability to view patient information including treatment information and device settings).

A Sharesource user must be assigned at least one role, but may be assigned up to all 5 roles.

Critical Design Elements

The SHARESOURCE platform is built with multiple design considerations and supports software design best practices such as disaster recovery, scalability to meet the growing demand, logging, monitoring, auditing, role-based access control, multi-factor authentication, data privacy, and security.

Fig. 3. Treatment summary run sheet and cycle profile example for a patient with an AMIA cycler.

Security is a primary design requirement for Sharesource. The SHARE-SOURCE platform supports and meets various industry standards and implements security at various levels such as application, device communication, network, and infrastructure.

At an application level, all clinicians are required to have a login and password to access the SHARESOURCE Clinical Portal. While setting up the account, clinicians need to meet strict password requirements and are required to setup security questions. Clinics which have stricter security needs can opt for a second level authentication such as one time token or SMS (short message service). Clinicians are required to change their password at regular intervals. These activities are recorded and stored in an encrypted data store for future audit and compliance needs.

Table 1. Features available in SHARESOURCE clinical portal

SHARESOURCE clinical portal functional area	Features available to clinicians
Treatment logs	Treatment dashboard Patient snapshots (7/30 day) Treatment summary
Device settings	Device program Patient and system settings
Clinical utilities	Flag rule configurations Device setting templates Offline viewing of selected data using reports
Administration	Patient administration Clinic/clinic user administration

All communications between the cyclor, remote connectivity server, and Sharesource are encrypted with industry standard protocol (128 bit SSL/HTTPS). An additional level of security is implemented directly between the cyclor and Sharesource, all data (treatment files and device settings) exchanged between the cyclor and the SHARESOURCE platform is encrypted with a highly secured encryption algorithm. The remote connectivity server cannot read these data packets, and it acts as a postman delivering the packets without accessing the contents.

Sharesource Features

The majority of Sharesource features and functionalities can be divided into 2 pieces: remote connectivity and device communication, which is transparent to clinicians; and the SHARESOURCE Clinical Portal which provides an intuitive and user friendly interface for the clinicians.

Remote Connectivity and Device Communication

The SHARESOURCE Medical Device Connectivity platform uses a remote connectivity server to bridge the communication between the cyclers and Sharesource. Clinicians can create and edit Device Settings using Sharesource which is transmitted to the cyclor upon request. The patient uses an activation code that is provided by their clinician to initially connect and communicate with Sharesource. At defined intervals, the cyclor will check for device settings updates. However, once a patient starts the treatment, the cyclor blocks all inbound

and outbound communication for the duration of therapy. This removes any possibility of external updates to the data during the therapy. Once the treatment is completed, the cyclor transfers the treatment file to Sharesource.

SHARESOURCE Clinical Portal

SHARESOURCE Clinical Portal provides a user-friendly interface with intuitive navigation supporting the clinicians and specifically aligned to their expected day-to-day activities within a clinic. It offers a variety of features and data views controlled by the clinician's Sharesource user role (Table 1).

Sharesource Workflow

When a clinic decides to use the SHARESOURCE platform for remote patient management, a Sharesource administrator will determine which region the clinic is to be associated and creates a Sharesource clinic in that region. As part of that process, the Sharesource administrator will create a clinic administrator user and identify which Sharesource products the clinic will have access to (Fig. 4).

The clinic administrator will create user accounts for the clinic staff that require access to Sharesource. The created user accounts will identify what Sharesource role(s) each user will have. At least one clinic user will have the patient administrator role with the ability to manage patient records for the clinic. The patient administrator(s) will create a patient record for each of the clinic's patients that will use an AMIA, HOMECHOICE CLARIA or KAGUYA cyclor that will be remotely managed through Sharesource.

If clinic-wide device settings templates or flag rules are to be used, at least one clinic user will have the Clinic Settings Manager role assigned to them and be responsible for their setup. Flag rules can be created and adjusted at any time. The changes will be applied the next time the event flags are evaluated for display.

The clinician who manages the patient's therapy will have the Device Manager role and will create the Device Settings for the patient within Sharesource. This includes identifying the survey questions that the clinician requests the patient to respond to, which will be used to aid in the monitoring of the patient's status. Once the patient is trained and ready to go home, the clinician will provide the patient activation code (PAC) to the patient. The PAC is a global unique identifier that the patient will be prompted to provide the first time they interact with their cyclor. The cyclor will communicate with Sharesource to provide the PAC and request the Device Settings for the patient. When Sharesource responds to the cyclor, it will provide additional patient information so the cyclor can ask the patient to confirm their identity. Upon confirmation, the Device Settings are pre-

Fig. 4. High-level workflow view.

sented to the patient for review and acceptance. Once the patient accepts the Device Settings, the cyclor is available to provide the programmed therapy.

When the patient is ready, they set up the cyclor with their disposable set and solutions, connect to the cyclor, and perform their treatment. The cyclor does not communicate with Sharesource during the treatment, so real-time monitoring of the patient's treatment is not available. The patient's cyclor will communicate with Sharesource when the treatment is complete to securely send the treatment information details. When Sharesource receives a treatment file from a patient's cyclor, it is confirmed to be valid, and the patient and clinic are identified from the information. As the information is being processed, it is evaluated against the flag rules criteria and the result stored in the patient's record.

The patient's record is available for the clinician to view at a summary level on the Treatment Dashboard. The use of Patient Event icons can help the clini-

cian to prioritize the review of the patient's more detailed treatment information compared to those that report a condition or event that the clinician has indicated that they want to be notified of. Patients who have a status of "no treatment" or "no communication" may also be a priority for clinician review. These 2 status provide the clinician with a view to their patient's recent compliance to therapy which allows issues to be identified and addressed early.

Patient Snapshot and Treatment Summary provide a more detailed treatment information. Patient Snapshot provides a view of 7 or 30 days of information. Some information is presented graphically that allows for visual identification of trends that would not be apparent when reviewing a single treatment. Treatment Summary allows the clinician to review all of the details of a specific treatment. Review of the data may prompt communication with the patient, but the discussion can be focused on areas of concern identified through review of the treatment information. While Sharesource supports the clinician reviews, it is not intended to be a substitute for clinical practice, nor does it create decisions or treatment pathways.

If the clinician determines through their assessment that the patient's therapy requires an adjustment, they can review the Device Settings for that patient and make the necessary modifications. The Device Settings feature allows clinicians to create a therapy for patients which can be transmitted to the cyclor. Clinicians can program various therapy parameters, patient and system settings. Clinicians have the flexibility to create and maintain multiple device programs alongside the designated primary program. Device program templates allow clinicians to create generic templates which can be used as starting point to create the patient-specific device programs.

The patient's cyclor will communicate with Sharesource prior to their next treatment to check for any updates to their Device Settings. If there are updates, they will be provided to the cyclor, the patient will be notified and asked to accept the updates which will then be available for their next treatment.

This cycle repeats with each treatment that the patient performs.

Reports provide the ability to view the selected set of data for offline view. Clinicians can generate reports by visiting reports tabs within the clinic portal. Clinicians can select the patient and date ranges to filter the data. Report format selection allows the clinician to download and save the data in PDF or spreadsheet format.

References

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