Baxter

Center Letter

Date: 3 March 2010

Urgent Device Notification

Dear Peritoneal Dialysis Clinician:

RE: HomeChoice Automated PD System and HomeChoice PRO Automated PD System
Product Codes: 5C4474 and R5C8320

Baxter Healthcare is sending you this Urgent Device Notification letter to help reduce or eliminate overfill, also referred to as Increased Intraperitoneal Volume (IIPV), associated with HomeChoice/HomeChoice PRO cyclers. IIPV can result in serious injury or death from conditions including, but not limited to, hydrothorax, heart failure, pulmonary edema or pericardial effusion. Baxter has received complaints of IIPV, which resulted from patient use errors and/or prescription errors.

Description of IIPV

Overfilling or not draining enough fluid can result in excess fluid in the abdomen. While some patients may not have any symptoms, the most common symptoms of IIPV (overfill) include:

- Feeling full, bloated, or overfull
- Abdominal pain or discomfort
- Expanded or tense abdomen
- Vomiting or spitting-up
- Difficulties feeding
- Localized swelling around the PD catheter exit site, belly button, groin region, or genital area
- Leakage of fluid from the PD catheter exit site
- Difficulty breathing
- A child complaining of a "funny feeling" in the abdomen
- A child crying
- Unexpected increase in blood pressure

Additional care should be taken to monitor patients who are not able to communicate IIPV symptoms to their caregiver during treatment, such as small children or infants.

How IIPV Occurs

IIPV is a condition that occurs when there is more fluid in the abdomen than was prescribed. This condition is sometimes called "overfill." Baxter has received reports of IIPV associated with patient use error or prescription error when using either the HomeChoice Automated PD System or HomeChoice PRO Automated PD System.

IIPV can occur if the prescription parameters are not programmed appropriately. It is important that clinicians consider these parameters when setting new patient prescriptions. It is also

Baxter Healthcare (M) Sdn Bhd (159204-W)
Suite 12.01, Level 12 / The Gardens, South Tower / Mid Valley City / 59200 Kuala Lumpur, Malaysia.
T 603.2267.6000 F 603.2283.1784

important for clinicians to consider whether current patient prescriptions need to be revised. Baxter may contact you if, during the course of complaint investigations, we determine that patient prescriptions are potentially contributing to IIPV.

The following prescription parameters can influence the risk of IIPV:

- Fill Parameters such as Fill Volume, Day Fill Volume, Night Fill Volume, Last Fill Volume
- Drain Parameters such as I-Drain Alarm, Minimum Drain Volume %, Last Manual Drain, UF Target, Tidal Volume %, Total UF, Tidal Full Drains
- Low Fill Mode Only such as I-Drain Time, Minimum Drain Time, Negative UF Limit %

Actions to Take

Clinicians must carefully program patient fill volumes to prevent IIPV situations. Clinicians must also program drain alarms and ultrafiltration percentage to ensure patients are draining sufficiently. Insufficient draining could lead to an IIPV situation during their subsequent cycle or accumulation of ultrafiltration volume within the peritoneal cavity.

IF YOU SUSPECT YOUR PATIENT HAS IIPV, PLEASE TELL YOUR PATIENT OR PATIENT CAREGIVER TO DO THE FOLLOWING:

1.) Press STOP immediately, then press ▽ and initiate a Manual Drain. The Manual Drain procedure is located in the HomeChoice manual.
2.) Once the fluid is completely drained from the abdomen, call your nephrologist.
3.) Call your nephrologist immediately if you have ANY complaints or symptoms of IIPV including those listed above.
4.) For assistance in performing the above steps, call the Baxter Clinical Hotline, available 24 hours a day, 7 days a week at 017-722 9837.

HomeChoice Labeling and Software Changes

Baxter is developing changes to the HomeChoice/HomeChoice PRO product labeling and software to reduce the potential incidence of IIPV due to patient use errors or prescription errors. Baxter will notify you when these changes are available and arrange for your cyclers to be upgraded.

Attached to this letter is information on IIPV. This attachment contains Patient guidance and Clinician Guidance. Please read the attachment and share this important information with your home patients. The attachment includes:

- A definition of IIPV, the related symptoms, and guidance on how to address IIPV should it occur.

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- Warnings and cautions about IIPV.
- Programming instructions for the HomeChoice/HomeChoice PRO cyclers to improve clinicians' understanding of how programming the device relates to IIPV. New details have been added to specifically address Low-Fill Mode.
- Tables have been included with recommendations for the Initial drain (I-drain) alarm settings, recommendations for maximum Fill Volume based on patient's weight, and targets for Tidal Therapy ultrafiltration levels.

Adverse reaction reporting

Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to Baxter Pharmacovigilance / Quality Assurance Specialist at 03-2267 6015.

Please complete the enclosed reply form and fax it to Baxter at the number provided on the form. The completed reply form will acknowledge receipt of this letter and will prevent you from receiving repeat notices.

We apologize for any inconvenience you may experience as a result of this notification.

Sincerely,

Ng Yu Seen
Assistant Manager, Regulatory Affairs

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HomeChoice Automated PD System and HomeChoice PRO Automated PD System
Product Codes: 5C4474 and R5C8320
CUSTOMER REPLY FORM
Urgent Device Notification Letter dated 3rd March 2010

Please complete, sign and return this form to Baxter using FAX number below (a fax cover is not required): 03-2283 1784

Center Name and Address:	
Reply Confirmation Completed By: *(Please print name)*	
Title:	
Telephone Number (including Area Code):	

Check all that apply:

____ I have read, understand, and disseminated the content of the letter.

____The HomeChoice Automated PD System or HomeChoice PRO Automated PD System is no longer used.

Signature/Date: **REQUIRED FIELD**	

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