Insulin pump users require recurrent education for the management of pump failure

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Article points

1. Insulin pump users are at risk of hyperglycaemia and diabetic ketoacidosis if the pump system malfunctions.
2. They require knowledge and skills, as well as back-up insulin supplies and ketone tests, to manage pump system failure.
3. Pump specialist teams need to provide effective education at pump start-up programmes and to regularly review pump users' knowledge and skills regarding the management of pump system failure.

Key words

- Back-up insulin supplies
- Continuous subcutaneous insulin infusion
- Insulin pump failure
- Patient education

Authors

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Insulin pump therapy is associated with an increased risk of diabetic ketoacidosis (DKA) as a consequence of pump or infusion set failure. In this audit, the authors evaluated qualitative data from 360 questionnaires sent to insulin pump users regarding their hyperglycaemia management skills and whether they kept appropriate back-up supplies. Despite a detailed curriculum of education and instruction at the authors' institution, some users remain at risk of hyperglycaemia and DKA from pump failure because they do not know or fail to apply appropriate strategies for ketone testing, correction dosing and back-up insulin supplies. Pump services should ensure regular review of patients' knowledge during clinic attendance and provision of recurrent education sessions with access to management guidelines.

The Bournemouth Diabetes Service adopted continuous subcutaneous insulin infusion (CSII) pump technology in 1998 and has since developed a comprehensive pump service, with a database of more than 500 current pump users. The service provides high-quality care, encouraging users to develop skills to ensure effective and safe insulin pump self-management. In this article, we outline the principles of CSII and how hyperglycaemia can occur whilst using pump therapy. We report the results of a local survey assessing users' insulin pump self-management skills and the steps undertaken to reduce morbidity risk in these people.

Background

Risks associated with insulin pump therapy

CSII is the continuous delivery of short-acting insulin from a pump via a subcutaneous cannula and infusion set. Insulin is delivered at a predetermined, continuous basal rate, supplemented by boluses. Insulin delivery settings are programmed to suit individual requirements, and the user decides the amount of insulin required in boluses when food is consumed. The criteria that need to be considered when calculating bolus doses include the food's carbohydrate content, the current blood glucose level and any anticipated exercise or activity. The cannula and infusion set are replaced by the user every 2–3 days.

When first introduced, insulin pump therapy was considered to be unsafe, as it was associated with a high risk of diabetic ketoacidosis (DKA), severe hypoglycaemia and CSII-associated deaths (Pickup et al, 1978). However, pump technology and patient education improved, and new pump systems were introduced to the UK in the late 1990s. Superior effectiveness over multiple daily insulin injection (MDI) regimens has previously been demonstrated (Pickup et al, 2002), and in 2008 NICE recommended CSII as a treatment option for people with type 1 diabetes in specific circumstances, including those experiencing frequent hypoglycaemia affecting quality of life and those with persistent poor glycaemic control (HbA_{1c} ≥69 mmol/mol [8.5%]) despite best efforts at optimised self-management (NICE, 2008).

Concerns about the safety of CSII remain, with malfunctions and adverse events reported by users, and patients need to be aware of the potential risks associated with pump therapy (Pickup et al, 2014; Ross et al, 2015). Only short-acting insulin is used with pump therapy, and any interruption to its supply will, therefore, rapidly lead to hyperglycaemia and DKA within a short time frame, as no long-acting background insulin is present. Under controlled conditions, ketones appear approximately 4 hours after interruption of insulin delivery (Torlone et al, 1996), which can occur because of mechanical or electronic pump failure, misplacement of the subcutaneous cannula or damage to the infusion set's tubing.

Untoward events can be detected and prevented by using troubleshooting strategies, which underlines the importance of patient education when initiating pump therapy. There are a number of guidelines for the safe and appropriate management of CSII (Morrison and Western 2013; Wilmot et al, 2014). It is essential that blood glucose readings are taken at least four times a day to identify any potential problems. On detection of hyperglycaemia, users should follow specific instructions and guidelines, including testing for ketones if their blood glucose levels are above 14 mmol/L. If ketones are present, insulin should be administered according to specified guidance using a pen or syringe. Infusion sets should be changed every 2–3 days to avoid potential occlusions and infection of the infusion site (Kerr et al, 2008). Hand washing and the "no touch rule" (i.e. not touching the ends of the infusion set unnecessarily) is especially important. The site needs to be inspected daily for inflammation, warmth, pain and leakage. If any of these are present, a different site must be used.

Given the degree of user instruction required, pump centres need to provide a comprehensive pump start-up education programme, backed up with a detailed curriculum provided by a highly skilled, experienced team (NICE, 2008; Morrison and Western, 2013).

CSII at Royal Bournemouth Hospital

In Bournemouth, we have a multidisciplinary pump team consisting of dietitians, nurses, a psychologist and two consultant physicians. Appropriately trained and with expert pump therapy management skills, they deliver a structured curriculum-based education programme over the first year of insulin pump use. People meeting NICE criteria to commence pump therapy have their self-management skills and knowledge assessed by members of the pump specialist team. On initiation of pump therapy, users attend three morning sessions over the course of a week, followed by review sessions of 2 hours' duration at 1, 3, 6 and 9 months post-initiation. Pump users also attend a multidisciplinary pump clinic every 4–9 months, according to individual needs.

All users are made aware of the pros and cons of pump therapy, including the additional risk of hyperglycaemia and DKA. Advice includes the need to have an in-date alternative insulin supply for use in emergency, including both long-acting (background) and fast-acting (mealtime) insulins with their required pens or syringes, and an awareness of the doses required if they need to revert to MDI (Wilmot et al, 2014).

The current audit

As a result of telephone calls to the department and general discussions within pump clinic appointments, the Bournemouth insulin pump team suspected that, despite provision of rigorous education, some CSII users struggled to manage their diabetes during times of pump failure. More worryingly, between January 2013 and June 2015, 18 pump users were admitted with DKA, four of whom attributed this to pump failure. It was also apparent that many users did not have adequate back-up insulin supplies. In response to these concerns, in March 2015 the Bournemouth team undertook a survey of current pump users, with the following aims:

1. To assess pump users' understanding of the consequences and management of pump failure.
2. To determine what insulin and equipment users have as back-up in case of pump failure.
3. To develop education resources to inform users and improve their self-management knowledge and skills.

Method

Self-report postal questionnaires were sent to 360 adult insulin pump users attending the Bournemouth Diabetes and Endocrine Centre during the month of March 2015. The survey assessed the duration

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1. Any failure of the insulin pump system can result in hyperglycaemia and diabetic ketoacidosis, with ketones appearing as little as 4 hours after insulin delivery ends.
2. Pump users should check their blood glucose levels at least four times per day to identify potential problems, and test for ketones if glucose levels are above 14 mmol/L.
3. Given the degree of user instruction required, pump start-up teams need to provide a comprehensive pump education programme.

of pump therapy and asked whether participants could recall receiving education regarding pump safety and the required actions upon detection of hyperglycaemia and pump failure, and whether they had received information regarding back-up insulin supplies, emergency equipment and appropriate insulin doses.

Results

The survey response rate was 47% (170 of 360 people), with 50% of participants reporting CSII use for more than 5 years and 19% for more than 10 years. Only 37% recalled having received education regarding pump failure at their pump start-up programme, while most others recalled receiving education from pump clinics and other individual consultations (*Figure 1*). Education had been provided within the previous 2 years in 66% but more than 5 years previously in 8%.

Regarding awareness of the need to test for ketones, 46% of participants stated they would test for ketones at a blood glucose level of >14 mmol/L, and 40% stated they would also test if they felt unwell. However, 23% stated they would only test for ketones at glucose levels >20 mmol/L (*Figure 2*). When testing for ketones, the majority (68%) stated they would test for urinary ketones. Only 72% had readily accessible facilities for testing ketones, whilst 18% stated they never tested for ketones.

For correction doses, 42% of participants stated they would use an insulin pen if ketones were present (*Table 1*). Availability of back-up insulin and emergency equipment indicated that 72% had ketone testing equipment, 59% carried spare infusion sets, 58% kept a supply of background insulin and 53% carried a fast-acting insulin in a pen (*Figure 3*).

When seeking advice regarding pump failure management, 78% stated they would call the diabetes department, 77% would make use of pump company care lines, 18% would call or attend Accident and

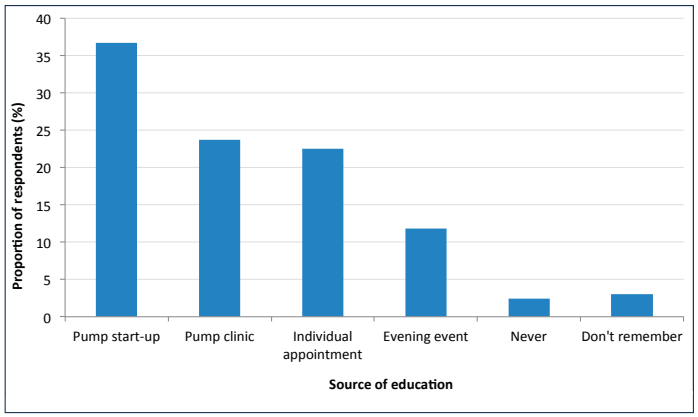

Figure 1. Participants' sources of education on management of pump failure (n=170).

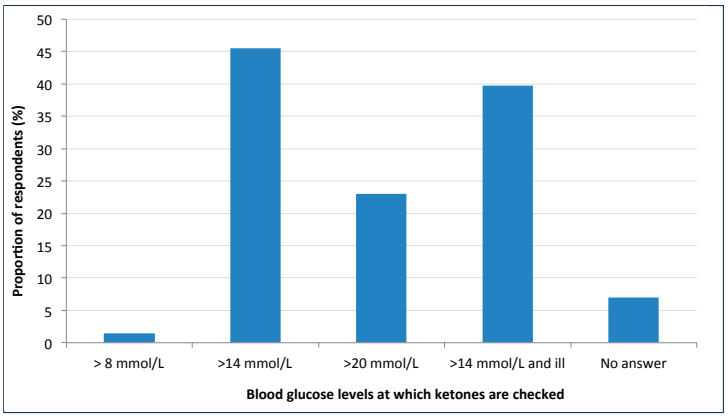

Figure 2. Blood glucose levels at which participants state they test for ketones (n=170).

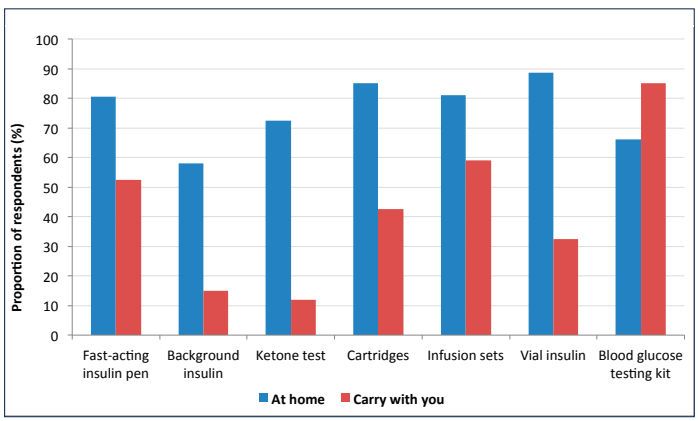

Figure 3. Percentage of participants with access to back-up insulin and essential supplies for emergency use (n=170).

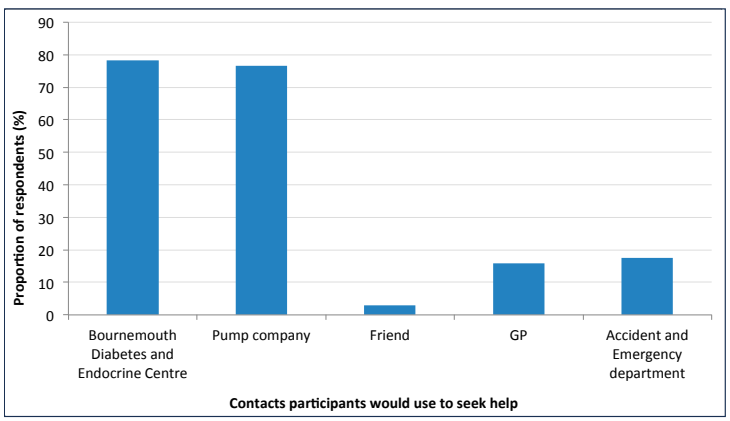

Figure 4. Contacts participants would use for help in case of emergency (n=170).

Emergency for assistance and 16% would contact their GP (*Figure 4*). Overall, 58% of participants had a record of the required background insulin doses for a switch over to injectable insulin therapy in case of complete pump failure (*Figure 5*). Overall, 54% wanted more information or guidelines.

Discussion

This study assessed knowledge about the management of hyperglycaemia/DKA in insulin pump users attending the Bournemouth Diabetes and Endocrine Centre, and the availability of back-up insulin equipment in the event of pump system failure. An increased risk of hyperglycaemia and DKA whilst on CSII has previously been reported (Bruttomesso et al, 2009; Hanas et al, 2009; Shetty and Wolpert, 2010). A recent patient survey also reviewed the non-metabolic complications of CSII and showed that, despite the increasing sophistication of insulin pump technologies, nearly 50% of users experienced pump malfunction, with commonly reported problems being total pump failure, failure of insulin delivery, keypad/button problems, pump vial rewind malfunction and battery compartment problems (Pickup et al, 2014). Other reported challenges included difficulties with the infusion set and site insertion, with 17% reporting insertion site infections and 25% experiencing lipohypertrophy. The most common problems with the infusion set were kinking (64%) and blockage (54%), and these were regular problems in 10% of participants. A delay in changing infusion sets beyond 3 days is associated with complications such as itching, bruising and pain, which can lead to a deterioration in glycaemic control (Thethi et al, 2010). These data emphasise the need for users to be observant, knowledgeable and competent in their pump management.

We investigated the approach our participants would take in response to pump problems and the extent to which they felt appropriately informed and prepared to manage pump failure. We found that, despite a comprehensive education programme, our patients are not always prepared to deal with pump system failure, and many lack the knowledge and skills required to overcome the challenges raised by pump use. A significant proportion did not have access to appropriate back-up insulin supplies or knowledge of their required insulin doses in the event that a switch to MDI therapy was required.

Half of the people we surveyed had been using CSII for >5 years and 19% for >10 years, and many might not have received the structured education that is currently available at the Royal Bournemouth Hospital. Only 37% of pump users recalled having received education on pump failure at pump commencement, with 24% stating they had received information at a consultant-led pump clinic appointment and a further 22.5% receiving education at subsequent contact with the pump service. Review clinics are an important opportunity

Table 1. Actions undertaken by insulin pump users upon ketone detection.

Action	Proportion of pump users (%)
Give correction dose using bolus advisor feature on the pump	37.8
Give own calculated (double) dose, using the pump, and recheck	30.5
Give own (double correction) dose, using an insulin pen or syringe, and recheck	42.1
No answer	6.0

Note: some participants responded with more than one answer.

"We found that, despite a comprehensive education programme, our patients are not always prepared to deal with pump system failure, and many lack the knowledge and skills required to overcome the challenges raised by pump use."

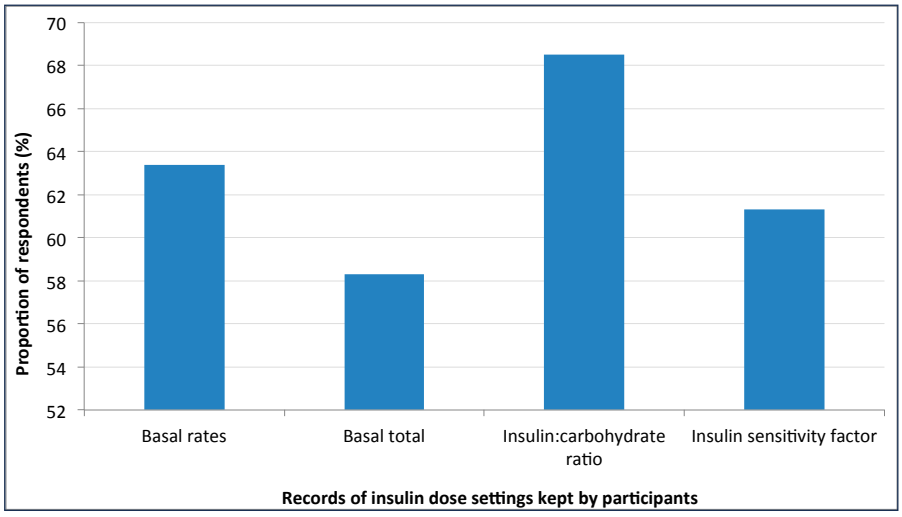

Figure 5. Percentage of participants with records of insulin doses required in case of pump system failure (n=*170*).

Table 2. Participants' comments demonstrating the need for education on ketone testing.

Participant comment	Healthcare professional considerations
"Never had ketones, so don't test"	The individual is still at risk of ketoacidosis in the future and needs education on the need to test for ketones when blood glucose levels are >14 mmol/L
"Irrelevant to test for ketones, I give a bolus to get glucose down"	When ketones are present, pump users need to be aware that bolus correction doses may need to be increased, and to know which guideline they can follow to treat ketosis
"My Ketostix are years out of date, maybe I need some more!"	The individual needs improved awareness that access to ketone testing with pump therapy is important
"I don't have facilities to test for ketones"	All pump users should have access to ketone testing. Ensure provision and prescriptions for up-to-date testing equipment
"Probably should be 14 mmols"	The user is aware of the need to test for ketones when blood glucose levels are raised but would benefit from access to guidelines
"Can't remember how to calculate (correction dose)"	The user needs re-education and provision of guidelines on management of hyperglycaemia and ketosis whilst on insulin pump therapy

for healthcare professionals to check on users' knowledge and access to back-up insulin supplies; this is especially important given our finding that 34% of participants were unable to recall getting any education in the two years prior to the survey. We would recommend that knowledge of pump failure management is assessed annually and that, as some people may not have had to administer subcutaneous insulin for many years, it is especially important to review their access to back-up insulin supplies, and to give education on the required insulin doses for an emergency MDI regimen.

Standard advice for pump users is to test for ketones on detection of an unexpected blood glucose level of >14 mmol/L or when feeling unwell (Walsh and Roberts, 2006; Hanas, 2015). Half of our surveyed users follow this advice, with 40% also testing for ketones when they feel ill. However, 20% stated they would wait until blood glucose levels were >20 mmol/L before ketone testing. It is important for pump users to understand that blood glucose levels can rise rapidly and ketones can develop within 4–5 hours if insulin delivery is interrupted, and that this may not necessarily be associated with feeling unwell (Torlone et al, 1996).

If ketones are present, pump users should give a correction dose double that of their usual correction factor (Walsh and Roberts, 2006), using a pen or syringe if administration via a malfunctioning pump or infusion set is likely to be ineffective. In our survey, 42% of participants would use a pen to administer correction doses whilst 38% stated they would use their usual bolus advisor, although the advisor would not recognise the need for a double dose. Worryingly, only 72% of pump users had facilities to test for ketones and 18% admitted to having never tested for ketones. These patients could be putting themselves at risk of DKA in the longer term. When testing ketones, 68% continue to use a urine test, although it should be noted that recent NICE guidelines recommend using blood ketone testing (NICE, 2015).

The majority of our participants keep back-up supplies of insulin at home, with 81% having access to fast-acting insulin but only 58% having access to long-acting insulin. Spare infusion sets are kept by the majority of pump users, but it is important to review and provide appropriate prescription requests for GPs, and healthcare professionals should act on the responses provided by pump users in *Table 2*. In particular, pump users need to make sure they have adequate back-up supplies when travelling away from home and should be provided with written information to support their pump use when travelling.

Our survey highlighted the need to provide more guidance on insulin pump failure and, at the request of more than half of our participants, we have developed guidelines to inform users of potential pump system failures and the actions required, including information on back-up insulin pen use and the steps to take in response to hyperglycaemia and DKA (*Figure 6*).

Insulin pump training should be delivered by trained educators and needs to instruct on the importance of appropriate blood glucose monitoring, the mechanisms underlying pump failure and when to administer insulin by replacement pens/syringes. Pump users should also be encouraged to use the customer helplines provided by the manufacturers for assistance with technical problems. It is important to recognise any barriers users might have regarding seeking advice, including concerns that they may have

"failed", or even that their pump therapy might be taken away (Pickup et al, 2014).

Conclusion

Despite provision of a detailed curriculum and education at pump initiation, users do not always have appropriate knowledge and skills to manage insulin pump failure, and many do not have adequate back-up supplies and information. Safe use of insulin pump therapy should be reviewed at least once annually with any member of the multidisciplinary pump team, and topics should include managing unexpected highs, cannula changes, sick day rules, access to back-up insulin pens and syringes, and the insulin doses required in the event of pump failure (Wilmot et al, 2014). Ongoing education, clear guidelines and provision of equipment for pump failure are integral to reducing the incidence of DKA in insulin pump users. ■

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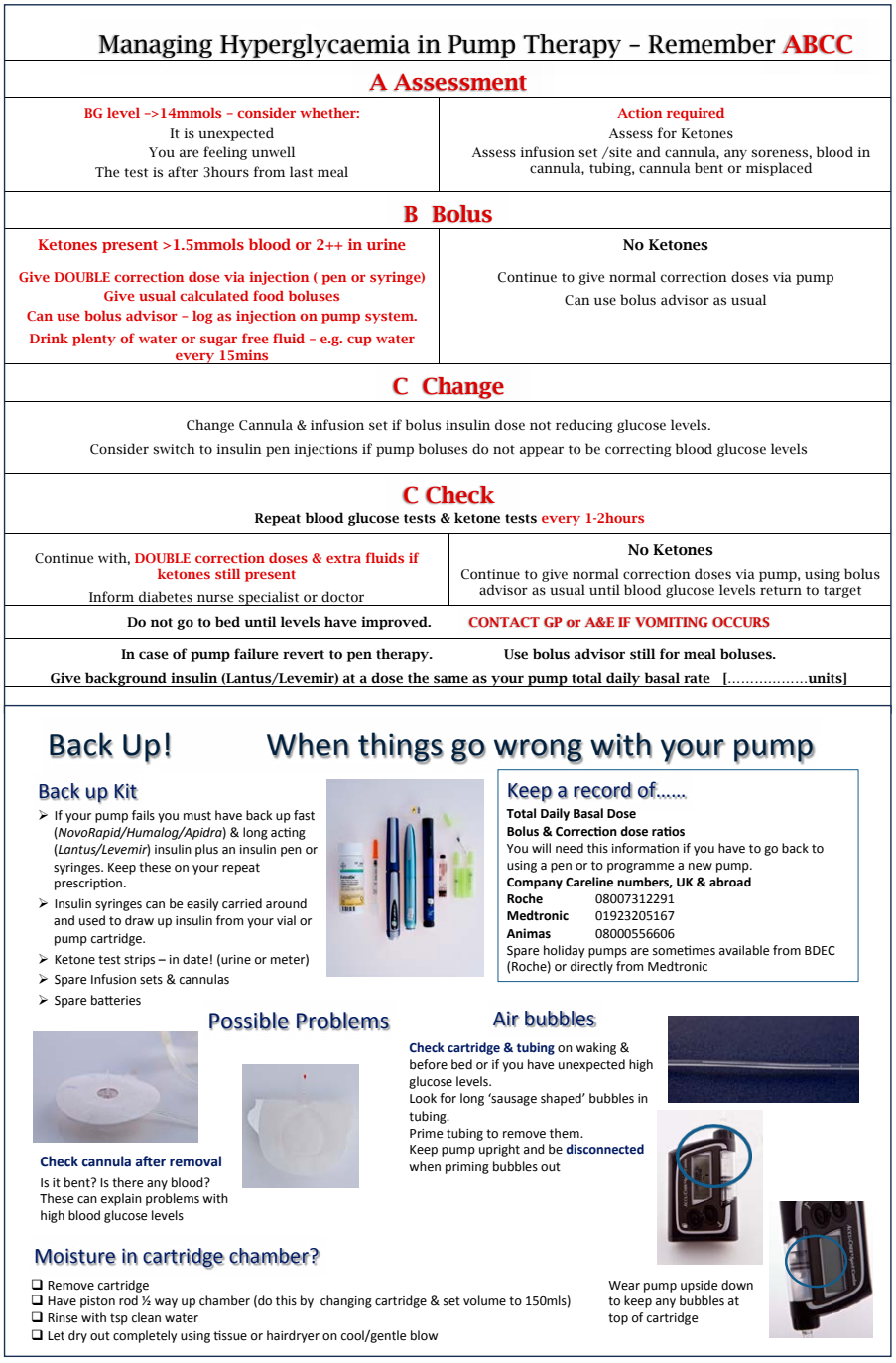

Figure 6. Bournemouth Diabetes and Endocrinology Centre's guidelines on the management of pump system failure and hyperglycaemia.