Evidence review

Redsense blood loss detection device for venous needle dislodgement monitoring in haemodialysis

CEP08050

March 2009
The product

The *Redsense blood loss detection device* is intended to monitor the venous needle, through which blood is returned to the patient during haemodialysis. It consists of an alarm unit and a sensor patch. The alarm unit transmits infrared light through an optical fibre to the sensor, which is placed over the venous needle access site. Blood leakage at the access site interrupts the infrared signal, activating a red warning light and audible alarm.

Field of use

The product is intended for use in patients undergoing haemodialysis, where dislodgement of the venous needle can be fatal if undetected.

National guidance

Although there are national guidelines on renal dialysis, they do not specifically deal with venous needle dislodgement (VND). The National Service Framework for Renal Services (Renal NSF) sets out five standards and 30 markers for good practice.

Evidence reviewed

The available evidence on venous needle dislodgement monitors was limited, consisting of two peer-reviewed papers, an abstract, a briefing paper, a journal club discussion, articles in professional newsletters and a personal communication awaiting publication. The occurrence of venous needle dislodgement was determined from data obtained from the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Reporting and Learning System (NRLS) database, National Patient Safety Agency (NPSA).

CEP’s verdict

The evidence indicates that whilst VND poses the greatest risk of harm during haemodialysis it is rarely fatal. Between 2004 and June 2008, twelve incidents of venous needle dislodgement were reported to the MHRA, of which two resulted in death. Universal use of the Redsense monitor, at a cost of approximately £8.6 million per annum, might therefore be difficult to justify. However, the Redsense monitor offers greatest potential value for patients at increased risk of VND, such as those receiving haemodialysis at home or in isolation rooms, and restless patients. For patients receiving home haemodialysis, use of the Redsense monitor would add around £450 per patient per annum to treatment costs.

Staff and patients should be aware of the risks associated with VND and that venous pressure monitoring alarms on haemodialysis equipment do not always detect blood
leaks straightaway and stop the blood pump immediately. The Redsense monitor will detect blood loss as soon as the venous needle dislodges but will not stop the blood pump as it does not currently interface with the dialysis machine. To prevent serious injury or death, vigilance is required to ensure that taping is secure, the patient’s vascular access is visible at all times, and frequent checks are made for evidence of extracorporeal blood loss.
Renal dialysis

End-stage renal disease is a chronic renal impairment that is irreversible and permanent and is managed by either a kidney transplant or renal dialysis. There are two types of renal dialysis; haemodialysis and peritoneal dialysis. The focus of this evidence review is only on haemodialysis.

The incidence of end stage renal failure requiring renal replacement therapy (RRT) is rising, with 43,901 adult patients in the UK in 2006. The number of patients on haemodialysis was approximately 19,000 and highest in those over 65 years of age. Home haemodialysis treatment is an option for some patients with 2.1 % receiving home haemodialysis [1]. Patients on haemodialysis generally undergo dialysis three times a week, for 3 to 5 hours under supervision at renal dialysis or satellite units.

Haemodialysis involves pumping the blood outside the body to a dialysis machine which removes impurities and toxins before returning it to the patient. Effective long-term access to the circulating blood flow is enabled by surgically creating an arteriovenous fistula (AVF), a direct passage between a vein and an artery, usually in the forearm (figure 3). The resulting large diameter vein is capable of withstanding high blood flows at high pressure.

Figure 3. Diagrammatic representation of an arteriovenous fistula (AVF)
If the blood vessels are not suitable for an AVF, a graft is created either from the patient’s own blood vessel or artificial material to connect the artery and the vein.

**Double-needle dialysis**

Double-needle dialysis employs two large-diameter needles, as in figure 3. The ‘arterial’ needle takes blood from the patient to the dialyser, and the ‘venous’ needle returns blood to the patient from the dialyser. The needles are securely taped in place on the patient’s skin, at the access site. Double-needle dialysis is more efficient than single-needle dialysis (see below).

**Single-needle dialysis**

During single-needle dialysis, the blood flow through the needle alternates every few seconds between the arterial (blood taken to dialyser chamber) and venous phases (blood returned to the patient) of the cycle. Due to the reduced blood flow, it is less efficient than double-needle dialysis and is not the preferred method for frequent dialysis in haemodialysis units. However, it is suitable for home dialysis, especially nocturnal dialysis, conducted over an extended time whilst the patient is asleep. If the needle is dislodged during dialysis, there is minimal risk to the patient of excessive blood loss or introduction of air into the vascular system.

**Venous needle dislodgement**

The NRLS database “suggests that there are over 700 renal incidents per year in renal units in England and Wales that result in moderate or severe harm or death of patients” [2]. The Renal Association and the NPSA have looked at the process of “formulating and sharing solutions to clinical incidents and risk prone situations”. Ten common risk prone situations related to haemodialysis procedures and equipment were identified including dislodgment of the venous needle during haemodialysis.

Blood loss to the environment during haemodialysis can occur due to the cannula slipping from the vein, leaks in the extracorporeal circuit or disconnection of blood lines from blood access devices [3]. One or both needles may be completely or partially dislodged or removed from the access site during a treatment, either intentionally by the patient, or accidentally due to blood lines becoming caught on the treatment chair during postural change, or to clothing or blankets brushing against the needles and tapings during normal movements. The needles can also slip out if the tape on a patient simply comes off due to excessive skin moisture. Arterial needle dislodgement poses a minimal risk to the patient as the unit will alarm and shut down stopping the blood flow to the dialyser. However, undetected venous needle dislodgement can be fatal, as the blood pump is typically set between 200 and 400 ml/minute, leading to rapid exsanguination. A partially dislodged needle may cause the blood to infiltrate the surrounding tissue, causing pain, or to leak around the needle entrance, or a combination of both.
Searches for devices to detect venous needle dislodgement during haemodialysis revealed:

- the Redsense blood loss detection device (Redsense Medical AB, Sweden)
- the use of enuresis alarms, intended for detecting bed wetting, being used outside their “intended purpose” in some renal centres
- numerous patents for products not yet commercially available.

**Venous pressure monitors**

The European standard IEC 60601-2-16:2008(E) covers the safety and performance of haemodialysis, haemodiafiltration and haemofiltration equipment. It states that the dialysis machine “shall include a protective system to protect the patient from extracorporeal blood loss to the environment that can cause a safety hazard” [4].

The venous pressure monitor (VPM) on a dialysis machine measures the pressure in the extracorporeal circuit between the outlet from the dialyser and the return to the patient and should be able to detect when the vein needle has become dislodged by the subsequent drop in the venous pressure, and an audible alarm triggered. However, the VPM may fail to register a sufficient pressure change to trigger an alarm due to the high pressure gradient created in the blood lines [5] by the use of small bore needles [6], high blood pump speeds and high blood velocities in the narrow tubing segment.

**EDTNA / ERCA recommendations**

The European Dialysis and Transplant Nurses Association (EDTNA) and the European Renal Care Association (ERCA) recently published ‘12 practice recommendations to help reduce the risk of VND and to detect blood leakage as early as possible’ [7].

- Staff, patients and carers should be aware of VND and the consequences
- An area around the vascular access large enough for taping should be cleaned and dried before cannulation.
- Haemodialysis units should have consistent taping procedures.
- Blood lines should be looped loosely to allow movement of the patient and to prevent blood lines pulling on the needles.
- If it is necessary to reposition to needle, all taping should be replaced.
- Staff to patient ratio should be adequate to allow routine monitoring of vascular access during treatment.
- All patients should be assessed for level of risk of VND and if appropriate an alarm device intended for venous needle dislodgement used.
• Vascular access and needles should be visible at all times during haemodialysis.
• When the venous pressure alarm is activated, the vascular access and fixation of needles and blood lines should always be inspected prior to resetting the alarm limits.
• The lower limit of the venous pressure alarm should be set as close as possible to the current venous pressure.
• Staff, patients and carers should be aware that the venous pressure monitoring system of the dialysis machine will often fail to detect VND.

Additional protection can be provided by devices intended to detect blood loss to the environment.

**The Redsense monitor**

The Redsense device is an alarm system for detecting blood loss if the venous needle becomes dislodged during haemodialysis. It comprises an alarm unit (figure 1) and a blood sensor that is incorporated into an adhesive sensor patch (figure 2).

![Figure 1. Redsense alarm unit](image1)

![Figure 2. Redsense sensor patch](image2)

The alarm unit can be used on multiple patients, with a new sensor patch every time for each patient. Any blood leakage at the access site is absorbed into the sensor patch, attenuating the infrared signal, thereby activating a red warning light and audible alarm. The Redsense sensor patch is single-use and is disposed of as normal clinical waste.
The alarm unit transmits infrared light through an optical plastic fibre to the sensor, which is placed directly over the venous needle access. The alarm unit is attached to the patient’s arm or clipped onto clothing (figure 4). When the device is switched on a green light confirms the system is fully operational and monitoring. The alarm unit is powered by a rechargeable battery that lasts 15 - 20 hours when fully charged. When less than 5 hours of charge remains a warning light appears against the battery symbol (figure 5). The battery is changed by the manufacturer during servicing of the alarm unit, which will be at approximately 2 - 3 year intervals.

Figure 4. The Redsense monitor in use

The Redsense monitor has an in-built, real time clock and an internal memory that stores the last 20 treatments tagged with the date and time. Data are stored for every second during these 20 treatments, so that if an incident occurs data can be retrieved to determine the time and duration of a venous needle dislodgement, with information also available from which to establish the alarm, warnings and battery status.
Moisture detectors / enuresis alarms
Discussions with renal dialysis staff highlighted the use of enuresis alarms, intended to detect bed wetting, being used outside their intended purpose to detect blood loss. However, their reliability in detecting blood is questionable [8].

National guidance
Although there are national guidelines on renal dialysis, they do not specifically deal with venous needle dislodgement.

National Service Framework for Renal Services
Sources

The National Library for Health was used to search the literature across multiple sources including:

- PubMed
- Bandolier
- Cochrane Library Database of Systematic Reviews
- Database of Abstracts of Reviews of Effects (Dare)
- Health Technology Assessment Database (HTA)
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- National Library of Guidelines
- National Institute for Health and Clinical Excellence (NICE)
- NHS Economic Evaluation Database (NHS EED)
- Centre for Reviews and Dissemination.

Additional searches were conducted:

- National Institute for Health Research
- Emergency Care Research Institute (ECRI))
- Scottish intercollegiate guidelines network (SIGN)
- Turning research into practice (TRIP)
- Medicines and Healthcare Regulatory Agency (MHRA)
- National Patient Safety Agency (NPSA)
- DH hospital episodes statistics
- Google scholar
- US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database.
Methods

Search terms

Key words searched:

- venous needle dislodgement
- venous needle dislodgement during renal dialysis
- haemodialysis and blood loss
- exsanguination
- desanguination
- hypovolaemia
- venous disconnection
- loose needle during haemodialysis
- systems to monitor venous needle dislodgement
- Redsense monitor
- needle gauge and blood pressure
- venous pressure and blood loss
- safety aspects of haemodialysis

Inclusion and exclusion criteria

Inclusion criteria included any evidence regarding:

- renal patients undergoing haemodialysis from an arteriovenous fistula
- alarm systems for detecting venous needle dislodgement.

Exclusion criteria:

- haemodialysis by means of lines or catheters.
Venous needle dislodgement during haemodialysis

The evidence regarding the extent of venous needle dislodgement and use of venous needle dislodgement monitors was limited. Information was requested from the NPSA and MHRA on the number of incidents reported to the two agencies. Searches for information regarding the use of monitors to detect venous needle dislodgement produced mainly ‘grey’ literature.

MHRA

Twelve incidents of venous needle dislodgement were reported to the MHRA between 2004 and June 2008, of which two resulted in the death of the patient. Of the remaining 10 incidents, seven were categorised as serious whilst the other three were minor or resulted in no injury.

NPSA

The National Reporting and Learning System (NRLS) was set up by the NPSA to collect reports of patient safety incidents from NHS organisations in England and Wales. These incidents are analysed to determine patterns which can be used to facilitate learning and change clinical practice. Information was requested from the NRLS using the search terms:


Data from 1st February 2005, the start of the NRLS, to 30th June 2008 revealed 52 reported incidents. Of these, 47 were categorised as causing no harm or low harm, three as moderate harm and two severe harm. Age was recorded for 41 incidents, with the majority, 79%, of the patients being over 65 years.

Rylance

Rylance distributed questionnaires to all 72 renal units in the UK during 2008 to determine the occurrence of venous needle dislodgements [10]. The data submitted was either from renal unit databases or from estimation of occurrences of venous needle dislodgements in the previous five years. Twenty-four (33%) questionnaires were returned. The data are shown in tables 1 and 2.
Table 1. Severity of venous needle dislodgement in previous five years

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Numbers of dislodgements in five years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1</td>
</tr>
<tr>
<td>Moderate / Severe harm</td>
<td>10</td>
</tr>
<tr>
<td>Mild / No harm</td>
<td>146</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>157</strong></td>
</tr>
</tbody>
</table>

Table 2. Percentage of renal units who would use a monitor to detect blood loss

<table>
<thead>
<tr>
<th>Patient category</th>
<th>Units who would use a VND detector (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>29.2</td>
</tr>
<tr>
<td>High risk</td>
<td>62.5</td>
</tr>
<tr>
<td>None</td>
<td>8.3</td>
</tr>
<tr>
<td>Home dialysis</td>
<td>20.8</td>
</tr>
</tbody>
</table>

Study conclusion

This study estimates that there were approximately 7 incidents of venous needle dislodgement per unit during the past five years (table 1), with a median of 5 which is just significantly non-normal (p=0.025) with a lower quartile of 3 and upper quartile of 10. It also highlighted (table 2) that 92% of renal units would use a monitor to detect blood loss. Two units were using enuresis alarms, whilst one unit was trialling the Redsense monitor.

Ahlmen et al

Ahlmen et al conducted a study which clinically tested the Redsense monitor in five dialysis units in Sweden [11]. The device was tested on forty-one patients, mean age 65 years (range 33 – 86 years) for two months, with feedback provided by dialysis nurses and patients via a simple questionnaire. Two hundred dialyses were studied of which 71 were carried out after two modifications had been made to the sensor patch. The sensitivity was reduced to react to at least 1 ml of blood and the sensor patch adhesive modified.

Results

The sensor correctly sounded an alarm on contact with blood in 179 tests (table 3). A warning light correctly identified failure in the sensor patch on 6 occasions. The monitor correctly sounded an alarm in 92.5% of all tests.
Evidence review

Table 3. Included results

<table>
<thead>
<tr>
<th>Reason</th>
<th>Unmodified sensor patch</th>
<th>Modified sensor patch</th>
<th>Total tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarm sounded correctly</td>
<td>113</td>
<td>66</td>
<td>179</td>
</tr>
<tr>
<td>Sensor failure warning alarm</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Did not sound an alarm</td>
<td>13</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>129</strong></td>
<td><strong>71</strong></td>
<td><strong>200</strong></td>
</tr>
</tbody>
</table>

Thirteen results were excluded from the study (table 4).

Table 4. Excluded results

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not completed test procedure</td>
<td>5</td>
</tr>
<tr>
<td>Broken sensor patches</td>
<td>3</td>
</tr>
<tr>
<td>Incomplete test protocol</td>
<td>2</td>
</tr>
<tr>
<td>Dialysis monitor alarm sounded</td>
<td>1</td>
</tr>
<tr>
<td>Defective sensor patch</td>
<td>1</td>
</tr>
<tr>
<td>Unclear result</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>13</strong></td>
</tr>
</tbody>
</table>

If the alarm had not been activated, at the end of the dialysis the nurses simulated a blood leak by dropping some blood from the removed venous needle onto the sensor patch to check that the monitor would have alarmed if a blood leak had occurred. To verify that the venous pressure alarm would not activate and stop the blood pump, the venous needle was intentionally removed, in some cases, at the end of the dialysis without stopping the dialysis, which was correctly detected by the Redsense monitor. During the study period there was increased interest in venous needle dislodgement, with five episodes reported, equating to an incidence rate of 0.1%.

Study conclusion
The responses to the questionnaire from both nurses and patients indicated that the Redsense monitor was well accepted, and did not hamper the dialysis session.

The authors concluded that during the study the Redsense monitor increased safety of routine dialysis, especially during low level supervision, home haemodialysis or when the patient was sleeping.
Sandroni

In an abstract submitted at the 25th Annual Dialysis Conference in 2005, Sandroni [12] stated that venous needle dislodgement was a “potentially lethal event”, and that the risk was “compounded by the failure of the dialysis machines to detect the problem” due to the back pressure created by the blood flow through the venous needle. From informal discussions with other sources he concluded that VND events were more frequent than indicated by the FDA published reports. Locally, units have introduced enuresis detection devices and protocols requiring that “access needles are always visible”.

Sandroni concluded that the only way to overcome venous needle dislodgement was to have an engineered solution to “reliably detect needle position and blood flow discrepancies, alarm and feedback to stop the blood pump”.

Lindley

The European Dialysis and Transplant Nurses Association (EDTNA) / European Renal Care Association (ERCA) journal club in 2005 discussed [8] the Sandroni briefing paper [13]. This recounted an incident of an elderly patient undergoing hemodialysis who was found unconscious with blood dripping on to the floor beneath the chair, with the venous needle partially dislodged, and who subsequently died. The venous pressure monitor on the dialysis machine had not set off the alarm and investigation of the equipment did not find any fault. At the time of the incident, the renal unit, which was of an open design, was fully staffed with all patients visible. Sandroni suggested that deaths resulting from venous needle dislodgement were under reported, citing fear of reporting incidents as a possible explanation.

The discussion centred on how venous needles became dislodged, especially if there were no changes in the normal routine when an incident occurred and reasoned that many incidents of venous needle dislodgement were not detected immediately due to clothing and bedding soaking up a significant amount of blood before it began to form a pool on the floor. It highlighted limitations of the venous pressure monitors of dialysis machines to trigger the venous pressure alarm even upon excessive blood loss.

Dialysis machine manufacturers are aware of the potential for the dialysis machine not to sound an alarm if the venous needle becomes dislodged and that staff vigilance is required. However, the effect of numerous false positives against the very rare occurrence of an actual VND may lead to annoyance and complacency. Ideally, the alarms on dialysis machines should detect any discrepancies in blood flow caused by decreases in blood pressure and automatically stop the pump. During the discussions it was highlighted that two major dialysis machine manufacturers had patented technology based on the pressure pulse of the dialysis machine or patient’s
own pulse to detect VND. However, these inventions had not been implemented, possibly because the IEC standard only mentions venous pressure monitoring specifically, although it acknowledges that no system has been developed that can be totally relied upon to detect blood loss to the environment.

A number of contributors to the discussion monitored blood leaks using enuresis pads. However, the reliability of such devices for this purpose is undetermined as some members found that when blood was poured onto these pads they did not sound an alarm, whilst others recounted their experience of using an enuresis detector, the DRI Sleeper device (Anzacare Ltd, New Zealand), that did sound an alarm on contact with blood.

Renal care professionals who contributed to this discussion paper felt that in the absence of technical solutions to detect venous needle dislodgement, most incidents could be prevented by adherence to protocols for securing and monitoring needles; and by using the dialysis machine’s venous pressure monitoring system effectively.

**Mactier et al**

Mactier et al report on a workshop that identified ten incidents of venous needle dislodgement in a six month period at nine renal units in Yorkshire and Bolton [14] during 2006. The ten incidents were categorised according to whether they concerned securing the needle, monitoring of the patient, or technical issues. The paper also highlighted that two fatalities were reported during 2004 - 2006 due to dislodgement of the venous needle.

The article refers to information gathered from renal units in the UK, by the Renal Association Clinical Services Committee on the occurrence of venous needle dislodgements in the 10 years 1996 - 2006. The data showed that seven units reported no incidents; 10 units reported one serious incident and four units reported having two non-fatal incidents. Exsanguination following dislodgement of the venous needle is rare, but the evidence indicates greater effort is needed to improve prevention and early detection of VND.

The authors recommended that blood leak detectors may be useful for high risk patients and that there need to be technical improvements in dialysis machines to enable early detection of blood loss.

**ECRI**

An ECRI medical device safety report [15] on undetected venous line needle dislodgement during haemodialysis discussed the failure of the venous pressure monitor (VPM) to trigger an alarm, resulting in the loss of a significant quantity of blood with patients requiring hospitalisation, or dying. The report pointed out that the failure to detect venous needle dislodgement is due to high blood flow through small bore needles, which produces back pressure that exceeds the patient’s venous
pressure. The problem was made worse by users increasing the set alarm limits to minimise nuisance alarms, which affected the ability of the VPM to detect a fully or partially dislodged needle.

ECRI stated that the venous pressure monitor was not a reliable means of detecting needle dislodgement and agreed with manufacturers that visually monitoring the state of the blood lines was the only sure way to spot these problems. ECRI made four recommendations:

- to inform dialysis staff that secure needle placement is crucial to avoiding dislodgements. This involves taking the time to securely tape the needle to the patient’s skin, arm, or access device
- to alert dialysis staff to the dangers associated with relying on the venous pressure alarm to detect a venous line needle dislodgement. To advise them to continually examine haemodialysis blood lines during treatment if this is not already routine
- to instruct operators to keep the entire venous line from being covered by anything that might prevent good visualisation of the needle insertion so that it can be easily monitored
- to encourage users to continue to use the venous pressure monitor as it is useful for detecting obstructions or disconnections that occur elsewhere in the venous line. Also instruct the users to ensure that the monitor’s alarm limits are set to clinically appropriate levels.
The proportion of the total NHS budget spent on renal services is currently 2% and is set to rise [16]. According to the UK Renal Registry annual report 2007, there were 72 renal centres in the UK [1]. In 2006 there were approximately 19,000 patients receiving haemodialysis with 2.1% receiving home haemodialysis [1]. The cost of hospital based haemodialysis per patient was £35,023 per annum [17]. Dialysis treatment and transport account for 70% of the costs, with hospitalization (12%), medication (12%) and social service (6%) costs making up the remainder [18]. The cost of an inpatient day corresponding to renal complications, in particular those associated with access problems, was £295 [19]. Satellite unit-based costs were £32,669, whilst home dialysis costs were £20,764 per year [17].

The cost of the Redsense device per dialysis session over the 5 year lifetime of the monitor is shown in table 5. A new sensor patch is required for every patient at each dialysis session. The rechargeable battery is replaced by the manufacturer during routine servicing carried out at two to three year interval. The Redsense device is supplied with an individual battery charger, however, a recharging unit, capable of recharging up to 5 monitors simultaneously is also available at an additional cost of £65.00. Most patients in the UK receive haemodialysis treatment three times a week, and based on the number of patient receiving haemodialysis in 2006 [1] this equates to a total of 2.96 million dialysis sessions per annum. Using the Redsense monitor would add approximately £2.89 to the treatment costs per haemodialysis session. Minor miscellaneous and staff costs are not included in this calculation.

Table 5. Annual cost of using the Redsense blood loss detection device

<table>
<thead>
<tr>
<th></th>
<th>Costs</th>
<th>Costs/ dialysis session</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redsense Monitor</td>
<td>£495.00</td>
<td>£0.63</td>
</tr>
<tr>
<td>Sensor patch</td>
<td>£2.20</td>
<td>£2.20</td>
</tr>
<tr>
<td>Service costs</td>
<td>£50.00</td>
<td>£0.06</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>--------</td>
<td><strong>£2.89</strong></td>
</tr>
</tbody>
</table>

The MHRA data highlighted that a single death occurred due to venous needle dislodgement in each of the years 2004 and 2006. Use of the Redsense needle loss device for all dialysis patients, would cost approximately £8.6 million per annum, and would therefore be difficult to justify, since the risk of fatality is low. However, the Redsense monitor offers greatest benefit when used to monitor patients at high risk of venous needle dislodgement. Home haemodialysis patients are amongst those at the highest risk of undetected venous needle dislodgement and comprise approximately 2.1% of the total number receiving haemodialysis [1]. NICE has
recommended that all patients who are suitable for home haemodialysis should be offered this option [9] and using the Redsense monitor may increase the number of patients willing to consider home haemodialysis. The cost of using the Redsense monitor for all patients in this group would be approximately £180,000 per annum (£450 per patient per year).

Cost of VND
Analysis of the costs, including legal costs, associated with episodes of VND is beyond the scope of this review but NHS trusts will wish to take these into account when considering use of VND monitors.
The evidence available for this review was limited and mainly comprised ‘grey’ literature. It consisted of two peer-reviewed papers, an abstract, a briefing paper, journal club discussion, articles in professional newsletters and a personal communication awaiting publication.

The evidence reviewed indicated that although venous needle dislodgement might be under-reported, it is nevertheless very rare and we estimate that it occurs in less than 0.001% of all dialyses in England and Wales. It is, however, a hazard that can be fatal [2].

Renal patients are assessed prior to dialysis for the potential risk of VND. Generally patients at high risk include: restless patients; patients with cognitive impairment; isolated patients; patients with co-morbidities; or patients receiving home haemodialysis. From the evidence reviewed the Redsense blood loss detector may be of value in high risk patients [14], such as those receiving haemodialysis, at home or in isolation rooms, and restless patients.

Annually, the additional cost of using the Redsense monitor for patients on home haemodialysis would be approximately £450 per patient. In Rylance’s survey of UK renal units [10], 92% of respondents stated that they would use a blood loss detector if available, with the majority stating they would use it on all high risk patients and 20.8% on home haemodialysis patients. In addition, two renal centres indicated that they currently use enuresis alarms to detect blood loss.

The Redsense blood loss monitor is a ‘stand alone’ system and does not currently interact with the dialysis machine in any way. Ideally, venous needle dislodgement monitors should feed back to the dialysis machine and stop the venous blood pump if an alarm is triggered [12, 14, 20]. It should be noted, however, that adverse incidents arising from venous needle dislodgement can generally be prevented by constant monitoring of the extracorporeal circuit and adherence to protocols for securing and monitoring needles. EDTA / ERCA have issued 12 practice recommendations to help reduce the risk of VND and to detect blood leakage as early as possible [7].
We should like to thank the following for their contribution to this evidence review.

Dr Paul Rylance, Consultant Physician and Nephrologist, New Cross Hospital, Wolverhampton.

Jean-Pierre Van Waeleghem, Chair of the VND Project Group and past president EDTNA/ERCA.

Dr Catherine Meads, Lecturer in HTA, University of Birmingham

Roopa Prabhakar, Medicines and Healthcare products Regulatory Agency.

Dr Beverley Norris, National Patient Safety Agency.

Dr David Worth, Nephrologist, York Hospital NHS Foundation Trust.

Elizabeth J Lindley, Department of Renal Medicine, St James's University Hospital, Leeds.

Satyen Yadav, renal operational support sister, University Hospital NHS Foundation Trust, Queen Elizabeth Hospital

Mary Dutton, renal operational support sister, University Hospital NHS Foundation Trust, Queen Elizabeth Hospital.

Chris Pearson, Health Tec Medical Ltd.

Susanne Olauson, Redsense Medical Inc

Patrik Byhmer, Redsense Medical Inc.


(http://webstore.iec.ch/preview/info_iec60601-2-16%7Bed3.0%7Den.pdf)


Appendix 1: Supplier contact details

Supplier contact details

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