

PROBLEM

Eighty percent of the 40 million hospital patients in the U.S. annually require intravenous (IV) therapy, amounting to 150 million peripheral IVs.¹ Three percent of these IVs result in infiltration, causing complications such as erythema, pain, tissue necrosis, and even death.² Infiltration may be caused by faulty insertion of the catheter, the catheter working loose from the vein, or the IV drug increasing the permeability of the vein. Infiltration is a serious problem, especially for those patients unable to communicate with caregivers that they are experiencing pain. Infiltration events often lead to serious financial consequences. In early 2009, Wyeth Pharmaceuticals paid a \$6.7 million out-of-court settlement (a mislabeling claim) to a patient who suffered permanent nerve damage and the loss of a limb due to IV infiltration. The Ohio Hospital Association reported that IV infiltration is the most frequent allegation in pediatric patient monitoring, and multi-million dollar malpractice awards are not uncommon. For the cost of one infiltration per year, a hospital can hire ten full-time nurses to monitor IVs more often. Obtaining a means of detecting infiltration at an early stage is of paramount priority for healthcare providers.

SOLUTION

CW Optics has developed the ivWatch™ to help solve this problem. The ivWatch™ is a self-contained bedside unit consisting of a disposable skin contact sensor and an electronic unit that will notify a nurse that there is a problem. The contact sensor mounts proximal to the IV insertion site. It is connected to the electronic unit via optical lightguide. The nurse communicates with the electronic unit using a handheld PDA running proprietary software. The ivWatch™ collects signals autonomously and continuously from the insertion site during infusion. It can be incorporated into hospital networks for an integrated monitoring system. The ivWatch™ uses IrDA protocol to communicate wirelessly with the PDA. When the ivWatch™ detects an infiltration, it alerts the nurse via audio and/or visual alarms. The alarm notification can be sent via wired or wireless communication protocols. The ivWatch™ can be modified and integrated into infusion pumps. The optical lightguide and the IV fluid line can be incorporated into one conduit for easy operation and reducing cost.

COMPETITIVE LANDSCAPE

- Visual inspection by the clinical staff is the primary means for detecting IV infiltration.
- The MedRad device uses microwave technology to detect leakages of contrast agent. It is used during CAT scan procedures.
- The Venoscope is used for locating veins. It has very limited usage for detecting infiltration and nurse observation is still required.

FDA NSR DESIGNATION

FDA has determined ivWatch™ is a non-significant risk device (Q030041).

ANIMAL AND HUMAN STUDY RESULTS

An animal study was conducted at Eastern Virginia Medical School and a simulated infiltration study on healthy subjects was conducted at University of Virginia. Both studies demonstrated high specificity (97%) and sensitivity (98%) of ivWatch™. The animal study demonstrated that the minimum fluid volume can be detected by the ivWatch™ was 0.02 ml. In both studies, the ivWatch detected infiltration much earlier than the skilled IV nurses did.

FOCUS GROUP

A focus group of infusion nurses provided invaluable design suggestions for ivWatch™. The ivWatch™ was developed by implementing the suggestions made by the focus group, including a flat, smooth, and transparent surface for the contact sensor, and an audible and visual alarm system.

CLINICAL TRIALS

Two clinical trials will begin in Winter of 2009 to investigate the device safety and efficacy. An 800-patient trial will be conducted at Virginia Commonwealth University Hospitals and a trial specifically designed for pediatric patients will be conducted at Cincinnati Children's Hospital. The VCU trial will be focused mainly on adult patients undergoing peripheral IV infusions. The ivWatch™ will be placed on the patient to continuously collect signals from the infusion site. In addition to monitoring peripheral IV infusions, the Cincinnati trial will include monitoring of bolus injections of contrast agents.



MARKET SIZE

There are 40 million hospital patients in the U. S. per year receiving about 150 million peripheral IV infusions, and about 35 million of these infusions are for children. The patient monitoring device market was \$3.8 billion in 2008, with an annual growth rate of >6%. The revenue for ivWatch™ is projected to reach \$150 million by 2014.

REFERENCES

- (1) Yucha, C.B., M. Hastings-Tolsma, and N.M. Szeverenyi, "Differences among intravenous extravasations using four common solutions," J. Intraven. Nurs. 16, 277-281, 1993.
- (2) Kagel, E.M. and G.M. Rayan, "Intravenous catheter complications in the hand and forearm," J. Trauma 56, 123-127, 2004.

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Peripheral Venous* Infusion Risk

This is an estimate of risk for phlebitis or local tissue injury due to extravasation.
Risk derived from available evidence, CCHMC data and CCHMC expert opinion, subject to review and change as further evidence becomes available.

This does not apply in situations of emergency medical treatment.
If a medication is not on this list please refer to the CCHMC formulary or contact pharmacy (9-4291) for information

Red High Risk	Yellow Intermediate Risk	Green Low Risk
<p>Acyclovir</p> <p>Calcium (add salt forms)</p> <p>Dextrose $\leq 12.5\%$</p> <p>Dopamine</p> <p>Mannitol 20% & 25%</p> <p>Promethazine</p> <p>Potassium (>40 mEq/L)</p> <p>Sodium bicarbonate</p> <p>Sodium chloride $> 3\%$</p> <p>TPN > 950 mOsm/L</p> <p>Vancomycin</p> <p>Chemotherapy Drugs</p>	<p>Amphotericin B (conventional)</p> <p>Ciprofloxacin</p> <p>Dextrose $\leq 12.5\%$</p> <p>Erythromycin</p> <p>Ganciclovir</p> <p>Lorazepam</p> <p>Magnesium sulfate (bolus)</p> <p>Midazolam</p> <p>Morphine</p> <p>Nafcillin</p> <p>Ondansetron</p> <p>Non-ionic Radiology Contrast</p> <p>Pentamidine</p> <p>Phenobarbital</p> <p>Phenytoin</p> <p>Potassium ≤ 40 mEq/L</p> <p>TPN ≤ 950 mOsm/L</p>	<p>Amikacin</p> <p>Amphotericin</p> <p>Amphotericin B Liposomal</p> <p>Amoxicillin</p> <p>Cefazolin</p> <p>Cefepime</p> <p>Ceftriaxone</p> <p>Cefuroxime</p> <p>Cefuroxime</p> <p>Cefuroxime</p> <p>Cefuroxime</p> <p>Chloramphenicol</p> <p>ESLR</p> <p>Diazepam - 10%</p> <p>Doxorubicin</p> <p>Fentanyl</p> <p>Fosfomycin</p> <p>Furazolidone</p> <p>Gentamicin</p> <p>Heparin</p> <p>Imipenem</p> <p>IVIG</p> <p>Levofloxacin</p> <p>Macropin</p> <p>Methylprednisolone</p> <p>Normal saline</p> <p>Pipercillin</p> <p>Pipercillin/tazobactam</p> <p>Tazacillin</p> <p>Tetracycline</p>

*Peripheral Venous Access is defined as any Venous Access Device whose tip lies outside the
Right Atrium, Superior / Inferior Vena Cava, or the Brachiocephalic Veins