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Creating the Evidence: Remicade© Infusions and Vital Sign Monitoring

Ellen Servetar, MS RN CPON, Debra Schissel, RN CPON, and Edward Hoffenberg, MD

Background In 2003, the Infusion Center in the Center for Cancer & Blood Disorders at TCH expanded its services to include any patient requiring an ambulatory infusion. Our first clients included the Gastroenterology and Rheumatology services that were treating patients diagnosed with Crohn's disease and Juvenile Rheumatoid Arthritis with Remicade© (Infliximab), a monoclonal antibody. Previously, these patients had been receiving their treatment either in the Emergency Department or were being admitted as Short Stay patients.

At the time, infusion orders included monitoring the patient for signs and symptoms of acute reactions and other reported rare side effects, such as hypotension, with a full set of vital signs every 30 minutes. After a year of delivering care to these patients, the nurses noted that transfusion reactions were infrequent and no changes were being made to the patient's treatment plan based on vital signs. The nurses requested the ordering physicians to decrease vital sign frequency, however, in response, the physicians stated that it was the recommendation of the manufacturer to monitor vital signs frequently and that every 30 minute vital signs was considered the "standard of care". Faced with this dilemma, the nurses chose to investigate the evidence to support and facilitate a change in practice. Therefore, the purpose of this study was to determine whether every 30 minute vital signs were needed to detect children's reaction to Remicade© infusions.

Design/Methodology A literature review was undertaken, the manufacturer's recommendations were examined, and policies and procedures used at other hospitals and home care agencies were obtained. It was concluded that there was no evidence to support the standard of every 30 minute vital signs during Remicade© infusions and that in order to change practice we would need to study the problem.

A non-experimental, descriptive study design was utilized with a convenience sample of all patients scheduled to receive Remicade© in the Infusion Center at TCH. Over a 20 month time period, 24 patients were enrolled in the study and over 100 infusions were documented from consenting patients. A data collection form was developed to standardize the information gathered, including: patient's age and sex, diagnosis, concomitant medications, pre-medications, Remicade© dose, vital signs, adverse events, and clinical interventions related to the infusion.



The investigators obtained approval for the study from the Colorado Multiple Institutional Review Board prior to obtaining informed consent/assent from the guardian and patient. The investigators also met with the Infusion Center nurses to explain the study and respond to questions. Vital signs were obtained every 30 minutes throughout the infusion with an average infusion lasting three hours. Study data were recorded by the nurses throughout the infusion.

Findings

| Variable | Subjects N=24 | Total infusions N=104 | Intervention |
|--|---|-----------------------------|--|
| Age | 5 – 20 yrs; Mdn 15 yrs. | | |
| Gender | 8 Female; 16 Male | | |
| Diagnosis | Crohns disease | 76 | |
| | Ulcerative colitis | 15 | |
| | Indeterminate IBD | 1 | |
| | Uveitis | 6 | |
| | Juvenile rheumatoid arthritis | 2 | |
| | Wegeners granulomatosis | 2 | |
| | Iritis | 1 | |
| | Vasculitis/urticaria | 1 | |
| Concomitant medications | Immunomodulator (Methotrexate or Azathioprine) | 24 | |
| Pre-medications: physician choice | None | 83 | |
| | Acetaminophen, Diphenhydramine, &/or Methylprednisolone | 21 | |
| Adverse reactions | Anaphylaxis: onset within 10 minutes of infusion initiation | 1 | Infusion stopped; reaction treated |
| | Chest pain | 2 | No change in vital signs; infusion completed without order changes |

The findings from this study supported the assumption that adverse reactions during Remicade© infusions are rare and they do not necessarily occur in relation to the time vital signs are being taken. Thus, nurses' time spent monitoring vital signs could be decreased without compromising patient safety or quality. Further, the standard of care could be changed to "close monitoring for adverse events and IV infiltration" without every 30 minute vital signs. Based on the evidence, standing orders were revised so that the current *standard of care* at The Children's Hospital for Remicade© infusions is to obtain a baseline set of vital signs at the start of the infusion and another set of vital signs prior to discharge of the patient from the Infusion Center.

Significance

Overall, this study directly resulted in a change in practice by decreasing nurses' time spent taking vital signs from a minimum of 7 times during an infusion to 2 times, with close monitoring throughout. It also demonstrated that vital sign monitoring did not affect patient outcomes or treatment decisions. This change was well received by patients, families, and staff. Reduction of vital sign monitoring allowed nurses to redirect their efforts to other necessary patient care demands. This research further reinforces the importance of nurses undertaking systematic investigations in order to expand the scientific underpinnings from which we practice.