

# Establishment of the First home administered Natalizumab Infusion Service for the Treatment of Relapsing Remitting Multiple Sclerosis (RRMS)

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## Introduction

Relapsing remitting multiple sclerosis (RRMS) is an immune-mediated, progressive demyelinating condition of the central nervous system. Advances in pharmacological treatment have revolutionised long term outcomes for RRMS patients; one such treatment is the monoclonal antibody to alpha-4 integrin, natalizumab which is increasingly prescribed first line. The administration of this intravenous infusion on a 4 weekly basis, and the numerous adverse effects often pose a great inconvenience to patients requiring them to attend hospital based centres in order to safely receive the treatment.

## Objectives

We aimed to establish a safe, patient centric home infusion service for patients being treated with natalizumab as monotherapy for RRMS. Establishment of the at home infusion service addressed regulatory requirements, risk minimisation strategies for known toxicities, occupational health and safety concerns and medication management (including storage and transport).

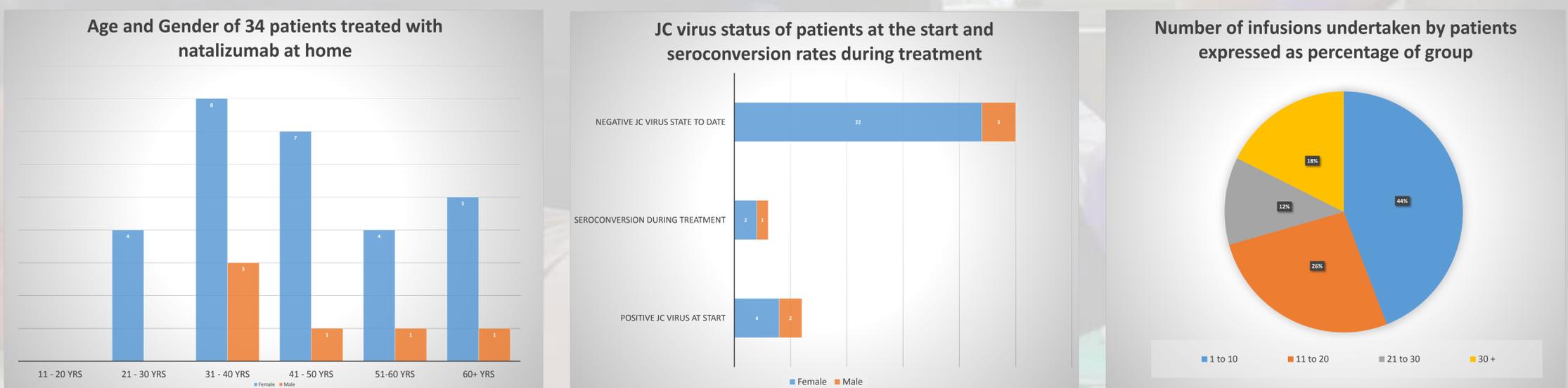
## Methods

An accredited, hospital-substitute service (chemo@home) developed a protocol for the administration of natalizumab at home. The protocol was approved by the health services Expert Reference Group (Neurology) and Medication Advisory Group. Medical governance of the patients is retained by the neurologist. All health professionals (medical, nursing and pharmacy) completed the relevant sections of the 'Tysabri Australian Prescribing Program' (TAPP). JC Virus status was monitored at start and on a 6-monthly basis for seroconversion. Resources for the management of adverse reactions (including defibrillators, resuscitation equipment and medications) were readily available in the patient's home. All pre-infusion regulatory and clinical requirements were fulfilled. Natalizumab infusions were prepared and administered at the patient's home by nursing staff using a closed system.

In addition to the above requirements, specific to the administration of natalizumab, chemo@home provided a comprehensive hospital-substitute service. This includes: patient education, infection control, medication reconciliation, falls risk assessment, skin integrity assessment, nutrition assessment, referral to other services, correspondence to treating specialists, cold chain storage, waste management and vehicle compliance. Chemo@home is fully accredited by the Australian Council on Healthcare Standards.

## Results

Between February 2014 and January 2017, 34 patients received 494 doses of natalizumab at home. A median of 11 infusions were given (range 1-37).



Whilst 3 patients seroconverted to JC virus positive during the treatment, there were no cases of progressive multifocal leukoencephalopathy (PML). In all these patients, the titre was considered low thus the treating clinicians' opted to continue therapy. There were no episodes of anaphylaxis-hypersensitivity, no unexpected toxicities and no additional safety concerns identified. Patient satisfaction was high. Patients reported the home service made treatment significantly easier and less stressful than in a hospital, and saved travelling time.

## Conclusion

To our knowledge this is the first establishment of a fully accredited, hospital-substitute service (chemo@home) in Australia which gives RRMS patients access to treatment at home with natalizumab. It was achieved without compromising safety and with a high level of patient satisfaction. A further patient experience questionnaire will be undertaken to assess the impact on patients and their families of home natalizumab therapy.