Implementation of RiskMAPs to Support Quality Use of Pharmaceuticals: Opportunities and Challenges

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Patient Perspectives on the TOUCH™ Protocol

(Tysabri® Outreach: Unlimited Commitment to Health)

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RiskMAP and **TOUCH**™ protocol:

- developed to track cases of **PML** (progressive multi-focal leukoencephalopathy) and other adverse events associated with Tysabri® administration.
- the end result of FDA Hearings in March 2006.

Patients

understand and agree

with the purpose of TOUCH™

BUT

some have experienced concern and confusion about the enrollment process

and

problems with scheduling their infusions.

Patients with Multiple Sclerosis may suffer from cognitive impairment caused by their disease.

Those for whom Tysabri® is prescribed
are also likely to have declining overall health
since Tysabri® is not considered a first line drug
for the treatment of MS.

These patients should not be further stressed with a confusing enrollment process to obtain Tysabri®.

The process for a patient to receive Tysabri®
begins with an appointment
with the prescribing neurologist to fill out the
TOUCH™ Patient / Prescriber Enrollment Form,
a 4-page document which becomes
the informed consent and prescription for Tysabri®.

At this appointment, the neurologist

- explains the risks/benefits of the drug
  and of the procedures to infuse it
- gives the patient time to ask any questions and to fill out and sign the enrollment form.

Then the neurologist signs the form and faxes it to Biogen.

Biogen now becomes the liaison for the final steps of the enrollment process.

Biogen will:

- assign the patient identification number
- ensure all the paperwork is filled out properly,
- ensure the patient has insurance coverage,
- identify and/or assign an infusion site if required,
- and notify the neurologist's office of any problems that need attention,
- and notify the infusion center that the patient has been approved for infusion.

When all these items have been completed
the patient has been enrolled into the **TOUCH™** program.

The patient enrollment number is

- a unique identification number
  that stays with the patient as long as they receive Tysabri®.

- attached to
  - all of their paperwork,
  - each vial of Tysabri® they receive.

Two types of pharmacies can dispense Tysabri®:
Specialty Pharmacies
and
Central Pharmacies.

Both can order on a “just in time” basis as the patient is scheduled to receive an infusion.

BUT a **Central Pharmacy** is allowed to order Tysabri® without an enrollment number
to dispense for unscheduled patients.

When the unidentified vial is dispensed,
the patient identification number is assigned to that vial
meeting the mandated RiskMAP protocol
for controlled distribution of Tysbari®.

BEFORE each infusion
TOUCH™ protocol requires completion of a mandatory **“Pre-Infusion Checklist”** by the infusion site staff.

The checklist includes
a **"Notice of Patient Authorization“**
or
a **"Notice of Patient Discontinuation"**
for the infusion of Tysabri.

If an authorization is not on file
the infusion procedure stops there.

After authorization is confirmed

4 questions

must be read aloud

and vocally responded to by the patient.

IF the patient answers **YES**

to **any** of these questions,

the infusion site staff must call the patient's neurologist prior to commencing the infusion.

IF the neurologist can not be reached

then the infusion is rescheduled.

Once the infusion has been completed,
the form is signed by the infusion site staff
and faxed to Biogen.

This form must be completed and faxed
within 24 hrs of completion OR
cancellation of the infusion.

If these steps are not followed,
the infusion site could lose their certification.

The **Notice of Patient Authorization**
is one of the **reminder tools**
that the Neurologist is sent
after the patient has been on Tysabri
for 5 months
and every 6 months thereafter
as long as the patient is receiving Tysabri.

The goals

of the TOUCH protocol Pre-Infusion checklist

are **safety and tracking of PML**

and any other adverse events

that may occur during the Tysabri infusion.

Because Tysabri was re-released less than a year ago, the TOUCH protocol is a relatively new process.

The reminder tools that are in place haven’t had much time for feedback with regard to their effectiveness.

The prescribing neurologist has an obligation
to make sure the patient is well informed
with regard to understanding the forms
and information of the RiskMAP,
as well as enrollment in the **TOUCH™** protocol
and
understands the procedures fully
even if the patient has cognitive issues
and is illiterate.

Questions:

- How do these issues get resolved?
- Are these issues for which the infusion site personnel should be responsible?
- Or are they the responsibility of the treating neurologist?
- **Literacy?**

Some questions that patients have asked:

- What is the ***real purpose*** of the TOUCH protocol?

To my knowledge, no one at MSActiveSource was able to answer this question.

I have responded that its purpose is to minimize the risk of PML.

Some questions that patients have asked:

- Why can’t MSActiveSource help me with insurance related questions?
- act as a liaison to assist with insurance approval problems?

Several patients have complained about the difficulty in obtaining accurate insurance coverage data, i.e. out of pocket expenses, reimbursement information, what part of the plan covers the infusions. They get bounced around between the doctor’s office, the infusion center, and the insurance company.

Some have been playing the game for over 9 months.

Some questions that patients have asked:

- Can I switch infusion sites when I go on extended vacations?

No one has been able or willing to answer this question for several patients.

Some questions that patients have asked:

- How many days can I slide my infusion appointment?

One week either side from my prior infusion?

The recommended time between infusions

is 4 weeks.

Is it possible to go 3 weeks or 5 weeks?

Other topics for discussions:

- **Continuity of care at the infusion sites.**

Do the patients have the same infusion staff person each time they are infused?

This is important for the safety goals:

PML observation - cognitive changes.

One patient I interviewed said
the Pre-Infusion checklist was not even covered before her infusion!

Other topics for discussions:

- Could the drug be available outside of the system?
- Infusion sites not receiving the drug in time for infusion appointments.

Why is this happening?

It places undue hardship on MS Patients, especially those in rural areas who have to travel great distances only to find they have to be re-scheduled.

Also, there have been several incidences of the drug being mixed improperly with D5W instead of saline.

RECOMMENDATIONS:

- Mandatory recurrent or periodic retraining of infusion site personnel and neurologists.
- Survey of patients after 6 months of infusions to check on their opinions of the infusion site experience.
- Make it very clear during the neurologist training process, who initiates the TOUCH enrollment process for the patient.
- Solve the drug delivery process to the infusion sites.

Thank you!

for allowing me the opportunity
to speak to you
about the RiskMAP and **TOUCH™** protocol
for Tysabri®.

and for giving patients a voice.