

Summary of research results

In this research study a total of 10 interviews were conducted with 6 health professionals (doctors, pharmacists and nurses) and four people living with inflammatory arthritis who have been treated with biologic therapy. Based on these interviews, I developed a new theory called "Pragmatic Situational Practice Outcomes", which helps to explain thoughts and beliefs about reporting suspected side effects to biologic medications (called adverse drug reactions or "ADRs"). The theory explains why rheumatology healthcare professionals and people living with inflammatory arthritis, may report or underreport suspected side effects to medications, associated with the use of biologics, to the U.K. Yellow Card Scheme. The Yellow Card Scheme is a system run by the U.K. medicines agency to allow reporting of suspected side effects seen with different medications.

The theory I developed includes key definitions (below).

- "Pragmatic" is defined as the ability of healthcare professionals and patients to make different decisions in different situations. This means they weigh up practical considerations, thoughts, feelings, and emotions, and then make practical choices, judgments, and decisions.
- "Situational" is defined as the circumstances (i.e. context) in which healthcare professionals and patients exist, function, and survive, which includes conditions such as healthcare professionals and patients making time to report suspected side effects and other factors such as healthcare professionals and patients' existing level of knowledge and understanding of the Yellow Card Scheme, and healthcare professionals' existing workload demands.
- "Practice" is defined as healthcare professionals and patients' practical thoughts, feelings (including emotions), actions and interactions relating to a suspected drug side effect. "Practice" also includes "process", which are the things that healthcare professionals and patients say and do to report a suspected side effect using Yellow Card reporting.
- "Outcomes" is defined as real or expected consequences of healthcare professionals and patients' decisions.

How the theory works in practice is summarised (below)

Rheumatology healthcare professionals, like doctors, nurses and pharmacists and people living with inflammatory arthritis, exist within a complex situation that requires them to be "pragmatic", to deliver and receive treatment. This strongly determines other circumstances in their lives and work and everything else is viewed as less important. This means healthcare professionals and patients weigh up "pragmatic" thoughts, feelings, and emotions, and then make "pragmatic" choices, judgments, and decisions, in any given clinical situation faced. These decisions and choices must fit within their "situational" existence and support their key goals. Their "pragmatic" approach is a daily flexible rhythm of survival. It functions as a strong influence that both guides and determines their "situational" "practice" and the "outcomes" they reach, which explains why they both report and underreport suspected drug side effects.

A further summary of the reporting behaviour of patients and healthcare professionals is below.

Patients

A patient is likely to report suspected side effects, associated with the use of biologics, to the U.K. Yellow Card Scheme, if certain conditions apply, for example, a patient is aware of the Yellow Card Scheme and knows how to report to it. A patient might consider possible outcomes of Yellow Card reporting such as whether their report is going to be read and an answer received, which are both discouraging uncertainties. Some patients, at the same time, will also consider other options to report the suspected side effect, which may be an alternative to the

Yellow Card system or in combination with it. For example, a patient can report a suspected side effect to their rheumatology team.

Healthcare professionals

A healthcare professional is also likely to report suspected side effects, associated with the use of biologics, to the U.K. Yellow Card Scheme, when certain conditions apply, for example, a patient has experienced a rare reaction. A healthcare professional will also consider other options to report the suspected drug reaction, as an alternative to the Yellow Card system or in combination with it. For example, a suspected drug reaction could be reported in the patient's medical notes.