

Executive Summary: Adverse Event Pathway Project (AEPP)

Early Recognition and Rapid Treatment of Immune-related Adverse Events (IrAE)

Joint Working Project between Hull and East Yorkshire Hospitals NHS Trust and Bristol-Myers Squibb Pharmaceuticals Ltd

Final version

Parties to the Agreement (Partners)

- Hull and East Yorkshire Hospitals NHS Trust (HEY)
- Bristol-Myers Squibb (BMS)

BMS works with NHS organisations through a joint working “BMS NHS Support Team” which provides support to the NHS with Project Management, Project Execution, Workshop Facilitation, Pathway Mapping and Stakeholder Engagement. BMS have engaged Quintiles to provide resources to the BMS NHS Support Team on behalf of BMS for the project. The work undertaken as part of this Joint Working arrangement is by no means intended nor shall act in any way as to promote any product to the NHS.

Produced by Bristol-Myers Squibb

1. Project Background

Immuno-oncology (I-O) agents have led to a paradigm shift in the way some cancers are treated. Their adverse event profile is very different from standard chemotherapy. Adverse events are generally immune related and these present in many different ways. The unfamiliarity of immune-related adverse events within the health service can lead to poor management and this will be directly linked to the outcomes of a patient. At present there is an uncertainty around:

- the number of patients experiencing IrAEs in the community
- where they report their IrAEs
- how long it takes them to get optimal treatment.

It was against this background that the partners sought to work together to plan a service that maximises the chances of immune related Adverse Events (IrAEs) associated with I-O agents being recognised and treated quickly.

Clinical Implications of Immune-related Adverse Events (IrAEs)

- IrAEs can be serious and potentially fatal
- IrAEs need to be identified, diagnosed and treated by HCPs within a realistic short time frame with an aim of giving the patient the best chance of therapeutic success
- Patients and their healthcare professionals need to remain vigilant throughout and after treatment

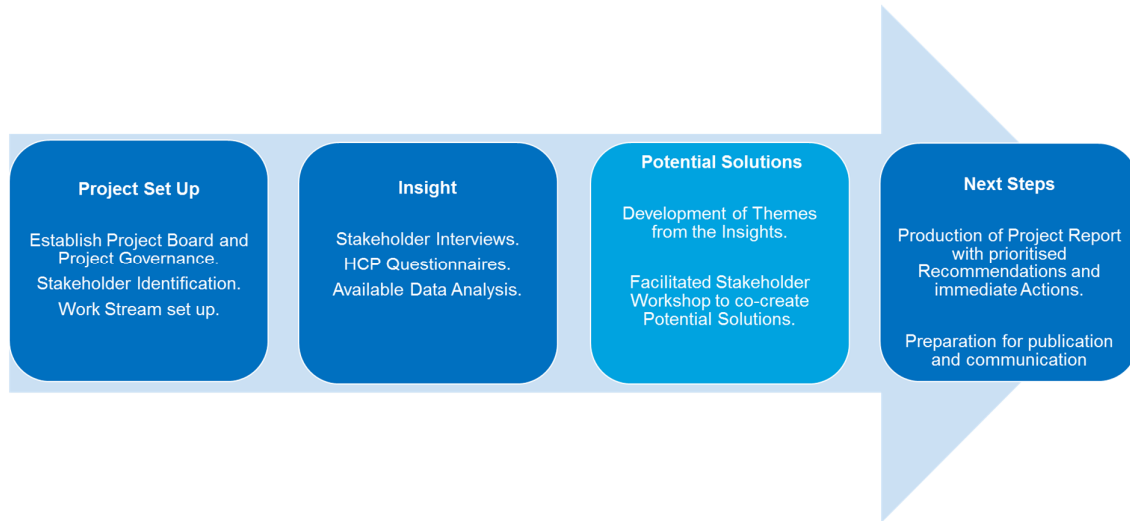
2. Project Objectives

The project intent was to

- Define the real issues in terms of the management of IrAE in order to develop a system that captures, identifies and treats the presentation of an IrAE quickly and effectively. Currently these systems do not exist in the hospitals involved.
- Produce a peer-generated set of recommendations which describe essential elements needed in a service that is effective for the Early Recognition and Rapid Treatment of Immune-related Adverse Events (IrAE). These should be applicable to any configuration of hospital organisation and make a significant contribution

towards addressing the issues described above. Implementation of the peer-generated recommendations is not part of this project.

3. Process Overview



4. Project structure and deliverables

4.1 Six workstreams

- The project had six workstreams defined by the project board:
 - Workstream 1 Communication
 - Workstream 2 Stakeholder Engagement
 - Workstream 3 Healthcare Professional (HCP) Questionnaires
 - Workstream 4 Internal Review of Acute Oncology and Hotline
 - Workstream 5 Mapping Current Pathway*
 - Workstream 6 Stakeholder Workshop

**Whilst the various routes through which patients enter and travel through the service were discussed and considered in terms of generating an optimal solution, the paucity of data and the inconsistency of the current pathway precluded the production of a quantifiable map.*

4.2 Constituent activities

- The project consisted of the following:
 - 15 Telephone/Face to Face Interviews completed and were complemented by additional ad-hoc follow-up discussions.
 - Participating Disciplines included:

- Medical Oncology
 - Chemotherapy/Oncology Nursing
 - Clinical Nurse Specialists
 - Nurse Practitioners
 - Infective Diseases
 - Hepatology
 - Endocrinology
 - Ophthalmology
 - Cardiology
 - Gastroenterology
 - Rheumatology
- A multi-disciplinary Workshop was held
 - for key stakeholders to validate the insights and feedback gleaned from the HCP Questionnaires and stakeholder engagements.
 - to refine a set of recommended high impact actions developed by the stakeholder group, to help towards achieving a system for quick and appropriate recognition and management of IrAEs.
 - A Project Report that will cover:
 - how IrAEs are recognised, identified and managed by HCPs
 - the effectiveness of information sharing and communication between HCPs
 - the quality and accessibility of information recorded throughout the services which would assist in the assessment of service effectiveness
 - areas of effectiveness which could be used to create best practice guidelines for safe implementation of treatment pathways for patients presenting with IrAEs

5. Major recommendations

- HEY Oncology and Acute Medicine representatives to develop a Patient Profiling methodology to identify patients at higher risk of IrAE. This can be delivered as a research project and should be linked to the establishment of an IO MDT (below). This can be commenced immediately.

<ul style="list-style-type: none">• The Patient Information DVD developed for Castle Hill Hospital should be rolled out for use at all sites immediately. A Medical Oncologist at Castle Hill has been identified to lead this.
<ul style="list-style-type: none">• Using the existing Vasculitis Rheumatology MDT as a template, immediately identify IO Champions in medical specialties and Oncology to form a pilot MDT. The MDT should meet monthly with virtual access available to provide advice to specific IrAE cases in between.• Develop an MDT Training plan.
<ul style="list-style-type: none">• Develop a costed Business Case (with supporting standard operating procedures) for an Advanced Nurse Practitioner led, health-economy wide, single point of access (triage) service.
<ul style="list-style-type: none">• Develop a business case for additional Autoimmune Conditions rapid access assessment service akin to that currently delivered in Rheumatology.
<ul style="list-style-type: none">• Develop standard treatment protocols for IrAE patients, including Organ Specific Escalation Protocols.

6. Acknowledgements

Authors:

- Paul Sutton, IQVIA
- Prof Anthony Maraveyas, HEY

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- Jeremy Pelton, IQVIA
- Sarah White, IQVIA