Welcome to the 2nd edition of the British Association of Dermatologists Biologic Interventions Register (BADBIR) study patient newsletter. Here are some news updates since our first edition in 2016:

**Who are we?**
BADBIR is a drug safety register interested in studying the long term safety of drug treatments for psoriasis. The study started in 2007 and our aim is to recruit as many participants receiving conventional systemic and biologic treatments until 2028 (current study end date). A biologic is a protein based drug taken from living cells handled in a laboratory. Biologics target specific parts of the immune system that play a role in psoriasis.

**Purpose of the study**
Biologic agents have been tested for safety in clinical trials over a relatively short period of time.

BADBIR was established to assess the long-term safety of biologics by following a real world population of psoriasis patients from all areas of the United Kingdom and Republic of Ireland.

**Safety events**, or reactions, are medical occurrences that may or may not be related to the drug you are receiving. We collect all safety events to investigate whether a drug is related to safety events reported.

**The Process**
Most of the dermatology centres in the United Kingdom and Republic of Ireland are taking part in this study and, subject to patient consent, the dermatology team provide data to BADBIR. This is how:

**Step 1**: Your dermatologist or someone in his/her team will discuss BADBIR with you, if you meet the following criteria for the study:
- Have a diagnosis of psoriasis
- Provide written informed consent
- Currently under the care of a dermatologist and receiving drugs for psoriasis included in BADBIR

**Step 2**: Via your dermatologist, BADBIR will follow your progress with treatment on a regular basis.

**Step 3**: Your dermatologist or someone from his/her research team will enter your treatment details and safety events on to the secure BADBIR database.

**Step 4**: Additionally BADBIR links with other national registries to ensure the greatest capture of safety events experienced as long as the patient is participating in the study. Details of how BADBIR links with national registries can be accessed via the following web link: www.badbir.org.uk

**Step 5**: The BADBIR research team processes and analyses all data. Rates of safety events are compared between the two study groups (conventional and biologic).

**Step 6**: The results will ultimately be used to provide healthcare specialists and you (the patient) with a better understanding of any increased risk of the newer therapies.

**Comparing biologics**

<table>
<thead>
<tr>
<th>BIOLOGIC</th>
<th>CONVENTIONAL</th>
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<tr>
<td>Humira (adalimumab)</td>
<td>Actretin</td>
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<td>Stelara (ustekinumab)</td>
<td>Ciclosporin</td>
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<td>Benepali (etanercept biosimilar)</td>
<td>Fumaric Acid Esters</td>
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<td>Cosentyx (secukinumab)</td>
<td>Hydronycuramide</td>
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<td>Taltz (ixekizumab)</td>
<td>Methotrexate</td>
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<td>Oral PUVA</td>
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* In the past, BADBIR also recruited patients receiving Raptiva (efalizumab), Remicade (infliximab) and up until recently Enbrel (etanercept)
BADBIR has been collecting patient data for 10 years now making it a rich data source. Since 2007, there have been many milestones achieved. The timeline below illustrates some of these milestones:

- **September 2007:** Pilot phase begins with 1st patient registered to BADBIR
- **February 2010:** 1,000th participant registered at the East Lancashire Trust
- **August 2008:** Main study begins following pilot year. Registrations are accepted for 4 biologic treatments
- **March 2012:** Paper summarising study protocol published
- **March 2015:** 10,000th participant registered at Great Western Hospitals, Swindon
- **June 2015:** First paper published using BADBIR study data
- **March 2017:** BJDeblishes BADBIR paper on patterns of biologic therapy use
- **May 2017:** 14,000th participant registered at Guy’s and St Thomas’ Trust
- **September 2015:** Landmark amendment for BADBIR - study end date extended to 2028 and under 16s now accepted on to BADBIR
- **2016:** Registrations now accepted on 3 new biologic treatments.
- **June 2012:** 5,000th participant registered at Kettering General Hospital
- **2028:** BADBIR end date

Visit our website www.badbir.org/Participants/ to find out more about BADBIR

We invite staff and patients to follow @BADBIR on twitter

Thanks to all BADBIR participants!
We currently have **14,675** patients on the registry (15/08/2017) and recruit from **156** centres across the United Kingdom and Republic of Ireland.

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Introduction

Drug guidelines provide recommendations on how biologic therapies should be used. However, in some situations doctors may decide to prescribe outside the recommendations. For example, by changing the number of days between the doses or adding in a traditional conventional drug. These changes are often made to get psoriasis under better control.

Research aim

To understand how biologic drugs (Humira, Enbrel and Stelara) were used for the treatment of psoriasis alone and together with conventional treatments such as methotrexate.

What did we find?

During the first 12 months of starting a biologic treatment:

25% of patients were prescribed a traditional conventional therapy in combination with biologic therapy with methotrexate being the most common.

What does this information mean for patients with psoriasis?

Most patients were treated with the recommended dose. The use of other conventional therapies in combination with biologic therapies should be considered when measuring response to treatment and risk of side-effects.
3) Comparing how effective biologic therapies are in improving the quality of life in patients with psoriasis

Research aims
1) To compare how effective different biologic therapies (Humira, Enbrel and Stelara) are on improving quality of life using Dermatology Life Quality Index (DLQI) and European Quality of Life - five dimensions questionnaire (EQ-5D). A high DLQI score (maximum possible score 30) indicates poor quality of life. In contrast, a high EQ-5D average score indicates good quality of life.

2) To identify factors associated with improvements in quality of life.

What did we find?
- The use of biologic therapy was linked with big improvements in quality of life over the first 12 months of treatment:

The average DLQI score improved

![Figure 1. Bar chart showing the proportion of patients scoring 0 or 1 for DLQI vs an improvement of 4 or more points from baseline at 6 and 12 months.]

Nearly 50% of patients reported a total DLQI score of 0 or 1 (indicating no impairment in quality of life) at 6 and 12 months.

The average EQ-5D score improved

![Figure 2. Bar chart showing the average EQ-5D score at baseline and 6 months.]

The five dimensions of the EQ-5D are:

- Mobility, Self-care, Usual activities, Pain/Discomfort and Anxiety/Depression.

The biggest improvement was in the pain/discomfort area and the smallest improvement was found in the self-care area.

Factors associated with improvements in quality of life

Improvements in quality of life were influenced by the choice of biologic therapy, lifestyle choices and diagnoses of other medical conditions:

- Patients receiving Enbrel were less likely to achieve a total DLQI score of 0 or 1 compared to patients receiving Humira
- Female patients, patients with multiple medical conditions, current smokers as well as obese patients were also less likely to achieve a total DLQI score of 0 or 1 or show improvement in the EQ-5D.

What does this information mean for patients with psoriasis?

We found that biologic therapies improved the quality of life for psoriasis patients and is influenced by (i) the choice of biologic therapy, (ii) lifestyle characteristics (e.g. obesity and smoking) and (iii) other medical conditions. Lifestyle changes, including quitting smoking and weight loss for obese patients, may improve the effectiveness of biologic therapies. The findings should be also considered along with the other known benefits and risks of biologic therapies to help inform selection of the best therapy for patients with psoriasis for improvements in quality of life.

Here is a full list of references of these summaries including the main author and full title of the paper:

References

