BADBIR

BADBIR Newsletter
November 2012
BADBIR Adverse Events
Special Supplement

This supplement is intended to help clarify the reporting of adverse events to the British Association of Dermatologists Biologic Interventions Register (BADBIR). Around 35 adverse events are reported to BADBIR everyday. The pharmacovigilance team review each event and assess it according to the information given. Therefore, complete, accurate and informative recording of adverse events is essential.

What information needs to be reported

The only information we know from an adverse event is what is entered by you on the database. From this information we have to extract what the event is, what occurred, how serious the event is and how it was resolved. It is therefore important to report accurate and clear information.

When reporting an adverse event it is essential the following information is documented:

- A description of the event
- Any medicines suspected of causing the event
- Date of onset of event
- Details of how the event was treated including any drugs administered
- Any new drugs started as a result of the event
- Any new diagnosis as a result of the event
- The outcome of the event and stop date

Additional Information

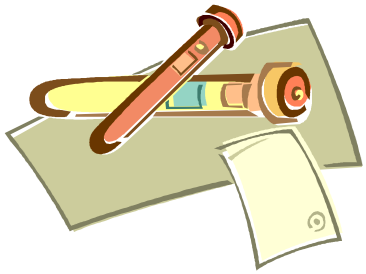
If for any reason, complete information is not available at time of reporting please state this in the event description box during data entry.
On occasion, we will request extra information on reported events. We will request this information via the querying system on the BADBIR database. It is important the queries are answered as soon as possible with as much information as possible.
A guide to using the querying system can be found by following this link *www.badbir.org/databasefaq.aspx*

Clinically Significant Lab Results

All **clinically significant** laboratory findings need to be reported to BADBIR as adverse events. This is not necessarily just an abnormal lab result but a result that requires further actions to be taken, is indicative of a worsening or an exacerbation of a current disease or indicates a new disease process.

When reporting clinically significant results please ensure the following information is given:

- Which results were altered?
- What effect did these have on the patients health?
- Where any drugs prescribed?
- Was there an end diagnosis?



The following is how NOT to report these events as they give us no relevant information of the event or what the end result was.
Raised ALTs
Raised Cholesterol
Hb 13.2, Plts 305, Wbc 1.2

Examples of Serious Adverse Event Reporting

Bad Examples

"abdomen uss"
Indication for scan not given. Ideally need symptoms leading to scan being performed and outcome of the scan. Was there any diagnosis or new drugs started

" platelet count had dropped to 91x10^{9}L."
Is the drop in platelets clinically significant, if so why? Were any further investigations done? Was there a diagnosis or change in medicine?

"BCC"
Not enough information. Would ideally like to know site of BCC, histological classification, what treatments were given and outcome of those treatments.

"Nodular BCC excised."
This was reported as non serious. It is important to remember that even if the cancer has been excised and resolved, it is still a Serious Adverse Event. This is also a medically important event and would require the completion of an ESI Form.

Influenza
This event was entered as serious, however not enough information is reported. The description does not give symptoms, reason the event is serious, treatment given, or outcome.

Good Examples

"Back pain for 4 days (immobilised) GP arranged for transfer to hospital in ambulance (03/03/2012). ECG done. MI diagnosed. Some SOB. No chest pain. Admitted that day for PPCI to RCA following inferior STEMI. Then transferred to CCU. Discharged from CCU 10/05/2012. Echo pre discharge showed good systolic function."
Reason is good: gives in depth event description , diagnosis and discharge date.

"Diagnosis of a BCC with squamous differentiation located on the left ear helix. We removed the tumour in a 2 stage, 9 section micrographic (Mohs) procedure. The resultant defect measured 34 x 20 mm and we have transferred the patient to Plastic Surgery for reconstruction on 24/08/2011."
Reason is good: Gives diagnosis, site of BCC and treatment

Smear test showed severe dyskaryosis. Seen in colposcopy clinic on 25/09/2012. Examination revealed moderate aceto white into canal. Loop excision treatment performed. Histology revealed CIN 3. For review in colposcopy clinic in 6 months.
Reason is good: gives histological classification, action taken, and outcome.

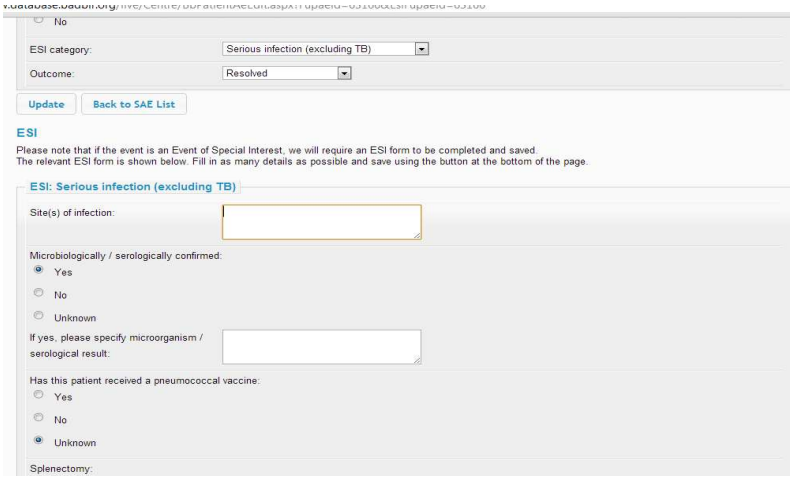
Decline in renal function - admitted from dermatology clinic after a decline in his renal function was noted, stayed 1 night. His Cr had increased from 100 to 200 over a period of 6 months. A renal biopsy was performed 25/7/12: Followed up in 2 weeks. Continued on his methotrexate, as long as his renal function is stable.
Reason is good: explains change in creatinine, explains patient stayed in hospital overnight and is

Medically Important Events

One of the serious adverse events (SAE) categories is Medically Important Events. These are events which do not fit any of the other SAE outcomes but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples of these are Cancers, Pregnancies, and Lupus.

Completing ESI Forms

For certain adverse events we collect extra information on Events of Special interest (ESI) forms. Although previously these forms were filled on paper and faxed to the BADBIR office they now need to be completed directly onto the database. After entering information for an adverse event on the database, select which ESI category the event covers and submit the form. Once this is done an additional page will automatically generate where you will be able to enter additional information.

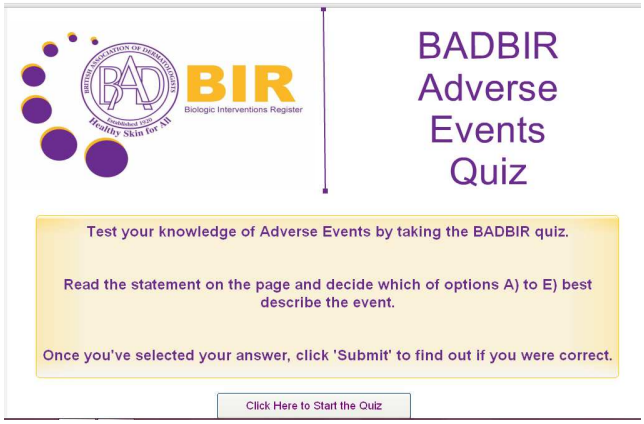


Please remember the Psoriasis Flare ESI only needs to be completed if the patient was hospitalised overnight.

Adverse Events Quiz

The BADBIR adverse events quiz, can be found under the Clinicians section of the BADBIR website. This is being updated with new questions regularly. Please ensure that all members of staff working on BADBIR complete this quiz at least once every 6 months.

The quiz will not be available as soon as you log in to the database.



Need help with an Adverse Event? Please feel free to contact the Pharmacovigilance team on 0161 306 1911

Conventional Patients

It is just as important to report events for conventional patients as it is for patients on biologic treatment. We require as much information about these patients as possible, so that we can effectively compare the two cohorts.