ADVERSE DRUG REACTIONS ADVISORY COMMITTEE (ADRAC)

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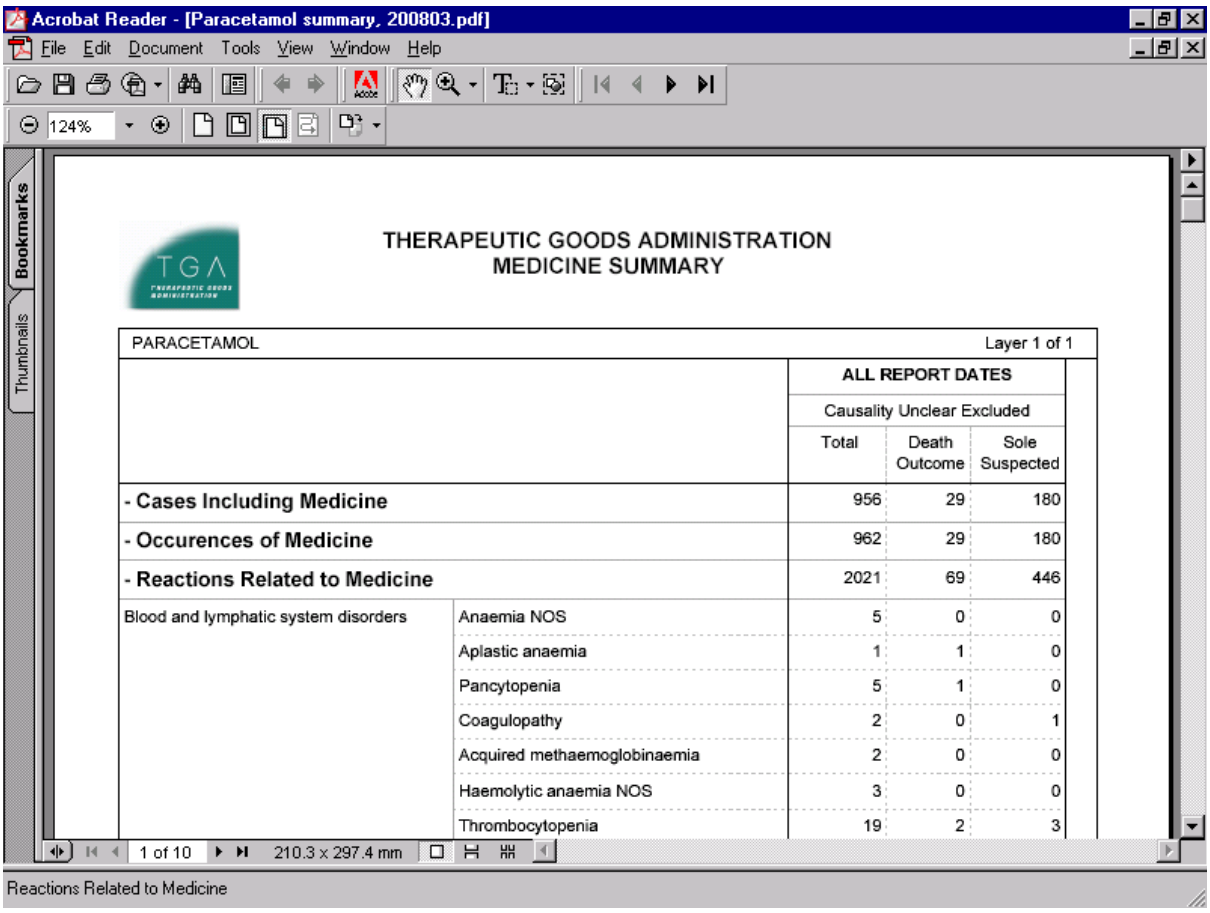
ADRAC DATABASE OF SUSPECTED ADVERSE REACTIONS TO DRUGS
EXPLANATORY NOTES
FOR MEDICINES SUMMARY PRINTOUTS

The Adverse Drug Reactions Advisory Committee (ADRAC) database holds details of Australian reports of ***suspected*** reactions to drugs received since 1 November 1972. The majority of these reports were submitted ***voluntarily*** by Australian doctors, dentists and pharmacists. It should be noted that reporting of a suspected adverse reaction does not necessarily imply a causal relationship.

This basic report provides a cumulative listing of all reactions received to a specified drug. An example is shown on the following page. A guide to interpretation follows:

- The name of the medicine is provided on the top line of the report.
- The default report provides data for all report dates, ie from November 1972 or the date the first report was received (whichever is the latest) until the present time. It is possible, however, to limit the report to a particular date range (in years, quarters or months).
- The report only provides data for those reports where the causality is certain, probable or possible. Other causality gradings are excluded from all reports produced by ADRAC.
- The first row of the report lists the total number of cases in which the medicine has been suspected as being a possible, probable or certain cause of the reaction (s).
- The second row of the report lists the number of times the medicine has been suspected in cases. This number will always be equal to or more than the number of cases. The number of occurrences can be more than the number of cases due to different products of the same medicine being suspected in the same case (eg. a generic product and an innovator product) or the medicine being suspected more than once because it was used at different dosages or in different dosage forms.
- The third row of the report lists the number of reactions reported. Since more than one reaction is often reported in a particular case, this number will almost always be much greater than the number of cases.
- The first column refers to the total number of cases, occurrences or reactions.
- The second column refers to the number of cases, occurrences or reactions where the outcome was fatal.
- The third column refers to the number of cases, occurrences or reactions where the medicine was the only medicine suspected in that case, occurrence or reaction.
- Under Reactions, the reaction terms are listed using elements of the MedDRA hierarchy.[1]
- The format shown in the first example lists all reactions in association with paracetamol. It is possible to break these down under each brand of trade name, including situations where this is not specified. The second example shows this with paracetamol. The first page is identical except that the heading now states Layer 1 of 24. The first layer is always the total for the medicine and each subsequent layer will show the data for each trade name in alphabetical order including paracetamol without a brand name specified.



Interpretation of data

The data have been collected mainly by the 'voluntary' drug surveillance program, and thus are influenced by selection processes subject to major, and to a large extent unknown, biases. Some of these influencing factors include: extent of drug use, source of reports, status of the drug, severity of reaction and prior knowledge of the drug.

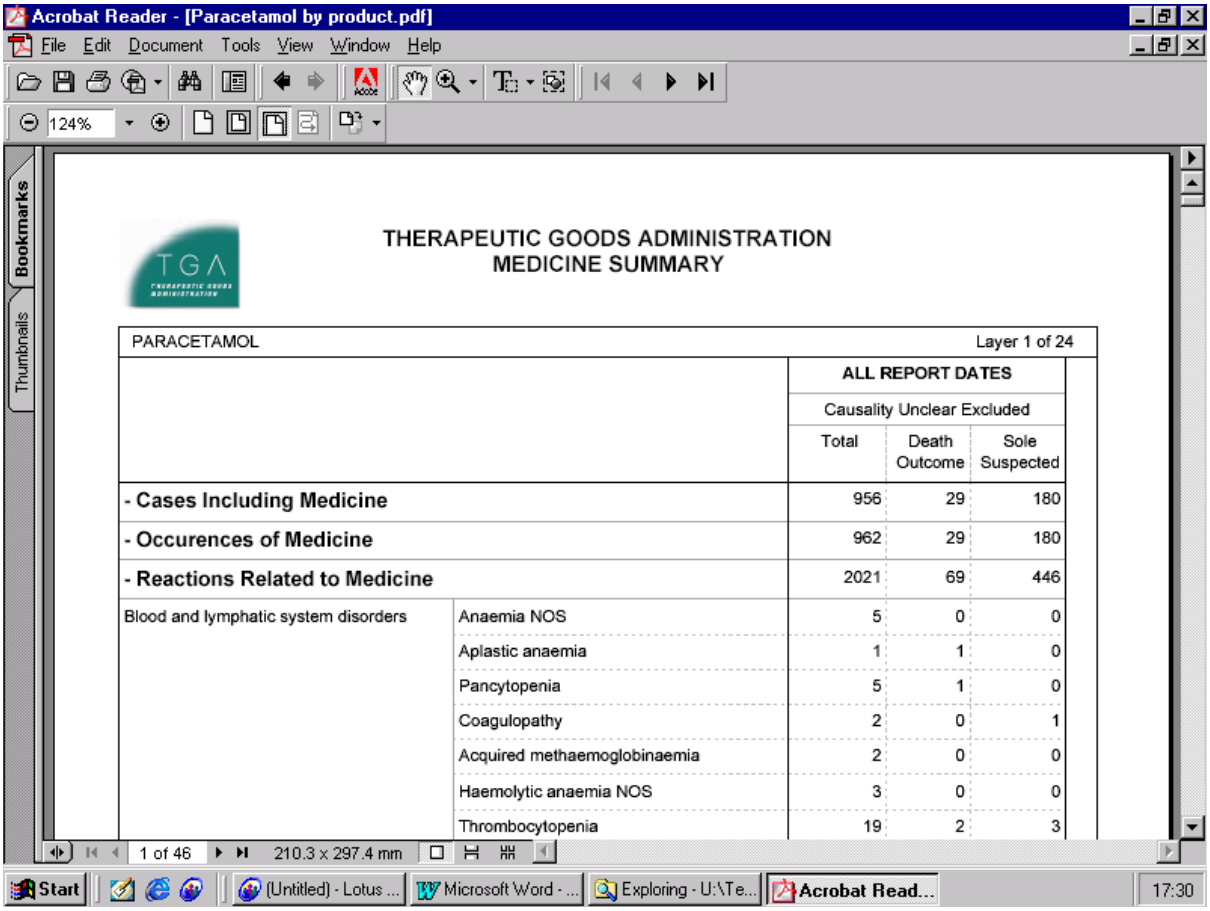
As a result, caution should be exercised when comparisons are made between the number of reports implicating different drugs used for similar purposes, or between reports of reactions to various brands of the same drug. **Incidence cannot be reliably calculated based on data gathered from a spontaneous reporting program.**

It is **strongly** encouraged that the data provided in the case summary printouts be interpreted in consultation with a health care professional.

Disclaimer

Every attempt is made to ensure that information is coded accurately. Our resources do *not* permit us to check printouts before transmission to you. Please notify ADRAC of any suspected errors.

Drug safety monitoring is a dynamic process. Additional information is often sought by the Adverse Drug Reactions Advisory Committee. Note that the reports provided are subject to amendment by ADRAC without notice.



[1] The default format lists each preferred term within a system organ class. The system organ classes are grouped alphabetically but the preferred terms are grouped according to the MedDRA hierarchy. MedDRA has 5 hierarchical levels – lowest level term, preferred term, high level term, high level group term and system organ class. The lowest level term is used for data entry and the other 4 levels are used for reporting. The most commonly used level for reporting is the preferred term which represents a single medical concept. In addition to the default format, any other format using either one or two MedDRA levels is available. For example, a simple listing of preferred terms either alphabetically or in order of number of times reported.