

CASE STUDY

Embase™

Dr. Su Golder, Research Fellow, University of York

Embase is an essential resource for post-market monitoring of medical devices.



SUMMARY

Adverse events are the focus of Dr. Su Golder's work at the University of York. She's looking into methods for searching for adverse events across a broad range of literature sources, including social media. We met with her to talk about the current state of adverse event monitoring and systematic review planning.

“Subheadings in databases like Embase provide the most useful support for finding adverse events, but not every database has indexing or subheadings.”

– Dr. Su Golder, Research Fellow, University of York



Dr. Su Golder
Research Fellow, University of York

How did you become interested in your current research?

I actually started out in information science. My undergraduate research focused on health-related informatics topics and then I did a Master's in information management. I went on to employment in the academic setting doing systematic searches, which led to more research-focused work. I wanted to evaluate the searches that we were doing to see if we could make them more evidence-based. I realized I had a real passion for research and I've remained focused on it since then.

What's your main research focus at the moment?

Text mining and monitoring for adverse events have been my focus recently. I'm very interested in strategies based on automated text mining. I'm starting to do more research on finding adverse event information in areas like social media and unpublished data.

Why is research so interesting to you?

I love discovering new methodologies. It's so interesting to discover whether a method works or in fact doesn't work as well as we think. For example, when I was doing my PhD, I took a critical look at the databases used for adverse event searches. A lot of systematic reviews rely on MEDLINE® for data and the opinion is that it returns the most records. This was not the case! It actually placed fourth. Embase and Science Citation Index placed first and second. It's important to realize that the reality doesn't always match our expectations if we're looking for the best search results — and that's the type of information that research brings out.

What do you find stressful about research?

Funding of course! Writing proposals without knowing if they'll go anywhere, trying to get money to keep projects going — it all takes a lot of time and causes a lot of stress.

What are the main challenges in finding adverse events?

The main issue is that they are generally poorly reported. Adverse events are often the second or third focus of a paper, so you are really reliant on indexing to find them. They're unlikely to be mentioned in the title or abstract. Subheadings in databases like Embase provide the most useful support for finding adverse events, but not every database has indexing or subheadings. If you rely on the title and abstract, you rely on what the author puts there, and if the adverse event is not the primary outcome in the paper, it won't be included. That means, you need to order the full text of many more articles and read them all.

Are the current common practices to search for adverse events effective or are improvements needed?

There is a bias toward doing systematic reviews that look at benefits or clinical effectiveness. Not everyone realizes how important adverse event reports are in the decision-making process. They may be leaving it up to companies to report on adverse events, or are thinking about the negatives.

Embase is an essential resource for post-market monitoring of medical devices.



Also, when people think of side effects, they think of drugs – but other things, including diagnostic tests, can also have adverse effects. When people look for adverse events, they only look in papers they've already used for their effectiveness studies, but these can be biased towards randomized controlled trials, which are designed to study effectiveness and don't include vulnerable groups: pregnant women, people with co-dependencies, the elderly and so on.

Adverse events are difficult to search for, but it's becoming easier because of better indexing and reporting by authors.

Most interestingly, there's a whole new emerging resource for finding information about adverse events, and it's one we need to find ways to tap into. A recent study showed that three times as many patients in the UK report adverse events via social media rather than via the standard reporting system, which provides information to the regulatory body, the MHRA.

How do you plan or design a systematic review?

You need to design a preliminary search strategy at the proposal stage when asking for funding. This helps to determine the cost of the systematic review — for example, how many records you expect to get influences the cost. You need to take a 'big bang' approach — come up with a broad and comprehensive search strategy at the beginning and then update it later. You can tweak the search strategy after you get funding or submit the proposal and can also do supplementary searching (e.g., for cost effectiveness).

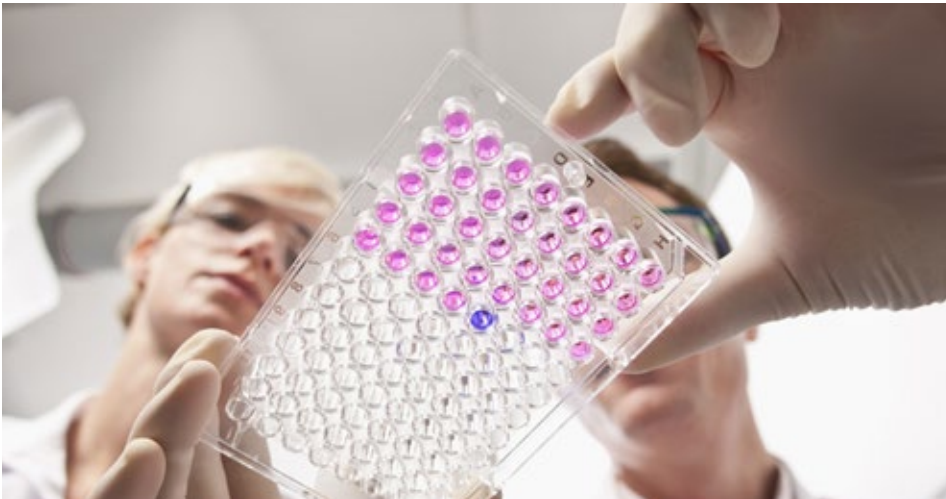
One issue to always remember is that adverse events are just as important for decision making as clinical effectiveness. Adverse events should be part of the main search, not supplementary searches.

It can take weeks to design a search strategy. You need to run through a lot of iterations, and share them and a random selection of search results with your review team. The search strategy also has to be translated for all the different databases.

It is very important to get this step right and not to rush it. The search strategy and an example of the expected results can help reviewers think about the question being asked and the type of papers they get — i.e., the search strategy helps to inform the review process.

How many different databases would you recommend for a thorough SR?

There's no one database to rely on. In one study, I found that the top four for adverse events in terms of records returned are Science Citation Index, BIOSIS Previews, Embase and MEDLINE. For medical device adverse events,



I found that it was Embase, Science Citation Index, MEDLINE and PubMed. You can also find unique references by hand searching, reference checking and contacting experts.

Many people only search MEDLINE, although at least two or three databases should be sourced. It also depends on the topic area — if it's a topic where more is published or if there's a specialty database for the topic area, then it may be less important to search multiple general sources.

What about search strategies?

If you're looking at more recent literature, you can reliably input adverse event terms into your search strategy using as many synonyms as possible along with generic adverse event terms. This works a lot better than it did in the past due to better indexing and reporting by authors as well as database curators. For very old studies, adverse events are far more difficult to find.

You definitely need to use multiple terms to get near 100% coverage. For example, using the floating subheading "side effect" in Embase, 83% of adverse events were identified. That is good, but not good enough. You need to use more search terms to find 100%. In MEDLINE, the best term was an adverse event subheading that only returned 51%. If you know the actual adverse event, always search by that as well (e.g., fracture).

You mentioned medical devices. Does finding adverse events for devices require a different type of strategy than drug monitoring?

As mentioned, Embase and Science Citation Index are the best databases for medical device monitoring. It's important to realize that you need to use a different set of search terms for medical devices. You will get much better results with complication terms than with adverse event terms.

Do you commonly use Embase for your work?

I certainly do! I've used Embase for 15 years. It's extremely useful for SRs. You find a lot of information that you won't find in MEDLINE. Furthermore, Embase is an essential resource for post-market monitoring of medical devices – I can't imagine doing that kind of safety monitoring without it.

We use Embase, MEDLINE and Science Citation Index regularly. We do also use some specialty databases, but they can be difficult to use because they are not as well indexed. Ultimately, Embase is a crucial part of my research and work.