

Is 'data on file' a valid reference?

The father of the modern wound dressing, George Winter (1962), could not possibly have perceived how his research in the 1960s would lead to the plethora of wound dressings available today. The insight he provided into wound physiology spawned the development of a new generation of products adhering to the concept of moist wound healing.

With literally thousands of products now available and more being added each week, often the only way for the clinician to keep up-to-date is to read relevant literature on a regular basis.

It is common practice for an author to cite references from the literature in order to support statements. The provenance of the references used may well have an impact on the publication's veracity. With this in mind, where do citations using 'data on file' as the source leave the author and the reader? 'Data on file' refers to data or information that the owner (usually a commercial company) has compiled but has not published. The data on file may be requested by the reader from the owners, but information on the precise means of accomplishing this is not usually included in the reference list. This means that in many circumstances the reader has to take the reference at face value. One may well question the value of this level of evidence and begs the question: are such citations justified? It is reasonable to ask could a clinical decision be made based on such evidence? In the era of evidence-based practice, where does this leave the academic, researcher, clinician and patient? KC

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For the clinician and the patient, are there any risks involved in relying on published statements that are supported by 'data on file' references when attempting to reach a clinical decision?

RW: Yes, there are risks for the practitioner should they base key clinical decisions on this type of data. Accountability in practice means that nurses and medical practitioners require evidence-based practice. This is based upon an agreed hierarchy and does not include data on file. The excellent SIGN Guidelines provide statements of evidence that are widely accepted, and they do not include data on file. A nurse using data on file exclusively to guide clinical decisions would be regarded as naïve, perhaps reckless, in light of the SIGN hierarchy.

ME: There are no risks. Data on file is used where it may not be possible to get the information peer-reviewed and published. An example of this would be a comparison of the absorption of exudate for two differing dressings. The majority of dressing manufacturers abide by the Surgical Dressing Manufacturer's Association's very strict Code of Practice for the promotion of surgical dressings to health care professionals. Within this Code of Practice all data used to support a product claim must be readily available to whoever requests it. If there is any doubt about the validity of the data supporting a claim this can be referred to the Association's Complaints Committee and if it agrees with the complaint it would result in a significant fine for the errant company.

It is said that there are lies, damn lies and statistics. Which category, if any, do data on file citations belong?

RW: Data on file, when one can obtain it, can be anything from well-conducted, rigorous scientific studies to something of little, or no value. There are no accepted standards for this data, nor is there independent peer review. I would not choose any of these categories, rather advocating extreme caution when confronted with this data. With regard to obtaining such data, personal experience shows a very varied response from industry — occasionally days, but more usually weeks. Data on file could be loaded on to the company website for scrutiny and rapid download; industry could then make all such data openly available for all to see.

ME: None of them. The information included in data on file is readily available from the author for scrutiny by anyone requesting it. It would not do the author's reputation any good if the data did not stand up to scrutiny. Just because a paper has been peer-reviewed and published does not mean it is good science. We have all read published work that lacks robustness and I would suggest that we allow the reader of the work to judge the validity of the data.

Is it reasonable to assume that any publication that includes a data on file reference is a commercially sponsored piece of work even if an accompanying statement to that effect is not included?

RW: No, not necessarily. Those with experience of publication in quality scientific or clinical journals know never

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to cite data on file — the editors of such journals will not accept them. This is entirely justifiable as to do so would be to devalue the publication process. Most editors now insist that terms such as 'Advertorial' or 'Product review' are attached to sponsored articles that cite data on file.

ME: It would be reasonable to assume this, but I would argue that this does not invalidate the data. Any data on file must be able to withstand scrutiny and, believe me, if the data concerns competitor products, the competitor will scrutinise the data very thoroughly. In addition, under the SDMA Code of Practice, companies are obliged to acknowledge company generated or sponsored data by inclusion of the company name or logo. Therefore, it should be clearly apparent when data on file has been generated by the company.

Do you believe that a failure to publish data that is kept on file casts doubt on the veracity of the data?

RW: It can do, but is not the rule. I know from my own experience working in the industry, that good data often languishes 'on file' and is not published. Industry could, and should, review the vast numbers of reports on file and

make an effort to publish wherever appropriate. Those charged with Cochrane databases and the publication of systematic reviews urge us all to publish all clinical trial evidence, whether positive or not.

ME: There are numerous reasons why companies keep data on file. The comment in an article may have been extracted from a complex piece of work, the remainder of which is not relevant to the discussion. Another reason, as discussed earlier, concerns direct comparisons between various attributes of products. Very few publications would publish such data as a peer-reviewed article. In today's climate of evidence-based medicine, we are dealing with a much more probing healthcare professional who does not take things on face value. So I would leave it to the healthcare professional to judge the veracity of the data.

What do you think are the reasons for companies allowing data to remain on file and not formally written up for inclusion in a publication?

RW: An emotive answer perhaps, but I would say indifference, or even laziness on the part of industry. They often don't have the time and

things that aren't regarded as crucial get overlooked. It is interesting, if somewhat cynical, to observe that data on file is good enough to support product marketing, yet somehow does not merit publication. This also reflects on the industrial view of the customer: if products are supported by data on file references, it shows a contempt for the customer who is, presumably, supposed to make clinical judgements on this basis. It has been made abundantly clear that practice must be evidence-based; data on file does not constitute that evidence.

ME: There are many reasons for allowing data on file to remain so, including publications not being interested in publishing the data, the time and effort needed to have the data peer-reviewed and then published, and the rapidly changing environment in which we work. Again, I would emphasise that any data on file, irrespective of how old it is, must be available for scrutiny for anyone who requests the data.

Winter GD (1962) Formation of the scab and the rate of epithelization of superficial wounds in the skin of the young domestic pig. *Nature* **193**: 293