

The new PubMed – underestimated regulatory obstacles?

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Abstract

NCBI's PubMed is a powerful literature retrieval tool widely utilised in many areas including science and regulatory affairs. In regulatory affairs, PubMed searches are employed to identify clinical evidence pertinent to product approval processes. To ensure traceability and reproducibility, a highly structured literature search strategy is advised, as laid out in numerous guidance documents issued by regulatory agencies such as the European Commission and the International Medical Device Regulators Forum.

Recently, a new version of PubMed was deployed, including a new user interface and, less visibly, potential changes to search algorithms, which may affect the results delivered by search strings. To unravel potential differences among the legacy and new version of PubMed, head-to-head comparisons with increasing search complexity were performed.

For the new version of PubMed, the user

interface was redesigned and allows feature customisation. Importantly, as compared to the legacy version of PubMed, the new PubMed delivered diverging numbers of search hits. Of note, the PubMed inherent result sorting methods produced alternating search hit numbers only in the legacy version. Intriguingly, each version identified literature that was not found by the respective other version, although these publications were considered relevant in the search context. Technically, translation of entered search strings into detailed search strings varied between interfaces.

Differences between the legacy (online at least until September 30, 2020) and the new version were found, affecting the traceability, reproducibility, and reliability of PubMed data used for approval processes.

Introduction

The National Institutes of Health (NIH) and its subsidiary organisation the National Center for Biotechnology Information (NCBI) provide access to biomedical and genomic information enabling scientific progress. One of the most popular resources developed and maintained by the NCBI is PubMed – the main entry point to the rich content of the Medline database. On an average working day, approximately 2.5 million users from around the world access PubMed to perform about 3 million searches and view 9 million pages.¹ PubMed is optimised for biomedical electronic research² and strategies on improving search techniques have been published.³

PubMed is a free resource supporting the search and retrieval of biomedical and life sciences literature from more than 30 million citations from MEDLINE, life science journals, and online books. PubMed citations and abstracts cover the fields of biomedicine and health, including portions of the life sciences,

behavioural sciences, chemical sciences, and bioengineering. The exponential increase in available scientific literature renders data extraction more and more difficult. To deal with the challenges of large and complex databases, tools are under development to identify and extract relevant literature.⁴ Indeed, the NIH revised the PubMed interface to meet users' needs. To accommodate changing user needs, a number of new features have been added to PubMed in recent years, such as sorting of results by relevance, faceted search, query auto-suggest, and author name disambiguation.¹ On October 21, 2019, the NCBI issued a blog entry introducing a new version of PubMed.⁵

PubMed is commonly used in a broad array of biomedical disciplines such as academic basic research and, moreover, in the field of medical device regulatory affairs. The implementation of PubMed searches in regulatory affairs procedures, especially during medical device regulatory approval, was widely recognised, however, has been subject to debates in the last decades. Back in the early 2000s, the FDA exempted new medical devices from clinical trials if manufacturers could confirm similarity to another

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product already on the market. The European Union established a similar conformity assessment procedure for new medical devices.⁶ Therefore, a CE mark might be awarded in cases of "existing similarity", where the new device closely resembles existing technical, clinical, and biological features.⁷ Thus, approval of new medical devices via the similarity route is a powerful approach to facilitate market access, often without having to carry out pre-market clinical investigations with a new product. However, market observations revealed that relying

on this approach occasionally resulted in faulty or ineffective medical devices that can harm the users' health and gain market access. Procedural failures possibly involving insufficiently structured literature searches (e.g., due to inappropriate search limitations, inadequate use

Supplementary tables and figures are available online for this article at:
<https://pro-liance.com/the-new-pubmed/>



of Boolean operators or application of unsuitable search terms), but also constraints of the similarity principle's applicability, for instance, allowed metal-on-metal (MoM) hip implants to reach the market. MoM hip implants were often approved on the basis of similar products that were recalled or removed from the market later on. Kynaston-Pearson et al. revealed that a considerable number of hip replacement implants on the market lacked evidence for clinical efficacy, precluding safe clinical use.⁷ Moreover, regulatory agencies informed about serious health concerns associated with MoM hip implants.^{8,9}

Nowadays, more than ever, clinical evidence gained from clinical investigations testing the medical device of interest is considered the gold standard to support the safety and efficacy of a medical device. This is in line with the provisions laid down in ISO14155, an international standard that addresses good clinical practices for design, conduct, recording, and reporting of clinical investigations carried out in human subjects to assess safety and performance of medical devices for regulatory purposes.¹⁰ To avoid the aforementioned difficulties after approval, the literature search for the similarity route must follow distinct

rules and deliver reliable searchability and accessibility of encompassing literature databases. The pertinent literature search must be clear, concise, systematic, traceable, and reproducible as laid out in the MEDical DEvices Documents (MEDDEV) 2.7/1 rev.4¹¹ and in the International Medical Device Regulators Forum document (IMDRF) MDCE WG/ N56FINAL: 2019,¹² and the evaluation has to consider favourable as well as unfavourable results.

As service providers supporting the efforts of medical device manufacturers to ensure initial and continued market access, we are aware of the pitfalls associated with the literature search applied for the similarity route. Major concerns are always related to traceability and reproducibility. Changes to database functionality, including, but not limited to the journals covered, amendments to the user interface, and modifications in article indexing and search algorithms, can have a substantial effect on the quality and reproducibility of searches. After recognising that a new version of PubMed was deployed by the NCBI, we wondered whether search results might differ and how traceability and reproducibility might be affected.

Methods

The following web pages were compared side-by-side:

- 1 <https://pubmed.ncbi.nlm.nih.gov/> (new version of PubMed)
- 2 <https://www.ncbi.nlm.nih.gov/pubmed/> (legacy version of PubMed; nowadays the link immediately redirects to the new version of PubMed)
- 3 <https://pmlegacy.ncbi.nlm.nih.gov/> (current connection to the legacy version of PubMed), which is available at least until October 31, 2020.

To search PubMed, results were sorted by "most recent", unless otherwise indicated in the main text.

To assess variations in database (DB) output, different search terms relating to distinct areas (immunology/immunological diseases and medical devices) were defined. Four different searches with increasing complexity were performed. The following search terms were used:

- 1 *ventilation and ARDS (Medical device search (MD) #1)* and
- 2 *(metal-on-metal hip implants) AND (compli-*

cations OR adverse events) AND surgery (MD #2)
 3 IL-31 (Immunology search (Im) #1) and
 4 (atopic dermatitis OR atopy) AND (skin OR dermis OR cutaneous OR dermal) AND (IL-31 OR IL-4) AND (antibody) (Im #2).

To add even more complexity, the searches were limited to certain time frames as indicated in the main body of text.

The differences regarding layout, handling, translation of search terms, traceability, and reproducibility were assessed.

Relevance of publications retrieved was mainly determined based on the title only. In individual cases, the abstract was checked to assess relevance in the search context. Importantly, in the common regulatory literature appraisal process, both title and abstract are considered for decision making. Here, for time reasons, the abstract was not factored in in most cases for the relevance determination.

Results of the searches Im #1 and #2 are presented in an online supplement to this article, available at <https://pro-liance.com/the-new-pubmed/>. Importantly, the early searches are employed to identify technical and visual updates associated with the new PubMed as compared to the legacy version of PubMed.

Results

This short investigation was intended to identify differences between the legacy and the new PubMed user interfaces, operational procedures, search results, and the overall traceability and reproducibility of results. The results section is divided in two major areas: 1. medical devices, and 2. immunology/immunological diseases.

Medical devices - Search for and translation of a 2-term search query (MD #1)

To evaluate the translation process for search queries with moderate complexity, a sample search was conducted using the terms *Ventilation* AND *ARDS*. Searches conducted with the legacy and the new version of PubMed delivered 4697

and 5116 hits, respectively (performed on November 19, 2019, sort by “most recent”). Of note, a later search using the same above-mentioned terms revealed 4714 and 4685 hits for the legacy and new version of PubMed, respectively (performed on December 5, 2019, sort by “most recent”). More iterations performed on January 16 and March 6, 2020, retrieved 4745 and 4801 results for the legacy version and 4715 and 5237

for the new version, respectively. Together, the number of hits increased constantly for the legacy search engine, as it would be expected since over time more publications are added to the database. However, the new PubMed delivered alternating numbers of search hits during the observational period (Figure 1).

Sorting by “best match” yielded 5118 (legacy version) and 5116 hits (new version) (performed on November 19, 2019). Again, a later search showed different results. Here, 4687 and 4685 hits for the legacy and new version of PubMed, respectively, were found (performed on December 5, 2019). In contrast to the legacy version of PubMed, no difference in terms of hit numbers between “most recent” and “best match” was identified for the new version of PubMed (Table 1). Interestingly, the number of hits in “best match” mode decreased for the legacy and new version of PubMed.

The legacy version of PubMed translated the entered search string into:

(“ventilation” [MeSH Terms] OR “ventilation” [All Fields] OR “respiration” [MeSH Terms] OR “respiration” [All Fields]) AND

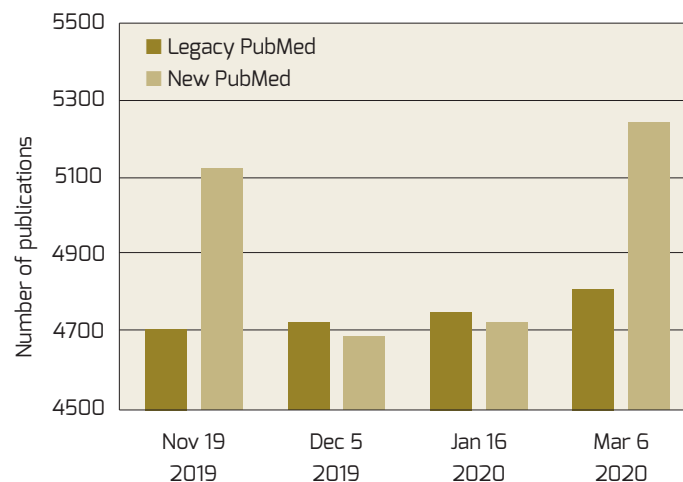


Figure 1. Development of number of search hits within the time frame from Nov 19, 2019, through March 6, 2020

ARDS [All Fields] (performed on December 5, 2019).

Instead, the query generated by the new version of PubMed showed a higher level of complexity in terms of search string translation:

(((((“ventilated” [All Fields] OR “ventilates” [All Fields]) OR “ventilating” [All Fields]) OR “ventilation” [MeSH Terms]) OR “ventilation” [All Fields]) OR “respiration” [MeSH Terms]) OR “respiration” [All Fields]) OR “ventilate” [All Fields]) OR “ventilations” [All Fields])) OR “ventilator’s” [All Fields]) OR “ventilators, mechanical” AND “mechanical” [All Fields])) OR “mechanical ventilators” [All Fields]) OR “ventilator” [All Fields]) OR “ventilators” [All Fields]) OR “ventillation” [All Fields]) AND “ARDS” [All Fields], (performed on December 5, 2019).

Medical devices – Search for and translation of a multi-term search query (MD #2)

A composite search was executed for a search string related to a recurrent topic in the medical device industry – MoM hip implants. Here,

Table 1: Comparative description of retrieved search results

Date of search	Legacy version of PubMed		New version of PubMed	
	“Most recent” number of hits	“Best match” number of hits	“Most recent” number of hits	“Best match” number of hits
November 19, 2019	4697	5118	5116	5116
December 5, 2019	4714	4687	4685	4685

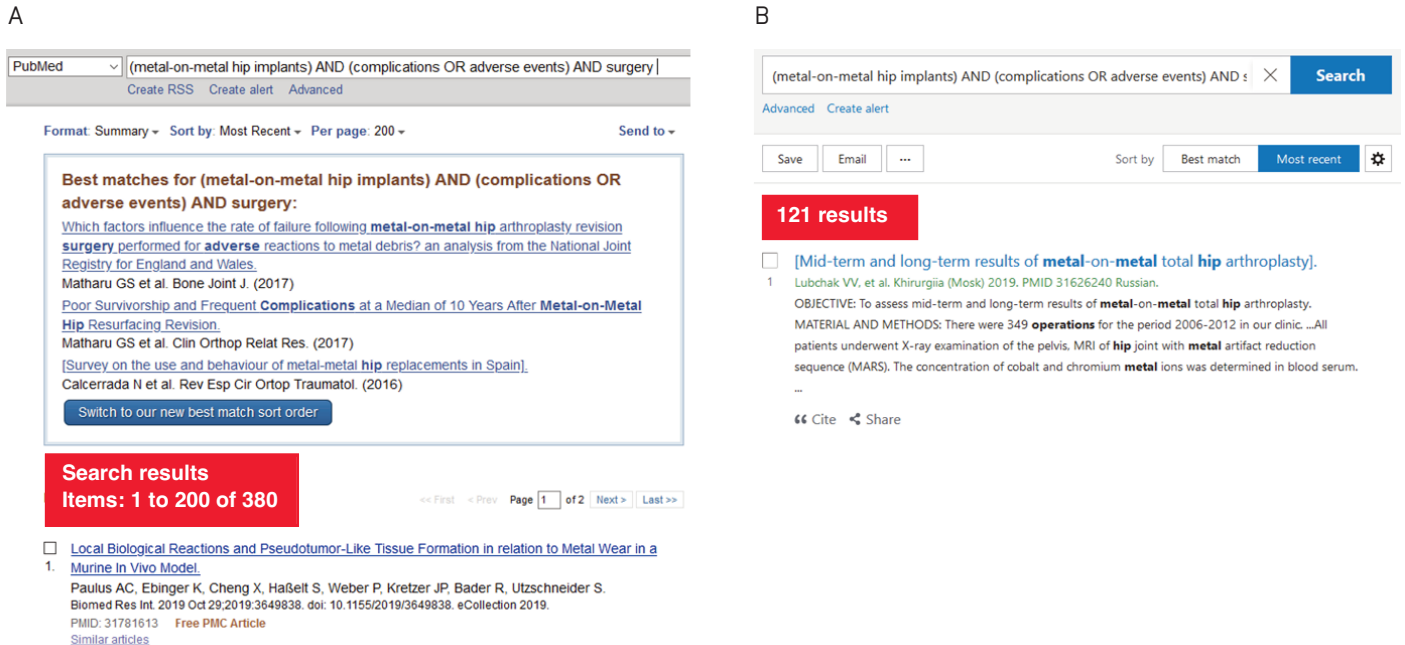


Figure 2. Database output. A, legacy version of PubMed. B, new version of PubMed. The very first search hit is displayed.

retrieval of sufficient and valid clinical evidence is especially crucial, as many assessments of hip implant conformity solely relied on publicly available clinical data from similar devices – a procedure that in some cases reportedly led to serious complications for patients.^{8,9}

To assess the performance of both PubMed versions, a search for *(metal-on-metal hip implants) AND (complications OR adverse events) AND surgery* was conducted on December 18, 2019. Two different time frames (January 1, 2010, through December 31, 2015, and January 1, 2015, through December 18, 2019) were searched.

For the time period ranging from January 1, 2015, to December 18, 2019, without any additional limitation and employing the “most recent” format, the search string found 380 and 121 hits in the legacy and new version of PubMed, respectively (Figure 2).

Application of a time window from January 1, 2015, to December 31, 2015, delivered 189 hits in the legacy version and 49 hits in the new version of PubMed. Of these citations, only 43 were found in both interfaces. In contrast, 146 citations were returned only by the legacy version (Supplementary Table 4), and 6 were returned only by the new version (Supplementary Table 5). After reviewing the titles – and in some cases additionally the abstracts – of the identified citations, 98 of 146 (>65%) hits from the legacy

search and 5 of 6 (>80%) from the new interface search were considered as “potentially relevant”, indicating that the legacy version of PubMed identified a higher absolute number of relevant citations as compared to the new version of PubMed.

Similar results were obtained from the search for the second time period ranging from January 1, 2015, to December 18, 2019. Briefly, the legacy PubMed delivered 133 hits in total, whereas 62 of 133 hits did not appear in the parallel search with the new PubMed. Forty-three of the 62 publications were considered potentially relevant in the search context after assessment of the title (Supplementary Table 6). The new version of PubMed identified 85 hits in total, of which 14 were found exclusively by this search. All of those 14 publications as assessed by title were considered potentially relevant (Supplementary Table 7).

The two versions of PubMed translated the search terms differently, as shown below for the search of the period January 1, 2015, to December 18, 2019.

Legacy version:

(metal-on-metal[All Fields] AND (“hip prosthesis” [MeSH Terms] OR (“hip” [All Fields] AND “prosthesis” [All Fields]) OR

“hip prosthesis” [All Fields] OR (“hip” [All Fields] AND “implants” [All Fields]) OR “hip implants”[All Fields])) AND (“complications” [Subheading] OR “complications” [All Fields]) OR (adverse [All Fields] AND events [All Fields])) AND (“surgery” [Subheading] OR “surgery” [All Fields] OR “surgical procedures, operative” [MeSH Terms] OR “surgical” [All Fields] AND “procedures” [All Fields] AND “operative” [All Fields]) OR “operative surgical procedures” [All Fields] OR “surgery” [All Fields] OR “general surgery” [MeSH Terms] OR (“general” [All Fields] AND “surgery” [All Fields]) OR “general surgery” [All Fields] AND (“2015/01/01” [PDAT] : “2019/12/18” [PDAT])

New version:

(((((“metal-on-metal” [All Fields] AND (((“hip prosthesis” [MeSH Terms] OR (“hip” [All Fields] AND “prosthesis” [All Fields])) OR “hip prosthesis” [All Fields]) OR (“hip” [All Fields] AND “implants” [All Fields])) OR “hip implants” [All Fields])) AND (((((((“compl” [All Fields] OR “compliances” [All Fields]) OR “complicate” [All Fields]) OR “complicated” [All Fields]) OR

“complicates” [All Fields]) OR “complicating” [All Fields]) OR “complication” [All Fields]) OR “complications” [All Fields]) OR “complications” [MeSH Subheading]) OR “complications” [All Fields]) OR (((“adverse” [All Fields] OR “adversely” [All Fields]) OR “adverses” [All Fields]) AND ((“event” [All Fields] OR “event’s” [All Fields]) OR “events” [All Fields])))) AND (((((((((((((((((((((((((((((((“operability” [All Fields] OR “operable” [All Fields]) OR “operate” [All Fields]) OR “operated” [All Fields]) OR “operates” [All Fields]) OR “operating” [All Fields]) OR “operation’s” [All Fields]) OR “operational” [All Fields]) OR “operative” [All Fields]) OR “operatively” [All Fields]) OR “operatives” [All Fields]) OR “operator” [All Fields]) OR “operator’s” [All Fields]) OR “operators” [All Fields]) OR “surgery” [MeSH Subheading]) OR “surgery” [All Fields]) OR “operations” [All Fields]) OR “surgical procedures, operative” [MeSH Terms]) OR ((“surgical” [All Fields] AND “procedures” [All Fields]) AND “operative” [All Fields])) OR “operative surgical procedures” [All Fields]) OR “general surgery” [MeSH Terms]) OR (“general” [All Fields] AND “surgery” [All Fields])) OR “general surgery” [All Fields]) OR “surgery’s” [All Fields]) OR “surgerys” [All Fields]) OR “operation” [All Fields]) OR “surgeries” [All Fields])) AND 2015/1/1:2019/12/18[Date - Publication].

By mid-May of 2020, the new version of PubMed had become the default search interface. To investigate whether the new, default version of PubMed delivered identical search results as during the transitional period, the search for (*metal-on-metal hip implants*) AND (*complications* OR *adverse events*) AND *surgery* within the time frame ranging from January 1, 2010, to December 31, 2015, was repeated on June 10, 2019. The search retrieved 226 hits in total, exceeding the number of hits (49) found on December 18, 2019, more than fourfold. To determine whether the results included potentially relevant citations that were missed in the initial search performed on December 18, 2019, the search results were compared to those obtained by the legacy PubMed. In detail, the search identified 32 previously unrecognised publications (Supplementary Table 8 – including



22 relevant publications), rediscovered 6 publications that were found in the previous search by the new PubMed exclusively (Supplementary Table 5), and retrieved 188 of 189 citations found in the legacy PubMed. A single publication was still not identified in the new search: Chen, Zhongbo, Hemant Pandit, Adrian Taylor, Harinderjit Gill, David Murray, and Simon Ostlere. “Metal-on-Metal Hip Resurfacings – a Radiological Perspective.” *European Radiology* 21, no. 3 (March 2011): 485–91. Based on title and abstract, the publication could be relevant in the context of complications in MoM implants.

Immunology/immunologic diseases

Two independent searches (Immunology Search (Im) #1 and Im #2) with increasing complexity were performed to assess technical and layout features as well as database output among both versions of PubMed. Results are presented in the Supplementary Information section to provide initial insights towards technical features and database outputs based on searches with simplified search terms.

Discussion

PubMed is a commonly used search engine for identifying clinical data from scientific literature for multiple purposes. Specifically, the present investigation focusses on the needs in the medical device field, which relies on clinical evidence from scientific citations to accelerate the approval process of medical devices based on data obtained for equivalent/similar medical devices. Indeed, published clinical data from equivalent/similar devices provides supportive information to demonstrate safety and performance/benefits of the medical device – two main aspects assessed during the approval procedures. To ensure traceability, clinical evidence is gathered in a highly structured data identification process, as laid out, for example, in the guidance document MEDDEV 2.7/1 rev.4. The guidance document repeatedly asks for an ordered process intended to deliver identical search results. Moreover, the IMDRF technical documents on clinical evaluation (IMDRF MDCE WG/N56FINAL: 2019) and on clinical evidence (IMDRF MDCE WG/N55 FINAL:2019) apply, providing additional information on key elements and requirements for literature searches.

The recent release of the new version of PubMed by the NCBI raised immediate concerns regarding the traceability and reproducibility of search results. Thus, the main goal of the present investigation was to analyse the comparability of the search results retrieved by both versions of PubMed that were accessible in the period from November 2019 to June 2020.

The presented side-by-side comparisons reveal several differences between both PubMed versions. Visually, the 3-column illustration in the legacy version of PubMed was replaced by a 2-column layout. Moreover, information provided on the results page was altered, but still supplements the reader with sufficient detail. In addition, an excerpt of the abstracts is included in the displayed results, promoting a quick review of search results. Furthermore, the read-through incorporates snippets that are highlighted text fragments related to the search query to accelerate decision-making towards the relevance of a search hit.¹³

Column 1 as depicted in Supplementary Figure 1 contained a sidebar to further narrow down the search results. To ease the search processes, pre-set filtering options were provided by default. Although differences regarding the pre-set filtering option were evident, these could be quickly overcome by adding missing categories manually. Moreover, the elevated number of pre-set filtering options was an asset, easing immediate result sorting. Nonetheless, the sidebar does not allow filtering by date. Instead, the date range has to be inserted in the search field using the YYYY/MM/DD:YYYY/MM/DD[dp] format, which adds complexity to the entire search process.

Furthermore, filtering options on “journal categories” are somewhat restricted now as filtering by “core clinical journals” is no longer available in the new PubMed. Although this filtering option was discussed controversially among regulatory professionals, some users nevertheless applied this filter to narrow down the amount of search hits. However, limiting the search output created a bias towards high rank, high quality clinical publications only, leaving the possibility of missing relevant information published in journals that do not focus primarily on clinical data.

To review the traceability and reproducibility of search results, four different search scenarios were conducted covering different search terms as described in the Methods section. The chosen

search terms pertain to clinical sciences and to medical devices, respectively, in order to cover two major research fields that strongly depend on reliable data retrievability in PubMed. The major finding across searches was that the legacy and new version of PubMed yielded inconsistent search results affecting the overall reliability of retrieved clinical evidence. Briefly, the legacy version of PubMed found more relevant publications than the new platform during the transitional period until May 2020. The New PubMed Transition FAQs webpage provides some valuable insights regarding the observed inconsistencies.¹⁴

Entered search terms were translated by PubMed’s automatic term mapping.¹⁵ The new version of PubMed appeared to massively use automated term mapping. Apparently, the new search adds synonyms, truncations, plurals, verbs, and British/American spelling variants to the translated search query. Of note, the review of translated search queries included misspellings like “antibodie”, “antibodys” or “ventillation”. The NCBI stated that the procedure aims to cover all publications as originally submitted by the publisher. Thus, although misspelled, all words deliver results. Moreover, the new version of PubMed takes advantage of an updated technology for document indexing, storage, and retrieval.¹³ Although we had anticipated that the technical refinements would result in an increased number of search hits, in most cases decreased numbers of hits were observed in the new version as compared to the legacy version during the transitional period. Of note, a search performed in June 2020 after the new version had become the default search interface, delivered more hits than an identical search performed during the transitional period in December 2019, indicating a continued update and improvement process. Further, after the new PubMed became the default search interface, 32 previously unrecognised, potentially relevant publications were identified covering the entire search period selected for the query. Intriguingly, these 32 publications were not retrieved using the legacy version of PubMed indicating that the previous



Differences
in terms of query
translation were
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legacy and the
new version of
PubMed.

search would have missed relevant citations. Moreover, in the presented search scenario the new, default PubMed failed to deliver one potentially relevant paper, that was found by the legacy PubMed only. These findings already pointed to a limited comparability between both versions of PubMed.

Thus, with regard to the medical device field, it must be advised to clearly indicate the version of PubMed that was used during the clinical evidence collection process and at what point during document updates the switch to the new PubMed version was made.

PubMed offers two alternative sorting methods “most recent” and “best match”. For the legacy version of PubMed, the number of hits varied between both methods, whereas the output from the new platform is identical for both sorting methods. According to information provided by the PubMed help desk, in the new PubMed, “best match” and “most recent” rely on the same platform, and retrieve the same results, which then are ranked differently, according to the selected sort order. With the legacy PubMed, only searches sorted by “best match” were taking advantage of the environment now utilised in the new PubMed. Therefore, the number of results between “best match” and “most recent” could be slightly different.

In legacy PubMed, the “best match” sort order is based on an algorithm analysing every single PubMed citation found with entered search terms. For each search query, “weight” is calculated for citations depending on how many search terms are found and in which fields they are found. In addition, recently published articles are given a somewhat higher “weight” for sorting. The top articles returned by the “weighted” term frequency algorithm are then re-ranked for better relevance by a machine-learning algorithm.

The new relevance ranking algorithm combines over 150 signals that are helpful for finding best-matching results. Most of these signals are computed from the query-document term pairs, e.g., number of term matches between the query and the document, while others are either specific to a document, e.g., publication type; publication year, or query, e.g., query length

(personal communication with National Library of Medicine Support, June 4, 2020).¹⁶ Importantly, the “best match” sorting is not designed for comprehensive or systematic searches (personal communication).

Differences in terms of query translation were observed between the legacy and the new version of PubMed. Of note, inserting the search string generated by the new version of PubMed into the search bar of the legacy version did not deliver similar results as compared to the new version, indicating that it was not only the search term translation process that was updated. Indeed, the new PubMed employs an updated search syntax that might lead to variable numbers of search hits compared to the legacy platform.¹⁴ Nonetheless, both versions of PubMed identified a substantial set of overlapping citations. However, additional literature was found by either search engine pointing to an obvious inconsistency. Importantly, the issue was reduced with the new, default PubMed, but not resolved completely. Thus, PubMed users from the regulatory field are advised to use PubMed with caution to not hamper the approval process. Useful combinations of search queries, as they are typical in such searches, should be employed and search strings should be designed with possible synonyms in mind. Moreover, to present a comprehensive state-of-the-art overview based on all the available literature, users from the regulatory field should consider the use of a second literature database.

In an email conversation with the National Library of Medicine (January 2020), it was confirmed that “the new PubMed is under active development, and features will be introduced and updated on a regular basis as we continue to enhance the system”. Indeed, improved search functionalities such as wildcards, groupings and joins have been implemented in the new version of PubMed. The wildcard search will be no longer limited to 600 variants.¹³

Overall, unstable database output might occur in the near future until feature development and usability testing has been completed successfully and the final version of the new

PubMed has been rolled out. From the NCBI’s blog entry and FAQ page it is obvious, that the new version of PubMed will be subject to further changes in the short and long term.^{5,14} It is highly likely that these amendments will further affect the quantity and quality of search results and also will make retrospective comparisons more difficult. Together, the presented observations and comments/replies from the NCBI suggest that the new version of PubMed will potentially be updated constantly and thus over time might deliver alternating results.

Thus, the use of the new version of PubMed to re-retrieve clinical evidence obtained using the legacy site for CE approval processes must be considered with caution. Although the new PubMed is set as default, the legacy PubMed is accessible at <https://pmlegacy.ncbi.nlm.nih.gov/> at least until end of September 2020. Furthermore, a search strategy in alignment with PubMed’s new common practice must be developed in the meantime, and it is recommended to clearly identify and disclose the version of PubMed applied during the transition period from old to new interface. Moreover, under special circumstances, it might be advisable to double check the automated term mapping and combine searches in both versions to draw comprehensive conclusions and avoid missing important literature for approval processes. In addition, a parallel search in a second literature database such as LIVIVO or the Cochrane Library may retrieve missed citations by PubMed providing a fuller picture of the scientific landscape pertaining to the subject medical device.

Conflicts of interest

The authors declare no conflicts of interest.

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