A new framework for the French Open Science Monitor

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November 2021

Keywords: open science, open access, unpaywall, clinical trials, observational studies, scientometrics

1. Introduction

The French Open Science Moniror was launched in 2019 as part of the first French National Plan for Open Science (MESRI 2018). Its methodology was detailed in (Jeangirard 2019). It currently focuses on scholarly publications whose one author has a French affiliations. It measures the rate of open access for these publications. It will eventually be extended to other dimensions of Open Science, whether they are transversal (management and opening of research data) or disciplinary.

To support the continuation of Open Science public poly with the second National Plan for Open Science (MESRI 2021), a new framework for the French Open Science Monitor. It introduces a monitor specific to the Health domain and also develops the features for the Open Access analysis.

Produce a dynamic vision of the evolution of the level of openness Analyse in detail how publications are opened, developing indicators specific to open repositories on one hand and indicators specific to the dissemination platforms on the other hand.

The objective of the French Open Science Monitor in Health is to report on some aspects of Open Science specific to medical research and health, in relation to the needs for sharing scientific knowledge that have become urgent during the COVID-19 pandemic. The aim is to have indicators that will make it possible to take stock of the situation and monitor the public policies that will be implemented.

In addition to the open access to the publications, which is critical for all do-

mains, the registration of clinical trials and observational studies, the publication of their results and the sharing of their data are specific dimensions in the Health domain, and more particularly of clinical research.

Clinical trials are research conducted on human subjects involving an intervention other than their usual care (delivery of a drug, treatment device, surgical procedure, etc.) for the purpose of developing biological or medical knowledge. Observational studies are "non-interventional" studies, also involving humans, but not involving any intervention other than the usual management of patients. They may focus on compliance with treatment, tolerance to a drug after it has been put on the market, etc. This is the case, for example, with cohort studies, which consist of statistical monitoring of a panel of individuals over the long term in order to identify the occurrence of health events of interest and the related risk or protective factors.

This clinical research is subject to various biases, including publication bias, which is well identified by public health researchers: it covers the tendency to publish only trials and studies whose results are conclusive and in line with the expectations of the researchers who carried them out (these are known as "positive" results). The consequence of this bias is that the syntheses or meta-analyses carried out on the basis of scientific publications with a view to guiding public health policies are in fact based on an erroneous view of scientific knowledge. Several solutions exist to correct this bias:

- systematic declaration of studies, before they are carried out, in dedicated registers;
- systematic publication of study results, even when they are "negative".

Regulations have been implemented to improve transparency: in the United States, the declaration of clinical trials and their results is compulsory, and in Europe, the declaration of clinical drug trials will be compulsory as of 2022. In contrast, observational studies are not subject to any regulations regarding their reporting or publication.

2. Method

2.1 Publications

2.1.1 Perimeter definition

2.1.1.1 French Open Science Monitor The French Open Science Monitor is a tool that aims at steering the Open Science policy in France. As such, it produces statistics that are analyzed over time, and it has to focus on "French" productions. Also, as stated in (COSO 2018), we want to use only public or open datasources. Two constraints of perimeter thus appear naturally:

- only publications with at least an author who has a French affiliation are considered. The nationality of the authors does not come into play. Still, this raises the issue of access to affiliation information. Affiliation metadata are present in specific sources, like PubMed, but very rarely in the whole Crossref data. To fill in the gaps, we propose to crawl the affiliation information displayed publicly from the publications webpages. On top of that identifying a country from an affiliation text is not that straightforward. If you are not convinced, think about a affiliation stating "Hôtel Dieu de France, Beirut, Lebanon": this does not refer to a French affiliation even thoug the word "France" is present. We use an automatic detection algorithm, based on Elasticsearch, described i (L'Hôte and Jeangirard 2021), to infer the countries from the affiliations texts.
- only the publications with a Crossref DOI are considered. Duplicates have to be avoided, in order not to coun twice (or more) a publication and thus add a bias to the statistics that are produced. It is then key to use a Persisten IDentifier. Also, we choose to use Unpaywall data for Open Access (OA) discovery. This service produces open data an offers the possibility to snapshot the whole database, which is an asset to analyse the OA dynamics. For now, Unpaywall focuses only on Crossref DOI, which leads us to adopt the same perimeter. We are aware this is a bias against some disciplines, Humanities and Social Sciences for example.

All genres of publications are considered (journal articles, proceedings, books ...) as long as the publication is associated to a Crossref DOI. Many types appear in the metadata, but for clarity, we group them in categories, namely journal articles, proceedings, preprints, book chapters, books, the rest being grouped in a category 'Others'. It is important to note that the 'preprint' type does not appear as such directly in the available metadata (it is generally declared as journal article). So preprint detection is based on the dissemination platform information. At the time of writing, only the Cold Spring Harbor Laboratory (BioRxiv, MedRxiv) case is covered, but it can be extended as soon as another preprint dissemination platform would start using Crossref DOIs.

2.1.1.2 French Open Science Monitor in Health The French Open Science Monitor also introduces a focus on the Health domain. Delimiting a clear

perimeter for Health is not very easy. For now, we simply have chosen to consider in the scope all PubMed publications, and only these. The publications' data used in the French Open Science Monitor in Health is then a subset of the publications descried above, adding the PubMed presence criterion. Note that "Health" is seen more as a domain than a discipline. In fact, publications from several disciplines are taken into account in the French Open Science Monitor in Health. A domain-specific set of disciplines is used in the French Open Science Monitor in Health, as described below.

2.1.2 Open access dynamic

From the first edition of the French Open Science Monitor, it was clear that the estimate of the open access rate should not be static but should try to capture the dynamics of the opening (Jeangirard 2019). Indeed, the 0-day open access exists but we cannot assume it represents the totality of the open access. Therefore, for a given set of publications, say the publications published during the year Y, it makes sense to measure the open access rate at different point in time, for example at some moment in year Y+1, Y+2 ...

To do so, it becomes necessary to historicize the database containing the open access information. So, instead of maintaining a database that keeps track of the opening of each publication, like Unpaywall is doing, we have to make regular snapshots of the whole Unpaywall database. Each snapshot is used as an observation date to measure the open access rate. It is important to note that this method natively embeds the potentials open access discovery errors from the underlying Unpaywall database, that can be false negative (a publication is actually open at this point in time but it is not detected) or false positive (wrongly seen as open whereas it is closed).

This method of analysis therefore reveals two temporal dimensions: publication dates and observation dates. Obviously, the observation date must be after the publication date. To avoid that the proliferation of possible analyses blurs the message, we propose to look mainly at two elements:

- A main statistics that is the **1Y Open Access rate**: it represents the open access rate of the publications published during year Y and measured (observed from the snapshot of the OA discovery database) at one point in time during year Y+1 (generally in December if the data is available).
- Also, the **shape of open access curve** (open access rate function of the publication year). For a given observation date, the open access rate can be estimated broken down by publication year. This then produces a curve of the open access rate, function of the publication year (at a given point in time which is the observation date). Of course this curve can have any shape, and in particular it is not always expected to be monotonic increasing. Indeed, a monotonic increasing curve means that more recent publications are more and more open. That can (hopefully!) happen, but moving barriers and embargoes would genereally brings another type of

shape, that would be an inverted-V shape. The next figure illustrates different shapes of Open Access curves.

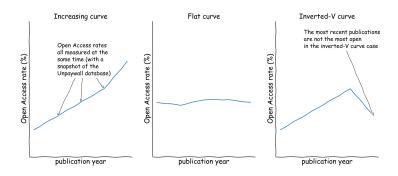


Figure 1: Different shapes of Open Access curves

From an observation date to another, the OA curve shape may change. This evolution of the shape gives an insight of the speed of opening. Indeed, moving from an inverted-V shape, where the most recent papers are not the most open, to an increasing shape would be a proof of the acceleration of the opening. The next figures illustrates the evolution from an inverted-V shape, to flat and then to an increasing OA curve shape.

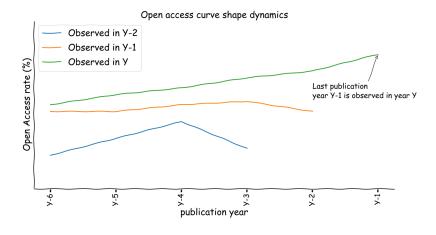


Figure 2: Open Access curve dynamics

2.1.3 Open access types

As Unpaywall is the Open Access discovery tool we used, we initially based our results on the OA classifications described in (Piwowar et al. 2018). It breaks

down the OA types in 5 categories: 'Gold', 'Hybrid', 'Bronze', 'Green', 'Closed'. These categories are also present in the Unpaywall database (and oaDOI API) in the field 'oa_status'. We first simply grouped the categories 'Gold', 'Hybrid' and 'Bronze' under a 'Publisher hosted' label. However, we now propose another classification that we think more appropriate for the French OA policy steering.

(Piwowar et al. 2018) defines 'Green' as 'Toll-access on the publisher page, but there is a free copy in an OA repository'. That implies that a publication that would be free to read on the publisher webpage and that would, at the same time, have a free copy on a repository would not be counted as 'Green'. When we observe the OA rate function of the hosting type, the contribution of the repositories is mechanically reduced in favour of the publishers. This therefore blurs the picture of the real activity of the repositories. That is why we propose to have a first level of analysis, with 3 categories (excluding 'Closed'):

- hosted only on an open repository: Toll-access on the publisher page, but there is a free copy in an OA repository, corresponging exactly to the 'Green' definition of (Piwowar et al. 2018), that we could rather label 'Green only'
- hosted only by the publisher: Free to read on the publisher webpage, but no free copy in an OA repository.
- hosted on an open repository and by the publisher: Free to read on the publisher webpage and there is a free copy in an OA repository.

Obviously this does not impact the overall Open Access rate, but this division rebalances the role of the different types of OA hosting. The next figure shows the kind of impact choosing one or the other OA type break down.

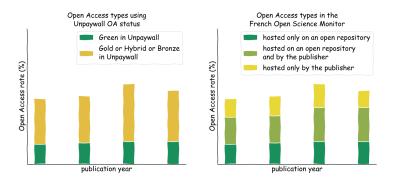


Figure 3: Open Access hosting types

Another graphical way to represent this balance is to use a bubble chart. Each bubble represents a cluster of publications (think about having a bubble for each discipline, for each dissemination platform ...), its size depends on the number of publications in the cluster. The x-axis represents the share of OA publications

hosted by the publisher: it is then the sum of the share of publication hosted only by the publisher and the share hosted on an open repository and by the publisher. Conversely, the y-axis represents the share of OA publications hosted on a repository: it is then the sum of the share of publication hosted only on a repository and the share hosted on an open repository and by the publisher.

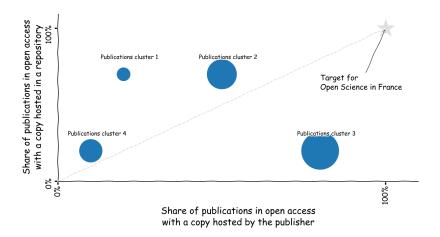


Figure 4: Share of publications in open access hosted on an open repository vs. by the publisher

The data used to compute these OA types still comes from Unpaywall, but instead of the 'oa_status' field, with use the 'oa_locations' field. For a publication which is open access, it lists all the existing free copies that Unpaywall detected, at the time of the snapshot. Each location is described, in particular with an URL that gives a link to the free copy, and some metadata of the location is associated, in particular the 'host_type', that can take two possibles values, 'publisher' or 'repository'. It is important to note that, for now, preprint servers are considered repositories.

2.1.4 Discipline and language impact

All disciplines and publication languages are covered. Again, however, no metadata exists for describing the discipline or the publication language. To enrich the metadata, we then rely on machine learning approaches, that try to infer discipline and language from the available metadata.

For the language detection, only the title, and the abstract are used if available, with the lid.176.bin fasttext word embedding machine learning algorithm (Joulin et al. 2016).

Discipline detection also uses journal and keywords metadata if available. A general classifier is implemented for all domains, it classifies the publications

into 10 macro disciplines: Mathematics, Chemistry, Physics & astronomy, Fondamental biology, Medical research, Computer sciences, Earth science ecology energy & applied biology, Humanities, Social sciences, Engineering. It is trained on data from the Pascal & Francis database and uses a Fasttext classifier. More details are discussed in the previous paper (Jeangirard 2019).

A domain-specific classifier is implemented for the Health domain. It classifies the publications into 17 disciplines, built from the Fields of Research taxonomy. The full methodology is detailed in (Jeangirard 2021).

The main purpose of these metadata enrichments is to be able to analyse the open access rate in function of languages and disciplines. We expect to observe differences not only in the global OA rate (which discipline is the most open?), but also in the dynamics trends (which discipline show the strongest increase over time?) or in the opening uses (relying on publisher hosted open access versus open repositories).

2.1.5 Publishers and dissemination platforms strategies

2.1.5.1 Identification of the dissemination platforms

2.1.5.2 Business models and open licenses As explained above, the 'oa_status' in Unpaywall data hides part of the role of the open repositories. It also hides Diamond open access, that is to say it mixes in the same 'Gold' category all publications published in an open-access journal that is indexed by the DOAJ, whether there are Article Process Charges (APC) or not. That is why we introduce another level analysis, about the dissemination platform business model, with 3 categories:

- **Diamond DOAJ**: journal-article published in an open-access journal indexed by the DOAJ, and without APC (according to the DOAJ data).
- (Full APC) Gold: publications published in an open-access journal (using the field 'journal_is_oa' from Unpaywall) and that are not Diamond DOAJ (either with APC or without information about APC)
- **Hybrid**: all other open access publication with a copy available on the publisher webpage.

On one hand, the 'Gold' category from (Piwowar et al. 2018) is broken down into 2 categories to make Diamond appear explictly. On the other hand, the 'Hybrid' and 'Bronze' categories from (Piwowar et al. 2018) are merged into 'Hybrid', without considering the license information. Indeed, the objective of this level of analysis is to separate different business models (APC vs no fee vs Hybrid), not to analyse the open licenses associated to the OA copies.

For that matter, a third analysis level is used that distingues, for open access publications:

• Creative commons licenses (cc0, cc-by, cc-by-nc etc ...)

- Other licenses (publisher sepcific ...)
- No license

To be clear, the no license category does not mean the publications are closed, on the contrary they are open but no open license was detected.

Again, the informations from the field 'oa_locations' in the Unpaywall data that is used, and therefore, the results are dependent on the Unpaywall database data quality.

2.1.5.3 Article Processing Charges (APC) estimation Estimating APC for each journal article remains difficult as few open sources exist. We leverage on the openAPC database (at the publication level) and on the DOAJ data (at the ISSN level). We use the following heuristics to estimate the APC of a publication.

- If the DOI is not open access with a free copy on the publisher webpage, there is no APC estimation to make.
- Else, if the DOAJ specifies there are no APC for the ISSN, then it is a Diamond DOAJ OA, with no APC.
- Else, if the DOI is explicitly in the openAPC database, we simply use the APC from openAPC.
- Else, if the DOI is not in the openAPC database, but its ISSN or publisher is, with a sufficient number of observations, we use the mean of the APC observed for the same ISSN or the same publisher, during the same year if enough data is available, or over the whole openAPC database otherwise.
- Else, if the DOAJ specifies there are APC for the ISSN, we simply use the APC from DOAJ, after a conversion to Euros if needed (based on the exchange rate at the publication date).
- Otherwise, no estimation is made.

We are aware this estimation is far from perfect but still brings some insights. On top of that, even if we focus on French publications (publications with at an author with a French affiliation), the sum of the APC estimated is higher than the real amount of money spent by France into APC, as a large fraction of the publications are co-authored with scholars affiliated to foreign institutions. Informations on corresponding author could be a proxy to focus on APC spent by France but for now, we do not have an open, reliable and massive source for this information.

2.1.6 The role of the open repositories

2.1.7 Other analysis axis

In the case of the Health domain, we use metadata coming from PubMed. These metadata are quite rich and enable extra analysis. In particular, some **funding metadata** are present in PubMed, as well as the **affiliations for each author** (not always the case when using other sources and scraped metadata).

PubMed gives info on grant declaration. To be clear, the absence of this metadata does not mean that there was no funding. So the only thing we can do is to check if there is a correlation, or no, between the open access rate and the presence of the grant metadata in PubMed.

As the affiliations informations are given for each author, we can use (L'Hôte and Jeangirard 2021) to infere the country of affiliations of each author. We would like to analyse if the country of affiliations of the corresponding author correlates to the open access rate. Unfortunately the corresponding author metadata is not available, so we chose an approximation looking at the affiliation country of the **first and the last authors**. That will give an insight to know whether, for French publications, the OA rate is in general higher when one of the first or last authors has a French affiliation, or, conversely, if the OA rate is higher when the first and last author are affiliated abroad.

2.2 Clinical trials and observational studies

The French Open Science Monitor focuses, for now, only on publications. Current work is being conducted on monitoring also Research Data and Software Code. The French Open Science Monitor in Health, however, laready introduces new research objects specific to the Health domains: the clinical trials and the observational studies.

In the US, reporting and publication of results is mandatory for all clinical trials, the reporting registry used is https://clinicaltrials.gov/. This site is also used by many international actors. It also offers the possibility to report observational studies (but this reporting is not mandatory).

In the European Union, the reporting obligation only concerns clinical drug trials and will take effect in 2022. The European registry https://www.clinicaltrialsregister.eu/ (EUCTR) therefore mainly includes clinical trials involving medicines, and less frequently observational studies, clinical trials involving surgical protocols, medical devices or psychotherapeutic protocols.

The issue of opening up or sharing data arises for clinical research in the same way as for other areas of scientific research. However, it has a particularly complex dimension, since it involves personal data, some of which directly concern the health of individuals. Nevertheless, it is possible to define the modalities for sharing this data. Two dimensions will be developed:

- the openness of the results and publications when the study is completed.
- the declaration of clinical and observational studies in these public registries.

2.2.1 Perimeter

Two datasources are used for now to collect metadata about clinical trials and observational studies: clinicaltrials.org and EUCTR. clinicaltrials.org proposes an API while EUCTR does not so the information is crawled from the website. Only the trials and studies that involves at least **one location in France** are analysed.

Some trials or studies appear in both registries, the matching between the two databases being done based on the PIDs NCTId (from clinicaltrials.org) and eudraCT (from EUCTR), both registries keeping track of external PIDs. Nevertheless, duplicates can still remain if no link can be established with the PIDs present in both registries.

To distinguish between clinical trials on one side and observational studies on the other, we use the study type field, that can be either 'Interventional' (for clinical studies) or 'Observational' (for observational studies).

2.2.1 Main opening indicators

Mainly two types of indicators are analysed:

- the declaration of results and / or scholarly publications after a trial or study is completed. (Goldacre et al. 2018) showed that a large fraction of trials do not report their results. On top of the results declaration rate itself, we look into the time to register the results, meaning how much time is spent between the end of the trial and the actual date when the results are reported. We propose both indicators mixing or separating results and scholarly publications. For the publications, it is important to note that only the metadata from the studies registries are used, without trying to link trials to DOIs using the publications metadata (whith PubMed for example). The open access status of these publications is also retrieved with the Unpaywall data.
- the time to register the study: is the trial or study publicly registered before it actually starts, or is it done after? And what is, in month, the actual time to register? Does it evolve over time?

2.2.2 Lead sponsor impact

(Goldacre et al. 2018) gives evidence that the rate of results declaration is very impacted by the type of lead sponsor, commercial sponsors having a much higher declaration rate. We therefore propose to break down most of the analysis

axis with the type of lead sponsor, being either academic or industrial. This categorization has been done manually based the lead sponsor name.

2.3 Data collection system and architecture

In this section, we will try to present the global workflow to collect, enrich and consolidate the data as described before with the technical and the storage challenges.

2.3.1 Data manipulation

Collect, Select, Enrich and Save As describe before, we collect data from multiple sources (PubMed via Medline, Crossref, our own list of DOIS), we then try to guess the country according to the affiliations. And from the DOIs, we collect more details about that publication via Unpaywall. By details, we mean open access, Each step is really time and CPU consuming. Assuming any step can fail at any time, we choose to develop each step as independent and idempotent.

From PubMed, collect all the database via Medline and store it as JSONL files on Object Storage on OVH Cloud in a dedicated container. At that point, we have all the notices of medical publications. We there find the affiliations of each publication. With the affiliation we tried to detect the countries of the institutions mentioned in the affiliations, in order to filter on French publications. The selected publications are stored as JSONL files in another dedicated container on Object Storage on OVH Cloud. Now focusing on the French publications, we use the extracted notices to match them against a MongoDatabase that we built on a dump of Unpaywall. We use th DOI to consolidate the data and then add many detail

2.3.2 Data storage

To do so, we needed to precisely define the input and the output of each step, and how to store the intermediate results. As JSON is the most common format to manipulate data, we choose to store the results into JSONL files and to save them into a dedicated container on the ObjectStorage of OVH Cloud. ObjectStorage is a data storage architecture that is easily queryable. MongoDB Elastisearch

2.3.2. Microservices

synchronous / asynchronous, Docker All the tasks before are developed in Python and running as microservices in a Docker images. We used Flask as a Web Framework. It enables us to launch the steps by calling the endpoint urls with the specified arguments. This way we were still the bandmaster of the wall workflow and where still able to follow the progress of all these asynchronous tasks.

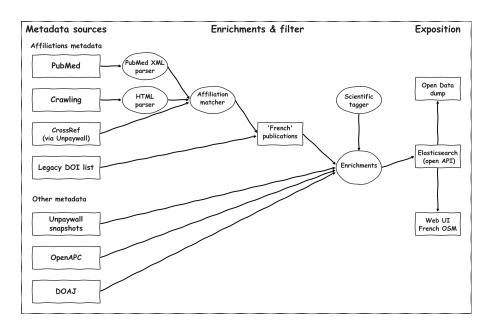


Figure 5: Global overview of the publications data flows

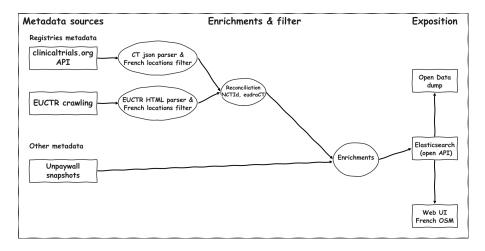


Figure 6: Global overview of the trials and studies data flows

2.3.3. Cloud

OVH Cloud, remote, scalability, kubernetes As a limitation, we chose to collect all the publications from 2013 to today. Only from Crossref, it's about 45 million publications. Let's call that "big". And the time to collect all these data could be quite long. So we had to

3. Results

4. Discussion and conclusion

4.1 Findings

4.2 Limitations and future research

4.2.1 Limitations

DOI only mixes preprint servers / open repo richer metadata based only on metadata from registries

4.2.2 Future work

research data, software code

Software and code availability

https://github.com/dataesr/bso-publications https://github.com/dataesr/bso-clinical-trials

Data availability

portail MESRI

Acknowledgements

WeDoData Florian Naudet (https://orcid.org/0000-0003-3760-3801) University of Rennes 1, Rennes, France

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