The METEOR initiative: the way forward for optimal, worldwide data integration to improve care for RA patients

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ABSTRACT

Objective. *The METEOR (Measurement of Efficacy of Treatment in the "Era of Outcome" in Rheumatology) initiative aims at improving care for RA patients by assisting rheumatologists in strict monitoring and tight control of disease activity. The state of the art of the METEOR initiative, the technical organisation of the database and future perspectives are described.*

Methods. *RA patients are followed in the daily practice setting; (follow-up) visits are registered via the tool or upload facility. The METEOR tool is an easy-to-use, stand-alone, web-based program free available to rheumatologists worldwide. The upload facility is developed to meet the wish of many local registries to upload their data into the METEOR database to benefit from benchmark and research facilities without giving up their own registries. Rheumatologists will always have access to full patient details of their own patients. Yet, patient identifying data are stored in an encrypted manner in the METEOR database in order to provide full patient anonymity to all other users.*

Results. *While the tool can be used without IT involvement, the upload facility requires IT support. The incorporation of local registries into the METEOR database is time consuming, requires endeavours as well as technical support of both the local registries and the METEOR organisation, however, the combination of the tool and the upload facility has enabled the successful creation of a strong research database with real life data of 35,000 RA patients with more than 140,000 visits from all over the world!*

Conclusion. *The METEOR database offers the unique opportunity to study daily practice care as well as dedicated research questions in worldwide real life setting. Moreover, the METEOR's collective experience can be accessed by those who think about initiating patient registries for all sorts of purposes. Consequently, these well-designed registries may help in treating RA patients even more successfully in future.*

Introduction

During the 1990s it became apparent that strict monitoring and tight control of disease activity in patients with rheumatoid arthritis (RA) leads to significantly improved outcomes compared to routine care (1). Therefore, the METEOR (Measurement of Efficacy of Treatment in the "Era of Outcome" in Rheumatology) initiative was started in 2006 by the Merit foundation. The foundation aims at improving patient care by supporting and assisting rheumatologists on a day-to-day as well as a long-term basis by setting goals and visually sharing treatment progress with the patient. Capturing patient data and outcomes over time allows the visualisation of trends by the patient and treating physician, thereby enhancing and simplifying rheumatologist-patient relationships. Moreover, in order to benchmark treatment optimally in regular patient care while preserving patients' privacy, it is pivotal to collect data in an anonymous way.

A central benchmarking database can also be used for research purposes (2, 3). In order to achieve these goals, the Merit foundation developed a free online software tool; the METEOR tool. Almost 10 years later, and after many hurdles – it was for example not known whether physicians would be willing to contribute and share data - the initiative has become successful, as shown by its considerable growth. In this article, the technical organisation of the METEOR database as well as the current status of the METEOR initiative and some perspectives for future development and exploitation are described.

The METEOR tool

The METEOR tool has been developed as a stand-alone web-based program and has been used since 2008. Rheumatologists can use the tool without – or with very limited – involvement of the local IT department. This strategy has proven to be very advantageous for a worldwide implementation. In addition, its ease of use and powerful graphic aids are vital to the METEOR tool.

Within one centre, one rheumatologist or research nurse or coordinator receives administrator rights from the METEOR organisation. The 'administrator' for that particular centre can create several user accounts. Thus, within one centre, several users can use the METEOR tool with their own account and may have access to all patients' data entered by their colleagues in the same centre.

However, during the last few years we have witnessed more and more hospitals using Electronic Health records (EHR) for daily patient care. This implies that entering data in a separate tool (double entry) is becoming a burden, regardless of how user-friendly such a tool is.

The METEOR upload and download facilities

In order to bypass the harassment of double entry, METEOR has developed upload and download facilities. The download facility allows the download of all relevant data from the METEOR database and upload those data in the local EHR system. Vice versa, the upload facility allows data stored in the local EHR system to be uploaded into the METEOR database.

Apart from the increasing availability of EHR systems, an increasing number of local and country-specific databases has been implemented in many countries. Many of these registries have expressed the wish to upload their data into the METEOR database in order to benefit from the benchmark and research facilities, without giving up their own registries. The upload facility can also be used to integrate these local databases in the METEOR database. The upload facility is currently being used in, among other countries, the Netherlands, Portugal and India. In addition, the METEOR initiative is ex-ploring the possibilities of integrating the METEOR tool in local EHRs.

Patients and data collection

The METEOR tool as well as the upload and download facilities are freely available to all rheumatologists worldwide. Data of all patients with RA visiting the rheumatologist are eligible to be entered into the METEOR database without restrictions on for example disease duration or age. Patients are followed in the setting of usual care, and (follow-up) visits are registered. Items that can be completed via the METEOR tool and that can be included in the file for upload are listed in Table I. In addition, the tool automatically calculates the various existing disease activity scores (original DAS, DAS-3, DAS28, DAS28-3, CDAI, SDAI, RAPID3) (4-8). In total, the METEOR database includes 200 data elements.

Design of the METEOR database

The leading principle is that the submitting rheumatologists stay in control of their own data. So, rheumatologists will always have access to full patient details of their own patients and rheumatologists will always be able to download those data. Yet, patient identifying data are stored in an encrypted manner in the METEOR database in order to provide full patient anonymity to all other users. Identifying data can only be decrypted by the site that has created the data. Moreover, since the METEOR database contains medical data, it is not possible to delete data. However, there is an option to 'invalidate' data and create new data.

The 200 included data elements are grouped in 7 tables. This complex structure is designed for high speed data entry and extracting data for research purposes, but this also implies that data must be provided in a very specific structure in the upload file. Moreover, the level of complexity serves the goal of being internally consistent while allowing for incomplete data as well. For example, not only data on individual joints is entered and stored, but also calculated DAS scores. Obviously, extensiveness and completeness of data assures a more valuable database better serving

Table I. Variables collected in METEOR.

Patient characteristics
  Age
  Gender
  Marital status
  Smoking habits
  Height
  Weight

Disease characteristics
  Date symptom onset
  Date diagnosis
  Erosions (present/absent/unknown)
  Rheumatoid factor (present/absent/unknown)
  Anti-CCP (present/absent/unknown)
  Tender joint count (53 or 28)
  Swollen joint count (44 or 28)
  RAI [13]
  ESR levels
  CRP levels
  Comorbidities

Physician reported outcomes
  Physician global disease activity

Patient reported outcomes
  Patient global disease activity
  VAS pain
  HAQ [14]
  RAPID3 [8]

Treatment
  Drugs (type, dose, start date, eventually end date)
  Intra-articular injections
  Surgery

the objectives of the Merit foundation, yet may violate time efficiency during regular patient visits. Therefore, rheumatologists have the option to enter, for example, medications by their generic names and without dose description, or alternatively in full detail.

Depending on the set-up of the local registries the number of data elements that needs to be integrated in the METEOR database via the upload file is between 150 and 200.

Integration of other registries in the METEOR database – general principle

There are various strategies to integrate data from other registries into the METEOR database. Data can be stored in various different manners in local registries (*e.g.* using 2 or 3 decimals, with commas or dots as decimal marks, or using generic or trade names of drugs, etc.) which may not fully comply with the specifications used in the METEOR database. So, an intermediate procedure is required. For this purpose, a standardised XML-file has been developed, as

well as a reference guide and additional documentation, which is sent to all local registries interested in the upload facility. Data from the local registry have to be extracted and stored in this XML-file. However, this process of storing the local registry in the standardised upload XML file is rather complicated and requires support from the local IT department. The IT-experts of the local registry liaises with a METEOR IT-expert and together they create first 'drafts' of the completed XML-file which will be uploaded in a testing environment for the validation step. During this validation step the quality and internal consistency of the XML-file is tested as well as the conformity of all items with the specifications of the METEOR database. Validation on solely a field by field level is relatively easy, but does not yield a consistent database. We therefore require a more extensive validation where we also take into account the relation between fields. This has proven to be a time consuming activity. Then, decisions have to be taken on which items can be transferred directly and which items need to be translated in different values or ranges to match the METEOR database. Some examples are described below.

In some registries it is possible to enter data of several visits on one common date (*e.g.* visit 3, 4 and 5 are all entered as performed on 03.03.2010). Some registries allow 'unrealistic data' as for example a future date in the year 2054. Further, reference values in local registries may differ from the reference values in the METEOR database. For example, in some registries ICD9 codes or MedDRA codes are used for the registration of comorbidities, while in the METEOR database ICD10 codes are used for this purpose. Another example, CRP values collected in mg/L in the METEOR database but in mg/dL in other registries. Sometimes recalculation is simple – as in the CRP-example – while converting ICD9 and MedDRA codes into ICD10 codes may be far more cumbersome. Furthermore, differences in storing data on medication are complicated, since medications are rarely collected according to specific guidelines. Moreover, drug forms and packages may differ across countries. During the validation process all possible errors and variations are identified both at the level of individual data entry and on the total file, and are listed in an error file. It is the mutual responsibility of the local registry and the METEOR organisation to solve all issues, adapt the detailed mapping, and eventually eliminate incorrect (type of) data.

Since METEOR prefers a scenario in which overtly incorrect data are deleted rather than stored, this procedure may leads to some missings.

Once the quality of the XML-file optimally matches the specifications of the METEOR database, the XML-file will be processed (*i.e.* the data will be added to the METEOR database). The upload facility allows insertion as well as replacement of data at a later stage in order to be able to replace incorrect data, for example an incorrect dose of medication.

Our experiences with several local registries has taught us that 5–10 iterative cycles may be necessary before reliable and useful data can be authentically integrated in the METEOR database for the first time. However, it has turned out that approximately 99% of the data are immediately correct in the first cycle in consecutive uploads, and integration can start already in the second or third cycle which tremendously expedites the process.

Nevertheless, particular structural differences between existing local registries and the METEOR database cannot be obviated. This is why we recommend the use of the reference guide and the XML documentation during the development of a new local registry or EHR which may benefit a more easily connection to the METEOR database at a later stage. Face-to-face meetings and workshops in which both rheumatologists and IT-specialists participate may be of tremendous help to discuss the advantages and disadvantages of different data models in order to yield the best outcome for both the local registries and the METEOR database.

Current status of the METEOR initiative in 2014

To date, the METEOR database contains data from 32 countries by 129 actively including sites (87 sites via the METEOR tool; 42 sites via the upload facility). The database has included data of nearly 35,000 RA patients (over 8,000 from the Netherlands) with more than 140,000 visits (over 36,000 from the Netherlands). Unfortunately, not all data of these patients and visits is complete, partly due to technical issues as explained above, partly because some data were never completed. Therefore, we are currently working on improving the quality of the data in the METEOR database. We regularly provide 'heat maps', showing the percentage of completeness of the variables in different colors (Fig. 1). These 'heat maps' are helpful in quickly checking the level of completeness of the data and to decide if it is possible to answer particular research questions. We regularly send these 'heat maps' to the participating sites as a stimulus to improve the completeness of their data. Nevertheless, continuous initiatives are necessary to further improve the quality of the data. METEOR exploits a booth at the ACR and EULAR annual congresses to support interaction and 'group building'. Moreover, METEOR has been successful in establishing an international scientific community that meets at least once per year to discuss research proposals as well as research projects already performed in the context of the METEOR database. The leading principle remains that the participating rheumatologists stay in full control of their own data. In addition, every rheumatologist providing data to the METEOR database can submit research proposals addressing the entire METEOR database (or a part of it) to the scientific committee. If the scientific committee approves a particular research proposal, every participating rheumatologist – being a representative of their site – can decide if their data either or not will be used in that particular research project. During the past 5 years, several research projects have been performed using data of the METEOR database. Results of these research projects have been presented during ACR and EULAR meetings (some examples are shown in Table II) (9-12).

Fig. 1. example of a heat map on the quality of the data in terms of completeness.

Dark green: 81 – 100% of the data complete
Light green: 61 – 80% of the data complete
Yellow: 41 – 60% of the data complete
Orange: 21 – 40% of the data complete
Red: 0 – 20% of the data complete

Table II. Examples of research performed in the METEOR database.

Topic	Introduction & goal	Results and conclusions
Patient's *versus* physician's global disease activity (10, 11)	It is unknown if differences between patient's and physician's assessment of global disease activity (PtGDA and PhGDA, respectively) exist which may influence treatment decisions. In addition, it is unknown if these possible differences may vary by country because of cultural differences.	Agreement between PtGDA and PhGDA was moderate; patients scored on average higher (worse) than rheumatologists. This difference between PtGDA and PhGDA is culturally influenced. In addition, patient's perception of pain (VAS) was positively associated with PtGDA. Similarly, ESR and swollen joint counts were positively associated with PhGDA. Thus, patients base their judgment primarily on the level of pain, while rheumatologists base it on the level of swollen joint count and ESR.
Obesity and disease activity (12)	Given the frequent occurrence of obesity and the apparent paradoxical relationship between increasing BMI and less radiographic joint damage in RA, it was investigated whether BMI is associated with RA disease activity in the METEOR database.	Interestingly, obese patients have higher DAS scores with significantly elevated levels of ESR, TJC and VAS scores compared to lean patients. These observations did not differ in early versus established RA patients. These findings urge an adequate reflection of DAS-scores in a treat to target approach in obese *versus* lean patients.
Quality Indicators in RA in clinical practice (9)	Quality of care for RA patient is measured by quality indicators (QIs), which are specific and measurable elements of practice. An international task force is currently developing a set of recommendations of which the feasibility is tested in the METEOR database.	Detailed analysis revealed that most of the QIs that were formulated by the task force, especially the assessment of disease activity (mostly DAS28) were feasible in clinical practice in most part of the worlds.
Is there an effect of treat to target training?	Currently a study is performed to disseminate the EULAR/T2T recommendations for the management of RA in order to facilitate the implementation of structured and target-oriented therapy in common clinical practice, and to investigate if patients are actually treated according to the EULAR/T2T recommendations. Rheumatologists from various countries received a training about the EULAR/T2T recommendations. A group of patients with newly diagnosed RA entered and followed in the METEOR database before the publication of the EULAR/T2T recommendations serve as control group.	Not yet available

Conclusion

The METEOR initiative, once started in pursuit of improving the care of patients with RA, has become a very successful project almost ten years later. The combined approach of both the facility to enter individual patient data via the METEOR tool and the facility to upload data of local registries into the METEOR database has allowed the METEOR initiative to build a database of nearly 35,000 patients with more than 140,000 visits! Whilst the incorporation of local registry databases into the METEOR database has proven to be time consuming, requiring endeavours as well as technical support of both the local registries and the METEOR organisation, the entire approach has enabled the successful creation of a strong research database with real life data of RA patients from all over the world. We expect a continuing growth of the METEOR database which offers the unique opportunity to study daily practice care as well as dedicated research questions in a worldwide real life setting. Furthermore, ten years of METEOR experience forms a wealth of information that can be accessed by those who think about initiating patient registries for all sorts of purposes and want to build upon METEOR's collective experience. Consequently, these well-designed registries may help us treating our patients even more successfully in future.

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