

Collecting clinical experience of homeopathic support in COVID-19, newsletter 19

Learning from Case Reports/Series, 2nd issue

2nd issue

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High quality clinical case reports: the qualitative backbone of homeopathy

I often refer to the 'quality value chain' in homeopathy. The most important 'elements' of this chain are:

1. High quality homeopathic medicinal products
2. High quality clinical case reports
3. High quality and reliable information in the materia medica and repertories
4. Optimal case taking and decision-making



Figure 1: the homeopathic quality value chain

All four elements contribute directly to the generation of high quality clinical case reports and clinical case material.

Clinical case reports can serve a variety of purposes: Prof Milos Jeniceck, one of the epidemiological 'godfathers' of promoting clinical case reports as an integral part of evidence medicine¹, distinguished 37 objectives for clinical case reports. Without going into the detail, broadly two categories of clinical case reports can be distinguished

1. Case reports that serve an EDUCATIONAL purpose; e.g. 'unusual' cases, typical cases, etc.
2. Case reports that serve a RESEARCH purpose; e.g. validation of proving symptoms, keynote symptoms, etc. in clinical practice

Metaphorically speaking the "quality value chain is as strong as the weakest link", so we need to address all four aspects.

Clinical Case reports in their wider context

High quality clinical case reports are not just important in their own right; such reports are also closely interconnected with the quality and reliability of information in the materia medica and repertories. The Bayesian symptom analysis that Lex Rutten and colleagues are conducting, is based on submitted COVID-19 Case Material submitted to the American Institute of Homeopathy (AIH) case registries (compiled by Peter Gold) as well as other case registries such as the Clifical database. This is a good example of clinical case material being used for research purposes.

The above-mentioned COVID-19 case registries primarily consist of quantitative data submitted in a predefined format. There is however also a qualitative element to this story: how can we be sure that the submitted case material is based on 'high quality' cases? As Indicated by Peter Gold in his 11 December Newsletter, the case material submitted was of 'varying quality', and based on assessing the submitted data, only 301 of the 800 submitted cases were deemed to be of 'analyzable' quality. Similarly Lex Rutten has excluded cases from his analyses. We have to take this question one step further though: how can we be sure that these 301 cases are of 'high quality'? And yet another step further: what exactly do we mean with a 'high quality' COVID-19 case?

Clearly, analysis of the data in these case registries do not provide a full answer to these questions.

Better defining what is a high quality (COVID) case report

This was one of the core themes of the 4 webinars that took place in collaboration with the Vithoukas Compass team in May (the first webinar is available on YouTube at <https://youtu.be/8WeKNmHRTGY>).

Fortunately, three important tools have been developed that enable us to more transparently define and identify high quality clinical case reports. As referred to in the first issue of this Newsletter, these tools are:

1. The CARE Clinical Case Reporting Guideline (for case reports in general) (<http://www.care-statement.org/>)
 2. The HOM-CASE CARE Extension² (additional items to consider for homeopathic case reports) was developed, and as part of this COVID project, this was converted into an 'easy to use' template in Word, which guides homeopaths in terms of the data that needs to be reported. A link to this document is given here: https://www.dropbox.com/s/v9nv9nic0mpufbo/LMHI2020_COVID-19_HOM-CASE_submission_form.docx?dl=0
 3. The MONARCH Causality attribution inventory³ (items to assess the likelihood of causal attribution of observed changes to the homeopathic remedy prescribed). A link to a checklist in (in Word) that can be used for assessing the homeopathic treatment of COVID-19 cases is given here: https://www.dropbox.com/s/499eevc2pmt6o94/LMHI2020_COVID-19_MONARCH_checklist.docx?dl=0
- The CARE guideline and HOM-CASE CARE extension primarily address the comprehensiveness of a clinical case report.
 - The MONARCH Causality attribution inventory assesses the likelihood that the purported 'remedy response' is actually due to the remedy. In some ways, this aspect is even more

important than the CARE guideline and HOM-CASE CARE extension: The wrong attribution of a case as e.g. a 'phosphorus' case, inevitably invalidates the case report. The MONARCH aims to create more transparency and consistency in this process. An important lesson learnt to date was that aspects of the 'direction of cure', such as the improvement of symptoms in reverse chronological order, were observed in successful COVID-19 Cases. However, learning this lesson was only possible because the chronology of symptom development prior to, and after, the remedy administration was reported in sufficient detail. So sufficient comprehensiveness of a clinical case report is essential for this type of assessment.

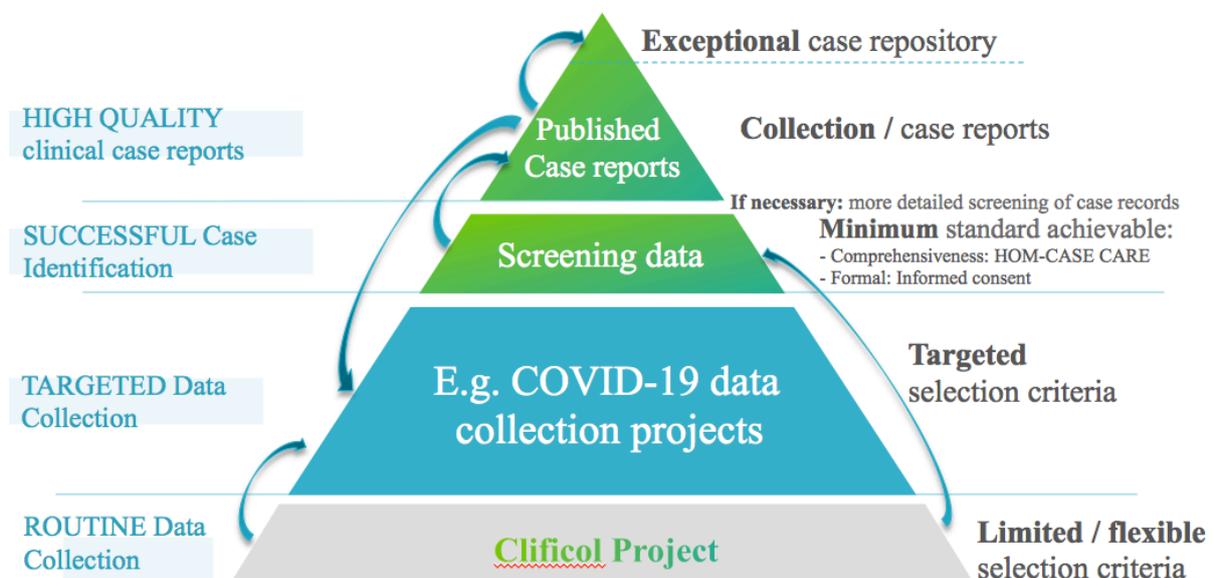
How many clinical case reports have been submitted to date?

This is the disappointing part: until now, only 28 case reports have been submitted, and moreover, in only 7 of these case reports the HOM-CASE CARE guideline template was used! This has led to some 'soul-searching' with regard to the possible explanations for this. The main contributing factors identified to date are:

- It takes time and effort to write up a detailed case report in line with the HOM-CASE CARE guidelines.
- Homeopaths are unfamiliar with applying guidelines and explicitly 'assessing the likelihood of causality' in their practice.
- Inefficiencies due to poor / insufficient Integration with existing software platforms and case registry projects
- There is a lack of incentives for homeopaths to make the effort to write up a detailed clinical case report

The solution: connecting the elements and broadening the collective effort

One of the conclusions is that there is a need to further increase the momentum by broadening the collective effort and further intensify collaboration between the different stakeholders. In this context, I am pleased to announce a closer collaboration with the Clificol project. The connections between the different projects are further illustrated in the figure below, which was also presented at the ECH General Assembly during the session on COVID-19 on the 14th of November.



The connections between a case registry project such as Clificol and high quality clinical case reports and case-series, are summarized in the table below.

Table: Comparison Clinical Case Registries and Clinical Case Reports / case series projects

Objective / benefit	Case Registry e.g. Clificol	Clinical Case Reports / case series	Comment
Collect routine and some targeted clinical data in selected or unselected patient populations	✓	✓	<p>This is one of the core strengths of clinical case registries. Case registries can focus on a selected patient population (like the Clificol COVID project) or unselected patient populations (e.g. all patients treated in participating practices)</p> <p>Case reports tend to originate from routine practice as well and can in principle be used to describe 'typical' (routine) cases, i.e. for educational purposes.</p>
Collect successful, 'atypical' cases	✓	✓	<p>Case registries can include, but are not specifically aimed at collecting atypical cases. The latter cases tend to be 'over-represented' in the homeopathic literature, leading to a 'positivity bias' in the minds of many homeopaths (actual clinical practice tends to be less 'rosy' than what one is led to believe based on the literature).</p> <p>Case registries CAN however in a complementary way contribute by identifying uncommon cases (for instance to identify successful cases receiving a 'small' homeopathic remedy).</p>
Deeper understanding of successful (or failed) cases	✗	✓	<p>The data collected in clinical case registries is not detailed / comprehensive enough for a deeper understanding.</p> <p>Clinical Case Reports therefore have an essential complementary function to better understand what is 'behind' the (quantitative) data.</p>
Identifying patterns in, and generating hypotheses based on, large datasets	✓	✗	This is one of the core strengths of case registries
Identifying and exploring	✓	✓	Case registries are useful for

biases in symptom selection and decision making			identifying and generating hypotheses based on quantitative data. This includes flagging potential biases in data submitted based on the identification of 'atypical' patterns in certain submitted data. These potential biases can then be fed back to the contributing homeopaths and analyzed further on the basis of individual case reports, creating a 'virtuous cycle' of continuous improvement.
PROVING the effectiveness of homeopathy	X	X	Neither can be used as proof for claims related to the effectiveness of homeopathy.
IMPROVING the effectiveness of homeopathy	✓	✓	Both contribute in their own way and complement each other

The main message is that both types of projects complement each other, but to maximise the synergies, there should be close communication between the stakeholders, continuous assessment of feedback, a mechanism for implementing appropriate corrective steps, etc.

Very concrete immediate steps that will be taken are:

- A link to the HOM-CASE CARE COVID-19 word template will be shortly be added to the following websites:
 - Clificol COVID-19: <https://www.clificol.net/en/> by clicking on 'Research Collaboration' under the 'The Project' button on the home page
 - RadarOpus: <https://www.radaropus.com/> under the 'Research' button on the home page
- The Clificol team will make reference to the clinical case report project in a series of webinars they will be launching as from February next year.

Further steps

- Homeopaths should continue sharing their most interesting COVID-19 cases. Perhaps initially by entering the case in one of the COVID-19 Case Registries.
- As referred to in the previous Newsletter, we will increasingly see chronic or semi-chronic 'sequelae' in patients that recovered from COVID, which is also referred to as 'long COVID'. It will be worthwhile to collect cases from such patients as well.

*The COVID-19 case collection team wishes you
happy holidays and all the best for the year 2021!*

References

1. Jenicek M. *Clinical Case Reporting in Evidence-based Medicine*. 2nd ed: Arnold; 2001.
2. van Haselen RA. Homeopathic clinical case reports: Development of a supplement (HOM-CASE) to the CARE clinical case reporting guideline. *Complementary Therapies in Medicine*. 2016;25:78-85.
3. Lamba CD, Gupta VK, Van Haselen R, et al. Evaluation of the Modified Naranjo Criteria for Assessing Causal Attribution of Clinical Outcome to Homeopathic Intervention as Presented in Case Reports. *Homeopathy*. 2020;109(4):191-197.