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1.

The Attitudes on Psychedelics Questionnaire (APQ): Validation of a new instrument for assessing attitudes on psychedelics in the general population

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Abstract

Background: Although there is research interest to assess attitudes on psychedelics, no validated instrument exists for this purpose. As psychedelics are mostly illegal worldwide, it is important to explore how the general public perceives them, considering the rising number of clinical trials involving psychedelics in psychiatry.

Objectives: Our aim was to develop and examine the psychometric properties of the Attitudes on Psychedelics Questionnaire (APQ) in a sample of the Croatian general population.

Methods: A cross-sectional, web-based survey study among the general population was conducted on 1153 participants (62.1% female, 77.7% with a graduate or high school

degree, 15.1% health care workers). We assessed participants' ability to recognize psychedelic substances using a short knowledge test.

Results: The APQ consists of 20 items with four sub-scales: *Legal Use of Psychedelics*, *Effects of Psychedelics*, *Risk Assessment of Psychedelics*, and *Openness to Psychedelics*. This model demonstrated best fit in a confirmatory factor analysis. Total scale reliability was excellent (McDonald's ω =0.949, 95% CI=0.944-0.953). A strong correlation with a similar unvalidated measure (r=0.885, P<0.001) demonstrated convergent validity. We observed an association between attitudes and knowledge on psychedelics (r=0.494, P<0.001). Younger age, male gender, and lower educational status were associated with higher APQ scores.

Conclusions: The APQ is valid, reliable, and could be applied in a wide range of settings, such as assessing educational interventions, patients' treatment outcomes, and the attitudes of different groups of experts. We encourage further validation of the APQ in English.

Key words: psychedelics, questionnaire, attitudes, psychometrics

2. Evidence behind policies, guidelines, and recommendations for the 2009 H1N1 and the COVID-19 pandemics: A cross-sectional study

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Abstract

Background: The H1N1 and COVID-19 pandemics tested decision-makers' abilities to create evidence-based policies, guidelines, and recommendations. Despite numerous tools for evidence-based decision-making developed by Cochrane and other organizations, and calls for transparency in creating policies, guidelines, and recommendations, the Centers for Disease Control (CDC), European Centre for Disease Control (ECDC), and the World Health Organization (WHO) were criticized for misusing evidence during both health crises.

Objectives: To determine the levels and accuracy of evidence representation in the policies, guidelines, and recommendations of the CDC, ECDC, and WHO for the H1N1 and COVID-19 pandemics.

Methods: A sensitive search strategy was used to retrieve policy, guideline, and recommendation documents from the three organization's repositories. Two sources publishing guidelines will also be searched (Table 1). We will analyze the evidence used in the retrieved policy, guideline, and recommendation documents using the Oxford Centre for Evidence-based Medicine's levels of evidence (Table 2). We will also assess the accuracy of evidence representation by comparing the statements in the retrieved documents to the referenced studies' findings (Table 3). The assessment will be done independently by two authors. We will use descriptive statistics.

Current state and plans: 59,153 documents were retrieved from three repositories using a sensitive search strategy (Table 1). Two repositories (WHO, CDC) were extracted into EndNote, while the third repository (ECDC) was extracted into an Excel spreadsheet using a Python script. The references were deduplicated either manually via EndNote or through a Python script. 23,442 documents remained for an accelerated screening process by two reviewers (LU, RR). The first screening was fully conducted (LU). The second reviewer (RR) is currently screening the excluded references. Documents

unrelated to the two pandemics and those not classified as policies, guidelines, and recommendations will be excluded. The analysis is planned for October 2022.

Keywords: H1N1, COVID-19, World Health Organization, European Centre for Disease Control, United States Centers for Disease Control

| Repository/source | Total | After deduplication |
|-------------------------|-------|---------------------|
| CDC Stacks | 38400 | 16900 |
| MMWR. Morbidity and | 150 | 150 |
| Mortality Weekly Report | | |
| WHO IRIS | 1426 | 600 |
| WHO Committee Approved | 337 | 337 |
| Guidelines | | |
| ECDC | 18375 | 5455 |
| OVERALL | 59153 | 23442 |
| | | |

Table 1. Repositories and sources searched in the study

CDC – Centers for Disease Control and Prevention, MMWR – Morbidity and Mortality Weekly Report, WHO – World Health Organization, WHO IRIS – World Health Organization Institutional Repository for Information Sharing, ECDC – European Center for Disease Control

| Level | Study design |
|----------------|--|
| 1a | Systematic reviews of randomized |
| | controlled trials (RCTs) |
| 1b | Individual RCTs with narrow confidence |
| | intervals |
| _1c | All-or-none case-series studies |
| 2a 2b | Systematic reviews of cohort studies |
| 2b | Individual cohort studies (including low- |
| | quality RCTs) with <80% follow-up |
| 2c | "Outcomes" research |
| 3a | Systematic reviews of case-control studies |
| 2c 3a 3b | Individual case-control studies |
| 4 | Case-series and poor-quality cohort/case- |
| | control studies |
| 5 | Expert opinions |

Table 2. Oxford Centre for Evidence-based Medicine's levels of evidence

RCT – randomized controlled trial

 Table 3. Accuracy of statements

| Accuracy grading | Description | |
|------------------|---|--|
| 1 | Accurately represents the referenced source of evidence | |
| 2 | Contains minor errors in accuracy compared to referenced source of evidence | |
| 3 | Contains major errors in accuracy compared to the referenced source of evidence | |

3.

Level of scientific evidence needed to make an informed decision about health among researchers, healthcare workers and consumers: a cross-sectional study

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Abstract

Background: The hierarchy of evidence is widely known to evidence-based medicine experts. However, it remains unknown how non-experts understand it and how they use it in decision-making.

Objectives: To assess what level of evidence is needed for different stakeholders in the healthcare system to make treatment effectiveness decisions.

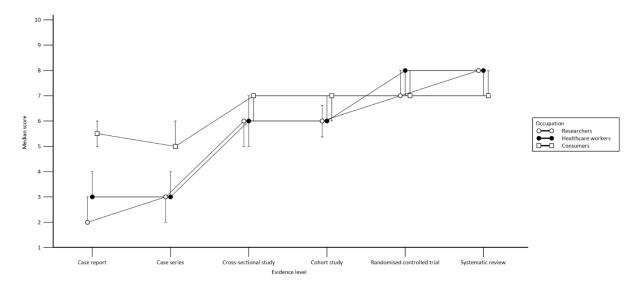
Methods: A quantitative cross-sectional study was conducted from November 2021 to February 2022 using an online survey. The participants were researchers, healthcare workers and consumers from Croatia. The survey had six scenarios about the same medical treatment presented within different study designs and in random order. Participants were asked to assess on a scale from 1-10 if the descriptions presented a sufficient level of evidence to conclude that the treatment was effective.

Results: A total of 584 participants were eligible for inclusion (97 researchers, 201 healthcare workers and 286 consumers). Participants were mainly women (74%, median age 43.5, interquartile range 33-52). Perceived sufficient level of evidence scores for all participants increased with the higher-level study designs. For researchers, as the number of participants and degree of variable control in the study design increased, the perceived level of sufficient evidence also increased significantly. Among consumers, no significant differences were observed in scores between cross-sectional study and cohort study and between randomised controlled trial and systematic review. Healthcare workers' assessments were significantly lower for case studies and case series compared to other study designs (Figure 1).

Conclusions: Consumers and healthcare workers did not increase their certainty about the effectiveness of the therapy when higher-level study designs were presented compared to lower-level study designs. There is a need to implement educational courses on basic research methodology in lower levels of education and as part of the Continuing Medical Education for all stakeholders in the healthcare system.

Keywords: hierarchy of evidence; researchers; healthcare workers; consumers

Figure 1. Scores per group for perceived adequacy of evidence about the effectiveness of the treatment.



4. Financial transparency in line with the EFPIA code of practice among pharmaceutical companies in Croatia: Observational study

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Abstract

Background: European Federation of Pharmaceutical Industries and Associations (EFPIA) has a collection of ethical rules, called EFPIA Code of Practice. The Code regulates promotion of medical products to healthcare professionals (HCPs) and interactions with them, their organisations and patient organisations, in order to apply the highest ethical standards to the industry. The Code includes a rule on writing disclosure reports, which should transparently state transfers of value for HCPs, healthcare and patient organisations and for research and development within those organisations. For both individuals and organisations, disclosure reports should provide information about event-related costs (travel and accommodation, registration fees, sponsorships for event management) and fees for service and consultancy, while for organisations donations and grants are also to be disclosed.

Objectives: Our objective was to determine if pharmaceutical companies that are EFPIA members in Croatia oblige to EFPIA Code of Practice, by analysing availability and transparency of the disclosure reports with contributions to Croatian HCPs and their organisations.

Methods: Using EFPIA website, we have identified EFPIA members in Croatia. From the company webpages we downloaded disclosure reports for years 2017, 2018 and 2019. If the report was not in a downloadable format, we used Beautiful soup, a Python library for scraping data out of HTML and XML files, to collect the transfers of value data from the page in a Microsoft Excel file. We sent a query for disclosure reports via e-mail to companies which did not have disclosure reports available on their websites. From disclosure reports, we analysed the following data regarding the transfer of value: existence of segmentation between HCPs and organisations and specification of expenses per each individual professional for each of the categories of transfers of value. We considered that transparent disclosure reports were those with all the required data regarding the transfer of value. We conducted descriptive statistics.

Results: There were 23 EFPIA members in Croatia; 21 had published disclosure reports online. Web scraping was done for reports from two companies. One of the two

companies that did not have any data available on their official website answered our query and provided disclosure reports. Thus, disclosure reports from 22 companies were analysed. Six companies did not have full data enclosed regarding transfer of value for individual HCPs, as they should per EFPIA Code of Practice. For healthcare organisations, the companies were more transparent, with just three companies not having full data disclosed. Full data for research and development were disclosed in 12 out of 22 companies.

Conclusions: Availability and transparency of the disclosure reports among the EFPIA members in Croatia were not optimal. To adhere to the EFPIA Code of practice fully, all disclosure reports should be available on the pharmaceutical company website, in a downloadable format, with all required information fully disclosed.

Keywords: pharmaceutical industry; code of practice; healthcare professionals; disclosure of payment