

Article

Adaptation of and Protocol for the Validation of the Alcohol Use Disorders Identification Test (AUDIT) in the Russian Federation for Use in Primary Healthcare

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Abstract

Aims: To adapt and validate the Alcohol Use Disorders Identification Test (AUDIT) for use in the Russian Federation and countries with Russian-speaking populations by:

- 1) Operationalizing alcohol use patterns to allow for the best identification of hazardous use patterns in the Russian context.
- 2) Determining the best cut-off values for brief advice/interventions in primary healthcare settings.
- 3) Determining the best cut-off values for potential alcohol use disorders.

Methods: Systematic review of past use and validation of the Russian-language AUDIT. Interviews to be conducted with experts to identify problems encountered in the use of existing Russian-language AUDIT versions. A pilot study using a revised translation of the Russian-language AUDIT that incorporates country-specific drinking patterns in the Russian Federation.

Results and Conclusions: The systematic review identified over 60 different Russian-language AUDIT versions without systematic validation studies. The main difficulties encountered with the use of the AUDIT in the Russian Federation were related to the lack of:

- a concept and definition for a standard drink;
- low-risk drinking guidelines/thresholds and
- inclusion of the specific drinking pattern of episodic heavy drinking.

A revised version of the Russian-language AUDIT was created based on the pilot studies, and was validated in primary healthcare facilities in all regions in 2019/2020.

THE ALCOHOL USE DISORDERS IDENTIFICATION TEST AS A SCREENING INSTRUMENT

The Alcohol Use Disorders Identification Test (AUDIT (Saunders, Aasland, Babor, et al., 1993; World Health Organization, 2001)) has arguably been the most successful screening instrument for hazardous and harmful use of alcohol and for alcohol use disorders (AUDs) worldwide. It was primarily intended for screening in the healthcare system to initiate interventions, but has since been used for screening in many other settings, including as part of global monitoring systems (Lundin et al., 2015; Rehm and Lange, 2019).

The original AUDIT was developed by research centres in Australia, Bulgaria, Kenya, Mexico, Norway and the USA, using primary healthcare (PHC) facilities to gather empirical data (Saunders, Aasland, Amundsen, et al., 1993; Saunders, Aasland, Babor, et al., 1993). The two conditions it was developed to screen for—hazardous and harmful alcohol consumption—have been formally defined by the World Health Organization (WHO (World Health Organization, 1994)) as follows (see more detailed discussion in Appendix 3).

In the International Classification of Diseases 11 (ICD-11), hazardous use was defined as a pattern of alcohol use, which increases the risk of harmful consequences for the user, including those to physical and mental health (as in harmful use), or as negative social consequences. The increased risk may be due to the frequency of substance use, the amount used on a given occasion, risky behaviours associated with substance use or the context of use, a harmful route of administration or a combination of the above (World Health Organization, 2018b).

In contrast, a harmful pattern of alcohol use denotes a pattern of alcohol use, which is causing clinically significant damage to health. The health damage may be physical (e.g. liver damage following chronic drinking) or mental (e.g. depressive episodes secondary to heavy alcohol intake), and it may be to the users themselves or to others. Harm may be caused by the intoxicating effects of a substance or the direct or secondary toxic effects on body organs and systems (World Health Organization, 2018a). Harmful use of alcohol and alcohol dependence constitute ‘alcohol use disorders’ in both the ICD-10 and the ICD-11.

The AUDIT contains 10 items that are divided into three domains: alcohol use, dependence symptoms and harmful use (World Health

Organization, 2001). The responses to each item are scored between 0 and 4, and then summed to yield a potential minimum score of 0 to a maximum score of 40 (World Health Organization, 2001).

While the original intent was to create a screening instrument that did not include items regarding consumption directly (akin to the ICD definition of AUDs), this proved to be impossible. Accordingly, the final version of the AUDIT included three consumption items that have been responsible for the vast majority of the variance seen in most populations (e.g. Bush et al., 1998); for a description of the close relationship between drinking level and AUDs, see Rehm et al., 2013, 2014). These three items also constitute an internationally used shorter version of the AUDIT, known as the AUDIT C (Bush et al., 1998; Bradley et al., 2003, 2007). However, the AUDIT C has not been included in the WHO manual, in part because the remaining items were supposed to provide clinicians with enough information about a person’s drinking to permit a conversation about possible problems and dependence.

The aim of the AUDIT from its inception was to:

- Develop a screening tool for use in clinical settings to identify hazardous drinkers requiring brief advice or more formalized brief interventions, in addition to identifying people with potential AUDs, who might require treatment at the PHC level or referral for more specialized treatment (World Health Organization, 2001). Thus, three thresholds were needed: (a) the first for brief advice on the reduction of hazardous drinking (in the original WHO AUDIT for scores from 8 to 15, inclusively); (b) the second for brief counselling and continued monitoring (original WHO AUDIT for scores from 16 to 19) and (c) the third for a score clearly warranting further diagnostic evaluation for alcohol dependence, often in specialized settings (WHO AUDIT scores for ≥ 20 ; but see Lange et al., 2019).
- Allow for standardization and cross-cultural comparability.

Two major obstacles in the AUDIT’s development needed to be overcome: first, healthcare systems differ in how and where they treat AUDs (Klingemann et al., 1992). Second, measurement of consumption was developed around the concept of a standard drink, often operationalized as containing 10–14 g of pure alcohol (=ethanol). In

the original version it was 10 g (World Health Organization, 2001), and to deal with differing standard drink sizes among countries (Kalinowski and Humphreys, 2016), encouragement was given in the AUDIT manual for users in countries with other average drink sizes to adjust cut-off scores accordingly. The situation may even be more complicated in some cultures that do not have the concept of a standard drink.

To surmount these problems, national validation studies were conducted in different countries and healthcare systems (e.g. Higgins-Biddle and Babor, 2018; Lange et al., 2019; Nemtsov et al., 2019), usually centred around local ways to measure consumption and local threshold. Cultural adaptations for other concepts used in the AUDIT might also have been necessary, but were usually not incorporated. The lack of any validation study became apparent for the Russian Federation, when in 2016, the WHO European Region and the Russian Ministry of Health instituted a 'train-the-trainer' programme to teach interviewers how to administer the AUDIT questionnaire and provide brief interventions (World Health Organization, 2019). Before long, experts involved in the initiative expressed concerns that the AUDIT might not be adequately assessing the specific drinking patterns in the Russian Federation and its neighbouring countries. Consequently, a new study was initiated to empirically lay the foundation for a revised Russian-language AUDIT, adapted to the Russian Federation's specific drinking patterns and healthcare system. This protocol describes the initial studies conducted, the resulting draft versions of the AUDIT and proposes a methodology to conduct a validation study in light of current drinking patterns and service needs specific to the Russian Federation.

RATIONALE, PURPOSE AND OBJECTIVES OF THE AUDIT VALIDATION IN RUSSIA

Minimum thresholds for hazardous use are often determined as exceeding the national lower risk drinking guidelines (Rehm et al., 1996). At the moment, no commonly accepted guidelines exist in the Russian Federation; however, there are Russian medical guidelines on how to deal with people qualifying for harmful consumption. Determining drinking thresholds from the literature alone is problematic. Research has clearly shown that even harmful use (in terms of impacting mortality) starts at fairly low levels of alcohol consumption (Shield et al., 2017; GBD 2016 Alcohol Collaborators, 2018; Wood et al., 2018; Shield and Rehm, 2019), for breast cancer at less than one drink containing 12 g of alcohol per day (Shield et al., 2016). However, it is neither effective from a health standpoint, nor cost-effective, to start brief interventions for patients in PHC at such low levels of alcohol use (Rehm et al., 2016). Moreover, it has been shown that, in general, interventions for lower levels of alcohol use seem to be less effective than interventions for higher quantities (see a comparison between two cochrane reviews (Kaner et al., 2007) vs. (Kaner et al., 2018)).

To determine the optimal threshold for daily alcohol use or thresholds for other patterns of use (e.g. frequency or level of heavy drinking occasions), the WHO initiated an activity to support the Ministry of Health of the Russian Federation in the revision, adaptation and validation of the AUDIT to further implement screening and brief intervention activities at the PHC level using this tool. The WHO invited key stakeholders involved in the prevention and control of health risks due to alcohol consumption to form an advisory board. The RUS-AUDIT Project Advisory Board was established in 2018 to provide advice to the WHO and the Ministry of Health of the

Russian Federation on the implementation of the AUDIT adaptation and validation to forward the following objectives:

- 1) To operationalize alcohol use in order to allow for the best identification of hazardous use patterns in the Russian context.
- 2) To determine the best cut-off values for brief advice/interventions in a PHC setting for Russia.
- 3) To determine the best cut-off values for harmful drinking patterns and AUDs, and for interventions in the PHC setting or referral to specialized treatment in Russia.

STEPS IN THE VALIDATION PROCESS: INITIAL STUDIES

Systematic review of use of the AUDIT questionnaire in Russia (completed June 2019)

We conducted a systematic review of the use of the AUDIT questionnaire in Russia as well as in the Russian language. In total, >60 unique Russian-language translations of the AUDIT were identified, most of which were from the Russian Federation (Neufeld et al., 2019). A content analysis of the different versions revealed that most of the differences were related to the first three consumption items, specifically the quantification alcohol volumes consumed (Bunova et al., in review). Several distinct AUDIT versions in Russian were also identified in official WHO publications (including manuals and guidelines), as well as in the clinical guidelines of the Russian Federation (for PHC and specialized narcological care).

More than half of the versions failed to provide a definition of a standard drink size, or its definition was not readily apparent from the source material, while others incorporated the concept of a standard drink as containing 10 g pure alcohol. However, one version from Ukraine suggested a standard drink containing 13 g pure alcohol although there has never been an official definition of a Ukrainian standard drink.

The majority of the sources that included a standard drink definition explained it in accompanying material, but not within the text itself. The rest of the sources featured an in-text explanation/definition that was part of the AUDIT instructions, or defined a standard drink in the second or third consumption item on the test. Some versions included pictures, a formula for calculating individual consumption levels or even conversion tables (Neufeld et al., 2019).

A considerable number of inconsistencies between different versions were found and none of these versions were properly empirically validated, and nor did they mention a predetermined protocol of systematic translation and back translation of the tool.

Pilot study: qualitative expert interviews (completed March 2019)

In addition, we conducted semi-structured personal interviews (Turner, 2010) with 37 experts that included both healthcare professionals ($N = 12$) as well as patients in primary and specialized healthcare ($N = 25$). The interviews aimed to:

- Explore problems in the understanding of the current AUDIT items.
- Improve the clarity of any AUDIT items causing difficulties with comprehension.
- Integrate experiences regarding the use of the AUDIT from prior studies (including not-yet-published studies).

The interviews were extracted via thematic content analysis. The findings corroborated the results from the systematic review. Major difficulties noted by the experts included:

- The definition of a standard drink in the context of Russian drinking.
- The definition of a single occasion of drinking.
- The assessment of the dimensions and concepts in the AUDIT more generally.
- The lack of systematically validated versions.

The following conclusions were drawn:

- The concept of a standard drink alone without visual aids such as a pictogram or a conversion table is not meaningful in the Russian Federation as there is no accepted definition of a standard drink known to patients in PHC (or to the general population for that matter). Thus, any version of the questionnaire in the Russian Federation measuring quantity of alcohol consumption must contain clear definitions of beverage-specific drink sizes.
- The term 'single occasion of drinking' was not understood by one group of patients, namely very heavy drinkers, who consume without interruption for >24 consecutive hours. This confusion over what constitutes a single occasion may lead to questions for the interviewer, who may have a vastly different understanding of what one occasion means. This difficulty was resolved by defining an occasion to be a time period of 24 hours.
- The use of conversion tables, conversion formulae and/or flashcards places a heavy cognitive load on both respondents and interviewers/physicians, and may lead to biases (Sudman et al., 1996; Schwarz, 2007).
- Accordingly, we suggest presenting a pictogram for quantity consumed (supported by conversion tables), which will ask respondents only to enumerate the number of glasses/bottles consumed.

Alternatively for future computer-assisted tools, we suggest using an electronic controller to indicate how much of a typical bottle of the respective beverage would remain after pouring their usual quantity into a glass. All the conversions can be performed by a computer programme, so neither the respondent nor the interviewer will be required to do any calculations.

Pilot study on the feasibility of the use of the new draft AUDIT items to assess alcohol use (finished November 2019)

Based on the systematic research and the expert interviews, a draft version of a new Russian-language AUDIT was constructed (see Appendix 2). Rules of translation and back translation by an expert panel were applied, and professional translators, communication specialists and linguists were consulted in the process. Based on requests from PHC institutions, the main version of the instrument devised was based solely on personal interviews. This version was then submitted for a pilot study and tested in 80 patients in a PHC and a hospital setting at the National Medical Research Center for Preventive Medicine in Moscow and included cognitive debriefing (Ryan et al., 2012). Cognitive debriefing followed every question and included listing any difficulties encountered in understanding the meaning of the question, in answering the question and any additional questions on the specific concepts asked during the interview (see Appendix 2). Only patients who had consumed alcohol in the past 12 months were included in the interview process.

In the next step, the draft version was adapted, based on the outcomes of 80 interviews, and tested again on another 30 patients. The entire sample of 110 participants included patients from a preventive medicine health centre, from the inpatient hospital wards of the cardiology, surgery and internal medicine units and participants

of an ongoing study in preventive medicine, all located in Moscow. The results were presented to the Advisory Board of the project and further amendments to the form based on results of the study were made, which was then tested on another 20 patients from a polyclinic, and 30 patients recruited from two specialized care (narcology) hospitals in Moscow.

Based on the outcomes of the entire pilot, a final version of the instrument was adopted, as part of an iterative process of adaptation, testing, cognitive debriefing, data analysis and discussion. The version of the Russian-language AUDIT for validation can be found in Appendix 2. The main conceptual changes concerned: (a) the introduction of a flashcard and conversion table for the assessment of the second consumption item to reduce the cognitive load on both the interviewer and the patient; (b) the replacement of a 'single occasion of drinking' with the period of '24 hours' and (c) the introduction of an additional consumption item assessing the maximum consumed alcohol volume within the past 3 months and the potential consequences of this drinking pattern (at the end of the questionnaire). Electronic and self-administered versions will be tested in future studies.

The additional consumption items will be asked last and may be dropped again, based on the results of the validation, i.e. based on its predictive power and its item-response characteristics. If the >10 items result from the validation study, the overall score of the AUDIT will be rescaled to correspond to international versions of the AUDIT.

Main validation to determine the best thresholds for use of the Russian AUDIT in PHC settings

The main goal of this study and the above-described initial studies has been to improve quality of care in the participating facilities and, as such, they were considered to be part of routine care (see also point on ethics below). As there are no Russian guidelines, the following criteria to determine the threshold for initiating brief advice and interventions for patients were suggested:

1. drinking of >20 g pure alcohol on average per day for women, or 40 g pure alcohol per day for men, based on the medium-risk drinking levels for chronic disease from the European Medicines Agency (European Medicines Agency, 2010); or
2. at least 1 drinking day of at least 100 g pure alcohol or higher in the past 3 months; or
3. at least 2 drinking days of at least 60 g pure alcohol each per week.

The latter two drinking scenarios or styles were empirically derived from an epidemiological study (Leon et al., 2007). In addition, we will determine the threshold for a variety of AUDs requiring interventions either at the primary or specialized healthcare level. This will be done by an expert consensus workshop composed of members from the Advisory Board.

Sites and settings The protocol will be implemented at PHC facilities including those whose primary purpose is preventive care (Garant.ru, 2019). The participating PHC facilities do not have to be representative of the Russian Federation in the statistical sense, but several different drinking styles within the country should be adequately represented. The validation interviews will be conducted via personal interviews, and will last between 5 and 30 minutes (see the section on data collection below).

Study design and sample The sample size will depend on the level of precision to be achieved in the study, and the expected number of

dropouts. A sample size of 900 patients will enable us to determine an area under the curve of 70% with a 95% confidence level within $\pm 5\%$. This is conservative, as we expect a higher area under the curve (Hanley and McNeil, 1982; Kryzanowski and Hand, 2009).

A probability sample will be recruited from participating PHC facilities (such as all patients seen on a particular day or a random algorithm to select patients to be tested). At least 50 patients will be interviewed in each PHC facility. Each participating patient will get an identification number beginning with a code identifying the institution to allow for clarifying questions at a later date if required.

Sampling should be undertaken to achieve a ratio of men to women of at least 1:1, with at least 50% of the sample aged 40 years or younger. These quotas were set to allow gender- and age-specific analyses.

Interview Personal interviews will be conducted by trained interviewers after oral informed consent is obtained. The following instruments will be used:

- The Russian-language AUDIT as based on the outcomes of the pilot (i.e. the 11 Russian AUDIT questions of the modified version developed in the pilot study).
- The WHO Composite International Diagnostic Interview (CIDI) for AUDs (i.e. for harmful use of alcohol and alcohol dependence), which was used in a large study in PHC in six European countries (Rehm et al., 2015), translated and back translated. While the CIDI certainly has weaknesses, it has been shown to perform similarly to psychiatric interviews or the Schedule for Clinical Assessment in Neuropsychiatry (SCAN) in the large WHO reliability and validity study (Ustün et al., 1997).
- The Kessler K10 instrument (Furukawa et al., 2003; Kessler et al., 2003), translated and back translated.

For patients reporting no alcohol consumption over the last year and having an AUDIT score of 5 or less, only a few sociodemographic characteristics will be collected (sex, age, socioeconomic status). For these patients, the interview will take <5 minutes.

For people with an AUDIT score above 5, the CIDI for AUDs and the Kessler K10 will be used, and sociodemographic information will be collected. For these patients, interviews will take ~20–30 minutes.

For people having an AUDIT score of 5 or less, only one out of three patients will randomly be selected and asked the same questions (i.e. WHO CIDI, Kessler K10 and sociodemographic questions). For the random selection of these patients, every third patient for each interviewer will be administered the full questionnaire.

For the remaining two-thirds of patients, who have a score of 5 or less, the interview will only consist of the Russian AUDIT and the sociodemographic questions, and should take only 5–10 minutes to complete.

Interviewer training The participating PHC facilities will choose the most appropriate people to conduct the interviews, which may be nurses, medical doctors or other healthcare workers. Alternatively, interviews could also be conducted by central staff for the project. All interviewers will have to be trained to administer the various questionnaires. Training modules in English and other languages exist for all three original instruments and these will be translated into Russian and adapted for Russian culture.

The training was conceptualized under a ‘train-the-trainers’ format. The trainers will be selected in collaboration with members of the Advisory Board (see Appendix 1). The sessions will take ~4–5 hours, will involve role plays and each interviewer will be given

a test at the end to demonstrate their ability in administering the interview.

Data collection During the interview, each answer will be registered by the interviewer directly onto the paper questionnaire. On the day of the interview, each filled-in questionnaire will be double-checked for completeness. Once completed, the surveys will either be transposed into a custom-made EXCEL assessment form at the PHC facility, or collected and sent weekly to the Moscow data collection centre at the WHO European Region Office.

Each patient will be given a unique identifier consisting of a code for their institution, a code for their interviewer and a consecutive identifier, which will allow for specific enquiries for quality control purposes (see below).

Quality control There will be four methods of assuring quality control. First, the electronic spreadsheets will be programmed so that only eligible values can be entered (e.g. if the valid answers to a question consist of the numbers 0, 1, 2, 3, 4 and the symbol ‘.’ to denote a refusal to answer, any other number, character or symbol will be blocked from being entered). Second, the PHC facilities and the data collection centre will keep the filled-in questionnaires for random control checks. Third, there will be routines set up for plausibility by the data processing centre and, if these routines signal problems, the answers will be double-checked (via the paper questionnaires first, and then by asking the interviewers directly in the event that there are still questions). Finally, random interviews will be observed by the trainers to ensure compliance with the interview rules.

DATA MANAGEMENT AND STATISTICAL ANALYSES

After the quality control procedures are completed, the data will be entered into the RUS-AUDIT database, situated at WHO Region European Office for the Prevention and Control of Noncommunicable Diseases.

The data analyses will involve:

- characterizing the feasibility of instruments in Russia using descriptive analyses (including missing values analyses);
- establishing the main analyses to test the hypotheses of the validation and to determine best thresholds for interventions at the PHC level (determination of sensitivity and specificity; determining receiver operating characteristics (Zweig and Campbell, 1993; Florkowski, 2008));
- conducting sensitivity analyses based on differing severities of AUDs and for alcohol dependence and
- analyzing the potential influence of gender, age and comorbidity on the sensitivity and specificity of AUDIT and AUDIT-C as composed of different items (e.g. 10 vs. 11 item version, three- vs. four-item version).

The results will be presented to the Advisory Board for their input in developing guidelines for screening and subsequent interventions. The results of this validation will thereby inform the wider questions of change in the healthcare system for handling hazardous use of alcohol and AUDs.

Ethical considerations

Since this study’s main goal is one of quality improvement in the participating PHC facilities without collecting any identifying patient

information, it was considered to be part of routine care by participating institutions, except for the specialized addition care centre, where it completed ethical review (this is similar to other implementation studies for screening and brief advice/interventions in other countries (Anderson *et al.*, 2017)).

Conclusion and further steps

As a result of failed efforts to implement screening and brief interventions in the Russian Federation due to the lack of instruments, a large study to adapt and validate the AUDIT for use in PHC was initiated, including participation of major stakeholders from PHC and prevention, specialized care and health services and systems administration. A systematic search of past versions of the AUDIT in the Russian language and expert consultations with both providers and patients identified problems, which then led to the development of a revised version. After pilot studies, a final test version of the AUDIT for validation was constructed, and a protocol was adopted.

After the analyses of the validation study, a Russian-language AUDIT will be available. This will, at long last, will serve to complement the successful population-based alcohol control policies in the Russian Federation (Neufeld and Rehm, 2013; Nemtsov *et al.*, 2019; World Health Organization, 2019; World Health Organization Regional Office for Europe, 2019) with interventions directed towards individuals with AUDs (see also the SAFER initiative (World Health Organization, 2018c)).

DISCLAIMER

João Breda, Carina Ferreira-Borges, Melita Vujnovic and Elena Yurasova are staff members of the WHO. Jürgen Rehm and Maria Neufeld are WHO consultants. The authors alone are responsible for the views expressed in this publication and they do not necessarily represent the decisions or the stated policy of the World Health Organization.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Alcohol and Alcoholism* online.

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CONFLICT OF INTEREST STATEMENT

None declared.

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