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TOP-ID: a Delphi technique-guided development of a prescription and deprescription tool for adults with intellectual disabilities

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ABSTRACT

Objectives Adults with an intellectual disability (AWID) are often polymedicated because of somatic and psychiatric health problems. Besides, they may display challenging behaviours, leading to off-label prescription of psychotropic drugs, without efficacy and with numerous adverse effects. In this context, a prescription/deprescription tool (Tool for Optimising Prescription in Intellectual Disability/TOP-ID) was developed to improve the care of AWID. This paper describes how TOP-ID was designed.

Design Four-step consensus-based process involving a review of the literature, eight semistructured interviews and a two-round Delphi process.

Setting Seventeen general practices and university and general hospitals from Belgium, France and Switzerland.

Participants Eighteen French-speaking physicians from different domains of expertise participated in the Delphi process.

Primary and secondary outcome measures For the Delphi iteration process, consensus was defined as at least a 65% agreement between the experts.

Results Two rounds were needed for the Delphi process. Eighty-one items of the tool were submitted to 18 out of 35 recruited French-speaking experts during the first round. Sixty-nine per cent of the items reached a rate of agreement of 65% or more in that round. Thirteen questions were reformulated and resubmitted for the second Delphi iteration round. All of the statements reached a rate of agreement of 65% or more in the second round.

Conclusion TOP-ID is the first prescription–deprescription tool developed specifically for AWIDs in French. It is intended to help prescribers document patient care in order to reduce prescription errors and to improve safety. The next steps of the project include the development of an electronic version of TOP-ID and a utility study.

INTRODUCTION

Intellectual disability (ID) is a neurodevelopmental disorder affecting conceptual, social and practical domains and impacting adaptive functioning. Based on international studies, the prevalence of ID is around 0.5% in adults.[1 2]

Strengths and limitations of this study

► Tool for Optimising Prescription in Intellectual Disability (TOP-ID) is the first prescription/deprescription tool dedicated to adults with intellectual disability.
► It was designed by a panel of French-speaking experts with a two-round Delphi iteration process.
► Due to the scarcity of the literature data, TOP-ID is mainly based on expert opinions and pharmacological data.
► TOP-ID's clinical utility will need to be tested.

The health status of adults with ID (AWID) is poorer than in the general population and in addition, somatic and psychiatric conditions are often difficult to diagnose or might be underdiagnosed due to atypical presentations, partly attributable to communication issues.

Besides, one of the major concerns in caring for AWIDs are challenging behaviours. They can be defined as a range of disruptive and dangerous behaviours that include aggression, self-injury, property destruction, stereotypies and pica.[3 4] Their prevalence increases with the severity of the disability and is linked to comorbid autism spectrum disorder. For these reasons, AWIDs are at risk of being polymedicated, in particular with psychotropic drugs.

Prescription in AWIDs is further complicated by the fact that they are systematically excluded from clinical trials aiming at assessing medication. As a result, indications and benefit–risk balances are never clearly determined for this population and evidence-based data are lacking. Despite this lack of evidence, polypharmacy, defined by the concurrent use of five drugs or more, is frequently observed in AWIDs and increases with the severity of the disability and the

associated comorbidities.[5 6] Polypharmacy is a risk factor for drug–drug interactions associated with numerous potential adverse effects.[7–9]

Among the few existing guidelines for the care of AWIDs, most of them cover challenging behaviours only and remain mainly theoretical.[10–13] A small number, such as the Frith prescribing guidelines,[14] or the Surrey Place primary care guidelines,[15 16] are more practice oriented. To our knowledge, these guidelines were not developed using a Delphi method. Moreover, they do not include deprescribing strategies.

The aim of this work was to develop the first prescription/deprescription tool for AWIDs: the Tool for Optimising Prescription in Intellectual Disability (TOP-ID). TOP-ID is based on literature data and on clinical expert opinions. Its goal is to help assess, diagnose and treat symptoms appropriately in four common clinical situations. A deprescription guide is included as well.

This paper describes how TOP-ID was elaborated.

METHODS
The development of the tool was split into three steps.

Step 1: selection of the medical domains
The project was led by a multidisciplinary research group composed of a psychiatrist, a psychopharmacologist, a psychologist and a PhD student in clinical pharmacology at the Geneva University Hospitals in Switzerland. The group first selected the medical domains to be addressed in the preliminary tool version, based on the following: their observed prevalence among patients hospitalised in a unit specialised in the care of AWIDs, the fact that communication issues have a high impact on their detection and management, and their association with significant prescription issues.

The selected domains were 'pain management', 'gastrointestinal disorders', 'sleep disorders' and 'challenging behaviours'. For each domain selected, a prescription guide was then developed. Each prescription guide was based on the same model: assessment, diagnosis, treatment, reassessment, and evaluation of the efficacy and safety of the treatment.

Due to the high prevalence of inappropriate polypharmacy in AWIDs, a deprescription guide was added. The deprescription guide includes two sections: 'When to deprescribe' and 'How to deprescribe'.

Attached to both prescription and deprescription guides were a number of annexes containing information on frequent disorders in AWID population, evaluation scales and tables, and information on specific drugs.

Step 2: literature reviews, semistructured interviews and draft agreement
Literature reviews and semistructured interviews
For each selected domain, a scoping review of the literature was conducted. Medline and Google Scholar databases were searched systematically using the keywords

described in online supplemental appendix 1. The data were complemented by information found in guidelines and books on ID such as the DM-ID2,[17] the Frith prescribing guidelines,[14] the Surrey Place guidelines[15] and the National Institute for Health and Care Excellence (NICE) guidelines.[18] Results of each literature review were analysed by the multidisciplinary research group and a first version of the prescription–deprescription tool was developed in 2017. A summary of each guide is presented in online supplemental appendix 2.

Regarding pain management, information was found on pain assessment in AWIDs,[19–26] but information on pharmacological treatment relied mainly on guidelines for the general population, based on the WHO pain ladder, and on local guidelines of the Geneva University Hospitals.[27–29] The scoping review on which the pain prescription guide is based has been published by the research group.[30] For gastrointestinal disorders, information was derived from guidelines for the general population, such as the World Gastroenterology Organisation,[31] NICE[32] and the American Gastroenterological Association.[33] For sleep disorders, information was based on the international classification of sleep disorders,[34] and on French guidelines for the general population and for individuals with ID.[35–37] The guide on challenging behaviours relied on guidelines such as the DM-ID2,[17] the Frith Prescribing Guidelines,[14] the Surrey Place Centre Guidelines,[15] the International Guide to prescribing psychotropic medication for the management of problem behaviours in adults with IDs[13] and the Royal College of Psychiatrists guidelines.[38] The deprescription guide was partly based on deprescription reviews, mainly in older people[39–44] augmented with theoretical pharmacological considerations. The four prescription guides are designed for clinical use. The deprescription guide should be used at preset time points (once a month for example) or whenever indicated by the clinical situation.

This first version of the tool was then presented to eight medical experts of the French-speaking part of Switzerland during semi-structured interviews. The experts were chosen based on their expertise in a domain addressed by the tool (clinical pharmacology, neurology, sleep disorders, ID psychiatry or internal medicine), on their interest for the project and on their availability to participate in the semistructured interviews. Each interview started with a short presentation of the project, followed by 43 specific questions. The interview ended with a discussion and general comments by the expert on the tool. All the answers and comments of the experts were reviewed by the research group and then included in the tool. This process resulted in the development of 81 questions presented to the Delphi experts.

Step 3: Delphi iteration process
A Delphi iteration process was then used to find a consensus on the 81 items of the questionnaire, which were based on the semi-structured interviews. The experts also had access to the tool in its entirety and could make
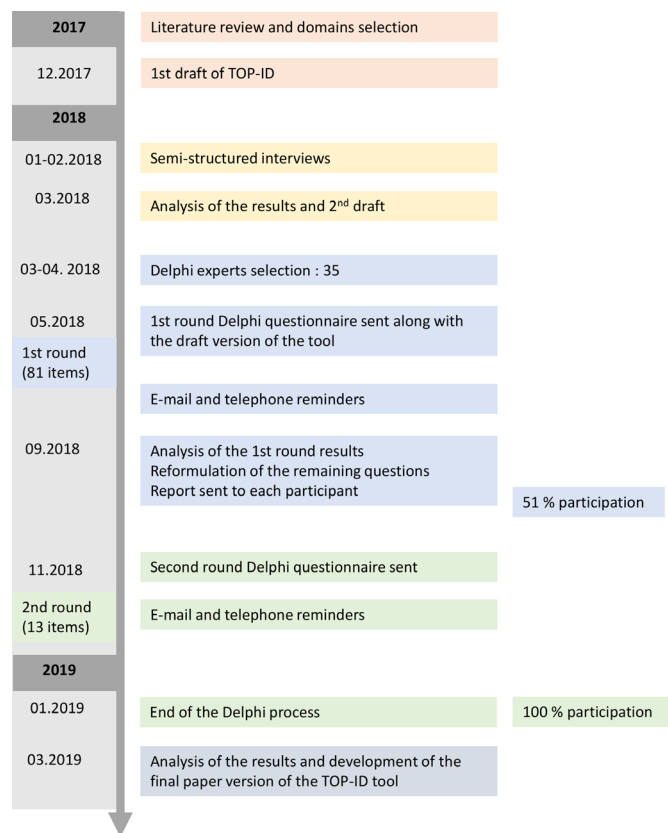
Figure 1 Flow chart of the development process. TOP-ID, Tool for Optimising Prescription in Intellectual Disability.

suggestions on every aspect of the tool. The Delphi technique is designed to build consensus on a specific topic by means of a questionnaire delivered to selected experts of the topic. The questionnaires are subject to multiple iterations until a consensus is reached among the experts.[45]

Recruitment of experts

Thirty-five French-speaking international experts (Switzerland, France, Belgium and Canada) in various fields of expertise (clinical pharmacology, psychiatry, neurology, sleep disorders, internal medicine) were contacted. The Delphi experts were approached through the research group network. They were working in ID, having a special interest for this population or being a specialist for the chosen domain of the tool.

Delphi rounds

The RedCap application was used to conduct the online survey.[46] Email and phone reminders were sent every 2–3 weeks to the experts who had not answered the survey yet. For the first round, experts had to answer yes/no questions or multiple-choice questions. 'Does not know' was also a possible answer. Each item contained a rationale and references to the literature. Evidence of the propositions was classified as follows: A: data coming from specific literature in AWIDs (any type of study, except for single case studies), B: data coming from Swiss or international recommendations for the general population

or other vulnerable populations, and C: consensus of the research group based on their clinical experience.

Experts were encouraged to motivate their answers and to provide useful references for each question. The 'does not know' answers were not recorded for the determination of the consensus.

In accordance with previous studies, the consensual agreement rate was fixed at 65%.[47–49] This means that items for which the consensus rate was 65% or more among the experts were kept in the tool.

Questions for which no consensus was reached in the first round were reformulated and submitted in a second Delphi round with further arguments and references to support the statement. For the second round, the experts were asked to take a definite position, based on the rationale and references. Therefore, the 'does not know' option was removed and only yes/no questions were left. The Delphi iteration process stopped when all the questions reached a 65% or more consensus rate.

Patient and public involvement

Patients and public were not involved in the study process.

RESULTS

The flow chart of the development process is shown in figure 1.

Semistructured interviews

Two investigators conducted one semistructured interview with each of the eight experts selected. Forty-three questions on TOP-ID were presented to the experts. Data from semistructured interviews were then analysed and discussed by the research group. These discussions resulted in the development of 81 questions for the Delphi iteration process.

Delphi method

Among the 35 French-speaking experts, 18 answered all the questions (51% response rate), which is in the acceptable range for this type of process according to the literature.[45] The characteristics of the Delphi experts contacted for the first round and of those who completed the whole process are detailed in table 1.

Eighty-one questions were generated about the non-consensual items of TOP-ID. Fifty-six (69%) of the 81 items reached consensus after the first Delphi round (table 1). For 6 (7%) of the 56 items with a consensus, the experts' position was in opposition with the research group's position. After discussion by the research group, four items were modified accordingly in the tool and two were kept unchanged. The concerned questions are detailed in online supplemental appendix 3.

Nineteen items (23%) were non-consensual and reformulated into 13 new questions based on the experts' comments and on the literature (see online supplemental appendix 4). The 'does not know' answers represented 15% of all answers.

Table 1 Characteristics of the Delphi experts contacted for the first round (left) and those who completed the whole process (right)

	All experts (n=35)	Experts who completed the Delphi process (n=18)
Domain of expertise		
Psychiatry	19 (54%)	7 (39%)
Internal medicine	5 (14%)	3 (17%)
Pharmacology	4 (11%)	4 (22%)
Neurology	4 (11%)	2 (11%)
Geriatric medicine	3 (9%)	2 (11%)
Country of activity		
Switzerland	20 (57%)	11 (61%)
France	9 (26%)	6 (33%)
Belgium	2 (6%)	1 (6%)
Canada	3 (9%)	0 (0%)
Spain	1 (3%)	0 (0%)

The 13 new questions were then submitted for the second Delphi round to the 18 experts who had completed round 1. All 18 experts that completed the first round also completed the second. The 13 (100%) items were validated during the second round. Table 2 summarises the answer and consensus rates of the two rounds of the Delphi iteration process.

The final version of TOP-ID is summarised in online supplemental appendix 2.

DISCUSSION

TOP-ID is the first prescription–deprescription tool dedicated to helping healthcare professionals in caring for AWIDs in four frequent clinical situations: pain, gastrointestinal and sleep disorders, as well as challenging behaviour management. The deprescription guide is meant to be used regularly, once a month for example, to decrease inappropriate polypharmacy.

Besides, TOP-ID should also help promote documentation of clinical situations and related prescriptions, which may generate clinical data on efficacy and adverse

Table 2 Answer and consensus rates of the two rounds of the Delphi iteration process

	Round 1	Round 2
Number of experts who answered (%)	18 (51)	18 (100)
Number of questions	81	13
Number of items with a consensus ≥65% (%)	62 (77)	13 (100)
Of which, items with a consensus in opposition (%)	6 (7)	0 (0)
Number of items with no consensus (%)	19 (23)	0 (0)

effects, and contribute to reducing repeated prescription errors. Finally, since TOP-ID contains multiple annexes—including evaluation tools, differential diagnosis clues, prescription algorithms and drug selection, as well as complete pharmacological information on drugs—it should represent an interesting teaching opportunity for residents in charge of AWIDs.

Strengths and limitations

TOP-ID was constructed in analogy to other validated prescription and deprescription tools in different vulnerable populations, such as the Screening Tool of Older Persons' Prescriptions/Screening Tool to Alert to Right Treatment,[50] the Beers criteria[51] for the geriatric population or the Potentially Inappropriate Medication-Check tool[48] in internal medicine. However, as the literature in the field of ID is scarce, a list of clear prescribing indicators could not be developed. The strong need for practical guides in that population led us to develop a comprehensive tool that includes guides for the assessment, treatment and documentation of the clinical process in four clinical domains.

The Delphi iteration process is a validated and robust method, often used in domains where knowledge and guidelines are sparse. This method is thus well adapted to the matter of prescription in AWIDs, which is an issue often overlooked by scientific research.

We were able to recruit 35 international French-speaking experts, coming from various areas of expertise. The response rate after the first round was 51%, and we ended up with 18 experts, which is in the range of what is observed in such a process.

Despite the lack of literature, by putting weight on clinical expert opinions, a consensus was reached in 76% of the items after the first round, and on 100% after the second round. This high and rapidly attained consensus among the experts is promising in terms of the clinical utility of the tool.

Compared with other prescription tools or guidelines and despite the lack of literature data, TOP-ID suggests simple clinical strategies aimed at helping systematise and harmonise practices.

Among the chosen clinical situations, pain and challenging behaviour are two conditions particularly difficult to manage because of communication issues, leading to a high subjective component in their assessment. Hence, TOP-ID proposes a two-step process in non-verbal patients: an assessment by a first carer, using validated scales but also including a hetero-evaluation of pain intensity on a Numeral Analogue Scale (NAS). A second carer is then asked to give her/his hetero-evaluation of pain intensity on a NAS. Treatment introduction and efficacy evaluation are then decided based on a consensus between both carers.

Regarding challenging behaviours, which is a frequent source of inappropriate polypharmacy, a simple intensity and severity scale has been developed to guide medication needs.

Last, TOP-ID proposes specific drugs for each clinical situation. These options were selected based on literature data, when available, but mostly on our clinical practice and on pharmacological considerations for safety. These clinical strategies need to be validated in a clinical study, but are a first step towards the rationalising of prescription in AWIDs.

Several limitations need to be mentioned.

First of all, despite being built on a validated method, due to the scarcity of literature data, TOP-ID is mainly based on expert opinions and its clinical significance needs to be assessed in a utility study. This is particularly the case for the drug strategies which were selected for challenging behaviours. In the absence of efficacy data, the choice was mainly based on pharmacological considerations, such as adverse effects, drug–drug interactions and inter-individual variability.

Second, the domains of expertise being heterogeneous, the experts did not have an opinion on all questions. The 'does not know' answers thus represented 15% of all answers in the first round, a percentage we deemed quite acceptable.

Third, even if the expert panel was international, this is a French-speaking tool and the final choice of drugs was widely influenced by local practices in Switzerland.

Fourth, TOP-ID is a prescription/deprescription tool, therefore it does not describe non-pharmacological interventions, which are a predominant part of the care in case of pain, sleep or gastrointestinal disorders, as well as challenging behaviours.

Finally, since TOP-ID contains many annexes and information, a user-friendly electronic version will be needed.

Unanswered questions and future research

The main unanswered question is the clinical utility of TOP-ID. Therefore, the next step of the process, which is currently ongoing, is the development of an electronic version to facilitate its use in a clinical setting. TOP-ID will then be tested in a clinical trial at the Unit for Intellectual Disabilities and Autism in Adults at the Geneva University Hospitals in order to assess the feasibility, reliability and validity of its use. TOP-ID will then be updated accordingly and translation into other languages will be considered.

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