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Aligning quality of life and guidelines for off-label psychotropic drugs in adults with intellectual disabilities and challenging behaviour

P. Laermans[1], F. Morisse[2], M. Lombardi[1], S. Gérard[3], S. Vandevelde[2], G. de Kuijper[4], K. Audenaert[5] and C. Claes[1]

[1]EQUALITY//ResearchCollective, University College Ghent, Ghent, Belgium; [2]Department of Special Needs Education, Ghent University, Ghent, Belgium; [3]Superior Health Council, Brussels, Belgium; [4]Centre for Intellectual Disabilities & Mental Health, Mental Healthcare Drenthe, the Netherlands; [5]Department of Psychiatry, Ghent University, Ghent, Belgium

Introduction: Adults with intellectual disabilities have an increased vulnerability to mental health problems and challenging behaviour. In addition to psychotherapeutic or psychoeducational methods, off-label pharmacotherapy, is a commonly used treatment modality.
Objective: The aim of this study was to establish evidence-based guideline recommendations for the responsible prescription of off-label psychotropic drugs, in relation to Quality of Life (QoL).
Method: A list of guidelines was selected, and principles were established based on international literature, guideline review and expert evaluation. The Delphi method was used to achieve consensus about guideline recommendations among a 58-member international multidisciplinary expert Delphi panel. Thirty-three statements were rated on a 5-point Likert-scale, ranging from totally disagree to totally agree, in consecutive Delphi rounds. When at least 70% of the participants agreed (score equal or higher than 4), a statement was accepted . Statements without a consensus were adjusted between consecutive Delphi rounds based on feedback from the Delphi panel.
Results: Consensus was reached on 4 general:the importance of non-pharmaceutical treatments, comprehensive diagnostics and multidisciplinary treatment. Consensus was reached in 4 rounds on 29 statements. No consensus was reached on 4 statements concerning: freedom-restricting measures, the treatment plan, the evaluation of the treatment plan, and the informed consent.
Conclusion: The study led to recommendations and principles for the responsible prescription – aligned with the QoL perspective – of off-label psychotropic drugs for adults with intellectual disabilities and challenging behaviour. Extensive discussion is needed regarding the issues on which there was no consensus to furthering the ongoing development of this guideline.

Keywords: quality of life; psychotropic drugs; intellectual disability; off-label use; guidelines; challenging behaviour; Delphi study

Introduction

The prevalence of behavioural and mental health problems in adults with intellectual and developmental disabilities (IDD) is estimated to be higher than in the general population (Crocker *et al.*, 2014, Emerson *et al.*, 2001, Hove and Havik, 2008, Lin and Lin, 2021, Lloyd and Kennedy, 2014, O'Dwyer *et al.*, 2018, Sappok, 2020). People with intellectual disabilities (ID) have an increased vulnerability to mental health problems. These problems are reported to occur in 30-50% of people with ID; as compared to 10% in persons without ID (Barron *et al.*, 2013, Bratek *et al.*, 2017, Došen, 2010, Morisse, Vandevelde and Došen, 2014). It is relevant to point out that adults with ID often have difficulties in communicating their needs, desires and emotions (Hagan and Thompson, 2014). Challenging behaviour often serve a communication function, when other

Correspondence to: Pauline Laermans, EQUALITY//ResearchCollective, University College Ghent. Email: pauline.laermans@hogent.be
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forms are not available (Smith *et al.*, 2020). Many people with ID are treated with psychotropic medication, according to the registered indication and off-label prescription norms, and polypharmacy is common (Bowring *et al.*, 2017). There are generally two reasons for prescribing psychotropic drugs in people with ID: (1) the presence or suspicion of a mental disorder, and (2) the presence of challenging behaviour, such as aggression, self-injurious behaviour, agitation and sexually unacceptable behaviour (De Kuijper *et al.*, 2019). Psychotropics are often administered to address challenging behaviour without a proper indication, in absence of an underlying psychiatric disorder, so-called off-label prescribing (De Kuijper *et al.*, 2019). According to a study by the World Psychiatric Association, 20% to 45% of adults with ID take psychotropics. 14% to 30% of these adults use psychotropic drugs for challenging behaviour, such as aggression or self-injurious behaviour, in the absence of a diagnosis of a psychiatric disorder (Deb *et al*. 2009). Reasons leading to the use of psychotropic drugs in people with ID and challenging behaviour include behavioural control or correcting underlying psychophysiological factors associated with aggression (de Kuijper *et al.* 2010, Matson and Neal 2009). Moreover, stopping or phasing out psychotropics is often considered to be difficult because of fear for symptoms of restlessness or because previous attempts have failed (de Kuijper and Hoekstra 2017).

In the field of intellectual disability care, the concept of Quality of Life (QoL) as an outcome evaluation framework, together with the supports paradigm, are increasingly being used (Gómez Sánchez et al. 2022, Schalock and Verdugo 2002, Schalock *et al.* 2005). Both the QoL framework and the supports paradigm are essential elements in the definition of intellectual disability in the 12th edition of the American Association on Intellectual and Developmental Disabilities (AAIDD) manual (Schalock *et al.* 2021). A central idea is a social-ecological perspective that focuses on person-environmental interaction, which pays attention to the use of individualized supports to enhance human functioning and personal outcomes. With a focus on the development and interests of adults with ID, efforts are made to improve well-being, individual functioning and QoL.

Despite the increased use of the QoL framework as well as the supports paradigm, there are many restrictive practices in the treatment of people with ID and challenging behaviour (Deveau and McGill 2009, Sanders 2009, Sturmey 2009). Prescribing psychotropic drugs to adults with ID for challenging behaviour is considered to be a type of chemical restraint (Deb 2007, Edwards *et al.* 2020, García-Domínguez et al. 2022, Trollor *et al.* 2016). Moreover, side-effects are common, and the effectiveness of psychotropic drugs for the treatment of challenging behaviour has not been proven (Deb *et al.* 2007, Mahan *et al.* 2010, Matson and Mahan 2010, Sturmey 2009). Although only a few studies address psychotropic side effects in the population, adults with IDD have been found to be more likely to experience side effects than those who do not have IDD (Charlot *et al.* 2020, Sheehan and Hassiotis 2017). The side-effects of psychotropic drugs may negatively influence one's QoL. A large majority of patients have had at least one adverse event associated with psychotropic drug use (Deutsch and Burket 2021, McMahon *et al.* 2020, Scheifes *et al* 2016). More attention needs to be paid to these adverse events and their negative influence on the QoL of these patients, taking into account the lack of evidence for the effectiveness of psychotropic drugs for challenging behaviour (Scheifes *et al.* 2016).

In this regard, the QoL framework is a relevant perspective for operationalising intended outcomes in the support of people with IDD and challenging behaviour (Scheifes *et al.* 2016). Medication monitoring is important because medication-related adverse events cause, or contribute to, challenging behaviour, which can sometimes be improved by dose reduction, discontinuing the medication, and/or eliminating polypharmacy and co-pharmacy. Importantly, medications themselves may interfere with self-reported measures of QoL. These medications can be associated with a variety of neurological and metabolic side effects and contribute to 'self-reported' lowering or worsening of QoL (Koch *et al.* 2015). Deutsch and Burket (2021) assume that adverse events associated with psychotropic drugs prescribed for challenging behaviour in adults with ID have a negative effect on QoL. According to Ramerman *et al.* (2019) discontinuation of antipsychotics have a positive impact on health-related QoL-domains.

The QoL framework has been empirically validated across different cultures and countries. The measurable construct includes eight domains and respective indicators (Wang *et al.* 2010). Although there is some variability on how predictors and outcomes are defined (Walsh *et al.* 2010), there is general agreement across studies that outcomes are influenced by personal and environmental factors (Schalock *et al.* 2010). In a study by Morisse *et al.* (2013), the application of QoL principles in people with ID and mental health problems was evaluated by professional workers and family members. The domains of 'emotional well-being', 'interpersonal relationships', 'self-determination' and 'social inclusion' were reported as most relevant in the case of people with ID and mental health problems. In a study by Koch *et al.* (2015), unmet needs and psychotropic medication were identified as the most important predictors of reduced self-rated QoL, whereas an increase of psychiatric symptoms, problem behaviours, and

psychotropic medication best predicted the reduced QoL proxy ratings (Koch *et al.* 2015).

The subject of QoL does not always seem to be (explicitly) addressed in international evidence-based guidelines for psychotropic drugs in adults with ID and challenging behaviour. For example, we found that in only half (four of eight) of the international western guidelines that were scanned – i.e. l'Agence Nationale de l'evaluation et de la qualité des Établissements et Services sociaux et Médico-sociaux 2016, Camden and Islington NHS Foundation Trust 2018, Deb *et al.* 2006, De Kuijper *et al.* 2019, Embregts 2019, Institut national d'excellence en santé et en services sociaux 2021, Nederlandse Vereniging van Artsen voor Verstandelijk Gehandicapten 2016, and Unwin and Deb 2010 – attention was paid to one or more QoL domains when addressing challenging behaviour in people with ID.

According to the Dutch and NICE (National Institute for Health and Care Excellence 2015) guidelines, QoL should be monitored and included in the evaluation of the treatment plan. The NICE guidelines emphasize not only the client's Quality of Life, but also the family's and caregivers' QoL, through the establishment of a risk-benefit profile. The NICE and Canadian guidelines state that reduction in polypharmacy leads to an increase in QoL. In all of the guidelines, health-related QoL is the most frequently mentioned; whereas personal development, self-determination, interpersonal relationships, emotional and material well-being, social inclusion and rights are far less often reported on.

The aim of our study was to develop a guideline with recommendations for the responsible prescription – aligned with the QoL perspective – of off-label psychotropic drugs for adults with ID and challenging behaviour, based on the literature and clinical practice. In this context, no statements are made about concrete doses and evaluation schedules. The objective was to establish principles for careful prescribing behaviour. The guideline is meant to lead to a reduction of off-label psychotropic drug prescription in clinical practice and the improvement of QoL in patients who are treated with psychotropic drugs for challenging behaviour.

Methods

Study design

A Delphi procedure was conducted to achieve consensus among clinicians from the ID working field about principles and guideline recommendations. The Delphi method is used to reach consensus on a topic through the (subjective) opinions of experts (McPherson *et al.* 2018)

The study was conducted in cooperation with, and under the supervision of, The Superior Health Council (Belgium). The Belgian Superior Health Council draws up scientific advisory reports that aim to provide guidance to political decision-makers and health professionals (FOD Gezondheid 2019). Responding to current events in public health, the Superior Health Council is a high-level scientific centre of expertise in Belgium. Government and health professionals recognize the Council for their high-quality contribution to health care (FOD Gezondheid 2019). This cooperation reinforces the potential impact and implementation of this study and opportunities for follow-up research. To develop the guideline and establish the recommendations and principles, an ad hoc Scientific Steering Committee, chaired by a Professor in Psychiatry, was established with experts ($n = 13$) in the following areas: ID medicine, orthopedagogy (special needs education), psychiatry and psychology. In addition, experts with lived experience (i.e. a person with an intellectual disability and a family member) were also included in the Scientific Steering Committee. The literature review was done as part of a master's dissertation by one of the authors. The experts in the Scientific Steering Committee completed a general statement of interest and an ad hoc statement, and the Committee on Deontology (an external and independent group, tasked with preparing opinions on the possible risk of conflict of interest) assessed the potential risk of conflict of interest.

The SSC took up different roles during the Delphi process: (1) the statements for the Delphi study were based on international guideline recommendations and guiding principles drawn up by the Scientific Steering Committee; (2) the Scientific Steering Committee defined criteria for the acceptance or rejection of the statements after each round of the Delphi study; (3) in consultation with the Scientific Steering Committee some of the statements were combined after the Delphi rounds to develop the Belgian guideline for off-label use of psychotropics in adults with ID.

Participants

The Delphi group participants were selected on the basis of their long-standing clinical expertise with the target group of people with intellectual disabilities and challenging behaviour. Fifty-eight experts were contacted: 27 Dutch-speaking and 12 French-speaking Belgian experts, and 19 international (United Kingdom, Italy, Spain and the Netherlands) experts. The majority of the participants ($n = 36$) were psychiatrists ($n = 33$). In addition, 2 doctors for people with intellectual disabilities and 1 neurologist were involved. The international experts were recruited through the European Association for Mental Health in Intellectual Disability, and the national experts all work in specialised residential services for people with ID and mental health problems. Six participants are attached to a university, and all have published scientific articles on this topic. As there were French-, Dutch- and English-speaking participants, the decision was made to present the principles

and recommendations in English in order to limit the differences related to language. Although there are no defined criteria on the minimum or maximum number of experts in a Delphi panel (McMillan *et al.* 2016), a group size of at least 10 experts is reported to be sufficient (Alizadeh et al. 2020). Of the 58 experts who were approached by email, 36 agreed to participate in the first round of the Delphi study. All 36 participants signed an informed consent form. In the successive Delphi rounds, only participants who completed the statements in the first round were sent the adapted statements for the next round. As sending a reminder between rounds is reported to increase the response rate by more than a quarter (Gargon *et al.* 2019), reminder e-mails were sent to non-responders who signed the informed consent and participated in the first round.

Procedure

As indicated above, the statements for the first round of the Delphi study were prepared by the researchers of the Scientific Steering Committee based on a literature review and expert opinions. The literature review focused on peer-reviewed scientific journals, reports of national and international organizations that are competent in this area (peer reviewed) and existing international evidence-based guidelines for the prescribing of psychotropic drugs to adults with ID. The PubMed, Web of Science and Scopus databases were used for the literature review. A search was conducted on the keywords 'psychotropic drugs', 'challenging behaviour', 'responsible prescribing' and 'adults with ID'. Members of the Scientific Steering Committee (experts on prescribing psychotropic drugs to adults with ID) examined, in addition to the evidence-based guideline of the World Psychiatric Association (Deb *et al.* 2009), the most cited guidelines and the guidelines of our neighbouring countries:

- Australia (Trollor *et al*. 2016)
- Canada (Sullivan *et al*. 2011, Institut national d'excellence en santé et en services sociaux 2021)
- Germany (Deutsche Gesellschaft für Kinder- und Jugendpsychiatrie, Psychosomatik und Psychotherapie, Berufsverband für Kinder- und Jugendpsychiatrie, Psychosomatik und Psychotherapie, Bundesarbeitsgemeinschaft der Leitenden Klinikärzte für Kinder- und Jugendpsychiatrie, Psychosomatik und Psychotherapie, Deutsche Gesellschaft für Sozialpädiatrie und Jugendmedizin, Deutsche Gesellschaft für Psychiatrie und Psychotherapie, Psychosomatik und Nervenheilkunde, and Gesellschaft für Neuropädiatrie 2014)
- France (ANESM 2016),
- Netherlands (De Kuijper *et al*. 2019, Embregts 2019, Nederlandse Vereniging van Artsen voor Verstandelijk Gehandicapten 2016)
- New Zealand (Trollor *et al*. 2016)
- United States (Bhaumik *et al*. 2015),
- United Kingdom (Bhaumik *et al*. 2015, Camden and Islington NHS Foundation Trust 2018, Deb *et al*. 2006, National Institute for Health and Care Excellence 2015, Unwin and Deb 2010).

During the literature review, specific attention was paid to the occurrence of the keyword QoL. The results of the literature review initiated the discussion among the experts in the Scientific Steering Committee. The statements for the first round of the Delphi study were developed based on the literature review, according to QoL and presented three times to the Scientific Steering Committee.

A structured online questionnaire with statements, using SurveyMonkey (an online survey site) was sent to the 36 participants. The experts were asked to give their opinion on 33 statements. Principles deal with general principles that should be taken into account in the off-label prescribing of psychotropics to adults with ID and challenging behaviour. The guideline recommendations contain concrete prescriptions (tools for following the recommendations) and checklists. For each principle or guideline recommendation, respondents were asked to what extent they agreed with the statements, using a 5-point Likert scale, ranging from totally disagree (1) to totally agree (5). They could also provide comments. The statements for which no consensus was reached were reformulated based on the comments provided and were resubmitted to the experts in the next round. Feedback from every round was given anonymously along with the invitation for the next round.

Analyses

In consultation with the Scientific Steering Group, the statements were considered accepted when at least 70% of the participants agreed (score equal to or higher than 4) and the median was equal to or higher than 4, with an interquartile range (IQR) of no more than 1. The statements for which more than 70% of the participants gave a score of 1 or 2 with a median less than 2 and an IQR less than 1 were rejected (Diamond *et al.* 2014, Von der Gracht 2012).

Results

In the first round of the Delphi study, 33 statements (13 principles and 20 guideline recommendations) were sent for assessment and agreement to the Delphi panel (36 respondents). Sufficient agreement among the panel members was reached for 29 out of the 33 (or 88%) of the statements. Appendix A lists the statements, the Delphi round in which consensus was achieved, and the reformulations of statements on which there was insufficient agreement. After the first round, the experts agreed on 21 of the 33 statements. The remaining 12 statements were reformulated based on feedback from the experts. Twenty-two of the 36 experts participated in the second round. After round 2, there was consensus on 4 of the 12 remaining statements. After the third

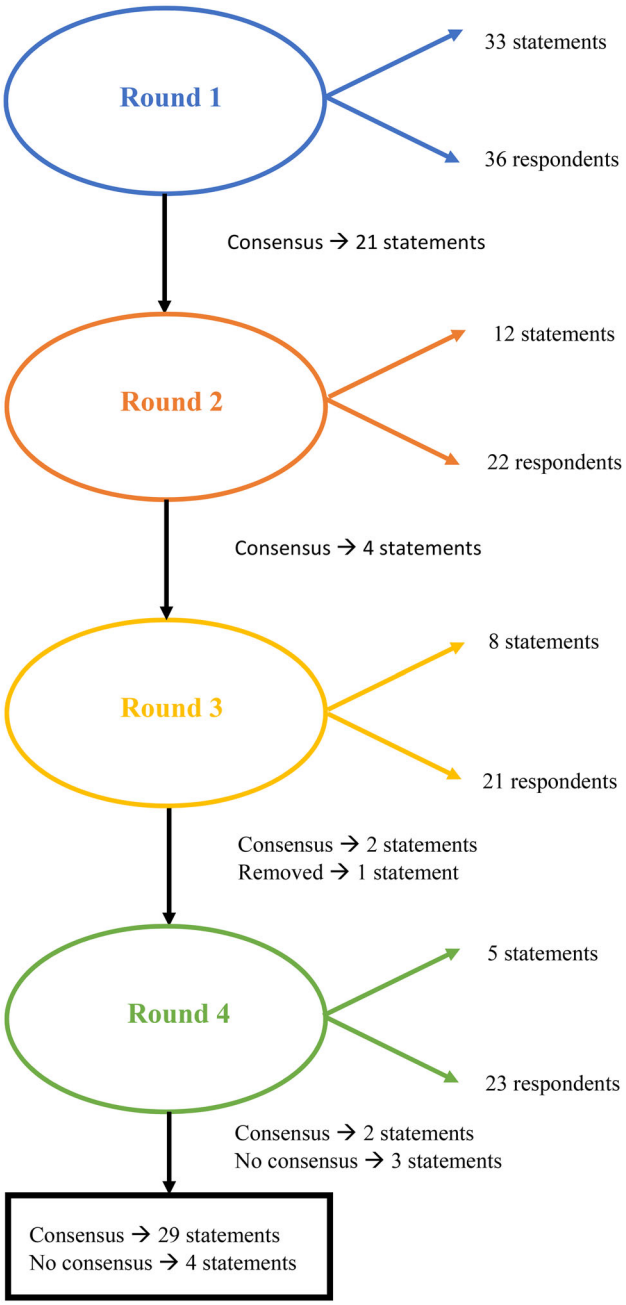

Figure 1. Delphi procedure.

round (with 21 respondents), 2 more statements were approved, and 6 statements did not reach consensus. Five statements were reformulated for the last round of the Delphi study, in which 23 experts participated (Figure 1). One principle was judged to be too controversial: Off-label use of psychotropic drugs or use outside professional guidelines' advice is regarded as a freedom-restricting measure from the perspective of 'Quality of Life'. The analysis of the feedback showed a discussion on medical liability. The Scientific Steering Committee decided to remove the statement because consensus could not be reached even after several adjustments.

Consensus could not be reached on some statements, and so these could not be included as guideline recommendations. The statements where no consensus was reached are presented in Table 1. The Scientific Steering Committee decided to delete 3 statements after the fourth round based on a lack of agreement (2 statements) or too many outliers (1 statement).

To complete the guideline of off-label psychotropic drugs for adults with ID and challenging behaviour, the Scientific Steering Committee developed a flow chart as an overview for the assessment and treatment of challenging behaviour for adults with ID, based on the feedback of the respondents. The model of the Nederlandse Vereniging Artsen Verstandelijk Gehandicapten (NVAVG, 2019) was used as an example for the flow chart. The cyclical nature of prescribing and the link with QoL were added to the NVAVG model.

By combining some of the statements after the Delphi rounds, the complete Belgian guideline for

Table 1. Statements where no consensus was reached in a Delphi procedure aimed to achieve consensus about statements on the responsible prescribing of psychotropic drugs in adults with intellectual disabilities and challenging behaviours (n respondents).

Principle	% ≥ 4 or 5[a]	Median	IQR[b]
Off-label use of psychotropic drugs or use outside professional guidelines' advices is regarded from the perspective of 'Quality of Life' as a freedom-restricting measure*. *Freedom restricting measures are all measures that entail a restriction of the patient's freedom of choice and/or freedom of movement and/or contact with the outside world. When applying freedom restricting measures, the criteria of proportionality, subsidiarity and effectiveness must be taken into account.	23.81	2	2.25
When commencing any psychotropic drugs for challenging behavior, an effort should be made to draw up a written multidisciplinary treatment plan, involving the patient's and his/her family views*. The treatment plan includes at least information about the mechanism of action, the expected effectiveness of the medication, and potential side-effects. It also includes the plan for evaluation in terms of maintenance, reduction or cessation. * Efforts should be made to involve the family. If the family is unwilling or unable to participate, this should be reported in the medical file.	60.87	4	2
Recommendation			
The prescriber and/or team should check and review the pharmacotherapeutic plan regularly. This should at least be taken into account the medical product's criteria as listed in the BCFI* or GGZ-standaarden (Quality standards for mental health care in the Netherlands)** ; and preferably more frequently, adapted to the population and especially in the initial phase, depending on the indication, the drug, the context and the patient characteristics. *https://www.bcfi.be/nl/start **https://www.ggzstandaarden.nl/	73.91	4	1.5
The individual, a family member and/or their legal representative* should be informed and must give their consent ('informed consent') before medicinal treatment is commenced. The professional support worker should be informed about the medical treatment and is responsible for requesting the informed consent and should register the consent in the medical file. Preferably, information and/or consent should be sought again with each major change of dose and/or drug, except when changes are already included in the treatment plan**. *If there is no legal representative or family member, the personal caregiver should be informed and must give his/her consent. **If there is no time to inform or request the consent due to acute danger, this should be done retroactively.	60.87	4	2

[a]At least 70% of the participants agreed (score equal to or higher than 4).
[b]Interquartile range.

off-label use of psychotropics in adults with ID, seen from the QoL perspective, contains: the 8 principles and 11 recommendations (Appendix B). The statements were combined so each principle/guideline recommendation addressed one topic - e.g. monitoring and evaluation of the treatment, side-effects, responsibility for prescribing, etc. The Belgian guideline was supplemented with a flow chart based on the Dutch guideline on problem behaviour in adults with ID (Figure 2), and an annex with concrete tools for following the guideline (Appendix C).

Discussion

This study used a Delphi method to develop a guideline – from the perspective of the concept of QoL – for prescribing off-label psychotropic drugs to people with intellectual disabilities and challenging behaviours. QoL and the careful prescription of psychotropic drugs relate to safeguarding the human rights of persons with ID (Sheehan 2018, Verdugo et al. 2012). The principles and guideline recommendations were not each tested separately for QoL. QoL was considered holistically in the development of the entire guideline. Medication discontinuation was approached from the Human Rights-Based Approach and the Supports Paradigm.

The Delphi procedure led to a high level of agreement on the principles and recommendations presented in the guideline. Consensus was found for 88% of the proposed statements in the Delphi procedure. The experts shared opinions on the statements related to the importance of non-pharmaceutical treatments, comprehensive diagnostics and multidisciplinary treatment. There was consensus on the statements that treatment with off-label psychotropic drugs should never be a first choice and that strict agreements should be made regarding the administration of 'if-necessary' medication.

Psychological problems in people with ID are often interpreted differently by other people e.g. family, health professionals, carers (Morisse *et al.* 2014). Involving the client's network in providing information and drafting the treatment plan (the bio-psycho-social model) is one of the principles retained in this study. The importance of QoL indicators in establishing goal behaviour and measuring treatment effectiveness is recognized by the experts. This result confirms the view that QoL can be seen as a criterion for developing support strategies (Schalock *et al.* 2016). We can conclude that it is an ongoing challenge for the natural and professional network to search for the most appropriate support strategies focused on improving the QoL of

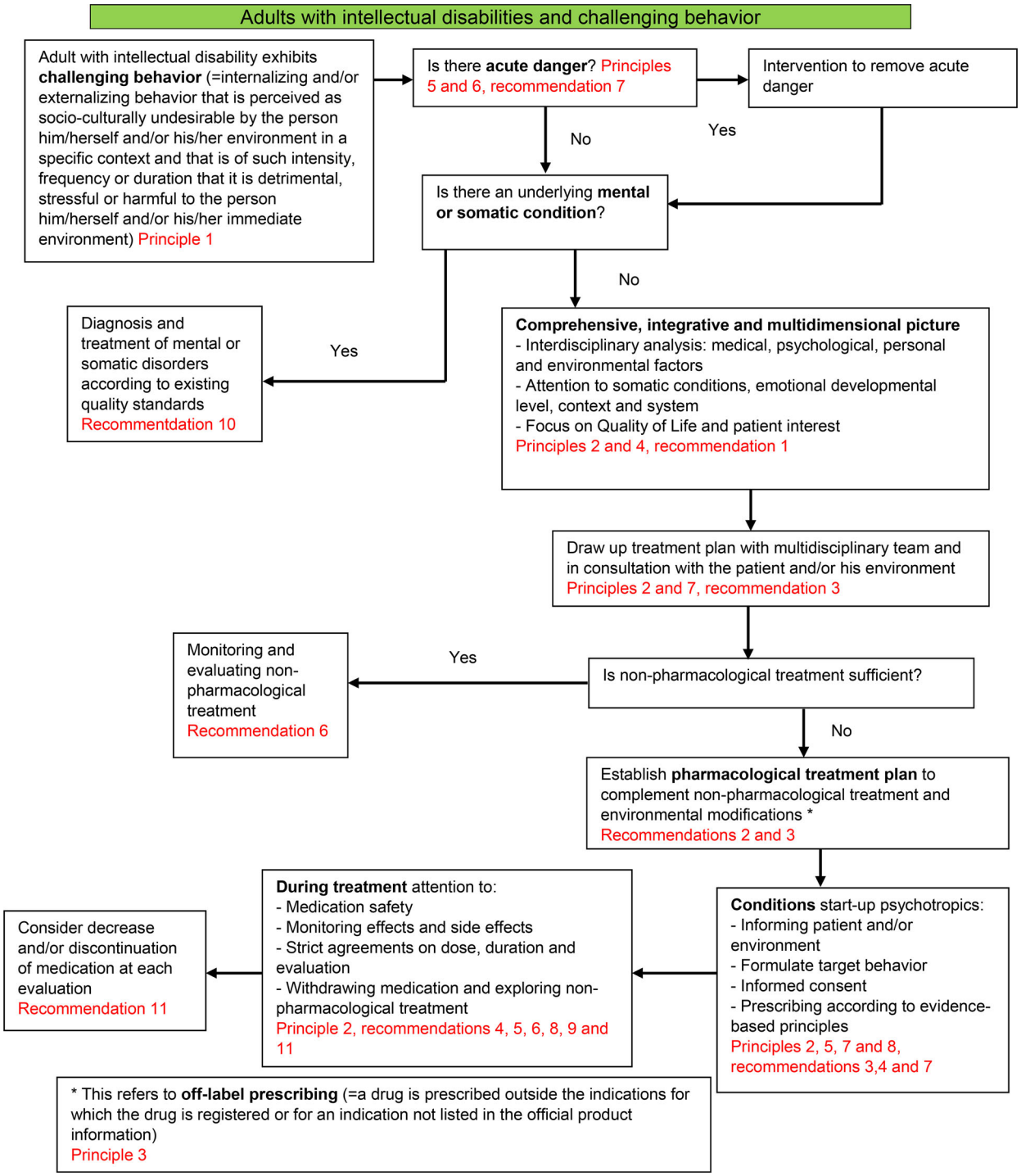

Figure 2. Flow chart based on Embregts (2019). Multidisciplinaire Richtlijn Probleemgedrag bij volwassenen met een verstandelijke beperking. NVAVG, 2019.

their family members or clients with ID (Morisse *et al.* 2013). When evaluating a treatment, whether medicinal or not, this should always include other factors that affect QoL such as communication opportunities, safety, access to support, community inclusion, etc. (Erickson *et al.* 2022).

Disagreement was found for the statements concerning freedom-restricting measures, the treatment plan, the evaluation of the treatment plan, and the informed consent. In our understanding, the underlying controversies can be divided into (1) ethical, (2) theoretical, (3) practical, and (4) policy-related aspects.

The first controversy (freedom-restricting measures) can be regarded as an ethical question. Some of the experts believe that off-label prescription of psychotropic drugs should not necessarily be seen as a freedom-restricting measure. An interesting question is whether or not such a measure should be labelled as freedom-restricting when the client requests this him- or herself. There seems to be a need for defining

'freedom-restricting measures' and how to assess them (Wet zorg en dwang: wat is onvrijwillige zorg? 2022). From a QoL and Human Rights perspective, the off-label prescription of psychotropic medication for challenging behaviour to adults with ID should always take into account: (1) proportionality: the measure is proportionate to the goal, (2) subsidiarity: the least intrusive measure is used, and (3) effectiveness: the measure must achieve the intended goal (Wet zorg en dwang: wat is onvrijwillige zorg? 2022).

We believe that it is important to develop a shared vision on the concept of freedom-restricting measure linked to QoL. In addition, another question is: can we consider the off-label use of psychotropic drugs as a freedom-restricting measure? A comprehensive debate is essential to discussing these ethical questions.

The second controversy (the treatment plan) primarily concerns theoretical issues. Expert opinions are less divided (as compared to the ethical question on freedom-restricting measures), but there is still no consensus according to the pre-defined criteria. There is an agreement that information is needed, whether written down in a treatment plan or not. The results reflect the need for involving the environment/family in drawing up the treatment plan. This finding confirms the view of Došen (2010) regarding the essential role of the environment. According to Morisse and Došen (2017), the search for appropriate treatment starts primarily from the environment by indicating that adjustments in the environment may lead to less focus on challenging behaviour. Research has also shown that involving family has a positive impact on the QoL of persons with ID (Lei & Kantor 2021). Disagreement among the experts on this statement was mainly due to a lack of theoretical background information, such as:

- What should be mentioned in the treatment plan?
- Should there be more emphasis on non-pharmaceutical treatment strategies?
- What is the feasibility of drawing up a written multidisciplinary treatment plan?

Experts disagree on what should be in the treatment plan. Further debate is needed to clarify this and to make theoretically underpinned choices on the content of a treatment plan.

The third controversy (evaluation of the treatment plan) relates to practical obstacles. The results suggest a gap between how often prescribers would ideally like to evaluate and the practical feasibility. Ramerman (2019) argues that long-term psychotropic use in adults with ID can often be attributed to a lack of monitoring the effect of treatment. Sheehan *et al*. (2015) also note that psychotropic drugs are often prescribed long-term without necessarily being properly evaluated. This confirms the importance of setting an evaluation timeframe, without losing sight of feasibility. The Delphi study shows that an evaluation term cannot always be fixed, but depends on the indication, the medication, the context and the patient. Still, frequent evaluation remains the target.

The fourth controversy (informed consent) concerns a policy choice to be made. A distinction should be made between the legal representative, the professional support worker, and a family member. In Belgium, the judge appoints a legal representative if he/she considers that the adult with ID is legally incapacitated (Federale Overheidsdienst, n.d.). The finding highlights the role of the context, as research by Schalock *et al.* (2009) confirms. The feedback of the experts shows the importance of providing information to the client and his/her network. Some experts argue that excessive control of the context can be detrimental to a patient's QoL. There is insufficient scientific research to support or reject this opinion. But if the patient is unable to give consent, the prescriber is responsible: the prescriber acts in the patient's best interest, according to good medical practice. Relevant questions include: Who is ultimately responsible? Is it a shared responsibility? What is the legality if the patient himself refuses? What information is required to make a consent valid? The above dilemmas point to policy barriers that need to be resolved before a consensus can be found.

These four controversies require further attention and debate, in close cooperation between experts, practitioners, policymakers and other stakeholders, including clients and their families. Organizing focus groups would be a useful and relevant pathway to discussing these complex controversies. Focus groups allow a more dynamic exchange of ideas on complex concepts such as QoL, restriction of freedom, and ethical and medico-legal issues.

Together with experts from clinical practice, we developed a guideline from a holistic approach. This guideline is meant to lead to a reduction of off-label psychotropic medication use and an improvement of QoL by addressing unmet needs with alternative treatments. After the guideline has been implemented and then evaluated, it could be further enhanced by the outcome of the debate concerning the controversies identified above. The developed guideline is a starting point for raising awareness and should be reviewed regularly.

Limitations of the study

In this study, the literature review was limited to examining how often, and in what way, QoL was addressed in 8 western international evidence-based guidelines. A literature review examining other issues – such as the extent of evidence, from which point of view, etc. – could have strengthened the study. This study may help to explicitly integrate the perspective of QoL in the

prescribing of off-label psychotropics for challenging behaviour to adults with ID.

The composition of the group of experts in Delphi studies is essential. Careful consideration was given to the selection of the expert panel. Nevertheless, despite this specific attention, it would be an added value if more countries were represented on the Delphi panel. Furthermore the results might be dominated by a psychiatric perspective, since all of the experts were psychiatrists. This might have limited a wider range of expertise across other (mental) health professionals, such as general practitioners, who are (at least in Belgium) authorised to prescribe psychotropic medication, including to adults with ID. Given the focus on a multidisciplinary treatment plan, the absence of experts from multidisciplinary service providers and the lack of clients in the Delphi panel could be seen as a limitation of this study. For example, general practitioners or multidisciplinary service providers could advise on the feasibility of some of the principles and guideline recommendations.

Furthermore, we have to remain aware that QoL is difficult to measure. Despite our focus on QoL during the study, we cannot make any statements about the increase of QoL when following the developed guideline. In this study, the focus was not looking for a normative framework, but to improve QoL at an individual level. A relevant follow-up study could be to assess whether the guideline leads to an increase in QoL and/or a reduction in using off-label psychotropic medication. Consequently, the guideline can be operationalized in terms of QoL by designing an instrument that links QoL and medication use in adults with ID, starting from a person-centered approach rather than a prescriptive framework. Finally, it is important to remember that consensus does not mean that a principle/guideline is not dynamic.

Conclusion and further research

A consensus guideline was developed. We described four underlying controversies that might have led to not reaching consensus for some recommendations or principles that, therefore, could not be included in the guideline. An extensive discussion regarding these controversies is needed – for example, by organising focus groups on these controversies, which might be helpful in furthering the ongoing development of this guideline.

Future research could focus on the effectiveness, implementation and feasibility in practice of the principles/recommendations on psychotropic medication use, as well as on the impact of the guideline on a patient's QoL. It is also advantageous to monitor and revise the principles/recommendations on a regular basis. A pilot study is currently being set up in Belgium in which, first of all, the effects of applying the developed guideline in adults with ID and challenging behaviour will be investigated (impact evaluation), and secondly, the process of phasing out the medication will be described in detail (process evaluation). The impact evaluation will identify the effect of the phasing out on QoL, global functioning, challenging behaviour and side effects.

The developed guideline focuses on adults with ID. According to McLaren and Lichtenstein (2019), psychotropics are also frequently prescribed, often off-label and long-term, to children and adolescents with ID and challenging behaviour. Therefore, it is recommended to set up a similar study for this target group.

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Appendix A. Statements in a Delphi consensus procedure on principles and recommendations for the responsible prescribing of psychotropic drugs to people with intellectual disabilities and challenging behaviours

I. Principles	Reformulation (if required)	Consensus
1. Definition of challenging behavior: 'internalizing and/or externalizing behavior that is seen as socio-culturally undesirable by the person him/herself and/or those around them in a specific context, and which is of such intensity, frequency or duration that it is harmful, stressful or damaging to the person him/herself and/or those around them' (Embregts, 2019).		Round 1
2. More specifically, it is mainly about behavioral symptoms such as verbal and physical aggression, destruction of objects and sexual inappropriate behavior, that are severe and persistent, which do not respond sufficiently to non-medicinal treatments (NVAVG, 2016).	More specifically, it is mainly about behavioral signs and symptoms such as verbal and physical aggression, self-destructive behavior, internalizing harmful behavior and sexual inappropriate behavior, which cannot be explained from a physical condition, and which do not respond sufficiently to non-medicinal or other (i.e.. aimed at changes in environment) treatments.	Round 2
3. Psychotropic drugs* for challenging behavior can only be prescribed off-label in the interests of the client, when the challenging behavior is severe and persistent, when the other options have been exhausted, and under strict agreements regarding the indication, duration, evaluation and side-effects of the treatment. *Psychotropic drugs are drugs used to treat individuals with psychiatric disorders. These drugs act through the central nervous system and exert their effect by influencing affective and cognitive functions, thus also affecting behavior.	Psychotropic drugs* for challenging behavior should only be prescribed off-label or prescribed outside professional guidelines' advices as an adjunctive therapy :1) in the interests of the patient;2) the diagnostics and the extent of non-pharmacological treatment are continuously cycled and reconsidered by a multidisciplinary team;3) there are strict agreements on following up on expected effectiveness, duration and side-effects of the treatment;4) with an informed consent of the patient and/or the legal representative;5) after a psychiatric assessment. *Psychotropic drugs are central to the treatment of a wide range of mental disorders. These drugs act through the central nervous system and exert their affect by influencing affective and cognitive functions, thus also affecting behavior	Round 4
4. Off-label prescription is defined as the prescription of a drug beyond the indications for which the medicine is registered, i.e. for an indication that is not mentioned in the official product information. (Embregts, 2019, p. 63)		Round 1
5. Treatment and evaluation of the treatment of challenging behavior should always be preceded by an interdisciplinary analysis of medical, psychological, personal and environmental factors (bio-psycho-social development model). After all, these factors – and the interaction between them – determine various domains and indicators of quality of life. Well-being, social participation and independence are central to this*. *Defining indicators to measure clinical changes and/or changes in functioning associated with improvements in quality of life is a strong driver for examining links and potential correlations between personal functioning and quality of life.		Round 1
6. Off-label use of psychotropic drugs is seen from the perspective of 'Human Rights' and 'Quality of Life' as a freedom-restricting measure and should therefore be regarded as such.		Removed
7. Consequently, psychotropic drugs are never the first choice for challenging behavior, with the exception of situations involving acute danger to the client or those around them.	Psychotropic drugs are not the first choice for challenging behavior, except for situations involving acute danger* to the client or those around them. *In case of acute danger, the person and/or his environment is in immediate danger and intervention is necessary.	Round 2
8. Situations in which the client him/herself is requesting the use of psychotropic drugs to improve his or her 'quality of life' are also exceptions.	In situations in which the patient him/herself is requesting the prescription of psychotropic drugs off-label and outside guidelines advice to improve his or her 'quality of life', prescribing should depend on the rationale of the request and on the estimation of the prescriber. The patient should be well informed about the risk benefit profile. Before starting medication, it is important that the patient or the legal representative should give their (oral or written) consent. The consent should be reported in the medical files.	Round 4

(*Continued*)

I. Principles	Reformulation (if required)	Consensus
9. The 'as-needed' use of psychotropic drugs is not permitted, unless previously discussed and indicated or in acute situations. The agreements (conditions, duration and evaluation) about this should clearly be stated in the records and on the prescription.		Round 1
10. When commencing any psychotropic drugs for challenging behavior, a treatment plan is always drawn up. The treatment plan includes information about the mechanism of action, the anticipated effect and potential side-effects of the medication, among other things. It also includes the plan for reduction and cessation.		None
11. If possible, the treatment plan will always be drawn up in consultation with the client, his/her family or legal representative, and consent must be obtained before starting any drug treatment (except in the event of acute danger). In the event of acute danger, the client, his/her family or legal representative are informed afterwards and an 'informed consent' is added to the records.		Round 1
12. Professionals work according to evidence-based principles on the judicious off-label prescription of psychotropic drugs. It is a matter of searching for a 'best practice' together.		Round 1
13. Prescribing off-label medication is medico-legally the responsibility of the prescriber; however, in spirit, it is a shared responsibility of the patient's entire team or network.	Prescribing off-label medication is medico-legally the responsibility of the prescriber; however, in spirit, prescribing, effect monitoring and evaluating is a shared responsibility of the patient and the patient's entire team and network.	Round 2
II. Recommendations		
Why do I prescribe?		
1. Prepare a comprehensive, integrative and multidimensional picture and have consideration for the causes, dynamics and perpetuating factors of challenging behavior in people with intellectual disabilities (consideration for somatic conditions, context and system, and emotional developmental level). These findings are recorded in a basic document and are placed on the client's integrated records.		Round 1
2. Make modifications to the environment to meet the client's unique developmental needs. Compensate for adjustment difficulties by increasing the client's skills.		Round 1
When do I prescribe?		
3. When prescribing psychotropic drugs for challenging behavior, the prescriber and/or the team are responsible for providing as much information as possible about the indication and the duration of the use of medication.		Round 1
4. The prescriber and/or team should check and review this information every three months.		None
5. Identifying challenging behavior is a multidisciplinary process. The prescriber should ensure that an appropriate formulation of the target behavior is expressed and included in the treatment plan.		Round 1
6. The effect should preferably be monitored using standardized and validated scales or tools.	The clinical effectiveness should, in addition to the clinical evaluation by the prescriber, preferably be monitored using standardized, validated and user-friendly scales or tools.	Round 3
How (long) do I prescribe?		
7. The prescribing doctor should ask the client and his/her supervisors about the potential presence of side-effects at every check-up. In addition, the doctor will have to systematically examine the client themselves. The frequency depends upon the indication and the drug that is prescribed. A plan for monitoring side effects will be drawn up.		Round 1
8. When examining potential side effects, the doctor may use several assessment measures, whereby validated scales should be used as far as possible.	When examining potential side effects, the doctor should use monitoring schedules (i.e. metabolic syndrome) and several assessment measures, whereby validated scales are strongly recommended, next to side-effect follow-up schemes.	Round 3

(*Continued*)

II. Recommendations		
9. Off-label medication for challenging behavior should be seen as a supplement to non-medicinal treatment. This non-medicinal treatment should therefore be clearly described, monitored and evaluated.		Round 1
10. Consideration for withdrawal of medication and exploration of non-medicinal treatment should be ongoing and described in the treatment plan.		Round 1
11. The prescriber is responsible for assessing the individual's ability to consent to treatment.		Round 1
12. The individual, their legal representative and/or personal supervisor must give their consent before medicinal treatment is commenced ('informed consent'). Preferably, consent should be sought again (e.g. through the personal supervisor) with each change of dose and/or drug.		None
13. In the event that psychotropic drugs are administered in cases of acute danger, a debriefing will take place afterwards and the client, legal representative and/or personal supervisor will be informed post hoc. A note of this must be made in the treatment plan.		Round 1
14. The responsibility for prescription is clearly known and described and lies with a doctor.		Round 1
15. Medication safety (administering medication in the right way, storing medication, etc.) is a shared responsibility (doctor, pharmacist, nurse, supervisor) that must be defined beforehand.		Round 1
16. Also for this (medication safety), a responsible person is appointed.	Handling medication is a shared responsibility with a clear procedure. For medication safety, a person overseeing medication safety protocols should be appointed in the treatment facility.	Round 2
17. Medication should be used at the lowest possible dose for the minimum time required.		Round 1
18. The simultaneous use of different drugs from one group of psychotropic drugs with the same treatment objective should be avoided as much as possible.		Round 1
19. For the use of specific psychotropic drugs in psychopathology as part of specific syndromes (i.e. Down's syndrome), reference is made to syndrome-specific guidelines. If there is a strong suspicion of a specific psychiatric disorder, disorder-specific guidelines should be followed for the choice of medication, dosage and duration of treatment		Round 1
20. Discontinue medication if there is no response to treatment with respect to the intended effect after 6 weeks, or sooner if an effect is achieved more quickly than expected and reduction or discontinuation of the medication is possible. A meticulous follow-up of the client is necessary to see the positive and negative effects. Review this evaluation with the client and those around them. Reassess the challenging behavior and consider further psychological or environmental interventions.		Round 1

Appendix B. Belgian guideline on off-label use of psychotropic drugs in adults with intellectual disabilities

Principles

1. Challenging behavior is defined as 'internalizing and/or externalizing behavior which is perceived as socioculturally undesirable by the person himself and/or his environment in a specific context, and which is of such intensity, frequency or duration that it is detrimental, stressful or harmful' (Embregts, 2019). More specifically, it involves behavioral signs and symptoms such as verbal and physical aggression, self-destructive behavior, internalizing harmful behavior and sexually transgressive behavior, which cannot be explained from a physical condition and which do not respond adequately to non-medicated or other treatments (i.e. focused on environmental changes).
2. Psychotropic drugs[1] for challenging behavior should only be prescribed outside the indications or recommendations of professional guidelines, as adjunctive therapy:
   - in the best interest of the patient;
   - if the diagnosis and extent of non-pharmacological treatment are continuously evaluated and reconsidered;
   - if there are strict agreements on monitoring the efficacy, duration and expected side effects of the treatment;
   - with the informed consent of the patient and/or his legal representative;
   - after psychiatric examination.

   [1] Psychotropic drugs are central to the treatment of a wide range of mental disorders. These drugs act through the central nervous system and exert their effects by influencing affective and cognitive functions and thus also affect behavior.
3. Off-label prescribing means prescribing a medicine outside the indications for which the drug is registered or, in other words, for an indication that is not listed in the official product information (Embregts, 2019, p. 63).
4. Treatment and evaluation of challenging behavior should always be preceded by an interdisciplinary analysis of medical psychological, personal and environmental factors (bio-psychosocial developmental model). After all, these factors - and the interaction between them – determine different domains and indicators of Quality of Life. Well-being, social participation and independence are central here[2].

   [2] Defining indicators to measure clinical changes and/or changes in functioning measure related to improvements in Quality of Life is a strong motivation to establish links and possible correlations between personal functioning and Quality of Life.
5. Psychotropics are not the first choice for challenging behavior, except in situations where there is acute danger[3] to the patient or his/her environment. In situations where the patient himself/herself is asking for the off-label use of psychotropic drugs to improve his/her Quality of Life, the prescribing should depend on the rationale of the request and the estimation of the prescriber. The patient should be properly educated about the risk-benefit profile. Before starting medication, it is important that the patient or his legal representative gives consent (verbal or written). The consent should be recorded in the medical records.

   [3] In acute danger, the person and/or his/her environment is in immediate danger and intervention is necessary.
6. 'If necessary' use of psychotropics is, unless previously discussed and indicated or in acute situations, not permitted. The agreements (conditions, duration and evaluation) on this should be clearly stated in the medical file and on the prescription.
7. If possible, the treatment plan is always drawn up in consultation with the patient, his/her family or legal representative. Consent should be given before any medicinal treatment is initiated (except in the case of acute danger). In case of acute danger, the patient, his/her family or legal representative is informed afterwards and can still receive an informed (and discussed) consent statement ('informed consent'). This should be added afterwards in the file, stating the date.
8. Professionals work according to evidence-based principles regarding the judicious off-label prescribing of psychotropic drugs. They have to search together for the best way of working. Prescribing off-label medication is medically-legally the responsibility of the prescriber; in spirit, the prescribing, effect monitoring and evaluation, however, is a shared responsibility of the patient and the patient's entire team and network.

Guidelines

Why do I prescribe?

1. Prepare a comprehensive, integrative and multidimensional picture and address the causes, dynamics and sustaining factors of challenging behavior in persons with intellectual disability (attention to somatic disorders, context and system and emotional developmental level). These findings are recorded in a baseline document and enter the patient's integrated file.
2. Implement environmental modifications to meet the unique developmental needs of the patient. Compensate adjustment difficulties by increasing the patient's skills.

When do I prescribe?

3. When prescribing psychotropics for challenging behavior, the prescriber and/or his team is responsible for providing as much information as possible about the indication and duration of medication use.
4. Mapping challenging behavior is a multidisciplinary process. The prescriber should ensure that an adequate formulation of the target behavior is pronounced and stated in the treatment plan. The clinical effectiveness, in addition to clinical evaluation by the prescriber, should preferably be monitored using standardized, validated and user-friendly scales or instruments.

How (long) do I prescribe?

5. The prescriber should ask the patient and his/her attendants at every check-up about the possible presence of side effects. In addition, the doctor should systematically examine the patient himself/herself. The frequency depends on the indication and the drug prescribed. A schedule around monitoring of side effects is established. When investigating possible side effects, the doctor should use monitoring schedules (i.e. metabolic syndrome) and various assessment measures, where validated scales are strongly recommended, in addition to schedules for the follow-up of adverse events.
6. Off-label medication in challenging behavior should be seen as complementary to the non-pharmacological treatment. That non-pharmacological treatment should therefore be clearly described, monitored and evaluated. Withdrawing of medication and exploring non-medical treatment should be continuously considered and described in the treatment plan.
7. The prescriber is responsible for assessing whether the individual is able to consent to treatment. When psychotropic drugs are administered at acute risk, a debriefing takes place afterwards and the patient, his/her legal representative and/or personal attendant will be informed post hoc. A note of this should be made in the treatment plan.
8. The responsibility for prescribing is clearly known and described. The prescriber is responsible. Medication safety (administering medication correctly, stocking medication, etc.) is a shared responsibility (doctor, pharmacist, nurse, supervisor) that needs to be defined in advance. Handling with medication is a shared responsibility with a clear procedure. For medication safety, one person should be designated in the treatment facility to oversee the medication safety protocols.

(*Continued*)

Principles
9. Medication should be used at the lowest possible dose for the minimum time required. The simultaneous use of different drugs from one group of psychotropics for the same treatment purpose should be avoided as much as possible.
10. For the use of specific psychotropic drugs in psychopathology as part of specific syndromes (i.e. Down syndrome), reference is made to syndrome-specific guidelines. If there is a strong suspicion of a specific psychiatric disorder, disorder-specific guidelines should be followed for the choice of medication, dosage and treatment duration.
11. Stop medication if there is no response to treatment after 6 weeks or sooner if an effect is achieved sooner than expected and reduction or discontinuation of the medication is possible. Close follow-up of the patient is necessary to see the positive and negative effects. Review this evaluation with the patient and his/her environment. Review the challenging behavior again and consider further psychological or environmental interventions.

Appendix C. Annex with concrete tools to follow the belgian guideline

Tools for the recommendations and principles - Comprehensive, integrative and multidimensional imaging
Etiological diagnosis of intellectual disability Medical history Medication history Somatic examination (focusing on a possible somatic cause for the behavioural problems) Psychiatric examination Intelligence test Developmental anamnesis Adaptive skills examination Social-emotional development Targeted autism measurement instruments Depression Personality problems Behavioural problems Context and subjective patient wishes Current physical condition Current social and system functioning. Comprehensive overview per drug: https://www.farmacotherapeutischkompas.nl/
Tools for the recommendations and principles - Environmental conditions
Check, among other things, the following environmental conditions: • Appropriate daily structure and routines • Exercise • Stress regulation • Calming or distracting strategies • Relaxation • Competence-oriented work • Increasing client capacities/resilience training • (Functional) communication training • Team training • Training those involved • Adapting/optimising the environment in terms of lighting/noise and temperature • Reinforcement of positive behaviour and environmental enrichment
Tools for the recommendations and principles- Pharmacological part of the treatment plan
When medication is used as part of the treatment, this is described in the pharmacotherapy part of the treatment plan. By definition, the pharmacotherapy part of the treatment plan is drawn up by the prescribing doctor. The treatment plan includes: 1) The complains (both of the client and the environment and/or counselling) and request for help 2) Concrete treatment goals (both from the client and the environment and/or counselling) 3) Possible additional research 4) (Sequence of) interventions 5) Monitoring and evaluations 6) Policy for crisis situations 7) Duration of the treatment 8) Responsibilities of those involved 9) Information 10) 'Informed consent' paragraph