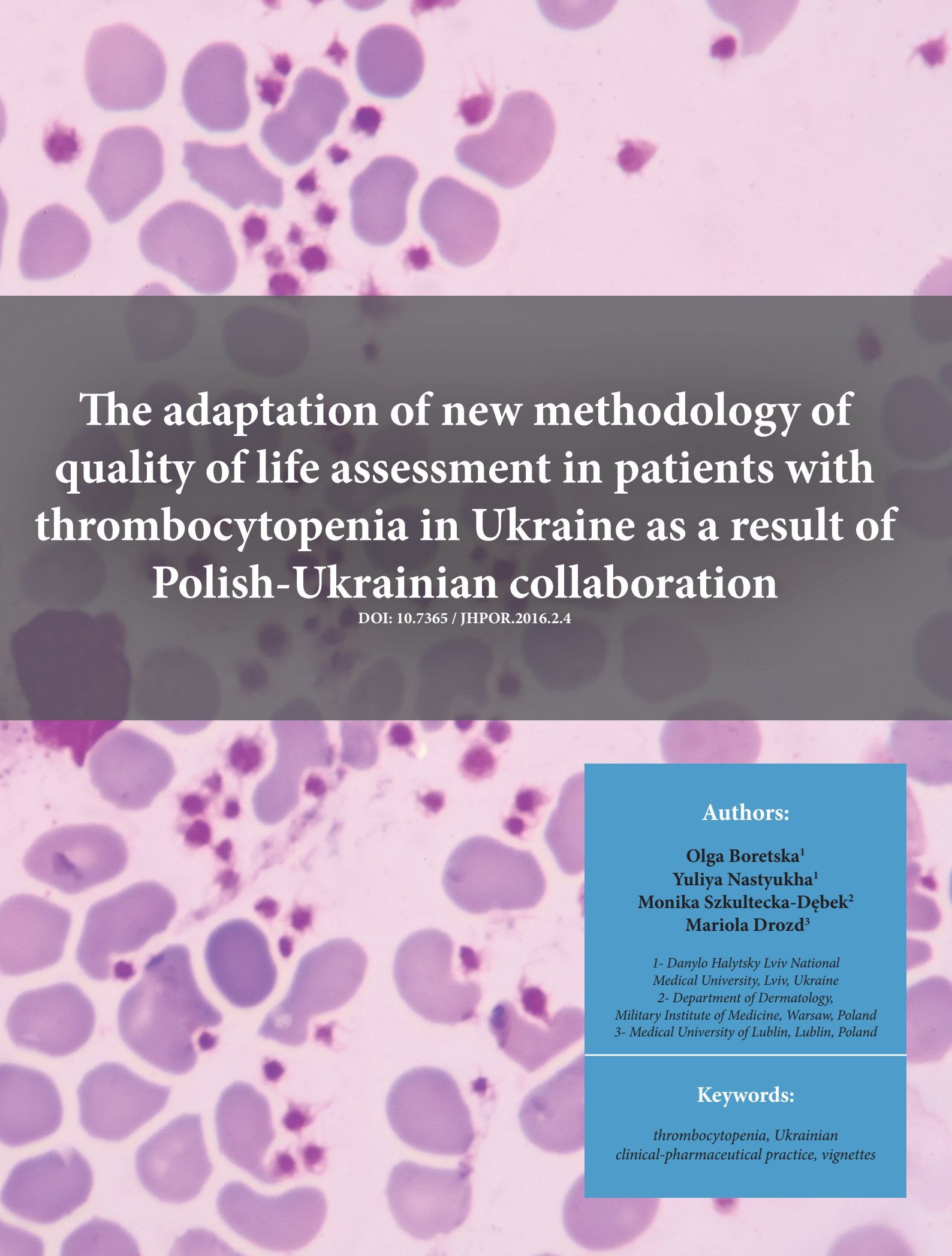

The adaptation of new methodology of quality of life assessment in patients with thrombocytopenia in Ukraine as a result of Polish-Ukrainian collaboration

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Abstract

Objective: Our aim was linguistic adaptation the Thrombocytopenia Symptoms and their Impact on patients Daily Activities Assessment Vignette (TSIDAV) into Ukrainian.

Methods: In the translation process were involved two translators who took into account the cross-cultural aspects during translation of the vignette. The translation was done from Polish to Ukrainian and then was translated back into Polish. The translated version was validated by the vignettes' Polish authors in order to verify the maintains the content, purpose and estimated tool properties of translated version.

Results: Vignettes were adapted according to the algorithm described in the methodology of the research. The adaptation algorithm of the vignettes into Ukrainian language follows ISPOR recommendations for translation. The obtained Ukrainian version of the vignettes was tested on a small group of lay people (n=9) in order to test alternative wording and to check understandability, interpretation, and identify potential cultural issues related to the translation. Thus, the last step of vignettes adaptation, such as a review of cognitive debriefing results, finalization and proofreading occurred with involving an Ukrainian professional philologist. As the final result, it was obtained a tool for evaluating the thrombocytopenia symptoms impact on patients' daily activities in Ukraine.

Conclusions: The obtained Ukrainian version of the vignette is a simple and fast instrument to assess the impact of symptoms of thrombocytopenia in patients' daily activities. The next step is the process of validating the instrument in Ukraine.

Introduction

Quality of Life (QoL) is a term used in medical and social science.[1] It is a very wide concept related to almost all significant spheres of life.[1] WHO defines QoL "as individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, the level of independence, social relationships, personal beliefs and their relationship to salient features of their environment".[2] In clinical medicine, the index of health-related QoL enters into the standards of diagnosis and treatment.[3] It is used to carry out the process of internal monitoring, evaluate the effectiveness of treatment and prognosis, and it is an integral part of the randomized pharmacoeconomic settlements.[3] The improvement of prognosis in many cases is the main goal of the treatment.[4] Along with this, it is considered as the optimum treatment, that one which not only increases the length of life but also improves the quality.[4] Therefore, the increase in QoL of patients is of concern of the doctor and patient.[5] In our opinion, an integral component of the treatment process is monitoring QoL. Therefore the current question is the process of measuring the QoL parameter and the application of valid questionnaires and scales. Currently, there are developed many methodologies that provide information about different aspects of QoL.[6] QoL questionnaires are the source of information useful for the decision making process regarding the therapy to be used which allow for a personalized treatment.[4,7] In general, the existing questionnaires can differ depending on how specific they are, what is their construction, volume and how the information is obtained[4]. The general questionnaires are used worldwide being translated and validated into local languages.[3] The weak point of the general questionnaires is an insufficient sensitivity when using a particular disease unit.[4] Currently, there is a tendency to use also disease specific questionnaires.[4,8] In addition to general questions, they include those associated with states characteristic of a disease.[3] Therefore, disease-specific questionnaires are the most sensitive to the particular disease.[9] Despite the great variety of existing QoL questionnaires, there are still areas when more information is needed.[10] A tool to be used to fill the gap for capturing, often a sensitive information, are vignettes.[10] The rating of vignettes is a promising additional technique to measure changes in QoL and utilities and it can be considered for use as a supplementary method to standard QoL measurement methods.[1,10] According to Collins, vignettes are short descriptions of hypothetical situations or scenarios and are useful in understanding how respondents would answer questions about these situations and in showing whether the conceptual boundaries of the domain vary as between respondents.[11] The descriptions, known as clinical vignettes, may be used as tools to measure a diversity of variables, including QoL, public perceptions of disease, and variations in healthcare practice across jurisdictions.[12] Clinical vignettes are often used to elicit information about health conditions in research studies.[12] An important consideration to make when designing a vignette-based study is the content of the vignettes.[12] Vignettes should present realistic situations to maximize study validity.[12] Vignettes can generate results that permit researchers to make valid inferences about the variables under study.[12] Vignettes are a useful method for making cross-national comparisons of the quality of care provided in very different settings.[13]

Polish authors created the vignettes with a special focus on the most frequent thrombocytopenia symptoms and those most life threatening which may produce particular fear and concern to patients.[11] In absence of evidence about usage of such tool in Ukraine, we decided to implement a study to assess the thrombocytopenia symptoms impact on daily patients' activities. However, due to the fact that the vignettes are developed in Polish for their later use in Ukraine, the needed step was the linguistic adaptation of vignettes which was our objective.

Materials and Methods

The aim of our project was the adaptation of the vignettes developed by the Polish scientist for the assessment of thrombocytopenia symptoms impact on patient daily activities in order to allow the use of the instrument in the Ukrainian health care system.

Materials: The adaptation process consisted of translating vignettes following the adequate translation process from the original Polish version into Ukrainian one. The adaptation algorithm of the vignettes into Ukrainian language is shown in Figure 1 and follows ISPOR recommendations for translation.[14]

The translators were Ukrainian native speakers. They know Polish language and they reside in Ukraine, so they are familiar with local cultural influencing factors. They used wording that enabled proper understanding of the vignettes content. After initial discussions and preparation, selecting the native translators the process had started. The forward translation was performed by translator 1 and followed by the back translation.

Translator 2 was not familiar with the original version of the vignettes and worked only with the Ukrainian version that was prepared by the translator 1. After the back translation being reviewed the vignette in Polish version which was obtained during translation in the next phase was shared with the Polish authors for the clarity and compatibility with the original vignettes content assessment.

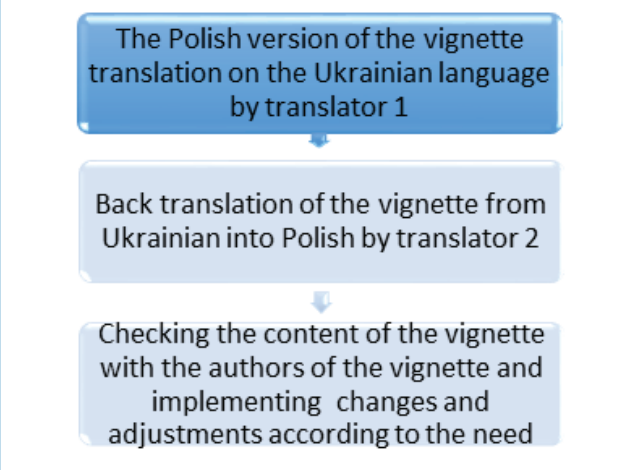

Figure 1. The adaptation algorithm of the vignettes – key steps

The obtained Ukrainian version of the vignettes was tested on a small group of lay people (n=9) in order to test alternative wording and to check understandability, interpretation, and identify potential cultural issues related to the translation.

Results

According to requirements of the Scientific Advisory Committee, Medical Outcomes Trust one of the main criteria which must have an instrument for evaluating the QoL is an adequate linguistic adaptation taking also into account the cultural characteristics.[15] Therefore, it is required to take into account verbal and socio-cultural characteristics of the country that will provide an accurate understanding of the questionnaires without losing its main measuring properties.[4] Therefore, the quality of the translation is important.[4] It should be noted that the translation is not enough to be literal and it should reflect the essence of the question.[4] In order to allow for the questionnaires to be used in one country or another, it has to undergo the procedure of validation after translation. That will assess its compatibility with the original.[4]

Vignettes successfully passed the adaptation process according to the algorithm described in the methodology of the study. The vignettes authors provided positive feedback after translation process and the Ukrainian version was considered to be adapted for measuring the impact of the symptoms on daily activities of patients with thrombocytopenia in Ukraine without bringing significant changes to the structure and content of the questions. During the review of the translation and back translation, there were few wording issues identified and corrections were implemented. The focus group (9 lay people) tested the proper understanding of the final translated Ukrainian version of the vignettes. Respondents were Ukrainian native speakers. They participated in the survey for cognitive debriefing aspects of the adapted vignettes. There were questionnaires created for this process, which consisted of following answers: question understandable, incomprehensible question, and requires stylistic corrections. Only 3 respondents pointed to inaccuracies noting items as «requires stylistic corrections». None of the respondents noted items as «incomprehensible question». Thus, the last step of vignettes adaptation, such as a review of cognitive debriefing results, finalization

and proofreading occurred with involving an Ukrainian professional philologist. The final translation was checked, and minor grammatical, and spelling errors were corrected.

There were three vignettes adapted. They are aimed to measure the impact of thrombocytopenia symptoms on daily activities of men, women, and children. The Ukrainian-vignettes structure corresponds to the original one and consists of two parts. The first part is focused on the identified disease symptoms which may influence the daily activity, especially those which may be of particular concern to the patient, the patient was asked to list them.[11] The second part provides for patient self-assessment of threatening symptoms that are identified by the authors who developed the vignettes.[11] The significance of the impact is assessed by Likert scale.[11] The brief characteristics of the second part of the vignette are shown in Figure 2.

The vignettes were validated within psychologists and clinicians in order to ensure proper context description.[11] An excellent feature of the adapted vignettes in comparison with other instruments assessing QoL is their relatively small volume and the focus on the impact of the major symptoms of thrombocytopenia QoL of patients.

Discussion

The problem of QoL is investigated by many scientists in Ukraine. In particular, the questionnaire widely used is the Questionnaire Medical Outcomes Study Short Form 36 (MOS SF-36), which was translated from English to Ukrainian.[16] The translation was made with the assistance of the international centre The International Quality of Life Assessment (Boston, USA).[16]

We have searched for a systematic review of use of QoL

№ з/п	На кого скерована віньєтка	Основні симптоми враховані у віньєтці
1.	Чоловік	•Петехії (точкові крововиливи) на шкірі і / або слизових оболонках •Легкі синці •Кровотеча з ясен або носа
2.	Жінка	•Петехії (точкові крововиливи) на шкірі і / або слизових оболонках •Легкі синці •Кровотеча з ясен або носа •Тривалі в часі менструації
3.	Дитина	•Петехії (точкові крововиливи) на шкірі і / або слизових оболонках •Легкі синці •Кровотеча з ясен або носа

-2 Сильний вплив
-1 Середній вплив
0 Байдуже
+1 Незначний вплив
+2 Немає впливу

Figure 2. The second part of the vignettes in Ukrainian

questionnaires in Ukraine but we haven't identified such publication. However, during the search, we identified single studies with many examples of the SF-36 questionnaire usage. E.g. for the assessment of QoL in patients with bronchial asthma[16]; in patients with idiopathic interstitial pneumonia[17]; in children aged 14-18 years old with chronic ulcer exacerbated and in remission[18]; for the study of QoL in patients with hypertensive disease[19]; in relation to abdominoplastic to study the effects of the deformation of the front abdominal wall and also obesity on the QoL of patients[20]; in patients with type 2 diabetes and hypertensive disease[21]; and in older people who had acute cerebrovascular accident.[22] SF 36 is a general questionnaire and it's widely used. It can be used as addition to a specific questionnaire like for patients with chronic bowel disease (using a special questionnaire that is designed for such patients and the general SF-36)[9]; for the examination of the impact of nutritional status on QoL of patients with chronic inflammatory bowel disease (general SF-36 and specific IBDQ [23]; for the patients with isolated course of chronic obstructive pulmonary disease and with his reconciliation with chronic pancreatitis (SF-36 and is a specialized respiratory questionnaire Hospital of St. George – SGRQ.[24]

There are also other questionnaires used to measure QoL. In particular the specific to psoriasis (index of incapacity law with psoriasis) and dermatologic indicators of QoL questionnaires (Skindex-29, dermatological index QoL).[25] In studies with epilepsy, a questionnaire "Quality of Life in Epilepsy Inventory 89" (QOLIE-89) adapted into Ukrainian it was used.[8] The QoL status of patients with chronic heart failure was evaluated on the basis of questionnaires answered by patients Minnesota Living with Heart Failure Questionnaire (MLHFQ).[26] QoL of women operated due to endometriosis was assessed at various time intervals after the surgical operation using the survey questionnaires (Adamyan L.V. et al., 1998) with the author's modifications.[27] The QoL of women with breast cancer T1-3N0-2M0 was studied with the European Organization for the Research and Treatment of Cancer (EORTC) QLQ-C30 and EORTC QLQ-BR23 Questionnaires.[28] The QoL of patients with cancer of the breast gland with metastases to the liver was evaluated by using the European quality of life questionnaires (EQ5D).[6] The problem of the QoL of patients with oncological diseases is currently rising in Ukraine and is mentioned in other publications.[29,30]

In some studies, scientists also apply their own questionnaires and scales. In particular, for assessment of QoL of the forms of primary open angle glaucoma[31]; for QoL assessment of patients with consequences of cervical spine traumatic injury[32] and for the assessment of psychoneurological status in children after surgical

treatment of hydrocephalus, caused by perinatal brain injury.[33]

QoL assessment of children is also carried out. An example of such assessment is a case of children with bronchial asthma, especially looking at the functioning of asthma-school.[34] There are used the QoL questionnaires with standardized activities for children suffering from bronchial asthma (PAQLQ (S)).[34] The questionnaires are adapted for Ukraine in Russian and Ukrainian language.[34]

Another QoL study in children was performed in a group with allergic diseases.[35] The measurement was based on questionnaires AQLA (S).[35] It is a questionnaire adapted for different types of allergy for children aged 5-17 years.[35] The QoL in children with juvenile rheumatoid arthritis was assessed by a Ukrainian-adapted version of the questionnaire Child Health Questionnaire (CHQ) Modified PF50 (parent form) with previously proven psychometric characteristics.[36] Questionnaires SF87 (v.2) and CHQ-PF50 (the copyright of the authors[37]) were used for the assessment of QoL in children age from 7 to 16 years with diseases of the nervous system.[37]

Summarizing, a variety of instruments generic and specific to various diseases and symptoms are used in Ukraine in order to assess the QoL of patients. That is evidenced by a number of publications. However, the use of specific vignettes for determining and monitoring the impact of various symptoms that can worsen QoL of patients for Ukraine is a new approach.

That applies also to the analysis of the impact of symptoms of thrombocytopenia which may influence patients' daily activities independently of the disease cause. [11] There can be some life threatening complication like intracranial bleeding.[11] Those symptoms can impact patients daily activities and indirectly their QoL.[11] With the vignettes created to assess those symptoms impact on daily activities, we may have a better understanding of such influence.[11]

Conclusion

Adapted for use in Ukraine vignette version is a simple for application and interpretation instrument of assessing the impact of disease symptoms on daily activities of patients with thrombocytopenia, both adults, and children. Using this vignettes in clinical practice could enable the personalized monitoring of the patients by assessing the impact of symptoms on daily activities of patients during treatment. Also, it will allow a better understanding of the patient's condition and improve doctor-patient collaboration. The use of a validated tool will make possible to compare the results obtained in Ukraine with the results in Poland, and in the perspective, in other countries.

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