BMJ Open

Translation to English, cross-cultural adaptation, and pilot testing of the self-report questionnaire on swallowing difficulties with medication intake and coping strategies (SWAMECO) for adults with polypharmacy

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To cite: Arnet I, Messerli M, Oezvegyi J, *et al*. Translation to English, cross-cultural adaptation, and pilot testing of the self-report questionnaire on swallowing difficulties with medication intake and coping strategies (SWAMECO) for adults with polypharmacy. *BMJ Open* 2020;**10**:e036761. doi:10.1136/bmjopen-2020-036761

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-036761).

Received 01 January 2020
Revised 22 June 2020
Accepted 30 June 2020

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ABSTRACT

Objectives To translate the SWAMECO from German into English; to complete content and face validity with healthcare professionals (HCPs) and with patients from the target population that is, community-dwelling adult patients taking three or more medicines for three or more months.

Design The process followed guidance from Sousa *et al* and included translation and cross-cultural adaptation, and cognitive testing among selected HCPs and patients. As the SWAMECO questionnaire is a screening instrument, pilot testing was performed in the target population.

Setting Three community pharmacies in and around Cork (Ireland) recruited patients for interviews and pilot testing.

Participants Community-dwelling patients with ≥3 oral medications for ≥3 months, aged ≥18 years.

Outcome measures Answers to the SWAMECO questionnaire; clarity of each question, each instruction and each response format.

Results Issues related to cultural and conceptual differences were resolved by rewording some items. Ten HCPs and 11 patients completed the questionnaire and gave their feedback and opinions on criteria according to Fitzpatrick *et al*. Revisions included rewording; deleting of two questions; using of colour to signpost that is, where to skip questions that were not applicable to the participants; and replacement of the A-14 medication adherence scale with three validated items. Of the 66 patients enrolled for pilot testing, eight (12.1%) indicated swallowing difficulties. Difficulties with ingesting foods or liquids correlated with swallowing difficulties (p=0.001). All patients perceived discomfort (mean 6.9 on a Visual Analogue Scale from 0 to 10). Patients with swallowing difficulties were significantly more likely to report modifying their medicines (p=0.004) and having poorer medication adherence (p=0.028) than those who had no swallowing difficulties.

Conclusions The version of the SWAMECO questionnaire in English contains 28 items and is ready for use in adults with polypharmacy.

Strengths and limitations of this study

- ► The SWAMECO questionnaire was translated and cross-culturally adapted to English speakers.
- ► The 28 items assess subjective swallowing difficulties with oral dosage forms including tablets or capsules and the coping strategies used, without being a diagnostic tool.
- ► Pilot testing was performed in the target population of community-dwelling patients over 18 years and receiving at least three chronic medicines for at least 3 months.
- ► We did not perform construct validity nor criterion validity.

INTRODUCTION

Medicines are crucial for protecting, maintaining or restoring people's health. Solid oral dosage forms, for example, tablets and capsules, remain the most prescribed medicines, and the oral route is the preferred route of drug administration as it is non-invasive and convenient. With the growing and the ageing of the population, healthcare problems have arisen relating to the increased consumption of medicines, coupled with the fact that many older people are not able to swallow medicines as well as their younger counterparts.[1] Dysphagia, that is, swallowing difficulties, describes a sensation of difficulty in the passage of solids or liquids from the mouth to the stomach, or the perception of obstruction during swallowing.[2] Patients may have difficulties swallowing medicines even in the absence of a clinical diagnosis of dysphagia.[3] Studies have suggested that swallowing difficulties with medicines are present in 9% of patients with polypharmacy

(those who take five or more medications concurrently) attending a community pharmacy[1] and 27% of patients attending a general practitioner (GP).[4] When patients have swallowing difficulties, they may try to alter the medicine in some way to make this process easier. This oral dosage form modification (ODFM) may include practices such as (but not limited to) splitting or crushing tablets, and opening capsules. While this makes sense to the patient, it may cause other problems associated with the pharmacokinetics of the drug and therefore could pose a patient safety risk. Thus, identifying those patients with swallowing difficulties and consequently, at risk of undertaking ODFM as a coping strategy may represent a pharmaceutical care issue.[1]

The SWAllowing difficulties with MEDication intake and COping strategies (SWAMECO) is a self-report questionnaire developed by Swiss pharmacists[5] and contains items focusing on issues relating to swallowing difficulties with medication intake. Originally designed as a screening tool, rather than a diagnostic, it captures patient outcomes. The questionnaire comprises five domains: complaints, intensity, localisation, coping strategies and medication adherence. The questionnaire has a mixture of questions that requires answers that are either dichotomous (yes/no), 4-point Likert scale (from 1=totally agree to 4=totally disagree), Visual Analogue Scale (from 0=no discomfort to 10=unbearable discomfort) or free-text options. The questionnaire was developed and validated with patients suffering from systemic sclerosis who have problems swallowing food and liquids due to the worsening of the underlying disease. The authors of the original tool recognised that further development of the questionnaire was needed in a more general population. Thus, validation in community-dwelling adult patients was required.

AIMS

The aim of this study was to translate to English, and cross-culturally adapt the SWAMECO questionnaire with the help of healthcare professionals (HCPs) and patients to extend its use to the target population that is, community-dwelling adult patients.

METHOD

Translation and cross-cultural adaptation process

Translation and cross-cultural adaptation was performed following international recommendations from Sousa and Rojjanasrirat.[6] Two translators performed the translation, one conducting the forward translation and the other conducting the back translation. After comparing the source language versions, discrepancies led to adaptations in the target language version until both translators agreed on semantic and conceptual equivalence between source and target languages. Cognitive debriefing of the English version was performed with interviews from HCPs and patients.

Table 1 Inclusion criteria for study participants, that is, patients and healthcare professionals

Target population	Inclusion criteria for study participants
Patient (interviews and pilot testing)	≥18 years. ≥3 oral medications for ≥3 months, community-dwelling.
Healthcare professionals	a. Pharmacists with experience in at least one of the following areas: community pharmacy, hospital pharmacy or academia. b. Doctors with experience in at least one of the following areas: hospital practice, general practice or academia. c. Speech and language therapists with experience in at least one of the following areas: hospital practice, community practice or academia. d. Nurses with experience in at least one of the following areas: hospital practice, community practice or academia.

Healthcare professionals

A heterogeneous panel of HCPs was contacted via email or phone and informed about the study. They consisted of professionals who are knowledgeable about the content areas of the construct of the instrument and the target population in which the instrument will be used (table 1). Once written informed consent was obtained, the HCP completed the questionnaire (online supplementary appendix A). They evaluated the items, response format and instructions for clarity (clear/unclear), and the relevance of content for each item (1=not relevant; 2=unable to assess relevance; 3=relevant but needs minor alteration; 4=very relevant and succinct) using data collection forms (online supplementary appendices B and C). If any participant rated either (i) the instructions, (ii) response format or (iii) any item of the instrument, 'unclear', they were asked to provide suggestions as to how to rewrite the statements and/or make the language clearer.

Patients

Patients attending a pharmacy in a suburban area of Cork (Ireland) were approached by the researcher (JO) or pharmacy staff and asked to participate in the study, and if eligible (table 1) then information about the study was given and written informed consent was obtained. Patients were then invited to the consultation room to fill out a copy of the questionnaire (online supplementary appendix A). After completing the questionnaire, they were asked to comment on the clarity of each question, each instruction and each response format, using a dichotomous scale (clear/unclear; online supplementary appendix B).

Interviews

In semistructured interviews (online supplementary appendix D), HCPs and patients could give general comments and feedback about the questionnaire. The interviews were audio recorded, transcribed verbatim and verified by a second member of the research team (LS) who is a native English speaker. Demographic information was gathered on all participants, including gender and age. For patients, any medical conditions and current medications were also gathered. For HCPs, profession, qualification, current role and years in practice were obtained.

Pilot testing with patients

Three community pharmacies in and around the Cork area were purposively chosen to reflect different settings and socioeconomic status. The different areas were selected using the Pobal Deprivation Index, which measures the relative affluence or disadvantage of a particular geographical area using data from various censuses (education, unemployment rate etc).[7] Patients waiting for their prescriptions were invited to participate in the study by the researcher (JO) or by the pharmacy staff. If the patients met the inclusion criteria and after written informed consent was obtained, they were given a paper copy of the SWAMECO questionnaire (online supplementary appendix E) to complete. The researcher was available for any queries. To guarantee privacy, the participants were invited into the consultation room in the pharmacy to complete the questionnaire. The data collection period lasted from 27 February to 12 May 2018.

Patient and public involvement

The development of the research question was informed by the necessity to validate the SWAMECO questionnaire with patients. Patients were not involved in the design of the study, patients were the subject of the study. They were recruited in community pharmacies during the current practice. The study participants agreed to participate anonymously. Thus, the information will be disseminated to the participants and public anonymously via articles in medical press and in lay language.

STATISTICAL ANALYSIS

Descriptive statistics analysed participants' characteristics, which are presented as percentages or means±SD.

Inter-rater agreement was calculated for each item, response format and instruction clarity of the instrument. Any element that was judged unclear by >20% of the participants was re-evaluated. Content Validity Index (CVI) at the item level was calculated by dividing the number of HCPs that arrived at an acceptable grade (3 or 4) for the item by the total number of assessments for the respective item.[8] The item was considered relevant for a value of 0.78 or above. Any items that did not meet this criterion were revised.[9] Statements from the patient interviews were collected. Quotes with participant number (p for patient, HCP) are provided for context. The interviews with HCPs were coded using the qualitative data analysis software NVivo Pro V.11. Inductive analysis of themes was performed. The answers to the items were entered into the SPSS V.24 (SPSS, IBM).

RESULTS

Cognitive testing

A total of 11 patients (four female; mean age 77.9±3.5 years) and 10 HCPs (four pharmacists, two GPs, two speech and language therapists, two nurses; mean 21.2±10.8 years in practice) completed the SWAMECO questionnaire and gave their opinions on clarity and relevance. The patient population comprised those who had comorbidities of cardiovascular disease (8/11) and/or diabetes (3/11), and were taking between 3 and 20 medications per day.

Patients felt that the questions were clear; in 82% of items, 100% of the instructions and 80.1% of the response formats. The questionnaire itself was well accepted and its length suitable, as the questions were 'appropriate for people to think about how they take their medication' (P2).

Overall, HCPs found the questionnaire 'well-constructed' (HCP10), 'laid out well' (HCP4) and 'not too wordy' (HCP10). They suggested a larger font for the instructions on the first page, to aid an older population. The HCPs estimated 17 items as unsatisfactory (CVI ≤0.78), 13 of them belonging to the A-14 adherence scale (CVI ≤0.4). Predominantly, the relevance of medication adherence in the context of swallowing difficulties was questioned. Clarity was not found for 12 items (8 belonging to the A-14 adherence scale). Three items focusing on the Sicca syndrome obtained a CVI <0.7 (item 7: 'Often I have to have a sip of water to help me to speak'; item 8: 'I have an unpleasant burning sensation in my mouth' and item 9: 'Both my eyes and my nostrils feel dry'). The answer option 'not applicable' was judged as not relevant for 10 items (items 6, 8–14, 19, 21). During the interviews, HCPs mentioned advantages of using a screening tool for swallowing difficulties, which might influence prescription practice. The diagram located at item 16 was questioned as to whether the retrieved data would be useful. The accuracy of the medicine names, causing swallowing difficulties (item 17) was also questioned, as 'patients know very little about their medication, particularly names and doses' (HCP5). The relevance of asking the position of the head while swallowing medicines (item 18) was also questioned (CVI=0.7).

Revision of the questionnaire

The revisions included the removal of two items (items 7 and 27 that duplicated items 6 and 5, respectively); replacing the A-14 scale with a validated 3-item self-report measure of adherence;[10] rewording of items (6, 8, 15, 20 and 25) and instructions (item 16); removal of 10 answer options 'not applicable'; increasing the font size and adding colour instructions to signpost the participant. A

Table 2 Characteristics of the three recruiting pharmacies and the recruited patients

	Pharmacy 1	Pharmacy 2	Pharmacy 3	Total
Location	Suburb of Cork	Moderately affluent area of Cork	Rural town in Cork county	
Deprivation index*	Marginally above average	Disadvantaged	Marginally below average	
No of patients enrolled	28	28	10	66
Patients mean age ±SD (years)	72±11	66±12	63±11	68±12

*The deprivation index measures the relative affluence or disadvantage of a particular geographical area using data from various censuses (education, unemployment rate, etc).

free-text comment section was added at the end of the questionnaire. The revised SWAMECO contains 28 items (online supplementary appendix E).

Pilot testing

The three recruiting pharmacies were independently owned. Characteristics of the recruiting pharmacies and the recruited patients are shown in table 2.

Of the 66 enrolled patients, eight (12.1%) patients indicated swallowing difficulties (five present, three past), of whom seven were women (87.5%). Swallowing difficulties did not correlate with age (p=0.623) nor gender (p=0.134) but with difficulties with ingesting foods or liquids, which occurred in six patients (p=0.001). Choking (item 5.1), and the feeling that medicines get stuck in the throat (item 9) were the sensations most frequently chosen (five and six patients, respectively). Pain was never marked (item 10). Five patients each indicated dryness of the mouth (item 6) and of the eyes/nostrils (item 8). All patients perceived discomfort (item 14), with a mean score of 6.9 (figure 1).

Swallowing difficulties (item 15) were predominantly located in the pharynx (figure 2), with comments describing mostly feelings of medicine getting stuck. Four types of medicines were specified as causing swallowing difficulties (item 16): painkillers; Buscopan (hyoscine butylbromide) tablets; Nexium (esomeprazole) and painkillers/antibiotics.

Coping strategies

Of the 66 patients, 12 reported dosage form modification (item 18) with tablet-splitting being the most common (11 patients). Opening capsules (n=2) and crushing and chewing (n=1) were also mentioned. The position of the head of the 66 patients while swallowing medicines was mostly straight for 38 patients (57.6%) or slightly back for 25 of them (37.9%) and was not associated with the occurrence of swallowing disorders (p=0.325). All but three patients would drink something to help swallowing medicines (item 25). Three-quarters of these patients asked neither physician nor pharmacist for advice before modifying the oral dosage form (item 20). Patients with swallowing difficulties were significantly more likely to modify their medicines than those without swallowing difficulties (p=0.004).

Medication adherence

Overall adherence rate in the past 30 days was high for the 66 enrolled patients and reached a mean of 92.5%±8.3 (items 26–28), with 24 patients (36.4%) who selected the highest adherence behaviour for each item and reached the maximum score of 100 (figure 3). Forty-seven patients (71.2%) indicated that they missed no days of medicine intake (item 26). Adherence score was lower for the eight patients with swallowing difficulties (88.1%±13.7) with four patients indicating that they missed a varying number of days of medicine intake (between 1.5 and 5 days), and to have done a 'poor' job at taking medicines (item 27). Having swallowing difficulties with medicines was associated with a lower adherence score (p=0.028).

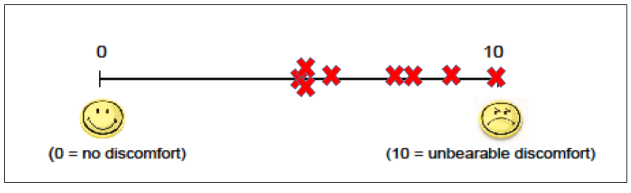

Figure 1 Discomfort caused by swallowing medicines and indicated by eight patients with swallowing difficulties (red cross) on a VAS of 10 (mean score: 6.9). VAS, Visual Analogue Scale.

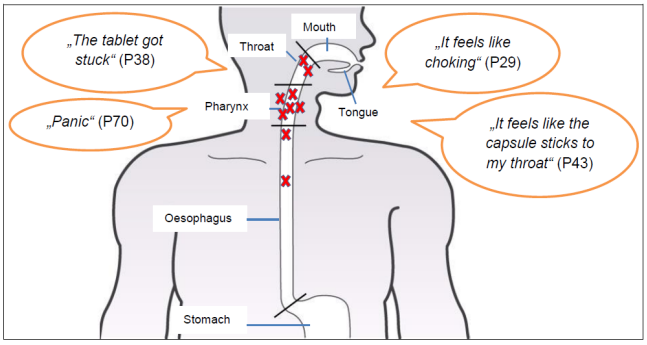

Figure 2 Cumulative view of the location of the swallowing disorders indicated by eight patients with swallowing difficulties (red cross) together with accompanying descriptions (with participant number).

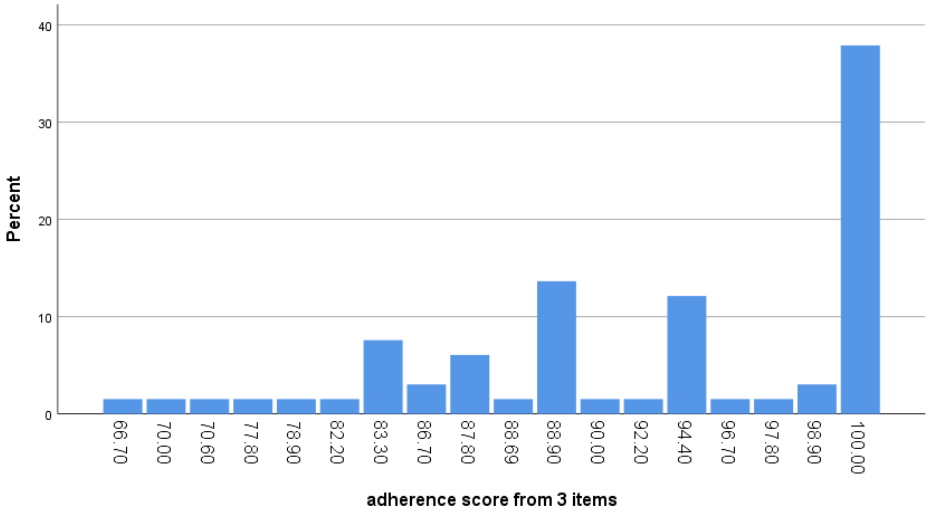

Figure 3 Repartition of the adherence score (from 0=worst to 100=best adherence) obtained from three questions (items 26–28) after linear transformation, according to Wilson *et al*.[10]

DISCUSSION

We validated the English version of the self-reported questionnaire on swallowing difficulties with medications, SWAMECO, with experts and with a sample of patients from the target population, that is, patients with multiple medications. The decision to test adults with three or more medicines was guided by the fact that patients with polypharmacy represent one target group for pharmacist-led services[11 12] and placed screening for swallowing difficulties in this context. Face and content validity confirmed the clarity, acceptability and appropriateness of the 28 items of the tool. Furthermore, HCPs, who were asked, acknowledged the necessity of screening for swallowing difficulties with medications in daily clinical and pharmacy practice. The SWAMECO questionnaire also revealed suboptimal coping strategies, that is, those that are inappropriate and may potentially be dangerous for the patient. HCPs can use the information gathered to structure their encounter with the patient and tailor their counselling in addition to correcting potentially erroneous strategies. This type of structured conversation is in line with the efforts put to exchange information on medications between HCPs and patients in a time-saving manner.[13] Further steps will now include the development of a score to facilitate the detection of patients in need of modified counselling, and interventions that are modelled on the items.

During the content validity procedure, the experts queried the appropriateness of some items, especially the indication of the location of the swallowing difficulties (item 15), and the names and doses of the responsible medications (item 16). Patients, however, seemed able to complete these tasks without hesitating and to mark the location of the difficulties on the human profile, and to name the relevant medications. Even if the terms 'antibiotics' or 'painkillers' are vague, the HCP will be able to identify the corresponding medications by checking their patient medication record and thus, adapt the formulation accordingly. Regarding the location of the swallowing difficulty, the presence of symptoms in the throat or in the chest signals the need for the assessment of dysphagia.[14] Another item questioned by the experts was the swallowing technique used by the patients (item 17). However, this may well represent counselling opportunities for HCPs in a patient who mentions difficulties with swallowing medicines. Swallowing with the chin close to the neck (chin-tuck posture) represents an effective technique to improve swallow control.[15] It is noteworthy that the chin-tuck technique was used by only 4.5% of the surveyed patients (and by none of the patients indicating swallowing difficulties) and might be a simple and effective intervention provided by pharmacists. Overall, however, the utility of some of the collected information is unclear, and particularly what, if any, recommendations can be made by pharmacists. Consequently, we will re-evaluate the necessity of some items and may end up with a shortened version of the SWAMECO questionnaire for use in daily practice, linked to concrete interventions.

From the 66 outpatients with polypharmacy who entered a community pharmacy and filled in the SWAMECO questionnaire, eight (12.1%) mentioned swallowing difficulties with medication. This frequency is in line with previous studies conducted similarly in pharmacy settings and is independent whether participants have dysphagia or not.[4 16] Accordingly, a validated eating assessment tool was able to detect 18% of healthy controls who reported difficulty swallowing medicines.[17] Interestingly, medication non-adherence measured by a three-item scale differed significantly between patients with and those without swallowing difficulties. In general, patients with swallowing difficulties more frequently indicated that they had missed doses, and that they do a poor job of taking medicines as prescribed, than those without swallowing difficulties. Although causality between missed doses, 'poor' job and swallowing difficulties is

not demonstrated with our study design, it is likely that swallowing difficulties with medication represent a strong indicator for suboptimal medication-taking behaviour including missing doses. Due to the impact of omitted doses on the pharmacological profile of medications and thus, on the clinical outcomes,[18] the availability of a self-reported questionnaire such as the SWAMECO is even more crucial in daily practice.

The presence of the dryness (Sicca) syndrome, that is, xerostomia and xerophthalmia, in the original questionnaire (items 6–10) was logical as these items were developed for patients with systemic sclerosis, an autoimmune disease with the fibrosis of multiple inner organs that leads to swallowing problems, among others.[5] The decision to retain these items in the assessment of the target population, contrary to experts' advice, was informed by large studies that demonstrated the increase of xerostomia in the elderly general population.[19] In our study, with eight community-dwelling individuals with swallowing difficulties, xerostomia and ocular/nasal dryness was indicated by five participants each (62.5%), while six (75%) mentioned the feeling of the medications stuck in the throat. Thus, dryness syndrome might reveal a specific opportunity for counselling in the older adult, and is thus justified within the current version of the SWAMECO questionnaire.

The SWAMECO questionnaire has been designed as a self-reported questionnaire to optimise time in medical and pharmacy practice. Thus, patients may complete the questionnaire in the waiting room of the GP surgery or while waiting for their prescription in the community pharmacy. However, the tool's burden seems high at 15 min, to complete. In addition during pilot testing, some patients needed assistance when it came to moving to another section of the questionnaire, indicating that finding its way through the items might be difficult for some patients. A subdivision of the items in a first part with yes/no answers for screening purposes and a second part with open-ended questions for complementary information might lessen this burden. An electronic version with logical structure might solve this problem.

The first strength of our study is that the surveyed patients were those aged 18 years and older, and receiving three chronic medicines or more, ranging up to 20. The average age of those surveyed was over 65 and thus represents the pattern of patients in most Western countries as polypharmacy can be the result of multiple diseases and multimorbidity in the older adult.[20] In our study, the presence of swallowing difficulties with medicines was not associated with the number of daily medicines. Consequently, the SWAMECO questionnaire could be used as soon as patients take several medications, and more systematically in patients receiving four or more regular medicines.[21] Second, this multicentre study took place in areas with different deprivation scores. Clarity of the questionnaire was demonstrated during content validation with experts, and pilot testing with patients. Thus, we feel that the SWAMECO questionnaire can be used in all social strata. Third, the SWAMECO questionnaire is paper-based and can be filled in medical or pharmacy waiting rooms. In spite of the increase of electronic formats, few countries have electronic patient health records whose access is shared between different healthcare providers. Thus, our paper-based questionnaire still represents a durable source of information, which can be carried by patients from one healthcare provider to the next. As long as many Western countries are still developing a networked infrastructure, and electronic patient records in card forms are still pending, our paper-driven tool corresponds to a real-life situation in most European community pharmacies.

We acknowledge some limitations. First, we did not perform construct validity (ie, to establish the relation of the measure to other variables) nor criterion validity (ie, to estimate the association of the measure with other measures of the same variable). However, the SWAMECO is not a diagnostic tool, it cannot detect pathological dysphagia that is measured with videofluoroscopic analysis[14] or with validated questionnaires.[22] Moreover, SWAMECO reveals a subjective feeling of difficulties when swallowing tablets or capsules, and reveals potentially suboptimal coping strategies. Thus, our tool helps to structure and target counselling in patients taking multiple medicines. Second, we pilot tested the tool in a small sample size and did not conduct a retest. Third, we did not investigate satisfaction of community pharmacists when using the SWAMECO questionnaire. However, the necessity of screening for swallowing difficulties with medications in daily clinical and pharmacy practice was regularly acknowledged by HCPs. There are many validated and widely used dysphagia tools asking patients about difficulties when they swallow pills.[14 17] However, those items are integrated into a global score and need to be analysed separately when pill dysphagia is under examination. The findings of this study indicated that the SWAMECO questionnaire, despite the fact that it is not a diagnostic tool, represents a simple and quick instrument that can be easily implemented by HCPs to assess swallowing difficulties with medications and individual coping strategies in the adult population with polypharmacy. Further development will consist of defining a score using compatible questions and then prioritising interventions in order to offer a comprehensive screening instrument to healthcare providers.

Acknowledgements The authors wish to sincerely thank Hanna Seidling for the back translation in German, and Professor Walter E. Haefeli for permitting the use of the A-14 adherence scale in German and English.

Contributors IA, LS and KH contributed to the concept of the work; JO acquired the data; LS and MM designed the work; IA analysed and interpreted the data, and drafted the work. All authors revised the work critically for important intellectual content, and approved the final version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Funding This work was funded by the Pharmaceutical Care Research Group.

Patient consent for publication Not required.

Ethics approval The study was approved by the local ethics committee (Clinical research Ethics Committee of Cork Teaching Hospitals Ref: ECM 4 (aa) 09/05/2017 and ECM (rrrrrr) 07/03/2018).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request.

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