Development and piloting of a survey instrument for evaluating the impact of multi-dose dispensing on medication adherence

 ¬ Jürgen Jänese
 Pharmacist
 Magnum Medical OÜ
 Tallinn, Estonia
 jyrgen.janese@gmail.com

 ¬ Jyrki Heinämäki
 Professor
 Department of Pharmacy
 Faculty of Medicine
 University of Tartu
 Tartu, Estonia
 jyrki.heinamaki@ut.ee

 ¬ Alo Arro
 Business Development Project Manager
 Terve Pere Apteeke OÜ
 Tallinn, Estonia
 alo.arro@magnum.ee

 ¬ Heret Liinve
 Pharmacist
 Mustamäe Apteeke
 Tallinn, Estonia
 heretl@apotheka.ee

 ¬ Ülle-Helena Meren
 Pharmacist
 East-Tallinn Hospital
 Tallinn, Estonia
 Ulle.Meren@itk.ee

 ¬ Daisy Volmer
 Associate Professor
 Department of Pharmacy
 Faculty of Medicine
 University of Tartu
 Tartu, Estonia
 daisy.volmer@ut.ee

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### SUMMARY

**Introduction:** Multi-dose dispensing of medicines (MDD) aims to increase medication adherence, cost-containment and quality of drug delivery. In Estonia, MDD was introduced in July 2012. The objective of this study was to develop a novel survey instrument for evaluating the impact of MDD on medication adherence of patients with polypharmacotherapy.

**Material and methods:** Survey instrument was designed for identification of patient-related factors on medication adherence. General aspects about health, medicines and the risk factors related to the use of prescription medicines were included in the MDD adherence instrument. The items were primarily derived from the following validated instruments to assess adherence: Beliefs about Medicines Questionnaire (BaMQ), Brief Medication Questionnaire (BMQ) and Medication Information Seeking Behavior (MISB). The research group also developed some items in order to more comprehensively cover the four dimensions of patient-related factors influencing medication adherence that were determined for the new MDD adherence instrument (1) knowledge and beliefs about medicines; 2) self-evaluated conditions; 3) expectations towards healthcare providers; and 4) potential risk behavior). The content and the structure of the new adherence assessment instrument were validated through 1) agreement within the research group and 2) pilot testing the instrument in older patients using MDD service for their medications. The pilot testing was carried out at a community pharmacy (Mustamäe Apteek) in Tallinn, Estonia. Customers with chronic diseases, aged 55+ and using more than four prescription medicines were invited to participate in the pilot study and they completed the MDD adherence instrument before joining the MDD service (baseline) and during the service (three times within six months).

**Results:** The developed MDD adherence instrument consists of two sections: the first section (26 mainly multiple choice items or statements) was designed to evaluate the general perceptions of patients towards health, use of medicines and related possible risk factors. This section was planned to be filled before initiation of MDD service. The second section (18 mainly multiple choice items or statements) focuses on identifying problems and risk factors related to the use of prescription medicines at the point of the assessment and evaluating the impact of MDD on medication adherence. This section was planned to be filled during MDD service.

Total, seven chronic patients (age 65±10 years) using 7.5±3.5 prescription medicines participated in the pilot study. The survey instrument enabled to identify patient-related risk factors towards medication adherence, such as insufficient understanding about the use of medicines and potential risk behavior of patients (e.g. picking up medicines, taking medicines in time, medicines-related worry) and to evaluate the decrease in above listed risk factors while using MDD.

**Conclusions:** The developed and piloted MDD adherence instrument was found to be a feasible tool for evaluating patient-related risk factors for medication adherence of patients using MDD service. Its applicability, sensitivity and specificity should be further studied with larger patient groups. Also larger patient groups are needed for studies determining the impact of MDD service on medication adherence.

**Keywords:** medication adherence, multi-dose dispensing of medicines, survey instrument, community pharmacist, intervention

### INTRODUCTION

Medication adherence is described as the extent to which individual’s behavior (taking medicines, following a diet, executing lifestyle changes) corresponds with agreed recommendations from a health care provider (Sabate 2003). Based on the definition, the medication adherence behavior could be divided into adherence and persistence. Although conceptually similar, adherence refers to the intensity of medicines use during the therapy, while persistence indicates the overall duration of drug therapy, which is crucial in long-term care (Heidenreich 2004, Caetano et al. 2006, Cramer et al. 2008, Ho et al. 2009).

Osterberg et al. (2005), as well as a recent Cochrane review (Nieuwlaat et al. 2014) have described both direct and indirect methods for the assessment of medication adherence. Direct methods involve, e.g., directly observed therapy, measurement of the level of active substance or
metabolite(s) in blood, and measurement of biological marker in blood. As indirect methods, patient questionnaires, self-reports, pill counts, rate of prescription refills, assessment of patient’s clinical response, electronic medication monitors, measurement of physiological markers and patient diaries are used (Osterberg et al. 2005, Nieuwlaat et al. 2014).

Multi-dose dispensing of medicines (MDD) is an indirect method, where regularly used medicines are machine-packed into unit-dose bags for each time of administration (The Association of Finnish Pharmacies 2003, Sinnemäki et al. 2013). In the Nordic countries, the MDD has been widely used in primary care, and corresponding guidelines for MDD service have been established in Sweden and Norway (Sinnemäki et al. 2013). In Estonia, MDD was introduced for the long term care hospitals as a pilot project in July 2012 and for the primary care and nursing home patients in August 2013. Currently, the service is available only at one community pharmacy in Tallinn and it is complimentary for patients (cost of MDD is covered by the service provider) (Apotheka 2015). In 2014, the qualitative focus group study performed amongst the stakeholders of social and healthcare specialists in Estonia revealed an urgent need for MDD, especially in nursing and elderly homes (Jänese et al. 2014).

Despite of being widely used in primary care, there are only a limited number of controlled studies about the impact of MDD on the medication treatment outcomes of home-dwelling medicine users (Sinnemäki et al 2013). There are studies reporting improvement in appropriateness and safety in the use of medicines for elderly patients with reduced cognitive and mental capacity using polypharmacotherapy (Bangalore 2007, Kwint et al. 2011, Bell et al. 2013, Sinnemäki et al. 2013). The recently published Finnish study (Sinnemäki et al. 2014) evaluated reconciliation of patients’ medication list before enrollment in the MDD by means of medication reviews, communication with multi-professional health-care team and evaluation of existing medication list. As a result, treatment-related changes were made for about half of the patients and technical changes for majority of the patients (Sinnemäki et al. 2014). It is important to emphasize that combination of regular medication review, patient education and control of IT technology and equipment are crucial for providing quality MDD service (Kwint et al. 2011, Bell et al. 2013, Sinnemäki et al. 2014).

The aim of the present study was to develop and pilot test a novel survey instrument evaluating the impact of MDD service integrated with regular medication review and patient education on the medication adherence of home-dwelling older patients with polypharmacotherapy.

MATERIAL AND METHODS
Development of the MDD adherence instrument
The main idea of the survey instrument was to focus on the identification of patient-related risk factors to medication adherence and on the evaluation of MDD-related change in medication adherence of patients with chronic diseases using polypharmacotherapy. The following three widely used instruments for evaluating medication adherence were reviewed to identify existing information about patient-related factors: Beliefs about Medicines Questionnaire (BaMQ) (Horne et al. 1999), Brief Medication Questionnaire (BMQ) (Svarstad et al. 1999) and Medication Information Seeking Behavior (MISB) (Carter et al. 2013). The BaMQ and BMQ instruments are designed for self-administration by patients with multiple prescription medicines. However, both instruments are mainly targeted to the evaluation of the use of particular group of medicines, e.g., antihypertensives (BMQ, Svarstad et al. 1999) or asthma medicines (BaMQ, Horne et al. 1999). As the present study was oriented to the assessment of MDD-related medication adherence, it was not possible to concentrate on a specific group of medicines, and thus, only general statements or sections, such as BaMQ General (Horne et al. 1999) were selected. The selection of items was guided by the following four dimensions of patient-related factors influencing medication adherence that were determined by the research group on the basis of the contents of the previous three instruments used in this study: 1) knowledge and beliefs about medicines; 2) self-evaluated conditions; 3) expectations towards healthcare providers; and 4) potential risk behavior (Figure 1).

To evaluate the patient-related worry associated to taking medicines, a concept introduced by McCaul and Goetz (2010), also applied in MISB questionnaire (Carter et al. 2013) was used: medication-related worry is defined as the frequency with...
which a person worries about health problems resulting from taking medicines (Carter et al. 2013). We wanted to include this concept, because health worry caused by medicine taking can considerable influence medication adherence among senior patients with multiple prescription medicines and impaired cognitive abilities (Carter et al. 2013, Elliott et al. 2015).

Based on the information derived from the existing international instruments the patient-related risk factors were classified, entitled and visualized by the research group having expertise in medication adherence, social pharmacy and medical technology. The research group also developed some items in order to more comprehensively cover the four dimensions of patient-related factors influencing medication adherence that were determined for the new MDD adherence instrument (Figure 1). The content and the structure of the new adherence assessment instrument were validated through 1) agreement within the research group and 2) pilot testing the instrument in older patients using MDD service for their medications.

**Pilot testing of MDD adherence instrument: setting and survey sample**

The pilot testing of MDD adherence instrument was carried out at a community pharmacy (Mustamäe Apteek) in Tallinn, Estonia. Customers with chronic diseases, aged 55+ and having polypharmacy (using more than four prescription medicines) were invited to participate in the pilot study and they completed the MDD adherence instrument before joining the MDD service (baseline) and during the service (three times within six months). The survey instrument was available for patients in Estonian and Russian language, and as hard and electronic copies. The outline of piloting the MDD adherence instrument is presented in Figure 2.

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**Figure 1. The guiding tool for identification of the major patient-related factors affecting medication adherence of patients using MDD.**

**Figure 2. Outline of piloting the MDD adherence instrument.**

- Recruitment of the ambulatory patients to MDD service (n=7)
  - Voluntary participation
  - Inclusion criteria: age 55+, polypharmacy (>4 prescription medicines)

- Identification and evaluation of prescription medicines of the patient: collaboration of pharmacist and GP
  - Scheduling MDD service for individual patients
  - Completing the MDD adherence instrument, section I (before the initiation of MDD service)

- Visit to community pharmacy every two months to pick up MDD prescription medicines
  - Medication review by pharmacist
  - Completing the MDD adherence instrument, section II (at every visit during the MDD service)
### SECTION I (TO BE FILLED BEFORE INITIATION OF MDD SERVICE)
#### GENERAL PERCEPTIONS ABOUT HEALTH AND MEDICINES

<table>
<thead>
<tr>
<th>Question, statement</th>
<th>Source</th>
<th>Purpose</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-perceived health</td>
<td>MISB,UT</td>
<td>Health status assessment</td>
<td></td>
</tr>
<tr>
<td>Attitudes towards medicines:</td>
<td>BaMQ</td>
<td>Beliefs about medicines, Expectations and trust towards physicians, Need for information and counselling about medicines</td>
<td></td>
</tr>
<tr>
<td>Most medicines are addictive.</td>
<td></td>
<td></td>
<td>1 “strongly disagree” to 5 “strongly agree”</td>
</tr>
<tr>
<td>Natural remedies are safer than medicines</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Medicines do more harm than good</td>
<td></td>
<td></td>
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<tr>
<td>Doctors use too many medicines</td>
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<td></td>
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<tr>
<td>People who take medicines should stop their treatment for a while every now and again.</td>
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</tr>
<tr>
<td>If doctors had more time with patients they would prescribe fewer medicines.</td>
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</tr>
<tr>
<td>Doctors place too much trust on medicines</td>
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</tbody>
</table>

### GENERAL PROBLEMS AND RISK FACTORS RELATED TO USE OF Rx MEDICINES

<table>
<thead>
<tr>
<th>Question, statement</th>
<th>Source</th>
<th>Purpose</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>General problems:</td>
<td>MISB,UT</td>
<td>Knowledge about diseases, Factor indirectly affecting medication adherence</td>
<td>Multiple choice items, description</td>
</tr>
<tr>
<td>List of diseases in case patient is taking Rx medicines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative influence of Rx medicines on patient´s life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk factors related to the use of Rx medicines:</td>
<td>UT</td>
<td>General factors directly affecting medication adherence</td>
<td>1 “never” to 5 “very often”</td>
</tr>
<tr>
<td>The use of tablets is easy and simple</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I forgot to take my medicines at the scheduled time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficulties with package opening</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I mix different medicines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I do not find my tablets</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dysphagia or other problems with taking medicines</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### PROBLEMS AND RISK FACTORS RELATED TO CURRENTLY USED Rx MEDICINES

<table>
<thead>
<tr>
<th>Question, statement</th>
<th>Source</th>
<th>Purpose</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Rx medicines used</td>
<td>BMO, UT</td>
<td>Knowledge about medicines used</td>
<td>Multiple choice item</td>
</tr>
<tr>
<td>Names of Rx medicines used</td>
<td></td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>Changes in drug regimen during the past two months</td>
<td>MISB, BMQ</td>
<td>Risk factors related to use of medicines</td>
<td>Multiple choice item</td>
</tr>
<tr>
<td>Hospitalisation related to the use of Rx medicines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication related worry</td>
<td></td>
<td>The extent of worry related to use of medicines</td>
<td>1 “never” to 5 “very often”</td>
</tr>
<tr>
<td>Stopped taking medicines during the past month</td>
<td>BMQ</td>
<td>Factors directly affecting medication adherence</td>
<td>Description</td>
</tr>
<tr>
<td>Used medicines regularly during the past month</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Structure and content of the final MDD adherence instrument, section I and section II

The patients fulfilling the inclusion criteria were recruited from the participating community pharmacy. The MDD was described and patients were invited to join the pilot study. The participation was anonymous and the participants’ data were coded. Before enrollment in MDD, reconciliation of medication list for each patient was performed by the community pharmacist and the general practitioner. All prescription medicines were identified and reviewed in terms of 1) potential risk of clinically significant interactions; 2) the administration details of the medicines and 3) a time-schedule for receiving medicines in multi-dose packages. The patients received reminders by phone to pick up another set of their medicines after every two months. During pharmacy visits, a short medication review and patient education session was performed for identification of possible problems in the medication use. For each patient, a medication record, including results of
the medication review, experienced problems (e.g., adverse effects of medicines) and problem-solving activities taken by the pharmacist was kept at the community pharmacy. Medication review was performed by using another self-developed instrument, different from the MDD adherence instrument. Patients were counselled about the use of their prescription medicines and concomitantly used over-the-counter medicines and food supplements, administration details of medicines and other information, if needed. In this survey, the control group was not used.

**Data analysis**

The coded data were entered to Microsoft Excel. The frequencies were calculated to assess self-evaluated changes in drug treatment and medication adherence before and during the MDD service for individual patients and in general (baseline and three follow ups during a six-month period). A Likert scale was used for the evaluation of patients’ perceptions (not for scoring the results).

**RESULTS**

**Development of the MDD adherence instrument**

Table 1 describes the structure and content of the final MDD adherence instrument developed: questions and statements included with the description of their sources, purposes and evaluation scales. The MDD adherence instrument consisted of two sections: the first section (26 mainly multiple choice items or statements) was designed to evaluate the general perceptions of patients towards health, use of medicines and related possible risk factors before starting MDD service (baseline). The second section (18 mainly multiple choice items or statements to be assessed during MDD service) focuses on problems and risk factors related to prescription medicines in use at the point of the assessment and evaluating the impact of MDD on medication adherence.

A five-point Likert scale was used for the assessment of general statements about drug information and use of medicines (from 1 “strongly disagree” to 5 “strongly agree”), medication-related worry and influence of MDD service on medica-
The survey instrument was capable of identifying patient-related medication adherence problems on different levels. The questions were applicable for self-completion by patients. In some cases, the assistance of community pharmacist was needed for the identification and documentation of all prescription medicines used by the patient.

The patients participating in the study considered medicines to be more useful than harmful. On the other hand, there was some concern about addiction caused by medicines and the need for regular use of medicines (Table 2). The described considerations and views could be related to little or insufficient contacts of the patients with doctors about medicines. Described outcome could be considered as one of the reasons for the decreased medication adherence.

In this small-scale pilot study, self-perceived capability of patients to use medicines was good, and patients considered it easy to take medicines sometimes (n=3) or always (n=4). None of the patients needed hospitalization related to the use/non-use of medicines during the study. The medication-related worry was reported as seldom (n=4) or occasional to frequent (n=3) before joining MDD, and was mostly related to memory problems (failure to find and take medicines in time). During the MDD pilot study, medication-related worry decreased for all patients.

### Table 2. Perception of chronic patients involved in the pilot study (n=7) about medicines and doctors.

<table>
<thead>
<tr>
<th>Statement in the MDD adherence instrument</th>
<th>Strongly agree/agree</th>
<th>Uncertain</th>
<th>Disagree/strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most medicines are addictive</td>
<td></td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Natural remedies are safer than medicines</td>
<td></td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Medicines do more harm than good</td>
<td></td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>People who take medicines should stop their treatment for a while every now and again</td>
<td>1</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Doctors use too many medicines</td>
<td></td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>If doctors had more time with patients they would prescribe fewer medicines</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
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<td>1</td>
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Before joining the MDD service, most of the patients reported “not taking medicines in-time” as a direct risk factor for medication adherence: very frequent to frequent (n=1) and sometimes (n=6). The other risk factors, such as “I do not find my medicines”, “I mix my different medicines” and dysphagia were considered to have less impact on medication adherence. The patients did not report any problems in taking out tablets/capsules from a container. During the MDD service, the in-time use and picking up of medicines increased for all patients. Despite the fact that patients did not complain about getting their medicines out of container, some of them mentioned difficulties in opening a multi-dose package.

In-time received repeat prescriptions, price of medicines and changes in the course of treatment were found as other medication adherence risk factors with chronic disease patients. Three patients reported changes in the course of drug treatment during the past two months before joining MDD, while four patients reported no changes. During the use of MDD service, only one patient informed about changes due to additionally prescribed medicines. Two patients reported to have “problem to some extent” with the price of medicines before the use of MDD, and the MDD service did not change this view. The problems in receiving prescribed medicines in-time were considered to diminish during the use of MDD (five patients versus two patients).

**DISCUSSION**

Decreased medication adherence and its influence on treatment outcomes have been widely concerned and discussed during the past decades (Nieuwlaat et al. 2014). Nevertheless, only few studies on this topic are available in Estonia to date (Vorobjov et al. 2005, Rätsep et al. 2007, Marandi et al. 2010). Different technology mediated interventions have been developed to improve medication adherence, but a recent review indicated inconsistent effectiveness of these interventions to medication adherence and clinical outcomes (Mistry et al. 2015). In our study, a novel research instrument for evaluating the impact of MDD and a pharmacy-led intervention on the medication adherence of chronic disease patients was developed and piloted. The survey instrument was capable of identifying patient-related medication adherence problems, but further testing for sensitivity, specificity and validity (content and face validity) is needed. Also the scoring of items needs further development: based on the Likert scale items, the scores describing “good”, “medium” and “low” medication adherence of chronic disease patients could be used in the future.

Based on the results of our small scale pilot study, the use of MDD may decrease the patient risk behavior (mostly different problems with regular use of medicines), medication-related worry and their impact on medication adherence. However, the general perception about drug treatment and specified knowledge on medicines among survey patients seemed to be vague to some extent. As patients’ general perception about medicines was evaluated only once, before entering to MDD service, it is difficult to say how and to what extent the ideas about regular use of medicines were changing while using MDD service. To support understanding about their medicines, patients have to be educated and regular medication review has to be performed in addition to MDD service. Kwint et al. (2011) have revealed that the community-dwelling recipients of MDD in the Netherlands have better medication adherence but poorer knowledge about medicines compared to the recipients of manual dispensing of medicines. The recent study carried out in UK indicated that the MDD service is often provided without discussion with patients (Nunney et al. 2011). A pharmacist-led medication review has been considered as the most effective strategy to improve the quality of medicine use among MDD patients (Bell et al. 2007, Midlöw et al. 2012, Sinnemäki et al. 2014). In the future, more specific guidelines about how to perform a medication review during MDD service could be included in the MDD service procedure, and thus, in the intervention.

The timely refill of prescriptions and out-of-pocket costs of chronic disease patients are most likely the other important factors affecting medication adherence (Matlin et al. 2015). This pilot survey identified some problems associated with refill of prescriptions in time and indicated also the impact of MDD to decrease this problem. Currently in Estonia, the cost of MDD is covered by the service provider, but it is unclear which institution will provide the reimbursement of this ser-
vice in the future. It is important to remember that increasing adherence to medication regimens will require funds to be allocated up front. Therefore, the structure of reimbursement has to create an inducement for investment (typically by providers) that is financed by the groups that will save (usually insurers) (Cutler et al. 2010). Our recent qualitative focus group study revealed that the Estonian Health Insurance Fund could be one of the participating (paying) stakeholders (Jänese et al. 2014). If the MDD will bring additional costs to patients, use of this service would not be possible for larger patient groups.

In this pilot study, only patients with the diseases other than mental health problems were involved. Cutler et al. (2010) suggested that the use of MDD can be also an important tool in monitoring regular use of medicines with patients suffering from mental health problems. It may turn out to be important to amend the present adherence assessment instrument, if there is a need to determine medication adherence of specified patient groups with respect to the chronic diseases and prescription medicines used.

The limitation of this pilot study is a small number of patients recruited and continued to use MDD service. During the study, two patients discontinued the MDD service due to relocation to another town. The hindering factors for the involvement of more patients in this type of follow up study include (1) a limited awareness among patients and general practitioners about this service, (2) only one pharmacy in Estonia providing MDD, and (3) the short follow up period. Further research with larger patient groups are needed for determining the impact of MDD service on medication adherence, as well as influence of different patient-related risk factors identified in this study on adherence.

CONCLUSION

The developed and piloted MDD adherence instrument was found to be a feasible tool for evaluating patient-related risk factors for medication adherence of patients using MDD service. Its applicability, sensitivity and specificity should be further studied with larger patient groups. Also larger patient groups are needed for studies determining the impact of MDD service on medication adherence. In the future, the adherence instrument could be supplemented with the structured medication list to support medication review and identify medication-related problems of the patient.

ACKNOWLEDGEMENTS

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TIIVISTELMÄ


**Tulokset:** Kehitetty mittari koostuu kahdesta osista: ensimmäinen osa (26 pääasiassa monivalintakysymystä sisältävää väittämää) kehitettiin mittaanotollaan yleisiä käsityksiä ja kokemuksia terveydestä, lääkkeiden käytöstä ja riskitekijöistä. Tämä osio oli tarkoitus täyttää ennen annosjakelun aloitusta. Toinen osa (18 pääasiassa monivalintakysymystä sisältävää väittämää) painottaa tunnistamaan ongelmia ja reseptilääkkeisiin liittyviä riskitekijöitä mittaanotollaan aikana ja arvioimaan annosjakelun vaikutusta hoitoon sitoutumiseen. Tämä osio on tarkoitus täyttääväksi annosjakelupalvelun aikana.

Tutkimukseen osallistui yhteensä seitsemän pitkäaikaistä asiakasta (iä 65±10 vuotta), ja heillä oli käytössään 7.5±3.5 reseptilääkettä. Mittari auttoi tunnistamaan potilaslähtöisiä riskitekijöitä liittyen hoitoon sitoutumiseen, kuten esimerkiksi puutteellista tietoa lääkkeiden käytöstä ja mahdollista riskikäyttäytymistä (esim. lääkkeiden nouto, lääkkeiden otto ajallaan, lääkkeisiin liittyvä huolto) ja arvioimaan annosjakelun vaikutusta riskitekijöiden vähennemiseen.


**Avainsanat:** lääkehoitoon sitoutuminen, koneellinen annosjakelu, kyselylomake, apteekkifarmasisti, interventio

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**REFERENCES**


