PRACTICAL APPLICATION

Development of an Instrument for the Assessment of Health-Related Multi-sectoral Resource Use in Europe: The PECUNIA RUM

Irina Pokhilenko[1,2] · Luca M. M. Janssen[1] · Aggie T. G. Paulus[1,3] · Ruben M. W. A. Drost[1] ·
William Hollingworth[4] · Joanna C. Thorn[4] · Sian Noble[4] · Judit Simon[5,6] · Claudia Fischer[5] ·
Susanne Mayer[5] · Luis Salvador-Carulla[7,8] · Alexander Konnopka[9] · Leona Hakkaart van Roijen[10] ·
Valentin Brodszky[11] · A-La Park[12] · Silvia M. A. A. Evers[1,13] on behalf of the PECUNIA Group

Abstract

Background Measuring objective resource-use quantities is important for generating valid cost estimates in economic evaluations. In the absence of acknowledged guidelines, measurement methods are often chosen based on practicality rather than methodological evidence. Furthermore, few resource-use measurement (RUM) instruments focus on the measurement of resource use in multiple societal sectors and their development process is rarely described. Thorn and colleagues proposed a stepwise approach to the development of RUM instruments, which has been used for developing cost questionnaires for specific trials. However, it remains unclear how this approach can be translated into practice and whether it is applicable to the development of generic self-reported RUM instruments and instruments measuring resource use in multiple sectors. This study provides a detailed description of the practical application of this stepwise approach to the development of a multi-sectoral RUM instrument developed within the ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluAtions (PECUNIA) project.

Methods For the development of the PECUNIA RUM, the methodological approach was based on best practice guidelines. The process included six steps, including the definition of the instrument attributes, identification of cost-driving elements in each sector, review of methodological literature and development of a harmonized cross-sectorial approach, development of questionnaire modules and their subsequent harmonization.

Results The selected development approach was, overall, applicable to the development of the PECUNIA RUM. However, due to the complexity of the development of a multi-sectoral RUM instrument, additional steps such as establishing a uniform methodological basis, harmonization of questionnaire modules and involvement of a broader range of stakeholders (healthcare professionals, sector-specific experts, health economists) were needed.

Conclusion This is the first study that transparently describes the development process of a generic multi-sectoral RUM instrument in health economics and provides insights into the methodological aspects and overall validity of its development process.

1 Background

Resource-use measurement (RUM) is a challenging and time-consuming but essential step in economic evaluations of health care interventions [1, 2]. Measuring valid and reliable quantities of resources utilized is of major importance

for generating valid cost estimates [1, 3]. A wide variety of measurement methods exist, including the use of self-reported data by patients collected via questionnaires or cost diaries, the use of administrative data, and the use of expert panels [4, 5]. However, methodological guidance on developing an appropriate measurement method is limited. There remains a striking difference between the small amount of research on methods for the appropriate measurement of resource use compared with the large amount of evidence on outcome measurement within economic evaluations [1, 6, 7]. Due to the absence of a gold standard and acknowledged guidelines, the measurement method is often selected based on practicality rather than methodological evidence

Key Points for Decision Makers

This study describes the development process of a multi-sectoral generic RUM instrument. The development process was structured into six steps, including the definition of the instrument attributes, identification of cost-driving elements, review of methodological literature, development of a harmonized cross-sectoral approach, and development and subsequent harmonization of questionnaire modules.

The PECUNIA RUM is intended for the measurement of resource use in several societal sectors, including health and social care, education, (criminal) justice, employment and productivity, patient, family, and informal care. Together with compatible reference unit cost calculation tools (PECUNIA RUC Templates), the PECUNIA RUM can contribute to producing comparable cost data for informing optimal decision making.

[1]. Although administrative data sources can provide accurate resource-use estimates, they often fail to capture potentially relevant societal costs (e.g. out-of-pocket expenses or productivity losses) [1]. Furthermore, linking multiple databases containing patient-level data can be challenging due to privacy regulations. Therefore, the use of self-reported data is currently the most feasible method of generating valid resource-use estimates for the measurement of broader resource use [1].

A number of self-reported RUM instruments are available, many of them accessible via the Database of Instruments for Resource-Use Measurement (DIRUM) [8]. DIRUM is a repository of RUM instruments based on patient recall for use in economic evaluations. As of March 2022, it contained 96 RUM instruments available in the form of diaries, logs or questionnaires. Of these instruments, the majority are designed for measuring disease-specific resource use, while only five instruments are meant for generic use [9–13]. In addition, most instruments focus on resource use in a limited number of sectors (e.g. health care and social care) [14–17]; few also include questions about broader resource use (e.g. informal care, education, and [criminal] justice) [9, 12, 18, 19]. Research shows that for some disease areas, resource use in sectors outside the health care sector can constitute a large proportion of the total costs and have a significant impact on the study results [20–22]. The growing interest in adopting a societal perspective in economic evaluations calls for appropriate measurement tools that enable measurement of multi-sectoral resource use [23]. There is little existing research on the feasibility, validity and reliability of RUM instruments [3, 11, 18, 19, 24], and even fewer studies report the process of instrument development [25–27]. This is particularly relevant because the decisions taken during the development process of an instrument, such as the framing and order of the questions, can affect the structure of the instrument and responses to its questions [28]. Furthermore, in several health-related disciplines (e.g. psychology, health promotion), it is common to report how new instruments were developed [29, 30]. However, this is not yet customary in health economics, in particular in relation to RUM instruments [27, 31, 32], even though transparent reporting of how RUM instruments are developed is crucial both for the developers and the users. For the former, the need for transparent reporting motivates the adoption of evidence-based methods when developing the instrument; for the latter, insights into how the instrument is developed allow for making judgements about whether it is appropriate for the given study. In addition, transparent reporting of the RUM instrument development process can support further research into the development of patient-reported measures as well as the use of mixed-methods and qualitative methods in health economics.

Thorn and colleagues [2] proposed a stepwise approach for the development and testing of RUM instruments in trial-based economic evaluations, based on discussions among a large group of health economists with expertise in RUM. The authors outlined an "ideal way of approaching instrument development", which entails several stages, including planning, development, piloting and deployment of the instrument. Several studies reported using this approach for developing a cost questionnaire for specific trials [33–35] without, however, describing the process of applying this approach in detail. Therefore, it remains unclear how this approach can be translated into practice and to what extent it is applicable to the development of (1) generic self-reported RUM instruments, and (2) instruments measuring broader resource use.

This paper describes the practical application of the approach proposed by Thorn et al. [2] to the development process of the RUM instrument in the ProgrammE in Costing, resource-use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluAtions (PECUNIA) project. The PECUNIA RUM aims to address the above-mentioned research gaps by capturing generic resource use in several societal sectors, including (1) health care; (2) social care; (3) education; (4) (criminal) justice; (5) employment and productivity; and costs borne by (6) patients or (7) families, including informal care. This instrument will support the measurement of broader resource use and the adoption of a societal perspective in future economic evaluations. Furthermore, to the best of our knowledge, this is the first article that describes the development process of a generic multi-sectoral RUM

instrument. This can be helpful for the researchers who would consider using the PECUNIA RUM in the future by providing insights into the feasibility, reliability and validity of the instrument.

2 Context: PECUNIA Project

The PECUNIA project is a network of 10 partners in six countries (Austria, Germany, Hungary, Spain, The Netherlands, and the UK) that aims to establish standardized costing and outcome assessment measures for conducting economic evaluations in Europe [36]. To reduce unnecessary variations in the resource-use and unit cost input data of economic evaluations [37], the PECUNIA project (2018–2021) aimed to develop a collection of internationally standardized, harmonized, generic and validated tools, including a self-reported, multi-sectoral RUM instrument. It was developed in conjunction with a compatible unit cost calculation tool, the PECUNIA Reference Unit Cost (RUC) Templates [38], intended for the generation of standardized and harmonized RUCs for economic evaluations [39], and for inclusion in a publicly accessible multi-sectoral, multi-country PECUNIA RUC Compendium [40]. Furthermore, to address the variations in the input cost data and to facilitate cross-country transferability of the results of economic evaluations, the PECUNIA RUM is intended to be applicable in multiple European countries. More information about the PECUNIA project structure can be found in electronic Supplementary File 1 and on the PECUNIA project website (https://www.pecunia-project.eu/).

3 Methods

The development process of the PECUNIA RUM was based on the approach proposed by Thorn et al. [2]. The approach covers all stages of instrument development and testing starting from the identification of relevant cost drivers to the piloting and deployment of the instrument. It also suggests optimal time points for considering important instrument attributes (e.g. recall period, length of questionnaire) as well as consultations with various stakeholders (healthcare professionals, patients, healthy volunteers) at multiple development and testing stages. The PECUNIA Group translated this theoretical method into a structured work plan in scientific discussions over 6 months. The development and testing process of the PECUNIA RUM was structured into nine steps with two milestones, outlined in Fig. 1. This current paper describes the application of this approach to the development of the

instrument, i.e. the first six steps up until the instrument was ready for testing.

Step 1. Definition of Instrument Attributes

In step one, the main attributes of the PECUNIA RUM were conceptualized by the PECUNIA Consortium in line with the general objectives of the PECUNIA project over the course of several in-person and online meetings when conceptualizing the PECUNIA project proposal. General attributes of RUM instruments that ought to be considered were outlined by Thorn et al. and included perspective, setting of care, disease, population, and nature of intervention [2].

Step 2. Identification, Definition and Classification of Main Cost-Driving Elements

In step two, cost-driving elements were identified and defined. First, an independent search of peer-reviewed and grey health economics literature was conducted to identify main cost-driving elements in health care, social care, education, (criminal) justice, patient, family, and informal care sectors. The cost drivers were extracted and compiled in a list. Second, the list of cost drivers was reviewed by sector-specific experts selected by purposive sampling via a survey (e.g. health care experts reviewed the list of main cost drivers in the health care sectors). Four literature reviews and subsequent expert surveys were independently conducted in parallel for (1) health and social care; (2) education; (3) criminal justice; and (4) patient, family, and informal care sectors by corresponding work package leads as described in electronic Supplementary File 1. More details on the methodology of each review and expert survey are available elsewhere [41–43].

The draft list of cost drivers needed to be defined and organized in conceptually harmonized clusters of units of analysis, which was done according to the PECUNIA Care Atom, a conceptual framework for semantic standardization [44]. Furthermore, the identified services were classified according to the Description and Evaluation of Services and DirectoriEs (DESDE) as modified for the PECUNIA project [45]. DESDE is a standard taxonomy for description, mapping and comparison of services that was developed over the past 20 years with the aim of improving the comparability of services across settings based on the content of the service rather than semantic equivalence [45]. Additional characteristics of services such as related interventions and professionals were classified according to the International Classification of Health Interventions (ICHI) and the multilingual classification of European Skills, Competences, Qualifications and Occupations (ESCO) as part of the overall PECUNIA Coding System [46].
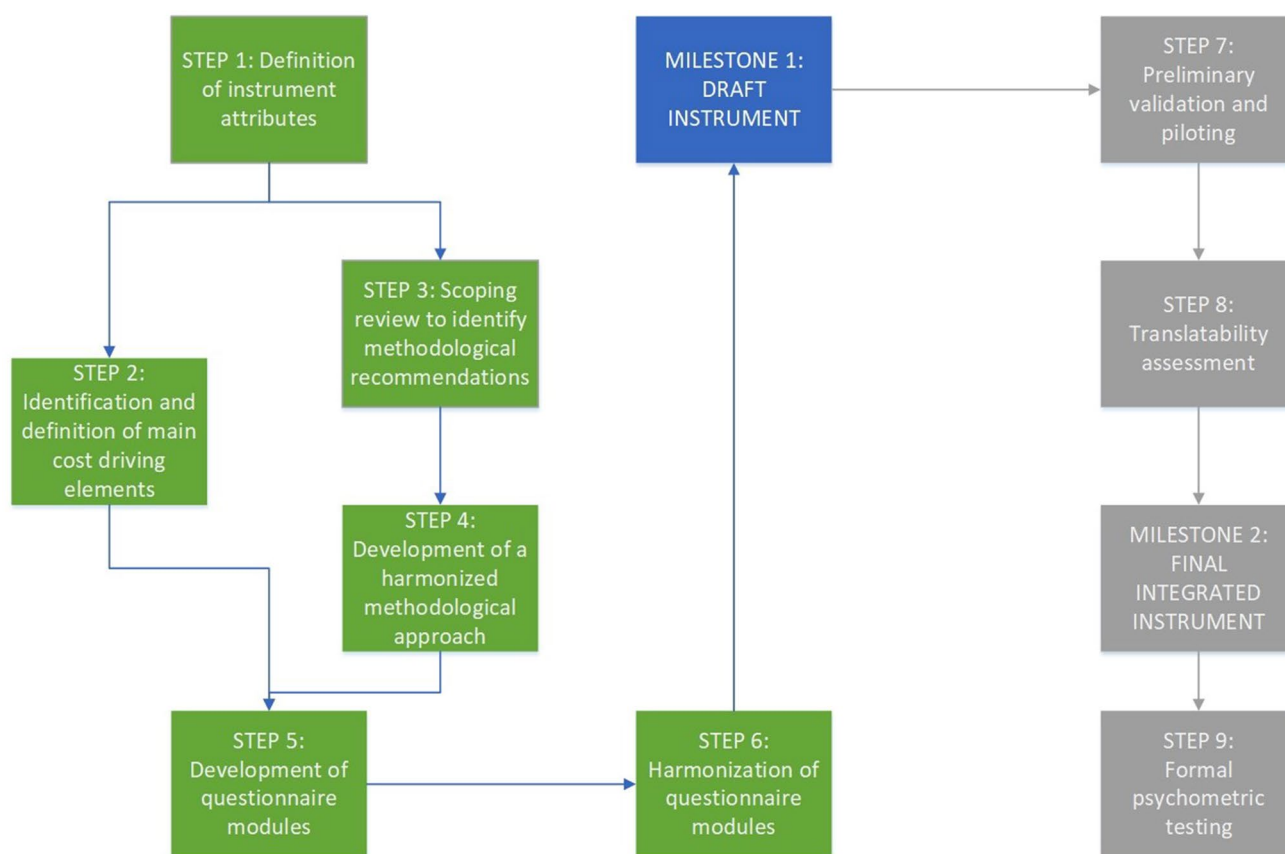
Fig. 1 Methodological steps of PECUNIA resource-use measurement instrument development. The *green boxes* illustrate methodological steps undertaken to develop the instrument; the *blue box* indicates the milestone of the instrument development; and the *grey boxes* indicate further steps of instrument validation that are not covered in this article (own illustration)

For the employment and productivity sector, a different approach was implemented. A systematic literature review of measurement instruments for measuring productivity losses was conducted in order to identify whether any of the existing instruments were suitable for economic evaluations conducted from a societal perspective. The results of this review indicated that the Institute of Medical Technology Assessment (iMTA) Productivity Cost Questionnaire (iPCQ) was the optimal instrument for capturing all domains of productivity relevant for health economic evaluations. Therefore, this instrument was incorporated into the PECUNIA RUM as one of the modules, for the measurement of resource use in the employment and productivity sector. More details about the review are available elsewhere [47].

Step 3. Scoping Review to Identify Methodological Recommendations

In step 3, methodological literature pertaining to RUM was reviewed to identify methodological recommendations for measuring resource use in economic evaluations. Relevant literature was identified via a systematic search of

six electronic databases (EconLIT, EMBASE [Ovid], Education Resources Information Centre [ERIC], MEDLINE [PubMed], PsycINFO, and the Social Science Citation Index [SSCI; Web of Science]), hand search of literature available in DIRUM, and consultation with health economics experts with experience in RUM. The results of the scoping review provided an overview of methodological issues in RUM that need to be considered when selecting a measurement method. These included such issues as what type of resource use to measure, how to frame questions and how to deal with missing resource-use data. While the literature was not able to provide clear-cut recommendations, the overview of challenges of measuring resource use in economic evaluations guided the methodological decisions made in step 4. More details about the scoping review are available elsewhere [48].

Step 4. Development of a Harmonized Methodological Approach

Given the multi-sectoral nature of the PECUNIA RUM and the fact that it was developed by multiple working

groups that were responsible for particular societal sectors (as described in electronic Supplementary File 1), the initial instrument was comprised of standalone modules that needed to be harmonized to make sure that the instrument is cohesive. Therefore, in step 4, a harmonized approach towards the development of a RUM instrument from its separate modules was developed. To develop text for each module, existing RUM instruments were used for illustrative purposes for each of the cost drivers that had been identified and classified in step 2. If no suitable questions were available, new questions were to be written from scratch. Furthermore, consistent use of units of analysis depending on the setting of care was to be implemented throughout the instrument. Outpatient services corresponded to the measurement unit 'per contact', day care services corresponded to the measurement unit 'per day' and residential care services corresponded to the measurement unit 'per night'. Decisions on the methodological aspects of the instrument were guided by the framework developed in the scoping review (step 3); all aspects of the framework were considered. The questions were to be developed to be clear and easily understandable by lay audience avoiding the use of double negatives, asking about more than one type of resource use per question and ensuring mutual exclusivity of the questions. Consistent recall period was to be implemented throughout the instrument. A Microsoft Excel template was developed to facilitate a structured approach to the development of the PECUNIA RUM modules for the module leads. The illustration of the template is available in electronic Supplementary File 2. The methodological approach was discussed with health economists at the PECUNIA satellite workshop at the conference of the International Health Economics Association (iHEA) in Basel (Switzerland) in 2019.

Step 5. Development of Questionnaire Modules

In step 5, the harmonized approach (step 4) was employed to develop RUM instrument modules. The process described in step 4 was applied to the development of all PECUNIA RUM modules with the exception of the module on employment and productivity, which was based on an existing instrument, iPCQ. iPCQ was shown to be an optimal instrument for measuring productivity losses in economic evaluations conducted from a societal perspective [47] and it has been extensively used to measure productivity losses (i.e. absenteeism and presenteeism) of paid and unpaid work. The development process and the validation of the iPCQ have been described elsewhere [27, 49].

Also in step 5, the DESDE codes developed in step 2 were used to link the services included in the PECUNIA RUM with the same services included in other PECUNIA costing tools. This step was instrumental in ensuring that the tools would be complementary and allow for harmonized collection of resource-use and cost data for economic evaluations. The PECUNIA costing concept based on the PECUNIA Care Atom linked the PECUNIA RUM instrument and the other PECUNIA costing tools, including the PECUNIA RUC Templates [38] and the PECUNIA RUC Compendium [40], to ensure that sufficient level of detail of resource-use data is collected for costing purposes. Some questions were expanded to accommodate the collection of detailed resource-use data, which is necessary for accurate costing.

All working groups were asked to fill in the Microsoft Excel template (electronic Supplementary File 2) with the information relevant to the PECUNIA RUM module they were in charge of developing. The templates were collated by researchers from Maastricht University, University of Bristol, and Medical University of Vienna, who were leading the Horizontal Axis 3 'Measurement' (as described in electronic Supplementary File 1).

Step 6. Harmonization of Questionnaire Modules

Because the PECUNIA RUM modules were developed by different working groups or were based on an existing instrument (i.e. iPCQ), as described in electronic Supplementary File 1, the format, phrasing, order of the questions and answer options needed to be harmonized. This was carried out iteratively in multiple teleconferences and rounds of revision internally within the PECUNIA Consortium between October 2019 and April 2021. Every meeting was chaired and consensus was sought on each point. All changes were documented using track changes mode and circulated across all working groups involved in the instrument development process before being incorporated. The setup of each questionnaire module was standardized.

The first complete draft of the PECUNIA RUM was reviewed by an international group of 14 health economics experts in November 2019. Convenience sampling was used to recruit the experts with the aim of having a multi-country representation. During the meeting, the experts were presented with a copy of the draft RUM instrument and were asked to complete it reflecting on their experience. Their feedback was recorded and used for the development of the subsequent version of the instrument.

Subsequently, the text of the draft PECUNIA RUM underwent a formal wording review in February 2020, which was outsourced to linguistics specialists and focused on simplifying the language and structure of the questionnaire. This was followed by professional English-language editing in June 2020. Both of these steps ensured that the instrument was respondent-friendly and understandable for lay persons.

4 Results

4.1 Development Process of the PECUNIA RUM

Table 1 provides an overview of the development steps of the PECUNIA RUM and the main results associated with each step.

4.2 PECUNIA RUM

The PECUNIA RUM was designed to contain eight modules corresponding to various types of resource use (Table 2). Each module begins with a short description of its content, including the types of resource use measured and the applicable recall period. The suggested recall period was overall set at 3 months. However, since the evidence on the optimal recall period, in particular regarding employment and productivity [50, 51], remains inconclusive, this methodological choice will have to be further scrutinized in the testing phase. Consistent format, phrasing, wording, order of the questions and the answer options were implemented.

It is important to note that the number of questionnaire modules (eight) does not correspond to the number of sectors (seven) included in the PECUNIA RUM. This was done to facilitate the adaptability of the instrument to various contexts. For example, the module on medication use is separate from the module on resource use in the health and social care sectors as it might not be relevant to include it in every study. This allows omitting it entirely without compromising the coherence of the instrument.

Several techniques were employed to facilitate the feasibility and understandability of the questionnaire for the respondents. First, the questions were accompanied by instructions such as:

"*Please tick all answers that apply and indicate the number of contacts you had with a given service*".

Second, examples were provided to aid recall such as:

"*Specialist Medical Care (e.g. orthopaedist, psychiatrist, gynaecologist)*"

Table 1 The PECUNIA Resource Use Measurement instrument overview of development steps and main results

Step	Main results	Publication
1. Definition of the instrument attributes	A plan was set up to develop a generic multi-sectoral instrument for collecting broader resource-use data (i.e. from a societal perspective) that would be applicable to any setting of care, disease, population and intervention. The instrument was initially developed in the form of a pen-and-paper version for use in the adult population and in the English language. While the PECUNIA RUM was intended to be a generic instrument, mental health was used as an illustrative disease area for the development and preliminary testing (reported elsewhere) of the instrument.	[44]
2. Identification, definition and classification of main cost-driving elements	The list of cost drivers that were identified in the literature, reviewed by the external experts, and categorized according to the PECUNIA Care Atom	[41–43, 54]
3. Scoping review to identify methodological recommendations	The results of the scoping review provided an overview of methodological issues in RUM that need to be considered when selecting a measurement method. These included such issues as what type of resource use to measure, how to frame questions and how to deal with missing resource-use data.	[48]
4. Development of a harmonised methodological approach	A Microsoft Excel template for developing RUM questions for the previously identified cost drivers	Electronic Supplementary File 2
5. Development of questionnaire modules	Standalone RUM modules to measure resource use in the (1) health and social care sectors; (2) education sector; (3) criminal justice sector; and (4) patient, family and informal care sector	Website of the PECUNIA project: https://www.pecunia-project.eu/tools/rum-instrument
6. Harmonization of questionnaire modules	The first complete PECUNIA RUM draft	Website of the PECUNIA project: https://www.pecunia-project.eu/tools/rum-instrument

RUM resource-use measurement

Table 2 Content of the PECUNIA Resource Use Measurement instrument modules

Module	Types of resource use measured
Place of living and overnight stays	Usual living situation, residential care, and institutional stay selected from a range of residential, health, social, educational and correctional facilities
Non-residential health and social care	Use of health and social services, including outpatient, daycare, helplines, and vocational services
Medication	Use of medications
Unpaid help (informal care)	Informal care provided by the respondent's friends, relatives, neighbors or volunteers
Education	Highest level of education, current educational status, absenteeism and presenteeism during education, the use of education services (e.g. tutoring)
Employment and productivity	Current employment status, absenteeism and presenteeism at paid and unpaid work
Safety and justice system	Contacts with police, fire-and-rescue and legal services, material damage caused by the respondent (e.g. theft, vandalism), incarceration
Out-of-pocket and other expenses	Personal expenses including expenses for household help, childcare, purchase of goods (e.g. wheelchair)

Third, an additional explanation was provided to make sure that the respondents understood what type of resource use they needed to recall, for example:

> *"Have you used legal services (e.g. contact with a lawyer) in the past 3 months? This could be a face-to-face meeting, an online consultation or a phone call with someone working in legal services."*

Furthermore, skip logic was introduced to direct the respondents through the questionnaire (Fig. 2). For most types of resource use, respondents were first asked whether they have used a resource; if yes, follow-up questions were asked; if not, the respondent could jump to the following module. This allows the respondents to only focus on relevant questions, minimizing burden on respondents.

In total, the PECUNIA RUM underwent 23 revisions before the instrument was ready for preliminary validation with potential respondents. The complete version of the PECUNIA RUM is available on the website of the PECUNIA project (https://www.pecunia-project.eu/tools/rum-instrument).

4.3 Expert Feedback

At the PECUNIA satellite workshop in July 2019, the experts indicated that the development of a multi-sectoral RUM instrument that would be applicable to a variety of settings was a difficult process requiring a lot of consensus building. Nevertheless, it was agreed that such an instrument was needed to facilitate the comparability of the results of health economic evaluations.

When the draft instrument was presented to 14 health economists in November 2019, the experts agreed that the availability of a standardized measure was important. They also argued that the full version of the instrument would often not be applicable to a specific setting, as the relevance of cost categories is dependent on the nature of the intervention. The experts suggested that the instrument could

be used as a basis that can be further adapted to specific research requirements. Developing a manual with suggestions regarding the selection of relevant cost categories and hence relevant modules of the PECUNIA RUM (e.g. consulting the patients and/or the literature) was recommended. The experts also raised concerns regarding the applicability of the PECUNIA RUM to the European context due to the differences in, for example, health care system structure. The planned validation activities and the link to the compatible method for the unit cost calculation were perceived by the experts as major strengths of the PECUNIA RUM.

4.4 Application of the Process

The method by Thorn et al. [2] was, overall, applicable to the development of the PECUNIA RUM. As proposed in the method, cost drivers and instrument attributes were defined at the start. Stakeholders (sector-specific experts and health economists) were involved at an early stage of the development process and potential respondents (patients and caregivers) will be involved at later stages when the instrument will be tested. Furthermore, the PECUNIA RUM was developed in conjunction with standardized costing tools, which allows for harmonized collection of resource-use and cost data. However, the development process of the PECUNIA RUM deviated from the method of Thorn et al. [2] in several ways. First, the method recommends that healthcare professionals are involved in the development process. However, due to the multi-sectoral nature of the PECUNIA RUM, a broader range of experts were involved in the development and testing, including experts from other sectors (e.g. education, [criminal] justice, productivity) and health economists. Second, while the method of Thorn et al. prescribes reliance on existing RUM instruments when developing a new one [2], the development of the PECUNIA RUM is guided by existing RUM instruments only to a limited extent. This can be attributed to the lack of comprehensive RUM instruments that incorporate cost categories beyond health care.

E6 Have you used education support services in the past 3 months?

This includes any additional educational support you received, such as tutoring, additional lessons, etc.

☐ Yes *Please go to question E6.1*

☐ No *Please go to question E7*

☐ I don't remember/I would rather not say *Please go to question E7*

E6.1 How much did you use other education support services in the past 3 months?

		Average number of hours per week
1	Education support at your place of study	_____ hours
2	Education support in a private setting (e.g. private tutoring)	_____ hours
3	Other, please specify:_____	_____ hours

Fig. 2 PECUNIA RUM (draft version): example questions from the section on education resource use (section E); the complete version of the instrument can be found via https://www.pecunia-project.eu/tools/rum-instrument

Existing instruments were used as illustrative examples, but no parts of questionnaires or questions were used verbatim, with the exception of the module on employment and productivity, which was fully based on an existing RUM instrument (iPCQ). Furthermore, many existing RUM instruments were developed for use in specific contexts [52], while the PECUNIA RUM was meant to be a generic, internationally applicable instrument. Third, two additional steps in the planning phase of the Thorn et al. method [2] were needed to account for the complexity of developing a multi-sectoral RUM instrument, i.e. the scoping review (step 3) and establishing a uniform methodological basis (step 4), as well as one additional step in the development phase, i.e. harmonization of instrument modules (step 6).

5 Discussion

This article aimed to transparently describe the practical application of the method described by Thorn et al. [2] for the development of the PECUNIA RUM. To our knowledge, this is the first study that outlines the development of a generic multi-sectoral RUM instrument. The methods described by Thorn et al. [2] were, overall, applicable to the development of this generic multi-sectoral RUM instrument. However, because the instrument comprises eight modules developed by four distinct research teams, as well as due to the inherent differences among the sectors included in the PECUNIA RUM, additional steps such as establishing a sound methodological basis (step 4) and harmonization of the instrument modules (step 6) were necessary. On the other hand, a scoping review (step 3) is not likely to be a necessary step for developing new RUM instruments, as the current scoping review's findings have broader applicability beyond this study. Furthermore, in addition to healthcare professionals, other sector-specific and health economics experts needed to be involved in the development process. This is due to the inclusion of the cost categories beyond health care and the overall complexity of the instrument, for which the involvement of healthcare professionals would not be sufficient to get insights into the feasibility of the instrument.

Compared with other studies that reported using the same method for the development of a RUM instrument [33–35], the current study provides more detail and insights into the development process. This could be helpful by providing guidance to researchers undertaking the development of

RUM instruments, and also by providing insight into the context in which methodological choices behind the current instrument were made. Several previous studies reported the development process of either a disease-specific RUM instrument [25] or an instrument intended for measuring resource use related to productivity losses [27, 53], which limits the generalizability of the process to the development of generic multi-sectoral RUM instruments. In contrast, the current study provides a structured stepwise approach to instrument development based on available best practices [2] and presents the development process of an instrument that relies significantly less on existing RUM instruments. Furthermore, this study demonstrates that the methodological approach to the development of an RUM instrument is determined by the type of RUM instrument being developed. For example, in the case of the PECUNIA RUM, the involvement of a broader range of experts in the instrument development process was needed due to the multi-sectoral nature of the instrument.

Compared with other generic RUM instruments available in DIRUM [8], the PECUNIA RUM allows for measuring resource use in more sectors (e.g. education, [criminal] justice) and for collecting standardized evidence for informing optimal decision making. Connections to the DESDE-based PECUNIA coding system [54], which facilitates the comparability of services, and to the compatible PECUNIA costing tools [38–40] allow for producing comparable resource use and cost estimates across studies. The PECUNIA RUM instrument was developed by a multinational consortium and will be tested in several European countries in addition to formal translatability assessment and concept elaboration to ensure its applicability to various geographical, linguistic, cultural and system settings. In addition, the flexible structure of the instrument makes it possible to adapt the instrument to a specific setting by selecting only relevant modules. This allows researchers to make a trade-off between, on the one hand, having an incomplete instrument that is easier to complete and, on the other hand, a comprehensive instrument that is too lengthy and difficult for the respondents to fill in.

The PECUNIA RUM can be compared with other comprehensive RUM questionnaires covering broader resource use, such as the Client Service Receipt Inventory (CSRI) [55], the Treatment Inventory of Costs in Patients with psychiatric disorders (TiC-P) [11], or the Health Economics Questionnaire (HEQ) [9, 56]. The aim of developing the PECUNIA RUM is not to replace other existing instruments but to offer a broader alternative, which has certain benefits such as a valid, structured and documented development process, inclusion of more resource-use items and cost categories within and beyond the healthcare sector, and a modular structure, which makes the instrument more easily adaptable to various contexts.

5.1 Reflections on the Development Process

Several aspects of the development process need to be mentioned. First, using a different methodological approach to the development of the PECUNIA RUM could have resulted in a different instrument, both in terms of the content as well as the structure. The PECUNIA Group selected the method developed by Thorn and colleagues [2] as, to the best of our knowledge, it is the only available systematic method for the development of a RUM instrument in health economics. This approach was generally applicable given the aim of the PECUNIA project. However, due to the complexity of the instrument, additional steps were needed. Second, as argued by the health economics experts, the applicability of the instrument to various settings (e.g. patient groups, disease areas) is difficult to ensure during the development phase. This would require additional testing of the instrument in different patient groups with respect to disease and national context. Although the PECUNIA RUM will initially be tested among former mental health service users and carers, the cost categories included in the instrument are also relevant for other conditions (e.g. chronic diseases) [52]. Third, instruments used for data collection in research are developed by researchers with high educational level and specialized knowledge, while the instruments are usually completed by patients and caregivers with varying levels of education and (health) literacy. To ensure understandability of the text, a formal wording review and revision of the text by a professional English editor were conducted. Fourth, RUM instruments are commonly used to collect resource-use data in randomized controlled trials alongside many other measures. This means that participants are often asked to fill in multiple questionnaires. Therefore, it is important to determine the appropriate length of the questionnaire by finding a balance between sufficient detail to obtain necessary data and patient burden. Testing the instrument with the potential end users will provide more insights into whether the current length is optimal.

5.2 Implications for Further Steps

To optimize the draft PECUNIA RUM, piloting will be conducted in the form of think-aloud interviews. Mental health service users and informal caregivers of patients with mental illness will be consulted in relation to the completeness, difficulty and feasibility of filling in the instrument. Furthermore, the instrument will undergo linguistic translatability assessment to prepare it for formal translation to multiple languages. The results of the preliminary validation and piloting will be used to develop the final, integrated, multi-sectoral PECUNIA RUM [57]. The PECUNIA RUM is planned to undergo formal psychometric testing and several further versions of the instrument are planned to be

developed (e.g. child and proxy versions). More extensive, i.e. midi and maxi, versions of the instrument may also be developed that would allow for an even more in-depth data collection for specific health care systems and costing purposes. As suggested by the health economics experts, a user guide will be developed with the aim of providing guidance on how to use the PECUNIA RUM and how to apply it to specific settings. Furthermore, costs in other categories (e.g. environmental costs) might be of relevance for inclusion in economic evaluation. Modules on resource use in other sectors can be developed following the process described in the current paper and added to the PECUNIA RUM in the future. This is a particular strength of the structure of the PECUNIA RUM given that it can be easily adapted to include new modules without compromising its structural coherence.

6 Conclusion

This study describes the practical application of the method outlined by Thorn et al. [2] to develop the PECUNIA RUM, a multi-sectoral generic RUM instrument [57]. The process was divided into six steps starting from the identification of general attributes of the instrument (e.g. perspective, disease), to the harmonization of the instrument modules in relation to the format, phrasing and order of the questions to form a coherent instrument. While the method by Thorn et al. [2] was, overall, suitable for the development of the PECUNIA RUM, additional steps were needed to account for the complexity of developing an instrument to measure broader resource use. Further steps are needed to fully test the validity of the instrument in different settings and population groups.

Declarations

Conflicts of interest Irina Pokhilenko, Luca M.M. Janssen, Aggie T.G. Paulus, Ruben M.W.A. Drost, William Hollingworth, Joanna C. Thorn, Sian Noble, Judit Simon, Claudia Fischer, Susanne Mayer, Luis Salvador-Carulla, Alexander Konnopka, Leona Hakkaart van Roijen, Valentin Brodszky, A-La Park, and Silvia M.A.A. Evers have no conflicts of interest to report.

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Authors and Affiliations

Irina Pokhilenko[1,2] · **Luca M. M. Janssen**[1] · **Aggie T. G. Paulus**[1,3] · **Ruben M. W. A. Drost**[1] · **William Hollingworth**[4] · **Joanna C. Thorn**[4] · **Sian Noble**[4] · **Judit Simon**[5,6] · **Claudia Fischer**[5] · **Susanne Mayer**[5] · **Luis Salvador-Carulla**[7,8] · **Alexander Konnopka**[9] · **Leona Hakkaart van Roijen**[10] · **Valentin Brodszky**[11] · **A-La Park**[12] · **Silvia M. A. A. Evers**[1,13] on behalf of the PECUNIA Group

✉ Irina Pokhilenko
i.pokhilenko@bham.ac.uk

1 Department of Health Services Research, Care and Public Health Research Institute (CAPHRI), Faculty of Health, Medicine and Life Sciences (FHML), Maastricht University, Maastricht, The Netherlands

2 Health Economics Unit, Institute of Applied Health Research, University of Birmingham, Birmingham, UK

3 School of Health Professions Education (SHE), Faculty of Health, Medicine and Life Sciences (FHML), Maastricht University, Maastricht, The Netherlands

4 Department of Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK

5 Department of Health Economics, Center for Public Health, Medical University of Vienna, Vienna, Austria

6 Department of Psychiatry, Warneford Hospital, University of Oxford, Oxford, UK

7 Mental Health Policy Unit, Faculty of Health, Health Research Institute, University of Canberra, Canberra, ACT, Australia

8 School of Public Health, Menzies Centre for Health Policy, University of Sydney, Sydney, NSW, Australia

9 Department of Health Economics and Health Services Research, University Medical Center Hamburg, Hamburg, Germany

10 Erasmus School of Health Policy and Management, Erasmus University of Rotterdam, Rotterdam, The Netherlands

11 Department of Health Policy, Corvinus University of Budapest, Budapest, Hungary

12 Department of Health Policy, Care Policy and Evaluation Centre, London School of Economics and Political Science, London, UK

13 Trimbos Institute National Institute of Mental Health and Addiction, Utrecht, The Netherlands