

A GENERAL PROCESS INDICATOR SET FOR PARENTERAL MEDICATION ADMINISTRATION IN THE PATIENT'S HOME SITUATION

Development and pilot benchmark

mprove

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Abstract

Objective:

A general organisational structure is needed for the administration of parenteral medication from the hospital to the home situation. Despite parenteral medication administration in the home situation (PMAH) being in practice for around two decades and process indicators (PIs) having been developed for specific care pathways related to a particular patient group or medicines, there is a lack of a general assessment tool. The lack of a generic set of PIs specific to PMAH has been found to contribute to significant variations in the PMAH process of different hospitals. In this study, we aimed to develop a general set of PIs to assess and improve the quality of PMAH and evaluate the set in a pilot benchmark between hospitals.

Methods:

The PIs were developed using a modified RAND/UCLA appropriateness method. A literature review with a systematic search was conducted to develop a general set of PIs. Additionally, the comprehensiveness of the general PI set was verified for the care pathways oncology and antibiotic. The PIs extracted from literature were subsequently assessed for their appropriateness by a group of stakeholders (n=19) involved in the PMAH process. The assessment of appropriateness entailed an online survey, three focus groups and a meeting with experts. The online survey employed a Likert scale ranging from 1 to 9, and the median and mode scores were utilized to assess the individual PIs. PIs were categorized as inappropriate if their median or mode scores fell within the range of 1-3, as uncertain if their median or mode scores fell within the range of 4-6, and as appropriate if their median or mode scores fell within the range of 7-9. Initially an online survey was conducted, followed by a round of focus group meetings held in three mProve hospitals, where the PIs that received uncertain ratings were discussed in detail. After obtaining final approval through consensus among a group of experts, a pilot benchmark was conducted in three hospitals to assess the performance of the set of PIs. Based on the findings from the pilot benchmark, the necessary adjustments were made to further refine the upcoming benchmarking process. Additionally, the initial differences and potential quality improvements in the three mProve hospitals were identified through a pilot benchmark.

Results:

The literature search resulted in 38 general, 9 antibiotic and 18 oncology-related PIs, regarding PMAH. Through the process of appropriateness assessment, a total of 21 indicators were identified as uncertain and were discussed in three focus groups. Throughout the development process of creating a PI set, 33 PIs were excluded due to reasons such as being too general and not specific to PMAH, not applicable within the Dutch healthcare context, or overlapping with other PIs already included in the PI set. Ultimately, a final set of 31 general, 2 antibiotic, and 2 oncology-related PIs were selected. According to the pilot benchmark, it was found that 34 out of the 35 developed PIs were available in at least one of the three mProve hospitals. This result demonstrates that the PIs are measurable, and therefore, the benchmark can be implemented across the seven mProve hospitals. Insights from the pilot benchmark in the three mProve hospitals indicate that quality improvements can be made in the areas of self-administration and establishing a safe and effective framework.

Conclusion:

To the best of our knowledge, this is the first study to develop a general set of PIs for the use of PMAH, encompassing multiple medication care pathways. With the use of 35 PIs, the PMAH process can be assessed and evaluated from healthcare institutions to the home situation. The developed general set of PIs can be utilized as an assessment and monitoring tool for the PMAH process, contributing to the improvement of the quality of care.

Keywords:

Parenteral medication administration; Home situation; Process indicator; RAND/UCLA appropriateness method.

Preface

Before you lies the master thesis *A process indicator set for general use of parenteral medication administration in the patients home situation*. This thesis has been written as the final product of the Master Health Sciences program at the University of Twente.

My master thesis was conducted as part of the Medication@Home project within the mProve hospitals. I would like to express my gratitude to Jan Gerard Maring for his guidance and supervision during the course of my research. Sharing his knowledge and experience on home administration was of great value in realizing this study. Additionally, I would like to express my gratitude to Cecile Bekkers and Margreet Filius for their assistance and contributions within this study. I would also like to extend my appreciation to Jedidja Lok-Visser for her warm hospitality within the organization and for sharing her research insights and experiences. Furthermore, I would like to express my gratitude to all stakeholders involved in the data collection process. Their cooperation and willingness to contribute to this research were essential in gathering the necessary data.

From the University of Twente, I would first like to express my gratitude to my supervisors Gréanne Leeftink and Anke Lenferink for their guidance and support throughout my research process. Their expertise and valuable insights played an important role in the development of this study. I would like to extend my appreciation to Stephanie Schouten for sharing her knowledge and experience regarding organizing focus groups. Additionally, I would like to thank Judith Brands for her involvement and guidance regarding the literature review. Her research experience she shared took the literature review of this study to a higher level.

Apart from the contributions from mProve and the University of Twente, I would like to extend a special thanks to my two sisters, Femke and Lindy Hunneman, who are also graduating from their studies. Their encouragement in words and chocolates during this process was appreciated. Additionally, I would like to thank my girlfriend, Fleur van Brouwershaven, for her support in controlling grammar and hearing about my research. Lastly, I would like to thank my family and friends for their involvement and encouraging words throughout this master's period.

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1. Introduction

In recent years, the shortage of personnel in Dutch hospitals has continued to increase. Hospitals are regularly forced to close beds due to a lack of staff [1]. The underlying causes are an increasing ageing population, a rise in comorbidities, and pressure on healthcare budgets [2]. In the coming years, the workload will continue to increase given that the demand for care will grow with 4% every year until 2030 [3].

The Dutch government's approach, as outlined in the Integral Care Agreement (IZA) (Integraal Zorg Akkoord), emphasizes that simply allocating more funds to the healthcare sector is not the solution to the increasing workload [2]. Instead, the IZA advocates for a focus on strengthening the (regional) organization of health care services, specifically by shifting hospital care to the patient's home situation. The home situation includes not only care delivered at the patient's home, but also care provided close to the patients home in an infusion center or a local hemodialysis unit [4-6]. A shift to providing care in the home situation is a consequence of (1) a greater interest in more personalized care for patients, (2) people living at home longer and longer, and (3) people living longer with multiple diseases [2, 7]. Cooperation between organizations providing hospital care and care close to the patient's home is central to this transformation of healthcare [8].

One of the initiatives resulting from cooperation between hospitals and homecare organizations is parenteral medication administration (PMA) in the home situation [9, 10]. To enhance the readability of this thesis, the abbreviation *PMAH* will refer to *PMA from the hospital to the home situation*. The term *parenteral* encompasses intravenous (IV), intramuscular (IM) and subcutaneous (SC) administration [11]. The advantage of PMAH is that the patient does not have to travel (far) to get the medication administered. Moreover, it often reduces mental stress for patients by avoiding a clinical setting [12, 13].

Despite the ongoing change around PMAH, it is crucial to ensure that the quality of care and safety of the patient and caregiver remain at the same level as in the hospital [14]. The definition of quality of care following The Institute of Medicine (IOM) is as follows: '*Quality of care can be defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge*' [15]. In addition to ensuring quality and safety, patient and caregiver satisfaction are important factors to remain the same or increase [16].

To assess and ensure the quality of care and safety in the context of PMAH, the use of process indicators (PIs) is considered essential [17, 18]. PIs provide insight into the specific steps and activities involved in the administration of medication at home. PIs also allow the evaluation of adherence to standardized protocols, guidelines, and best practices [19]. PIs play a key role in monitoring and evaluating the quality, efficiency and effectiveness of processes, identifying areas for improvement, and to facilitate benchmarking across different health care settings or providers [17, 18, 20].

Currently, there are several studies that have evaluated the quality and safety of PMAH using indicators [10, 21, 22]. However, these studies have predominantly focused on specific care pathways related to a particular patient group or medicines, such as antibiotics. To the best

of our knowledge, there is currently no study or guideline available that examines a set of PIs that encompass generic, non-drug specific, requirements for PMAH.

The lack of a generic set of PIs specific to PMAH has been found to contribute to significant variations within different hospitals regarding the medication administration process [23-25]. These variations encompass various aspects of PMAH, including storage and transportation practices, collaboration and communication between healthcare providers and patients, and have been associated with potential negative consequences [23, 26]. By identifying and implementing appropriate PIs, health care organizations can establish clear guidelines, promote consistency in medication administration practices, enhance collaboration between health care providers and patients, and ultimately optimize the quality of PMAH provided in the home situation [5, 18, 27].

This leads to the following research question: *What are essential generic PIs for the quality assessment of parenteral medication administration from hospitals to the home setting, and to what extent are the developed PIs met in a pilot benchmark among Dutch hospitals?*

The primary aim of this study is twofold. The first objective is to construct a generic set of PIs, consisting of essential preconditions regarding the PMAH process. Second, to conduct a pilot benchmark to evaluate the developed PI set and to determine the extent to which the PIs are met. In addition to the general set of PIs, we investigated whether the care pathways *antibiotics* and *oncolytics* require additional indicators. The rationale behind choosing these two care pathways is based on communication with experts, indicating that antibiotics and oncolytics are recognized as complex care pathways that entail specific requirements related to PMAH.

2. Methods

A modified version of the RAND Appropriateness Method (RAM) [28], which is widely used for indicator development, has been used to develop a comprehensive set of PIs, suitable for implementation in hospitals providing PMAH. RAM has been selected over other consensus methods because of its evidence-based methodology, and ability to integrate available evidence and expert opinions to formulate clinical recommendations [18]. The process has been divided into three main phases (see Figure 1): 1) preparatory phase, 2) consensus phase, and 3) benchmark phase. The three main phases addressed in this thesis consist of 7 sub phases, namely: (1a) literature review, (1b) PIs based on selected literature, (2a) an online survey, (2b) review of PIs in focus group meetings, (2c) an expert meeting, (3a) a pilot benchmark, and (3b) determining a final set of PIs. Due to time limitations, phase 3c was not included in this thesis. This thesis received ethical approval from the University of Twente (Application number: 230125).

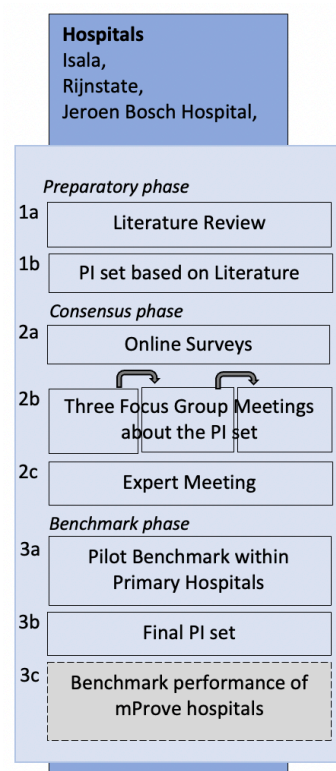


Figure 1 – Study flow diagram

2.1 Study Setting

This thesis was conducted within a Dutch hospital group including 7 top clinical hospitals, known as the mProve hospitals (i.e., Albert Scheitzer Hospital, Isala, Jeroen Bosch Hospital, Noordwest Hospital Group, Máxima Medical Centre, Rijnstate, and Zuyderland Hospital) [29]. One of their joint projects is the *Medication@Home* project. The objective of this project is to optimize and standardise the logistics and procedures concerning the administration of parenteral medication from the hospital to the home situation. Not only process optimisation, but also process related quality and safety is part of the project *Medication@Home*. Consequently, a relevant PI set is needed as an essential tool to benchmark the different hospitals on their quality of PMAH [30, 31]. With respect to this thesis, *Medication@Home* will serve as a case-study. Initially, the focus will be on three mProve hospitals (i.e., Isala, Jeroen Bosch Hospital, and Rijnstate), followed by setting out a pilot benchmark within these three hospitals. This pilot benchmark will serve as a crucial basis for the subsequent implementation of a comprehensive benchmark across all seven mProve hospitals (see Phase 3c in Figure 1).

Preparatory phase

2.2 Literature review with systematic search

A literature review with systematic search was conducted to search for studies on PMAH and available guidelines regarding PMAH (see Phase 1a in Figure 1). The initial search was executed in two databases: PubMed and Scopus. Varying techniques were used for searching, namely, truncation, Boolean operators, synonyms, and medical subject headings (MESH). Keywords were divided into three categories according to the PCC framework (population, concept, and context), used in identifying key concepts in a review [32]: (1) population: patients treated with parenteral medication; (2) concept: organization of PMAH; (3)

context:outpatient treatment (e.g., hospital at home or outpatient clinic). In Appendix 1.1 the search syntax is given.

The selection of literature followed a structured way with the program Covidence (see Appendix 1.2) [33]. Literature was identified, analysed on title and abstract, and full-text screening based on the inclusion and exclusion criteria stated in table 1. Two reviewers (RH and JGM) independently screened the titles and abstracts that were identified in the initial search, to give this systematic search a reliable and reproducible body. The two reviewers collectively evaluated and resolved discrepancies regarding the title and abstract screening through discussion (see Phase 1a of Figure 1). When consensus could not be reached, a third reviewer (JLV) was asked for assistance.

Table 1 - Inclusion and exclusion criteria for literature review

Inclusion:	Exclusion:
<ul style="list-style-type: none"> - description of PMA in outpatient care. - organization of health care (i.e., the structure and processes involved in the delivery of healthcare [34]). 	<ul style="list-style-type: none"> - written in a language other than English or Dutch. - guidelines provided for paediatric patients. - guidelines provided for parenteral nutrition.

After the full-text screening, the first reviewer (RH) extracted potentially appropriate PIs from the full texts. The extraction of PIs was done based on the predetermined inclusion and exclusion criteria, which were established to define the target population (see Table 2). The second reviewer (JGM) judged the included and excluded PIs, based on the criteria stated in Table 2.

Table 2 - Inclusion and exclusion criteria for extracted process indicators from literature

Inclusion:	Exclusion:
<ul style="list-style-type: none"> - focus on parenteral medication administration (i.e., infusion, subcutaneous, intra muscular injection). - close to the patient's home (e.g., infusion center, hemodialysis center, or at the patients home). - focus on the process and organization of health care. 	<ul style="list-style-type: none"> - focus on in-patient treatment. - Focus only on children/pediatric/neonatology/infants. - Focus on cost-effectiveness of a drug. - Focus on the effectiveness of a drug in comparison with another drug.

2.3 Pre-screening of appropriateness

Appropriateness of the extracted PIs from literature was assessed for practical use in three stages (an online survey round, focus group meetings, and an expert team meeting). To facilitate the implementation of this thesis, an expert team was established in the three mProve hospitals. This expert team consisted of three hospital pharmacists (CB, JGM, MF) each employed in a different mProve hospital, with extensive expertise in managing the transition of PMAH. In addition, they oversee the entire process from procurement to administration in the home situation.

The pre-screening of appropriateness regarding the extracted PIs from literature encompasses an initial meeting with the expert team (see Phase 1b in Figure 1). This pre-screening was conducted to increase the relevance of the PI set, prior to the consensus phase, by identifying PIs that exhibited overlapping content with other PIs or did not meet the

requirements for home administration. To ensure the reliability of the study, a third researcher (JLV) was involved to oversee and ensure the integrity of this phase.

Consensus phase

During the consensus phase, the identified PIs were evaluated for suitability by stakeholders who have experience with PMAH. To gather their input, an online survey was conducted, presenting the PIs found in the literature. PIs that received uncertain ratings in the survey were further discussed in the focus group meetings. Any PIs considered as *inappropriate* were removed from the PI set, while those considered as *appropriate* were retained. Subsequent to the focus group meetings, the PI set was presented to the expert team for their final judgement on the PIs that were considered as appropriate by the stakeholders from the focus group meetings.

A broadly composed group of 35 stakeholders employed in the three mProve hospitals were invited by the expert team to participate in the online survey and focus group meetings. A population of at least 5 stakeholders per hospital was targeted, as recommended in literature as the minimum sample size for conducting a focus group [28, 35]. The selection of stakeholders for the online survey and focus group meetings was conducted using a snowball sampling technique, in which the experts from the expert team were asked to recruit stakeholders, based on their involvement in the process of PMAH [36]. This, to establish an experienced and diverse group of stakeholders, regarding different levels of care [35]. The *stakeholders* were included based on the criteria: (1) having at least one year of experience regarding PMAH, and (2) holding one of the following professional roles: (district) nurse, medical specialist, infectious disease specialist, clinical microbiologist, pharmacist, administrative officer, or a PMAH project leader [10]. Stakeholders were excluded if they declined to provide informed consent.

2.4 Online survey rounds

An online survey round was conducted to evaluate the appropriateness of the PIs selected from the literature review. Stakeholders anonymously rated the PIs based on a 9-point Likert scale, where 1 represents inappropriateness and 9 represents appropriateness. Per indicator, per mProve hospital, the median and the mode scores were calculated and classified into three levels of appropriateness: (1) *inappropriate* was defined as a median or mode score falling within the range of 1-3, (2) *uncertain* was defined as a median or mode score falling within the range of 4-6, and (3) *appropriate* was defined as a median or mode score falling within the range of 7-9 [18, 28, 37]. Table 3 shows the classification of individual PIs from the online surveys based on the Likert scale, considering whether the median or mode score in one, two, or three hospitals falls into the categories of appropriate, uncertain, or inappropriate. In order to enhance the effectiveness

Table 3 – Conclusions per PI, based on a 9-point Likert scale after online survey in three hospitals

1 hospital	2 hospitals	3 hospitals
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

Caption:
■ Appropriate
■ Uncertain (discussed in focus group)
■ Inappropriate
■ Depended on score other hospital

of the selection process we decided that when more than one hospital scores 'uncertain', the PI will be scored inappropriate and will be removed from the PI set.

The use of a 9-point Likert scale was chosen because of its more nuanced assessment than other Likert scales (e.g., 3-point, 5-point) and contributes to improved discernment [28, 38]. Furthermore, this scale was selected due to its wide use as a measurement scale in the context of RAM [18]. Distribution of the PIs extracted from literature among the stakeholders, was done by an online survey programme called Qualtrics version: 0423 (see Phase 2a in Figure 1). Stakeholders were asked to score the PIs by adjusting a slider from 1 to 9 (see Appendix 2). Moreover, after each PI set in the survey (i.e., generic, antibiotic and oncolytic), stakeholders were given the opportunity to provide comments and additional input. The text was presented in Dutch, with a corresponding English translation provided for each indicator, ensuring validity [39].

2.5 Focus group meetings

Three separate focus group meetings were conducted to collect data from each hospital regarding the PIs that were scored during the online survey (see table 3). The aim of conducting these focus group meetings was to gather a deeper understanding and actively involve stakeholders in the final set of PIs to be drawn up [35]. PIs that were scored as *uncertain* by one hospital were discussed during the focus group meetings (see Appendix 3). Additionally, PIs scored as *inappropriate* or *appropriate* in the online survey were summarized in a handout with open fields for comments (see Appendix 4).

Instead of holding one central (online) focus group meeting, it was decided to hold three separate focus group meetings within the three mProve hospitals (see Phase 2b in Figure 1). This decision was made because of the wide geographical spread of the three hospitals across the Netherlands, and the limited time of healthcare professionals. For the focus group meetings, a duration of 1.5 hours was scheduled by the hospitals. Results that emerged in the first focus group meeting were discussed in the second focus group meeting, and the results of these two focus group meetings were then discussed in the third focus group meeting.

These focus group meetings were held in the Dutch language to ensure effective communication. Efforts were made to have an additional researcher present in each focus group meeting to handle logistical matters, such as assigning seats to latecomers and ensuring equal participation among attendees [35]. The handout served as a verification tool for determining the appropriate and inappropriate PIs, because during the focus group meetings there was limited time. This verification was implemented by asking stakeholders to review the handouts and make annotations regarding any specific observations. This approach allowed for cross-referencing during the collection of handouts to ensure consensus among stakeholders regarding the appropriate and inappropriate PIs.

Audio recordings were made with the consent of the stakeholders during the three focus group meetings, and transcribed verbatim to ensure accurate data processing, thereby enhancing the reliability of this study [40]. Subsequently, the data was anonymized by removing references to individuals, localities, and organizations. The transcripts were segmented into sections based on the individual PIs in the PI set, to draw conclusions for each PI.

After the preparations for data analysis were completed, the data was analyzed using *Directed content analysis* [41]. This is a widely used analysis method in social science research that combines deductive coding with inductive coding. The deductive codes used in this study were based on the RAM, namely *appropriate*, *uncertain* and *inappropriate* [28]. During the coding process, inductive codes were included iteratively by adding them to the existing code scheme (see Appendix 5) [40, 41]. The transcribed texts were analyzed and conducted in Dutch, using the qualitative data analysis software ATLAS.ti version: 23.1.1. Based on the coding process, the transcribed texts were categorized into relevant codes to identify recurring themes and patterns, regarding the consolidation of the transcripts from the three mProve hospitals concerning the individual PIs. These codes were then organized and analyzed, leading to the generation of meaningful conclusions and insights per PIs (see Appendix 6). These conclusions were based on the majority consensus. During the focus group discussions, the participants were asked to provide a final judgement on each individual PI. Based on these conclusions, PIs were rejected, approved, modified, relocated or added to the PI set.

2.6 Expert team meeting

The expert team carefully reviewed the PIs set, consisting of PIs scored as appropriate in the online survey and focus group meetings (see Phase 2c of Figure 1). The purpose of this step was to critically review the PIs evaluated by the stakeholders from the focus group meetings and arrive at a concise PI set for the pilot benchmark. Any ambiguities or restatements regarding the PI set could be made by the experts during this session. These changes were made only when there was consensus within the expert team on the possible modifications. Consensus was reached when a majority of the expert team supported the modification of the respective PI. After the meeting, the changes to the PIs were implemented to the PI set. Subsequently, written consent was asked from the expert team regarding the finalization of the PI set for a pilot benchmark.

Benchmark phase

2.7 Pilot Benchmark

A pilot benchmark was conducted among the three mProve hospitals, based on the developed PI set. The aim of the pilot benchmark was to evaluate the applicability of the developed PI set and providing initial insights regarding quality improvements of PMAH. The experts of the expert team were asked to assess each PI as present, absent, or not applicable in relation to all care pathways pertaining to PMAH within their respective hospitals (see Appendix 7). The pilot benchmark was performed through the use of an online survey programme, Qualtrics version 0423. Subsequently, the data was analyzed using descriptive statistics. This analysis involved examining variabilities between the three mProve hospitals through the use of means, percentages and frequencies [42, 43].

After the pilot benchmark, the final adjustments to the PI set were made based on the experts' input, in order to finalize the PI set (see Appendix 8). The developed and pilot benchmarked PI set was then presented to the Medication@Home working group to kick-start the benchmark implementation across the seven mProve hospitals (see Phase 3c in Figure 1).

3. Results

Preparatory phase

3.1 Literature review with systematic search

As shown in Figure 2, 279 articles were identified by a systematic search and included for screening (see Appendix 1.2). After title and abstract screening, 35 articles were included. In total, 26 articles were included after the full texts screening. In addition, one article was included by screening the references of the included literature and two articles were included through exploratory literature study. Out of the 29 included studies, 22 focused on antibiotics, 4 on oncology, 1 on both antibiotics and oncology and two articles were general (see Appendix 1.3). A total of 38 general, 9 antibiotic, and 18 oncological PIs were extracted from the consulted literature (see Table 4).

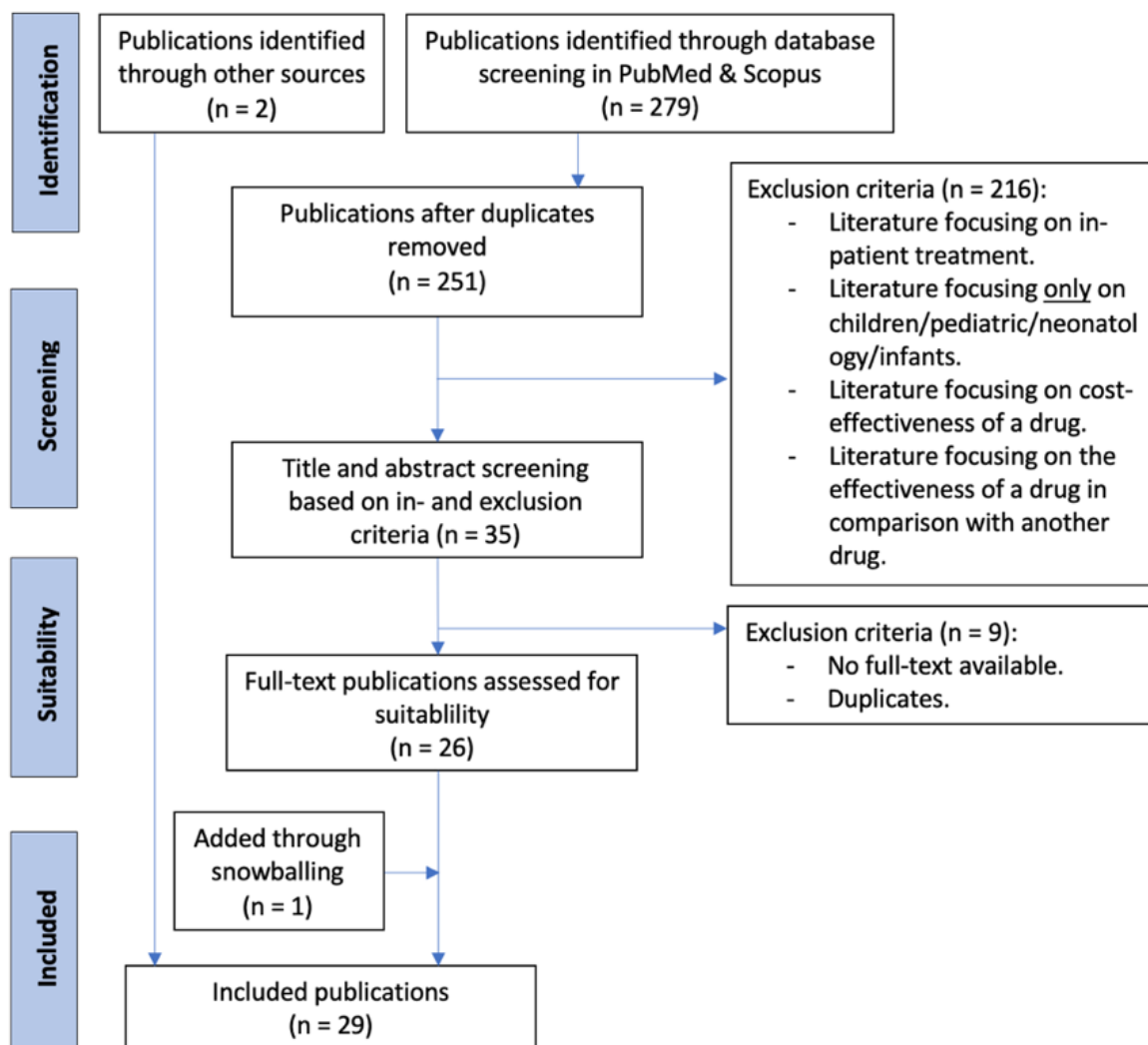


Figure 2 – Flow diagram of literature review with systematic search

Figure 3 presents a schematic representation of the PIs within the research process. This figure indicates the number of PIs that are modified, relocated, rejected, or added to the PI set in each phase of this study. Based on the pre-screening of appropriateness regarding Table 4, 1 general PI (38) and 3 oncological PIs (O16, O17, O18) were scored as inappropriate by the expert team as they overlapped with other PIs or were focussed on inpatient care rather than PMAH (see Appendix 8).

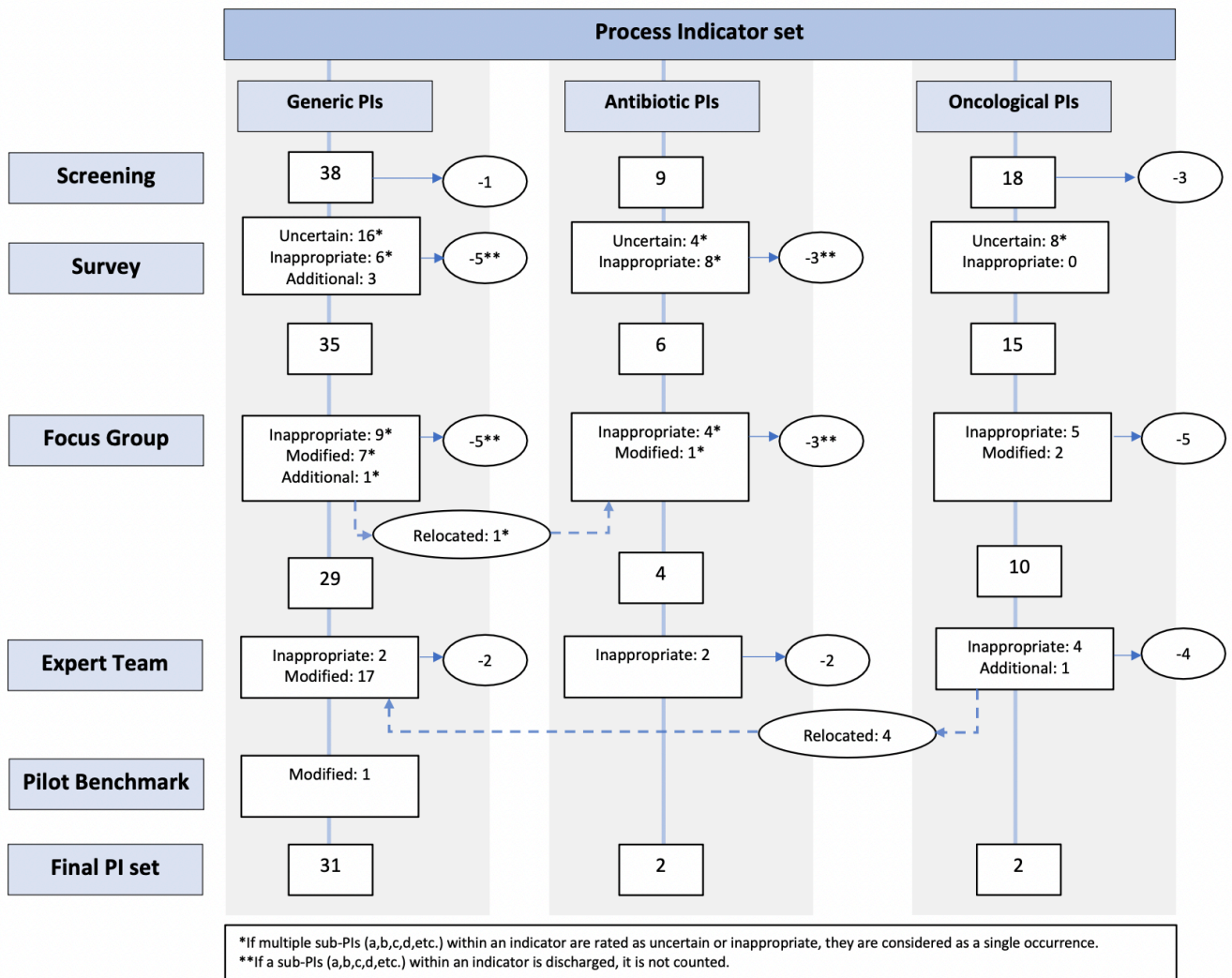


Figure 3 - flow diagram of modifications on the process indicator set during the research process

Table 4 – Results of literature screening on process indicators for the administration of parenteral medication.

Generic Process Indicators	References
1. A structured program is available which provides a framework for safe and effective care.	[5, 6, 10, 44]
2. There is a formal PMAH-transfer team. This team will have to include at least: a. A physician experienced with the administered medication b. A pharmacist experienced with outpatient infusion c. A nurse experienced in intravenous therapy	[10, 44-50]
3. An identifiable, medically lead clinician takes leadership of the PMAH in homecare and has identified time for this.	[6, 10, 49-51]
4. There are patient selection criteria for the eligibility for PMAH in homecare. This includes: a. The patient is willing to comply with the follow-up plan and has given informed consent. b. There is no clinical contradiction to discharge the patient from the hospital. c. A switch from intravenous to oral medication is not possible. d. The patient has a hemodynamic stable condition. e. There is a safe home environment and adequate support (i.e., the place of administration is clean, running water, needle disposal, and space for storage of supplies). f. Additional need for complex care will be taken into consideration (e.g., wound care, physical therapy). g. Taking care of the psychosocial factors of a patient (e.g., alcohol and drug abuse, cognitive burden). h. There is a patient understanding regarding PMAH in home situation. i. Access to transportation for physician appointments and access to emergency services.	[6, 44, 45, 47-49, 51-59]
5. There are (internal) qualification requirements to establish a minimum standard to caregivers involved in the process of PMAH in homecare, this includes: a. Requirements regarding initial qualification. b. Periodic monitoring regarding qualification.	[6, 44, 51, 60]
6. Defined roles per medication pathway which outlines the responsibilities of the caregivers involved within the process of PMAH in homecare. This includes responsibility for: a. Patient selection b. Facilitation of medical materials c. Adequately trained personnel d. Preparation of medication e. Transportation of medication f. Administration of medication g. Monitoring h. Follow-up	[5, 6, 44, 48, 49, 56, 57, 59]
7. There is a protocol in place for urgent discussions, handling and review of emergent clinical problems during PMAH according to clinical need.	[10, 22, 49, 56-59]
8. There is a system in place for rapid communication between the patient and care givers.	[6, 10, 44, 55, 59]
9. There should be communication between the PMAH-team and other stakeholders in the process of PMAH in homecare. This includes: a. General practitioner b. Community team (if applicable) c. Referring clinician The communication includes at least: notification of the start of treatment to the general practitioner (or if else, responsible specialist), notification of acceptance of PMAH in homecare, notification of completion of therapy, notification of complications.	[5, 10, 44, 45, 55, 59, 61]

10.	In case of comorbidity (e.g., diabetes mellitus, cardiac diseases), responsibilities between physicians, general practitioners and other medical specialists are clearly defined.	[58]
11.	The PMAH-team should document the clinical response to medication management.	[10, 48, 49, 56, 57, 62]
12.	There is a policy for educational programs for caregivers to provide safe care regarding PMAH in the home situation.	[5, 48, 51, 63]
13.	There is a policy regarding the travel distance from the patients home to the hospital [48, 51, 63].	[51, 54, 65]
14.	There is a system for ongoing quality assurance and outcome monitoring.	[5, 6, 45, 51]
15.	A standard order set is available for patient discharged out of the hospital with PMAH. This includes at least: a. Patients full name. b. Date of birth. c. Diagnosis. d. Regimen name and cycle number. e. (If applicable) protocol name and number. f. Intolerances, contra-indication and allergies (ICA). g. Dosages. h. Route of administration. i. Duration of infusion. j. Duration of treatment. k. Supportive care treatments appropriate for the treatment program.	[5, 10, 22, 44, 46, 51, 59]
16.	A competent caregiver involved in PMAH in homecare should perform an initial assessment for inclusion.	[6, 10, 49]
17.	The patient and caregiver should be able to decline or accept the PMAH in homecare.	[10, 44, 49]
18.	The patient and their family should be informed (orally and written) about PMAH in homecare. The information should at least contain: a. Benefits b. Side effects c. Potential complications d. Vascular access e. Sterile techniques f. Responsible physician for non-treatment related diseases g. Instruction for emergencies h. Medication use i. Patient responsibilities j. Contact lists	[10, 48, 51, 54, 56, 57, 59, 60]
19.	There is a policy in case of self-administration. Patients or caregivers should be trained in the administration of intravenous medication.	[10, 45, 47, 49, 64]
20.	In case of self-administration, both the nurse specialist and patient/caregiver should be satisfied of the patient's/caregiver's competence, and this should be documented.	[4, 10, 45, 47, 49, 64]
21.	Patients educational material should be available in written or in multimedia form.	[6, 10, 48, 51, 56, 57, 59]
22.	The treatment and monitoring plan for PMAH in homecare should include: a. Indication b. Medication name c. Dose	[5, 6, 10, 21, 44-46, 48, 51, 56, 57, 59, 60]

	<ul style="list-style-type: none"> d. Frequency e. Duration f. Type of administration (e.g., continuous or bolus infusion) g. Access device used (e.g., peripherally inserted central catheter, tunneled catheter) h. Follow-up plan i. Parameters for the notification of abnormal vital signs j. (If applicable) laboratory monitoring should be considered. In addition, treatment can be modified based on laboratory results (i.e., therapeutic drug monitoring). 	
23.	The PMAH-team should select the drug delivery device in agreement with the home health agency.	[6, 10, 44]
24.	There are selection criteria regarding which administration setting (i.e., infusion center, home, HD center) is most appropriate for each patient.	[4, 5, 52, 55]
25.	PMAH in homecare is structurally implemented in the process, by means of an early and frequent engagement of caregiver initiating the PMAH process.	[52, 59]
26.	Policy regarding administration of first dose of medication.	[6, 45, 47]
27.	Frequent formal meetings between stakeholders in the PMAH-process with the aim to constantly modify the protocol (up-to-date protocols).	[44, 51]
28.	Rescue medication from the list of essential medications should be available in health facilities that dispense PMAH in homecare.	[60]
29.	A guideline is available for vascular access systems (e.g. PICC or Proth-A-Cath) used regarding the outpatient setting.	[10, 44, 45, 47]
30.	Policies regarding frequency of clinical assessment of the patient by physicians and nurses.	[6, 49, 56, 57]
31.	Policies regarding communication through multimedia (e.g., an application, phone or website).	[6, 57, 59]
32.	The satisfaction status and experience of patients receiving PMAH in homecare should be monitored.	[10, 56, 57]
33.	The program outcome of patients receiving PMAH in homecare should be monitored.	[6, 10, 44, 45, 51]
34.	The survival status of patients who received PMAH should be documented (e.g., patients alive, died of infection, died of other causes, lost to follow-up, or status unknown).	[21, 45]
35.	The PMAH team should document adverse events related to device, medication use, and toxicity.	[10, 47, 51, 52, 60]
36.	The intravascular access device should be removed at the end of therapy (if not needed for another reason).	[10, 47]
37.	There is a policy regarding double check of medication in homecare.	[22, 60]
38.	Availability for a patient to be easily and quickly administered to the hospital in case of unforeseen circumstances.	[58, 65]
Antibiotic Process Indicators		
A1	The PMAH in homecare program should be part of an antimicrobial stewardship program.	[10, 21, 45, 46, 65]
A2	<p>Additionally, to the PMAH-team, the OPAT team also includes:</p> <ul style="list-style-type: none"> a. An ID specialist or physician knowledgeable about IDs and the use of antimicrobials in OPAT b. A social worker c. A laboratory technician d. A microbiologist e. A home care coordinator f. A home care pharmacist 	[6, 10, 47, 49-51, 59, 65]
A3	The OPAT ID physician should specify infection-related inclusion and exclusion criteria for OPAT.	[6, 10, 45]
A4	<p>The criteria for the infection disease specialist are well defined, including:</p> <ul style="list-style-type: none"> a. analyzing the need for (parenteral) anti-infective therapy b. recommending the anti-infective agent c. providing orders for therapy d. monitoring the patient during the course of treatment comprehensively evaluate the patient's clinical response 	[5, 6, 49, 55, 59]

A5	The OPAT treatment plan is a responsibility of the infection disease physician.	[6, 47, 51]
A6	An OPAT ID physician consultation should take place prior to intravenous access device placement.	[6, 45-47, 55, 59]
A7	The case manager confirms scheduling of the first outpatient follow-up appointment within two weeks of patient discharge.	[59]
A8	There is a policy regarding laboratory monitoring, including: a. Measurement technique and frequency per antibiotic. b. Responsibility of sample collection in outpatient setting. c. (If applicable) Antibiotic blood levels should be measured regularly (narrow therapeutic window) throughout the course of OPAT treatment. d. Laboratory results should be delivered to physicians within 24 hours after obtaining material for testing.	[6, 10, 45, 47, 51, 59, 60]
A9	The treatment plan of patients who receive in excess of 1 week of antimicrobial therapy should be regularly reviewed by the OPAT specialist nurse and physician (narrow-spectrum antibiotics, intravenous-oral switch) in conjunction/consultation with the referring specialist, as necessary.	[10, 51]
Oncological Process Indicators		
O1.	If the practice/institution site administers chemotherapy that is prepared (mixed) off site, the practice/institution maintains a policy for quality control of that chemotherapy.	[22]
O2.	Additionally, to the PMAH-team, the oncological team also includes: a. An oncologist who is experienced in outpatient therapy b. Two clinical nurse specialists	[22, 66]
O3.	There is a policy regarding responsibilities for standby (24 hours a day) and preparedness for home visits.	[22, 59, 63]
O4.	The organization has a comprehensive educational program for new staff administering chemotherapy, including a competency assessment, or the practice/institution uses an off-site educational program regarding chemotherapy administration that ends in competency assessment.	[22, 48, 51, 66]
O5.	The quality of keeping knowledge up to date among medical staff is ensured in a policy.	[56, 57, 66]
O6.	Orders for parenteral chemotherapy are written and signed by licensed independent practitioners who are determined to be qualified by the practice/institution according to the practice's/institution's policies, procedures, and/or guidelines.	[22]
O7.	Chemotherapy drugs (oral or parenteral) are prepared by trained personnel which is qualified according to the practice's policies, procedures, and/or guidelines.	[22]
O8.	There is a consistent communication and documentation of toxicity across sites of care.	[22]
O9.	(If applicable) there is a process available to track cumulative doses in the patients' home situation of chemotherapy agents associated with a risk of cumulative toxicity.	[22]
O10.	Only qualified physicians, physician assistants, advanced practice nurses, or registered nurses administer chemotherapy.	[22, 56, 57, 63, 66]
O11.	The practice/institution maintains written statements that determine the appropriate time interval for regimen-specific laboratory tests.	[22]
O12.	On each clinical visit or day of treatment during chemotherapy administration, staff: a. Assess and document clinical status and/or performance status b. Document vital signs and weight c. Verify allergies, previous reactions, and treatment-related toxicities Assess and document psychosocial concerns and need for support, taking action when indicated.	[22]
O13.	Policies regarding disposal of hazardous drugs in a designated container.	[66]
O14.	Practice recommendations regarding secure fellow residents (i.e., a partner, children, and pets) from chemotherapy.	[66]
O15.	Standards regarding safety concerns and risks associated with handling chemotherapy.	[66]
O16.	In addition to the general criteria set must a complete order for PMAH of chemotherapy include: a. Appropriate chemotherapy criteria to treat (e.g., based on relevant laboratory results and toxicities). b. Assessment of organ-specific function.	[6, 58]

	c. Reference to the methodology of the dose calculation or standard practice equations (e.g., calculation of creatinine clearance). d. Height, weight, and any other variables used to calculate the dose.	
O17.	Orders for parenteral chemotherapy should be written with a time limitation to ensure appropriate evaluation at predetermined intervals.	[6, 22]
O18.	If outpatient organization manages its own pharmacy, the practice/institution has a policy regarding the storage of chemotherapy (including separation of look-a-like products, sound-a-like products, and agents available in multiple strengths). Chemotherapy is stored in a designated area according to regulatory guidelines.	[22]

Consensus phase

3.2 Online survey

Among the 35 approached stakeholders, 18 of them completed the online survey (response rate 51%). The response rates varied among the three mProve hospitals, ranging from 38% to 83% (see Table 5). Table 5 provides an overview of stakeholder participation in both the online survey and focus group meetings, highlighting the heterogeneous nature of the stakeholder group across the participating hospitals. The stakeholders who filled in the survey, included: 3 oncologists, 1 district nurse, 2 hospital nurses, 3 ID specialists, 1 medical microbiologist, 1 unit head, 1 medical secretary, 4 hospital pharmacists, and 2 project leaders.

Table 5 – Stakeholder characteristics

Variable:	Population (n):		
Hospital:	Group A	Group B	Group C
<i>Stakeholders consulted</i>	6	16	13
<i>Response rate (survey)</i>	83%	38%	54%
<i>Response rate (focus group)</i>	100%	25%	69%
<i>n of filled in survey (n=18)</i>	5	6	7
<i>n of participants focus group(n=19)</i>	6	4	9
Function:			
<i>Nurse:</i>			
<i>Hospital Nurse</i>			1
<i>Oncological Nurse</i>			1
<i>Transfer Nurse</i>		1	1
<i>Nurse Practitioner</i>			1
<i>District Nurse</i>	1		
<i>Physician Assistant</i>		1	
<i>Medical Specialist:</i>			
<i>Oncologist</i>	1		
<i>Haematologist</i>			1
<i>Infectious Disease Internist</i>			1
<i>Project leader</i>	1		
<i>Medical Secretary</i>	1		
<i>Hospital Pharmacist</i>	1	1	2
<i>Outpatient Pharmacist</i>			1
<i>Unit head</i>	1		
<i>Coordinator</i>		1	

Regarding the Likert score, 8 PIs and 6 sub-PIs (e.g., 6. a,b,c,d) were removed from the PI set by the 18 stakeholders based on a median or mode score of <7 in more than one hospital or a median or mode score of <3 (see Appendix 9). The removed PIs from Table 4 included: role distribution within the PMAH team (PI; 3, A2, A5), monitoring of clinical outcomes (PI; 11, 34), travel distance (PI; 13), communication through multimedia (PI; 31), and consultation for medical device placement (PI; A6) (see Appendix 8).

Stakeholders suggested 3 additional PIs for inclusion (see Appendix 8). These additional PIs included: employee satisfaction, patient relocation in case of staff shortage and infection prevention measures. Furthermore, 21 PIs were classified as uncertain, based on a Likert score ranging from 4 to 6 in one of the hospitals (see Appendix 4).

3.3 Focus group meetings

19 out of the 35 approached stakeholders participated in the focus group meetings (response rate 54%). The response rate per hospital varied from 25% to 100% among the stakeholders. As shown in Table 5, hospital B did not meet the sample size criterion (i.e., ≥ 5 stakeholders), described in Section 2.8. However, hospital B was included in the data analysis, based on participation of a physician assistant and a care coordinator, as stakeholders with the same roles did not participate in the other two focus group meetings. Additionally, the care coordinator brings 18 years of experience in PMAH, while the other participating hospitals have three years of experience.

Prior to conducting the focus group meeting in hospital A, it was decided not to inquire about *uncertain* indicators from the antibiotic PI set, as the participating stakeholders lacked experience in this area. Upon data analysis, it was determined to discard the data from hospital B concerning the oncological PI set, as all participants during the focus group meeting indicated a lack of experience with oncological PIs.

The initial findings derived from the focus group meeting pertain to the introductory question that was posed. To summarize, the stakeholders indicated that: (1) the PI set includes several indicators that are overly general (i.e., general hospital care) and not specifically relevant to PMAH, (2) the PI set includes several indicators that are not applicable in the Dutch healthcare setting, (3) the survey was perceived as excessively time-consuming, and (4) there is a need for more concise formulation of the PI set to prevent bureaucratic complexities (see Appendix 10).

During the focus group meetings 16 PIs were removed from the PI set (see Figure 3). In 12 out of the 16 removed PIs by the focus group meetings, the PIs were rejected, because stakeholders deemed them not specific to PMAH but rather applicable to general healthcare standards. Stakeholders indicated that the PIs often referred to flied standards applicable to all healthcare settings. The removed PIs from Table 4 include: switching to oral medication (PI; 4c), access to emergency care (PI; 4i), responsibilities within the PMAH process (PI; 10, A4, A7, A8c, O6, O10, O11, O12), patient information (PI; 18), follow-up plan (PI; 22h, 24, O9), anti-microbial stewardship program (PI; A1), and processing of laboratory results (PI; A8d). Appendix 8 gives detailed information on why this PIs were removed.

The 3 additional PIs that were extracted from the online survey comments were discussed in the focus group meetings. It was found that two PIs, namely employee satisfaction and patient relocation in case of staff shortage were classified as inappropriate. An additional PI from the online survey has been added to the PI set, which pertains to infection prevention measures (see Appendix 8).

Regarding the infection prevention PI, a medical microbiologist who participated in the online survey raised the concern that more attention should be given to the domain of infection prevention in the PI set. Unfortunately, the medical microbiologist was unable to participate in the focus group meetings. Stakeholders in the focus group meetings expressed doubts about adding a PI related to infection prevention measures, as they stated that the home environment is the safest place to receive PMA (see Appendix 8). Despite these doubts being acknowledged, the stakeholders ultimately agreed to include the PI related to infection prevention in the PI set.

3.4 Expert team

There was consensus among the experts regarding PIs that were considered as *inappropriate* by the stakeholders of the focus group meetings. Additionally, as shown in figure 3, it was revealed that 17 general PIs needed to be reformulated based on textual preferences (see Appendix 8). During the expert team meeting, it was expressed by the experts that they desired a concise PI set. As a result, 8 PIs were excluded from the PI set. 2 general PI (PI; 12, 33) were excluded from the PI set due to their overlap with other PIs. These removed PIs include policy regarding education and monitoring of patient outcomes. Additionally, the

experts indicated PI 22j (i.e., laboratory monitoring) is inappropriate due to overlap with PI A2. PI A3 (i.e., in- and exclusion criteria specific to antibiotics) was removed from the PI set based on a lack of applicability to PMAH. 4 oncological PIs (PI; O2, O5, O7, O8) were excluded from the PI set due to their lack of specificity for the home situation. These excluded PIs include, keep knowledge up to date, trained personnel for administration, and communication and documentation regarding toxicity. 4 oncological PIs were relocated to the general PI set as they apply to all care pathways related to PMAH. 1 additional PI has been added to the oncological PIs by the expert team.

Experts indicated that a distinction in the PI set can be made between *structure indicators* and *process indicators*. Structure indicators are defined as parameters that provide insight into what systematic steps are taken in the process, while PIs are more focussed on the substantive process of PMAH and provide insight into what is regulated around PMAH [17]. This distinction was made in the general set of PIs considering there are two indicators for antibiotic and oncology PIs.

Benchmark phase

3.5 Pilot benchmark

Table 6 shows the results of the pilot benchmark, conducted by the expert team. From this, it can be concluded that 34 out of the 35 PIs are scored as present in at least one of the three mProve hospitals. Furthermore, 23 out of the 35 PIs (65.7%) are present in all three mProve hospitals. Among them, hospital B complied with the highest number of PIs, specifically 32 out of 35 (91.4%). Hospital A met 29 out of the 35 PIs (82.9%), while hospital C met 25 out of the 35 PIs (71.4%). On average, 81,9% of the PIs were present per hospital.

From Table 6 several conclusions can be drawn, including: (1) All hospitals met the specific PIs for both antibiotics and oncology, (2) The presence of structure indicators was relatively lower (mean across the three mProve hospitals: 71.1%) compared to process indicators (mean across the three hospitals: 87.5%), (3) with respect to PI 1, none of the hospitals complied, as no hospital had a structured framework in place for safety and effectiveness in the context of PMAH, (4) PIs related to self-administration (i.e., PI 5 and 21) scored low. It was discovered that only hospital B met the requirements of the PIs regarding self-administration.

Regarding the survey comments of the pilot benchmark, one expert indicated that if a care pathway does not meet the established PI, it implies that the entire hospital fails to score well on that particular indicator. Additionally, one expert provided a suggestion for a possible textual modification. This involved a change in formulation from *treatment team* to *committee* in PI 2 (see Appendix 8). This because *committee*, in the context of Dutch hospitals is a more comprehensive approach in place of *treatment team*. Overall, after considering the identified areas for improvement, the experts concluded that the PI set in the pilot benchmark are appropriate to use as a definitive PI set.

Table 7 presents the final set of PIs, which consists of 31 generic PIs, 2 antibiotic PIs, and 2 oncology PIs. In the *OLD* column in table 7, the old codes from Table 4 are listed to trace the origin of the PIs.

Table 6 – Pilot Benchmark among three mProve hospitals with process indicators scored as available

General Process Indicators			
Structure Indicators	Available		
	Hospital A	Hospital B	Hospital C
1) framework for safe and effective care			
2) Formally treatment team consisting of physician, pharmacist, nurse	✓	✓	
3) System for quality assurance		✓	
4) (internal) qualification requirements		✓	
5) Policy in case of self-administration		✓	
6) System for rapid communication	✓	✓	✓
7) Communication between PMA-team and stakeholders	✓	✓	✓
8) policy regarding responsibilities for standby	✓	✓	✓
9) Selection of drug delivery device	✓	✓	✓
10) PMA structurally implemented	✓	✓	✓
11) Hospital applies quality criteria for PMA process.	✓	✓	
12) Policy first dose of medication	✓	✓	✓
13) Double check of medication	✓	✓	✓
14) Frequent formal meetings	✓	✓	✓
15) Monitoring of satisfaction status and experience		✓	
Sub-total:	10	14	8
Process Indicators	Available		
	Hospital A	Hospital B	Hospital C
16) Patient selection criteria for PMA	✓	✓	✓
17) Initial assessment for inclusion.	✓	✓	✓
18) Decision possibilities for PMA.	✓	✓	✓
19) Defined roles per medication pathway	✓	✓	✓
20) Protocol for urgent discussions	✓	✓	✓
21) In case of self-administration, satisfaction by stakeholders		✓	
22) Patients educational material	✓		✓
23) Standard order set form PMA	✓	✓	✓
24) Monitoring plan for PMA	✓	✓	✓
25) Rescue medication in PMA	✓	✓	✓
26) Protocol for vascular access systems	✓	✓	
27) Removal of intravascular access device	✓	✓	
28) Frequency of clinical assessment	✓	✓	✓
29) Adverse events are documented	✓	✓	✓
30) Instructions regarding disposal (hazardous) drugs	✓	✓	✓
31) Hazards and safe handling of high-risk medication	✓	✓	✓
Sub-total:	15	14	13
Antibiotic Indicators			
	Available		
	Hospital A	Hospital B	Hospital C
A1) Laboratory monitoring,	✓	✓	✓
A2) Regularly review by the OPAT specialist nurse and physician	✓	✓	✓
Sub-total:	2	2	2
Oncologic Indicators			
	Available		
	Hospital A	Hospital B	Hospital C
O1) Competency and proficiency in administering oncolytics	✓	✓	✓
O2) Administration records is available to the treatment team	✓	✓	✓
Sub-total:	2	2	2
Total:	29	32	25

Table 7 - Definitive List of Generic Process Indicator

	Definitive General Process Indicators	Reference	OLD
1.1 Structure Indicators			
1.	A structured program is available which provides a framework for safe and effective care.	[5, 6, 10, 44]	1
2.	The hospital has a formally established committee dedicated to the policy regarding administration of parenteral medication (PMAH) in the home situation. This treatment team consists at least of: a. A physician. b. A pharmacist. c. A nurse.	[10, 44-50]	2
3.	There is a system for ongoing quality assurance regarding PMAH.	[5, 6, 45, 51]	14
4.	There are (internal) qualification requirements to establish a minimum standard to caregivers involved in implementing PMAH, this includes: a. Requirements regarding initial qualification. b. Periodic monitoring regarding qualification.	[6, 44, 51, 60]	5
5.	There is a policy in case of self-administration. Patients or caregivers should be trained in the administration of intravenous medication.	[10, 45, 47, 49, 64]	19
6.	There is a system in place for rapid communication between the patient and care givers.	[6, 10, 44, 55, 59]	8
7.	There should be communication between the PMAH-team and other stakeholders in the process of PMAH. This includes: a. General practitioner. b. Home-administering organization. c. Referring clinician. The communication includes at least: - notification of the start of treatment to the general practitioner. - notification of completion of therapy. If applicable: notification of complications.	[5, 10, 44, 45, 55, 59, 61]	9
8.	There is a policy regarding responsibilities for standby (24 hours a day).	[22, 59, 63]	03
9.	The PMAH-team should select the drug delivery device in agreement with the home health agency.	[6, 10, 44]	23
10.	The ability of PMAH in homecare is structurally implemented in the process.	[52, 59]	25
11.	If medications are prepared for administration outside the hospital's premises, the hospital applies quality criteria for this process.	[22]	01
12.	Policy regarding administration of first dose of medication.	[6, 45, 47]	26
13.	There is a policy regarding double check of medication in homecare.	[22, 60]	37
14.	Frequent formal meetings between stakeholders in the PMAH-process with the aim to constantly modify the protocol (up-to-date protocols).	[44, 51]	27
15.	The satisfaction status and experience of patients receiving PMAH in homecare should be monitored.	[10, 56, 57]	32
1.2 Process Indicators			
16.	There are patient selection criteria for the eligibility for PMAH in homecare. This includes at least: a. The patient is willing to comply with the treatment plan and has given informed consent. b. There is no clinical contradiction to discharge the patient from the hospital. c. The patient has a hemodynamic stable condition. d. There is a safe home environment and adequate support (i.e., the place of administration is clean, running water, needle disposal, and space for storage of supplies).	[6, 44, 45, 47-49, 51-59]	4

	e. Additional need for complex care will be taken into consideration (e.g., wound care, physical therapy). f. Taking care of the psychosocial factors of a patient (e.g., alcohol and drug abuse). g. Cognitive burden of a patient.		
17.	A competent caregiver should perform an initial assessment for inclusion.	[6, 10, 49]	16
18.	The patient and caregiver decide together on the possibilities for PMAH.	[10, 44, 49]	17
19.	Defined roles per medication pathway which outlines the responsibilities of the caregivers involved within the process of PMAH in homecare. This includes responsibility for: a. Patient selection. b. Facilitation of medical materials. c. Adequately trained personnel. d. Preparation of medication. e. Transportation of medication. f. Administration of medication. g. Monitoring. h. Follow-up (including treatment of related and/or unrelated co-morbidities).	[5, 6, 44, 48, 49, 56, 57, 59]	6
20.	There is a protocol in place for urgent discussions, handling and review of emergent clinical problems during PMAH according to clinical need.	[10, 22, 49, 56-59]	7
21.	In case of self-administration, both the nurse specialist and patient/caregiver should be satisfied of the patient's/caregiver's competence, and this should be documented.	[4, 10, 45, 47, 49, 64]	20
22.	Patients educational material should be available regarding home administration in written or multimedia form.	[6, 10, 48, 51, 56, 57, 59]	21
23.	There is a standard order set to the home administering organisation regarding the discharge of patients with PMAH. This includes at least: a. Patients full name. b. Date of birth. c. Diagnosis. d. Regimen name. e. Protocol home administration. f. Contra-indication and allergies. g. (if applicable) other relevant protocols. h.(if applicable due to treatment and/or because of illness) additional infection prevention measures.	[5, 10, 22, 44, 46, 51, 59]	15
24.	The treatment and monitoring plan for PMAH in homecare should include a. Indication b. Medication name c. Dose d. Frequency e. Duration f. Type of administration (e.g., continuous or bolus infusion) g. Access device used (e.g., peripherally inserted central catheter, tunneled catheter) h. Criteria for the notification of deviating vital signs	[5, 6, 10, 21, 44-46, 48, 51, 56, 57, 59, 60]	22
25.	Rescue medication is available during PMAH.	[60]	28
26.	A protocol is available for vascular access systems (e.g. PICC or Proth-A-Cath) used regarding the outpatient setting.	[10, 44, 45, 47]	29

27.	There are agreements established regarding the removal of the intravascular access device at the end of treatment (if not needed for another reason)	[10, 47]	36
28.	Agreements have been established regarding frequency of clinical assessment of the patient by physicians and nurses	[6, 49, 56, 57]	30
29.	Adverse events related to device, medication use, and toxicity are documented in a traceable way.	[10, 47, 51, 52, 60]	35
30.	Instructions are available regarding disposal of (hazardous) drugs.	[66]	O13
31.	There are instructions regarding the hazards and safe handling of high-risk medication.	[66]	O14 + O15
2. Definitive Antibiotic Process Indicators			OLD
A1.	There is a policy regarding laboratory monitoring, including: a. Measurement technique and frequency per antibiotic. b. Responsibility of sample collection in outpatient setting. c. (If applicable) Antibiotic blood levels should be measured (narrow therapeutic window) throughout the course of OPAT treatment.	[6, 10, 45, 47, 51, 59, 60]	A8
A2.	The treatment plan of patients who receive in excess of 1 week of antimicrobial therapy should be regularly reviewed by the OPAT specialist nurse and physician (narrow-spectrum antibiotics, intravenous-oral switch) in conjunction/consultation with the referring specialist, as necessary.	[10, 51]	A9
3. Definitive Oncology Process Indicators			OLD
O1.	There are arrangements for the home-administrating organization regarding competency and proficiency in administering oncolytics in the home setting.	[22, 48, 51, 66]	O4
O2.	Up-to-date information about the date and time of each administration (administration records) is available to the treatment team.		-

4 Discussion

This study aimed to develop a general set of process indicators to assess and improve the quality of PMAH and evaluate the developed set in a pilot benchmark between Dutch hospitals. Based on a modified version of the RAND appropriateness method, a set of 65 PIs has been extracted from literature. From this set, a total of 35 PIs has been defined as appropriate for inclusion. Among these, 31 PIs are identified as general PIs applicable to all care pathways within the context of PMAH, while 2 PIs are specifically relevant to antibiotic use and another 2 PIs are designated for oncology. The pilot benchmark, utilizing the 35 developed PIs, evaluate the applicability of the PI set, and provides initial insights into the presence and absence of elements within the PMAH process across three mProve hospitals.

Out of the 65 extracted PIs from the literature, a total of 33 PIs were rejected by the participating stakeholders and experts. The PIs rejected in this thesis were removed from the PI set for the following most common reasons, given by the stakeholders and experts: (1) being general and not specific to PMAH, (2) not applicable in the Dutch healthcare setting, and (3) overlapping with other PIs included in the PI set. The stakeholders who participated in the online survey and focus group meetings expressed a preference for a concise set of PIs. In comparison to other studies using the same methodology, the percentage of PIs removed in this study (54.1%) is not deviating from the amount of removed PIs in other studies (64.7% [10], 57.6% [20], 25.0% [67], 67.8% [68], 50.1% [69]). In future similar studies to this study, it may be considered to include the applicability of a PI to a specific healthcare system in a country as an inclusion criterion in the extraction of PIs from literature.

The RAND appropriateness method is commonly used to assess PIs in practice through focus group meetings, however stakeholders in the focus group meetings expressed that they perceived the online survey with 61 PIs as excessively time-consuming. The average time taken by stakeholders to complete the survey could not be determined, as most stakeholders filled it out between their regular employments and did not register the time spend on filling in the survey. The RAND appropriateness method does not provide specific recommendations regarding the length of a PI set, and when looking at similar studies using the same method, the number of PIs assessed in the studies varies widely from 16 till 117 PIs [10, 20, 67, 68, 70-72]. However, these studies do not indicate that the surveys were perceived as time-consuming. It is possible that the target group regarding the stakeholders in this thesis, consisting of healthcare professionals who already have busy schedules, contributed to the perception of the survey as time-consuming. Additionally, 12 PIs were removed after the focus group meetings because they were considered to be generally applicable, indicating that a more stringent pre-selection of the PI set could have been conducted. For future studies, it is important to consider that surveys among healthcare professionals may be perceived as time-consuming, and it is crucial to keep the surveys as concise and focused as possible.

The stakeholders from the focus group meetings reveal a lack of clarity regarding the formalized PMAH team, including its members and functions, regarding PI 2 of Table 4. In one of the focus group meetings it was emphasized that there is a need to transition from a project phase to a fully operational process that could incorporate a PMAH team. These findings correspond with a recent study by McGlen et al. [62], which suggests that the rapid

development of home administration may not allow sufficient time for concurrent changes in other process aspects. In contrary, the OPAT practice guide emphasize that there should be a pre-defined formal PMAH team implemented in the hospital [73]. Due to the rapid development of PMAH in recent years, mProve hospitals have not yet had the opportunity to establish a formal team dedicated to PMAH, which is recommended from the OPAT practice guide [73].

The pilot benchmark yielded several results. Nevertheless, the results of the pilot benchmark are indicative, as the pilot benchmark was conducted among a small homogeneous group consisting of three hospital pharmacists. However, the aim of the pilot benchmark was to evaluate the developed PIs. It was found from the pilot benchmark that 34 out of the 35 developed PIs were available in at least one of the three hospitals. This result demonstrates that the PIs are measurable within the mProve setting, and therefore, the benchmark can be implemented across the seven mProve hospitals. The PI that was not assessed as present in any of the three mProve hospitals is *a structured program is available which provides a framework for safe and effective care*. This finding is not in line with the expectation that hospitals place a high emphasis on quality and safety [74-76]. Respondents indicated that currently in most hospitals an established framework per care pathway regarding safety and effective care is in place, but an overarching structural program within the hospitals is still lacking. This finding is confirmed in a recent study conducted by NIVEL, in which *interdepartmental collaboration* was rated low by healthcare professionals in Dutch hospitals in relation to patient safety [26]. Given that PMAH entails collaboration between the hospital and a home care organization, this could potentially explain the lack of joint efforts in establishing a structured framework for ensuring safe and effective care. However, the implementation of the developed PI set within the mProve hospitals could serve as a structured framework for monitoring safe and effective care. By consistently applying the PI set, hospitals can establish standardized measures and processes to ensure the quality of care provided [18].

The three mProve hospitals in which the pilot benchmark was conducted collectively met 23 out of the 35 established PIs. This result is in line with a study showing that accreditation requirements of the safety management system (VMS) are not being fulfilled by the Dutch hospitals [77]. Additionally, an evaluation study conducted by NIVEL demonstrates that no hospital fully complies with the VMS quality standards [78]. A possible explanation for this result is that the Medication@Home project is still in the process of being integrated in the hospital system, as highlighted during the focus group meeting of hospital C. However, this highlights the significance of the PI set, as it indicates room for improvement and enables continuous measurement over time to assess the hospitals' progression with respect to the established PIs. This ability to track and monitor progress provides valuable insights into the evolving implementation of Medication@Home.

The pilot benchmark indicates that only one hospital has both PIs pertaining to self-administration in place. This result implies that there is currently no policy in 67% of the three mProve hospitals. An underlying reason to this lack of policy regarding self-administration could be inadequate focus on promoting patient self-management. Contrary to this, guidelines from other studies advocate for the perceived benefits of self-administration [10, 45, 47, 73]. A potential rationale for this finding may be healthcare providers' hesitancy to

delegate autonomy to patients in their routine practice. Moreover, it is noted that a lack of trust in patients' knowledge regarding self-administration acts as barrier to stimulate self-administration [79].

This study is subject to certain limitations. First, the same group of experts was involved in multiple phases, including screening, online survey, focus group meetings, and pilot benchmark. This could introduce expertise bias, potentially resulting in incomplete representation of perspectives and opinions from other experts [80]. Consequently, there might be limited diversity of viewpoints, which could affect the generalizability of the study findings. However, to address this limitation, multiple focus group meetings were conducted, and a broadly composed group of stakeholders with various roles within the different hospitals were included in the online survey. This attempt aimed to consider a diverse stakeholder group and reduce the potential impact of expertise bias.

Second, it is essential to acknowledge the potential presence of selection bias in this study. While similar consensus studies have relied solely on the median for determining consensus, in this thesis a conscious decision was made to include the mode as a factor in suitability within the PI set [10, 67, 70]. By basing the results of the online survey on both median and the mode, due to time limitations for the focus group meetings, there was a smaller number of PIs discussed in the focus group meetings. The disadvantage of this approach is that some PIs may have been classified as inappropriate or appropriate, leaving no room for discussion in the focus group meetings. However, the distribution of a handout was aimed to correct this form of bias. This handout contains a comprehensive compilation of appropriate, questionable, and inappropriate PIs and has given stakeholders the opportunity to comment during the focus group meetings. Nevertheless, no stakeholder provided any comments or feedback in the handout. This could indicate either a general agreement or a lack of engagement and active participation from the stakeholders.

Third, a comparison and integration has been carried out between the antibiotic and oncology care pathways and the generalized indicator set to incorporate any necessary adaptations specific to these pathways. However, this procedure is not being performed for other care pathways (e.g., palliative treatments). While the inclusion criteria involve stakeholders from various care pathways, it is advisable to engage experts from specific care pathways during the implementation of the PI set to address any specific additions.

Fourth, during the focus group meetings, we made the decision to exclude the antibiotic PI set in hospital C and the oncological PI set in hospital A. As a result, the conclusions are based on a smaller and less diverse group. However, the likelihood of selection bias is minimal because stakeholders themselves acknowledged a lack of expertise in the respective PI sets. In both PI sets (antibiotics and oncology), the conclusions regarding the appropriateness of the PIs were relatively consistent among the two participating hospitals.

Fifth, due to the absence of a medical microbiologist in the focus group meetings, the aspect of infection prevention was not thoroughly examined for suitability in the PI set. This is attributed to attrition bias and is defined as a selective drop out of stakeholders who systematically differ from stakeholders who participated in a study [80]. In this study the medical microbiologist was unable to participate in the focus group meetings and is therefore

underrepresented in this study. However, the focus group meetings, including infectious disease specialists, were asked if additional PIs were needed, resulting in the inclusion of one supplementary PI in the PI set. Although infection prevention is included in the PI set, future research may consider the involvement of a medical microbiologist for further investigation.

Sixth, regarding the pilot benchmark, there was no specific survey into stakeholders' feedback on the process of completing the pilot benchmark and whether any aspects were missing. This absence of stakeholders' feedback may lead to a less valid PI set. To assess the stakeholders' perception of the PI set, further research is necessary to determine the validity of the developed PI set.

Last, this study could not determine the performance regarding the established PIs in all seven mProve hospitals due to time limitations. Carrying out a benchmark across seven hospitals is a complex and time-consuming task that, upon closer examination, could not be accomplished within the scope of this study. Therefore, based on the existing literature, a decision was made to conduct a pilot benchmark within the three mProve hospitals [30, 31].

In addition to the limitations, this study also has several strengths. First, the development of the PIs has been based on the use of validated measurement instruments. The RAND appropriateness method, a widely employed approach has been utilized for the development of the PIs [28]. This involved conducting a literature review and holding three focus group meetings. Second, data has been collected from three different hospitals, involving 19 stakeholders with diverse backgrounds in medical practice, administrative, and even external home care organizations. Third, the study provides a first insight into the applicability of the developed PI set in professional practice through the use of a pilot benchmark. Fourth, The PIs obtained from the literature are based on international guidelines and studies, making the PI set internationally applicable.

The findings of this study have implications for research, clinical practice, and healthcare organizations. Existing PIs focussed on assessing the quality of PMAH are targeted towards specific treatments and medical conditions [10, 22, 45, 58, 73]. However, to our knowledge, there is no universally applicable PI set available that addresses PMAH across multiple care pathways. The PI set developed in this study distinguishes itself from other studies due to its general approach. Through stakeholders' evaluation based on existing literature, indicators suitable for universal use across multiple care pathways were assessed. This broad applicability was further validated through the inclusion of a diversity of stakeholders in the focus group meetings representing various care pathways, including antibiotics and oncology. Additionally, the developed PI set was pilot benchmarked. Unlike many consensus studies that conclude upon reaching consensus on the final PI set [10, 31, 60], this study examines the practical application of the PI set through pilot benchmarking. The PI set provides initial insights into the presence or absence of the developed PIs in the three mProve hospitals. The presence of 34 out of the 35 developed PIs in at least one hospital demonstrates the feasibility of the developed PI set.

The implementation of the developed PI set has the potential to not only assess the quality within the participating mProve hospitals, but also to evaluate the quality of PMAH across other healthcare organizations. Since the PI set has been developed based on international

literature, it is expected to be a general tool that can be applied in developed countries with similar healthcare systems to the Netherlands. It should be noted that a few PIs were removed during the development process because they were not suitable for the Dutch healthcare system. Furthermore, when the PI set is incorporated and utilized within the organizations, it facilitates the exchange of information and the dissemination of best practices among various healthcare institutions.

Future research can be conducted to implement a benchmark among the seven mProve hospitals in order to obtain representative results. This can provide insights into areas where the seven hospitals can improve regarding the quality of PMAH. In addition to the benchmark, a questionnaire can be included to gather participants' feedback on their experience of completing the benchmark and to identify any missing points. This can help enhance the validity of the PI set. Potential challenges and issues encountered by (external) homecare organizations could be explored, regarding the referral of patients with PMAH from hospitals to their care. Gaining a deep understanding of these factors could positively impact the collaboration between hospitals and home care organizations. Additionally, further research could delve into the domain of infection prevention to provide a more comprehensive and extensive investigation, by examining more closely the perspective of a medical microbiologist. Lastly, an implementation study could evaluate the effectiveness of the developed PI set, monitoring the continuation of the developed PI set within the mProve hospitals or a broader context.

5 Conclusion

A comprehensive set of 35 PIs has been developed and pilot benchmarked using the modified RAND appropriateness method to assess the process of PMAH in the home setting. Within this PI set, 2 PIs have been specially tailored for the antibiotic, and 2 PIs for oncological care pathway. The evaluation of the PI set through a pilot benchmark in three mProve hospitals has demonstrated its applicability for conducting a benchmark among seven mProve hospitals. This because, 34 out of the 35 developed PIs were scored as present in at least one of the three mProve hospitals. However, the implementation of the PI set within the seven mProve hospitals may reveal areas where the hospitals can improve in terms of the quality of care. By embedding this PI set systematically within the organizations and repeatedly assessing compliance with the PIs, continuous quality improvement may be achieved. Furthermore, the PI set is developed for applicability beyond the mProve hospitals, making it relevant for similar healthcare settings.

6 References

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8. Appendix

Appendix 1 – Literature Review with systematic search

1.1 Search Syntax

PUBMED – Number of articles: 221		
Date	Search Term	Results
29-03-23	(Parenteral OR infusion) AND Outpatient	5,133
29-03-23	(Parenteral OR infusion) AND (Outpatient OR Discharged)	11,689
29-03-23	Parenteral AND (Outpatient OR Discharged) AND Medication	1,764
29-03-23	Parenteral AND (Outpatient OR Discharged) AND Medication AND (Organi*)	172
29-03-23	(Outpatient OR Discharged) AND Medication AND (Organi*)	20,949
30-03-23	(Outpatient OR Discharged) AND Medication AND (Organi* OR Regulations)	30,272
30-03-23	Parenteral AND (Outpatient OR Discharged) AND Medication AND (Organi* OR Regulations)	203
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations)	383
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR “Hospital Transferred Care”)	442
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR “Hospital Transferred Care” OR Process)	588
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR “Hospital Transferred Care” OR Process OR Policy)	660
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR “Hospital Transferred Care” OR Process OR Policy) NOT nutrition	405
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Hospital Transferred Care OR Process OR Policy OR “Hospital based care”)	661
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Hospital Transferred Care OR Process OR Policy OR “Hospital based care” OR framework)	673
30-03-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Hospital Transferred Care OR Process OR Policy OR “Hospital based care” OR framework) NOT “Nutrition”)	402
30-03-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Hospital Transferred	395

	Care OR Process OR Policy OR "Hospital based care" OR framework) NOT "Nutri*")	
30-03-23	("Parentera*" AND (Thuis OR Polikliniek) AND ("ziekenhuisverplaatste zorg" OR Organisatie OR Proces))	5
30-03-23	("Parentera*" AND ("ziekenhuisverplaatste zorg" OR Organisatie OR Proces OR Richtlijn))	7
3-4-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Hospital Transferred Care OR Process OR "Hospital based care" OR framework) NOT "Nutri*")	126
3-4-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Guideline OR Regulations OR "Hospital Transferred Care" OR Process OR "Hospital based care" OR framework) NOT "Nutri*") Free Text Available	149
3-4-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Guideline OR "performance metrics" OR Regulations OR "Hospital Transferred Care" OR Process OR "Hospital based care" OR framework) NOT "Nutri*") Free Text Available	149
4-4-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Guideline OR "performance metrics" OR Regulations OR "Hospital Transferred Care" OR Process OR "Hospital based care" OR framework) NOT "Nutri*")	431
4-4-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Guideline OR "performance measure" OR Regulations OR "Hospital Transferred Care" OR Process OR "Hospital based care" OR framework) NOT "Nutri*")	431
4-4-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Guideline OR "performance measures" OR Regulations OR "Hospital Transferred Care" OR Process OR "Hospital based care" OR framework) NOT "Nutri*")	431
4-4-23	(Parenteral AND Medication AND (Outpatient OR Discharged) AND (Organi* OR Guideline OR Regulations OR "Hospital Transferred Care" OR Process OR "Hospital based care" OR framework) NOT "Nutri*")	240
4-4-23	(Parenteral AND Medication AND (Outpatient OR Discharged) AND (Organi* OR Guideline OR Regulations OR "Hospital Transferred Care" OR Process OR "Hospital based care" OR framework) NOT "Nutri*") Only Dutch AND English	221

SCOPUS – Number of articles: 58		
Date	Search Term	Results
29-03-23	(Parenteral OR infusion) AND Outpatient	7,288
29-03-23	(Parenteral OR infusion) AND (Outpatient OR Discharged)	11,212
29-03-23	Parenteral AND (Outpatient OR Discharged) AND Medication	318
29-03-23	Parenteral AND (Outpatient OR Discharged) AND Medication AND (Organi*)	31
29-03-23	(Outpatient OR Discharged) AND Medication AND (Organi*)	2491
30-03-23	(Outpatient OR Discharged) AND Medication AND (Organi* OR Regulations)	3,017
30-03-23	Parenteral AND (Outpatient OR Discharged) AND Medication AND (Organi* OR Regulations)	37
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations)	339
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR “Hospital Transferred Care”)	339
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Process)	465
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Process OR Policy)	509
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Process OR Policy) NOT nutrition	49
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Process OR Policy OR “Hospital based care”)	509
30-03-23	Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Process OR Policy OR framework)	524
30-03-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Process OR Policy OR framework) AND NOT “Nutrition”)	51
30-03-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Process OR Policy OR “Hospital based care” OR framework OR “Hospital Transferred Care”) AND NOT “Nutri*”)	382
3-4-23	(Parenteral AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR “Hospital Transferred Care” OR Process OR “Hospital based care” OR	366

	framework OR "Hospital at Home") AND NOT "Nutri*")	
4-4-23	(Parenteral AND Medication AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR "Hospital Transferred Care" OR Proses OR "Hospital based care" OR framework OR "Hospital at Home") AND NOT "Nutri*")	44
4-4-23	(Parenteral AND Medication AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Guideline OR "Hospital Transferred Care" OR Proses OR "Hospital based care" OR framework OR "Hospital at Home") AND NOT "Nutri*")	67
4-4-23	(Parenteral AND Medication AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Guideline OR "Performance Metric*" OR "Hospital Transferred Care" OR Proses OR "Hospital based care" OR framework OR "Hospital at Home") AND NOT "Nutri*")	67
4-4-23	(Parenteral AND Medication AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Guideline OR "Performance Measure*" OR "Hospital Transferred Care" OR Proses OR "Hospital based care" OR framework OR "Hospital at Home") AND NOT "Nutri*")	67
4-4-23	(Parenteral AND Medication AND (Outpatient OR Discharged) AND (Organi* OR Regulations OR Guideline OR "Hospital Transferred Care" OR Proses OR "Hospital based care" OR framework OR "Hospital at Home") AND NOT "Nutri*") AND (LIMIT-TO Language, "English")	58

1.2 Selection of literature

Selection search syntax			
Search syntax	Database / Scope	Date	Number or Results
(Parenteral AND Medication AND (Outpatient OR Discharged) AND (Organi* OR Guideline OR Regulations OR "Hospital Transferred Care" OR Process OR "Hospital based care" OR framework) NOT "Nutri*") Only Dutch AND English	PubMed / All fields Limited to language, English and Dutch	4-4-23	221
(Parenteral AND Medication AND (Outpatient OR	Scopus / All Fields	4-4-23	58

Discharged) AND (Organi* OR Regulations OR Guideline OR "Hospital Transferred Care" OR Prosess OR "Hospital based care" OR framework OR "Hospital at Home") AND NOT "Nutri*") AND (LIMIT-TO Language, "English")	Limited to language, English		
Total number of articles in Convidence		279	
Exclusion duplicates		28	
Exclusion based on title and abstract		216	
Exclusion based on no free access for scientists		7	
Exclusion based on other exclusion criteria		2	
Total number of literature included in this research		26	
Total number of literature included through other sources		2	
Total number of literature included through snowballing		1	

1.3 Selected Articles

Selected Articles by literature search		
Title	Year	Author
Outpatient treatment in the University Hospital Utrecht: organization and infrastructure	1994	P.O. Witteveen
Outpatient Parenteral Antibiotic Therapy in Older Adults	2023	N.T. Oliver, M.J. Skalweit
Practice Guidelines for Community-Based Parenteral Anti-Infective Therapy	1997	D.N. Williams, S. J. Rehm, A.D. Tice, J.S. Bradley, A.C. Kind, W.A. Craig
Parenteral Antibiotic Therapy in Outpatients: Quality Assurance and Other Issues in a Prothospital	1991	L.J. Eron
The impact of an infectious disease expert team on outpatient parenteral antimicrobial treatment in the Netherlands	2019	R. Wijnakker, L.E. Visser, E.F. Schippers, L.G. Visser, N.D. Burgel van, C. Nieuwkoop van
Current Practices and Opportunities for Outpatient Parenteral Antimicrobial Therapy in Hospitals: A National Cross-Sectional Survey	2022	H. H. Stoorvogel, M.E.J.L., H.F. L. Wertheim, E.P.F. Yzerman, M. Scholing, J.A. Schouten, J. Oever ten
Outpatient Parenteral Antimicrobial Therapy and Antimicrobial Stewardship	2016	K.A. Bauer, J.E. Mangino, D. Paolo-Hohman, D.A. Goff
Quality of outpatient parenteral antimicrobial therapy (OPAT) care from the patient's perspective: a qualitative study	2018	M.A.H. Berrevoets, A.J.M. Oerlemans, M. Tromp, B.J. Kullberg, J. Oever ten, J.A. Schouten, M.E. Hulscher

2018 Infectious Diseases Society of America Clinical Practice Guideline for the Management of Outpatient Parenteral Antimicrobial Therapy	2018	A.H. Norris, N.K. Shrestha, G.M. Allison, S.C. Keller, K.P. Bhavan, J.J. Zurlo, A.L. Hersh, L.A. Gorski, J.A. Bosso, M.H. Rathore, A. Arrieta, R.M. Petrak, A. Shah, R.B. Brown, S.L. Knight, C.A. Umscheid
Quality indicators assessing antibiotic use in the outpatient setting: a systematic review followed by an international multidisciplinary consensus procedure	2018	M. Maréchal Le, G. Tebano, A.A. Monnier, N. Adriaenssens, I.C. Gyssens, B. Huttner, R. Milanic, J. Schouten, M. Stanic Benic, A. Versporten, V. Vlahovic-Palcevski, V. Zanichelli, M.E. Hulscher, C. Pulcini
Applicability of Quality Indicators for Appropriate Antibiotic use in Outpatient Parenteral Antimicrobial Therapy (OPAT): A Point Prevalence Survey	2021	P. March-López, Inés A. Freixa, M.M. Gil, G.A. Espinoza, L.O. Polonio, E.C. Paredes, M.C. Sanchez, C. Sangrador, J. Pardo, J. Nicolás, E. Calbo
Impact of a Multidisciplinary Team Review of Potential Outpatient Parenteral Antimicrobial Therapy Prior to Discharge from an Academic Medical Center	2011	B.H. Heintz, J. Halilovic, C.L. Christensen
Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society	2011	J.O. Jacobson, M. Polovich, T.R. Gilmore, L. Schulmeister, P. Esper, K.B. LeFebvre, M.N. Neuss,
The oncology pharmacist as part of the palliative treatment team	2020	M. Crul, P. Oosterhof
2013 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for the Safe Administration and Management of Oral Chemotherapy	2013	<i>M.N. Neuss, M. Polovich, K. McNiff, P. Esper, T.R. Gilmore, K.B. LeFebvre, L. Schulmeister, J.O. Jacobson</i>
Quality Assurance	1993	M.J. Kunkel
Recommendations for outpatient parenteral antimicrobial therapy in Brazil	2017	<i>P.R. Oliveira, V.C. Carvalho, S. Cimerman, A.L. Munhoz Lima</i>
Monitoring guidelines for home and outpatient parenteral antibiotic therapy	2000	A.Y. Martel
National Guidelines on the Provision of Outpatient Parenteral Antimicrobial Therapy (OPAT)	2020	E. Sweeney, N. Curtin, E. Barra de, K. Burns, E. O'Neill, E. Feeney, H. Tuite, A. Jackson, P. Gavin, S. Clarke, S. O'Connell, E. Muldoon
Optimization of a model of out-of-hospital antibiotic therapy (OPAT) in a Belgian university hospital resulting in a proposal for national implementation	2016	T. Ravelingien, F. Buyle, S. Deryckere, E. Sermijn, M. Debrauwere, K. Verplancke, S. Callens, S. Commeyne, C. Pattyn, D. Vogelaers

Supervised self-administration of outpatient parenteral antibiotic therapy: a report from a large tertiary hospital in Australia	2015	S. Subedi , D.F.M. Looke, D.A. McDougall, M.M. Sehu, E.G. Playford
Training Patients to Administer Intravenous Antibiotics at Home	1981	P. Jhen, M. Swens
The Team Concept	1993	A.D. Tice
Safe Handling of Hazardous Drugs in Home Infusion	2021	S. Eisenberg, C. Klein
Failure modes and effects analysis to improve transitions of care in patients discharged on outpatient parenteral antimicrobial therapy	2021	E.D. Sadler
Selected Articles through other sources		
Title		Author
The delivery of chemotherapy at home: an evidence synthesis	2015	M, Corbett, M. Heirs, M. Rose, A. Smith, L. Stirk, G. Richardson, D. Stark, D. Swinson, D. Craig, A. Eastwood
Hospital at home: A systematic review of how medication management is conceptualized, described and implemented in practice - A study protocol	2023	S. McGlen, C. Crowley, D. Lasserson, Z.A.L. Qamariat, R.H.M. Lim
Selected Articles by snowballing		
Title		Author
Quality Indicators for Appropriate Outpatient Parenteral Antimicrobial Therapy in Adults: A Systematic Review and RAND-modified Delphi Procedure	2020	M.A.H. Berrevoets, J. Oever ten, A.J.M. Oerlemans, B.J. Kullberg, M.E. Hulscher, J.A. Schouten

Appendix 2 – Example Survey Question



Onderdeel 1 - Generieke Indicatoren

Deze vraag is opgedeeld in twee gedeelten. De eerste vraag gaat over hoe u de procesindicator in zijn geheel beoordeeld. De tweede vraag gaat over hoe u de sub-indicatoren afzonderlijk van elkaar beoordeeld.

2) Het ziekenhuis beschikt over een formeel ingesteld team dat zich bezighoudt met toediening van Parenterale Medicatie in de Thuisituatie (PMT) Dit PMT-team bestaat ten minste uit:

- Een arts die ervaring heeft met het toe te dienen medicament.
- Een apotheker die ervaring heeft met infusie in de thuissituatie.
- Een verpleegkundige die ervaring heeft met parenterale medicatie toediening.

(There is a formal PMA-transfer team. This team will have to include at least:

- A physician experienced with the administered medication*
- A pharmacist experienced with outpatient infusion*
- A nurse experienced in intravenous therapy)*

Ongeschikt Geschikt
1 2 3 4 5 6 7 8 9



Hoe geschikt vindt u onderstaande sub-indicatoren op de bovenstaande procesindicator?

- a. Een arts die ervaring heeft met het toe te dienen medicament.

Ongeschikt Geschikt
1 2 3 4 5 6 7 8 9



- b. Een apotheker die ervaring heeft met infusie in de thuissituatie.

2) *Het ziekenhuis beschikt over een formeel ingesteld team dat zich bezighoudt met toediening van Parenterale Medicatie in de Thuissituatie (PMT) Dit PMT-team bestaat ten minste uit:*

a. Een arts die ervaring heeft met het toe te dienen medicament.

b. Een apotheker die ervaring heeft met infusie in de thuissituatie.

c. Een verpleegkundige die ervaring heeft met parenterale medicatie toediening.

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mprove

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Opbouw

Wat in het dikgedrukt en onderstreept staat **wordt mogelijk verworpen of ter discussie gesteld:**

- Ongeschikte algemene proces indicatoren
- Twijfelachtige algemene proces indicatoren
- Ongeschikte antibiotica proces indicatoren
- Twijfelachtige antibiotica proces indicatoren
- Twijfelachtige oncologische proces indicatoren

- Notitie veld
- Tips & Tops

- Beoogde kern set algemene proces indicatoren
- Beoogde kern set antibiotica proces indicatoren
- Beoogde kern set oncologie proces indicatoren

Ongeschikte algemene proces indicatoren

3	<u>Een medisch specialist is voorzitter van het PMT-team en heeft hiervoor aantoonbaar tijd beschikbaar.</u>	
4	<p>Er zijn selectiecriteria voor patiënten die in aanmerking komen voor PMT in de thuissituatie. Deze omvatten:</p> <ul style="list-style-type: none"> a. De patiënt is bereid zich aan het vervolgplan te houden en heeft hiertoe toestemming gegeven. b. Er zijn geen medische contra-indicaties om de patiënt uit het ziekenhuis te ontslaan. c. Een overstap van parenterale naar orale medicatie is niet mogelijk. d. De patiënt is hemodynamisch stabiel. e. Er bestaat een veilige thuisomgeving met adequate voorzieningen (een schone plaats om toe te dienen, stromend water, opslagmogelijkheid voor hulpmiddelen). f. Aanvullende noodzaak om complexe zorg te moeten verlenen wordt meegenomen in de afweging voor PMT. g. Psychosociale factoren (bijv. alcohol en/of drugsverslaving, cognitieve stoornissen) moeten worden meegewogen. <u>h. De patiënt heeft begrip voor de keuze voor PMT.</u> i. Toegang tot vervoer voor doktersafspraken en toegang tot nooddiensten. De patiënt heeft de mogelijkheid om zich te (laten) verplaatsen voor afspraken in het ziekenhuis en toegang tot spoedeisende hulpdiensten. 	
11	<u>Het PMT-team draagt zorg voor het vaststellen van klinische uitkomsten van de medicamenteuze behandeling.</u>	
13	<u>Er zijn afspraken vastgelegd over de (maximale) reisafstand tussen het woonadres van de patiënt en het ziekenhuis.</u>	
31	<u>Er is beleid vastgesteld met betrekking tot communicatie via multimedia (bijvoorbeeld een applicatie, telefoon of website).</u>	
34	<u>De overlevingsstatus van patiënten die in aanmerking komen voor PMT, wordt gedocumenteerd (bijv. patiënten in leven, overleden aan infectie, overleden aan andere oorzaken, lost-to-follow-up, of status onbekend).</u>	

Twijfelachtige algemene proces indicatoren

- 2 Het ziekenhuis beschikt over een formeel ingesteld team dat zich bezighoudt met toediening van Parenterale Medicatie in de Thuisituatie (PMT) Dit PMT-team bestaat ten minste uit:
- a. Een arts die ervaring heeft met het toe te dienen medicament.
 - b. Een apotheker die ervaring heeft met infusie in de thuisituatie.**
 - c. Een verpleegkundige die ervaring heeft met parenterale medicatie toediening.

- 4 Er zijn selectiecriteria voor patiënten die in aanmerking komen voor PMT in de thuisituatie. Deze omvatten:
- a. De patiënt is bereid zich aan het vervolgplan te houden en heeft hiertoe toestemming gegeven.
 - b. Er zijn geen medische contra-indicaties om de patiënt uit het ziekenhuis te ontslaan.
 - c. Een overstap van parenterale naar orale medicatie is niet mogelijk.**
 - d. De patiënt is hemodynamisch stabiel.
 - e. Er bestaat een veilige thuisomgeving met adequate voorzieningen (een schone plaats om toe te dienen, stromend water, opslagmogelijkheid voor hulpmiddelen).
 - f. Aanvullende noodzaak om complexe zorg te moeten verlenen wordt meegenomen in de afweging voor PMT.
 - g. Psychosociale factoren (bijv. alcohol en/of drugsverslaving, cognitieve stoornissen) moeten worden meegewogen.
 - h. De patiënt heeft begrip voor de keuze voor PMT.
 - i. Toegang tot vervoer voor doktersafspraken en toegang tot nooddiensten. De patiënt heeft de mogelijkheid om zich te (laten) verplaatsen voor afspraken in het ziekenhuis en toegang tot spoedeisende hulpdiensten.**

- 9 Informatie-uitwisseling tussen het PMT-team en andere relevante stakeholders is ingeregeld. Dit omvat communicatie tussen het PMT-team en:
- a. Huisarts
 - b. Thuiszorg**
 - c. Hoofdbehandelaar
- (De communicatie omvat ten minste: melding van de start van de behandeling aan de huisarts (of indien anders, verantwoordelijke specialist), melding van acceptatie van PMT in de thuisituatie, melding van afronding van de therapie, melding van complicaties)

10	<p><u>In geval van co-morbiditeit (bijv. diabetes mellitus, hart- en vaatziekten) zijn de verantwoordelijkheden voor de behandeling van deze bijkomende aandoeningen tussen betrokken artsen, huisartsen en andere medische specialisten duidelijk gedefinieerd.</u></p>	
15	<p>Er is een standaard order set beschikbaar voor patiënten die uit het ziekenhuis worden ontslagen met PMT. Deze omvat ten minste:</p> <ul style="list-style-type: none"> a. De volledige naam van de patiënt. b. Geboortedatum. c. Diagnose. d. Naam van het geneesmiddel en cyclusnummer. <u>e. (Indien van toepassing) naam en nummer van het protocol.</u> <u>f. Intoleranties, contra-indicaties en allergieën (ICA).</u> g. Doseringen. h. Toedieningswijze. i. Inlooptijd van de infusie. j. Duur van de behandeling. <u>k. Ondersteunende zorgbehandelingen passend bij het behandelingsprogramma.</u> 	
18	<p>De patiënt en zijn familie worden geïnformeerd (mondeling en schriftelijk) over PMT in de thuissituatie. Deze informatie bevat ten minste:</p> <ul style="list-style-type: none"> a. Voordelen <u>b. Bijwerkingen</u> c. Mogelijke complicaties <u>d. Toegang tot een bloedvat</u> <u>e. Steriele technieken</u> <u>f. Verantwoordelijke arts voor niet-behandeling-gerelateerde ziekten</u> g. Instructie voor noodgevallen h. Gebruik van medicijnen i. Verantwoordelijkheden van de patiënt j. Contactenlijst 	
22	<p>Het behandelings- en monitoringplan voor PMT omvat de volgende elementen:</p> <ul style="list-style-type: none"> a. Indicatie. b. Naam van het geneesmiddel. c. Dosis. d. Frequentie. e. Duur. f. Type toediening (bijv. continue of bolus infusie). g. Gebruikt toegangssysteem (bv. perifeer ingebrachte centrale katheter, getunnelde katheter). <u>h. Follow-up plan.</u> i. Parameters voor de melding van abnormale vitale functies. 	

	<u>j. (Indien van toepassing) laboratoriumbewaking wordt overwogen. Bovendien kan de behandeling worden gewijzigd op basis van de laboratoriumresultaten (d.w.z. therapeutische geneesmiddelenbewaking).</u>	
24	<u>Er zijn criteria vastgesteld om de meest geschikte toedienlocatie (d.w.z. infuuscentrum, thuis, hemodialyse centrum) voor iedere patiënt vast te stellen.</u>	
25	<u>PMT is structureel in het klinische zorgproces geïmplementeerd, door een vroegtijdige en frequente betrokkenheid van de zorgverlener die het PMT-proces initieert.</u>	

Ongeschikte antibiotica proces indicatoren

A2	<u>Naast het PMT-team omvat het <i>Outpatient Antimicrobial Treatment (OPAT)</i>-team ook een:</u> <u>a. Infectieziekten-specialist of arts met kennis van infectieziekten en kennis van het gebruik van antimicrobiële middelen bij OPAT</u> <u>b. Maatschappelijk werker</u> <u>c. Laboratoriumtechnicus</u> <u>d. Microbioloog</u> <u>e. Coördinator thuiszorg</u> <u>f. Thuiszorg apotheker</u>	
A4	De criteria voor de infectieziekten-specialist zijn goed gedefinieerd: a. Vaststellen van de noodzaak van (parenterale) anti-infectieuze therapie. <u>b. De keuze van het antibioticum</u> <u>c. De wijze van aanvragen van de beoogde behandeling.</u> <u>d. Het monitoren van de patiënt tijdens de behandeling en de wijze van evaluatie van de klinische respons van de patiënt.</u>	
A5	<u>Het OPAT-behandelplan is een verantwoordelijkheid van de infectieziekten-specialist.</u>	
A6	<u>Een infectieziekten artsenconsult dient plaats te vinden voorafgaand aan de plaatsing van een intraveneus toegangssysteem.</u>	

Twijfelachtige antibiotica proces indicatoren

A1	<u>Parenterale thuistoediening van antibiotica maakt deel uit van een Antimicrobial Stewardship programma.</u>	
A4	<u>De criteria voor de infectieziekten-specialist zijn goed gedefinieerd:</u> <u>a. Vaststellen van de noodzaak van (parenterale) anti-infectieuze therapie.</u>	

	<p><u>b. De keuze van het antibioticum</u></p> <p><u>c. De wijze van aanvragen van de beoogde behandeling.</u></p> <p><u>d. Het monitoren van de patiënt tijdens de behandeling en de wijze van evaluatie van de klinische respons van de patiënt.</u></p>	
A7	<p><u>Een casemanager regelt de planning van een eerstvolgende poliklinische vervolgspraak binnen twee weken na ontslag van de patiënt.</u></p>	
A8	<p>Er is beleid vastgesteld over noodzakelijke laboratorium monitoring, waaronder:</p> <p>a. Soort meting en frequentie per antibioticum.</p> <p>b. De verantwoordelijkheid voor monsterafname in ambulante setting.</p> <p>c. (Indien van toepassing) Antibiotica bloedspiegels wordt regelmatig gemeten gedurende de loop van de behandeling.</p> <p><u>d. De laboratoriumresultaten moeten binnen 24 uur na het verkrijgen van de monsters beschikbaar zijn.</u></p>	

Twijfelachtige oncologie proces indicatoren

O2	<p><u>Naast het PMT-team bestaat het chemotherapie specifieke PMT-team uit:</u></p> <p><u>a. Oncoloog die ervaring heeft met PMT in de thuissituatie.</u></p> <p><u>b. Twee klinisch verpleegkundig specialisten</u></p>	
O4	<p><u>Er is een uitgebreid scholingsprogramma (intern of extern georganiseerd) voor nieuw personeel dat chemotherapie toedient, inclusief een competentiebeoordeling.</u></p>	
O6	<p><u>Orders voor parenterale chemotherapie worden voorgeschreven en ondertekend door bevoegde artsen volgens het beleid, de procedures en/of de richtlijnen van het ziekenhuis.</u></p>	
O9	<p><u>(Indien van toepassing) is er een systeem beschikbaar voor het bijhouden van de cumulatieve dosis van chemotherapiemiddelen met een risico op cumulatieve toxiciteit.</u></p>	
O10	<p><u>Alleen bevoegde artsen, physician assistants, 'advanced-practice' nurses of geregistreerde verpleegkundigen dienen chemotherapie toe.</u></p>	
O11	<p><u>De organisatie, verantwoordelijk voor PMT, hanteert behandelprotocollen waarin tijdstippen en tijdsintervallen zijn vastgelegd voor kuur-specifieke laboratoriumonderzoeken.</u></p>	

012	<p>Bij elk klinisch bezoek of op een dag tijdens de toediening van chemotherapie, is het personeel in staat:</p> <ul style="list-style-type: none"><u>a. De klinische status en de algehele toestand van de patiënt beoordelen en documenteren</u>b. Vitale functies en gewicht documenterenc. Allergieën, bijwerkingen en behandeling-gerelateerde toxiciteit controleren.<u>d. Psychosociale zorgen en noodzaak tot hulp beoordelen en documenteren en indien nodig actie ondernemen.</u>	
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Notities:

Tips:

Tops:

Terugkoppeling onderzoek

Wilt u een terugkoppeling van het onderzoek, laat dan hieronder uw mailadres achter.

Beoogde kern set algemene proces indicatoren (29)

Proces Indicatoren

Notitie veld

1	Er is beleid vastgesteld dat een kader biedt voor veilige en effectieve zorg thuis.	
2	Het ziekenhuis beschikt over een formeel ingesteld team dat zich bezighoudt met toediening van Parenterale Medicatie in de Thuisituatie (PMT) Dit PMT-team bestaat ten minste uit: a. Een arts die ervaring heeft met het toe te dienen medicament. c. Een verpleegkundige die ervaring heeft met parenterale medicatie toediening.	
4	Er zijn selectiecriteria voor patiënten die in aanmerking komen voor PMT in de thuisituatie. Deze omvatten: a. De patiënt is bereid zich aan het vervolgplan te houden en heeft hiertoe toestemming gegeven. b. Er zijn geen medische contra-indicaties om de patiënt uit het ziekenhuis te ontslaan.	

	<p>d. De patiënt is hemodynamisch stabiel.</p> <p>e. Er bestaat een veilige thuisomgeving met adequate voorzieningen (een schone plaats om toe te dienen, stromend water, opslagmogelijkheid voor hulpmiddelen).</p> <p>f. Aanvullende noodzaak om complexe zorg te moeten verlenen wordt meegenomen in de afweging voor PMT.</p> <p>g. Psychosociale factoren (bijv. alcohol en/of drugsverslaving, cognitieve stoornissen) moeten worden meegewogen.</p>	
5	<p>Er zijn kwalificatie-eisen vastgesteld voor het bevoegd en bekwaam verklaren van medewerkers die betrokken zijn bij het proces van PMT. Dit omvat:</p> <p>a. Eisen betreffende initiële scholing.</p> <p>b. Periodieke herbeoordeling van de kwalificatie.</p>	
6	<p>Per zorgpad zijn de taken en verantwoordelijkheden van de zorgverleners die betrokken zijn bij het proces van PMT vastgelegd. Dit omvat de verantwoordelijkheid voor:</p> <p>a. Patiëntselectie</p> <p>b. Beschikbaar stellen van medische materialen</p> <p>c. Adequaat opgeleid personeel</p> <p>d. Bereiden van de medicatie</p> <p>e. Transporteren van de medicatie</p> <p>f. Toedienen van de medicatie</p> <p>g. Monitoring</p> <p>h. Follow-up</p>	
7	<p>Er zijn afspraken vastgelegd over de afhandeling van urgente (klinische) problemen die zich tijdens PMT kunnen voordoen.</p>	
8	<p>Er is een systeem ingericht en beschikbaar voor snelle toegankelijke communicatie tussen de patiënt en zijn/haar zorgverleners.</p>	
9	<p>Informatie-uitwisseling tussen het PMT-team en andere relevante stakeholders is ingeregeld. Dit omvat communicatie tussen het PMT-team en:</p> <p>a. Huisarts</p> <p>c. Hoofdbehandelaar</p> <p>(De communicatie omvat ten minste: melding van de start van de behandeling aan de huisarts (of indien anders, verantwoordelijke specialist), melding van acceptatie van PMT in de thuissituatie, melding van afronding van de therapie, melding van complicaties)</p>	
12	<p>Er is een beleid rondom scholingsprogramma's voor zorgverleners met betrekking tot PMT.</p>	
14	<p>Er is een systeem voor permanente kwaliteitsborging en monitoring van uitkomsten.</p>	

15	Er is een standaard order set beschikbaar voor patiënten die uit het ziekenhuis worden ontslagen met PMT. Deze omvat ten minste: a. De volledige naam van de patiënt. b. Geboortedatum. c. Diagnose. d. Naam van het geneesmiddel en cyclusnummer. g. Doseringen. h. Toedieningswijze. i. Inlooptijd van de infusie. j. Duur van de behandeling.	
16	Een gekwalificeerde zorgverlener die betrokken is bij PMT beoordeelt of een patiënt geschikt is voor thuisbehandeling.	
17	De patiënt en de zorgverlener hebben de mogelijkheid om PMT te kunnen weigeren.	
18	De patiënt en zijn familie worden geïnformeerd (mondeling en schriftelijk) over PMT in de thuissituatie. Deze informatie bevat ten minste: a. Voordelen c. Mogelijke complicaties g. Instructie voor noodgevallen h. Gebruik van medicijnen i. Verantwoordelijkheden van de patiënt j. Contactenlijst	
19	Er is een beleid voor zelftoediening van parenterale medicatie. Hiervoor worden patiënten of verzorgers opgeleid in het toedienen van parenterale medicatie.	
20	In geval van zelftoediening zijn zowel de beoordelend verpleegkundige als de patiënt/verzorger overtuigd van de bekwaamheid van de patiënt/verzorger en dit wordt gedocumenteerd.	
21	Er is schriftelijk of digitaal voorlichtingsmateriaal beschikbaar voor patiënten.	
22	Het behandelings- en monitoringplan voor PMT omvat de volgende elementen: a. Indicatie. b. Naam van het geneesmiddel. c. Dosis. d. Frequentie. e. Duur. f. Type toediening (bijv. continue of bolus infusie). g. Gebruikt toegangssysteem (bv. perifeer ingebrachte centrale katheter, getunnelde katheter). i. Parameters voor de melding van abnormale vitale functies.	
23	Over de te gebruiken toediensystemen vindt afstemming plaats met de thuiszorgorganisatie(s).	

26	Er is een beleid met betrekking tot het toedienen van de eerste dosis van een geneesmiddel.	
27	Er vindt regelmatig afstemming plaats tussen zorgverleners betrokken bij het PMT-proces met als doel de protocollen en werkinstructies up-to-date te houden.	
28	Noodmedicatie van de lijst van essentiële geneesmiddelen is beschikbaar in de gezondheidsinstelling die PMT in de thuissituatie verzorgt.	
29	Er is een richtlijn beschikbaar voor het toepassen van vasculaire toegangssystemen (zoals PICC / Porth-A-Cath) in de thuissituatie.	
30	Er is beleid vastgesteld met betrekking tot de frequentie van klinische beoordeling van de patiënt door artsen en verpleegkundigen.	
32	De tevredenheid en de ervaringen van patiënten die PMT krijgen, wordt gemonitord.	
33	De uitkomsten van patiënten die PMT krijgen, worden gemonitord.	
35	Het PMT-team documenteert ongewenste voorvallen met betrekking tot het hulpmiddel, het medicijngebruik en de toxiciteit.	
36	Het intravasculaire toegangssysteem wordt aan het einde van de behandeling verwijderd (als het niet om een andere reden nodig is).	
37	Er is beleid vastgesteld met betrekking tot dubbele controle van PMT.	

Beoogde kern set antibiotica proces indicatoren (3)

A3	De infectieziekten-specialist heeft de infectie gerelateerde in- en exclusiecriteria gespecificeerd.	
A8	Er is beleid vastgesteld over noodzakelijke laboratorium monitoring, waaronder: a. Soort meting en frequentie per antibioticum. b. De verantwoordelijkheid voor monsterafname in ambulante setting. c. (Indien van toepassing) Antibiotica bloedspiegels wordt regelmatig gemeten gedurende de loop van de behandeling.	
A9	Het behandelplan van patiënten die meer dan 1 week antimicrobiële therapie krijgen, wordt regelmatig geëvalueerd door een specialistisch verpleegkundige en arts in samenwerking met de verwijzende specialist (indien van toepassing).	

Beoogde kern set oncologie proces indicatoren (9)

O1	Indien de chemotherapie wordt bereid buiten de muren van het ziekenhuis (d.w.z. door een externe partij), hanteert het ziekenhuis een beleid voor de kwaliteitscontrole van die chemotherapie.	
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O3	Er is beleid vastgesteld met betrekking tot de verantwoordelijkheden rondom 24-uurs beschikbaarheid van zorg, inclusief een regeling voor thuisbezoek.	
O5	Er is beleid vastgesteld voor het op peil houden van kennis onder bij betrokken zorgpersoneel.	
O7	Chemotherapie wordt bereid door opgeleid personeel dat gekwalificeerd is volgens het hiertoe geldend beleid, procedures en/of richtlijnen.	
O8	Er vindt eenduidige communicatie en documentatie plaats over toxiciteit van de behandeling, ongeacht de locatie waar de toediening plaatsvindt.	
O12	Bij elk klinisch bezoek of op een dag tijdens de toediening van chemotherapie, is het personeel in staat: b. Vitale functies en gewicht documenteren c. Allergieën, bijwerkingen en behandeling-gerelateerde toxiciteit controleren.	
O13	Er is beleid vastgesteld over het afvoeren van risico-geneesmiddelen in een daarvoor bestemde container.	
O14	Er zijn aanbevelingen beschikbaar over de bescherming van medebewoners (d.w.z. partner, kinderen en huisdieren) tegen chemotherapie (o.a. aanwezig in excreta).	
O15	Er zijn instructies beschikbaar over de risico's en het veilig werken met chemotherapie.	

Appendix 5 – Coding scheme

Category	Category	Inductive/ Deductive	Sub-category	Definition
Category 1:	Appropriate	Deductive	<ol style="list-style-type: none"> 1. Relevance 2. Deep understanding 3. Validation 4. Conform 	<p>Statements that substantiate the relevance of the indicator.</p> <p>Statements that add a deep understanding of the indicator to the discussion.</p> <p>Statements that attribute the appropriateness of the indicator.</p> <p>Statements about joining counterargument regarding indicator.</p>
Category 2:	Uncertain	Deductive	<ol style="list-style-type: none"> 1. Speculative 2. Knowledge shortage 3. Unclear 4. Contradictory 5. Prospective 	<p>Statements based on presumptions or assumptions.</p> <p>Statements that place a limit on knowledge with respect to the indicator.</p> <p>Statements that are vague, ambiguous or unclear with respect to the indicator.</p> <p>Statements that contradict other statements.</p> <p>Statements that indicate that the indicator may be applicable in the future.</p>
Category 3:	Inappropriate	Deductive	<ol style="list-style-type: none"> 1. Redundance 2. Overkill 3. Incorrect 4. Irrelevant 5. General 	<p>Indicators that contain repetition.</p> <p>Indicators that are too specific.</p> <p>Indicators that are factually incorrect.</p> <p>Indicators that do not apply to the topic.</p> <p>Indicators that apply to general care and not specific to home administration.</p>
Category 4:	Reformulate	Inductive	<ol style="list-style-type: none"> 1. Clarifying 2. Simplify 3. Concreteness 4. Structure 	<p>Indicator that requires rewording to increase clarity.</p> <p>Indicator that is too complex or substantive.</p> <p>Indicator that is abstract or vague.</p> <p>Indicator that requires sentence structure adjustment.</p>
Category 5:	Additional	Inductive	<ol style="list-style-type: none"> 1. Information 	<p>Statements containing missing information.</p>
Category 6:	Relocate	Inductive	<ol style="list-style-type: none"> 1. Context 2. Order 3. Consolidate 	<p>Indicator where the content falls under a different category.</p> <p>Statement where an indicator must be moved to create a logical order.</p> <p>Indicator that can be merged with another pre-existing indicator.</p>

Appendix 6 – Conclusions per Process Indicator

**Codes in this appendix are based on the numerical order in Table 4.*

General Process Indicator 2b

In all three focus group meetings, people indicated that there is no specific 'PMT-team' defined at the moment. However, the hospital pharmacist at hospital C does mention that it may be time to take the next step and move from project to some structure such as a 'PMAH team'. As a result, stakeholders of hospital C indicate that the presence of a pharmacist in this focus group meeting is relevant. To substantiate, an outpatient pharmacist of hospital C explains the value of having a pharmacist within the PMAH-team with a practical example:

"That still sometimes gets some advice that you are then given in the home situation of well prick one more 'Vanco-level' or something like that and where we know from the logistics that it is not a useful advice. So, in that sense, it can help if a pharmacist at least has knowledge of the logistics and home situation and takes that into account in his advice."

Additionally, the participants in Hospital B also sees the added value of a hospital pharmacist as it prescribes parenteral medication. In hospital A, the group believes that the indicator should be simplified to just 'the pharmacist', given that he or she does not necessarily have to have experience with home administration. To conclude, this indicator is simplified to just 'the pharmacist' (see Appendix 8). This because all three hospitals substantiate the added value of a pharmacist in a PMAH-team.

General Process Indicator 4c

In hospital C, they consider that the indicator should be moved to antibiotic indicators because it does not apply to oncolytics. In the other two hospitals, they indicate that the indicator is inappropriate because it is a generally applicable indicator for regular care. A hospital pharmacist in hospital B argues that it is common policy:

"This step is not depending on whether you treat at home or in-hospital treatment. I think, this is something you have to do anyway even in hospital already so. We have a switch team. Well a two days when the treatment kicks in, you're going to look at oral continuation anyway, so whether this should be in this? Yes or no, this should be common policy for all of us".

This process indicator is considered as inappropriate following the stakeholders in the three focus group meetings and will be removed from the initiated set (see Appendix 8).

General Process Indicator 4i

All three hospitals stated that the indicator is part of general care and not specifically for home care. In two hospitals the stakeholders from the focus group meetings mentioned that this indicator is particularly suitable for countries like America, where people have to travel far for hospital care. Because of this, it is inappropriate for the Dutch healthcare. In this regard, an oncologist in hospital A indicates the relevance and that this is prerequisite for carrying out care:

"For transport, doctor's appointments and access to emergency services, that's a fringe condition to get treatment at home for to get medication. If you can't come to the doctor, you won't get this treatment either."

Due to the fact that all three hospitals highlighted that it is not the case in the Netherlands that people have to travel far for care, the indicator is considered inappropriate.

General Process Indicator 9b

The three hospitals substantiate the relevance of home care. However, it emerges in the focus group meetings that the processes in the hospitals are set up differently and there can also be variation within a hospital. This regarding hospital nurses providing home care. As mentioned by a physician assistant of hospital B:

"No, I think there are different situation at your department. You guys do the treatment yourselves, and we ehm just outsource it to the technical home-administration teams so and then that ehm that information exchange is essential."

In the focus group meeting of hospital A, it emerges that the indicator can be reformulated according to 'administering organisation', as this involves both internal and external administering parties (see Appendix 8).

General Process Indicator 10

In two of the three hospitals, participants indicated that in practice it does happen that responsibilities are unclear, but they feel that this does not need to be recorded within this indicator set. It is argued that this increases the administrative burden and that it is a generally applicable indicator that is no different in the home situation than for the hospital. This is also mentioned by a hospital pharmacist of hospital C:

"Surely you don't do that to those other patients who go home"

Two participants from Hospital B indicate that they have included this point in the care paths, the third indicates that this is a nice aim, but doubts about the feasibility of securing it within all care paths. Based on the composition of focus group meeting A and C indicating that this indicator can be rejected, more weight is given to the outcomes of Hospital A and C (see Appendix 8).

General Process Indicator 15e

Within the three hospitals, there is ambiguity about which protocol is meant stated in this indicator. As stated by a polyclinical pharmacist:

"In principle, this does have more value this far. So I would not name and number the protocol, but I would name a reference to a protocol"

In two of the three hospitals, people say they see the relevance of including a protocol, but that a protocol number does not add value to the indicator set. Hospital A suggests changing the indicator to 'protocol home-administration' as a medical secretary mentioned:

“Protocol home-administration, that’s clear”

On this basis, the indicator is rephrased to *'protocol home-administration'*, as the relevance was agreed by the stakeholders of the three focus group meetings and the suggestion of the medical secretary of hospital A emerged and was agreed by the other participants of hospital A.

General Process Indicator 15f

In all three hospitals, there is uncertainty about adding the process indicator. The participants in hospital B gives the argument that this does not occur in their protocol. In hospital C, they state that this is the responsibility of the homecare organization. In hospital A, an (external) homecare nurse participates in the focus group meeting and indicates that this is necessary to carry out the treatment:

“Well, with situation you outline with the dexa for example in an allergic reaction, it is necessary for us to know...”

The other participants of hospital A conform to that argument. Based on the input of the external home care nurse and the argument she gives, the indicator is reformulated and 'intolerances' is removed (see Appendix 8).

General Process Indicator 15k

Within the three hospitals, participants indicate that they find the indicator unclear in the way it was formulated. In two of the three hospitals, participants indicate that they find the indicator relevant with practical examples. A coordinator of hospital B states:

“Well, I think “k” does matter if you want to send someone home with what kind of care treatment they need to go home with. I mean, we are going to have so many streams in the near future”

In Hospital C, the participants indicates that if there are additional relevant aspects appropriate to the treatment, they should be included. An oncologist in Hospital C formulated the indicator as follows:

“Yes, but then formulate it as ‘other relevant protocols’. Think PICC-line care, that’s how we do it then, but not ‘support care treatments appropriate to the treatment programme”

On this basis, the indicator was reformulated (see Appendix 8).

General Process Indicator 15

Indicator 15 as a whole was not rated as questionable during the survey. However, in all three focus group meetings it emerged that the indicator was unclearly formulated. In hospital B, for example, people indicated that the term 'standard order set' could have several meanings within the hospital. As the transfer nurse of hospital B state, it is agreed

that the purpose and to whom the order set is addressed should be clearly formulated in indicator 15:

“No, no, order to whom and for purposes of which. I would like to know that, to be able to assess this properly”

In hospital A, it emerged that indicators 'g', 'h', 'i' and 'j' are felt to fit under protocol home administration and are ambiguous. Based on the above points and to avoid confusion regarding the indicator, the suggestions will be implemented and modified.

General Process Indicator 18

Indicator 18 as a whole was not rated as questionable during the survey. However, during the focus group meetings, it emerged that in all three hospitals indicators 'b', 'd', 'e' and 'f' are not relevant to the indicator set. Only for indicator 'e' it was mentioned by an outpatient pharmacist in hospital C that the patient was given information in the form of precepts on what the patient should bear in mind with regard to parenteral home administration:

“And all you can imagine with those ‘sterile techniques’ and ‘access to blood vessels’. Then I can imagine that if you have an infusion line or you have a PICC-line you do want that patient to be informed about what to consider then to avoid problems”

Afterwards, a hospital pharmacist of hospital C states which of the indicators apply to home administration at all:

“Which of these points belongs specifically to PMT in the home situation?”

Here, all participants agree. Based on the inappropriately rated indicators within all focus group meetings and the argument of the hospital pharmacist in hospital C, the indicator is rejected (see Appendix 8).

General Process Indicator 22h

Two of the three hospitals indicated that they find the indicator confusing. They also feel it is separate from administration at home. One of the hospital pharmacists of hospital A mentioned:

“No, that is separate from home administration”

In Hospital C, people indicate that they find the indicator confusing, but assess the indicator as appropriate. Based on the confusion surrounding this indicator and that two of the three hospitals assess the indicator as inappropriate, this indicator is rejected (see Appendix 8).

General Process Indicator 22j

Two of the three hospitals indicate that the indicator 'laboratory monitoring' is relevant to the indicator set but should be moved to the antibiotic set. The oncologist in hospital A made the following comment:

“Both for antibiotics at Vanco, not oncolytics”

In hospital C, they find the indicator ambiguous compared to indicator 22h. However, it was rejected based on the conclusions from stakeholders of the other focus group meetings. Based on these arguments, the indicator is moved to the antibiotics set.

General Process Indicator 24

All three hospitals indicated that they did not consider this indicator suitable for the indicator set. A hospital pharmacist of hospital C stated:

"I don't know if it adds value whether we think it should be in the patient's home or whether it should be in a community center or somewhere else."

Hospital B does cite an example of an outpatient setting where patients can receive parenteral administration close to home. However, based on the overall arguments regarding the three focus group meetings, this indicator is rated as inappropriate.

General Process Indicator 25

In all three hospitals, it emerges that the indicator is relevant, but needs to be reformulated. Two of the three hospitals indicated that it contains ambiguous words, and the indicator is also adequate up to the word 'implemented' as mentioned two participants in Hospital A and B. A hospital pharmacist of hospital B states the following:

"We could also demolish the whole sentence to the comma. PMT is implemented structurally in the clinical care process, then in your case it is in orthopedics yes. That's much simpler than involvement of caregivers who, that just complicates it..."

To conclude, this indicator is reformulated.

Antibiotic Process Indicator 1

In hospital C, the internist-infectiologist indicates that the indicator is inappropriate, because it is unnecessary to name it in an indicator set:

"Yes, that's semantics. That's pure semantics. I I yes. With us, the one who does OPAT is someone different from the one who does the A-team, so that's..., it doesn't matter."

In hospital B, they say they have secured it in another way with an 'A-team'. On this basis, the indicator is rejected.

Antibiotic Process Indicator 4

In hospitals B and C, there is consensus on rejecting the indicator. It is indicated that this does not differ from generic care. The internist-infectiologist of hospital C suggests that it is important to mention that there is someone responsible for monitoring anti-infective treatment and that this is not done by every medical specialist. However, the internist-infectiologist also states the following:

"No I am an internist-infectiologist, but this should apply to all hospitals right this? Is not only for us right? Other hospitals may not have an internist infectiologist. It may be done by someone completely different does"

To conclude, this indicator is rejected, because it emerged in the hospitals.

Antibiotic Process Indicator 7

It is indicated that there is no case manager involved within home administration of antibiotics in both hospitals and that the indicator is too specific. On this basis, both hospitals consider the indicator irrelevant.

Antibiotic Process Indicator 8c

Beyond the survey results, Hospital B indicates that the word 'regularly' can be omitted from the indicator. According to the cardiology coordinator, this does not add anything:

"I would take away at "C" regular, because then you get the question, what is regular?"

Antibiotic Process Indicator 8d

Despite hospital C stating that it is important to obtain laboratory results as soon as possible after sampling, both hospitals assessed the indicator as inappropriate. The internist-infectiologist stated the following:

"What do you want to achieve with that? Sometimes you have to do vancomycin levels in Drachten or something. Yes, then it can take a while before I get a call from Pietje or Jantje whether it goes through the pharmacy or through us, or whether we have to call ourselves, yes."

To conclude, there is no need for a separate indicator on this subject, they stated in both focus group meetings in hospital B and C. Therefore, the indicator is rejected.

Oncological Process Indicator 2

In both hospitals, it is indicated that the term "chemotherapy" is not all-encompassing. In Hospital A, the oncologist suggests changing it to "oncolytics". As mentioned by a hematologist, besides an oncologist, a hematologist can also be involved in the home administration of oncolytics.

"And then it makes sense for it to be an oncologist or haematologist with experience with those drugs. And yes experience with home administration. None of us were until two years back, so to speak. That, of course, is the development. And ehhm that experience, we all get now. So, I think it actually makes sense."

Furthermore, it is believed that a medical specialist does not need to have experience with home administration but rather with the administered medication. It is also suggested that "two clinical nurses" should be changed to an "oncology nurse" or "advanced practice nurse." Based on these considerations, the indicator is reformulated (see Appendix 8).

Oncological Process Indicator 4

In both focus group meetings, there is doubt about the applicability of the indicator as it overlaps with general care. However, in both hospitals, it is considered important to pay attention to the administration of oncolytics by authorized and competent home administration organizations. As mentioned by an oncologist of hospital A:

"You also receive home care if there is no oncology nurse available, in that case, we will send a nurse from the outpatient department to the patient's home today. So she must be equally well-trained, yes."

It is also mentioned in both hospital A and C that this should be ensured when an external organization is involved, which is currently not the case at Hospital C. In Hospital C, it is suggested that something should be included in the indicator set regarding authorization and competence. This is why the indicator is reformulated (see Appendix 8).

Oncological Process Indicator 6

This indicator is rejected from the initiated set. This because in both hospitals, stakeholders of the focus group meetings consider this as a field standard. As mentioned by the polyclinical pharmacist of hospital C:

"but that is no different for home than for here, so it can just go away"

Oncological Process Indicator 9

This indicator is rejected from the initiated set. This because in both hospitals, stakeholders of the focus group meetings consider this as a field standard. As mentioned by the hospital pharmacist of hospital A:

"It has nothing to do with home."

Oncological Process Indicator 10

This indicator is rejected, because in both hospitals, stakeholders of the focus group meetings consider this as a field standard, moreover, it is partly accommodated in indicator 'O4'. As mentioned by a care coordinator of hospital A:

"It's about administration, but we've just had this with that ehhm. How does the safeguarding of training go"

Oncological Process Indicator 11

In both hospitals, stakeholders of the focus group meetings consider this as a field standard. As mentioned by an oncologist of hospital A:

"This is something that, this is just our work. And, I would even find it irritating if the PMT team starts harassing you about this kind of thing when this is just my job"

Oncological Process Indicator 12

From the focus group meetings, it emerges that the indicator as a whole is unsuitable, as it is part of the daily work of healthcare providers and therefore no different in the home-administration of oncolytics. The home care nurse from an external organization in the focus group meeting of hospital C agree:

"But I do think that should just be our base of work"

On this basis, the indicator is rejected.



Onderdeel 1 - Generieke Indicatoren

2) Het ziekenhuis beschikt over een formeel ingesteld behandelteam dat zich bezighoudt met het beleid omtrent toediening van parenterale medicatie in de thuissituatie (PMT). Dit behandelteam bestaat ten minste uit:

- a. Een arts.
- b. Een apotheker.
- c. Een verpleegkundige.

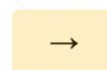
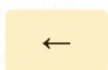
The hospital has a formally established treatment team dedicated to the policy regarding administration of parenteral medication (PMA) in the home situation. This treatment team consists at least of:

- a. A physician.*
- b. A pharmacist.*
- c. A nurse.*



- Aanwezig
- Afwezig
- Niet van toepassing

Notitie veld



Appendix 8 - Modification Table

Indicator from literature:				Hospital:			Clarification of modification:	
Caption:				A	B	C		Conclusion
Inappropriate:	X	Modification:	M					
Ambiguous:	±	Replace:	R					
Appropriate:	V	Additional:	A					
1. Modifications After Screening								
Availability for a patient to be easily and quickly administered to the hospital in case of unforeseen circumstances [58, 65].							X	Similarity with PI '4i'
In addition to the general criteria set must a complete order for PMAH of chemotherapy include [6, 58]:							X	Inpatient indicator
a. Appropriate chemotherapy criteria to treat (e.g., based on relevant laboratory results and toxicities).								
b. Assessment of organ-specific function.								
c. Reference to the methodology of the dose calculation or standard practice equations (e.g., calculation of creatinine clearance).								
d. Height, weight, and any other variables used to calculate the dose.								
Orders for parenteral chemotherapy should be written with a time limitation to ensure appropriate evaluation at predetermined intervals [6, 22].							X	Inpatient indicator
If outpatient organization manages its own pharmacy, the practice/institution has a policy regarding the storage of chemotherapy (including separation of look-a-like products, sound-a-like products, and agents available in multiple strengths). Chemotherapy is stored in a designated area according to regulatory guidelines [22].							X	Inpatient indicator
2. Modifications After Survey								
3. An identifiable, medically lead clinician takes leadership of the PMAH in homecare and has identified time for this.				±	±	±	X	Inappropriate after survey.
4h. There is a patient understanding regarding PMAH in home situation.				±	V	±	X	Inappropriate after survey.
11. The PMAH-team should document the clinical response to medication management				±	V	±	X	Inappropriate after survey.
13. There is a policy regarding the travel distance from the patients home to the hospital.				X	V	±	X	Inappropriate after survey.
31. Policies regarding communication through multimedia (e.g., an application, phone or website).				±	V	±	X	Inappropriate after survey.
34. The survival status of patients who received PMAH should be documented (e.g., patients alive, died of infection, died of other causes, lost to follow-up, or status unknown).				±	V	X	X	Inappropriate after survey.
A2. Additionally, to the PMAH-team, the OPAT team also includes:				±	V	±	X	Inappropriate after survey.
a. An ID specialist or physician knowledgeable about IDs and the use of antimicrobials in OPAT								

b. A social worker c. A laboratory technician d. A microbiologist e. A home care coordinator f. A home care pharmacist					
A5. The OPAT treatment plan is a responsibility of the infection disease physician [6] [47] [51].	±	±	±	X	Inappropriate after survey.
A6. An OPAT ID physician consultation should take place prior to intravenous access device placement [6] [45] [46] [47] [55] [59].	±	±	V	X	Inappropriate after survey.
				A	(if applicable due to treatment and/or because of illness) additional infection prevention measures.
				A	In case of staff illness, patient will be moved in time or location (hospital)
				A	The satisfaction of PMAH employees is measured
3. Modifications after Focus Group Meetings					
2b. A pharmacist experienced with outpatient infusion	M	V	M	M	b. A pharmacist
4c. A switch from intravenous to oral medication is not possible.	X	X	R	X	Inappropriate after focus group
4g. Taking care of the psychosocial factors of a patient (e.g., alcohol and drug abuse, cognitive burden).		A		A	g. Taking care of the psychosocial factors of a patient (e.g., alcohol and drug abuse). (+) h. Cognitive burden of a patient.
4i. Access to transportation for physician appointments and access to emergency services.	X	X	X	X	Inappropriate after focus group
9b. Community team (if applicable).	M	V	M	M	Home-administering organization.
10. In case of comorbidity (e.g., diabetes mellitus, cardiac diseases), responsibilities between physicians, general practitioners and other medical specialists are clearly defined.	X	±	X	X	Inappropriate after focus group
15. A standard order set is available for patient discharged out of the hospital with PMAH. This includes at least	±	M	±	M	There is a standard order set to the home administering organisation regarding the discharge of patients with PMAH. This includes at least: a. Patients full name. b. Date of birth. c. Diagnosis. d. Regimen name. e. Protocol home administration. f. Contra-indication and allergies. g. (if applicable) other relevant protocols.
15 e. (If applicable) protocol name and number.	M	M	M	M	e. Protocol home administration.
15 f. Intolerances, contra-indication, and allergies (ICA).	M	±	X	M	f. Contra-indication and allergies.
15 g. Dosages. h. Route of administration. i. Duration of infusion. j. Duration of treatment.	X			X	Inappropriate after focus group
15 k. Supportive care treatments appropriate for the treatment program.	V	V	M	M	g. (if applicable) other relevant protocols.

15h. (if applicable due to treatment and/or because of illness) additional infection prevention measures.	V	±	V	V	15h. (if applicable due to treatment and/or because of illness) additional infection prevention measures.
18. The patient and their family should be informed (orally and written) about PMAH in homecare. The information should at least contain:...	±	±	X	X	Inappropriate after focus group
22 h. Follow-up plan	±	±	±	X	Inappropriate after focus group
22 j. (If applicable) laboratory monitoring should be considered. In addition, treatment can be modified based on laboratory results (i.e., therapeutic drug monitoring).	R	R	±	R	Relocation after focus group to antibiotic indicators: A4. (If applicable) laboratory monitoring should be considered. In addition, treatment can be modified based on laboratory results (i.e., therapeutic drug monitoring).
24. There are selection criteria regarding which administration setting (i.e., infusion centre, home, HD centre) is most appropriate for each patient.	X	X	X	X	Inappropriate after focus group
25. PMAH in homecare is structurally implemented in the process, by means of an early and frequent engagement of caregiver initiating the PMAH process	M	M	M	M	PMAH in homecare is structurally implemented in the process.
In case of staff illness, patient will be moved in time or location (hospital)				X	Inappropriate after focus group (reason:
The satisfaction of PMAH employees is measured				X	Inappropriate after focus group
A1. The PMAH in homecare program should be part of an antimicrobial stewardship program		±	X	X	Inappropriate after focus group
A4. The criteria for the infection disease specialist are well defined,		X	X	X	Inappropriate after focus group
A7. The case manager confirms scheduling of the first outpatient follow-up appointment within two weeks of patient discharge		X	X	X	Inappropriate after focus group
A8 c. (If applicable) Antibiotic blood levels should be measured regularly (narrow therapeutic window) throughout the course of OPAT treatment.		M		M	c. (If applicable) Antibiotic blood levels should be measured (narrow therapeutic window) throughout the course of OPAT treatment.
A8 d. Laboratory results should be delivered to physicians within 24 hours after obtaining material for testing.		X	X	X	Inappropriate after focus group
O2. Additionally, to the PMAH-team, the oncological team also includes: a. An oncologist who is experienced in outpatient therapy b. Two clinical nurse specialists	M			M	Additionally, to the PMAH-team, the oncological team also includes: a. Oncologist or haematologist who has experience with the drug in question. b. Oncology nurse practitioner or nurse specialist who has experience with the drug.
O4. The organization has a comprehensive educational program for new staff administering chemotherapy, including a competency assessment, or the practice/institution uses an off-site educational program regarding chemotherapy administration that ends in competency assessment	M			M	There are arrangements for the home-administrating organization regarding competency and proficiency in administering oncolytics in the home setting.
O6. Orders for parenteral chemotherapy are written and signed by licensed independent practitioners who are determined to be qualified by the practice/institution according to the practice's/institution's policies, procedures, and/or guidelines	X			X	Inappropriate after focus group
O9. (If applicable) there is a process available to track cumulative doses in the patients' home situation of chemotherapy agents associated with a risk of cumulative toxicity	X			X	Inappropriate after focus group
O10. Only qualified physicians, physician assistants, advanced practice nurses, or registered nurses administer chemotherapy	X			X	Inappropriate after focus group

O11. The practice/institution maintains written statements that determine the appropriate time interval for regimen-specific laboratory tests	X		X	X	Inappropriate after focus group
O12. On each clinical visit or day of treatment during chemotherapy administration, staff:	X		X	X	Inappropriate after focus group
...					
4. Modifications after Expert Team:					
4. There are patient selection criteria for the eligibility for PMAH in homecare. This includes:				M	There are patient selection criteria for the eligibility for PMAH in homecare. This includes at least:
4a. The patient is willing to comply with the follow-up plan and has given informed consent.				M	The patient is willing to comply with the treatment plan and has given informed consent.
5. There are (internal) qualification requirements to establish a minimum standard to caregivers involved in the process of PMAH in homecare, this includes:				M	There are (internal) qualification requirements to establish a minimum standard to caregivers involved in implementing PMAH, this includes:
6h. Follow-up				M	Follow-up (including treatment of related and/or unrelated co-morbidities).
9. There should be communication between the PMAH-team and other stakeholders in the process of PMAH in homecare. This includes: a. General practitioner. b. Home-administering organization. c. Referring clinician. (The communication includes at least: notification of the start of treatment to the general practitioner (or if else, responsible specialist), notification of acceptance of PMAH in homecare, notification of completion of therapy, notification of complications).				M	There should be communication between the treatment-team and other stakeholders in the process of PMAH . This includes: a. General practitioner. b. Home-administering organization. c. Referring clinician. The communication includes at least: - notification of the start of treatment to the general practitioner. - notification of completion of therapy. - If applicable: notification of complications.
12. There is a policy for educational programs for caregivers to provide safe care regarding PMAH in the home situation.				X	Inappropriate after expert team (reason: overlapping with PI 5).
14. There is a system for ongoing quality assurance and outcome monitoring.				M	There is a system for ongoing quality assurance regarding PMAH..
15 d. Regimen name and cycle number.				M	d. Regimen name
16. A competent caregiver involved in PMAH in homecare should perform an initial assessment for inclusion.				M	A competent caregiver should perform an initial assessment for inclusion.
17. The patient and caregiver should be able to decline or accept the PMAH in homecare.				M	The patient and caregiver decide together on the possibilities for PMAH.
21. Patients educational material should be available in written or multimedia form.				M	Patients educational material should be available regarding home administration in written or multimedia form.
22 i. Parameters for the notification of abnormal vital signs				M	Criteria for the notification of deviating vital signs
25. PMAH in homecare is structurally implemented in the process				M	The ability of PMAH in homecare is structurally implemented in the process
28 Rescue medication from the list of essential medications should be available in health facilities that dispense PMAH in homecare.				M	Rescue medication is available during PMAH
29. A guideline is available for vascular access systems (e.g. PICC or Proth-A-Cath) used regarding the outpatient setting				M	A protocol is available for vascular access systems (e.g. PICC or Proth-A-Cath) used regarding the outpatient setting
30. Policies regarding frequency of clinical assessment of the patient by physicians and nurses [6] [49] [56] [57].				M	Agreements have been established regarding frequency of clinical assessment of the patient by physicians and nurses [6] [49] [56] [57].

33. The program outcome of patients receiving PMAH in homecare should be monitored.			X	Inappropriate after expert team (reason: general, not specific for outpatient setting).
35. The PMAH team should document adverse events related to device, medication use, and toxicity.			M	Adverse events related to device, medication use, and toxicity are documented in a traceable way.
36. The intravascular access device should be removed at the end of therapy (if not needed for another reason).			M	There are agreements established regarding the removal of the intravascular access device at the end of treatment (if not needed for another reason).
A3. The OPAT ID physician should specify infection-related inclusion and exclusion criteria for OPAT.			X	Inappropriate after expert team (reason: general, not specific for outpatient setting).
A4. (22 j.) (If applicable) laboratory monitoring should be considered. In addition, treatment can be modified based on laboratory results (i.e., therapeutic drug monitoring).			X	Inappropriate after expert team (reason: overlapping with PI A2).
O1. If the practice/institution site administers oncolytics that is prepared (mixed) off site, the practice/institution maintains a policy for quality control of that oncolytics.			R	Replaced after expert team to generic process indicators: 28. If medications are prepared for administration outside the hospital's premises, the hospital applies quality criteria for this process.
O2. Additionally, to the PMAH-team, the oncological team also includes: a. Oncologist or hematologist who has experience with the drug in question. b. Oncology nurse practitioner or nurse specialist who has experience with the drug.			X	Inappropriate after expert team (reason: general, not specific for outpatient setting).
O3. There is a policy regarding responsibilities for standby (24 hours a day) and preparedness for home visits.			R	Replaced and modified after expert team to generic process indicators: 29. There is a policy regarding responsibilities for standby (24 hours a day).
O5. The quality of keeping knowledge up to date among medical staff is ensured in a policy.			X	Inappropriate after expert team (reason: overlapping with PI 4)
O7. Oncolytics drugs (oral or parenteral) are prepared by trained personnel which is qualified according to the practice's policies, procedures, and/or guidelines.			X	Inappropriate after expert team (reason: general, not specific for outpatient setting).
O8. There is a consistent communication and documentation of toxicity across sites of care.			X	Inappropriate after expert team (reason: general, not specific for outpatient setting).
O13. Policies regarding disposal of hazardous drugs in a designated container.			R	Replacement and modified after expert team, to generic process indicators: 30. Instructions are available regarding disposal of (hazardous) drugs.
O14. Practice recommendations regarding secure fellow residents (i.e., a partner, children, and pets) from oncolytics. + O15. Standards regarding safety concerns and risks associated with handling oncolytics.			R	Replacement and modified after expert team, to generic process indicators: 31. There are instructions regarding the hazards and safe handling of high-risk medication [66].
			A	Additional process indicator after expert team: Up-to-date information about the date and time of each administration (administration records) is available to the treatment team.
5. Modifications after Pilot Benchmark:				
2. The hospital has a formally established treatment team dedicated to the policy regarding administration of parenteral medication (PMAH) in the home situation. This treatment team consists at least of: ...			M	The hospital has a formally established committee dedicated to the policy regarding administration of parenteral medication (PMAH) in the home situation. This treatment team consists at least of

Appendix 9 – Survey Results

Question	Inclusion Focus Group	Hospital C					Hospital B					Hospital A				
		Total (n=)	Min	Max	Median	Mode Uncertain/ Inappropriate	Total (n=)	Min	Max	Median	Mode Inappropriate	Total (n=)	Min	Max	Median	Mode Inappropriate
2b	?	6	7	9	8	9	6	3	9	9	9	4	4	9	5	4?
3	X	6	1	7	5	7?	6	2	9	6	6?	4	1	7	5	7?
4c	?	6	3	9	8	9	6	4	9	6	5?	4	6	9	8	9
4h	X	6	1	9	4	4?	6	5	9	9	9	4	6	9	8	6?
4i	?	6	1	9	5	5?	6	5	9	9	9	4	5	9	7	9
9b	?	6	6	9	7	6?	6	2	9	9	9	4	6	9	8	8
10	?	6	4	9	7	4?	6	6	9	9	9	4	6	9	9	9
11	X	6	1	9	5	5?	6	1	9	9	9	4	1	8	6	1X
13	X	6	1	9	2	2X	6	1	9	8	8	4	4	8	4	4?
15e	?	6	1	9	4	9?	6	8	9	9	9	4	1	7	7	7
15f	?	6	1	9	5	9?	6	8	9	9	9	4	5	9	7	7
15k	?	6	3	9	5	9?	6	8	9	9	9	4	2	9	7	7
18b	?	6	1	9	7	7	6	6	9	9	9	4	5	9	7	5?
18d	?	6	1	9	7	9	6	5	9	9	9	4	5	7	5	5?
18e	?	6	1	9	7	7	6	5	9	8	9	4	1	8	6	6?
18f	?	6	1	9	7	7	6	8	9	9	8	4	2	9	5	?
22h	?	6	5	9	7	8	6	7	9	9	9	4	6	9	7	6?
22j	?	6	1	9	8	9	6	8	9	9	9	4	5	9	6	5?
24	?	6	1	9	7	7	6	6	9	9	9	4	1	7	5	5?
25	?	6	5	9	8	8	6	2	9	9	9	4	4	8	6	6?
31	X	6	1	9	6	9?	6	8	9	9	8	4	1	9	6	6?
34	X	6	5	9	6	5?	6	4	9	9	9	4	1	8	3	1X
A1	?	4	1	9	6	?	5	1	9	8	9	2	5	8	7	?
A2	X	4	5	8	6	5?	5	1	9	7	7	2	5	6	6	?
A2b	X	4	1	3	1	1X	5	1	4	2	1X	2	3	6	5	?
A2c	X	4	1	3	1	1X	5	1	7	5	5?	2	3	6	5	?
A2d	?	4	1	9	7	1?	5	7	9	8	7	2	6	9	8	?
A2e	?	4	5	8	7	8	5	7	9	9	9	2	3	6	5	?
A2f	?	4	7	9	8	7	5	4	9	8	9	2	3	6	5	?
A4	?	4	4	9	8	8	5	5	9	8	9	2	5	6	6	?
A4a	?	4	5	9	8	8	5	2	9	7	9	2	5	6	6	?
A4b	X	4	5	9	8	9	5	2	9	7	9	2	1	5	3	X
A4c	X	4	1	7	5	5?	5	1	9	5	5?	2	5	6	6	?
A4d	X	4	5	8	8	8	5	1	9	5	5?	2	5	6	6	?
A5	X	4	4	8	6	?	5	1	9	8	1X	2	5	6	6	?
A6	X	4	1	9	6	?	5	1	7	4	1?	2	7	7	7	7
A7	?	4	1	9	5	5?	5	1	9	8	9	2	6	7	7	?
O2	?	4	5	8	7	8	4	1	9	8	7	4	5	8	6	5?
O2a	?	4	5	8	8	8	4	1	9	8	7	4	5	9	6	6?
O4	?	4	3	8	6	6?	4	1	9	9	9	4	7	9	8	7
O6	?	4	4	9	8	4?	4	1	9	9	8	4	8	9	9	9
O9	?	4	4	8	5	8?	4	1	9	9	9	4	3	9	9	9
O10	?	4	5	9	8	8	4	1	9	9	9	4	4	9	7	4?
O11	?	4	5	9	8	8	4	1	9	9	9	4	1	9	6	?
O12a	?	4	4	8	6	8?	4	1	9	9	9	4	8	9	9	9
O12d	?	4	1	8	7	8	4	1	9	6	9?	4	6	9	8	9

Appendix 10 – Personal Communication Focus Group

Personal Communication (S = Stakeholder)	
Dutch:	English:
<p>Focusgroep A: S4: “want ik dacht, Bedoel je nou eigenlijk, dus daar liep ik tegenaan. Ik vond het lang. Ik dacht, wanneer komt er een einde aan deze vraagstelling?”</p> <p>S2: “En ik denk inderdaad als je 1, 1, 1 goede set wil hebben dan is het In de praktijk ook belangrijk, hè? Dat die handzaam is en dat die niet te lang is en niet te veel overlap, want ik vond er soms ook wat overlap in zitten.”</p>	<p>S4: "because I thought, Do you actually mean, so that's where I stumbled upon. I found it long. I thought, when is this question going to end?"</p> <p>S2: "And I do think that if you want to have a good set, a good set of 1, 1, 1, it's also important in practice, right? That it's manageable and not too long and doesn't have too much overlap, because I also found some overlap in it sometimes."</p>
<p>Focusgroep B: S5: “Ik vond het wel achteraf van 0 tot 9 te veel opties. Het had voor mij betreft ook met een Likert 3 puntenschaal weggooien, weet niet, of toelaten. Dat had evenveel invloed op informatie opgeleverd. Ik denk ook statistisch simpel te analyseren.”</p> <p>S3: “En, het was te veel, zeg maar”</p> <p>S4: “Heel kort gezegd lang.”</p>	<p>S5: "I found it too many options in hindsight, from 0 to 9. As far as I'm concerned, it could have been discarded or allowed with a Likert 3-point scale, I don't know. That would have yielded the same amount of information. I also think it's statistically easy to analyze."</p> <p>S3: "And, it was too much, you know, the question afterwards, I thought."</p> <p>S4: "In short, long."</p>
<p>Focusgroep C: S8: “En er zijn nog wel dingen tussen die wel in het algemeen gelden bijvoorbeeld voor oncologische toediening, maar waarbij het niet uitmaakt of je het op de dagbehandeling geeft of thuis en dan krijg je de neiging om te zeggen “ja, dit is wel van belang dat dit goed geregeld is dat je het meet”, maar eigenlijk wil je misschien hier alleen meten wat specifiek is voor de thuis toediening en eigenlijk niet als dat ook geldt voor het algemeen.”</p> <p>S2: “Nou, ik vond sommige dingen wel inderdaad lastiger te beantwoorden, omdat ik denk dat sommige dingen erg toegespitst zijn op een stuk hoofdbehandelaar schap.”</p>	<p>S8: "And there are still things in between that apply generally, for example, for oncology administration, but where it doesn't matter if you give it in the outpatient department or at home, and then you tend to say 'yes, it is important that this is well regulated and measured', but actually you might only want to measure what is specific to home administration and not if it also applies generally."</p> <p>S2: "Well, I did find some things indeed more difficult to answer because I think some things are very focused on a part of being the main treating physician."</p>