Zorginstituut Nederland

Room for Improvement report Peripheral arterial disease

Zinnige Zorg | ICD-10: IX I73 9

DATE: AUGUST 2016

Zorginstituut Nederland and Zinnige Zorg

Zorginstituut Nederland's motto is "Taking care of good health care: no more and no less than necessary". Every citizen must be able to count on receiving good health care. No more and no less than is necessary, while also avoiding unnecessary costs.

As a public organisation, the *Zorginstituut* assesses health care systematically. We assess whether diagnostics and (therapeutic) interventions are being deployed in a patient-oriented, effective and cost-effective manner.

We discuss our findings with care professionals, patients, care institutions, health insurers and colleague governmental agencies. Together with them, we examine what is needed to improve patients' care and avoid unnecessary costs.

The parties in health care are responsible for improving that care. *Zorginstituut Nederland* provides an overview of points for improvement, promotes cooperation and monitors the results.
This is how we contribute to good and affordable health care for everyone.

More information about the activities of *Zorginstituut Nederland* and Zinnige Zorg can be found on www.zorginstituutnederland.nl.

Content

Summary

What is claudicatio intermittens?

Literally, claudicatio intermittens (CI) means 'periodical skipping'. CI is where a person experiences pain in the calf muscle, thigh or buttock while walking, which disappears after a short rest. The symptoms of CI are due to atherosclerosis (hardening of the arteries). This can lead to narrowing (stenosis), or even to the total occlusion of an artery, resulting in circulatory disorders. These patients have a three to four times increased prevalence of cardiac and/or cerebrovascular diseases, often due to systemic atherosclerosis. In the Netherlands, the prevalence of CI among persons aged 55+ is about 85,000. Treatment can comprise of cardiovascular risk management (CVRM), supervised exercise therapy and an endovascular or operative intervention.

What are the contents of this room for improvement report?

This Room for Improvement Analysis describes the research and the resulting actions and agreements that focus on further improvements in care for patients with CI. We have analysed the care pathway together with the umbrella organisations of patients, care givers, health institutions and health care insurers, within the framework of the 'Zinnige Zorg' [Appropriate Care] programme of *Zorginstituut Nederland*, and the conclusion is that improvement is desirable.

What will patients notice about the quality improvement?

There will be more agreement between general practitioners, physical therapists and medical specialists about what constitutes good care. Patients will receive care according to the guidelines. Diagnostics can be performed under the responsibility of the general practitioner (no need for referral to a vascular surgeon). First treatment for new patients with CI is supervised exercise therapy. Complex interventions are only offered if supervised exercise therapy have proved ineffective. Patients will receive better information about the importance of supervised exercise therapy. In addition, more high-quality information about health care outcomes will be made available for CI patients.

What will the parties in health care do?

Based on their role, expertise and responsibility, the various health care parties will tackle the jointly established improvement activities. Agreements have already been made for most of the improvement activities. For the remaining activities, more detailed agreements will be made during the implementation phase.

The table on the following page provides an overview of the improvement activities and the responsibilities of the different parties in the implementation.

What happens next? Implementation, monitoring and evaluation

Implementation of these improvement activities by the parties in health care is in line with their accountabilities within the health care system. After approving this Room for Improvement Report, the *Zorginstituut* will organise meetings with the parties in order to promote collaboration, discuss progress and resolve any signs of stagnation. We can use data to reflect with parties on the level of implementation. The *Zorginstituut* will monitor and evaluate the implementation process and report on it annually in the form of progress reports.

Which parties are involved in this plan?

- On behalf of the patients: Dutch *Hart&Vaatgroep*;
- On behalf of the professionals: NHG (Dutch Association of General Practitioners), NVvH, NVvV, NVR (Dutch Associations of Surgeons, Vascular Surgeons and Intervention Radiologists), KNGF (Royal Dutch Society for Physical Therapy) and FMS (Association of Medical Specialists);
- On behalf of the health institutions: NVZ (Dutch Hospitals Association), NFU (Dutch Federation of University Medical Centres) and ZKN (Association of Private Hospitals);
- On behalf of the health insurers: ZN (Association of Dutch health care insurers);
- On behalf of national networks: ClaudicatioNet (regional network).

Overview of improvement activities

Improvement activities	Who?
The organisation of ankle-brachial pressure index diagnostics in primary care will be improved. Quality requirements will be drawn up on implementation, and expertise will be encouraged. Information will be made available for primary care professionals on the possibility of having these diagnostics carried out in primary care diagnostic centres and vascular laboratories. Accessibility of the latter will also be improved.	*NHG, NVvH, together with the Zorginstituut*
Clear agreements will be made between primary care and hospital care about advice on diagnostics and treatment. *The Zorginstituut may place this point on the Multi-Year Agenda*	NHG, VVvH, together with other relevant parties
Patient information must improve. This could be achieved by offering reliable patient information in a single location.	*The Hart&Vaatgroep*, NHG, NVvH
Responsibility also rests on professionals in primary care and hospital care. Attention should be given to stepped-care, i.e., explaining properly why an operation is not the first choice.	This applies to all professionals
Shared decision-making will increasingly take place. To support this, the decision aid (incl. an option grid) will be developed further for use in primary care and hospital care. *The Zorginstituut will place this on the Multi-Year Agenda*	*The Hart&Vaatgroep*, together with other relevant parties
In principle, professionals will implement stepped-care consistently.	This applies to all professionals
Monitoring the effects of supervised exercise therapy	ClaudicatioNet, ZN
Duplex ultrasound will be used according to the guidelines.	NVvH
More attention will be paid to practice variations in placing stents in the Netherlands, and to activities that can lead to improvement.	NVvH, NVR, NVvV
Information will be made available nationally on the quality of care provided in primary care and hospital care, from the perspective of CI patients. This information will be transparent. *The Zorginstituut will place this on the Multi-Year Agenda*	*The Hart&Vaatgroep* and the Dutch Patients Federation, together with other relevant parties

In the picture: Zinnige Zorg for people with intermittent claudication

Research question

ZIN

Zinnige Zorg
(appropriate care) programme

How do matters stand with regard to *Zinnige Zorg* for people with intermittent claudication?

Patients	Care professionals	Health care insurers	Care institutions	National network
Harteraad	*KNGF, NHG, NVvR, NVvH, NWV, V&VN*	*ZN*	*NFU, NVZ, ZKN*	*Claudicationet*

Research

What perceptions exist regarding good care?

How is care provided in actual practice?

Results

Diagnostics

Guideline
Ankle brachial pressure (ABP) indexes can be performed under the responsibility of the general practitioner (GP). Options: by GP or in vascular laboratory.

Data
Still too many referrals to vascular surgeon for diagnostics.

Guideline
Duplex ultrasound should only be used if endovascular revascularisation (ER) or operation is being considered.

Data
11.000 unnecessary duplex ultrasounds a year.

Treatment

Guideline
Supervised exercise therapy (SET) should be delivered as first treatment to all new patients with intermittent claudication.

Data
- 75% of patients received no SET as first-line treatment.
- 20% of patients may undergo ER unnecessarily.

Improvement activities

Improved agreements between care professionals

Provision of reliable patient information

Insight into quality is being developed

Inform general practitioners that diagnostics can be outsourced to a vascular laboratory without referral to specialist.

- Newly diagnosed patients receive SET as first-line treatment.
- Reimbursement of SET.
- From 35% to 11% ER.

Avoidable costs (a year)

€ 30.000.000

Implementation and monitoring

Reimbursement of SET since January 2017.

Parties are responsibel for the implementation of the other improvement activities.

ZIN will monitor the improvement actions.

1 Introduction

1.1 Systematic analysis

This Room for Improvement Report of *Zorginstituut Nederland* is an in-depth study of care for peripheral arterial disease (PAV), with a specific focus on claudicatio intermittens (CI). The *Zorginstituut* published this report within the context of a systematic analysis of the insured package.[1] It is an in-depth study within the ICD-10 domain Cardiovascular Diseases (IX I00-I99). The entire systematic analysis can be found in appendix 4.

The aim of this Room for Improvement Report is to chart the potential for improving care for people with CI and provide a concrete method for realising improvements. We will establish this potential for improvement and how it can be achieved in joint collaboration with relevant parties. We provide an indication of the consequences for health care costs if the improvements are implemented in clinical practice. Lastly, we will monitor implementation of the improvements. Appendix 2 provides detailed information about the working method of Zinnige Zorg, the process that resulted in realising this PAV Room for Improvement Report, and which parties were involved.

The *Zorginstituut* is responsible for the contents of this Room for Improvement Report.

1.2 Why focus on CI?

Mid-2014, during the screening phase of the full ICD-10 domain Cardiovascular Diseases (IX I00-I99), *Zorginstituut Nederland* identified three topics with a major potential for realising quality improvement in care: peripheral arterial disease, the placement of Implantable Cardioverter-Defibrillators (ICD) and Stable Angina Pectoris. CI had already been placed on another annual package agenda programme of *Zorginstituut Nederland*, based on the realisation that the proposed stepped-care approach, i.e., with (supervised) exercise as first treatment option, was not yet being implemented in practice. Parties cited the lack of adequate reimbursement for supervised exercise as contributing to this problem. The *Zorginstituut* concluded that more insight needed to be provided into the optimum care pathway for people with CI, which is why we chose the topic CI. This choice was supported by an exploratory analysis of ours (see appendix 3), which showed that, among the distinct stages of peripheral arterial disease, care for CI holds first place due to the combination of volume and costs.

Various parties in health care, e.g. associations of medical specialists, have ongoing programs for improving the quality of care for CI patients. The *Zorginstituut* can also contribute to these improvements, by providing knowledge, data and research and through its combined tasks in the field of package management and quality improvement. By choosing this topic, the *Zorginstituut* envisaged possibilities for synergy with other initiatives and programs, e.g. the Quality and Effectiveness of Care Agenda of Medical Specialists. This resulted in a jointly organised meeting in January 2016, as they too had put peripheral arterial disease on the agenda within the framework of their improvement programme.[2]

1.3 Research topics

Within the care pathway for CI patients, the *Zorginstituut* selected four topics for further research, based on an initial exploratory analysis of hospital data (based on activities for which medical specialist submit claims to Dutch insurance companies) and signals picked up by the parties involved: diagnosis of CI with the ankle-brachial pressure index, management of CI with supervised exercise therapy, imaging for revascularisation, and management of CI with stenting.3 A systematic analysis was carried out per topic. The system is discussed in more detail in the following section.

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1 *Zorginstituut Nederland is doing this within the framework of the Zinnige Zorg Programme it was commissioned to carry out by the Ministry of Public Health, Welfare and Sport. Appendix 2 provides a description of the objective and working method of the Zinnige Zorg programme.*

2 *The parties to the outline agreement on care provided by medical specialists are developing and realising an integral approach to improving the quality of 30 elements of this care during the next year, including PAV. These topics, which have been placed on the Quality and Appropriateness Agenda, were determined jointly by health insurers, care providers, patients and the Zorginstituut.*

3 *CVRM was not included as a topic in this Room for Improvement analysis, but was dealt with in the Room for Improvement analysis for Stabile Angina Pectoris (CVRM relates to all vascular disorders caused by arteriosclerosis (of the head, heart and peripheral nervous system.).*

1.4 Eight elements of good care

The systematic analysis is based on elements of good care that are derived from the *Zorginstituut*'s tasks relating to quality and package management (see the following overview for more details).

Eight elements of good care	
Knowing what constitutes good care	Availability of quality standards (such as guidelines), information standards, patients' information/decision aids and measuring instruments (PREMs/PROMs).
Use in practice	Implementation level of quality standards, patients' versions/decision aids and measuring instruments; analysis of data on practices, literature. • Are recommendations being followed in practice? • How is care implemented?
Care outcomes	Is quality information on care outcomes available and accessible?
Effectiveness	Is the care effective, do patients benefit from the treatment? • Scientific substantiation of guidelines. • Signs may form a reason to examine (again) whether the care really is effective and fulfils the criterion established medical science and medical practice by making use of the formal GRADE system of assessment.
Cost-effectiveness	Is the care cost-effective? • Do the guidelines say anything about this? • Signs may form a reason to examine (again) whether the care really is cost-effective.
Necessity	What quality circles exist, who is involved in them and what cohesion exists between the various quality circles?
Implementability	Have the prerequisites and sustainability of being part of an intervention in the basic package been fulfilled?
Consistency in the quality circles	Which quality circles exist, who is involved in them and what consistency exists between the various quality circles?

The eight elements of good care were discussed, per topic. If needed, additional research was carried out and presented. This included, e.g., analyses of clinical guidelines, analyses of data from daily practice, analyses of quality data, or carrying out our own systematic review into the (cost-)effectiveness of a specific aspect of the care process. Most analyses were performed by colleagues at the *Zorginstituut* but some were performed by external companies. All these analyses contributed to identifying possible leads for further improvement in the quality of care. The results are summarised in section 3. An extensive report of the analyses performed can be found in appendix 4.

See appendix 2 for a detailed explanation of the method used and the eight elements of good care.

1.5 Structure of this report

Section 2 discusses the disorder CI, paying attention to the symptoms, burden of disease, what a patient actually experiences, epidemiology and developments in volume and costs. **Section 3** discusses the conclusions based on findings from the analyses and the meeting. A full elaboration of the analyses can be found in appendix 4. All the input finally resulted in a number of recommendations, which are presented in **section 4**, for improving the quality of care for CI patients. The section provides an overview of points for further improvement and agreements made with parties about tackling these points with targeted actions. Furthermore, we describe the effects of using care appropriately and the consequences for costs if the improvements are implemented. **Section 5** discusses implementation, monitoring and evaluation.

2 What is CI?

2.1 The clinical picture

CI literally means 'periodical skipping'. CI is where a person suffers pain in the calf muscle, thigh or buttock while walking, that disappears after a short rest, and the patient can continue walking. CI is also known as 'window-shopper's disease': sufferers frequently camouflage their symptoms by stopping at high-street window displays. The symptoms of CI are due to atherosclerosis (hardening of the arteries). Atherosclerosis is the deposit of fat ('plaques') on artery walls and the hardening or 'calcification' of artery walls. This can cause narrowing of the artery (stenosis), or even the total occlusion of an artery, resulting in circulatory disorders.

The severity of peripheral arterial disease can be classified on the basis of complaints and symptoms using the clinical classification criteria of Fontaine:

- stage 1 or PAV1: there is some constriction, but no symptoms;
- stage 2 or PAV2: CI, there are symptoms during exercise;
- stage 3 of PAV3: ischemic pain during rest; symptoms persist even when resting;
- stage 4 or PAV4: ischemic ulcers or gangrene, non-healing wounds, necrosis or gangrene. This stage involves the risk of amputation.

Between 70 and 80% of CI patients have stage 2 CI. The symptoms of 10-20% of patients diagnosed with CI exacerbate within 5 years and 5-10% of patients develop critical ischemia.[4,5] In the latter case blood flow to the legs is so restricted that walking is almost impossible. Pain is felt in the legs and/or feet even while resting, and wounds or ulcers develop on the feet. Symptoms often return after treatment.

Atherosclerosis is not limited to the legs, but is almost always present in other blood vessels too. As a result, the prevalence of cardiac and/or cerebrovascular disorders in patients with peripheral arterial disease, including CI, is three to four times higher and their chance of cardiovascular mortality is two to three times higher than that of people without peripheral vascular disorders.5

Risk indicators for a poorer clinical course of peripheral arterial disease, including CI, are advanced age, familial history of cardiovascular disorders, smoking, severity of symptoms, the presence of constrictions at various levels, coronary and cerebrovascular disorders, diabetes mellitus and a low ankle-brachial pressure index.5

Five years after first being admitted to hospital due to CI, 34% of men and 31% of women will have died, half of them due to cardiovascular disease.[6]

2.2 Burden of disease

In the 2010 list of the World Health Organisation (WHO), the disability weight for CI was estimated to be 0.016 (0.008-0.028).[7] In this respect, using the simplified description of the disorder is important to be able to interpret the GBD (Global Burden of Disease) value in its true perspective. This description for claudication is: *Claudication has cramping pains in the legs after walking a medium distance. The pain goes away after a short rest*. In determining this value, the WHO included only quality of life and not reduced life expectancy as a result of the disorder.

4 *National Institute for Health and Care Excellence (NICE): Lower limb peripheral arterial disease. Diagnosis and management (2012).*
5 *Dutch College of General Practitioners (NHG): Standard Peripheral Arterial Disease (2014).*
6 *Cardiovascular disorders in the Netherlands (2014). Dutch Heart Foundation.*
7 *The WHO uses the term 'disability' to refer to loss of health, whereby health is defined in terms of capacity to function in a number of ways, e.g., mobility, cognition, hearing and eyesight. So-called 'disability weights' give a weighting to this loss of health. A 'disability weight' of 0.0 means that there is no 'disability' whatsoever during that life-year, while a rating of 1.0 equates with death. In other words, a higher value means a greater 'disability' (and a lower quality of life).*

2.3 What do patients experience?

A person who experiences recurring pain during walking will generally consult his/her general practitioner (hereafter: GP). The latter will draw up a differential diagnosis based on the anamnesis and a physical examination. Based on the differential diagnosis, the GP may decide to carry out further diagnostics. The ankle-brachial pressure index is indicated as diagnostic tool in cases of suspected peripheral arterial disease. Peripheral arterial disease can be diagnosed based on the difference in blood pressure measured in the ankle and arm while resting. In some cases, it can be of additional value to measure this index after exercise on a treadmill. GPs can do this themselves, but they can also decide to outsource this diagnosis to a regional diagnostic centre or the hospital's vascular laboratory. Once the diagnosis CI has been established, a patient should be given the right information, which explains the underlying problem, its causes and what the patient can do to prevent further problems. Treatment is comprised of cardio-vascular risk management (CVRM) and referring the patient to supervised exercise therapy. Only in the case of failure of supervised exercise therapy (insufficient effect), should a patient be referred to a medical specialist for further imaging and treatment.

Within the framework of this report, we interviewed four patients suffering from CI. These interviews illustrate that individual experiences can vary and that patients have different coping strategies for dealing with their disease. Summaries of their experiences with health care (professionals) and their disorder are documented in yellow text boxes which can be found at the end of sections 2-5, respectively.

2.4 Epidemiology and cost development

To obtain more insight into the epidemiology of CI, we conducted research into the incidence and prevalence, care consumption and care costs. The data were taken from various sources, which means they cannot be directly compared.

The Dutch Heart Foundation estimates a total prevalence of 85,000 among adults aged 55 years and older.[8]

To the best of our knowledge, the only source of data on new patients (incidence) in primary care in the Netherlands is the study published by Van de Lisdonk et al. dating from 2008.9 We extrapolated these incidence statistics using 2014 population data from the CBS (Statistics Netherlands) in order to be able to obtain a more recent estimate of the number of new patients per year in primary care (table 1). The estimated number of new patients in primary care is 23,080.

Table 1 Calculation of CI incidence statistics in primary care

	Incidence	CBS	Total		Incidence	CBS	Total	Overall
Men's age				Women's age				
25-44	0,1	2.148.195	215	**25-44**	0,0	2.139.463	0	215
45-64	3,1	2.365.507	7.333	**45-64**	1,5	2.348.751	3.523	10.856
65-74	5,0	820.512	4.103	**65-74**	2,9	854.195	2.477	6.580
75+	3,7	494.368	1.829	**75+**	4,8	749.949	3.600	5.429
Total								23.080

The number of new patients (incidence) in hospitals is based on hospital claim data (activities for which medical specialist submit claims to health insurance companies) from 2011. These relate to 19,473 new CI patients.

8 *Cardiovascular disorders in the Netherlands (2014). Dutch Heart Foundation.*

9 *Van de Lisdonk EH, van den Bosch WJHM, Lagro-Janssen ALM, et al. 2008. Diseases in GP practice. Fifth edition. Elsevier Gezondheidszorg [in Dutch].*

Based on the same claim data, we calculated developments in the costs of hospital care for CI patients (PAV2) between 2008-2011. These trend-analyses showed a mean of 39,100 patients with the diagnosis *claudicatio intermittens*. In this period the average costs for a CI patient were €2,170. The total average costs for hospital care were 85 million per year (39,100*€2,171). See appendix 3 for a full summary of volume and costs.

At the time of the analysis, we did not have access to the costs of care provided by general practitioners and physical therapists.

Mr K only recently discovered he has PAV. In 2012 he received a new knee, after which he still suffered a lot of pain which resulted in a reversal operation being performed. However, he continued to suffer pain. His GP subsequently carried out an ankle-brachial pressure index (without a treadmill), the results of which were negative (no CI). Eventually, the orthopaedic surgeon referred him to the vascular surgeon. The ankle-brachial pressure index (with treadmill) carried out by this vascular surgeon showed that a 39% blood flow in the painful leg, while it was 100% in the good leg. Besides the advice to stop smoking, he was also advised to participate in supervised exercise therapy. Mr K currently does this once a week and also exercises independently on a daily basis. He is convinced of the need to exercise, and emphasises the importance of the support he receives from his physical therapist, who really encourages him to exercise. He hopes he can avoid having to undergo revascularisation.

3 Most important conclusions

The *Zorginstituut* carried out further research into four areas of the clinical pathway of CI: diagnosis of CI with the ankle-brachial pressure index, management of CI with supervised exercise therapy, imaging for revascularisation, and management of CI with stenting.[10] The eight elements of good care (as described in section 1.4) were discussed, per topic. Where necessary, additional research was carried out and presented. The outcomes of these analyses are described in detail in **appendix 4**. This section is a summary of the most important findings and conclusions.

3.1 Ankle-brachial pressure index

The analysis shows that further improvements can be made in the quality of care for CI patients, particularly in:

- agreement on what constitutes good care in different guidelines;
- applying guidelines in daily practice.

Knowledge about good care

Recent high-quality national and international guidelines are available that provide recommendations about using the ankle-brachial pressure index for CI patients based on a systematic assessment of the literature. The recently revised Dutch multidisciplinary guideline: *diagnostics and treatment of patients with peripheral arterial disease of the lower extremities*, was in the process of being approved when this report was being written. Expectations are that these guidelines and a patient version of the renewed guidelines will be included (tripartite) in the *Zorginstituut*'s quality register.[11] Making this information available for professionals and patients can improve shared-decision making.

An analysis of the guidelines shows that the ankle-brachial pressure index, in combination with anamnesis and a physical examination, is an adequate diagnostic instrument for establishing the diagnosis CI in patients presenting with symptoms. The national guidelines agree that the ankle-brachial pressure index can be used as a diagnostic tool in primary care, though it should only be used by care professionals with sufficient experience and training.

The 2014 Dutch guidelines for GPs about diagnosis and treatment of CI state that a GP or a GP's assistant can use this diagnostic tool as long as they have sufficient training and experience. Another possibility is that GPs outsource use of this diagnostic tool to a regional diagnostic centre (EDC) or an in-hospital vascular laboratory. These guidelines for GPs describe in great detail a standardised method for carrying out the ankle-brachial pressure index, in order to guarantee the quality of the diagnostic tool. On the contrary, the Dutch multidisciplinary guidelines for medical specialists about diagnosis and treatment of CI questions the use of this diagnostic tool by primary care professionals, based on a literature review. However, the level of evidence was qualified as very weak.[12]
Therefore, the medical specialists agreed that the GPs could indeed be responsible for establishing the diagnosis and that immediate referral to a vascular specialist is not necessary. Nevertheless, they recommend that the diagnostics are performed in vascular laboratories in a hospital setting. Note: in the Netherlands, this can be performed without a referral to a vascular specialist.

10 *This report is about new patients with (suspected) claudicatio intermittens. The report pays no attention to care for patients with recurring symptoms.*

11 *The objective of the Register of Zorginstituut Nederland is to shed light on what the health care parties regard as good care. The Zorginstituut uses the criteria of the Appraisal framework to assess this. Tripartite means that associations of patients, professionals and health care insurers jointly approve newly developed guidelines, quality instruments or patient information/option grid.*

12 *The systematic search resulted in three observational studies. Only one study related to a population with symptoms of peripheral arterial disease (indirect), and it involved few patients (imprecision). This study found a discrepancy between the ankle-brachial pressure index in primary care and hospital care, but it is still not clear which measurement is most accurate. The other two studies involved volunteers from the high-risk population for peripheral arterial disease (i.e., patients not suspected of having PAV based on symptoms). As a result, the power of the evidence is very low.*

Bottlenecks:

- The national guidelines provide no clarity on the preferred place to perform the ankle-brachial pressure index;
- To date there are no specific quality requirements on the level of training and experience of professionals who perform ankle-brachial pressure indexes.

Applying guidelines

Improvements can be made in making sure the ankle-brachial pressure index is used in daily practice according to the description of good care in the guidelines. We tested the guideline recommendations against actual practice in order to answer the following question: do professionals implement recommendations in daily practice and can claim data confirm this? As mentioned previously, the national guidelines agree that the ankle-brachial pressure index can be used as a diagnostic tool under a GP's responsibility. Nevertheless, claim data show that a considerable number of ankle-brachial pressure indexes are still carried out in hospital under the responsibility of a vascular surgeon (more expensive DBC claims[13]). In addition we see that GPs only request a few ankle-brachial pressure indexes in vascular laboratories (less expensive OVP claims[14]).

Bottlenecks:

- No clear agreements exist between guidelines of GPs and those of medical specialists about how the diagnostic process is organised. Furthermore, no clear agreement exists within primary care about quality improvements that can be made to optimise the diagnostic process. One can imagine that at least some – though not all – GPs/GP assistants could be trained in order to increase their competence and add this diagnostic tool to their expertise.
- GPs are still insufficiently aware that they can request diagnostics in a hospital's vascular laboratory, without an actual referral to a vascular surgeon.

3.2 Supervised exercise therapy

The analysis shows that further improvements can be made in the quality of care for CI patients, particularly in:

- Applying guidelines in daily practice:
- Making health care outcomes transparent;
- Clarity about the need to insure.

Applying guidelines

Improvements can be made in making use of supervised exercise therapy in practice in accordance with the description of good care in guidelines. Consensus exists in (inter)national guidelines that the treatment of CI patients should take place according to the stepped-care principle. Stepped care is an evidence-based system comprising a hierarchy of interventions, from the least intensive to the most intensive, based on an individual's needs. More complex interventions are only offered if the results of simple interventions proved insufficient. Supervised exercise therapy should be offered as first treatment option to all new patients with CI. We assessed guideline recommendations against actual practice data, and it seems that supervised exercise therapy is still not used optimally in the Netherlands; not all patients attend exercise therapy before undergoing revascularisation or an operation. Briefly, stepped care is not being implemented sufficiently.

Both patients and professionals cite the current reimbursement system as one of the most important reasons for this (Note: in the Netherlands the first 20 sessions of physical therapy are currently not covered in the basic health care package. This was a political decision that paid little regard to any negative effect it might have). The Ministry of Health asked the *Zorginstituut* to carry out an analysis of the effectiveness of supervised exercise therapy for CI patients and to map out any possible substitution effect (hypothesis: lack of reimbursement of physical therapy could lead to more revascularisations in

13 *Diagnosis-treatment combination.*

14 *OVP-OP list: An OVP is a care activity provided by a portal specialist in response to a request from primary care or another specialist within the same organisation for which the DBC-system does not apply. (Source: NZa).*

hospitals, as the latter is reimbursed).[15] We concluded that supervised exercise therapy for CI patients is indeed effective in newly diagnosed CI patients. Furthermore, a budget impact analysis showed that reimbursing physical therapy could lead to savings in hospital care. In order to provide this good (high quality) care, the *Zorginstituut* recommended that the professionals should carry out further research in order to realise the efficient organisation, implementation and content of supervised exercise in cases of CI, including monitoring and evaluation. The above-mentioned advice of the *Zorginstituut* was published in March 2016. As a result, the Ministry of Health announced that, as of 1 January 2017, the first 37 sessions of supervised exercise therapy would again be reimbursed through the basic health care package.

Apart from the reimbursement problems, good, unequivocal patient information about the various treatment options is often lacking. The Dutch association that represent cardiovascular patients (the *Hart&Vaatgroep*) confirmed this for CI after consulting their members within the framework of developing guidelines for medical specialists on the diagnosis and treatment of CI. Many developments are taking place in this respect. The guideline working group and the *Hart&Vaatgroep* are working together on a patients' version of the new guidelines. In addition, based on the new guidelines, reliable information about peripheral arterial disease (updated in June 2016) can be found on thuisarts.nl[16], and patients can also consult kiesbeter.nl[17] for up-to-date information about the disorder and links to good alternative sources. The *Hart&Vaatgroep* is also busy developing a decision aid to improve and encourage shared decision-making. This is taking place in collaboration with researchers from the Academical Medical Center in Amsterdam, within the framework of a ZonMw project18. Subsequently, an option grid will be developed for professionals. Decision aids and option grids, for the use of both patients and professionals during consultation, contribute to optimising the shared decision-making process. This is work in progress. The researchers will continue their work in order to realise national dissemination of the decision aid and option grid.

Lastly, during the meeting in January 2016, the parties realised that insufficient harmonisation and collaboration existed between GPs and medical specialists in organising the clinical pathway of CI patients: the responsibilities of different professionals in performing diagnostics and managing CI, referrals from GPs to medical specialists and back referrals from medical specialists to GPs, follow-up and which professional takes the lead. This involves a risk of undesirable variations in clinical pathways for patients.

Bottlenecks:

- Lack of reimbursement for supervised exercise. The *Zorginstituut* has advised the Minister of Health on this;
- Lack of good, unequivocal patient information about various treatment options. This has resulted in all sorts of initiatives being started;
- Insufficient harmonisation and collaboration between GPs en medical specialists.

Making the quality of care transparent

Numerous initiatives exist in relation to improving quality. For instance, Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) are being developed for use in national surveys in primary care and hospital care. Patient-Reported Outcome Measures (PROMs) make it possible to measure the effectiveness of treatment from the perspective of a patient. This is a questionnaire that patients complete before and after treatment. Their answers show whether treatment has improved their quality of life. An example is the VascuQol-6-NL PROM that is currently being validated.[19]

15 *Zorginstituut Nederland: report supervised exercise therapy in cases of claudicatio intermittens. 2016: document number 2016021852.*

16 *Thuisarts is a Dutch website, developed in close collaboration with general practitioners, medical specialists and unions that represent patients' interests. The website summarises current recommendations and provides information for patients about good care for all kinds of diseases.*

17 *Kiesbeter is a Dutch website, developed by the Zorginstituut, that brings together a range of information about the diagnosis and treatment of diseases based on guidelines. The website provides patients with information about good care for all kinds of diseases.*

18 *ZonMw is the Netherlands organisation for Health Research and Development.*

19 *NIVEL 2014: Cognitive validation of the VascuQol for the Netherlands*

The Royal Dutch Society for Physical Therapy (KNGF) and ClaudicatioNet are developing registers for measuring the quality of delivered care.20,21 These record, among other things, PROMS and PREMS. In hospital care, national registers for measuring quality of life already exist. In 2015, a working group (consisting of associations representing medical specialists, GPs, CI patients and health care insurers) with a special interest in care for CI patients developed a set of indicators which could be measured to provide patients with information about the quality of care delivered. Within the framework of ZIN's Transparency Calendar[22], this group offered a set of indicators for peripheral arterial disease for inclusion in the *Zorginstituut*'s quality register. These are seven structural indicators and four former customer-preference indicators.[23] As these indicators are now included in the *Zorginstituut*'s transparency calendar, hospitals are obliged to supply quality data for these items on a yearly basis. The *Zorginstituut* publishes these quality data on a Dutch website: www.zorginzicht.nl. This information is now visible and transparent for all patients and can contribute to patients' preferences in choosing a hospital, medical doctor etc. Another quality register is the Dutch Audit for Peripheral Artery Disease (DAPA), which is part of the Dutch Institute for Clinical Auditing (DICA).[24] DAPA is a national quality register for peripheral arterial disease, in which the diagnosed indication and the courses of treatment offered are registered together with case-mix factors and patient feedback (PROMs). DAPA should result in feedback information for the various care providers, the objective being to reduce variations in practice and improve the quality of care. This clinical register focusses in particular on internal quality improvement. Results are not available for patients or other interested parties. Expectations are that the VascuQol-6-NL will be included in this register during the course of 2016, but it is uncertain whether this information will be transparent/made public and how many hospitals will participate in this register.

Bottleneck:

- Instruments do exist for measuring the quality of delivered care, so called indicators. However, up till now, these indicators were only used to assess the quality of hospital care. No information was available about care provided by GPs and physical therapists. Existing indicators for hospital care only provide information about the quality of the arrangements made in the organisations/hospitals (e.g. which medical specialists – and how many –work in the hospital, is a multidisciplinary meeting held to decide on the best treatment). Outcome indicators (PROMs) are not yet incorporated. As a result, to date there is a lack of national information on the quality of care supplied from the perspective of CI patients, about both GP care and hospital care.

The need to insure

As early as in 2004, the Ministry of Health decided that the reimbursement of physical therapy was no longer justified. The main reason was the excessive increase in costs relating to physical therapy, and that fact that a growing number of questions were being raised about the effectiveness of physical therapy interventions. The Ministry decided that the government should again be responsible for deciding for which diseases physical therapy is effective and thus reimbursable. The government came up with a list of chronic conditions. Physical therapy would only be reimbursed for conditions on the so-called Chronic List. CI is on that list. However, the Ministry of Health decided that the first nine sessions of physical therapy for diseases on the Chronic List were still excluded from reimbursement. Over the years this was extended to twelve and eventually twenty sessions. According to the parties in health care, since then the limited entitlement to physical therapy and exercise therapy at the expense of the basic insurance has hampered the feasibility of deploying exercise therapy in practice in the Netherlands. At the meeting of the Second Chamber Standing Committee on Package Measures on 18 June 2015, attention was drawn to

20 KNGF: The Quality in Movement Masterplan (MKIB) will result in an integral physiotherapeutic quality system: the Physical therapy Quality Register NL.

21 ClaudicatioNet is a national network of specialised physical therapists. The objective of the quality register is to measure - and increase the transparency of - performance indicators, process indicators (including referrals to GP/specialist, start of treatment <5 days, etc.) and PROMS.

22 The Transparency Calendar contains information about quality of care in the Netherlands. The Transparency Calendar was drawn up by Zorginstituut Nederland in collaboration with the umbrella organisations: PF Nederland, FMS, NFU, NVZ, ZN and V&VN. In 2015 the Minister decided that information on the quality of care had to be supplied to the Transparency Calendar for more than 30 disorders, including PAV.

23 Up until 2013-2014, information was supplied via Client Preference questions: Chronic Occlusion of Blood Flow to the Leg. These questions were about the supply of care, and helped patients choose a care provider.

24 https://www.dica.nl/dapa/home. The DAPA emerged from a relationship between the Dutch Vascular Surgery Association (NVvV, Nederlandse Vereniging voor Vaatchirurgie), a sub-association of the Dutch Surgery Association (NVvH, Nederlandse Vereniging voor Heelkunde), the Hart&Vaatgroep, the Miletus Foundation and health insurers.

the fact that the contents of the insured package may have promoted the unnecessary use of burdensome forms of hospital care. Not reimbursing the first 20 sessions of exercise therapy and physical therapy could lead to undesirable substitution with care provided by medical specialists. The disease CI was explicitly mentioned as an example of this. On 6 November 2015, the *Zorginstituut* was asked for advice on three separate matters of substitution possibilities in relation to physical therapy (appendix 4, section 2.2.8). The advice should re-examine the package criteria necessity and feasibility for exercise therapy and physical therapy. The results were expected mid-Q4 2016 to Q1 2017. Clarity already exists for one disorder, CI, as the Minister had already decided to reinstate reimbursement of the first 37 sessions of supervised exercise therapy as of 1 January 2017. As a result, the need to insure is no longer a bottleneck for CI patients.

3.3 Further imaging with duplex ultrasound

The analysis shows that further improvements can be made in the quality of care for CI patients, particularly in:

- Applying guidelines in daily practice.

Applying guidelines

Improvement is possible in using duplex ultrasound in practice according to the description of good care in the guidelines. The guidelines agree that duplex ultrasound should only be used if revascularisation is being considered. We assessed these recommendations against actual hospital data. These claim data show that in one year at least 11,000 duplex ultrasounds were carried out on patients who were receiving conservative treatment and did not undergo revascularisation or an operation.

Bottleneck:

In view of the large number of duplex ultrasounds carried out on patients receiving conservative treatment only, more duplex ultrasounds are probably being carried out than necessary.

3.4 Stent placement

The analysis shows that further improvements can be made in the quality of care for CI patients, particularly in:

- Applying guidelines in daily practice:
- Making health care outcomes transparent;
- Feasibility of care.

Applying guidelines

In practice, improvements can be made in making use of stenting according to the description of good care in the guidelines. Despite the lack of a clear standard or indication for revascularisation with stenting (both primary and secondary stenting), the guidelines advise caution in performing revascularisation with stenting. We tested this recommendation against actual hospital data. The claim data show that considerable variations in practice exist between Dutch hospitals in the ratio of revascularisation with and without stenting. For 42 hospitals, the ratio is 50:50 and for 12 hospitals it is as high as 25:75. This means that some hospitals place a relatively large number of stents, despite the recommended caution.

Bottleneck:

- The absence of indication criteria for revascularisation with or without stenting makes it difficult to draw conclusions about the variations between Dutch hospitals, but this feedback information does reflect current practice and, according to the *Zorginstituut*, this is sufficient reason for the parties to discuss this further.

Making health care outcomes transparent

Various initiatives exist in the field of improving quality. As described in section 3.2, within the framework of the transparency calendar[25], a set of indicators for peripheral arterial disease was made available to – and has been included in – the quality register of *Zorginstituut Nederland*. As these indicators have been included in the transparency calendar, hospitals are obliged to supply quality data for them. *Zorginstituut Nederland* publishes the quality data supplied on their website www.zorginzicht.nl annually. In addition, there is also the DAPA quality register mentioned earlier, which contributes to internal improvements in quality for professionals in a hospital setting.

Bottlenecks:

- Instruments do exist for measuring the quality of delivered care, so-called indicators. However, up till now these indicators were only used to assess the quality of hospital care. Existing indicators for hospital care only provide information about the quality of existing arrangements in hospitals (e.g. which medical specialists – and how many – work in the hospital, is a multi-disciplinary meeting held to decide on the best treatment). Outcome indicators (for instance PROMs) are not yet incorporated. Outcome indicators (PROMs) are not yet incorporated. As a result, to date there is a lack of national information on the quality of care supplied from the perspective of CI patients.
- Distinguishing between types of interventions in quality assessments is not currently possible. Parties can comment on the desirability of such information becoming available.

Feasibility of care

There was no reason for *Zorginstituut Nederland* to examine the feasibility of stenting in CI patients in more detail. This treatment is already being carried out on CI patients. For claims relating to this treatment, (specific) payment titles exist for vascular surgeons and intervention radiologists and there are no indications of organisational constraints on care providers in supplying this treatment. During consultations for this Room for Improvement Report, several parties informed us that in the Netherlands there are various ways for submitting claims for the same treatment in hospital. It depends on the type of medical specialist carrying out the treatment (clinical neurophysiology, intervention radiologist or a vascular surgeon). A different amount applies to each type of claim. The *Zorginstituut* discussed this matter with the Dutch Health Care Authority (NZa) in June 2016. The information was confirmed so it became a point for attention for further improvements in the claim system used by hospitals.

3.5 Consistency in quality chains

Various parties in health care, e.g. associations of medical specialists, have ongoing programs that contribute to improving the quality of care for CI patients. *Zorginstituut Nederland* can contribute to this improvement by providing knowledge, data and research and by means of its combined tasks in the field of package management and quality improvement. By choosing this topic, the Zorginsituut envisaged possibilities for synergy with other initiatives and programs, e.g. the Quality and Effectiveness of Care Agenda of Medical Specialists.

25 *The Transparency Calendar contains information about quality of care in the Netherlands. The Transparency Calendar was drawn up by Zorginstituut Nederland in collaboration with the umbrella organisations: NPCF, FMS, NFU, NVZ, ZN and V&VN. In 2015 the Minister decided that information on the quality of care had to be supplied to the Transparency Calendar for more than 30 disorders, including PAV.*

3.6 Summarising table: where are the bottlenecks?

Table 2 Elements of appropriate care: where are the bottlenecks in care for CI patients?

	Ankle-brachial pressure index	Supervised exercise therapy	Duplex ultrasound	Stent placement
Knowing what constitutes good care	+	+	+	+
Use in practice	+ -	-	+ -	+ -
Care outcomes	-	-	-	-
Effectiveness	+	+	+	+
Cost-effectiveness	+	+	+	+
Necessity	+	+	+	+
Feasibility	+	+	+	+ -
Consistency in quality circles	+	+	+	+

- bottleneck, +- partial bottleneck , + no bottleneck

Mr G is 72 years old and has suffered vascular problems for 33 years. He started as a claudication patient, but has also had many other vascular disorders and courses of treatment: vascular operations on his carotid artery, femoral artery, renal artery and in 2013 a bypass of the coronary arteries. He has an aneurysma of the abdominal artery.
He puts his long survival down to his intensive walking activity. “Carry on walking, despite the pain, that’s the best medicine, because this is the way to increase your collateral”. The key to his message is that you are a patient for the rest of your life: once a vascular patient, always a vascular patient. This is why you have to intensify your walking and take on board – as part of your daily schedule – lifestyle advice that will reduce the risk of cardiovascular disorders. Support is an important aspect of this.
Lastly, Mr G emphasised how important it is that physical therapy is reimbursed through the basic insurance package for CI patients. Personal excess also forms a barrier to obtaining the right care for patients.

4 Room for improvement

Together with the parties, *Zorginstituut Nederland* has determined that there is room for improvement in the quality of care for CI patients. All input from the analyses, the established bottlenecks and the consultations with the parties involved have resulted in a final Room for Improvement Report with improvement activities that are explained in more detail below.

4.1 Ankle-brachial pressure index

Professionals will be provided with a clear explanation that accountability for deploying the ankle-brachial pressure index for the diagnosis of CI belongs in primary care.

GPs or practice assistants can use this diagnostic tool, as long as they have sufficient experience and training. GP practices can make (regional) agreements about a select group of professionals who specialise in using this diagnostic tool (e.g. in collaboration with the GP in Cardiovascular Disorders Framework).

GPs can also outsource use of this diagnostic tool to a regional diagnostic centre or an in-hospital vascular laboratory. This takes place without an actual referral to a medical specialist in a hospital (in most cases a vascular surgeon). GPs will receive more information about these outsourcing possibilities and accessibility will be improved.

GPs and medical specialists will agree on how the diagnostics are organised. They will formulate quality requirements (training and experience). Finally, the parties will put more thought into actions that contribute to the quality of using this diagnostic tool for CI patients.

4.2 Supervised exercise therapy

The renewed multidisciplinary guidelines for the diagnosis and treatment of PAV (including CI) now recommend that newly diagnosed CI patients receive physical therapy as first treatment. Next step is implementing this recommendation optimally in daily practice, indicating that stepped care is being used more consistently.

The Ministry of Health announced that as of 1 January 2017 the first 37 sessions of supervised exercise therapy will be reimbursed from the basic package. Supervised exercise therapy will be carried out in accordance with the Dutch guidelines for physical therapists on how to treat CI.

The associations of physical therapists and exercise therapists will promote – and carry out – further research into the efficient organisation, implementation and content of this intervention in cases of CI, including monitoring and evaluation.

In principle, referral to a vascular surgeon in hospital for further imaging and treatment will only take place if supervised exercise therapy has proven ineffective or in the event of progression to PAV stages 3 or 4.[26]

More attention will be paid to informing patients adequately. This could means providing reliable patient information at central locations; e.g. a translation of the renewed guidelines on the diagnosis and treatment of CI into simplified guidelines for patients, and adequate information on websites such as *thuisarts.nl* and *kiesbeter.nl*. More is needed, however. Professionals also share in the burden of responsibility. The choice of treatment is made based on a proper consideration of efficacy, risks, burden and patients' personal circumstances. The principle of stepped care takes precedence, and this should be clearly communicated to patients; i.e., a proper explanation as to why an operation is not indicated in first instance. Developing and implementing a decision aid and option grid for use during consultation can improve shared decision-making further. Such instruments enable patients to ask professionals the

26 *Naturally, according to the multidisciplinary guidelines, in practice exceptions do exist to this stepped-care policy, and some patients are unable to participate in the appropriate exercise programme due to, e.g., comorbidity, such as invalidating arthrosis, polyneuropathy, severe COPD and angina pectoris.*

right questions and, vice versa, they help professionals explain to patients in more detail the treatment possibilities, the underlying evidence, advantages and disadvantages, potential risks and outcomes of care.

Clear agreements will be made between general practitioners and medical specialists about organising the clinical pathway of CI patients: the responsibilities of various professionals in performing diagnostics and managing CI, who is in charge, referrals from GPs to medical specialists, back referrals and controls after treatment. This involves the risk of undesirable variation in clinical pathways for patients.

It is important to incorporate outcome indicator questionnaires (PROMs) in quality registers, to provide both professionals and patients with an overview of the effects of supervised exercise therapy from the perspective of patients. These outcomes must be transparent and accessible.

4.3 Duplex ultrasound

According to the Dutch multidisciplinary guidelines for the treatment and diagnosis of PAV (including CI), further imaging with duplex ultrasound is only appropriate if an indication exists for revascularisation.

4.4 Stent placement

Zorginstituut Nederland has shown that in the Netherlands considerably more stents are placed in some hospitals than in others. This feedback information reflects current practice and forms sufficient reason for the parties to discuss this further. Points for attention are the desirability of placing so many stents and thinking about possible actions that can be linked to this in order to improve the quality of this care, e.g. developing indication criteria for placing stents and inserting a recommendation in the guidelines.

It is important that outcome indicator questionnaires (PROMs) are incorporated into quality registers, to provide both professionals and patients with an overview of the effects of interventions in hospital from the perspective of patients. These outcomes must be transparent. To this end, registers will facilitate distinguishing between outcome measurements after revascularisation with and without stenting.

4.5 Agreements with parties

This Room for Improvement Report was drawn up in close collaboration with the parties. The parties defined the improvement activities during the meeting on 26 January 2016. Based on their roles and expertise, the parties will tackle the jointly determined activities. Agreements have already been made for most of them. For the remaining improvement activities, more detailed agreements will be made during the next meeting.

The table on the following page provides an overview of the improvement activities and the responsibilities of the different parties in implementing them.

4.6 Effects of appropriate use on quality of health

We expect the quality of care to improve if the above-mentioned improvements are implemented.

If the guideline recommendations are implemented properly in clinical practice, the ankle-brachial pressure index will be used under the responsibility of GPs. They can opt to outsource the diagnostics to a diagnostic centre or an in-hospital vascular laboratory). In the event of a positive CI diagnosis, GPs can start initial treatment. All patients newly diagnosed with CI will receive supervised exercise treatment as first treatment. This treatment will be carried out by a specifically trained physical therapist or exercise therapist, according to Dutch guidelines.
If everyone works according to the stepped-care principle, patients will receive care that is not more burdensome than necessary. Complex interventions will only be considered when simple interventions have proven insufficiently effective. When conservative treatment is effective for a patient, invasive treatment is inappropriate for a variety of reasons: CI does not require an acute intervention[27], exercise therapy is a

27 NHG Standards 2014. The disorder is generally not progressive.

Overview of improvement activities

Improvement activities	Who?
The organisation of ankle-brachial pressure index diagnostics in primary care will be improved. Quality requirements will be drawn up on implementation, and expertise will be encouraged. Information will be made available for primary care professionals on the possibility of having these diagnostics carried out in primary care diagnostic centres and vascular laboratories. Accessibility of the latter will also be improved.	*NHG, NVvH, together with the Zorginstituut*
Clear agreements will be made between primary care and hospital care about advice on diagnostics and treatment. *The Zorginstituut may place this point on the Multi-Year Agenda*	NHG, VVvH, together with other relevant parties
Patient information must improve. This could be achieved by offering reliable patient information in a single location.	*The Hart&Vaatgroep*, NHG, NVvH
Responsibility also rests on professionals in primary care and hospital care. Attention should be given to stepped-care, i.e., explaining properly why an operation is not the first choice.	This applies to all professionals
Shared decision-making will increasingly take place. To support this, the decision aid (incl. an option grid) will be developed further for use in primary care and hospital care. *The Zorginstituut will place this on the Multi-Year Agenda*	*The Hart&Vaatgroep*, together with other relevant parties
In principle, professionals will implement stepped-care consistently.	This applies to all professionals
Monitoring the effects of supervised exercise therapy	ClaudicatioNet, ZN
Duplex ultrasound will be used according to the guidelines.	NVvH
More attention will be paid to practice variations in placing stents in the Netherlands, and to activities that can lead to improvement.	NVvH, NVR, NVvV
Information will be made available nationally on the quality of care provided in primary care and hospital care, from the perspective of CI patients. This information will be transparent. *The Zorginstituut will place this on the Multi-Year Agenda*	*The Hart&Vaatgroep* and the Dutch Patients Federation, together with other relevant parties

safe treatment with few complications[28], exercise therapy has a positive effect not only on distance walked and quality of life, but also on general state of health, which in turn has a positive effect on the cardiovascular risks and comorbidity that CI patients often face, exercise therapy influences not only a specific artery (as in the case of revascularisation), but has a positive effect on the underlying problems that this chronic progressive disorder involves. In the end, altering the behaviour and lifestyle of this group of patients – an important component of which is exercise therapy – is an extremely important element of treatment. In most cases, referral to a vascular surgeon is only appropriate if a newly diagnosed patient has already fully participated in supervised exercise therapy and this treatment proved ineffective. The advantage of this stepped-care approach is that patients are not unnecessarily exposed to the risks a surgical intervention involves, particularly in view of the limited duration of effects of revascularisation and the risk of morbidity and mortality.[29,30] Exceptions do exist in daily practice. Stepped-care policy may not be possible for patients who are unable to participate in the appropriate exercise programme due to, e.g., comorbidity, such as invalidating arthrosis, polyneuropathy, severe COPD and angina pectoris.

For patients, it is important that explicit attention is paid to providing information about treatment possibilities, the advantages and disadvantages, potential risks and outcomes of care. This information will help professionals and patients to make a proper assessment when choosing a treatment strategy. An important responsibility lies with professionals who need to inform patients adequately about the advantages of supervised exercise therapy as primary treatment.

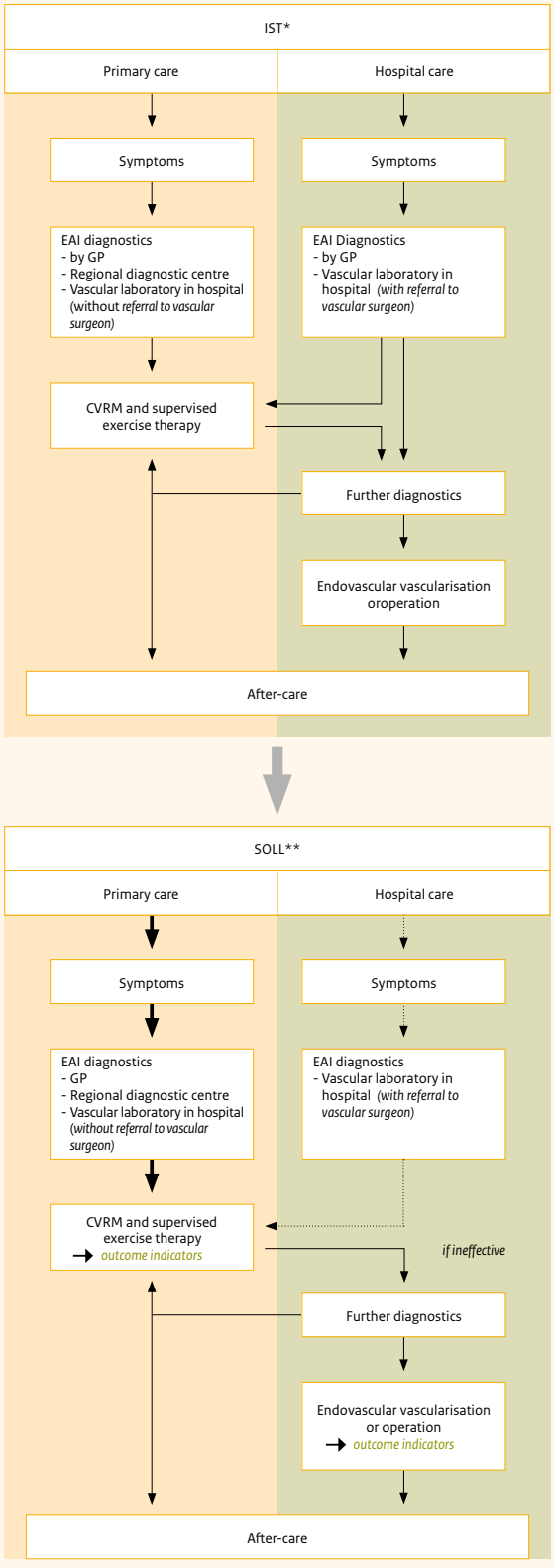
When further imaging with duplex ultrasound is used according to the guidelines, patients for whom a conservative pathway is indicated will not have to undergo this diagnostic tool unnecessarily.

The figure on the following page depicts the current care process for CI patients (IST model) and how it will look once the improvement actions have been implemented (SOLL model).

28 *Gommans LN, Fokkenrood HJ, van Dalen HC, Scheltinga MR, Teijink JA, Peters RJ. Safety of supervised exercise therapy in patients with intermittent claudication. Journal of Vascular 2015.*

29 *Multidisciplinary guidelines on diagnostics and treatment of patients with PAV of the lower extremities, 2016 (subject to reservation; to be approved by the parties) [in Dutch].*

30 *McDermott. Erasing Disability in Peripheral Artery Disease. The Role of Endovascular Procedures and Supervised Exercise. 2015.*



*IST = term meaning 'as things currently stand'.
**SOLL = term meaning 'as things should be in the future' (if acts are carried out).

4.7 Cost consequences

The main focus of this Room for Improvement Report is to improve the quality of care and health gains for CI patients. Implementation of these improvement actions will also have consequences for the costs of care. These can be found in the Budget Impact Analysis (BIA). The calculations in this BIA provide an indication. We had to make some assumptions.
The Budget Impact Analysis estimates that implementation of the improvement activities will economise on avoidable costs to the health care budgetary framework (BKZ) amounting to circa 30 million euros per year, in addition to favourable effects on the health of patients with CI.

4.7.1 *Ankle-brachial pressure index*

The question is: "What would the financial consequences be if, as of today, diagnostics for new patients suspected of suffering from CI were to take place strictly under the responsibility of GPs (independently, in a diagnostic centre (available especially for GPs) or an in-hospital vascular laboratory)?" In order to reply to this question, answers are needed to the following sub-questions:

- What current annual costs do hospitals incur for the diagnostics and care of new patients suspected of suffering from CI performed under the responsibility of the vascular surgeon?
- What are the costs for diagnostics of new patients suspected of suffering from CI performed under the responsibility of the GP?
- What is the difference between 1 and 2?

Nothing changes for CI patients who undergo revascularisation or get a bypass. They continue to receive their diagnostics and treatment in hospital as usual.

Question 1: What current annual costs do hospitals incur for the diagnostics and care of new patients suspected of suffering from CI performed under the responsibility of the vascular surgeon?
We selected patients who attended a vascular surgeon in 2012 and were diagnosed with CI. Patients were excluded if the hospital had already registered them for the diagnosis in 2010 or 2011. Also excluded were CI patients who received revascularisation or a bypass (claim codes 99699004, 99699098, 99699099 and 99699100). From the remaining patients, we selected CI-related care products used within the first 12 months after the diagnosis. These appear in table 3. The symptoms of some patients exacerbated. From the moment that these patients reached PAV stage 3 (ischemic pain during rest) or PAV 4 (ischemic ulcers or gangrene), the claim data of these patients were excluded from this analysis.

Table 3 Overview of care products for CI patients in hospitals (2012): volume and costs

Care product code	99699010	99699011	99699012
Average number of care activities per care product, insofar as relevant to the disease *claudicatio intermittens*			
• First visit to out-patients' department	0,80	0,87	0,99
• Repeat visit to out-patients' department	1,82	1,12	2,10
• Day-time nursing	0,06		0,15
• Ankle-brachial pressure index/Doppler		1,16	1,14
• Duplex imaging		0,78	0,71
• Angiography leg arteries	0,05		0,10
• Angiography aorta + branches	0,02		0,08
Source: https://zorgproducten.nza.nl/ZorgproductViewer.aspx, visited on 13-4-2016			
Average price per care product *Source: www.opendisdata.nl, visited on 13-4-2016*	€ 560	€ 405	€ 900
Number of unique patients with CI from the cohort described who received this care product	1.961	10.946	3.616
Number of care products	2.132	12.824	3.812
Total costs	**€ 1.193.920**	**€ 5.193.720**	**€ 3.430.800**

Question 2: What are the costs for diagnostics of new patients suspected of suffering from CI performed under the responsibility of the GP?
In 2012, the hospital data showed that 15,192 new patients presented with CI, after deducting the sub-group of patients who underwent revascularisation or received a bypass.

Prices of ankle-brachial pressure index:

- performed by a GP = 55 euro[31]
- performed by a regional diagnostic centre under responsibility of a GP = 55 euro
- performed in-hospital in a vascular laboratory under responsibility of a GP = 66.99 euro[32].

If half of these patients were to receive an ankle-brachial pressure index through their GP or regional diagnostic centre, while the other patients received an ankle-brachial pressure index through the vascular laboratory, then the annual costs of examining 15,192 new patients suspected of having CI by means of an ankle-brachial pressure index would be €926,712.
For shifting diagnostics from under the responsibility of a vascular surgeon to primary care, we assume three long consultations with their GP per patient: 1) suspected PAV, 2) outcome of diagnosis/advice, 3) guidance (18.13 euro per consultation, source: NZA). This is fairly consistent with the number of out-patient visits for diagnostics in hospital care.

Question 3: What is the difference between 1 and 2?

Costs of PAV-2 diagnostics and care in hospitals	€ 9.818.440
Costs of PAV-2 diagnostics in primary care (15,192 * ((55+67)/2))	€ 926.712
Costs of 3 long consultations with the GP (15,192 * 3 * €18,13)	€ 826.293
Difference	**€ 8.065.435**

Comments

- The above analysis was carried out in April 2016, unlike the other analyses in this report.
- If new CI patients remain under control in hospital care for longer than 12 months, then the 8.0 million euro is an underestimation.
- Budget ceilings were not taken into consideration.

4.7.2. *Supervised exercise therapy*

To map possible substitution effects, we performed a budget impact analysis. In this analytical model, we assumed optimal implementation of the recommendation to use supervised exercise therapy as first treatment for CI patients, i.e., making use of stepped care. In the model we assume that the reimbursement of supervised exercise therapy improves the degree to which supervised exercise therapy is used as primary treatment.

Costs

In order to shed light on the costs of including supervised exercise therapy in the basic insurance as primary care treatment for CI patients, we made use of the following points of departure:

- number of new persons with the diagnosis CI: 23,080 (calculated based on the CBS and a study by Van de Lisdonk);
- number of persons who are first – based on stepped care – offered supervised exercise therapy: 21,926 (assumption: 95% of 23,080);
- number of sessions of supervised exercise therapy: 29-46 treatment sessions spread over one year are sufficiently effective.[33] To calculate the costs we kept to an average of 37 treatment sessions;
- costs per treatment session: €30 (calculated based on Vektis data 2013-2014: actual, per treatment session, at the expense of the basic insurance).

31 (public sources: Vektis, Menzis, Zorg and Zekerheid, CZ, visited on 12-4-2016).
32 Prices of two large Dutch hospitals: AMC and UMCG.
33 Based on the guidelines for Dutch physical therapists.

Revenues

In order to shed light on the revenues of including supervised exercise therapy in the basic insurance as first treatment for CI patients, we examined on the one hand the physical therapy and exercise therapy costs incurred for this disorder in 2013 and 2014 from the list of Chronic disorders. On the other hand we looked at the possible reduction in the number of invasive interventions, as a result of effective supervised exercise therapy.

Revenue from the contemplated removal of CI from the list of Chronic disorders

Currently, CI is included on the list of chronic disorders: 'CI (vascular) level 2 or 3 Fontaine'. Treatment lasts at most 12 months. In the current situation, this means that the costs of physical therapy and exercise therapy will be at the expense of the basic insurance after the insured client has paid for the first 20 treatment sessions and insofar as the insured person is reasonably dependent on the treatment.

The Minister has decided to reimburse 37 sessions of supervised exercise therapy for patients with CI from the basic insurance. Between 70 and 80% of patients with PAV have CI. The symptoms of 10-20% of the patients diagnosed with CI exacerbate within 5 years and 5-10% of the patients develop critical ischemia (NICE guidelines).

Based on the above, in connection with the possible removal of CI from the list of chronic disorders, we calculate, on average, an annual revenue of 90% of €4,906,477 (source: Vektis), i.e. €4,400,000 (rounded off).

Revenue from a possible reduction in the number of invasive interventions

For the difference in costs of invasive treatment versus non-invasive treatment (supervised exercise therapy), we took Fokkenrood's earlier calculation (published paper) as our point of departure. That calculation give a price difference of €9,010 (€9,850 minus €840).

For the decrease in the number of persons undergoing invasive treatment after starting supervised exercise therapy, we applied the following points of departure.
The basic chance of an invasive intervention amounts to 35.4%. This percentage is based on the number of interventions in 2011 from hospital claim data.

Patients who undergo supervised exercise therapy as first treatment are left with an 11% chance of invasive treatment. This percentage is the result of a conservative translation of the outcomes found in the literature (Fokkenrood et al., 2014, Nicolaï et al., 2010).

Calculating the substitution effect

We calculated the (theoretical) substitution effect based on the above-mentioned points of departure and assumptions.

Activity	Costs	Revenues
Number of new persons diagnosed with CI	23080	
Number of patients making use of supervised exercise therapy (95%)	21926	
Number of physical therapy sessions	37	
Price per physical therapy session	€ 30,00	
Costs: stepped care with supervised exercise as treatment	€ 24.337.860	
Revenues: no longer reimbursing CI on the chronic list (90% of €4,906,477)		€ 4.400.000
Reduction number of people with invasive intervention*		4606
Price difference invasive versus conservative trajectory		€ 9.010
Revenues: substitution effects		€ 41.503.128
Total		**€ 21.565.268**

Calculation: basic chance (35.4%) * effectiveness (70%) * (number of persons making use of supervised exercise therapy – number of persons (3338) who already made use of supervised exercise therapy in 2011.

Based on the points of departure and assumptions used, including 37 sessions of supervised exercise therapy in the basic insurance can lead to a (theoretical) substitution effect of (rounded off) €21.5 million euro annually.[34]

The degree to which this substitution effect is actually realised will depend in part on how supervised exercise therapy is included in legislation (entitlement and funding) and on its form and content in actual practice.

4.7.3 *Duplex ultrasound*

The impact of excluding further imaging with duplex ultrasound when it is not followed by an endovascular intervention has already been incorporated – to a degree – in the analysis in section 5.3.1. This is because a combined ankle-brachial pressure index and duplex ultrasound takes place in a single care product (an activity claimed by a medical specialist). This is why we did not calculate this.

4.7.4 *Stent placement*

We did not include this element in the section on cost consequences because the guidelines do not provide any firm recommendations on indications for revascularisation with and without stenting.

Ms B, 82 years old, was diagnosed with CI 3 months ago. The diagnosis was made based on a wound on her foot, noticed by the podiatrist treating her feet in connection with her diabetes mellitus diagnosis. The vascular surgeon referred her to a physical therapist for running training. A discussion took place with Ms B about her lifestyle, but this is already good. Ms B does not smoke or drink alcohol, she takes her medication properly and she is physically active (swimming, folk-dancing, daily walks or cycling on a home-trainer).
Initially she attended running training twice weekly and after three months it was reduced to once weekly. She feels it is important to be supervised by a physical therapist who gives her clear advice and supervises her exercises on a treadmill set at a gradient. She has improved: from 30-45 minutes walking with pain to 45-60 minutes with few pain symptoms.
Ms B is motivated to achieve her treatment objectives and feels it is normal to avoid undergoing an operation if you can reduce the problem yourself by training. Reimbursement of the running therapy did not form a problem for Ms B. She has adequate supplementary insurance, so her physical therapy is reimbursed.

34 *The comment should be made her that this may be an overestimate. The KNGF guidelines recommends 29-46 exercise and physical therapy sessions for patients with CI. The Minister has decided to reimburse 37 treatment sessions. Patients who need the maximum amount of treatment will have to pay for the last 9 treatment sessions themselves. This means there is the risk that patients will still ask for a hospital intervention. It is not clear just how big this group will be.*

5 Implementation and monitoring

The parties have already introduced some good initiatives. This Room for Improvement Report summarises and supplements these initiatives, and intensifies joint effort. This is the start of a joint implementation plan for the parties that will result in further improvements in care for CI.

The parties in health care will implement these improvements in line with their accountabilities within the health care system. Where necessary, (further) collaboration will be sought with other parties.

After this Room for Improvement Report has been approved, the *Zorginstituut* will organise an implementation meeting with the parties, at which we will translate the improvement points into executable actions. Furthermore, we will decide on timelines and deadlines. This includes the possibility of granting parties who so desire access to an implementation study or advice.

The *Zorginstituut* will monitor the improvement actions as follows:
- Using qualitative and quantitative methods, we will monitor annually whether any progress has been made in the various improvement actions;
- We will organise follow-up meetings in order to promote collaboration, discuss progress and resolve any signs of stagnation;
- We will facilitate parties to realise national agreements on how care is organised;
- After three years we will write an evaluation report.

In view of the involvement and accountability of all parties, *Zorginstituut Nederland* expects implementation of the improvements proposed in the guidelines and the organisation of care to be successful, and sees no need for statutory instruments.

This report was approved by the Executive Board on 1 August 2016.

Zorginstituut Nederland
Chairman of the Executive Board

Arnold Moerkamp

Mr R (72) has been a heart patient since 1996. In 1996 he unexpectedly suffered a heart infarction. The doctors placed a stent. After this heart infarction, Mr R also started suffering vascular problems in his right leg and later in his left leg, specifically aorta-iliac. He received PCI treatment and stenting and in 2012 a bypass operation, but without the expected results.
Mr R. did receive running advice, but he was never offered supervised exercise therapy, nor lifestyle interventions.
In the meantime Mr R. has also undergone two total hip operations which resulted in his walking ability being reduced permanently.
He knows that walking is good, preferably supervised and on a regular basis; therapy provides the necessary external motivation. Mr R. says that such processes have to be customised, paying attention to the individual. Exercise gives you a sense of reassurance, both before and after a surgical intervention. It is also important to think about alternative options for people who are unwilling or unable to run. An exercise therapist could draw up an individual plan of approach. He also argues for some form of openly accessible in-patients' clinic for claudicatio patients, similar to that for heart failure.
Mr R. also mentioned the problems surrounding reimbursement. This sends out the wrong incentives, both for carers and for patients.

Appendix 1: List of abbreviations and concepts

Concept	Explanation
Aorta-iliac	Blood vessels in the region around the hips
Bypass	A bypass is treatment for severe constriction of the arteries. A surgeon takes a blood vessel from the patient's body and creates a bypass that circumvents the constriction.
CBBB	Chronic Occlusion of Blood Flow to the Leg
CI	*Claudicatio intermittens*
DBC	Diagnosis-treatment combination
DAPA	Dutch Audit for Peripheral Arterial disease
DICA	Dutch Institute for Clinical Auditing
EAI	Ankle-brachial pressure index
Femoro-popliteal	Blood vessels in the region around the knees
FMS	Federation of Medical Specialists
GLT	Supervised exercise training
The *Hart&Vaatgroep*	Patients' association for people with a cardiovascular disorder
Incidence	Number of new cases of a disorder per year, per thousand or hundred thousand of the population.
KNGF	Royal Dutch Society for Physical Therapy
Miletus	NThe Miletus Foundation is a partnership between health insurers for measuring patients' experience in health care
MRA	Magnetic resonance angiography
NFU	Federation of University Medical Centres in the Netherlands
NHG	Dutch College of General Practitioners
NVvH	Dutch College of Surgeons
NVvR	Dutch Radiology Association
NVvV	Dutch Association of Vascular Surgery
NVZ	Dutch Hospitals Association
NZa	Dutch Health Care Authority
Occlusion	Obstruction of a blood vessel
PAV	Peripheral arterial disorder
PREM	Patient Reported Experience Measure
PROM	Patient Reported Outcome Measure
Prevalence	Number of cases per thousand or per hundred thousand of the population at a specific moment
PTA	Percutaneous transluminal angioplastics
Stenosis	Constriction of a blood vessel due to calcium deposits
Vascular hallmark	Quality instrument developed by the Hart&Vaatgroep, so patients can see whether a hospital fulfils a number of quality requirements in the field of care for arterial disorders
VascuQol	The VascuQol is a questionnaire for measuring health-related quality of life and contains questions about patients' activity, symptoms, pain, emotions and social functioning.
VascuQol-6-NL	The questionnaire is referred to as the Vascular Quality of Life six-point scale (VascuQoL-6-NL) for health-related quality of life (HRQoL).
WIQ	Walking Impairment Questionnaire. This is comprised of three sub-domains: walking distance, speed of walking and climbing stairs

Concept	Explanation
ZiZo	Visible (Zi) Care (zo), a government programme that makes it possible to compare the quality of care within the care sector.
ZN	Association of Dutch Healthcare Insurers

Appendix 2: Zinnige Zorg's working method for the systematic assessment programme

Version 20-10-2016

1 Points of Departure

The *Zorginstituut* designed a systematic working method for the Zinnige Zorg Programme in order to examine the degree to which care in the insured package is used. The key is to identify and combat ineffective and/or unnecessary care, thus improving the quality of care for patients, increasing health gains and avoiding unnecessary costs. We carry out a systematic assessment for a field of disorders as defined in the ICD-10 classification system. A systematic assessment is carried out based on a number of points of departure.

1.1 Central role for patients

When assessing care, we give patients and the care path they follow a central role. The underlying question is always how much do patients benefit from the care supplied? Do they receive care that is appropriate to their situation, or perhaps too little care (under-treatment) or too much care (over-treatment)?

1.2 Shared decision-making

Care must be in keeping with the personal circumstances of patients. Apart from the established indication, patient-related matters also play a role in the choice of treatment, such as patients' expectations, their professional situation, impact on social functioning, pain perception, motivation, etc. For some diagnoses it is clear which treatment options have to be deployed. Often, however, various treatment options exist, each with their pros and cons and the choice of a given treatment will depend more on the preferences of patients and their carers. Shared decision-making is a way of arriving at an optimum treatment pathway together with a patient. Various instruments exist that can support shared decision-making of doctors and patients effectively, such as decision aids, option grids and patients' versions of guidelines; these can increase the quality of the decision-making process.

1.3 Stepped care

We assume that courses of treatment are started based on the stepped care principle. According to this principle, care is offered based on a step-by-step plan: the least burdensome effective treatment is used first, and only when this gives insufficient results are more complex or more invasive interventions offered. Stepped care is a general point of departure, not a mandatory requirement. The 'start moment' is not necessarily step 1, as steps may be skipped as necessary, according to the symptoms with which a patient presents.

1.4 Parties in health care are involved throughout the entire process

The objective of the *Zorginstituut* is to realise active agreement with the parties in health care. This will benefit the quality of the analyses and the basis of support for improvement measures. We involve the parties responsible in all phases of the systematic assessment.
The parties are invited to attend various consultations via umbrella arrangements. They are also given an opportunity to participate in supervising the research of external research bureaus. Lastly, we ask parties for comments on the draft versions of reports.

2 Phases of systematic assessment

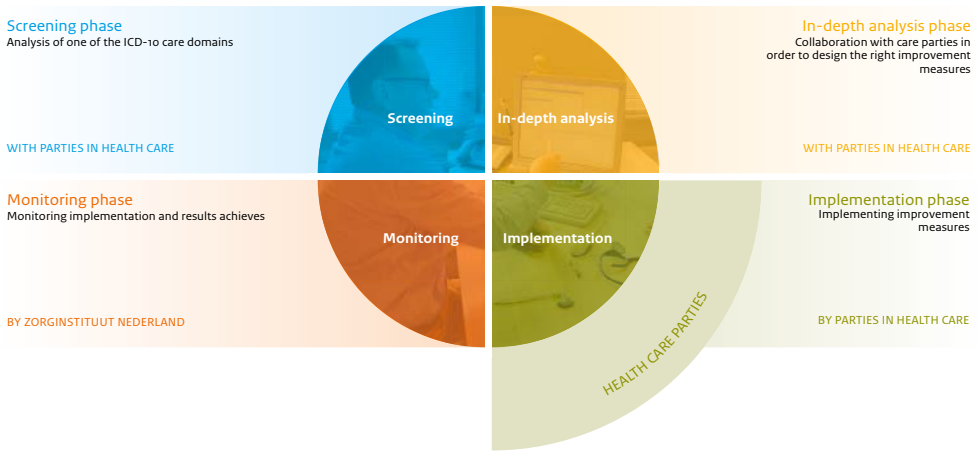
In order to promote good care, we carry out a systematic assessment according to a quality circle, or improvement circle, as illustrated in the following figure. This circle is comprised of four sequential phases:

1. Screening phase
2. In-Depth Analysis phase
3. Implementation phase
4. Evaluation phase

Figure 1: Zinnige Zorg's circle of improvement

Methodology

Purpose: promoting appropriate care in the consultation room



Zinnige Zorg's circle of improvement starts with a screening phase, in which we analyse how care is currently being given ('photo'). Based on this, a number of topics are chosen for in-depth analysis. In the second phase, the in-depth phase, we determine the potential for improvement, per topic. In the third phase (implementation) it is mainly up to the parties in health care to implement the agreed improvement measures. Lastly, in the evaluation phase we examine the extent to which the goals set have been achieved and whether a new circle of improvement should start, possibly using different instruments for improvement. Where necessary, the *Zorginstituut* can make use of its statutory instruments (e.g., clarification, advising on inclusion in – or exclusion from – the package, powers of persistence within the framework of the Multi-Year Agenda[35]) if insufficient results are realised. Below we describe the four phases of the improvement circle in more detail.

2.1 *Screening phase*

The objective of the screening phase is to select a number of topics for in-depth analysis with a possible potential for improving the quality and effectiveness of care by using care more appropriately. These topics are recorded in a report that is sent, together with the underlying analysis, to the parties in health care and to the Minister of Health Welfare and Sport.

Figure 2 shows how we arrive at a good substantiation of the in-depth topics by consulting various sources in an systematic analysis. Sources include the quality standards (guidelines, care standards and care modules), scientific literature, claim data and other data, and the parties in health care. This involves collecting and analysing not only all the information in great detail, but also searching for signals from daily practice in order to obtain a succinct picture of the care provided in the current situation. We look at the care pathway that a patient follows from the perspective (the "spectacles") of the *Zorginstituut*, with the elements that the *Zorginstituut* defines as good and appropriate care (see explanation below).

35 *The Multi-Year Agenda offers an overview of fields of care which have priority in the development of quality standards, measuring instruments and information standards (hereafter: quality products). If the Zorginstituut sees that the parties involved are in default, after the periods in the Multi-Year Agenda have lapsed, the Zorginstituut will take over the initiative or the coordination of developing a quality product. This is referred to as powers of persistence.*

Figure 2: From sources to in-depth topics in the screening phase

The choice of in-depth topics is based on the systematic analysis (based on the elements of good and appropriate care), the size of the topic (number of patients, burden of disease, budget impact), possible improvements and what the parties in health care feel is important.

2.2 *In-Depth Analysis Phase*

The screening phase is followed by the in-depth phase. The objective of this phase is to give as concrete as possible an indication of which potential improvements can be achieved.

Per topic, based once again on the elements of good and appropriate care, we carry out an in-depth study and we supply any missing knowledge in the form of extra data-analyses, scientific reviews, studies of daily practice and/or literature studies.

The final results are recorded in a so-called Improvement Report. This states which improvements in care and in health the *Zorginstituut* feels are possible, in respect of both content and amount, and provides an estimate of the total sum of costs involved (budget impact). We try to make agreements with the parties on improvement measures as concrete as possible. The Improvement Report is also sent to the parties in health care and to the Minister of VWS.

2.3 *Implementation phase*

The implementation phase is primarily a task for the parties in health care: patients, care professionals, institutions and health insurers. It takes place based on agreements made in the in-depth phase. In the implementation phase the *Zorginstituut* can play a supportive and facilitative role, for instance, by organising meetings, providing data and feedback, and by carrying out additional research. In order to guarantee compliance with agreements, both in respect of content and time, the *Zorginstituut* can place action points from the Improvement Report that relate to quality standards and measuring instruments on the Multi-Year Agenda.
Periodically, the *Zorginstituut* reports progress made to the accountable parties and to the Minister of VWS.

2.4 *Evaluation phase*

During the evaluation phase, the *Zorginstituut* examines, together with the parties involved, whether the results mentioned in the Improvement Report have been achieved. Based on this, we determine whether a new circle of improvement should start, possibly using different instruments for improvement. During this phase, we also examine whether all necessary information is structurally available.

3 Elements of good and appropriate care

We carry out an analysis of care both in the screening phase and in the in-depth phase. To do this, we use the "elements of good and appropriate care". Together, these give an idea of what the *Zorginstituut* regards as good and appropriate care. They are also in keeping with our quality and package management tasks. The analysis scheme used is as follows:

3.1 Knowledge about good care

A description of what we know about the availability of (inter)national quality standards (such as guidelines), measuring instruments (questionnaires and indicators) and information standards.[36] We see whether these can be found in, e.g., the *Zorginstituut*'s Register. Their entry in the Register shows that they fulfil the procedural criteria of the Assessment Framework[37]. We try to ensure that everything that can be found is included in Zorginzicht.nl.
Does patients' information exist, such as a patients' version of guidelines, or information about diagnosis and treatment on the website of a patients' association or on KiesBeter or thuisarts.nl?
Are there decision aids, option grids or outcome indicators which are relevant to patients, such as measures of quality of life, PROMs[38] and PREMs[39]? On which websites (public database and public information) can they be found?

In addition to procedural matters, we also look at the content of standards and guidelines: what recommendations are made that are relevant to our topic and are the (recommendations in the) guidelines sufficiently scientifically substantiated? Lastly, we look at the agreement between primary care and hospital care guidelines.

3.2 Application in practice

This is where we use various sources (such as claim data, publications, formal and informal consultations) to look at how care takes place in practice (including agreement between primary care and hospital care) and what the experts think about it.
We compare this to what we found in practice on recommendations in quality standards.

3.3 Care outcomes

Do patients benefit from the treatment? Is information available about quality of care and the outcomes of care, and can it be found by care providers, patients and citizens? For instance, is there a complication register, statistics on post-surgery mortality, experiences of patients with outcomes or experiences (measured with PROMs and PREMs)? And where can we find this information, e.g. on websites such as ZorginZicht.nl (public database), Kiesbeter.nl or Zorgkaartnederland.nl?

3.4 Effectiveness

Is the care effective? If we feel that the scientific substantiation of the guidelines (as assessed under element 1, Knowledge about good care) is of sufficient quality, we use the recommendations from the guidelines as point of departure for good care. If the guidelines are of insufficient quality, or are dated, then we can let the parties know that the guidelines need to be updated. A formal assessment based on the criteria established by the *Zorginstituut*, including a systematic review based on the GRADE system[40], only takes place if demanded by bottlenecks and there are no recommendations in the guidelines or they seem to be insufficiently scientifically substantiated.

An important part of an assessment of effectiveness are the starting questions, as described in the so-called PICOT: Patient – Intervention – Comparator Outcome – Time. For which group of patients is the care intended and is that the group for which research is available? Which treatment or care is being

36 *Zorginstituut Nederland. Assessment Framework for quality standards, information standards & measuring instruments 2015. Diemen, 2015. (Version 2.0).*
37 *Zorginstituut Nederland. Assessment Framework for quality standards, information standards & measuring instruments 2015. Diemen, 2015. (Version 2.0).*
38 *PROMs: Patient-Reported Outcome Measures: outcome measures of care, reported by patients without the mediation of a care provider. Source: Zorginstituut Nederland. Conceptual framework for appropriate care and variations in practice. Diemen, 2015. Report no. 1504.*
39 *PREMs: Patient-Reported Outcome Measures: outcome measures of care, reported by patients without the mediation of a care provider. Source: Zorginstituut Nederland. Conceptual framework for appropriate care and variations in practice. Diemen, 2015. Report no. 1504.*
40 *Zorginstituut Nederland. Assessment of established medical science and medical practice. Final updated version. Diemen, 2015.*

offered and has this care been studied? With which control treatment (regular care, standard therapy) was that care compared and what is the added value of the recommended care? And which outcomes relevant to patients were examined in order to determine whether the care was effective and for how long?

3.5 *Cost-effectiveness*[41]

Cost-effectiveness shows whether the (added) costs of treatment are reasonably in proportion with the added effectiveness. We look at whether the guidelines have anything to say about cost-effectiveness and we look at the (scientific) literature. Where we feel it is necessary, we carry out our own cost-effectiveness study.

3.6 *Necessity*[42]

This is where we examine whether a form of care should be part of the basic health insurance and whether it involves costs that people could pay for themselves. Weighing this up involves two different aspects: the severity of the disease (burden of disease) and the societal necessity of actually insuring the treatment concerned. Whereas the emphasis with burden of disease is on medical necessity, with 'necessity to insure' the emphasis is on whether insurance is actually necessary.

3.7 *Feasibility*[43]

Care cannot be supplied if it is not feasible. The feasibility element indicates whether the preconditions have been fulfilled and how sustainable it is to include an intervention in the basic package. Relevant to this are, e.g., basis of support, organisation (of care, indication and administration), funding, jurisdiction and ethics. This also involves, for instance, whether a funding formula (intervention description) exists for an intervention that should be included in the basic package.

3.8 *Consistency in quality circles*

This is where we look at whether quality circles are used which focus on improving care, who uses them and what interdependence exists between the quality circles.

4 Difference in the screening phase and the in-depth phase

The spectacles we use to look at care are, in principle, the same for all phases of the assessment, based on the eight elements mentioned above. Sometimes there is a difference in the nature and intensity of the systematic analysis in the screening phase and in the in-depth phase. The terminology itself shows that the first involves a global inventory, at the level of a disorder (ICD-10), and that the selected topics are examined in more detail during the in-depth phase. This phase often also combines various data sources.

5 Use of data in the analysis

The *Zinnige Zorg* programme makes regular use of quantitative data. Using these data meticulously is particularly important for the quality of the analysis, acceptance of the findings and the protection of privacy. The *Zorginstituut* explicitly recognises the importance of this and takes all necessary measures for processing the available data meticulously. The following is an explanation of key elements of how we process quantitative data.

Based on care-related questions, the *Zorginstituut* carries out data research into how care from the basic package is used in daily practice.[44] To do this we collect information from many sources: from discussions with interested parties to scientific publications, from RIVM statistics to claim data.

These are in part quantitative data, often claim data such as those of the Declaration Information System (DIS), Care Interventions and Claims (ZPD), and the Medicines and Medical Device Information Project

41 *Zorginstituut Nederland. Cost-effectiveness in practice. Diemen, 2015.*
42 *Zorginstituut Nederland. Package Management in Practice, part 3. Diemen, 2013. (pages 33 etc./43 etc.).*
43 *Zorginstituut Nederland. Package Management in Practice, part 3. Diemen, 2013. (pages 33 etc./43 etc.).*
44 *This may involve related fields, such as prevention, self-care and other forms of care not included in the basic package, based on the point of departure that we examine the care pathway integrally.*

(GIP). When using data, we take various measures to ensure that security and privacy are guaranteed optimally. For example, the *Zorginstituut* uses pseudonymised personal data over several years and from various sources, which are combined for a specific problem.

We used claim data to get an idea of daily practice in health care. Claim data reflect registration practices and not always the care actually provided. Nevertheless, these data do form an important source of information, sometimes the only one, and can provide valuable signals relating to quality of care. An in-depth exploration of the possibility of using other data sources is currently being studied, in collaboration with VWS and other parties in health care.

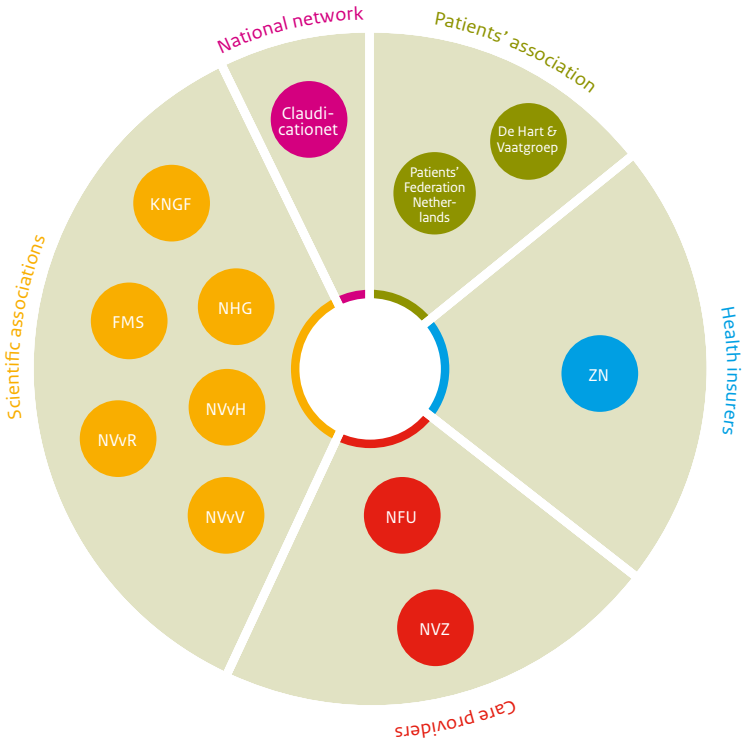
Safeguarding privacy is of paramount importance. Personal data used are therefore pseudonymised and cannot be traced back to individuals. Nevertheless, they are regarded as sensitive personal data so we are extremely meticulous in carrying out the analyses and we comply with current legislation. The data are only used for research goals/analyses defined in advance, they are not made available/used for other objectives and they are not disseminated. The results of the analyses are published at a level that precludes any tracing back to the level of individual persons, patients, insurers or care providers.

6 Parties involved

This systematic analysis was realised in consultation with care professionals, patients, institutions, health insurers and the government. The figure on the next page shows which parties were consulted in this process.

In January 2016 the Zorginstituut organised a meeting at which the analyses were discussed (the parties received the draft versions of the analyses in advance of the meeting) and the parties discussed possibilities for improving the care process for CI patients. Afterwards, the Zorginstituut gave the parties an opportunity to make comments and suggestions in a written response to the draft Room for improvement report.

The parties' responses (see appendix 7) added nuances and helped clarify our analysis. All parties received an individual written response to their contribution.



7 Description of how the PAV Room for improvement report developed

The figure on the next page describes the process for arriving at the Room for improvement report on peripheral arterial disease, with the focus on claudicatio intermittens. The steps are explained in brief below.

7.1 *Analysis for inclusion in the Room for Improvement report*

Within the care trajectory for CI patients, the Zorginstituut selected four topics for further investigation based on an exploratory analysis we carried out of claim data and signals received from care providers: ankle-brachial index, supervised exercise therapy within the care trajectory, duplex imaging and stent placement.

Per topic, the Zorginstituut carried out an analysis. This analysis involved eight perspectives that the Zorginstituut has identified as the above-named eight elements of good care. The goal of the analyses was to identify potential points for improvement. See appendix 4 for the results of the analyses carried out.

7.2 *Meeting on 26 January 2016*

The Minister commissioned both the HLA partners and the *Zorginstituut* with a view to the goal of improving the quality of care for peripheral vascular disease. Both organisations carried out this task according to their individual roles: the HLA partners by means of the K&D agenda; the Zorginstituut within the framework of the systematic assessment of the insured package, carried out via the Zinnige Zorg programme. Both parties prioritised the topic of peripheral arterial disease, though the accent of the programmes and how they were implemented differed. To avoid duplication and burdening the parties unnecessarily, the Zorginstituut and the HLA partners organised a joint meeting on 26 January 2016 to discuss any bottlenecks and lacunas in care for people with peripheral vascular disease and suggest actions for dealing with them.

The *Zorginstituut* disseminated the analyses that had been carried out in preparation of the meeting. During the meeting, the initial analyses were discussed and together with the parties, opportunities for improvement were identified.[45] These were recorded in a report that was sent to the parties, to which the parties could respond in writing. The final report was sent to all parties on 7 April 2016.

7.3 *Draft Room for Improvement report*

The findings from the analyses and the meeting resulted in a draft Room for Improvement report in which improvement actions were formulated for improving care for CI patients. We also provided an indication of the cost consequences if the improvements points are carried out. This is known as the Budget Impact Analysis (BIA).

7.4 *Consultation*

Het draft Room for Improvement report was sent to the parties, for consultation, in April-May 2016. We asked the parties for their responses in writing. A summary of all responses of the parties consulted and how the Zorginstituut incorporated them can be found in appendix 7.

7.5 *Room for improvement*

Together, the findings from the analyses and the meeting, as well as the parties' written responses to the draft Room for Improvement report, resulted in this final Room for Improvement report for claudicatio intermittens.

45 *The HLA partners and the Zorginstituut tried as far as possible to work together in elaborating on the various action points. Nevertheless, they both fulfilled their role and task independently of one another, and reported on progress of the various action points. The HLA partners recorded the action points in their Office Consultation. The Zorginstituut recorded the action points in a Room for Improvement report and monitored progress.*

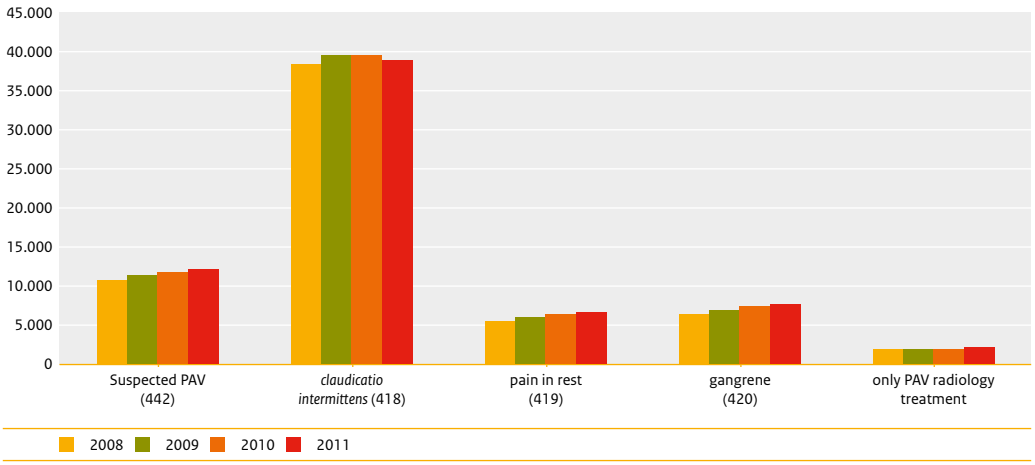
Appendix 3: Analyses of volume and costs for PAV patients

This appendix sketches how care for PAV patients developed in recent years (2008-2011), regarding both volume and costs. We limit ourselves to national data on care invoiced by hospitals.

The treatment of PAV is in the hands of GPs, physiotherapists and vascular surgeons, sometimes in partnership with a hospital's intervention radiologist. Patients may also receive treatment from other care providers. In recent years, the initial care provided by GPs and physiotherapists in primary care has changed. Attention is increasingly paid to chain care for patients with diabetes mellitus (DM) and Cardiovascular Risk Management (CVRM); both chains have been widely implemented in the Netherlands. Expectations are that this will result in PAV being diagnosed earlier, and also that prevention will be deployed earlier, in the form of lifestyle advice, quitting smoking and medication.

1 Volume for PAV care

Figure 3 Prevalence statistics on patients, per PAV stage, over the years 2008/2011, based on hospital claim data



The data show that the number of patients receiving hospital treatment for suspected PAV remains reasonably constant over time. Figure 3 shows that the group of patients diagnosed with claudicatio intermittens is by far the largest, on average 39,100 patients per year in the Netherlands. The number of people with this diagnosis rose from 38,300 to 39,000 in the period 2008-2009, remained stable in 2010 and fell slightly in 2011. The number of patients with critical ischaemia (pain in rest and gangrene) is much lower, about 5,800 patients with pain in rest and 6,7000 patients with gangrene. This number rises each year. Only a small proportion of patients with CI go on to develop a more serious form of PAV. The data show that a small number of patients are treated only by an intervention radiologist (within requiring a vascular surgeon and the corresponding DBC).

Figure 4 Number of patients, according to gender, per 5-year age classification, for PAV stage 2 *claudicatio intermittens* (DBC 418). The average age is 72 years.

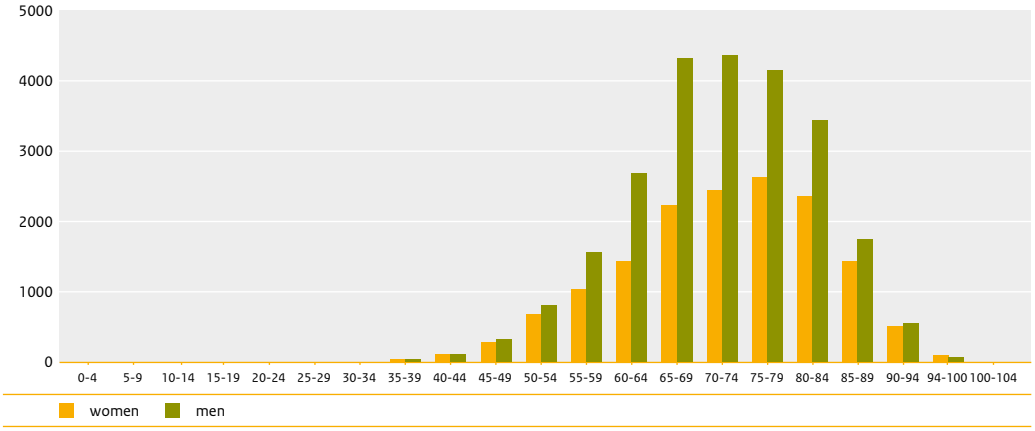


Figure 5 Number of patients, according to gender, per 5-year age-group, for PAV stage 3 pain in rest (DBC 419). The average age is 75 years.

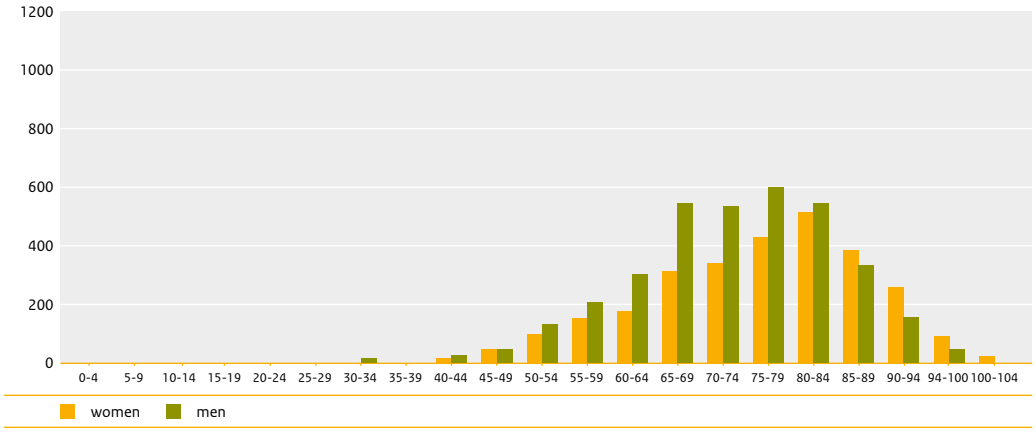
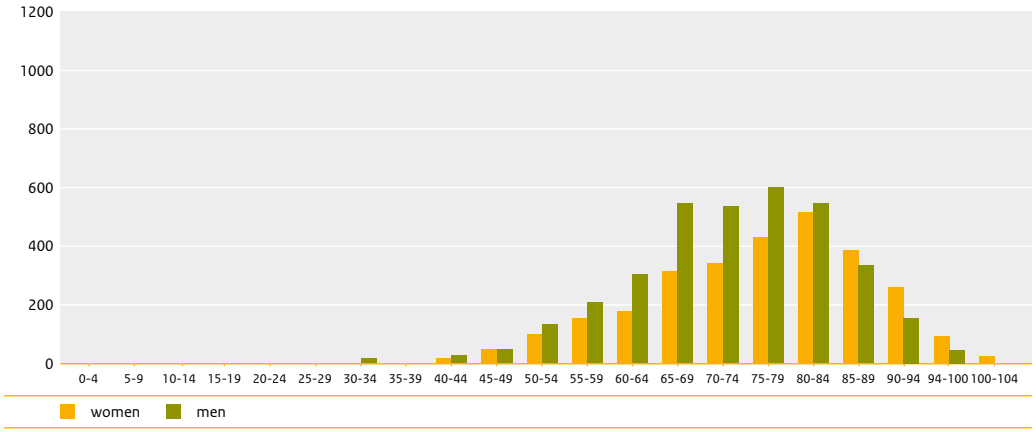


Figure 6 Number of patients, according to gender, per 5-year age-group, for PAV stage 4 critical ischaemia (DBC 420). The average age is 78 years.

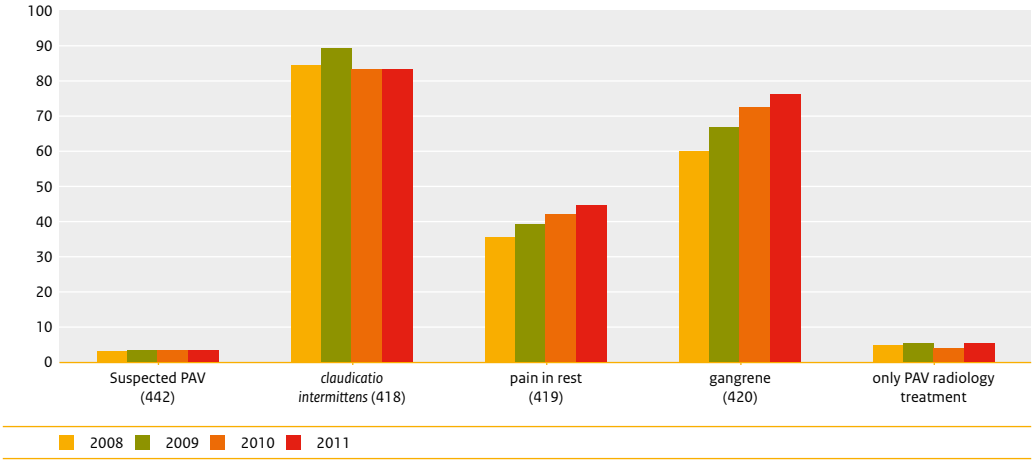


Figures 4-6 shows that the number of men suffering from CI and critical ischaemia is larger than the number of women. The statistics also show that patients with critical ischaemia are older than those with *claudicatio intermittens*.

2 Costs for PAV care

Figure 7 shows the medical costs for PAV, per stage, over the years 2008-2011, based on hospital claim data.

Figure 7 Medical costs for PAV, per stage, over the years 2008-2011, based on hospital claim data



Based on the bar charts on the costs and volume of hospital care for PAV, the following average costs can be calculated:

- A patient with suspected PAV costs on average €270;
- A patients with CI (PAV2) costs on average €2,170;
- A patient with pain in rest (PAV3) costs on average €6,930;
- A patient with gangrene (PAV4) costs on average €10,270.

The above statistics show that the hospital costs per patient for those with critical ischaemia (particularly those with gangrene) are much higher than those of patients with CI and also increase considerably each year (more expensive interventions, longer recovery period, more complications and multi-morbidity).

Appendix 4: Analyses serve as input for the Room for Improvement Report

Zorginstituut Nederland carried out in-depth analyses in the field of care for claudicatio intermittens (CI). These analyses, which focus on new patients with (suspected) CI, contributed to realising the Room for Room for Improvement Report.

In section 1, the *Zorginstituut* drew up a general inventory of all national and international guidelines that have formulated recommendations on the diagnostics and treatment of CI patients, the methodological quality of which was determined using AGREE II. We also looked at the availability of patient information and measuring instruments for increasing the transparency of quality of care.

Next, in section 2, based on an initial exploratory analysis of declaration data and signals picked up from care professionals, the *Zorginstituut* selected four topics in the category of care for CI patients for in-depth research: diagnosis of CI with the ankle-brachial pressure index, management of CI with supervised exercise therapy, imaging for revascularisation, and CI management with stenting. Cardiovascular risk management (CVRM), an important aspect of CI care, was dealt with in detail in the Room for Room for Improvement Report on Chest Pain, so this was not examined in detail.

Per topic, eight elements of good care were discussed. These eight elements, which are described in the following summary, were discussed in detail in appendix 2.

Eight elements of good care	
Knowing what constitutes good care	Availability of quality standards (such as guidelines), information standards, patients' information/decision aids and measuring instruments (PREMs/PROMs).
Use in practice	Implementation level of quality standards, patients' versions/decision aids and measuring instruments; analysis of data on practices, literature. • Are recommendations being followed in practice? • How is care implemented?
Care outcomes	Is quality information on care outcomes available and accessible?
Effectiveness	Is the care effective, do patients benefit from the treatment? • Scientific substantiation of guidelines. • Signs may form a reason to examine (again) whether the care really is effective and fulfils the criterion established medical science and medical practice by making use of the formal GRADE system of assessment.
Cost-effectiveness	Is the care cost-effective? • Do the guidelines say anything about this? • Signs may form a reason to examine (again) whether the care really is cost-effective.
Necessity	What quality circles exist, who is involved in them and what cohesion exists between the various quality circles?
Implementability	Have the prerequisites and sustainability of being part of an intervention in the basic package been fulfilled?
Consistency in the quality circles	Which quality circles exist, who is involved in them and what consistency exists between the various quality circles?

Lastly, in section 3, the *Zorginstituut* looked at consistency in quality circles involved in improving the quality of care for PAV patients and specifically those with CI.

1 Knowledge about good care for CI

This section describes the inventory that we drew up of what is known about the availability of quality standards (such as guidelines), information standards, patients' information and measuring instruments (questionnaires and indicators).[46] Are there any guidelines with recommendations on diagnostics and treatment for CI and what is the methodological quality of these guidelines? Do any outcome indicators

46 *Zorginstituut Nederland. Assessment Framework for quality standards, information standards & measuring instruments 2015. Diemen, 2015. (Version 2.0)*

exist that are relevant for patients, such as measures for quality of life, PROMs and PREMs.[47,48] We looked at whether the guidelines, measuring instruments and information standards are included in the *Zorginstituut*'s register, thus indicating that they fulfil the procedural criteria of the Assessment Framework[49].

1.1 Quality Standards

Quality Standards are publically available documents describing good care. Quality Standards are comprised of guidelines, care standards and/or modules. Various guidelines exist with recommendations about various aspects of the care process for CI patients (tables 4 and 5). None of the national guidelines mentioned are included in the Register.[50] Expectations are that the revised multidisciplinary guidelines of medical specialists will be offered tripartite for inclusion in the Register in 2016.

Table 4 Overview of national guidelines on care for CI

	Organisation	Year	Insight into care	Maintenance plan	Topics			
					EAI	Physiotherapy	Duplex	Stent
Multidisciplinary guideline: Arterial vascular disease of the lower extremities	NVvH	2016 (in draft)	Expected	Yes	√	√		√
Standard peripheral arterial disease	NGH	2014	No	No	√	√		
Symptomatic peripheral arterial disease	KNGF	2014	Library	No		√		
Multidisciplinary guideline: Arterial disease of the lower extremities	NVvH	2005	No	Yes	√	√	√	√

1.2 Methodological quality of the guidelines

An external bureau assessed the quality and autonomy of the available guidelines discussed in this Room for Room for Improvement Report, making use of the AGREE-II system (Appraisal of Guidelines for Research & Evaluation).[51] Table 6 presents the AGREE scores and the most important limitations of – in total – seven sets of guidelines.

47 *PROMs: Patient-Reported Outcome Measures: outcome measures of care, reported by patients without the mediation of a care provider. Source: Zorginstituut Nederland. Conceptual framework for appropriate care and variations in practice. Diemen, 2015. Report no. 1504.*

48 *PREMs: Patient-Reported Outcome Measures: outcome measures of care, reported by patients without the mediation of a care provider. Source: Zorginstituut Nederland. Conceptual framework for appropriate care and variations in practice. Diemen, 2015. Report no. 1504.*

49 *Zorginstituut Nederland. Assessment Framework for quality standards, information standards & measuring instruments 2015. Diemen, 2015. (Version 2.0)*

50 *Quality products in the Register are jointly developed by the parties and comply with the Assessment Framework. See https://www.zorginzicht.nl/Paginas/Home.aspx for additional information*

51 *https://www.agreetrust.org/.*

Table 5 Overview of international guidelines on care for CI

	Organi-sation	Year	Country	Topics			
				EAI	Physio-therapy	Duplex	Stent
Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication	SVS	2015	USA	√	√	√	√
Revascularization for lower limb peripheral arterial disease	KCE	2015	Belgium		√	√	√
Lower limb peripheral arterial disease. Diagnosis and management	NICE	2012	UK	√	√	√	√
Focused update of the guideline for the management of patients with peripheral artery disease	ACCF/AHA	2011	USA	√	√	√	√

Table 6 Overview of assessment of the AGREE II methodological domain

Guidelines	Score*	Most important methodological limitations
NVvH 2016	..	These guidelines had not been approved when this report was published, which hampers determining an AGREE score. Expectations are that the AGREE score will be considerably higher than for these guidelines in 2005, as this update is far more systematic and the quality of evidence was assessed using GRADE.
KNGF 2014	55%	Criteria for selecting evidence is not entirely clear; only a brief description of method used for drawing up recommendations; not always clear how weighing up took place on the health gains expected from interventions.
NGH 2014	14%	Methodology used for drawing up the guidelines is not described, so almost all items on the AGREE II checklist have a poor score.
NVvH 2005	49%	Criteria for selecting evidence not clear; little systematic description of strong points and limitations of evidence; only a brief description of method used for drawing up recommendations.
International guidelines		
ACCF/AHA 2005/2011	28%	Only a brief description of the search for evidence; criteria for selecting evidence not very clear; no description of method used to draw up recommendations; not always clear how weighing up took place on the health gains expected from interventions; assessment by external experts is not description; no description of revision.
KCE 2014	89%	No important methodological limitations.
NIVR 2012	80%	No important methodological limitations.
SVS 2015 • Ankle-brachial pressure index, follow-up diagnostics, primary stent placement	40%	No description of search for evidence; no description of criteria for selecting evidence; no description of revision.
• Supervised exercise therapy	70%	No important methodological limitations.

Score on the methodological domain AGREE II (minimum 0%, maximum 100%)

Footnote: In the meantime the NHG has improved the 2015 manual which has been published. However, it would be inappropriate to score a 2014 standard based on a manual from 2015.

There is evidence of quality differences in methodology. Particularly evident from table 6 is that the international KCE guidelines, the NICE guidelines and the section on supervised exercise therapy of the SVS guidelines do not seem to have any significant methodological limitations (scores of 70% or more). The SVS guidelines score well for the section on supervised exercise therapy, as no recent systematic review has been carried out. The three sets of guidelines mentioned are transparent about their search strategy, the selection of studies, determining the quality of the studies and considerations on which the recommendations are based. This is not the case with the national guidelines, which are not always transparent

about how the working group arrived at specific recommendations based on systematic analyses of the literature. This does not apply to the revised multidisciplinary guidelines of the NVvH (2016; draft), the new version of which is transparent on the above-mentioned matters.

Furthermore, the revised Dutch multidisciplinary guidelines of the medical specialists, the KCE, NICE and SVS guidelines[52] use the GRADE (Grading of Recommendations Assessment, Development and Evaluation) method for assessing and classifying the quality of the available evidence. For their procedures they refer to the Cochrane manual[53] of the GRADE working group.[54] GRADE offers a system for assessing the quality of scientific evidence transparently and systematically, and for drawing up evidence-based recommendations. Nowadays, this method is regarded as the 'gold' standard for developing evidence-based guidelines.

1.3 *Information standards*

There are no information standards on care for CI patients.[55] The NHG and the KNGF have written a general information standard on the structured exchange of information between GPs and physical therapists. In 2015 this information standard was offered (tripartite) to – and accepted for inclusion in – the Register of *Zorginstituut Nederland*.

1.4 *Patients' information and decision aids*

Table 7 Overview of patients' information and decision aids

Organisation	Field of attention	Topics			
		EAI	Physiotherapy	Duplex	Stent
www.thuisarts.nl	Claudicatio intermittens (including an explanatory film)	√	√		√
Kiesbeter	Claudicatio intermittens		√	√	√
www.etalagebenen.nl	Claudicatio intermittens	√	√		
Hartstichting	Brochure: stop and think about claudicatio intermittens (2015)	√	√	√	√
www.harteraad.nl	Website: treating leg arteries	√	√	√	√
Hart&Vaatgroep	Brochure: claudicatio intermittens, walk! (2010)	√	√		
Hart&Vaatgroep	Vascular disease of the legs: guidelines for patients		√	√	√
Hart&Vaatgroep	Vascular hallmark		√		
Hart&Vaatgroep	Decision aid (incl. option grid)		under development		

The website www.thuisarts.nl was last revised on 13 June 2016 and refers to the Dutch guidelines.

Shared decision-making is important because it can support decision-making for a given treatment (conservative or invasive). Choices are sensitive to preferences and personal circumstances. Decision aids for patients can support shared decision-making and increase the quality of the decision-making process. During the meeting on 26 January, a discussion took place on the extent to which one should enforce the desired stepped care treatment with supervised exercise therapy as first intervention before allowing an endovascular intervention. The opposing argument named was that this does not stroke with the practice of shared decision-making which is also regarded as desirable. Not every patient is prepared – and/or able – to first participate in exercise therapy. The obstacles to implementation noticed by the UK and

52 *The SVS guidelines make use of a different classification that that commonly used within the GRADE method (see appendix 5).*
53 *The Cochrane manual for systematic reviews of interventions. https://training.cochrane.org/handbook.*
54 *http://www.gradeworkinggroup.org/.*
55 *Information standards play a crucial role in standardising registration and the exchange of care data, thus enabling care professionals to do their work rapidly and safely. For more information: https://www.zorginstituutnederland.nl/quality /toetsingskader+en+register/informatiestandaarden.*

the revised guidelines also mention the preference of some patients for a rapid (endovascular) solution to their symptoms.
The initial precondition for shared decision-making is that the patient is properly informed about the advantages and disadvantages of the various treatment options. This was apparent from the narrative of Ms B (p. 31). Ms B was motivated to achieve her treatment objectives and felt it was only natural to avoid undergoing an operation if you could reduce the problem yourself by training.
Furthermore, a 'standard form' of supervised running training is not feasible for some patients, as can be seen from the narrative of Mr R. (p. 33) who has already had two hip operations. These patients need customised exercise training.

The revised multidisciplinary guidelines (2016; draft) have a section on providing patients with information. In the focus groups (an initiative of the Hart&Vaatgroep), it became clear that patients feel they do not receive sufficient information about the various treatment options. Recommended is that this takes place verbally, in writing and via websites, thereby paying attention to the following aspects: treatment methods, advantages and disadvantages of the treatment, effects/expected results in the short and the long term, possible complications and side effects, lifestyle advice, after-care and who to contact with questions. The guidelines discuss specific points, e.g., information on running therapy carried out by a specifically trained professional.

The Hart&Vaatgroep is developing a decision aid to support this. This is taking place in collaboration with researchers from the AMC (Amsterdam Medical Centre), within the framework of a ZonMw project. This development process started last year and is expected to be rounded off at the end of 2016. The current state of affairs is that focus groups are meeting, the draft version of the decision aid is ready, texts, pictures and films have been made and all the input is currently being assessed by relevant parties. A decision aid will be made for patients to support them when sharing in decision-making. An option grid based on this will subsequently be developed for professionals in their consulting rooms/policlinics. Researchers are working on an implementation process for realising national dissemination of the decision aid and option grid.

The indicator set provided (tripartate), as mentioned earlier, includes the following indicator on providing patients with information:[56]

Is every patient given adequate information prior to elective treatment (written and digital)?	Vascular hallmark: written information
Can every patient being treated in your hospital location by an (endo-)vascular specialist ask questions by telephone, and expect an answer the same day?	Vascular hallmark: accessible by telephone

The first indicators were supplied in 2016. An improvement task specifically for this indicator on patient information should have been completed before 1 July 2016.[57]

1.5 *Measuring instruments*

We have drawn up an inventory of data available on care for patients with peripheral arterial disease or, more specifically, for CI patients. We looked at which measuring instruments/indicators exist, their quality and which transparency registers record their use and how this information is subsequently made transparent.

Quality Registers

In November 2015, within the framework of the Transparency Calendar[58], a set of indicators for peripheral arterial disease was offered (tripartite) to, and included in, the *Zorginstituut*'s quality register. These are

56 https://www.zorginzicht.nl/Paginas/Home.aspx.
57 *More information can be found on the Zorginzicht website.*
58 *The Transparency Calendar contains information about quality of care in the Netherlands. The Transparency Calendar was drawn up by Zorginstituut Nederland in collaboration with the umbrella organisation NPCF, FMS, NFU, NVZ, ZN and V&VN. In 2015 the Minister decided that information on the quality of care had to be supplied to the Transparency Calendar for more than 30 disorders, including PAV.*

seven structural indicators and four former customer-preference indicators. As these indicators have been included in the Transparency Calendar, hospitals are obliged to supply quality data for them. This information promotes transparency of quality of care. This topic is also on the *Zorginstituut*'s Multi-Year Agenda.[59] *Zorginstituut Nederland* publishes the quality data supplied on www.zorginzicht.nl.

Two indicators are extra relevant to this report.

4a	Does your care institution offer supervised, standardised run therapy as basic intervention for patients with claudicatio intermittens?	Running therapy
4b	Does your institution make use of a list of physiotherapists with proven training in supervised running therapy to whom patients with claudicatio intermittens can be referred?	Running therapy
4b1	Yes, list for care-seekers on ClaudicatioNet	Running therapy
4b2	Yes, from a different list of physiotherapists with proven training in supervised running therapy, namely ...	Running therapy
4b3	No,	Running therapy
4b4	N.A.	Running therapy

All arterial and complex venous endovascular interventions are carried out under the supervision of a certified endovascular specialist	Vascular hallmark: endovascular interventions

The first indicators were supplied in 2016.

In addition there is the Dutch Audit for Peripheral Artery Disease (DAPA) which is part of the Dutch Institute for Clinical Auditing (DICA).[60] DAPA is a national quality register for peripheral arterial disease, in which the diagnosed indication and the courses of treatment offered are registered together with case-mix factors and patient feedback (PROMs). DAPA should result in feedback information for the various care providers, the objective being to reduce variations in practice and improve the quality of care. This is a real clinical register. DAPA registers the following (version 22 April 2016):

- Which PAV-related treatment has the patient received for his/her leg for this complaint in the past? (options: PCI/stent, operation, supervised exercise therapy?
- With which intervention/surgery is the patient being treated for the current diagnosis? (options: idem)
- Has the patient undergone an amputation? Did the patient die?
- It is not clear how many hospitals participate in this DAPA register and to what extent this information will become public.

Hallmark for good care

The *Hart&Vaatgroep* promotes the interests of all cardiovascular patients in the Netherlands. They are working together with patients and professionals, health insurers, scientists and the government in order to improve the quality of care. The *Hart&Vaatgroep* currently has two hallmarks:

- Vascular hallmark (15 criteria): hallmark for courses of treatment for disorders of leg arteries, arteries of the stomach, aorta and neck.
- Varicose veins hallmark: hallmark for the treatment of varicose veins. For PAV patients it is the first hallmark – the vascular hallmark – that is important. The aim of the Vascular Hallmark is to encourage quality improvement and to inform patients, those who refer them, and health insurers about the quality of vascular care provided in hospitals.

59 *Zorginstituut Nederland uses the Multi-Year Agenda to encourage the parties in care to develop quality products, such as quality standards or measuring instruments. https://www.zorginstituutnederland.nl/kwaliteit/meerjarenagenda.*

60 *https://www.dica.nl/dapa/home. The DAPA emerged from a relationship between the Nederlandse Vereniging voor Vaatchirurgie (NVvV, Dutch Vascular Surgery Association), the sub-association of the Nederlandse Vereniging voor Heelkunde (NVvH, the Dutch Surgery Association), the Hart&Vaatgroep, the Miletus Foundation and health insurers.*

Until recently there were three types of hallmarks:
- Independent hallmark: A hospital (location) itself fulfils all criteria.
- A collaboration hallmark: partnerships between various hospitals that have merged and work in various locations, or a hospital that is unable to fulfil all criteria alone and works together with a hospital that has an independent hallmark. Formal collaborations exist.
- Partial hallmark: extra location of a hospital with a hallmark.
- In 2015 the Hart&Vaatgroep issued the Vascular Hallmark to 84 hospitals that fulfil the quality criteria of the patients' association (97%).

An update took place very recently. There are still three types of hallmarks, but they are now described differently:
- Full domain hallmark: The hospital fulfils all quality indicators for the domains peripheral arterial disease, aneurysma and carotid artery. This may or may not be in collaboration with another hospital.
- Domain hallmark: The hospital fulfils the quality indicators for the DAVC-set and also 1 or more other domains (treatment of peripheral arterial disease, aneurysma, carotid artery).
- Extra location of a hospital with a hallmark: Some hospitals with a hallmark have another, extra location, in addition to the main location where interventions take place, where certified vascular surgeons hold a vascular out-patients' clinic.

Quality criteria of care for people with PAV from the perspective of patients

Within the Quality in Sight Programme of the Netherlands Patients' Federation, the Hart&Vaatgroep has developed a number of quality criteria about the wants and needs of patients in relation to the treatment and care of PAV. These quality criteria supplement existing guidelines and treatment programmes in health care, and can be used for several objectives, such as:
- input of care providers for patient-oriented quality improvements;
- input of care-purchasers for purchasing high-quality care;
- input for regional consultations with care providers, patients' associations and health insurers about high-quality care;
- input in developing a care standard, guidelines, a hallmark or patients' information.

PAV quality criteria supply content for such topics as managing care, effective care, information, and provision of information and emotional support. The generally applicable criteria for chronic care relate to accessible care, continuity of care, patient-oriented environment, safe care, and the transparency of quality of care and costs.[61]

2. Specific topics within the CI care process

Within the category of care for CI patients, the *Zorginstituut* selected four topics for in-depth research, based on an initial exploratory analysis of claim data and signals picked up from care providers: ankle-brachial pressure index, supervised exercise therapy in the care process, duplex ultrasound and stenting.

2.1 *Ankle-brachial pressure index*

In this instance we specifically looked at use of the ankle-brachial pressure index as primary diagnostic tool for patients who present with symptoms indicative of CI. We are not currently looking at preventive use of the ankle-brachial pressure index as a diagnostic tool within the framework of CVRM, i.e., during diagnostic determination for estimating the risk of cardiovascular disorders.

2.1.1 *Description*

Diagnostics for CI starts with an anamnesis (questions about symptoms, expectations and the presence of risk factors) and a physical examination of the legs, feet and arteries. An ankle-brachial pressure index is subsequently performed if the symptoms indicate CI. A doctor or other professional uses simple doppler-flow equipment to measure systolic blood pressure in the ankle and arm during rest, and calculates an ankle-brachial pressure index based on these values. If any doubt exists about the results, an ankle-brachial pressure index can be carried out again, e.g., after exercise on a treadmill.

61 https://www.harteraad.nl/.

2.1.2 *Knowledge about health care*

As described in sections 1.1 and 1.2, there are three national and three international sets of guidelines with recommendations about using the ankle-brachial pressure index to establish the diagnosis CI. Apart from the national guidelines, based on methodological quality, we describe two sets of international guidelines, namely the NICE and KCE guidelines.

Guideline recommendations on the ankle-brachial pressure index

National. The NHG Standards recommend determining the ankle-brachial pressure index using doppler equipment and they recommend the following cut-off values: chronic obstructive arterial vascular disorder is almost certain (chance >95%) with a single ankle-brachial pressure index less than 0.8 or with an average of 3 readings less than 0.9. How to measure this ankle-brachial pressure index is described in minute detail, with attention to standardisation. The NHG Standards suggest that GPs should remain alert to divergent ankle-brachial pressure indexes (high values) in diabetes patients because their arteries are less flexible. In a case of suspected peripheral arterial disease (symptoms) and an ankle-brachial pressure index >0.9 (dubious cases), advised is to determine either the ankle-brachial pressure index after running on a treadmill or the toe-arm index. In connection with this, the NHG refers to the recommendations of the American Heart Association. The NHG Standards suggest that GPs can determine the ankle-brachial pressure index (or have it determined by a practice employee) in their own surgery or in a regional diagnostic centre or hospital's vascular laboratory. When patients are referred to a surgeon, agreements are made about reverse referrals. According to the NHG Standards, carrying out the ankle-brachial pressure index in one's own surgery demands sufficient training and experience, and this requires clear agreements, but they do not describe exactly which agreements. In short, to date, specific quality requirements are still lacking. The NVvH guidelines recommend determining the ankle-brachial pressure index, thereby suggesting that arterial disease is probable with an index of <0.9. The revised guidelines of the NVvH (2016; draft) conclude that indications suggest there is limited agreement between an ankle-brachial pressure index measured in a GP's surgery and in a vascular laboratory. The guidelines recommend that an ankle-brachial pressure index is carried out by employees with sufficient experience and exposure, even for diagnostics in primary care. Doubt exists about the quality of using ankle-brachial pressure indexes in primary care. For this reason, recommended is that primary care is given access to a hospital vascular laboratory for diagnosing peripheral arterial disease.

International. The KCE guidelines specifically discuss revascularisation (the treatment pathway after diagnostics), but does report that the diagnosis CI is made based on clinical symptoms and/or diagnostics and/or the ankle-brachial pressure index. The NICE guidelines recommend an ankle-brachial pressure index for patients with suspected arterial disease, in combination with a structured anamnesis, examination of the leg and foot for signs of critical ischemia, and examination of the femoral, popliteal and foot pulsations. The guideline working group opted for a cut-off value of 0.9 based on sensitivity and negative predictive value, in order to avoid missing any patients with peripheral arterial disease. Its accuracy seems limited in the case of diabetic patients. This test is good, simple to use, non-invasive and inexpensive. The NICE guidelines also indicate the importance of standardisation: supine position, cuff-size, period of rest before the measurement, using manual doppler equipment, measuring over all three arteries.

Scientific substantiation of the recommendations

Based on the methodological quality of the guidelines (table 6), in order to increase the transparency of the scientific substantiation of the guideline recommendations, we looked at the quality of the guidelines with the highest scores: the revised NVvH guidelines and the KCE, NICE and SVS guidelines.

National The revised multidisciplinary guidelines of the NVvH (2016; draft) bases its recommendations regarding use of the ankle-brachial pressure index on a systematic search, which resulted in three observational studies that examined the correlation between an ankle-brachial pressure index in primary care and one from a vascular laboratory. Only one study related to a population with complaints of peripheral arterial disease (indirect) and it involved few patients (imprecision). This study found a discrepancy between the ankle-brachial pressure index in primary care and hospital care, but it is still not clear which measurement is most accurate. The other two studies involved volunteers from the high-risk population

for peripheral arterial disease (i.e., patients who are not suspected of having PAV based on symptoms). As a result, the power of the evidence is very low.

International In its recommendations on using the ankle-brachial pressure index, the NICE guidelines (2012) are based on five diagnostic studies of moderate quality that were found after carrying out a transparent systematic search. The underlying evidence varies from average to very low quality, the recommendations are formulated as consensus statements. The NICE guidelines are fully transparent about the considerations and line of argument that resulted in the recommendations.

Are the recommendations of the various guidelines in line with one another?
All guidelines see a firm place for the ankle-brachial pressure index in determining the diagnosis, although most guidelines emphasise that the ankle-brachial pressure index is only one element of the clinical diagnosis. Consensus exists about the 0.9 cut-off value.

Table 8 Diagnostic accuracy of the ankle-brachial pressure index (NICE)

		Sens	NVW*	GRADE
EAI versus angiografie				
Cut-off <0.9	1 studie; n=106; pt met diabetes	71%	65%	Average
EAI versus duplex				
Cut-off <0.9	1 studie; n=100; pt met diabetes	71%	53%	Average
Cut-off <0.9 Lower ankle pressure	1 studie; n=216	89%	88%	Average

EAI= ankle-brachial pressure index; Sens= sensitivity; NVW= negative predictive value: the proportion of patients with a negative test result who do not actually have the disease.

The guidelines all agree that the ankle-brachial pressure index as a diagnostic tool should be used by care professionals with sufficient experience and training. Nevertheless, there are some discrepancies in the national guidelines regarding how use of this diagnostic tool is organised. The NHG Standards pay a lot of attention to a standardised method of using the ankle-brachial pressure index and describe how a GP or a GP's assistant can use this diagnostic tool (as long as they have sufficient training and experience), or it can be performed in a regional diagnostic centre or a hospital's vascular laboratory. The multidisciplinary guidelines express doubts, based on weak evidence, about using the ankle-brachial pressure index in primary care, and recommend giving primary care access to a hospital vascular laboratory for diagnosing CI.

In the Netherlands, both primary care and hospital care feel that using the ankle-brachial pressure index is part of their domain and competence. The risk is that this can lead to unnecessary repetition of diagnostics in primary care and hospital care.

2.1.3 *Application in practice*

Level of implementation of guidelines and measuring instruments
NHG Standards pay a lot of attention to standardising ankle-brachial pressure index diagnostics. The NHG states that determining the ankle-brachial pressure index takes about 17 minutes and can easily be done in a GP's surgery, and can be delegated to the surgery assistant. This tool is used routinely in a number of diagnostic centres and vascular function departments in hospitals. There are tariffs for invoicing use of this tool, both in primary care and in hospital care. A professional who wants to use doppler equipment to determine the ankle-brachial pressure index in practice will need to gain – and maintain – experience. The NHG states that they recommend delegating this task to one person in a GP surgery or group practice, e.g. the surgery assistant or nurse practitioner.

Data from daily practice
The *Zorginstituut* has received signals that, to date, it is not clear how many times the ankle-brachial pressure index is actually carried out in primary care by GPs and/or nurse practitioners.

Dutch experts agree that repeating the ankle-brachial pressure index makes no sense once the diagnosis peripheral arterial disease has been made. A study has shown that it is not a suitable instrument for measuring the effects after an intervention.[62]

In this section the *Zorginstituut* investigates use of the ankle-brachial pressure index in practice based on specific questions.

Question 1: How many ankle-brachial pressure indexes are determined in primary care?
At the time of this investigation, the *Zorginstituut* did not have access to data on care consumption in primary care. Insurers do have access to these data. We asked an insurer to carry out a trend analysis based on first-line declaration data.[63] GPs can invoice ankle-brachial pressure index diagnostics as M&I intervention 13001: Diagnostics with the aid of a doppler.[64] It seems that between 2010 and 2013, on average this insurer claimed 21,000 ankle-brachial pressure indexes per year for its insured clients. As this health insurer has a market share of 4.5 million insured clients, we estimate that, nationally, GPs claim circa 80,000 ankle-brachial pressure indexes per year.[65]
Furthermore, the health insurer was able to determine, retrospectively, for which proportion of second-line CI patients (DBC 418) an M&I intervention was claimed in primary care (M&I 13001). In the same year, GPs invoiced ankle-brachial pressure index diagnostics for 25% (n=2168) (see figure 8) of the 8642 patients who presented for the first time in hospital with CI (DBC 418) or suspected CI (DBC 442). This suggests that 75% of the patients who were referred to hospital had not undergone ankle-brachial pressure index diagnostics in primary care.[66] In view of the NHG Standards, which pay a lot of attention to optimising diagnostics in primary care, this means there is room for improvement.

Question 2: How many patients receive ankle-brachial diagnostics in hospital after having had ankle-brachial pressure index diagnostics in primary care?
Both professionals in primary care and those in hospitals regard these diagnostics as their domain and competence. The guidelines do not agree on this matter. Furthermore, the NVvH second-line guidelines show a lack of standardisation for carrying out ankle-brachial pressure index diagnostics. Both matters can lead to the unwanted repetition of diagnostics. We therefore tried to obtain insight into this, but this proved impossible.[67]
Question 3: How often are ankle-brachial pressure index diagnostics repeated in hospital after the diagnosis CI has been made?

As Dutch experts agree that it makes no sense repeating an ankle-brachial pressure index after the diagnosis has been made, we checked this standard based on declaration data.

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62 Lane R, Ellis B, Watson L et al. Exercise for intermittent claudication. Cochrane Database Syst Rev.2014; 7:CD000990.

63 This is an initial inventory-based analysis of one health insurer. The results are not publicly accessible. We report this, nevertheless, because it is an indication of a trend. If so desired, we can verify this analysis by putting the same questions to another large health insurer.

64 M&I is a claim code that GPs use for invoicing special interventions in the field of Multidisciplinary collaboration and Innovation. M&I list of tariffs; NZa 2015.

65 We have two marginal comments about these analyses: an ankle-brachial pressure index can also be used for other purposes than determining the diagnosis claudicatio intermittens and a GP can carry out and invoice an ankle-brachial pressure index on several occasions for any given patient. In other words, the figure of 80,000 does not necessarily tell us anything about individual patients.

66 This could be an underestimation, because in the previous year an EAI-measurement may have been carried out and a conservative care pathway was started at the time.

67 The Zorginstituut does have access to hospital register data (at DBC level) and underlying care activities (including the ankle-brachial pressure index), but not to primary care data. The health insurer mentioned above does have access to primary care data and hospital data, but in 2011 could not yet look at these at the level of care activities, only at the DBC level.

Figure 8: Patient flows, seen in hospital, in relation to CI

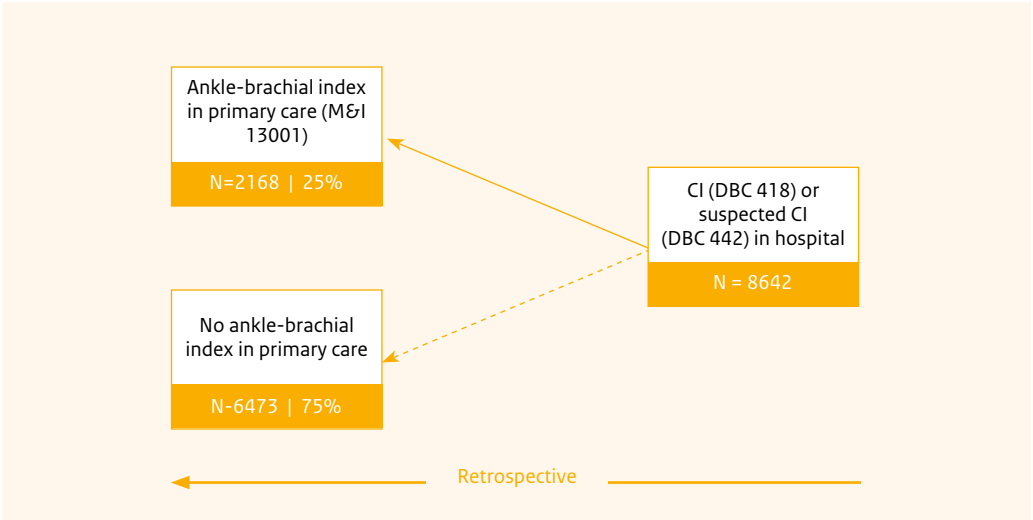

Table 9 shows that in 2011 19,473 patients were diagnosed with CI in hospital (DBC 418). Of these, 12,381 (19,473-7,092) patients underwent ankle-brachial pressure index determination at least once. In 23% of the cases (2,815/12,381) the ankle-brachial pressure index was invoiced again after a positive diagnosis, sometimes on several occasions (6%). In total, 16,049 ankle-brachial pressure indexes were carried out on 12,381 patients (9,566+4,260+1,650+436+95+42).

Table 9 Number of ankle-brachial pressure indexes determined per patient, in hospital (2011), in the first 365 days since creating the first DBC 418

	Number of patients with 418 first diagnosed in 2011	Total number of EAI
Total DBC 418	**19.473**	
No EAI	7.092	
EAI	12.381	
1 EAI	9.566	9.566
2 EAI	2.130	4.260
3 EAI	550	1.650
4 EAI	109	436
5 EAI	19	95
6 EAI	7	42

EAI: ankle-brachial pressure index; DBC 418: diagnosis CI

Meeting

During the plenary discussion at the meeting on 26 January 2016, both medical specialists and the NHG representative expressed doubts about the quality of carrying out the ankle-brachial pressure index in primary care (by a GP or Nursing Practitioner). GPs generally do not gain sufficient expertise with the tool, unless groups of GP practices collaborate (GP with specialist field). In that case most GPs refer patients to a vascular surgeon in hospital.

It is agreed that responsibility for diagnostics can remain with primary care, as long as the quality of implementing diagnostics is guaranteed and GPs can make use of, e.g., a vascular laboratory. The discussion showed that not everyone knows that GPs can request these diagnostics from a vascular laboratory without actually referring to a vascular surgeon. Separate tariffs apply for this, which can be found on the OVP-OP list.[68] Also mentioned was the lack of clear agreements between GPs and vascular surgeons

68 *OVP-OP list: An OVP is expressed as a care activity that is provided by a portal specialist in response to a request from primary care or another specialist within the same organisation for which the DBC-system does not apply. (Source: NZa).*

about diagnostics, using CVRM, and supervised exercise therapy, referrals, referring back, the responsibilities of professionals, a coordinating role and collaboration.

In response to the meeting, we formulated an extra study question.

Question 4: To what extent do GPs currently request ankle-brachial pressure index diagnostics in a vascular laboratory?
We examined hospital DIS declaration data for the number of OVP ankle-brachial pressure indexes. When an OVP is claimed, this implies that diagnostics were carried out for a patient in a vascular laboratory, but this patient was not seen by a vascular surgeon (as no DBC resulted) but was referred back to the GP who requested the diagnostics. In 2014 (the most recent and complete year in respect of DIS declaration data), we were able to form a picture of the numbers in which the ankle-brachial pressure index was invoiced in hospitals as OVP. Care activity code 039737 was used.[69] In 2014, it seems that 22 hospitals invoiced in total 320 OVP 039737 (range 1-114 claims). This shows that GPs make little use of a hospital's vascular laboratory.

2.1.4 *Care outcomes*
No outcome indicators exist for these diagnostics.

2.1.5 *Necessity*
In the past, there was no reason for the *Zorginstituut* to issue a statement on the necessity of using ankle-brachial pressure index diagnostics in the care pathway for CI patients, nor any societal need to actually insured this form of diagnostics. There still seems no reason to issue a statement specifically about this.

2.1.6 *Effectiveness*
In order to determine the effectiveness of ankle-brachial pressure index diagnostics, we examined existing EBM guidelines, and our analysis of the guidelines shows that, despite the predominantly low to moderate quality of the evidence, consensus exists about using the ankle-brachial pressure index and the 0.9 cut-off value that is used. For this reason we decided not to carry out a supplementary study (which involves writing a systematic review) to assess the diagnostic accuracy or the clinical value of these diagnostics.

2.1.7 *Cost-effectiveness*
The *Zorginstituut* did not carry out its own study into the cost-effectiveness of ankle-brachial pressure index diagnostics. The NICE guidelines did pay attention to this, but found no literature. They looked at which supplementary resources are needed for diagnostics, apart from anamnesis and physical examination, and the working group agrees that the costs of an ankle-brachial pressure index are small in relation to the improvement in diagnosis accuracy by using these diagnostics.

2.1.8 *Feasibility*
The *Zorginstituut* saw no reason to examine in greater detail the feasibility of ankle-brachial pressure index diagnostics for CI patients. These diagnostics are already used for CI patients. For claims relating to these diagnostics, (specific) payment titles exist for GPs and vascular surgeons, and there are no indications of any organisational constraints on care providers in supplying this treatment.

2.1.9 *Summary of the analyses*
The systematic analysis shows that the quality of care for CI patients can improve further, particularly in respect of:
- Knowledge about good care;
- Applying guidelines.

69 *Study of arterial obstructions in extremities by means of measuring the blood pressure in the arms and/or legs or penis using CW doppler or plethysmography incl. PVR curves or doppler flow velocity curves incl. a burden test.*

Knowledge about good care

Recent, high-quality, national and international guidelines exist that provide recommendations about using the ankle-brachial pressure index diagnostic tool for CI patients based on a systematic assessment of the literature. The revised multidisciplinary guidelines: diagnostics and treatment of patients with peripheral arterial disease of the lower extremities was in the process of being approved when this report was being written; expectations are that it will be offered (tripartite) to the *Zorginstituut*'s quality register.[70] It also contains patient information that can provide support in making the right treatment choices.

An analysis of the guidelines shows that the ankle-brachial pressure index, in combination with an anamnesis and physical examination, is an adequate diagnostic instrument for establishing the diagnosis CI in patients presenting symptoms. The national guidelines agree that the ankle-brachial pressure index as a diagnostic tool can be carried out in primary care. This diagnostic tool must be used by care professionals with sufficient experience and training.

The 2014 NHG Standards state that a GP or GP's assistant can use this diagnostic tool (as long as they have sufficient training and experience), or it can be performed in a first-line diagnostic centre (EDC) or a second-line vascular laboratory. The NHG Standards pay a lot of attention to a standardised method for carrying out the ankle-brachial pressure index, in order to guarantee the quality of using this diagnostic tool in primary care. On the contrary, due to very weak evidence, the multidisciplinary guidelines express doubts about professionals using the ankle-brachial pressure index in primary care.[71] They therefore recommend allowing first-line professionals access to a second-line vascular laboratory. They emphatically state that this can take place without requiring a referral to a vascular surgeon.

Bottlenecks:

- The national guidelines do not provide clarity on the preferred place for performing ankle-brachial pressure index diagnostics;
- To date no specific quality requirements exist for the training and experience of professionals who perform ankle-brachial pressure index diagnostics.

Applying guidelines

Improvements can be made in how the ankle-brachial pressure index is used in practice according to the description of good care in the guidelines. We assessed the guideline recommendations against actual practice. As mentioned previously, the national guidelines agree that the ankle-brachial pressure index as a diagnostic tool can be used in primary care. Nevertheless, in practice, data show that a considerable number of ankle-brachial pressure indexes are carried out in hospital under the responsibility of a vascular surgeon (declarations in the form of DBCs). In addition we see that few ankle-brachial pressure index diagnostics are requested by GPs in vascular laboratories (OVP declarations[72]).

Bottlenecks:

- No clear agreements exist between primary care and hospital care about organising this diagnostic tool, nor between GP practices about which professionals will train in using this diagnostic;
- GPs are still insufficiently aware that they can request diagnostics in a hospital's vascular laboratory without having to actually refer the patient to the vascular surgeon.

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70 The objective of the Register is to shed light on what the health care parties regard as good care. The Zorginstituut uses the criteria of the Appraisal framework to assess this.

71 The systematic search resulted in three observational studies. Only one study related to a population with complaints of peripheral arterial disease (indirect), and it involved few patients (imprecision). This study found a discrepancy between the ankle-brachial pressure index in primary care and hospital care, but it is still not clear which measurement is most accurate. The other two studies involved volunteers from the high-risk population fir peripheral arterial disease (i.e., patients who are not suspected of having PAV based on symptoms). As a result, the power of the evidence is very low.

72 OVP-OP list: An OVP is expressed as a care activity that is provided by a portal specialist in response to a request from primary care or another specialist within the same organisation for which the DBC-system does not apply. (Source: NZa).

2.2 Supervised exercise therapy

2.2.1 *Description*

CI is treated according to the stepped care principle. This is a step-by-step plan involving increasingly intensive forms of care, the idea being not to take all steps, but to book success (= relieve symptoms) by taking as few steps as possible.[73]

The various steps for CI are as follows:

- The least intensive form of treatment is a conservative treatment comprised of cardiovascular risk management (CVRM), medicines, exercise therapy or running training (supervised or not);
- The following step is an endovascular intervention, such as percutaneous transluminal angiography (PTA), whether or not in combination with stenting;
- The most invasive form of treatment is a vascular surgical intervention, a bypass operation.

Exercise therapy or running training forms an essential element of care for people with CI. This is described as primary treatment in most national and international guidelines. It is not always clear just what form exercise therapy or running training takes. Various studies and systematic reviews compare different forms of training (such as running advice only, structured exercises at home or supervised exercise therapy) with one another,[74,75] but there is still no clarity about the best practice in this respect.

2.2.2 *Knowledge about health care*

As described in sections 1.1 and 1.2, there are four national and four international sets of guidelines with recommendations about using supervised exercise therapy in cases of CI. Based on the methodological quality, apart from the national guidelines, we describe three sets of international guidelines, namely the NICE, the KCE and the SVS guidelines.

Guideline recommendations

National The NHG Standard names supervised running training as treatment of first choice. These refer to, inter alia, the KNGF guidelines. The most important recommendation in the KNGF guidelines relates to exercise therapy – whereby running training is the preferred choice – three times weekly, during at least 30 minutes per session, for a minimum of 6 months. This exercise therapy may comprise only running/walking, active (leg) exercises, physical training or treadmill training, possibly in combination with muscle strengthening. Supervised training programmes are preferred, though the marginal comment is made that no advice can be given about the optimum number of supervised training sessions. In 2005 the NVvH guidelines recommended running training as primary treatment, but the authors concluded that for the moment there is no evidence for supervised running training. However, the revised guidelines of the NVvH (2016; in draft) do now recommend supervised running training as primary treatment, whereby supervision is provided by a physical therapist or exercise therapist adequately trained to do this in accordance with the KNGF guidelines. If running training has insufficient effect after 3 to 6 months, the patient can be considered eligible for an intervention.

International The KCE guidelines focus on revascularisation. For this reason, exercise therapy is only compared to revascularisation. The KCE guidelines recommend an exercise period during which CI patients can consider participating in a cardiovascular risk management programme with supervised exercise therapy and angiography, and an invasive operation is only considered if this exercise therapy proves ineffective. The NICE guidelines recommends that all CI patients are offered primarily supervised exercise therapy. An endovascular intervention is only offered if cardiovascular risk management has been offered, supervised exercise therapy has been given and did not lead to the desired effect, and

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73 Under the auspices of the former Quality of Care Supervisory Council, a list of frequently used terms from health care has been drawn up, whereby each is provided with an explanation. This list has currently been deposited with the Quality Institute of Zorginstituut Nederland: http://glossarium.zorginstituutnederland.nl.

74 Fokkenrood HJP, Bendermacher BLW, Lauret GJ et al. Supervised exercise therapy versus non-supervised exercise therapy for intermittent claudication. Cochrane Database Syst Rev 2013; 23:8.

75 Gommans LN, Saarloos R, Scheltinga MR, et al. The effect of supervision on walking distance in patients with intermittent claudication: a meta-analyses Eur J Vasc Endovasc Surg 2014;48:169-84.

diagnostics show that an endovascular intervention is necessary. The SVS guidelines also recommend supervised exercise therapy as primary care treatment. If a supervised programme is not available or has been completed, these guidelines recommend non-supervised exercise therapy in the form of 30 minutes walking three to five times a week. In addition, endovascular treatment is recommended for patients with severe function limitations if improvement can reasonably be expected of this treatment, if conservative therapy has failed, and if the advantages outweigh the possible risks.

Scientific substantiation of the recommendations

Based on the methodological quality of the guidelines (table 6), in order to increase the transparency of the scientific substantiation of the guideline recommendations, we looked at the quality of the guidelines with the highest scores: the revised NVvH guidelines, and the KCE, NICE and SVS guidelines.

National The revised multidisciplinary guidelines of the NVvH (2016; draft) base the recommendation of offering supervised exercise therapy on a systematic search that resulted in three systematic reviews. The results are as follows. Supervised exercise therapy seems more effective than non-supervised exercise in increasing the maximum walking distance of CI patients. The quality of the evidence found is moderate, based on GRADE. Furthermore, there are indications that supervised exercise therapy is more effective than non-supervised exercise in improving quality of life. The quality of the evidence found is low, based on GRADE.

International The KCE guidelines base their weak recommendations relating to exercise therapy on studies of a largely low to very low quality. These guidelines lack cost-effectiveness considerations, though the guideline working group emphasises the importance of such considerations in the future. The NICE guidelines bases its recommendations regarding exercise therapy on studies of an average to low level of evidence. Despite the low evidence, this recommendation is given priority in the extensive NICE guidelines, along with another eight recommendations. The NICE guidelines are the only ones that involved any cost-effectiveness in the recommendation. They did mention the lack of good information on (cost-) effectiveness in the long term. In its 2014 update, NICE concludes that recent literature substantiates the recommendations from 2012. The NICE guidelines are fully transparent about the considerations and line of argument that resulted in the recommendations. The SVS guidelines base their recommendations regarding exercise therapy on a systematic review they carried out themselves, in which the quality of the evidence found was assessed as high. The quality of the evidence found for the recommendation regarding endovascular treatment is described as average.

Are the recommendations of the various guidelines in line with one another?
Consensus exists in the guidelines that supervised exercise therapy is designated as primary treatment for CI patients.

2.2.3 *Application in practice*

Level of implementation of guidelines and measuring instruments

In clinical practice, CI patients must be treated according to the stepped care principle. Based on this principle, care is offered that is no more burdensome than necessary, and more complex interventions are only offered if the results of simple interventions proved insufficient. Consensus exists in the guidelines that supervised exercise therapy is designated as primary treatment for CI patients.

Invasive treatment is not indicated where conservative treatment is effective, for the following reasons:
- in CI cases there is no need of an immediate intervention. The disorder is generally not progressive1;
- supervised running therapy seems a safe intervention for all CI patients, independent of the level of the lesion[76];
- CI is a chronic recurring disorder. Furthermore, it is a symptom of atherosclerosis of the legs, but this atherosclerosis is not restricted to the legs. As a result, effective supervised exercise therapy has a broader effect than increasing the maximum walking distance and, when continued, it also has a positive effect on the general state of health of this group of patients. Furthermore, running training can have a positive effect on hypercholesterolaemia, hypertension and diabetes[77], which can also result in reduced cardiovascular mortality and morbidity[78]. This does not seem to be the case with an endovascular intervention, which only removes the stenosis or occlusion and does not tackle the cause;
- the population of CI patients is an older population with a median age of 69 years in the intervention group and 70 years in the control group. This is a vulnerable population with a three to four times increased prevalence of cardiac and cerebrovascular disorders, and a two to three times increased risk of cardiovascular mortality.[79] Most of them are male (45-92%). They depend on continual care for their chronic disorder, i.e., cardiovascular risk management. Realising a behavioural change in lifestyle is an important objective for this population, with an important role for physical therapists;
- due to the increased risk of cardiovascular and cerebrovascular morbidity and the mortality of this population, this group should be exposed to as few unnecessary interventions as possible and be given maximum encouragement and guidance in the direction of a healthy lifestyle (within the framework of CVRM);
- based on appropriate care, patients should not be unnecessarily exposed to surgical interventions at all, because of the risks involved;
- the sustainability of endovascular interventions seems limited: the number of secondary endovascular interventions increased from 13% in 2003 to 22% in 2011.16 Furthermore, secondary revascularisation has negative consequences: it is associated with graft failure, morbidity and mortality.

There are signals, however, indicating that this is not always realised in practice.

The revised multidisciplinary guidelines of the NVvH (2016; draft) cite the following factors as points obstructing implementation:
- supervised exercise therapy is not reimbursed via the basic insurance. It seems that many patients have insufficient supplementary insurance, which means they have to pay privately for (part of) the first twenty treatment sessions;
- not every referring party (GP or vascular surgeon) is aware of the fact that a conservative treatment pathway is sufficient in most CI cases;
- not all patients have received sufficient information to become aware of the usefulness of training or they are insufficiently motivated to start it.

In the Netherlands, apart from the reimbursement problem, other factors may affect the degree to which supervised exercise therapy is implemented. In 2014 an editorial was published about this problem in the UK.[80] In 2012, the NICE guidelines were published which recommend supervised exercise therapy as primary treatment for all CI patients. However, mid-2014, they noticed different limitations in implementing this recommendation in practice and they saw little change (from operations to running training). They wrote that health insurers have doubts about the effect of supervised exercise therapy as it has only been demonstrated on walking distance and not on quality of life, the effectiveness is based on small RCTs, supervised exercise therapy has not yet been standardised, there are problems with compliance and there is still a lack of clarity about the long-term effects. Patients want a quick solution to their symptoms, not exercising three times a week. Furthermore, according to the author of the editorial, a lot of money is earned with endovascular interventions.

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76 Gommans LN, Fokkenrood HJ, van Dalen HC, Scheltinga MR, Teijink JA, Peters RJ. Safety of supervised exercise therapy in patients with intermittent claudication. Journal of Vascular 2015.

77 Watson L, Ellis B, Leng GC. Exercise for intermittent claudication. Cochrane Database Syst Rev 2008.

78 Heran BS, Chen JM, Ebrahim S. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database Syst Rev 2011.

79 NHG standard. Peripheral arterial disorder. 2014.

80 Why Do Health Systems Not Fund Supervised Exercise Programmes for Intermittent Claudication? Eur J Vasc Endovasc Surg (2014) 48, 608-610.

Many initiatives have started in the Netherlands based on the above-mentioned signals. For instance, the *Zorginstituut* is working on the reimbursement problem. Health insurers are involved in all sorts of initiatives so they can offer affordable supplementary packages to insured clients which will provide the latter with a chance of reimbursement.[81] Health insurers increasingly purchase care from certified physical therapists. Patients can access a growing amount of patient information about treatment options, stating advantages and disadvantages, and decision aids are being developed. The latter is a spearhead of the Hart&Vaatgroep.

Data from daily practice

As a means of mapping current practice (a so-called baseline measurement) and improving the transparency of the potential for improvement, the *Zorginstituut* has initiated an in-depth study to form a picture of the degree to which this treatment is currently used as primary treatment.

Question: To what extent is supervised exercise therapy used in the Netherlands as primary treatment for CI patients?

We studied data from practices in order to answer this question. Unfortunately, at the time of our study, we could not access first-line register data that supply insight into the use of supervised exercise therapy via primary care for CI patients. We could access hospitals' claim data, which showed that the majority of patients diagnosed with CI who are seen by a vascular surgeon (surgery 0303) receive conservative treatment (80%): on average, this amounted to 31,900 patients per year between 2008 and 2011.[82] The significance of registering conservative treatment in practice is not transparent:

- Did they receive running advice or were they referred to a physical therapist for supervised running therapy?
- Are they being treated by their GP for increased cardiovascular risk?

We looked at an existing study in order to obtain some insight into the use of supervised exercise therapy via hospital. Fokkenrood et al. used CZ data from 2009 to take a retrospective look at all patients diagnosed with CI who received treatment in hospital. The results are presented in the form of a flow diagram (see figure 9 on the following page).

The initial analysis showed that of the 4,954 CI patients in 2009, 14% received supervised running training (SET; n=701), 28% received an invasive intervention (INT; n=1363) and 58% received no treatment (REST; n=2890).[83] After correction of register errors and a follow-up analysis (two years), it seems that in the end 24% of the patients received supervised running training in hospital, either immediately or after some delay.

The above-mentioned analyses only provide insight into one aspect of reality, as we do not know how many CI patients were treated only in primary care. We do know that only a quarter of the CI patients received supervised exercise therapy via hospital.

Meeting

In the meeting on 26 January it became apparent that as yet no clear agreements existed between primary care and hospital care about diagnostics, using CVRM and supervised exercise therapy, referrals, referring back, the responsibilities of professionals, the coordinating role and collaboration.

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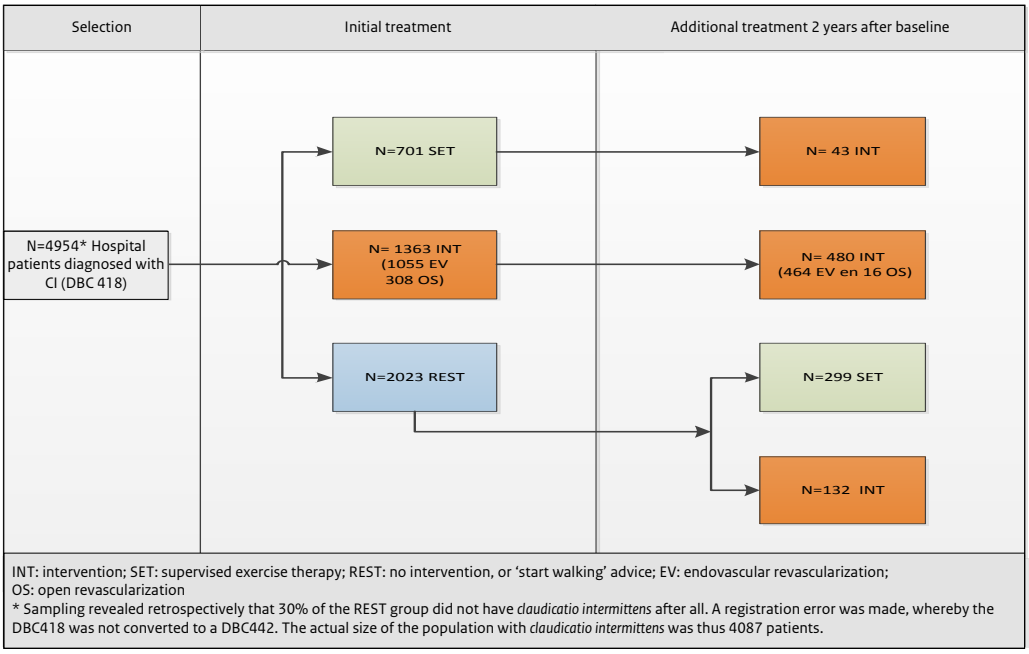
81 Zilveren Kruis Achmea recently announced its care purchasing policy for 2017: We are purchasing GLT nationally and will also be reimbursing the first 20 treatment sessions for all our clients who have supplementary insurance and who visit a Pluspractice. CZ has also announced its care purchasing practice for 2017: We will only purchase physical therapy for the treatment of our patients with claudicatio intermittens from physical therapists who are affiliated with the claudication network.

82 Based on analyses we carried out on hospital DBC claim data. These analyses were carried out and validated on 29-04-2015.

83 Thesis H.J.P. Fokkenrood. Innovative strategies for intermittent claudication; towards a stepped care approach and new outcome measures; June 2015.

Figure 9 Retrospective analysis of patients diagnosed with CI (DBC 418) and the course of treatment they received.



INT: intervention; SET: supervised exercise therapy; REST: no intervention, or 'start walking' advice; EV: endovascular revascularization; OS: open revascularization
* Sampling revealed retrospectively that 30% of the REST group did not have *claudicatio intermittens* after all. A registration error was made, whereby the DBC418 was not converted to a DBC442. The actual size of the population with *claudicatio intermittens* was thus 4087 patients.

2.2.4 *Care outcomes*

We examined whether quality data are available that can provide starting points for identifying where more scope exists for appropriate care.

Numerous initiatives exist in the field of improving quality. For instance, PROMs and PREMs are being developed for use in primary care and hospital care. An example is the VascuQol-6-NL PROM that is currently being validated.

To date, patient satisfaction (PREMs) is measured with the physical therapy CQI, and Miletus has drawn up a benchmark for purchasing care, information about options and quality improvement.[84] In the meantime, discussions have taken place with the KNGF and the Federation of Patients in the Netherlands about converting the CQI list into a compact generic first-line PREM for Paramedics, including the development of the KNGF's Nelson Beattie[85]. In 2016 this generic first-line PREM, which has tripartite support, will undergo validation measurement. The aim is to starting using this new list as of 1 January 2017. The objective is to propose placing the list in the *Zorginstituut*'s Register.

The KNGF has also initiated PROM pilots. These can be used to demonstrate the effectiveness of physiotherapeutic interventions.
As supervised exercise therapy is a form of treatment used via primary care, it would be relevant to carry out a quality measurement/outcome measurement in primary care in relation to the use and outcomes of supervised exercise therapy.

All sorts of national registers for measuring quality of care are being created in primary care, e.g. by the KNGF and ClaudicatioNet .[86,87] ClaudicatioNet has developed a national database that facilitates setting up a benchmark for comparing the various interventions and thus promote quality improvement. The

84 https://stichtingmiletus.nl/.
85 *The Nelson Beattie is a questionnaire, or American origin, into patient satisfaction.*
86 *KNGF: The Quality in Movement Masterplan (MKIB) will result in an integral physiotherapeutic quality system: the Physical therapy Quality Register NL.*
87 *ClaudicatioNet is a national network of specialised physical therapists. The objective of the quality register is to measure – and increase the transparency of – performance indicators, process indicators (including referrals to GP/specialist, start of treatment <5 days, etc.) and PROMS.*

KNGF is developing a Quality in Movement Masterplan (MKIB), which should result in an integral physiotherapeutic quality system: the Physical Therapy Quality Register NL.
The objective is to promote transparency and guarantee quality and continual improvement.[88]
These national registers will carry out and register PROMS and PREMS.

National registers for measuring quality of life already exist in hospitals. As described in section 1.5 of appendix 4, in November 2015, within the framework of the Transparency Calendar[89], a set of indicators for peripheral arterial disease was offered (tripartite) to, and included in, the *Zorginstituut*'s quality register. Hospitals are obliged to supply these quality data (as of 2015). *Zorginstituut Nederland* publishes the quality data supplied on Zorginzicht. The NVvH states that the 2016 report included a question about the consumption of physical therapy during the past year. In addition there is the Dutch Audit for Peripheral Artery Disease (DAPA), which is part of the Dutch Institute for Clinical Auditing (DICA).[90] DAPA is a national quality register for peripheral arterial disease, in which the diagnosed indication and the courses of treatment offered are registered together with case-mix factors and patient feedback (PROMs). This clinical register focusses in particular on internal quality improvement. Expectations are that during the course of 2016 the VascuQol-6-NL will become part of this registration, but the question is to what degree this information will be made transparent/public.

2.2.5 *Necessity*

CI is one of the indications on the physical therapy "chronic list"; entitlement is limited to one year. The first 20 treatment sessions are excluded. In 2011, in one of its reports, the *Zorginstituut* (then still CVZ) concluded that the number of treatment sessions per treatment episode does not justify describing this as care that needs to be insured (i.e., justifying a claim based on solidarity).[91]
Patients can pay for these treatment sessions themselves. In 2001 CVZ investigated whether this opinion had consequences for accessibility to physical therapy and exercise therapy.
In practice it turned out that health insurers offer various forms of supplementary insurance to cover uninsured elements of the provision physical therapy and exercise therapy.
An overwhelming majority of the Dutch population (90%) has taken out supplementary insurance.
In 2011, CVZ concluded that this means that accessibility to physical therapy and exercise therapy is not negatively affected.
At the time this was about the first 12 treatment sessions. In 2012 the Minister decided that the first 20 treatment sessions for physical therapy would no longer be reimbursed via the basic insurance. See appendix 6 for more information on this historic context. In section 2.2.8 we explain why renewed attention was given to this topic in 2016.

2.2.6 *Effectiveness*

The Minister of VWS asked the *Zorginstituut* for advice on three aspects of physical therapy.
This was about, inter alia, advice on the possible inclusion of the first sessions of physical therapy treatment for CI.

The *Zorginstituut* assessed whether supervised exercise therapy fulfils established medical science and medical practice.
In addition, the *Zorginstituut* examined what the significance would be of a possible substitution effect of including supervised exercise therapy in the basic insurance.

In its outcome of assessment, the *Zorginstituut* concluded that, in comparison with unsupervised exercise, supervised exercise therapy can be regarded as an effective treatment for CI.

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88 https://www.kngf.nl/.

89 The Transparency Calendar contains information about quality of care in the Netherlands. The Transparency Calendar was drawn up by Zorginstituut Nederland in collaboration with the umbrella organisation NPCF, FMS, NFU, NVZ, ZN and V&VN. In 2015 the Minister decided that information on the quality of care had to be supplied to the Transparency Calendar for more than 30 disorders, including PAV.

90 https://www.dica.nl/dapa/home. *The DAPA emerged from a relationship between the Nederlandse Vereniging voor Vaatchirurgie (NVvV, Dutch Vascular Surgery Association), the sub-association of the Nederlandse Vereniging voor Heelkunde (NVvH, the Dutch Surgery Association), the Hart&Vaatgroep, the Miletus Foundation and health insurers.*

91 CVZ: Physical therapy and exercise therapy: Assessment of the list of chronic disorders. 2011. Series number 2011037337.

Based on the literature study and meta-analyses that they carried out, the *Zorginstituut* could not draw any firm conclusions about the optimum form and duration of supervised exercise therapy for CI patients. However, the KNGF guidelines include a substantiated proposal for a treatment schedule with a range of 29-46 sessions, thus allowing room for professionals to support their patients during a specific period to help them reach the desired treatment goals and to promote self-management.

For this reason, the *Zorginstituut* concludes that effective supervised exercise therapy should comprise of 29-46 treatment sessions spread over a year, in compliance with the treatment goals described in the KNGF guidelines. After a(n) (more) intensive initial period of supervised exercise therapy, treatment frequency should be gradually reduced, the aim being to reach the stage of independent continuation of the exercises.

In short, supervised exercise therapy is effective, but ways for using interventions differ, in respect of not only frequency, but also duration and content.
In the future, more insight will have to be obtained into the effective organisation, implementation and content of this intervention for CI, including monitoring and evaluation.

In the meantime, in her draft memorandum, the Minister indicated that as of 1 January 2017, people with CI will be entitled to the reimbursement of 37 sessions of supervised exercise therapy spread over a year.[92] This includes reimbursement of the first 20 treatment sessions with this supervised exercise therapy at the expense of the Zvw. Entitlement to physical therapy or exercise therapy for stage 3 Fontaine peri-
pheral arterial disease (ischemic pain during rest) remains unaltered as of 1 January 2017.

2.2.7 *Cost-effectiveness*

Within the framework of reviewing the multidisciplinary guidelines of the NVvH, the *Zorginstituut* has offered – for the benefit of the guideline working group – to increase the transparency of all studies on cost-effectiveness of interventions for PAV. This is within the framework of a work programme about cost-effectiveness that the *Zorginstituut* is working on, one of the topics of which is to allow cost-effectiveness to become a structural part of clinical guidelines in the future.[93] The Institute for Medical Technology Assessment (iMTA) carried out this task in 2015.

Based on the iMTA report, the revised guidelines drew the following conclusion:
"Supervised exercise therapy has proven to be a cost-effective treatment in comparison with unsupervised exercise therapy. If supervised exercise therapy is compared with invasive interventions, supervised exercise therapy barely has any complications and costs significantly less."

Considerations resulted in part in the recommendation in the revised guidelines that supervised exercise therapy should be offered as primary treatment to CI patients.[94] The full report of the IMTA will be made available as appendix to the revised multidisciplinary guidelines of the NVvH.
The NICE guidelines (2012) also developed an economic model for comparing the cost-effectiveness of different interventions with one another. They concluded the following:
"Based on the results of the model, supervised exercise is a cost-effective treatment choice in over 75% of model simulations. Although supervised exercise is more expensive than unsupervised, it is also more effective".

Both guidelines reached the same conclusion. The NICE guidelines do indicate that there is a lack of good information about (cost-) effectiveness in the long term.

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92 Draft explanatory memorandum on amending the care insurance decree in relation to the Zvw care package 2017.
93 https://www.zorginstituutnederland.nl/.
94 Multidisciplinary draft guidelines on diagnostics and treatment of arterial disease of the lower extremities. These guidelines have not yet been approved, the draft version can be found on the website of the NVvH.

2.2.8 *Feasibility*

The revised multidisciplinary guidelines recommend that supervised exercise therapy should be given by a suitably trained physical therapist or exercise therapist in accordance with the KNGF guidelines on the symptomatic treatment of peripheral arterial disease.

In the Netherlands a form of step-by-step supervised running training (GLT) has been developed based on scientific substantiation. This form of supervised running training is used more broadly and is encouraged by a national platform, namely ClaudicatioNet.[95] Physical therapists who are affiliated with ClaudicatioNet have been specifically trained to recognise alarm symptoms and to make use of treatment protocols for running therapy for peripheral arterial disease, whether or not in combination with giving lifestyle advice. Good chain agreements have been reached within ClaudicatioNet throughout the regions. Furthermore, all affiliated physical therapists report the outcomes of the care supplied, thus providing insight into the quality of the care provided. ClaudicatioNet currently covers the entire country. ClaudicatioNet is not the only network. In the Netherlands there are a number of networks with which physical therapists can become affiliated, that involve an obligation to demonstrate having followed training.

According to the parties in care, proving the feasibility of using supervised exercise therapy in Dutch practice is difficult due to the limited entitlement to physical therapy and exercise therapy at the expense of basic insurance. Since 1996 a number of alterations took place in the provision of insured physical therapy and exercise therapy, mainly with a view to cost control.
For instance, since 2012 patients have to pay not for the first 12, but for the first 20 treatment sessions of exercise therapy and physical therapy. Personal excess also increased during recent years (for more information, see appendix 6).
In the Second Chamber Standing Committee on Package Measures on 18 June 2015, attention was drawn to the fact that the contents of the insured package may have promoted the unnecessary use of burdensome forms of care. Not reimbursing the first 20 sessions of exercise therapy and physical therapy could lead to undesirable substitution with care provided by medical specialists.

In response to this, the Minister replied that with a view to promoting substitution and appropriate care according to the stepped care principle, we should examine whether lighter forms of care should become part of the insured package.
On 6 November 2015, the Minister of Health, Welfare and Sport (VWS) asked the *Zorginstituut* for three counts of advice on substitution possibilities in relation to physical therapy. These were:

- advice on the possible inclusion of the first sessions of physical therapy treatment for CI. As an initial step, the *Zorginstituut* examined whether exercise therapy and physical therapy are effective treatment for CI patients and whether they fulfil established medical science and medical practice (section 2.2.6);
- advice on reimbursement via the basic insurance of the first sessions of physical therapy treatment for arthrosis of the hip and knee, rheumatoid disorders and hernia with loss of motor skills. The *Zorginstituut* will report on this at the start of February 2017;
- advice on a sensible, appropriate and economic plan for physical therapy in the Zvw package. This advice will pay attention to the necessity and feasibility of physical therapy and exercise therapy in the Netherlands. Are the right incentives being given to arrive at the best possible outcome? The *Zorginstituut* will report on this at the end of 2016.

2.2.9 *Summary of the analyses*

The systematic analysis shows that further improvements can be made in the quality of care for CI patients, particularly in:

- Applying guidelines;
- Making health care outcomes transparent;
- Clarity about the need to insure.

95 https://www.claudicationet.nl/home/.

Applying guidelines

Improvements can be made in using supervised exercise therapy in practice according to the description of good care. We carried out an appraisal of guideline recommendations against actual practice, and it seems that supervised exercise therapy is still not used optimally in the Netherlands; not all patients attend exercise therapy before undergoing an endovascular intervention or operation. Stepped care is not being sufficiently implemented as a result.

Bottlenecks:

- The current reimbursement system;
- The lack of good unequivocal patient information about various treatment options, despite the existence of patient information. This is why all sorts of initiatives have started;
- Insufficient harmonisation and collaboration between primary care and hospital care.

Making health care outcomes transparent

Despite all the initiatives in the field of developing PROMs/PREMs and (setting up) quality registers, we must conclude that, to date, no useful high-quality information is available about the outcomes of supervised exercise therapy for patients.

Bottleneck:

- Indicators in the current quality registers are limited to hospitals and relate only to structure and process indicators. Outcome indicators (PROMs) are not yet incorporated. As a result, to date there is a lack of national information about the quality of care supplied from the perspective of CI patients, both in primary care and in hospitals.

The need to insure

In 2011, in one of its reports, the *Zorginstituut* (then still CVZ) concluded that the number of sessions of exercise or physical therapy treatment, per treatment episode, does not justify designating this as care that needs to be insured (i.e., justifying a claim based on solidarity).[96] Since then, according to parties in health care, the limited entitlement to physical therapy and exercise therapy at the expense of the basic insurance has hampered the feasibility of deploying exercise therapy in practice in the Netherlands. In the Second Chamber Standing Committee on Package Measures on 18 June 2015, attention was drawn to the fact that the contents of the insured package may have promoted the unnecessary use of burdensome forms of care. Not reimbursing the first 20 sessions of exercise therapy and physical therapy could lead to undesirable substitution with care provided by medical specialists. On 6 November 2015 the Minister of Health, Welfare and Sport (VWS) asked the *Zorginstituut* for advice on three occasions about substitution possibilities in relation to physical therapy (appendix 4, section 2.2.8). The advice would re-examine the package criteria necessity and feasibility for exercise therapy and physical therapy. The results are expected mid-Q4 2016 to Q1 2017. Clarity already exists, but only for the disorder CI, in view of the decision of the Minister to reimburse 37 sessions of supervised exercise therapy as of 1 January 2017. As a result, the need to insure is no longer a bottleneck.

2.3 Duplex Ultrasound

2.3.1 Description

When an endovascular intervention is indicated, follow-up diagnostics take place. Duplex Ultrasound and Magnetic Resonance Angiography (MRA) are the least intensive forms for follow-up diagnostics, due to the lack of ionising radiation. Duplex ultrasound is a doppler examination combined with echography that is carried out when a surgical intervention is being considered in order to get a picture of the exact location and severity of the disorder in the blood vessel.

96 *CVZ: Physical therapy and exercise therapy: Assessment of the list of chronic disorders. 2011. Series number 2011037337.*

MRA involves administering contrast fluid via an artery in the arm and subsequently obtaining a picture of the blood vessels using magnetic equipment. Contra-indications for MRA are having a pacemaker and renal insufficiency. Other forms of angiography are Digital Substraction Angiography (DSA) and Computer-Tomographic Angiography (CTA), whereby contrast fluid is injected and patients are exposed to ionising radiation. DSA involves using a catheter to inject contrast fluid into the femoral vein, thus rendering blood vessels visible under radioscopy. Unlike with duplex and MRA, patients spend 24 hours in hospital after this examination, for monitoring. DSA use is declining.

2.3.2 *Knowledge about health care*

As described in sections 1.1 and 1.2, there is one national and four international sets of guidelines with recommendations about using duplex ultrasound for CI. Based on the methodological quality, apart from the national guidelines, we describe two sets of international guidelines, namely the NICE and KCE guidelines.

Guideline recommendations

National The NVvH guidelines recommends duplex ultrasound as reliable for demonstrating and precluding stenoses and occlusions in the aorta-iliacal and femoropopliteal arteries, and for selecting patients for percutaneous treatment. A peak systolic velocity (PSV) of >2.0-2.5 indicates a significant stenosis. The guidelines recommend magnetic resonance angiography (MRA) for drawing up a treatment plan, as an alternative to angiography that is regarded as a test for reference purposes. The revised guidelines have not formulated new recommendations on this.

International The KCE guidelines recommend duplex as first diagnostic technique for patients for whom revascularisation is being considered. Contrast MRA is recommended for patients who need additional diagnostics, to be replaced by CTA if MRA is contraindicated.

Scientific substantiation of the recommendations

Based on the methodological quality of the guidelines (tables 6), to increase the transparency of the scientific substantiation of the guideline recommendations, we looked at the quality of the guidelines with the highest scores: the KCE guidelines and the NICE guidelines.

The weak recommendations in the KCE guidelines on duplex ultrasound as initial diagnostic technique are based on evidence of a low to very low quality. The strong recommendation about using angiography is based on evidence of a moderate to low quality. The NICE guidelines also recommend duplex as first-line diagnostic, followed by MRA if necessary and CTA if MRA is contraindicated. This recommendation is based on evidence of a high to low quality. The NICE guidelines are fully transparent about the considerations and line of argument that resulted in the recommendations.

Are the recommendations from the various guidelines in line with one another?

The guidelines agree that follow-up diagnostics should only be used if an endovascular intervention is being considered. Only the KCE and NICE guidelines state a specific preference for the type of follow-up diagnostics: first duplex ultrasound, and only if necessary an MRA or CTA.

2.3.3 *Application in practice*

Data from daily practice

Based on an analysis of the guidelines, the *Zorginstituut* concluded that only in exceptional cases do follow-up diagnostics need to be used in the form of duplex ultrasound for patients who are not undergoing surgery. We tested this against data from daily practice.

Question: How many times was duplex ultrasound invoiced for CI patients with a conservative treatment pathway?
The 2011 DBC claim data show that 11,560 duplex ultrasounds took place in CI patients (DBC 418) who did not undergo subsequent (endo-) vascular surgery in that year.

Meeting
In the meeting on 26 January 2016, the comment was made that vascular laboratories often add a duplex ultrasound to the ankle-brachial pressure index so the patient does not have to come back if the decision is made to carry out an endovascular intervention. This seems to be the case particularly if an ankle-brachial pressure index is requested in a vascular laboratory via hospitals. GPs never request duplex ultrasound. According to the parties, duplex ultrasound without a follow-up intervention is currently hardly ever given if stepped care is used properly. If the guidelines are observed, patients only go to hospitals if they have already been through a conservative treatment pathway, this pathway proved ineffective and this is why they are eligible for an endovascular intervention or operation. In these cases duplex ultrasound is a logical follow-up step as preparation for an endovascular intervention or operation.

2.3.4 *Care outcomes*
Outcome indicators are not possible for these diagnostics.

2.3.5 *Necessity*
In the past, there was no call for the *Zorginstituut* to issue a statement on the necessity of using duplex ultrasound in the care process of CI patients, nor any societal need to actually insure this form of diagnostics. Even now there seems no reason to issue a statement specifically about this.

2.3.6 *Effectiveness*
In order to determine the effectiveness of duplex ultrasound, we looked at existing EBM guidelines and our analysis of the guidelines shows that, despite the predominantly low quality of the evidence, consensus exists about using duplex ultrasound. For this reason we decided not to carry out a supplementary study (by writing a systematic review) to assess the diagnostic accuracy or clinical value of these diagnostics.

2.3.7 *Cost-effectiveness*
The *Zorginstituut* did not carry out a cost-effectiveness study into the use of follow-up diagnostics. The NICE guidelines did study this and they arrived at the following conclusion:
"The group agreed that for patients in whom revascularisation may be beneficial, DUS (duplex ultrasound) represents the least costly and least invasive method of determining the location and extent of the lesion, and may well provide sufficient information".

Based on clinical effectiveness, cost-effectiveness and expert opinion, the Guideline Development Group agrees that duplex ultrasound is the first option for follow-up examination of patients who are eligible for an endovascular intervention.

2.3.8 *Feasibility*
The *Zorginstituut* had no reason to examine the feasibility of duplex ultrasound for CI patients in more detail. These diagnostics are already used for CI patients. For claims relating to these diagnostics, (specific) payment titles exist for vascular surgeons and there are no indications of any organisational constraints on care providers in supplying this treatment.

2.3.9 *Summary of the analyses*
The systematic analysis shows that improving the quality of care is particularly possible in:
- Applying guidelines

Applying guidelines

Improvements can be made in using duplex ultrasound in practice according to the description of good care. We carried out an appraisal of the guideline recommendations against actual practice. Despite the consistency between guidelines on using duplex ultrasound, in practice we see that at least 11,000 duplex ultrasounds were carried out on patients who received conservative treatment and did not undergo an endovascular intervention or operation.

Bottleneck:

- In view of the large number of duplex ultrasounds used on patients receiving only conservative treatment, more duplex ultrasounds are probably being carried out than necessary.

2.4 Stent placement

2.4.1 *Description*

Endovascular interventions that CI patients can receive in hospital are PTA treatment and/or stenting. PTA, or 'percutaneous transluminal angioplastics' (abbreviated to PTA) is a much-used technique for widening arteries in the event of a stenosis. This is done with the help of an inflated balloon. If necessary, a tube is left in situ at the location of the stenosis, i.e., stenting.

2.4.2 *Knowledge about health care*

Guidelines

As described in sections 1.1 and 1.2, there is one national and four international sets of guidelines with recommendations about the placement of stents for CI. Based on the methodological quality, apart from the national guidelines, we describe two sets of international guidelines, namely the NICE and KCE guidelines.

Guideline recommendations

This section specifically discusses the comparison between selective stenting and primary stenting. The question the guidelines wanted to answer with this comparison is whether stenting is required in all patients who undergo an endovascular intervention (primary stenting), or only in patients for whom PTA treatment proved insufficient (selective stenting).

National According to the NVvH guidelines, there is no reason for primary stenting in an uncomplicated PTA with good angiographic results. After a successful PTA, primary stenting is only necessary based on the indication: dissection or a pressure reduction above the lesion in excess of 10 mmHg. The revised multidisciplinary guidelines of the NVvH (2016; draft) re-examined the femoropopliteal artery pathway, and the guideline working group concluded again that primary stenting does not improve either walking distance or quality of life. For this reason, routine stenting in the femoropopliteal pathway and the crural pathway as endovascular treatment is not recommended.

International In the KCE guidelines, primary stenting is considered for patients with CI due to aorta-iliacal abnormalities. Primary stenting or coated balloon angioplastics is also considered for patients with CI due to femoropopliteal abnormalities, taking into account the duration, location and complexity of the abnormality, and the degree of calcification. On the contrary, the NICE guidelines reject primary stenting, except in a case of complete occlusion.

Scientific substantiation of the recommendations

Based on the methodological quality of the guidelines (table 6), in order to increase the transparency of the scientific substantiation of the guideline recommendations, we look at the quality of the guidelines with the highest scores: the revised NVvH guidelines, the KCE and the NICE guidelines.

National In the revised guidelines of the NVvH, evidence is reported based on a recently published, high-quality, systematic review that made use of the GRADE method. This described 23 RCTs, whereby 15 RCTs compared a PTA with a combination treatment of PTA with stent. The results are presented heterogeneously in the primary publications and the outcomes were measured at different moments. As a result it was not possible to pool the outcome parameters on walking distance and quality of life, but it was possible for restenosis. A difference in quality of life between using PTA alone and using PTA with stenting could not be demonstrated, but nor could it be precluded. This was established based on literature with very low quality evidence. The literature could neither preclude nor demonstrate that stenting in the femoropopliteal pathway improves walking distance in comparison with using PTA alone, and the value of the evidence is very low. Conditional evidence does exist that stenting in the femoropopliteal pathway leads to 19% to 34% less restenosis than when PTA alone is used in patients with peripheral vascular disease. The authors conclude that the studies have various limitations: small patient population, a clinically less relevant endpoint such as amputation in CI cases, a short follow-up, industry sponsoring and industry data management.

International The KCE guidelines formulate weak recommendations on stenting for aorta-iliacal disorders. These recommendations are based on very low quality evidence indicating that, two years after primary stenting, there were significantly fewer severe complications than two years after selective stenting, and that the difference is clinically relevant. The KCE guidelines also consider primary stenting or coated balloon angioplastics for patients with CI due to femoropopliteal disease, taking into account the duration, location and complexity of the abnormality and the degree of calcification.
This weak recommendation is based on moderate to low quality evidence that primary stenting leads to fewer re-interventions/revascularisations in comparison with selective stenting. On the contrary, the NICE guidelines reject primary stenting (strong recommendation) except in a case of complete occlusion (weak recommendation). The quality of evidence based on GRADE varies from low to average, and it reports only the short-term effect. Primary stenting is not yet standard care in the UK, and the GDG concludes that there is insufficient new evidence to revise this recommendation in view of the fact that the routine placement of stents involves extra costs and requires a longer treatment period. The NICE guidelines are fully transparent about the considerations and the line of argument that resulted in the recommendations.

Are the recommendations of the various guidelines in line with one another?
The national guidelines and the NICE guidelines agree with one another. This does not apply to the KCE guidelines. As far as effectiveness is concerned, the weak recommendations of the more recent KCE guidelines seem to be based on two new studies, published after the NICE guidelines, which both show fewer negative effects of primary stenting in comparison with selective stenting. These studies seem to have been decisive in the KCE guidelines. Furthermore, the fact that only the NICE guidelines included cost-effectiveness in the considerations may also have contributed to differences in the recommendations: primary stenting is less cost-effective.

2.4.3 *Application in practice*

Level of implementation of guidelines and measuring instruments
The *Zorginstituut* did not study this in more detail.

Data from daily practice
In view of the advised reticence in the national guidelines, we expect Dutch professionals to be cautious about placing stents.

The guidelines do not provide indication criteria for stenting. For this reason no examination against standard practice is possible. What we can do is look at variations in stenting practice in Dutch hospitals.

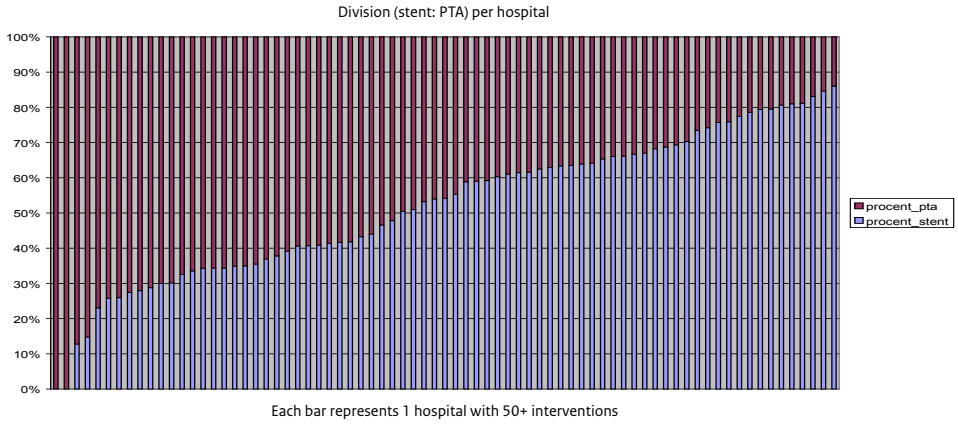
Question: Do variations in practice exist in placing primary stents in Dutch hospitals?
Per hospital we studied the relationship between PTA alone versus PTA in combination with stenting. This allowed us to chart variations in medical treatment. The data provide no insight into whether a primary or a secondary stenting was involved.

We limited ourselves to hospitals that carried out at least 50 interventions in the registration period 2010-2013. This left us with 75 of the original 82 AGB numbers (hospitals). Where several stents were placed during one PTA, they count as a single stent. As a percentage, the range in the relationship between PTA alone versus PTA plus stenting is 0% to 86%. This is a large spread in view of the reticence advised in the guidelines.

Casemix correction was not used.[97] The differences between hospitals are so large that we do not expect any casemix correction would cancel them.

Based on these analyses, the *Zorginstituut* concludes that variations in practice exist between Dutch hospitals in stent placement.

Figure 10 The relationship between PTA alone and PTA+stenting at hospital level in the registration period 2010-2013.



Meeting

The above data were presented during the meeting on 26 January. The parties were asked whether the large differences between hospitals would still exist if percentages were corrected for casemix, whether one would see stents and bypasses as interchangeable courses of treatment for long arterial stenosis, and whether participation in trials with stents explains in part the differences between hospitals.
The *Zorginstituut* re-examined this. Using claim data, we looked at the influence of age, gender and diabetes, which are common casemix factors for cardiovascular disorders, including CI. We then looked at hospital percentages, thereby regarding stents and bypasses as interchangeable courses of treatment. Per hospital we calculated the chance of stenting or a bypass in a case of an endovascular intervention. The spread still seems large. The Dutch Trial Register (http://www.trialregister.nl) shows that in the observation period only 1 registered trial took place in which stents were used for peripheral arterial disease. That was the DISCOVER-study (NTR3381) that started in May 2012, involving 3 Dutch hospitals and which continued during 2016. It is impossible to explain the hospital differences based on this trial, as it took place during part of the observation period and involved only 3 hospitals. Based on this additional analysis, we conclude that it is improbable that adding casemix correction, the exchangeability of stents with bypasses or the presence of trials with stents would substantially reduce the extent of the differences between hospitals.

97 Making proper use of casemix correction would require a great many clinical and radiological data, which we do not have.

In the meeting on 26 January, the comment was made that current claim data do not permit insight into which endovascular intervention was used: PTA alone, selective stenting after PTA or primary stenting. It would be useful if this were the case. The parties stated that this is a point for attention in developing the PROMs further. In addition there are inevitably doubts about the usefulness of PROMs because this group of older patients often has no internet access. Doubts were also expressed about whether PROMs can solve the problem of variations in practice, even if hospitals were obliged to complete them.

2.4.4 *Care outcomes*

This is where we examined whether quality data are available that can provide starting points for identifying where more scope exists for appropriate care.

To date, no useful information is available for patients about the outcome of stenting. Expectations are that the VascuQol-6-NL will be used in DAPA registration during the course of 2016.[98]

2.4.5 *Necessity*

In the past, there was no call for the *Zorginstituut* to issue a statement on the necessity of stenting in the care process of CI patients, nor any societal need to actually insure this form of diagnostics. Even now there seems no reason to issue a statement specifically about this.

2.4.6 *Effectiveness*

The *Zorginstituut* did not carry out a literature review (or have one carried out) to assess whether this care fulfils established medical science and medical practice (thus making it effective care). This did not take place in the past either. We did look at the EBM guidelines and discussed in detail the recommendations and their relevant scientific substantiation.

2.4.7 *Cost-effectiveness*

As described in section 2.2.7, at the request of the *Zorginstituut*, the iMTA drew up a systematic summary of studies that looked at cost-effectiveness for PAV interventions. This also included stenting.

Based on that report, the revised guidelines concluded as follows:
"All in all, PTA seems to be a desired first choice in comparison with a bypass.
PTA with selective stents can be seen as cost-effective in comparison with primary stenting. N.B., these results are based on one study, and did not take into account Dutch costs and effectiveness."

The full report of the IMTA will be made available as an appendix to the revised NVvH multidisciplinary guidelines.

The NICE guidelines (2012) also developed an economic model for comparing the cost-effectiveness of primary and selective stenting with one another. They concluded as follows:
The results in the model show that strategies which include primary stenting as a primary care intervention are both more expensive and less effective than most other options. Primary stenting is therefore not a cost-effective strategy for the treatment of IC in either the aorto-iliac or femoropopliteal arteries.

Both sets of guidelines reach the same conclusion.

98 *Dutch Audit for Peripheral Artery Disease (DAPA) is a national quality register for peripheral arterial disease, in which the diagnosed indication and the courses of treatment offered are registered together with case-mix factors and patient feedback (PROMs). DAPA should result in feedback information for the various care providers, the objective being to reduce variations in practice and improve the quality of care.*

2.4.8 *Feasibility*

In the past there was no cause for the *Zorginstituut* to issue a statement on the feasibility of stenting in CI patients.

During this consultation, the *Zorginstituut* did receive signals from several parties that in the Netherlands there are various ways for drawing up declarations for the same treatment in hospitals. Depending on the principal carer (clinical neurophysiology, radiologist or vascular surgeon), a different care product will be invoiced. As a result, the tariffs relating to these care products may differ (N.B.: tariffs are freely negotiated between health insurers and care providers).
The *Zorginstituut* discussed this matter with the Health Care Authority in June 2016. The information was confirmed and is a point for attention in the continued development of the claim system. What did change, in any case, is that as of 2016 intervention radiologists no longer invoice their own care product for supportive interventions. Since 1 January 2016, the supportive activities of intervention radiologists are part of the care product of the principal carer, e.g., a vascular surgeon. N.B.: the fact that supportive activities have become a part of the principal carer's care product is not an alteration in policy. However, the product structure for intervention radiology did not fit in sufficiently well with the declaration provisions. As of 2016, the product structure was adjusted accordingly.

2.4.9 *Summary of the analyses*

The systematic analysis shows that improving the quality of care can particularly be realised in:
- Applying guidelines
- Making health care outcomes transparent
- Feasibility of care

Applying guidelines

In practice, there is room for improving the use of stenting according to the description of good care. Despite the lack of a clear standard or indication for stenting, the guidelines advise caution in routinely placing stents. We assessed this recommendation against actual practice. Claim data from actual hospital practice show that considerable variations in practice exist between Dutch hospitals in the ratio of PTA alone versus PTA with stent.

Bottleneck:
- Due to the lack of a standard about whether or not to place a stent, we cannot draw any firm conclusions based on the variations in practice found, but this feedback information does reflect current practice and, according to the *Zorginstituut*, this is sufficient reason for further discussion between the parties.

Making health care outcomes transparent

Various initiatives exist in the field of improving quality. Despite this development, we have to conclude that at the moment no quality information is available on the outcomes of stenting.

Bottlenecks:
- Indicators in current quality registers are limited to structure and process indicators. Outcome indicators (PROMs) are not yet incorporated. As a result, to date there is a lack of available information about the supplied quality of care from the perspective of CI patients;
- The parties themselves commented on the desirability of being able to distinguish in quality registration between types of intervention: PTA alone versus PTA with stent. Such information is currently not available.

Feasibility of care

The *Zorginstituut* has had no reason to examine the feasibility of stenting in CI patients in more detail. This treatment is already carried out on CI patients. For claims relating to this treatment, (specific) payment titles exist for vascular surgeons and intervention radiologists and there are no indications of organisational constraints on care providers in supplying this treatment. During this consultation, we did receive

signals from several parties that in the Netherlands there are various ways in which to submit declarations for the same treatment in hospital. The *Zorginstituut* discussed this matter with the Dutch Health Care Authority in June 2016. The information was confirmed and is a point for attention in the continued development of the claim system.

3 Consistency in quality circles

Based on the outline agreement, a quality improvement cycle started in relation to the topic PAV (alongside 29 other topics). The various parties make agreements on improving care relating to PAV in the so-called Quality and Appropriateness Agenda. This involves a cyclic in-depth examination of such topics as guideline development, guideline implementation, quality registration, care purchasing and care evaluation. The *Zorginstituut* is systematically evaluating the topic CI, while involving the same parties. Due to the partial overlap of points of attention of Zinnige Zorg and the Quality & Effectiveness of Care agenda, it was decided that a joint meeting would be organised for this, which took place on 26 January 2016.

Appendix 5: Guidelines on the classification of level of evidence

As far as the Dutch guidelines are concerned, the KNGF and NVvH guidelines classify their recommendations according to the evidential value on which the recommendations are based (table 10), while the NHG does not classify the recommendations.

Table 10 Level of recommendations KNGF and NVvH

Level A	Studies from category 1: absolutely recommended. Intervention is always acceptable, proven to be safe and effective 'It has been demonstrated that ...'
Level B	Studies from categories 2 and 3: acceptable and useful. Regarded as treatment of choice by several experts. 'It is probable that ...'
Level C	Studies from category 4: acceptable and useful. regarded as a good (optional) alternative by several experts. 'There are signs that...'
Level D	No evidence available, insufficient evidence to be able to issue a statement on recommendations. 'In our opinion ...'

The KCE and NICE guidelines use GRADE to determine the level of evidence and then classify the recommendations into weak or strong recommendations (table 11).

Table 11 Level of recommendations KCE and NICE

High	Randomised study (or SR of a randomised study)	It is highly unlikely that further research would alter the certainty of the estimated effect
Moderate		Further research would probably have a significant impact on the certainty of the estimated effect, and the estimated effect itself may even alter
Low	Observational study	It is highly likely that further research will have a significant impact on the certainty of the estimated effect and will alter the estimated effect
Very low	Every other type	Every estimated effect is highly uncertain

The SVS guidelines also claim to have used the GRADE method to classify the recommendations (strong or weak) and to determine the quality of evidence for scientific substantiation. However, they used a different classification to that commonly used.[99] As previously reported, the Grades of Recommendation Assessment, Development and Evaluation (GRADE) framework was used to determine the strength of a recommendation and the quality of evidence. The quality of evidence is rated as high (A), moderate (B), or low (C). This rating is based on the risk of bias, precision, directness, consistency, and the size of the effect. The strength of a recommendation is graded based on the quality of evidence, balance between benefits and harms, patients' values, preferences, and clinical context. Recommendations are graded as strong (1) or weak/conditional (2). The term "we recommend" is used with strong recommendations, and the term "we suggest" is used with conditional recommendations.

99 *The Cochrane manual for systematic reviews of interventions.* http://handbook.cochrane.org/front_page.htm.

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Appendix 6: History of entitlement to exercise therapy and physiotherapy

1 Historical context

Entitlement to physiotherapy and exercise therapy, as regulated in the Decree on paramedical aid under the sickness fund insurance 1974, used to be unlimited.

In 1994, however, the cabinet wanted to limit entitlements to physiotherapy and exercise therapy and to this end asked for advice from the former Health Insurance Board (Ziekenfondsraad) and the Association of Dutch Healthcare Insurers (Zorgverzekeraars Nederland, ZN).

The Lubbers II cabinet proposed three possibilities for arriving at the desired level of austerity:
- limiting entitlements by charging insured clients for the first six treatment sessions;
- setting a maximum for the number of treatment sessions (e.g. 12 or 24);
- introducing a personal 50% contribution for the first twelve treatment sessions.

Based on the advice of ZN and the Health Insurance Board, the following cabinet (Kok I) concluded that a care-content limit was preferable to the possibilities suggested by the Lubbers III cabinet.
The Kok I cabinet decided to limit entitlement to physiotherapy and exercise therapy by introducing the list of 'Disorders for long-term and intermittent physiotherapy, Cesar exercise therapy and Mensendieck exercise therapy'.

A so-called 2-cluster model was used for limiting in this way.
- Cluster 1: limited to a maximum of nine sessions of physiotherapy, exercise therapy or child physiotherapy for more acute injuries and disorders of the locomotor apparatus, possibly extended with another nine sessions of exercise therapy or child physiotherapy.
- Cluster 2: limited to long-term or intermittent treatment with physiotherapy or exercise therapy of so-called 'chronic disorders', giving entitlement to the number of sessions needed. This related to the disorder, as included on the so-called chronic list.

Due to increased expenditure on collective insurance, on 1 January 2004 the Balkenende II cabinet decided to exclude entitlement for insured persons aged 18 years and older from reimbursement of the first nine sessions per disorder. The financial excesses of the Budgetary Framework for Care over 2009 and 2010 led the Balkenende IV cabinet to decide that, as of 2011, the first twelve sessions for a disorder on the chronic list were not in the basic package for insured persons aged 18 years and older.

The VVD-CDA coalition agreement, 'Freedom and accountability' established that, as of 2012, the first 15 physiotherapy and exercise therapy sessions would be at insured persons' own expense. As of 1 January 2012, this became the first 20 sessions per disorder.

Bijlage 7: Parties' comments

	Parties' comments *ZINL's responses*
De Hart& Vaatgroep	Compliments for the thorough work.
	Suggests that a degree of clarification is needed regarding the use of GLT as primary treatment for all CI patients, particularly within the framework of 'joint decision-making'. Conclusion may be that GLT is not actually possible for some (multi-morbid) patients.
	The clarification has been made in section 4.
ZN	A better description is needed of physiotherapists' expertise for carrying out GLT, otherwise there is the risk that all physiotherapists will deem themselves experts.
	Ultimately, the professional groups and insurers must determine which expertise is required to carry out this treatment. The KNGF guideline is looking into this. Furthermore, all sorts of developments are in progress for improving expertise with training and certification. ClaudicatioNet is the largest network, but there are also others that physiotherapists can join and which fulfil the requirements. Ultimately, insurers must take quality guarantees into account when purchasing this care.
	The report also covered diagnostics by GPs. The question is whether this is reliable and useful.
	We do not want to prematurely exclude the possibility that there are GPs who are capable of carrying out an adequate EAI-test and that GPs make regional agreements about this. We did suggest that quality requirements should be drawn up to guarantee the quality of the EAI. Furthermore, access to EDCs and hospitals' vascular laboratories must improve. Ultimately, insurers must take quality guarantees into account when purchasing this care.
	The report should state more clearly that the diagnosis (in-house/vascular lab diagnostics) and primary treatment should be carried out by GPs and that referral to the vascular surgeon should take place in the absence of improvement after running training and in the event of progression to Fontaine 3-4.
	DWe have stated this more explicitly in section 4.
	The BIA assumes that CI will be removed from the Chronic List, but CI actually is a chronic disorder.
	In May the Minister disseminated a draft bill with proposed alterations in the basic package, in which she declared her proposal to include entitlement to, on average, 37 sessions of supervised exercise therapy as of 1-1-2017 in the basic package. The letters says nothing about any change for the CI indication in relation to the chronic list. In our assessment report, we did not advise removing CI from the so-called chronic list. It does seem likely that if the minister decides to alter the entitlement based on this report, she will also arrange matters regarding the inclusion of CI on the so-called chronic list. We will ask the Ministry about the relationship between these two entitlements as of 2017.
NHG	Supports the analyses and sees it as a good inventory of possibilities for improvement.
	It is not possible to infer, from the estimation of 80,000 EAI-tests in GP practices per year, how often there is an indication for an EAI and whether it may be carried out too frequently.
	This topic can be examined during the implementation phase, when we have access to new data that may shed light on this.
	The 75% of referred patients who did not have an EAI-test in primary care could be an underestimation, as an EAI-test may have been carried out in the previous year.
	We endorse this comment and we added it as a Note to the report (footnote 63). This topic can be examined further during the implementation phase, when we have access to new data that may shed light on this.
	The NHG would appreciate improved substantiation, with the help of study data, of the degree to which the quality of measurements made in primary care is inadequate.
	The multidisciplinary guidelines describe 1 study that makes a hesitant claim on this matter (Nicolai et al. 2009). The quality of the evidence found is very low. This could be a topic for further investigation in the implementation phase.
	They are prepared to enter into discussions with GPs over cardiovascular diseases about how to ensure – with their help – that the quality of the EAI in GP practices is good, and how (better) agreements can be reached for diagnostics in vascular laboratories.
	ZINL greatly appreciates this promise. We are happy to discuss this further with the NHG.

	They are disappointed with the low AGREE score of the NHG 2014 PAV standard and cite the new 2015 'manual for developing NHG standards'. They ask us to make a re-assessment based on the new manual.
	The NHG has certainly done well by publishing the 2015 manual. However, we feel it inappropriate to score a 2014 standard based on a 2015 manual. We have added a Note to the report about this positive development.
KNGF	Is largely in agreement with the report.
	The question is what ZINL expects of the follow-up trajectory and how we can encourage its effect on agreements.
	We will plan a meeting with the parties for further discussion
	The KNGF has its doubts about the need to certify physiotherapists who give supervised exercise therapy. We would like to discuss and elaborate on this further.
	ZINL has indicated that the physiotherapy must be carried out by a specifically trained physiotherapist or exercise therapist based on: - *the KNGF sPAV guidelines. These describe that the training for physiotherapists inadequately addresses specific aspects relating to, e.g. the pathology and treatment of sPAV. Furthermore, recommended is that physiotherapists follow courses that focus on, e.g., CVRM and motivational training.* - *the PAV multidisciplinary guidelines, which recommend that, for CI, physiotherapy is carried out by an adequately trained physiotherapist or exercise therapist;* - *the meeting on 26 January, where parties who were present suggested the certification of physiotherapists as an action point.* *We feel it would be a good development if this care were carried out via a network in which there is contact between GPs, physiotherapists and vascular surgeons and where good care is provided (e.g., by training etc.) and the quality of care is made transparent.* *Ultimately, professionals and health insurers will determine how this takes shape. The KNGF is welcome to elaborate on this in more detail. ZINL would like to join any discussions.*
NVvH	In the opinion of the NVvH, it is a well-researched report.
	Allow the multidisciplinary guidelines to guide the report. The NICE and the AHA were used. The KCE focuses mainly on invasive treatment.
	The report follows the NICE guidelines and the multidisciplinary guidelines, particularly in relation to treatment in hospital.
	In the Netherlands there are various ways of claiming for the same examination or treatment. There is a claim version per specialism that is linked to different amounts. The NZa, and ZINL, must take this into account.
	ZINL is discussing this with the NZa. We have mapped only variations in practice and said nothing about cost economies within the framework of this topic.
	The final words of the NVvH were as follows: 'adding (unnecessary) duplex leads to a more burdensome care product. All the more reason to advise against it'.
NVvR	The NVvR agrees with the report, with a number of marginal comments.
	Allow the multidisciplinary guidelines to guide the report.
	The report follows the NICE guidelines and the multidisciplinary guidelines, particularly in relation to treatment in hospital
	On the matter of variations in practice and cost-effectiveness, it is remarkable that in the Netherlands there are various ways for claiming for the same test or treatment in hospital. They agree with the comments made about this by the NVvH.
	See our reply earlier to the NVvH.
NVvV	The report and its arguments are good and well-formulated.
	Custom-made medicine was not taken into account.
	ZINL did provide further substantiation of the choice for exercise therapy, but we have also added an explanation in section 4 because there may indeed be reasons why patients cannot undergo GLT or do not want to undergo GLT entirely. We indicated thereby that a great deal of responsibility lies with the professional who should inform the patient properly about treatment possibilities and risks.
	They would like to remain involved in decision-making in the future.

NFU	The general impression is that the primary goal is to realise cost economisation and that some aspects will be at the expense of the quality of care. Cost economies may be made by implementing the proposals and improvement actions, but there is a big risk of loss of quality in the treatment of CI patients.
	ZINL does not in any way subscribe to this opinion. Using the analyses in the Room for Improvement report, we establish where improvements can be made in the quality of care for CI patients. Patients will benefit if diagnostics and primary treatment can be used near their homes, via primary care, and if patients do not need to undergo unnecessary extra diagnostics and operations (with all the risks these involve). There is no urgency/reason to operate immediately on these patients; international agreement exists on this. Potential cost economisation that may result is an added bonus within the framework of efficiency.
	Recognising CI and interpreting the EAI is problematic, certainly in patients with comorbidity (e.g. diabetes mellitus). Repeatability largely depends on the number of indices made, but, as it is an infrequent event, making it routine is difficult to realise. Usually, an EAI carried out in primary care cannot be used for a historic check. Thus, for an optimum diagnosis, where a mixed picture emerges, it is realistic that patients are referred frequently. For instance, a GP should be able to ask a vascular laboratory for an EAI (which is not currently done in many places).
	We have indicated that quality requirements need to be drawn up to guarantee the quality of the EAI in primary care, but we do not want to prematurely preclude that there are GPs capable of carrying out an adequate EAI-test and that GPs can make regional agreements about this (framework GPs). Furthermore, access to primary care diagnostic centres and hospital vascular laboratories must improve. The report emphasises this.
	Patients are often not motivated to follow GLT and patients are not always insured for it.
	Based on a published report, the Minister has decided to reimburse the first 37 sessions for CI patients via the Zvw. Lack of motivation is often mentioned as a factor that impedes efficient implementation of the GLT. This is why physiotherapists and exercise therapists will receive extra training.
	No mention is made of the document published earlier by *Zorginstituut Nederland*, 'Report on supervised exercise therapy in cases of CI'.
	We discuss this in appendix 4, section 2.2.6.
	It would be better for organise primary care for the exercise therapy trajectory mainly via GPs.
	ZINL agrees wholeheartedly.
	The conclusion about inappropriate duplex imaging seems largely incorrect. In the Netherlands, Duplex imaging is actually requested too often without being followed by an intervention. However, the report says nothing about the fact that duplex imaging is also used as a diagnostic tool, i.e. to determine the severity of peripheral vascular disease. This is frequently followed by a decision to give endovascular treatment, but not surgery, or if endovascular treatment is not an option, then no intervention follows.
	What ZINL means is that follow-up diagnostics (e.g. duplex) should only be done if the patients may be deemed eligible for an intervention in hospital after they have completed GLT. The data do not indicate that duplex was used in the past on patients who subsequently followed a conservative trajectory. Expectations are that this number will fall if stepped care is implemented further. We agree that duplex imaging can be used as follow-up diagnostics if CI patients are referred to hospital after GLT.
	It is claimed that there is no good reason for carrying out stent placement initially. Preference goes out to PTA alone or stent placement in response to an indication. This agrees with the current guidelines. However, the field is continually changing, with a massive shift from operative to endovascular treatment. However, this is for a different category of patients than that described in the evidence in the guidelines. For them, stent placement will increasingly be indicated.
	In these analyses, ZINL has limited itself to CI patients.
	Variations in practice in relation to the use of stents suggests possible under-use or over-use. Communication with substantiated data, including PROMs, can provide more clarity on this matter.
	ZINL agrees wholeheartedly.

Colofon

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