KCE REPORT 221Cs

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

SUMMARY

REVASCULARIZATIOIN FOR LOWER LIMB PERIPHAL ARTERIAL DISEASE

Belgian Health Care Knowledge Centre

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KCE REPORT 221AS
GOOD CLINICAL PRACTICE

Federaal Kenniscentrum voor de Gezondheidszorg
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SUMMARY

REVASCULARIZATIOIN FOR LOWER LIMB PERIPHAL ARTERIAL DISEASE

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Other reported interests:	Membership of a stakeholder group on which the results of this report could have an impact.: Inge Fourneau (Belgian Society for Vascular Surgery), Philippe Kolh (Belgian Society for Vascular Surgery), Patrick Peeters, Muriel Sprynger (Société Française de Médecine Vasculaire), Frank Vermassen (Belgian Society for Vascular Surgery) A grant, fees or funds for a member of staff or another form of compensation for the execution of research: Frank Vermassen Participation in scientific or experimental research as an initiator, principal investigator or researcher: Inge Fourneau, Philippe Kolh, Geert Maleux (TALECRIS, TRIVASCULAR, MEDTRONIC), Serge Motte (Principal Investigator of APEX study, Sponsor PORTULA), Patrick Peeters, Muriel Sprynger, Frank Vermassen Consultancy or employment for a company, an association or an organisation that may gain or lose financially due to the results of this report: Frank Vermassen Payments to speak, training remuneration, subsidised travel or payment for participation at a conference: Olivier d'Archambeau (President of Satellite Symposium, CIRSE 2012, sponsored by BIOTRONIK), Geert Maleux (COOK MEDICAL, WL GORE), Patrick Peeters, Frank Vermassen Presidency or accountable function within an institution, association, department or other entity on which the results of this report could have an impact: Jean-Paul Joris (Secretary-Treasurer of the College of Radiology), Philippe Kolh (President of the Belgian Society of Surgery and President of the Belgian Association for Cardiothoracic Surgery), Patrick Peeters (President of the Belgian Society for Vascular Surgery), Muriel Sprynger (President of the Belgian Working group of Angiology), Frank Vermassen

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FOREWORD

It is the caricatural story of the old man who walks along the street and apparently very interested stops in front of the window of a local tattoo and piercing shop or kebab restaurant. Diagnosis? Intermittent claudication! In a more advanced stage it can evolve to gangrenous lesions and amputation. There was a time that this was the exclusive domain of surgery. With patches and grafts the arterial blood flow was restored, helping the patient to carry on. Also literally. But then, we gradually saw other approaches – also literally: through an endovascular approach the arteries were dilated, and soon also stented. Both approaches have their merits, but also their limitations of course, and their number is steadily increasing. Therefore the RIZIV – INAMI asked the KCE to submit this domain to a critical review.

With this study KCE wants to determine how substantial the differences between these different approaches are, both in the short and long term. And how one could clinically orient the patient with peripheral arterial problems based on this analysis. Today we are in a situation where the eventual approach is partly determined by the discipline that is available or by the medical specialism the patient happens to come in contact with first. And if these clinical alternatives were equal, economic aspects need to be taken into account, in addition, of course, to the patient's preferences.

As often with surgery or other procedures, little good study material was published. With what is available, we hope to provide some guidance for a number of outstanding issues. Finally, we want to thank the National Clinical Guideline Centre for their very structured literature review and the provision of the guideline that they produced for NICE.

Christian LÉONARD
Deputy general director

Raf MERTENS
General director

SUMMARY

1. INTRODUCTION

The most common initial symptom of lower limb peripheral arterial disease (PAD) is pain in the leg on walking, known as intermittent claudication (IC). In the majority of people with IC the symptoms remain stable, but approximately 20% will progress to develop increasingly severe symptoms with the development of critical limb ischemia (CLI). Those with CLI are at significant risk of developing irreversible ischemic damage to the leg or foot if they do not receive appropriate treatment, and this may lead to amputation.

Mild symptoms are generally managed in primary care, with referral to secondary care when symptoms do not resolve, or deteriorate. There are several treatment options for people with IC. These include advice to exercise, management of elevated cardiovascular risk (for example, aspirin, statins, smoking cessation, etc) and vasoactive drug treatment (for example, naftidrofuryl oxalate). There is considerable variation in the utilisation of these treatment options. Whilst supervised exercise programmes can improve walking distance and quality of life, access to such programmes in Belgium is limited because they are not reimbursed.

People with severe symptoms that are controlled inadequately are often referred to secondary care for assessment of the need for endovascular treatment (such as angioplasty or stenting), surgical revascularization or amputation. In recent years, there has been a move away from invasive investigation by catheter angiography to non-invasive investigation by duplex ultrasonography, magnetic resonance angiography or computed tomography angiography. Treadmill walking tests and segmental pressure measurements are other commonly used investigations.

2. OBJECTIVES AND SCOPE OF THIS GUIDELINE

According to data of the RIZIV/INAMI, a continuous increase is noticed in the number of percutaneous revascularizations of peripheral arteries since 1990, with an increase of 22% between 2006 and 2009. In view of a small increase of 'classical' surgical interventions (+2.39% between 2006 and 2009), the RIZIV/INAMI questions the appropriateness of these evolutions. A clinical practice guideline (CPG) on revascularization of lower limb peripheral arterial disease:

- Will assist clinicians in making appropriate choices when treating patients with the disorder;
- May provide scientific arguments for a change in the nomenclature to reduce the number of inappropriate interventions.

This guideline focuses on the diagnostic evaluation and therapeutic revascularization of patients with lower limb peripheral arterial disease. The following diagnostic interventions are addressed:

- Duplex ultrasound;
- Magnetic resonance angiography;
- Computed tomography angiography;
- Ankle/brachial index.

In addition, the following revascularization techniques are addressed:

- Angioplasty with or without stenting (selective vs. primary; bare metal vs. drug-eluting; drug-coated balloons);
- Bypass surgery (autologous vein vs. prosthetic bypass).

This guideline does not cover:

- Screening of asymptomatic peripheral arterial disease;
- Treatment of (cardio)vascular risk factors;
- Patients with acute ischaemia of the lower limb.

3. METHODS

3.1. Systematic review of the literature

A search for recent high-quality clinical guidelines was carried out in several databases and institutional websites (OVID Medline, National Guideline Clearinghouse, GIN database, NICE and SIGN websites). Seven relevant guidelines were identified. On the basis of a quality appraisal with the AGREE II instrument, the NICE 2012 guideline CG147 was eventually selected for adaptation. Using the NICE 2012 guideline as a basis for the scoping phase, twelve research questions were defined. For four research questions it was decided to use the evidence from the NICE 2012 guideline without performing an update, because it was considered to be sufficiently up-to-date by the guideline development group (GDG). For six research questions a literature search was done by a subcontracting team, i.e. NCGC, to identify new studies published since the NICE 2012 guideline and to update the original evidence reviews. Two additional research questions were proposed by the GDG, and since they were not addressed by the NICE 2012 guideline, they were answered with a new literature search.

For each clinical question requiring a literature search, a protocol was developed using the PICO framework. Primary studies were searched in Medline, Embase and the Cochrane Library. Two independent researchers performed the selection, the quality appraisal of the studies and the data extraction.

3.2. Formulation of recommendations

Based on the retrieved evidence, the first draft of recommendations was prepared by a small working group (KCE experts and the subcontracting team). This first draft, along with the evidence tables, was circulated to the GDG prior to the face-to-face meeting. Recommendations were only modified if important new evidence supported this change. Based on the discussions in the GDG, a second draft of the recommendations was prepared and once more circulated to the GDG for final approval.

To determine the level of evidence and strength of each recommendation, the GRADE methodology was followed (Tables 1 & 2). The strength of a recommendation depends on the balance between all desirable and all undesirable effects of an intervention (i.e., net clinical benefit), the quality of available evidence, values and preferences, and the estimated cost (resource utilization). For this guideline, no formal cost-effectiveness study was conducted.

The recommendations prepared by the GDG were submitted to key representatives of the relevant stakeholders (see colophon), who acted as external reviewers of the draft guideline. They rated all recommendations with a score ranging from 1 ('completely disagree') to 5 ('completely agree') and discussed them at a meeting.

Since there is no patient association for this disease in our country, it was decided to supplement the literature searches with a specific search for patient issues. If relevant, information from this search was included in the factor 'Values and preferences' during the GRADEing process.

Finally, prior to its publication, the current guideline was reviewed by 3 independent validators (see colophon), making use of the AGREE II checklist. The validation process was chaired by CEBAM. The validation of the report results from a consensus or a voting process between the validators.

Declarations of interest were formally recorded.

Table 1 – Levels of evidence according to GRADE [$]

Quality level	Definition	Methodological Quality of Supporting Evidence
High	We are very confident that the true effect lies close to that of the estimate of the effect	RCTs without important limitations or overwhelming evidence from observational studies
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies
Low	Our confidence in the effect estimated is limited: the true effect may be substantially different from the estimate of the effect	RCTs with important limitations or observational studies or case series
Very low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect	

[$] *Balshem H, Helfand M, Schunemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 2011;64(4):401-6.*

Table 2 – Strength of recommendations according to GRADE [$]

Grade	Definition
Strong	The desirable effects of an intervention clearly outweigh the undesirable effects *(the intervention is to be put into practice),* or the undesirable effects of an intervention clearly outweigh the desirable effects *(the intervention is not to be put into practice).*
Weak	The desirable effects of an intervention probably outweigh the undesirable effects *(the intervention probably is to be put into practice),* or the undesirable effects of an intervention probably outweigh the desirable effects *(the intervention probably is not to be put into practice).*

[$] *Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, et al. Going from evidence to recommendations.[Erratum appears in BMJ. 2008 Jun 21;336(7658): doi:10.1136/bmj.a402]. BMJ. 2008;336(7652):1049-51.*

4. CLINICAL RECOMMENDATIONS

The details of the evidence used to formulate the recommendations below are available in the scientific report and its supplements. The tables follow the sequence of the chapters of the scientific report.

4.1. Imaging for revascularization in peripheral arterial disease

Recommendations	Strength of Recommendation	Level of Evidence
Consider duplex ultrasound as first-line imaging in people with intermittent claudication for whom revascularization is being considered.	Weak	Low - Very low
Offer contrast-enhanced magnetic resonance angiography to people with peripheral arterial disease who need further imaging (after duplex ultrasound) before considering revascularization.	Strong	Moderate - Low
Offer computed tomography angiography to people with peripheral arterial disease who need further imaging (after duplex ultrasound) if contrast-enhanced magnetic resonance angiography is contraindicated or not tolerated.	Strong	Moderate - Low

4.2. Management of intermittent claudication

4.2.1. Revascularization compared with or in combination with exercise or best medical treatment

Best medical treatment usually consists of one or more of the following components:

- Secondary prevention of cardiovascular disease (e.g. smoking cessation, improved glycaemic control in diabetic patients, cholesterol management, hypertensive treatment, anti-platelet agents, other lifestyle changes);
- Exercise advice.

Recommendation	Strength of Recommendation	Level of Evidence
Consider a trial period of best medical treatment including supervised exercise in patients presenting with intermittent claudication.	Weak	Very low

4.2.2. Angioplasty versus bypass surgery

Recommendation	Strength of Recommendation	Level of Evidence
In patients with incapacitating intermittent claudication in whom, after a trial period with best medical treatment including supervised exercise treatment, clinical results are insufficient, consider angioplasty or bypass surgery in addition [#], taking into account the following factors: • **Type and length of lesion;** • **Availability of vein;** • **Patient preferences;** • **Symptoms;** • **Costs.**	Weak	Very low

[#] *The choice needs to be made after a multidisciplinary discussion. When a choice is made, the necessary medical expertise needs to be available to perform the intervention. Otherwise the patient needs to be referred.*

4.2.3. Angioplasty with or without stenting

Recommendations	Strength of Recommendation	Level of Evidence
Consider primary stenting in patients with intermittent claudication due to aortoiliac disease undergoing revascularization with angioplasty.	Weak	Very low
Given the absence of comparative RCTs, use bare metal stents instead of DES in patients with intermittent claudication due to aortoiliac disease undergoing revascularization with angioplasty and stenting.	Strong	Very low
Consider primary stenting or drug-coated balloon angioplasty in patients with intermittent claudication due to femoropopliteal disease undergoing revascularization with angioplasty, taking into account the following factors: • **Length of the lesion;** • **Complexity of the lesion;** • **Calcification;** • **Location of the lesion.**	Weak	Low – Very low
Use bare metal stents in patients with intermittent claudication due to femoropopliteal disease undergoing revascularization with angioplasty and stenting.	Strong	Very low

4.2.4. Autologous vein versus prosthetic bypass

Recommendation	Strength of Recommendation	Level of Evidence
Consider autologous vein grafting in patients with intermittent claudication due to femoropopliteal disease undergoing bypass surgery.	Weak	Low

4.3. Management of critical limb ischemia

Angioplasty versus bypass surgery

Recommendation	Strength of Recommendation	Level of Evidence
In addition to best medical treatment, offer angioplasty or bypass surgery for treating people with critical limb ischaemia who require revascularization, taking into account factors including: • **Comorbidities;** • **Pattern of disease;** • **Availability of a vein;** • **Patient preferences;** • **Costs.**	Weak	Very low

4.3.1. Angioplasty with or without stenting

Recommendations	Strength of Recommendation	Level of Evidence
Consider primary stenting in patients with critical limb ischaemia due to aortoiliac disease undergoing revascularization with angioplasty.	Weak	Very low
In the absence of evidence based on RCTs, do not use drug-eluting stents in patients with critical limb ischemia due to aortoiliac disease undergoing revascularization with angioplasty and stenting.	Strong	Very low
Consider primary stenting or drug-coated balloon angioplasty in patients with critical limb ischaemia due to femoropopliteal disease undergoing revascularization with angioplasty, taking into account the following factors: • **Length of the lesion;** • **Complexity of the lesion;** • **Calcification;**	Weak	Very low

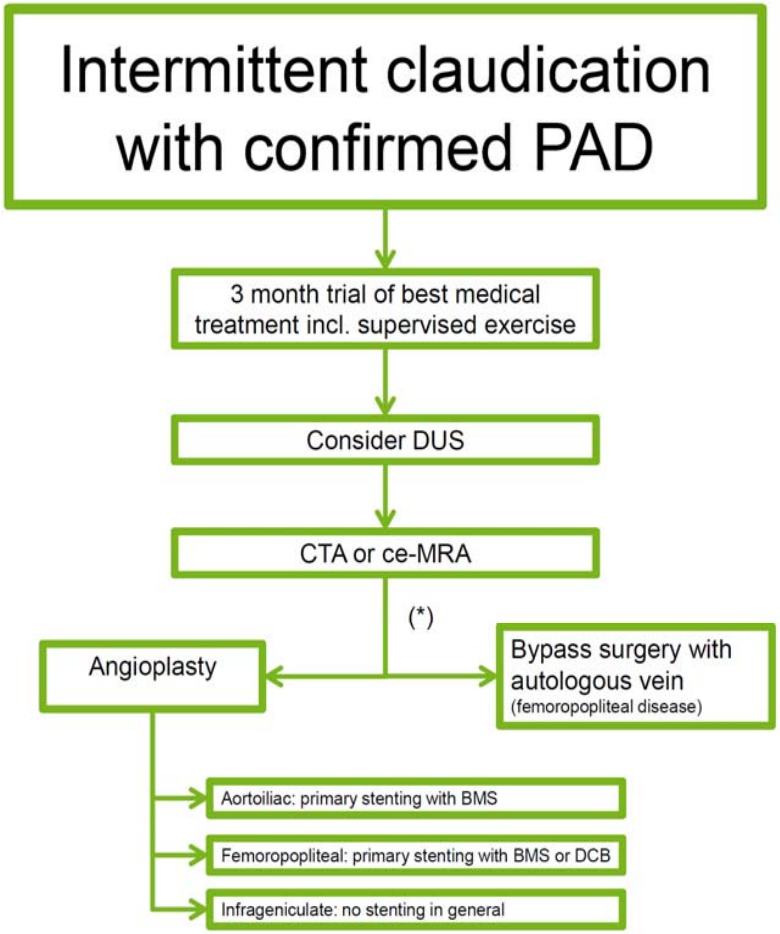
Recommendations	Strength of Recommendation	Level of Evidence
• **Location of the lesion.**		
Consider bare metal stents in patients with critical limb ischemia due to femoropopliteal disease undergoing revascularization with angioplasty and stenting.	Weak	Very low
Consider balloon angioplasty with bail-out stenting in patients with critical limb ischaemia due to infrageniculate disease undergoing revascularization with angioplasty.	Weak	Very low
Consider drug-eluting stents in patients with critical limb ischemia and short, focal lesions due to infrageniculate disease undergoing revascularization with angioplasty and stenting.	Weak	Very low

4.3.2. Autologous vein versus prosthetic bypass

Recommendation	Strength of Recommendation	Level of Evidence
Consider autologous vein graft in patients with critical limb ischemia due to femoropopliteal or infrageniculate disease taking into account the following factors: • **Availability of a vein;** • **Quality of the vein;** • **Location of the lesion (above or below the knee);** • **Comorbidities;** • **Urgency of the intervention.**	Weak	Very low

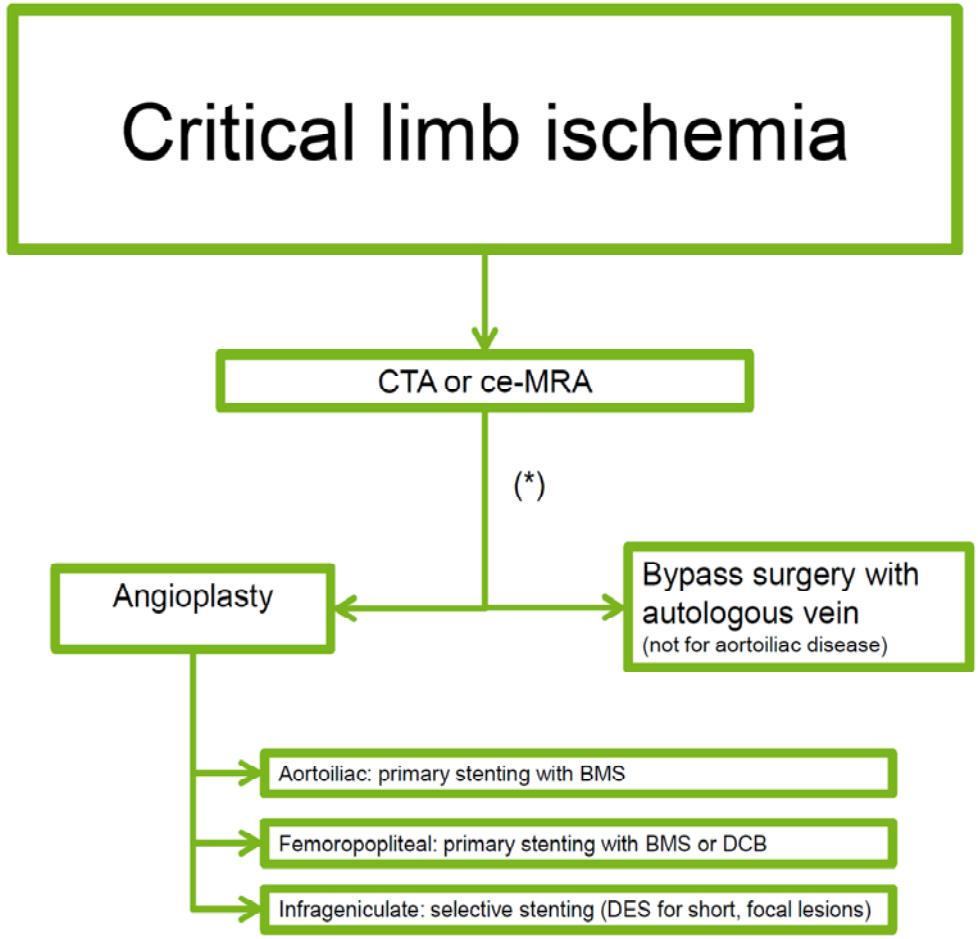
5. ALGORITHMS

5.1. Intermittent claudication



(*) In addition to best medical treatment.
PAD: peripheral arterial disease; DUS: Doppler ultrasound; CTA: computed tomography angiography; ce-MRA: contrast enhanced magnetic resonance angiography; BMS: bare metal stent; DCB: drug-coated balloon.

5.2. Critical limb ischemia



(*) In addition to best medical treatment.
CTA: computed tomography angiography; ce-MRA: contrast enhanced magnetic resonance angiography; BMS: bare metal stent; DCB: drug-coated balloon; DES: drug-eluting stent.

6. IMPLEMENTATION AND UPDATING OF THE GUIDELINE

6.1. Implementation

The implementation of this guideline will be conducted by professional associations involved in this guideline (Belgian Society for Vascular Surgery, Belgian Society on Thrombosis and Haemostasis, Royal Belgian Society of Radiology). An implementation plan will need to be developed in collaboration with the RIZIV/INAMI. This implementation plan should also target general cardiologists, general practitioners and physiotherapists.

For some recommendations, implementation could be hampered by the absence of a specific reimbursement:

- Drug-eluting stents and drug-coated balloons are currently not reimbursed in Belgium for peripheral arterial disease;
- Supervised exercise programmes are currently not reimbursed in Belgium for peripheral arterial disease.

Some recommendations contain a list of factors to be taken into account when considering a specific treatment. Experts from the GDG and stakeholders stressed that the exact definition of these factors (e.g. length of lesion, calcification, etc) continues to be a matter of debate.

Most recommendations are based on evidence of low to very low quality, and clinicians may be reluctant to implement such recommendations.

6.2. Monitoring the quality of care

This guideline could be considered as a starting point to develop quality improvement programs that target all caregivers concerned.

On the one hand it can be used as a tool to support health policies to improve the quality of care, e.g. through the support of actions to increase caregivers' awareness and to improve their practice, or through the development (or revision) of sets of process and outcome quality indicators. On the other hand the scientific material of this guideline is intended to be disseminated by scientific and professional organisations. They can transform this material into attractive and user-friendly tools tailored to caregivers groups. They will also play a key role by a dissemination that makes use of diverse channels such as websites or sessions of continuing education.

6.3. Guideline update

The KCE processes foresee that the relevance of an update would be yearly assessed for each published guideline by the authors. Decisions are made on the basis of new scientific publications on a specific topic (e.g. Cochrane reviews, RCTs on medications or interventions). Potential interest for groups of health practitioners is also considered in this process.

This appraisal leads to a decision on whether to update or not a guideline or specific parts of it to ensure the recommendations stay in line with the latest scientific developments.

POLICY RECOMMENDATIONS[a]

To the attention of scientific and professional associations:

- **This guideline should be transformed and disseminated in procedures, protocols, educational programs, etc. that are in a user-friendly format for daily use. This should be done in close collaboration with the professional organisations.**
- **Material for informed consent should be easily understandable and written in plain language.**

To the attention of the dedicated commissions of the NIHDI:

- **The appropriateness of reimbursement of drug-coated balloons (intermittent claudication and critical limb ischemia) and supervised exercise (intermittent claudication) should be evaluated by means of a cost-effectiveness analysis using Belgian health care data.**
- **In the meantime, it can be considered to provide a temporary limited reimbursement in a limited number of centres for those indications with some proven effectiveness and no important safety risks, on the condition of registration of clinical data that allow to further document the effectiveness and safety in a routine clinical context.**

Recommendations for further research:

- **Clinical studies should verify if the few available positive data about the effectiveness of drug-eluting stents in patients with intermittent claudication or critical limb ischemia due to femoropopliteal disease can be confirmed, before reimbursement can be considered.**
- **Qualitative research should be done to evaluate preferences and values of patients with peripheral arterial disease.**

[a] The KCE has sole responsibility for the recommendations.