1 **Quality Indicators in Vascular Surgery: towards a National Consensus on 20**

2 **Quality Indicators in Belgium**

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31 **Abstract**

32 **Objectives:** The aim of the present study is to develop relevant quality indicators (QI) to monitor and
33 improve quality of care in vascular surgery.

34 **Methods:** The Delphi method was used to incorporate expert opinion to reach consensus on a set of QI.
35 A national expert panel consisting of 52 vascular surgeons was installed on a voluntary basis and
36 endorsed by the Belgian Society of Vascular Surgery and the Flemish Hospital Network KU Leuven. A
37 task force team consisting of 12 surgeons was created to serve as a delegation of the expert panel to
38 discuss and filter the obtained data from the different Delphi rounds.

39 **Results:** A total of three Delphi rounds were needed to reach consensus on a set of 20 QI. Each QI had
40 a content validity index (using a 7-point Likert scale), a feasibility index and a target level. Twelve
41 outcome indicators and eight process indicators on several vascular topics were selected: overall for all
42 vascular treatments (n=1), arterial occlusive disease in general (n=3), arterial occlusive disease of the
43 lower limbs (n=4), arterial occlusive disease of the carotid arteries (n=5), arterial aneurysm disease in
44 general (n=2), arterial aneurysm disease with endovascular treatment (n=1) and venous disease (n=4).

45 **Conclusions:** This resulted in the successful identification of 20 validated and relevant vascular QI,
46 focusing on arterial occlusive disease, arterial aneurysm disease and venous disease. The next step in
47 this project will be the performance of an implementation study.

48 **Introduction**

49 In healthcare, QI are used for various purposes: by physicians for benchmarking and quality
50 improvement projects, by the government for accreditation, Pay for Quality (P4Q) initiatives and cost-
51 effectiveness and by patients to make informed choices about whether and by whom they want to be
52 treated ¹.

53 Worldwide, P4Q is increasingly used as a tool to improve the quality in healthcare ²⁻⁴. In Belgium, a
54 huge evolution was seen with the development of the Belgian Health Care Knowledge centre, the
55 Flemish Indicator project for Patients and Professionals and the onset of a policy shift towards value-
56 based healthcare with the actual start of P4Q on July 1st 2018. The healthcare worker is willing to assess
57 the quality of his work and thus create value ⁵. In order to improve value (= quality/cost equation), quality
58 must be improved, or cost or volume must be reduced ⁶.

59 Furthermore, QI are used in (inter)national clinical registries. The first population-based registry in
60 vascular surgery was created in Sweden in 1987: the Vascular Registry in Southern Sweden, later
61 renamed to Swedvasc. They registered all patients who underwent any arterial intervention. Leaders of
62 the Swedvasc registry played an active role in the creation of the International registry collaboration
63 network, the Vascunet. Vascunet was started in 1997. It is now an established subcommittee of the ESVS
64 in which about 20 European countries, Australia and New Zealand participate ⁷. Worldwide, similar
65 vascular registries exist including amongst other the International Consortium of Vascular Registries
66 (ICVR) and the American/Canadian Vascular Quality Initiative ⁸⁻⁹.

67 Many of these registries are established from a surgical point of view, focusing on per- and post-
68 operative outcome parameters ¹⁰. However, in 2017, the Society for Vascular Surgery Patient Safety
69 Organization® and the Society for Vascular Medicine in collaboration with the American Heart
70 Association® launched the Vascular Medicine Consult Registry for the Vascular Quality Initiative ¹¹.
71 The registry includes data of patients with carotid artery stenosis, abdominal aortic aneurysm and lower
72 extremity peripheral artery disease. It focuses on non-operative medical management approaches,

73 identifying optimal medication and dosages, evaluating best methods for secondary prevention and
74 assessing the need for subsequent interventional treatment.

75 Data collection for registries often needs to be done outside the electronic patient file (EPF) ¹². This
76 leads to an extra administrative workload. Manually transferring data from the EPF to an external
77 registry, can compromise the accuracy of data ¹⁰.

78 Evidence-based knowledge on how to develop good QI is scarce. Jan Mainz states that in the absence of
79 evidence-based knowledge, a good alternative to develop a set of indicators is the use of expert opinion
80 in a Delphi consensus model. The key to success in developing QI is the validation by the surgeons
81 themselves and the support by the national professional vascular organisations ¹³⁻¹⁴.

82 The aim of this project is to develop a valid and reliable set of QI, determined and supported by the
83 vascular surgeons themselves, to monitor and improve quality of care in vascular surgery. Over time,
84 this can give rise to an EPF-integrated system of data collection. In this paper the process of reaching
85 consensus, by means of a Delphi method, on a set of QI which are both relevant and feasible to monitor
86 in daily practice and which have a real impact on clinical care, is described in detail.

87 **Methods**

88 In September 2016, a clinical research project was initiated at the department of vascular surgery of the
89 University Hospitals Leuven to develop QI in vascular surgery. This was endorsed by the Belgian
90 Society of Vascular Surgery (BSVS) and realized in cooperation with the Flemish Hospital Network KU
91 Leuven (VzknkuL). As registration of all vascular interventions did not seem realistic, key procedures
92 were identified within the vascular pathologies including arterial occlusive disease, arterial aneurysm
93 disease and venous disease. These groups of pathology represent the vast majority of patients seen at
94 any vascular surgery department and were therefore considered to be representative for the global
95 activity in a vascular department in Belgium. It was decided not to focus on very specific or less common
96 pathologies in order to obtain a set of indicators that is appealing to the majority of vascular surgeons
97 and not only to a selected group.

98

99 ***Participants***

100 *Selection of an expert panel*

101 A kick-off meeting took place, Sep. 6th 2016, to explain to interested vascular surgeons the aim of this
102 project and to present the methods currently available to develop a set of validated QI. All heads of
103 Flemish vascular departments and their staff members were invited. Due to the Dutch-French language
104 barrier in Belgium, only Flemish hospitals were invited to the first explorative phase of this project.
105 Nevertheless, Walloon colleagues were given the opportunity to join after the kick-off took place.

106 *Selection of a task force team*

107 Among participants, a task force team was created to serve as a delegation of the expert panel to discuss
108 and filter the obtained data. Following criteria were taken into account: representation of both university
109 hospitals and non-university hospitals, of both surgeons with focus on arterial pathology and surgeons
110 with focus on venous pathology and inclusion of at least one Walloon colleague.

111 Participation to the kick-off meeting and the task force team were both on a voluntary basis; there was
112 no financial compensation.

113 ***The Delphi consensus survey***

114 The expert panel was asked to critically read existing international vascular clinical practice
115 guidelines ¹⁵⁻²¹ and were afterwards asked to identify domains in vascular surgery that were prone to
116 quality improvement and suitable for developing relevant QI.

117 An overview of the different steps/rounds of the Delphi consensus survey can be found in Figure 1. Data
118 obtained during all three Delphi rounds was processed anonymously. In the first round an open question
119 method by electronic mailing was used, inquiring the expert panel on which domains in vascular surgery
120 were thought to be susceptible to quality improvement, and allowing participating experts to suggest QI
121 in all vascular domains. The obtained data were analysed and discussed in the task force and a first set
122 of QI was proposed.

123 In the second round, the relevance and feasibility of the first set of QI was investigated. Relevance was
124 investigated using a 7-point Likert scale ranging from ‘do not want to answer (score 1)’ to ‘completely

125 agree (score 7)'. The option "do not want to answer" was provided since vascular surgeons are either
126 specialised in arterial disease or in venous disease. A score between 5 and 7 was seen as relevant (5:
127 rather agree - 6: agree - 7: completely agree). The cut off for retaining the indicator was arbitrarily set at
128 75% of the participating surgeons giving a score of 5-7 (content validity index (CVI) = proportion of
129 experts giving a score from 5-7). Moreover, experts were asked to give an appreciation on achievability,
130 to obtain a feasibility index (FI). Experts were asked to indicate whether or not they believed the QI was
131 feasible to monitor (yes/no). For indicators to be retained, a $FI \geq 60\%$ was arbitrarily set. All results were
132 analysed in the task force and the most relevant and feasible indicators per pathology were retained.
133 In case of lack of consensus, or in case of further QI refinement needed, it was decided to launch an
134 additional round in the Delphi consensus method. In each round, non-responders were sent a reminder
135 and a deadline was set.

136 To reassure a uniform interpretation and (future) monitoring/registration, strict inclusion/exclusion
137 criteria were set per QI. Furthermore, a detailed indicator flowchart was setup for every QI, using the
138 state-of-the-art European Pathway Association criteria ²². Moreover, a target level was set for each
139 indicator. These target levels were based on literature or existing guidelines in the first place. For the
140 remaining QI, target level consensus was obtained within the task force team. All target levels were
141 thoroughly discussed in the task force team in order to reach consensus on the proposed levels per
142 indicator.

143 Finally, a new general meeting was organised to inform the expert panel regarding the final list of QI.
144 Each participant was able to give his/her feedback on the final QI list, the in- and exclusion criteria, the
145 flowcharts and the target levels.

146 ***Pilot study***

147 A small qualitative pilot study was conducted in the departments of the task force members. This
148 encompassed a retrospective screening of 20 patient records per pathology and per department. The pilot
149 study was performed to explore achievability/practical feasibility of the monitoring process and for the
150 fine-tuning of the QI, the inclusion/exclusion criteria and the flowcharts. Criteria that needed to be

151 fulfilled in order to label the monitoring process as achievable and practically feasible were: a low
152 administrative burden, limited time investment needed and convenient data retrieval in patient records.
153 Since this was a first explorative study and no reference were available, these criteria were not
154 objectified.

155
156

157 **Results**

158 *The Delphi consensus survey*

159 At the beginning of this project, 45 Belgian surgeons joined the expert panel. Across the total duration
160 of the project, new vascular surgeons could join at any time, leading to a total of 52 Belgian vascular
161 surgeons by the time the final QI were determined. This final group of surgeons represent 42 unique
162 Belgian hospitals, amongst them 5 University Hospitals (UZ Leuven – UZ Gent – UZ Brussel – UZ
163 Antwerpen – CU Saint-Luc Bruxelles). Moreover looking at the number of vascular surgery associations
164 in Belgium, a total of 31 out of 45 hospitals (69%) in the Flemish region were represented, together with
165 2 out of 9 hospitals (22%) in the Brussels region, and 4 out of 23 (17%) hospitals in the Walloon region.
166 Twelve vascular surgeons (representing 9 hospitals) volunteered to join the task force team.

167 Response rate in the first round of the Delphi survey was 40% (18/45). A great number of items were
168 identified that were prone to quality improvement: 17 within arterial occlusive disease in general; 33
169 within arterial occlusive disease - lower limbs; 36 within arterial occlusive disease - carotid; 41 within
170 arterial aneurysm disease; 20 within venous disease (see table I).

171 These results were analysed within the task force team and led to a proposition of 30 indicators. This
172 proposition was launched in a second Delphi round (response rate: 55%, 26/47) where the 30 indicators
173 were judged on their relevance (CVI) and feasibility (FI).

174 After the second round, the definition of two indicators (“Unplanned readmission within 30 days after a
175 vascular surgery procedure” and “Treatment with anti-aggregantia/anticoagulant in patients with arterial
176 occlusive disease”) needed refinement and different variants were proposed. Due to a lack of consensus
177 on QI for venous pathology in the second round, five supplementary venous indicators were proposed.

178 The decision was made to launch a third round (response rate: 57%, 27/47). In this third round the new
179 variants and new venous indicators were separately inquired regarding relevance (CVI) and feasibility
180 (FI). Eventually, consensus was reached on the different variants and three of the five venous indicators
181 were retained. Based on these results, the final list of 20 QI was recorded (see Table II).

182 A new general meeting with the expert panel was organised on June 11th 2018. An update was given on
183 the final indicators, the inclusion/exclusion criteria, the flowcharts and the target values. Consensus
184 approval was obtained with no additional remarks.

185 Overall, the Delphi survey process resulted in twenty QI in seven vascular topics (see Table II): Eight
186 process indicators and twelve outcome indicators, each with their own CVI (ranging from 63-100%) and
187 FI (ranging from 67-96%).

188 ***Pilot study***

189 A small pilot study was executed in 6 out of 9 hospitals represented in the task force team who
190 volunteered to perform a first registration of the indicators. Registration of the indicators was performed
191 by the task force team member themselves. No specific training was given. Personal experience
192 regarding the registration process was discussed within the group of vascular surgeon that participated.
193 All surgeons confirmed that all of the 20 measured indicators were relevant and useful. However, the
194 achievability/practical feasibility was questioned. This pilot study revealed a high administrative burden
195 since full automatic data extraction was not any of the hospitals. Surgeons indicated a time investment
196 of 1 to 3 days to obtain the parameters needed to assess the indicators. Due to the absence of a clear label
197 indicating the specific vascular pathology of patient records, data retrieval was time consuming or not
198 straightforward and was therefore cited as a limiting factor.

199 During this pilot study, substantive remarks were very useful to refine the indicator flowcharts. It was
200 concluded that it was worth the effort, but that some work has to be done to reduce the administrative
201 burden and the time investment.

202

203

204 **Discussion**

205 A Delphi consensus method with a national vascular surgeon expert panel resulted in the successful
206 identification of 20 relevant and practically feasible vascular QI.

207 To the best of our knowledge, this is one of the first papers to describe the detailed process of reaching
208 consensus within a group of experts on QI in the field of vascular surgery. Effort was made to create a
209 set of indicators regarding several domains that is representative for the quality of care in vascular
210 surgery as a whole. The indicator development was based both on relevant scientific evidence and on
211 consensus among healthcare professionals.

212 With the help of this set of indicators and their inclusion/exclusion criteria, flowcharts and target levels,
213 we are ready to start a uniform measurement of quality across multiple Belgian vascular surgery
214 departments. Results of QI should be harnessed to search for variation in care and to explore the cause(s).
215 Feedback should be given on the performance per indicator in order to tackle future problems. Health
216 providers should be encouraged to voluntarily collect outcomes and to evolve to a multi-site comparison
217 (benchmarking), whether or not anonymous. The collected data can be used for local and/or national
218 improvement actions to ensure that all centres can adapt to the best practice. Besides the use of QI for
219 direct quality improvement, some of the QI can, on the long term, also be used for accountability. The
220 increasing interest in public reporting and P4Q initiatives raises the need for reliable QI.

221 In general, it is extremely important to motivate the team and to make quality registration routine, as an
222 integrated part of the care process ²³. A strong incentive of this project is to establish an EPF integrated
223 data collection system. Our pilot study showed that data needed to calculate the 20 QI are available and
224 accessible in the medical patient files, but that the workload linked to manual data extraction is
225 excessively high. Therefore, in order to obtain a durable project it is mandatory to develop an automated
226 and EPF integrated data extraction model. Automated EPF extraction will not only address the current
227 problem of the high administrative burden but will also enhance the completeness and reliability of the
228 registered data. Since the objective of reaching consensus on a set of indicators is achieved, the focus of
229 this project will now shift to the development of a national (semi-)automatic data extraction system.

230 An important strength of this project is national support throughout the entire project. Mainz et al. stated
231 that it is best to draw team members from different geographical areas and from different types and sizes
232 of organisation ¹⁴. A representative sample of Belgian vascular surgeons was ensured since both Flemish
233 and Walloon experts participated. Moreover 5 of 7 Belgian University hospitals were represented. Our
234 project was endorsed by the BSVS, the association for the professional interest of vascular surgeons in
235 Belgium which promotes the knowledge in the field of vascular surgery, consisting of 324 vascular
236 surgeons. Regularly, an update is given within the BSVS working group. Therefore, besides the 45 active
237 participants, this project is passively being followed by the other vascular surgeons. Moreover, the
238 majority of hospitals assigned one delegate vascular surgeon to participate actively within the project,
239 but this delegate acts as a channel to disseminate the information within their own hospital. A
240 discrepancy can be noticed between the representation of Flemish, Walloon and Brussels hospitals. Due
241 to a language barrier in Belgium, only Flemish hospitals were invited in the first phase of this project.
242 However, shortly thereafter also Walloon hospitals asked to participate. Throughout the entire course of
243 this project, new vascular surgeons have the possibility to join. Up until 31st December 2019, the number
244 of officially registered participants has grown to 68 vascular surgeons representing 45 of the
245 approximately 77 vascular surgery associations in Belgium (Figure 2).

246 Within this project, vascular surgeons were involved in the course of choosing QI from the start. This is
247 expected to be an intrinsic motivation to participate in the data collection process. When indicators are
248 determined by the government (top-down), chances exist that indicators are not relevant or not
249 practically feasible which can compromise the vascular surgeons' motivation to participate within that
250 quality initiative and to collect data.

251 With respect to the limitations of this study, three methodological issues need to be discussed. First,
252 participation of vascular surgeons in the expert panel was on a voluntary basis which could have created
253 a selection bias. In a Delphi study, it is preferred to use purposive sampling, recruiting individuals who
254 are perceived to have a certain expertise ²⁴. Another disadvantage of a Delphi survey is that different

255 opinions cannot be discussed face-to-face ²⁵. To solve this problem, a task force team was created to
256 discuss the obtained results of each question round.

257 Second, as patient experience has been stated to be an important part of healthcare quality. One may
258 criticize that the most important stakeholders in quality, the patients themselves, were not involved ²⁶.
259 Patient involvement in choosing QI could create a shift as patients most likely have other priorities ²⁷.
260 Patients were not involved in this phase of the project since this was the very first step towards a set of
261 Belgian QI in vascular surgery. However, we are convinced that patients involvement is key in future
262 phases, not with the intention to adapt our final set of 20 indicators, but to create an additional set of
263 indicators based on patient input.

264 Third, a remark needs to be made on selecting QI based on a CVI > 75%. Although this was based on
265 existing literature ²⁷, the cut-off of 75% was arbitrarily chosen. Nevertheless, indicator 18 and indicator
266 20 were retained with a CVI < 75%. This decision was based on the fact that these indicators are
267 reflecting recent guidelines and were thought to be important and relevant outcome indicators according
268 to the task force ¹⁸.

269 **Conclusions**

270 Using three rounds in a Delphi methodology, a set of 20 validated QI for vascular surgery were
271 developed. This set focusses on arterial occlusive disease, arterial aneurysm disease and venous disease.
272 A first pilot study in 6 hospitals showed the feasibility of using the indicators in daily practice, but also
273 demonstrated that an automated EPF data extraction is essential to obtain reliable and durable results,
274 and to allow implementation on a nationwide basis. The methods for benchmarking have to be further
275 discussed, keeping in mind that reporting outcome is a strong incentive to adopt best practice.

276 **Conflict of interest statement**

277 The authors report no conflict of interest. The authors alone are responsible for the content and writing
278 of this article.

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352 **Tables**

353 Table I. Items prone to quality improvement as stated by the participants in the first Delphi round

354 Table II. Vascular quality indicators with Content Validity Index (CVI), Feasibility Index (FI) and

355 Target Level

356 **Figures**

357 Figure 1. Process flow of the Delphi survey

358 Figure 2. Participating Belgian Hospitals on December 31st, 2019 (n=45).