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Project Protocol for AGREE II Extension for Guidelines in Surgery

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32
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34
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43 43 on the development of this protocol.
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3 49 **ABSTRACT**
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6 50 **Introduction** AGREE II is an instrument that informs development, reporting and
7
8 51 assessment of clinical practice guidelines. Previous research has demonstrated the
9
10 52 need for improvement in methodological and reporting quality of clinical practice
11
12 53 guidelines specifically in surgery. We aim to develop an AGREE II extension
13
14 54 document for application in surgical guidelines.
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16

17 55 **Methods and analysis** We have performed a structured literature review and
18
19 56 assessment of guidelines in surgery using the AGREE II instrument. In exploratory
20
21 57 analyses, we have identified factors associated with guideline quality. We have
22
23 58 performed reliability and factor analyses to inform the development of an extension
24
25 59 document. We will summarize this information and present it to a Delphi panel of
26
27 60 stakeholders. We will perform iterative Delphi rounds and we will summarize the
28
29 61 final results to develop the extension instrument in a dedicated consensus
30
31 62 conference.
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37 63 **Ethics and dissemination** Funding bodies will not be involved in the development of
38
39 64 the instrument. We will request board approval by Northern Care Alliance NHS
40
41 65 Group, UK. Conflicts of interest, if any, will be addressed by re-assigning functions or
42
43 66 replacing participants with relevant conflicts.
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48
49 68 **KEYWORDS**
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51 69 AGREE II; clinical practice guideline; reporting quality; development; methodology;
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53 70 EQUATOR Network
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3 73 **STRENGTHS AND LIMITATIONS**
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6 74 • This is the first project to address guideline development and reporting in surgery.
7
8 75 • It will combine statistical considerations, conceptual parameters to be derived
9
10 76 from qualitative synthesis and a formal Delphi process.
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13 77 • It will involve a panel of stakeholders from a variety of scientific, cultural and
14
15 78 geographical backgrounds.
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18 79 • The project will not address specific disciplines of surgery.
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97 INTRODUCTION

98 Research evidence is the primary source to inform medical practice forming the
99 cornerstone of evidence-based medicine.¹ An average of 5,639 new articles were
100 indexed per month under the subject heading 'Surgery' in the National Library of
101 Medicine over the past decade.² Given this fact, keeping abreast of the latest
102 evidence is a strenuous task for healthcare practitioners. Clinical practice guidelines
103 evaluate, summarize and contextualize research evidence into actionable
104 recommendations.³ As such, guidelines have a direct impact on delivery of
105 healthcare and surgical services. It is therefore of paramount importance to ensure
106 the highest quality standards in developing and reporting guidelines.

107 A great amount of scientific endeavor in the past few years has focused on
108 the quality of scholarly work, including clinical practice guidelines.⁴ Reporting
109 standards have been developed for virtually all study designs and have been
110 summarized by the EQUATOR (Enhancing the QUALity and Transparency Of health
111 Research) Network.⁵ AGREE II (Appraisal of Guidelines for Research and Evaluation)
112 constitutes a framework for developing, appraising and reporting clinical practice
113 guidelines.⁶ It is endorsed by major international and national agencies, including the
114 World Health Organization and the National Institute for Health and Care Excellence
115 (NICE) in the United Kingdom.^{7,8} AGREE II is a generic tool that applies to all
116 disciplines of medicine and no modification or extension of the framework has been
117 proposed, described or developed for specific clinical branches such as surgery.

118 The tool is comprized of 23 items organized in 7 thematic domains: Scope
119 and purpose, Stakeholder involvement, Rigor of development, Clarity of
120 presentation, Applicability, and Editorial independence. It concludes with an overall

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3 121 assessment and a statement of whether the guideline is considered of sufficient
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5 122 quality to be used or recommended in clinical practice (**Appendix**).
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10 124 *The need for an AGREE II extension*

11
12
13 125 Our research group has acted as methodological and content coordinators of
14
15 126 landmark surgical guidelines and have served as members of surgical guideline
16
17 127 development groups.^{9,10,11,12,13,14} Even though members of our group, in their role as
18
19 128 guideline developers, have made every effort to comply with the highest
20
21 129 methodological standards, as indicated by adherence to GRADE (Grading of
22
23 130 Recommendations Assessment, Development and Evaluation) and AGREE II
24
25 131 methodologies,^{15,16} we noticed that compliance with all aspects of several
26
27 132 parameters of the AGREE II instrument was not possible. For example, the item “The
28
29 133 potential resource implications of applying the recommendations have been
30
31 134 considered” may be difficult to be universally addressed, because cost-effectiveness
32
33 135 studies are scarce in the surgical literature and relevant evidence typically varies in
34
35 136 different settings.¹⁷ We have hypothesized that the original AGREE II document may
36
37 137 not be applicable to clinical practice guidelines in surgery, which often represent
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39 138 complex and multifaceted interventions.
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49 140 *Objective*

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52 141 There are a few guideline reporting documents in other fields of medicine,^{18,19}
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54 142 however a scoping literature review by our group has not identified any document to
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56 143 inform guideline development and reporting in the field of surgery. Our aim is to
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3 144 develop an extension of the AGREE II instrument that is specific for surgery through
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5 145 an evidence-informed and consensus-based approach.
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10 147 **METHODS**
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12
13 148 We have formed an international multi- and inter-disciplinary collaborative research
14
15 149 working group, that consists of surgeons, guideline developers, evidence synthesis
16
17 150 experts, GRADE methodologists,²⁰ biostatisticians and a lead member of the AGREE
18
19 151 collaboration. This is a tripartite project named *Guideline Assessment Project: Filling*
20
21 152 *the GAP in Surgical Guidelines*. A summary of the project is outlined in **Fig. 1**.
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25 153 This protocol complies with the Guidance for Developers of Health Research
26
27 154 Reporting Guidelines.²¹
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32 156 • *GAP I Project: Literature review and exploratory analyses*
33

34
35 157 We have previously performed a structured review to identify clinical practice
36
37 158 guidelines in the field of surgery published over a 10-year period.²² We have
38
39 159 assessed the methodological and reporting quality of the selected guidelines using
40
41 160 the original AGREE II criteria. Domain scores (calculated by summing up all the scores
42
43 161 of the individual items in a domain and by scaling the total as a percentage of the
44
45 162 maximum possible score for that domain)¹⁶ ranged between 0-56%, suggesting
46
47 163 generally inadequate and highly variable guideline quality. The median overall score
48
49 164 was 4 out of a maximum of 7, and 40% of guidelines were not considered suitable
50
51 165 for use based on their quality as assessed using the AGREE II instrument.
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57 166 In exploratory analyses, we have found guidelines produced by surgical
58
59 167 organizations with a high (≥ 1 guideline per year) output (odds ratio 3.79, 95%
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3 168 confidence interval, 1.01–12.66) and those produced by surgical organizations with a
4
5 169 guideline committee (odds ratio 4.15, 95% confidence interval, 1.47–11.77) have
6
7
8 170 higher odds of reaching sufficient quality and being recommended for use.²²
9

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13 172 • *GAP II: Statistically calibrating the AGREE II instrument*
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15 173 The second part of this project was focused on statistical calibration of the AGREE II
16
17 174 instrument. We employed a series of statistical methods to explore reliability,
18
19 175 internal consistency and unidimensionality of the AGREE II instrument. We
20
21 176 investigated the internal consistency that refers to the extent to which all items of
22
23 177 the instrument measure the same hypothetical construct. We explored if and how
24
25 178 test items are intercorrelated. Large intercorrelations among test items are
26
27 179 indicative of the items measuring the same construct. Using reliability analysis,
28
29 180 Kendall's tau statistics, factor analysis and the item response theory, we explored
30
31 181 whether items of each AGREE II domain are intercorrelated and are, therefore,
32
33 182 indicators of the same construct. We have finally drafted a modified AGREE II
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35 183 document for guidelines in surgery, on the basis of the outcomes of statistical
36
37 184 models.
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47 186 • *GAP III: AGREE II Extension for Surgical Guidelines*
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49 187 The third part of the project aims to use the information from the previous GAP
50
51 188 projects and other published information on the topic to develop the extension
52
53 189 document using a structured Delphi process involving relevant stakeholders.
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57 190 The multidisciplinary Delphi panel will include surgical specialists, journal
58
59 191 editors, guideline development bodies, GRADE representatives, and patient
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3 192 representatives. Under consideration of the evidence, stakeholders will be asked to
4
5 193 provide their input through a Delphi process, which will inform the preparation of an
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8 194 AGREE II extension for surgical guidelines.
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12 13 196 *Funding*

14
15 197 This third part of the project is funded by United European Gastroenterology and the
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17
18 198 European Association for Endoscopic Surgery. The funding bodies did not have any
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20 199 influence on the previous work and will not have influence on the upcoming process.
21

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23 200

24 25 201 *Participants*

26
27 202 The executive group consists of surgeons (MLC, SRM, GS, GAA, NKF, SAA), members
28
29
30 203 of surgical quality and research boards (MLC, NKF, SAA), guideline developers (MLC,
31
32 204 IF, MB, GS, NKF, SAA), evidence synthesis experts (IF, GAA, DM, SAA), GRADE
33
34
35 205 methodologists (MLC, SAA),²⁰ biostatisticians (DM, ST), and 2 leads of the AGREE
36
37 206 Group (IF, MB). It is further divided into 4 working groups with distinct functions and
38
39
40 207 responsibilities:

- 41
42 208 • The strategic steering group is responsible for overseeing the project.
43
44 209 • The methods group coordinates the methodology of the project.
45
46
47 210 • The evidence review group will review the literature for evidence on candidate
48
49 211 new items to be included in the extension document.
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52 212 • The evidence synopsis group will summarize evidence for presentation to Delphi
53
54 213 participants.
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3 214 The group attended a one-day meeting to discuss the findings of previous
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5 215 work, define the methodology and study design, and identify potential stakeholder
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8 216 groups to comprise the Delphi panel.
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13 218 *Delphi process*

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15 219 The Delphi panel will consist of key stakeholders, including; representatives from
16
17 220 different surgical disciplines (general surgery, urology, thoracic surgery, vascular
18
19 221 surgery, pediatric surgery), guideline developers from different continents and
20
21 222 representatives of guideline development organizations. The public will be involved
22
23 223 by participation of patient representatives from the European Patients Forum (**Table**
24
25 224 **1**). We will develop a web-based survey tool to facilitate Delphi exercises. Findings of
26
27 225 previous work (GAP I and GAP II) and further evidence that will be identified through
28
29 226 a scoping literature review will be summarized and presented to Delphi participants.
30
31 227 Summary information will also be available on the project website at [https://gap-
34
35 229 project.org](https://gap-
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33 228 project.org). Online links to full documents for detailed review of the evidence will be
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41 provided.

42 230 The first round will include open-ended questions to identify candidate items
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44 231 for inclusion in the extension document. Responses will be grouped and summarized
45
46 232 by the methods group before the second round is commenced.

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49 233 The second round will include closed-ended questions in a numeric Likert
50
51 234 scale to assess participants' opinions and level of agreement on including candidate
52
53 235 items or excluding existing items from the extension document. Candidate items will
54
55 236 have been identified through GAP I and GAP II, and the scoping literature review. We
56
57 237 will discard low-scoring items and use the shortlisted items in a third Delphi round.
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3 238 We will repeat the process until new information reaches saturation and consensus
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6 239 with an alpha level of 0.8.
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8 240 The Delphi panel's contribution will be acknowledged by group authorship in
9
10 241 subsequent publications of the extension document, the elaboration document and
11
12
13 242 supporting tools.
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18 244 *Qualitative synthesis*

19
20 245 We will perform qualitative evidence synthesis to identify factors of conceptual
21
22
23 246 importance to the quality of evidence in surgery. Furthermore, we will survey users
24
25 247 of social media to nominate parameters of importance in the development and
26
27
28 248 reporting of guidelines in surgery, and will group and summarize their responses.
29
30 249 Evidence identified from the above pathways, along with information from GAP I and
31
32
33 250 GAP II will be summarized and taken into account when developing the extension
34
35 251 document.
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40 253 *Consensus meeting*

41
42 254 Following the Delphi process, the executive group will meet to discuss the findings
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44
45 255 and compose the first draft of the extension document. We will present new items
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47 256 that will be identified through the Delphi exercise and the qualitative synthesis, and
48
49
50 257 discuss their plausibility and possible inclusion in the instrument. Similarly, items to
51
52
53 258 be excluded with the respective rationale will be discussed. The group will finalize
54
55 259 the extension document by ordering and allocating items into domains.

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57 260 The executive group will hold a further meeting with the advisory group that
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59 261 is comprised of journal editors and representatives of surgical associations to discuss
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3 262 dissemination and implementation processes of the developed extension
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6 263 instrument.

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10 265 *Pilot-testing and assessment of internal validity*

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13 266 The extension instrument will be pilot-tested by 2 members of the executive group.

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15 267 One member will apply the instrument on the surgical guidelines which were

16
17 268 identified by the structured search process as described in GAP I²² and on additional

18
19 269 guidelines that will be identified by extending the search to the present date. A

20
21 270 second member will independently follow the same process in a randomly selected

22
23 271 sample of 15 guidelines. The biostatistical team will assess the internal validity by

24
25 272 applying the statistical models of GAP II. Any difficulties encountered with the use of

26
27 273 the instrument will be documented and addressed. Results of the statistical

28
29 274 assessment will be appraised against statistical findings of the appraisal of the

30
31 275 original AGREE II instrument (GAP II).

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35 277 *AGREE II Extension Statement*

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37 278 The extension statement along with an explanation and elaboration (E&E) document

38
39 279 will be composed by the executive group. The E&E document will detail the use of

40
41 280 the extension instrument in developing and reporting a new surgical guideline and

42
43 281 appraising an existing surgical guideline.

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47 283 *AGREE II Extension Checklist*

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49 284 A checklist including the AGREE II Extension items will be developed with the aim of

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51 285 this checklist to be used by guideline developers (to summarize development and

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3 286 reporting parameters), guideline users (to appraise quality), peer reviewers and
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5 287 journal editors (to assess adequacy of reporting parameters).²³
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10 289 *Publication and dissemination strategy*

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13 290 We will submit the final paper with the extension document to be considered for
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15 291 publication in the UEG Journal and Surgical Endoscopy, as defined in the respective
16
17 292 pre-development agreements. We will negotiate simultaneous publications in other
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19 293 surgical journals for widest dissemination as recommended by the Guidance for
20
21 294 Developers of Health Research Reporting Guidelines.²¹
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25 295 We will make the extension document available in a dedicated website with
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27 296 links to the original publications. We will encourage surgical organizations with
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29 297 guideline development activities to use the instrument. We will further pursue
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31 298 dissemination through the websites of the funding bodies and channels of social
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33 299 media of major stakeholders, such as the Guideline International Network, GRADE
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35 300 and EQUATOR.
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39 301 Through direct contact, we will advise international surgical and guideline
40
41 302 development organizations, and policymakers to endorse the extension instrument.
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43 303 Furthermore, editors of surgical journals will be advised to provide an extension
44
45 304 instrument checklist that authors of clinical practice guidelines should submit along
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47 305 with the original manuscript.
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53 307 *Feedback and criticism*

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55 308 We will invite constructive feedback on the instrument through the dedicated
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57 309 website (<https://gap-project.org>) and we will consider comments in letters to the
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3 310 editor and via the social media. An ad hoc team will collect and summarize the
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5 311 feedback received in 3-monthly intervals for the first year after publication, and the
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8 312 executive group will discuss and address this information in web-based meetings.
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13 314 *Monitoring, update and future steps*

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15 315 The executive group will monitor the use of the extension document and appraise its
16
17 316 applicability in surgical guidelines for a reasonable period of time after dissemination
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20 317 and will publish their findings. Following consideration of the outcomes, feedback,
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22 318 criticism, suggestions and new evidence in the field, we will discuss the need for an
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24 319 update. The development of further extension instruments for national surgical
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26 320 guidelines and guidelines in distinct surgical or other interventional disciplines will be
27
28 321 considered following discussions with key stakeholders.
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35 323 **DISCUSSION**

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37 324 *Implications for practice and research*

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39 325 Clinical practice guidelines directly impact clinical practice and healthcare delivery
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41 326 and, as such, development must follow rigorous methodological and reporting
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43 327 standards. The AGREE II instrument has been designed as a generic tool for
44
45 328 development and appraisal of clinical practice guidelines.⁶ It is not intended to
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47 329 substitute established detailed guidance on guideline development principles,
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49 330 processes and procedures, such as the GRADE approach.¹⁵ It has addressed a vital
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51 331 need to summarize and detail essential development steps and reporting
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53 332 parameters for high quality guidelines. Furthermore, as an appraisal instrument, it
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3 333 may be used by healthcare practitioners, policymakers and other stakeholders to
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6 334 inform decisions regarding the use of an existing guideline.
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8 335 In addition, AGREE II has been shown to be a valuable tool for assessment of
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10 336 guideline quality in several clinical disciplines and evidence
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12 337 fields.^{22,24,25,26,27,28,29,30,31,32} Such summaries alert the scientific community to the
13
14
15 338 need for improving specific aspects of clinical practice guidelines (corresponding to
16
17 339 the instrument domains) or the overall quality of guidelines. Our previous research
18
19 340 has highlighted the need for improvement of the quality of surgical guidelines.²² An
20
21 341 AGREE II extension for surgical guidelines is expected to meet this need.
22
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24
25 342 The outcome of this project will be the first AGREE II extension document.
26
27 343 RIGHT (Reporting Tool for Practice Guidelines in Health Care) is another reporting
28
29 344 instrument for clinical practice guidelines.³³ We are aware of a planned RIGHT
30
31 345 extension for public versions of guidelines and a RIGHT extension for adapted
32
33 346 practice guidelines.^{34,35} An extension document of RIGHT for surgical guidelines
34
35 347 would be justified as well. However, in view of the evidenced gap in methodological
36
37 348 quality of surgical guidelines,²² we considered more appropriate to elaborate on
38
39 349 AGREE II, as it addresses guideline development, reporting and appraisal.
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46 47 351 *Strengths and limitations*

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49 352 This tripartite project is the first to employ statistical models to inform the validity of
50
51 353 an extension, modification or update document on guidelines reporting. We will
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53 354 correlate statistical findings with conceptual considerations of the need for
54
55 355 adjustments/extension of the AGREE II instrument. The project methods group has
56
57 356 adopted recommendations on developing research reporting guidelines, proposed
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3 357 by a collaborative team who have developed a significant number of such
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6 358 guidelines.²¹ The holistic approach to developing an extension document for clinical
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8 359 practice guidelines in surgery is reflected in the diverse scientific, cultural and
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10 360 geographical background of experts in the field involved in the project. Similarly, the
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12 361 Delphi panel will include stakeholders and members from a variety of backgrounds
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14 362 including clinicians/surgeons, methodologists, guideline developers, policy makers
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16 363 and the public (patient representatives).
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20 364 A face-to-face meeting of Delphi participants, instead of a full web-based
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22 365 Delphi process, might be more efficacious in developing the extension document
23
24 366 allowing direct exchange of opinions, information and ideas. We will encourage a full
25
26 367 participation and exchange of information by developing a user-friendly and
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28 368 interaction-allowing web-based platform. Furthermore, we will incentivize
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30 369 participation and engagement of potential Delphi members by proposing group
31
32 370 authorship and participation in future associated projects.
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38 372 *Research ethics*

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40 373 The executive group will seek Institutional Review Board approval by Northern Care
41
42 374 Alliance NHS Group, UK We will request electronic informed consent from Delphi
43
44 375 participants and the responses of the Delphi members will be anonymized.
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49 376 We have obtained conflict of interest forms of all executive group members
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51 377 and will request electronic and/or written informed consent by Delphi participants
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53 378 and members of the advisory group. We will deal with potential conflicts of interest
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55 379 by re-assigning functions or replacing participants who pose interest conflict.
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3 381 **CONCLUSION**
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6 382 The GAP III study aims to address the need for improvement of the methodology,
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8 383 reporting and appraisal of surgical guidelines. An extension document specifically
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10 384 designed for clinical practice guidelines in surgery will further improve the value, use
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13 385 and applicability of the AGREE II instrument in the surgical field with the ultimate
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15 386 goal of enhancing patient care, experience and outcomes.
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19
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21

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24
25 390 the excellent administrative support to the project.
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3 525 **FIGURE LEGEND**
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6 526 **Fig. 1:** Development steps of the Guideline Assessment Project with the ultimate
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8 527 objective to develop an AGREE II extension document for surgical guidelines
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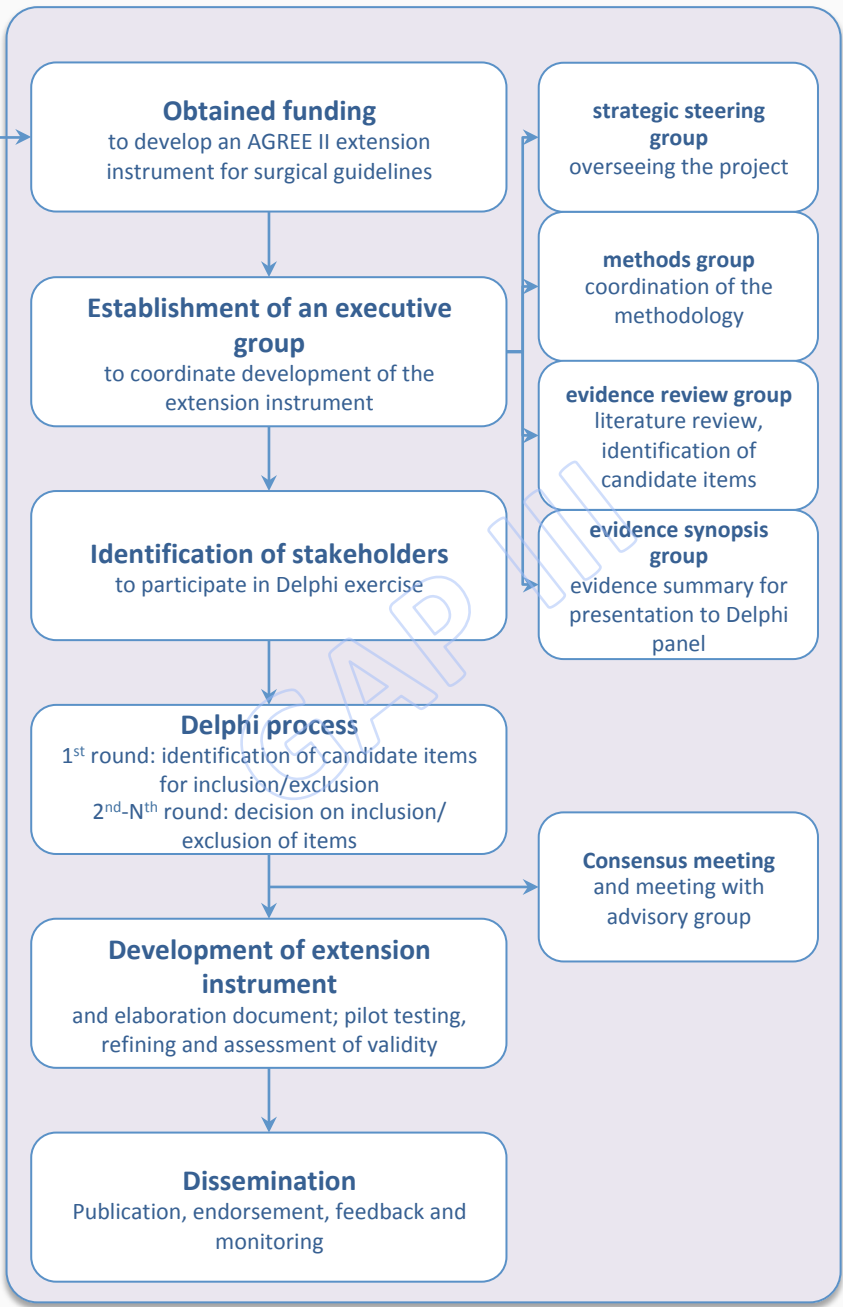
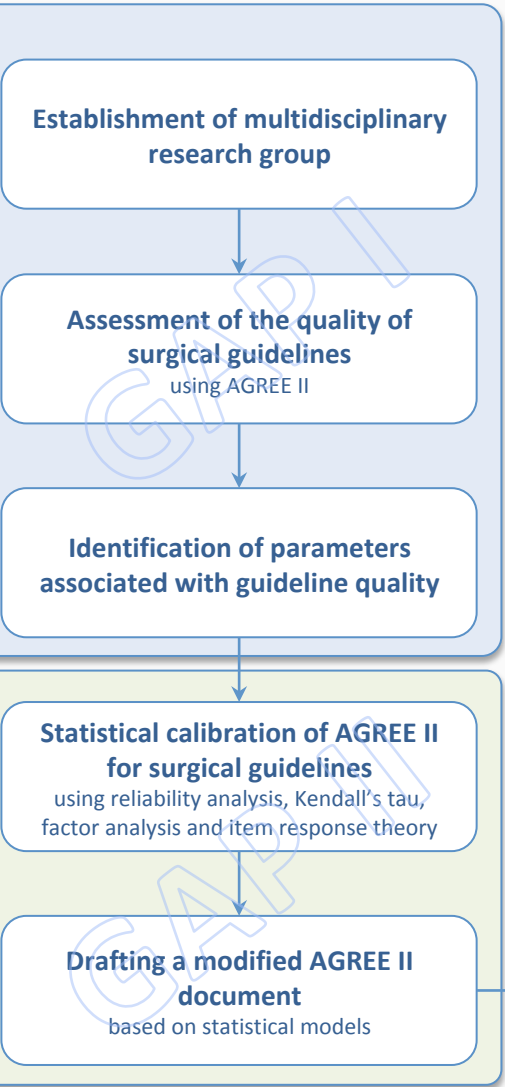
For peer review only

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3 549 **Table 1.** Stakeholders to participate in a web-based Delphi process
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Function
General Surgeon
Urologist
Thoracic Surgeon
Vascular Surgeon
Pediatric Surgeon
Journal Editor
National authority representative
NICE representative
Guideline developer/Representative from Europe
Guideline developer/Representative from North America
Guideline developer/Representative from Asia
Guideline developer/Representative from middle-income country
Healthcare provider representative
Representative from GRADE
Guideline implementer
Patient representative
WHO representative
European Commission representative
GIN representative
EQUATOR representative
NICE: National Institute of Health and Care Excellence GRADE: Grading of Recommendation Assessment, Development and Evaluation WHO: World Health Organization GIN: Guidelines International Network EQUATOR: Enhancing the QUALity and Transparency Of health Research

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APPENDIX

The AGREE II instrument

Adapted from: Brouwers MC, Kerkvliet K, Spithoff K. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. *BMJ*. 2016:i1152.

Domains	Items	Assessment*
I. Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.	1 to 7
	2. The health question(s) covered by the guideline is (are) specifically described.	1 to 7
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	1 to 7
II. Stakeholder involvement	4. The guideline development group includes individuals from all relevant professional groups.	1 to 7
	5. The views and preferences of the target population (patients, public, etc.) have been sought.	1 to 7
	6. The target users of the guideline are clearly defined.	1 to 7
III. Rigor of development	7. Systematic methods were used to search for evidence.	1 to 7
	8. The criteria for selecting the evidence are clearly described.	1 to 7
	9. The strengths and limitations of the body of evidence are clearly described.	1 to 7
	10. The methods for formulating the recommendations are clearly described.	1 to 7
	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	1 to 7
	12. There is an explicit link between the recommendations and the supporting evidence.	1 to 7
	13. The guideline has been externally reviewed by experts prior to its publication.	1 to 7
	14. A procedure for updating the guideline is provided.	1 to 7

IV. Clarity of presentation	15. The recommendations are specific and unambiguous.	1 to 7
	16. The different options for management of the condition or health issue are clearly presented.	1 to 7
	17. Key recommendations are easily identifiable.	1 to 7
V. Applicability	18. The guideline describes facilitators and barriers to its application.	1 to 7
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	1 to 7
	20. The potential resource implications of applying the recommendations have been considered.	1 to 7
	21. The guideline presents monitoring and/or auditing criteria.	1 to 7
VI. Editorial independence	22. The views of the funding body have not influenced the content of the guideline.	1 to 7
	23. Competing interests of guideline development group members have been recorded and addressed.	1 to 7
Overall guideline assessment	24. Rate the overall quality of this guideline.	1 to 7
	25. I would recommend this guideline for use.	<ul style="list-style-type: none"> • Yes • Yes, with modifications • No
* 7 corresponds to the highest possible quality.		

BMJ Open

Protocol of an Interdisciplinary Consensus Project Aiming to Develop an AGREE II Extension for Guidelines in Surgery

Journal:	<i>BMJ Open</i>
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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Evidence based practice, Health policy
Keywords:	SURGERY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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3 **1** Study protocol
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8 **3** **Protocol of an Interdisciplinary Consensus Project Aiming to Develop an AGREE II**
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10 **4** **Extension for Guidelines in Surgery**
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13 **5**

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35 38 **Disclosures**
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40 40

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42

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47 44 on the development of this protocol.
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3 49 **ABSTRACT**
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6 50 **Introduction** AGREE II is an instrument that informs development, reporting and
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8 51 assessment of clinical practice guidelines. Previous research has demonstrated the
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10 52 need for improvement in methodological and reporting quality of clinical practice
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12 53 guidelines specifically in surgery. We aim to develop an AGREE II extension
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14 54 document for application in surgical guidelines.
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17 55 **Methods and analysis** We have performed a structured literature review and
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19 56 assessment of guidelines in surgery using the AGREE II instrument. In exploratory
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21 57 analyses, we have identified factors associated with guideline quality. We have
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23 58 performed reliability and factor analyses to inform the development of an extension
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25 59 document. We will summarize this information and present it to a Delphi panel of
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27 60 stakeholders. We will perform iterative Delphi rounds and we will summarize the
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29 61 final results to develop the extension instrument in a dedicated consensus
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31 62 conference.
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37 63 **Ethics and dissemination** Funding bodies will not be involved in the development of
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39 64 the instrument. Research Ethics Committee and Health Research Authority approval
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41 65 was waived, since this is a professional staff study only and no duty of care lies with
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43 66 the NHS (National Health Service) to any of the participants. Conflicts of interest, if
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45 67 any, will be addressed by re-assigning functions or replacing participants with
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47 68 relevant conflicts. The results will be disseminated through publication in peer
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49 69 reviewed journals, the funders' websites, social media, and direct contact with
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51 70 guideline development organizations and peer-reviewed journals that publish
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8 75 **KEYWORDS**9
10 76 AGREE II; clinical practice guideline; reporting quality; development; methodology;11
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13 77 EQUATOR Network14
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20 80 **STRENGTHS AND LIMITATIONS**21
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23 81 • This is the first project to address guideline development and reporting in surgery.24
25 82 • It will combine statistical considerations, conceptual parameters to be derived
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27 83 from qualitative synthesis and a formal Delphi process.28
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30 84 • It will involve a panel of stakeholders from a variety of scientific, cultural and
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32 85 geographical backgrounds.33
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35 86 • The project will not address specific disciplines of surgery.36
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78 99 **INTRODUCTION**
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10 100 Research evidence is the primary source to inform medical practice forming the
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13 101 cornerstone of evidence-based medicine.¹ An average of 5,639 new articles were
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15 102 indexed per month under the subject heading 'Surgery' in the National Library of
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17 103 Medicine over the past decade.² Given this fact, keeping abreast of the latest
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19 104 evidence is a strenuous task for healthcare practitioners. Clinical practice guidelines
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21 105 evaluate, summarize and contextualize research evidence into actionable
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23 106 recommendations.³ As such, guidelines have a direct impact on delivery of
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25 107 healthcare and surgical services. It is therefore of paramount importance to ensure
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27 108 the highest quality standards in developing and reporting guidelines.
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32 109 A great amount of scientific endeavor in the past few years has focused on
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34 110 the quality of scholarly work, including clinical practice guidelines.⁴ Reporting
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36 111 standards have been developed for virtually all study designs and have been
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38 112 summarized by the EQUATOR (Enhancing the QUALity and Transparency Of health
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40 113 Research) Network.⁵ AGREE II (Appraisal of Guidelines for Research and Evaluation)
41
42 114 constitutes a framework for developing, appraising and reporting clinical practice
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44 115 guidelines.⁶ It is endorsed by major international and national agencies, including the
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46 116 World Health Organization and the National Institute for Health and Care Excellence
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48 117 (NICE) in the United Kingdom.^{7,8} AGREE II is a generic tool that applies to all
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50 118 disciplines of medicine and no modification or extension of the framework has been
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52 119 proposed, described or developed for specific clinical branches such as surgery.
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3 120 The tool is comprized of 23 items organized in 7 thematic domains: Scope
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5 121 and purpose, Stakeholder involvement, Rigor of development, Clarity of
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7 122 presentation, Applicability, and Editorial independence. It concludes with an overall
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9 123 assessment and a statement of whether the guideline is considered of sufficient
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11 124 quality to be used or recommended in clinical practice (**Appendix**).
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18 126 *The need for an AGREE II extension*

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20 127 Our research group has acted as methodological and content coordinators of
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22 128 landmark surgical guidelines and have served as members of surgical guideline
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24 129 development groups.^{9,10,11,12,13,14} Even though members of our group, in their role as
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26 130 guideline developers, have made every effort to comply with the highest
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28 131 methodological standards, as indicated by adherence to GRADE (Grading of
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30 132 Recommendations Assessment, Development and Evaluation) and AGREE II
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32 133 methodologies,^{15,16} we noticed that compliance with all aspects of several
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34 134 parameters of the AGREE II instrument was not possible.
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40 135 For example, the item “The potential resource implications of applying the
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42 136 recommendations have been considered” may be difficult to be universally
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44 137 addressed. Cost-effectiveness studies are scarce in the surgical literature and
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46 138 relevant evidence typically varies in different settings.¹⁷ Since surgical expertise
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48 139 varies across countries and institutions, there is a need for the instrument to
49
50 140 consistently apply to different healthcare settings. Surgical interventions are
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52 141 complex and details on the interventions/comparators are imperative for the target
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54 142 users to be able to assess the external validity of the guidelines. Specialists from
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56 143 different specialties and allied health professionals with a wide range of expertise
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3 144 are involved in the treatment of surgical patients, which makes their involvement in
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5 145 guideline development paramount. We have hypothesized that the original AGREE II
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7
8 146 document may not be applicable to clinical practice guidelines in surgery, which
9
10 147 offer represent complex and multifaceted interventions.
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15 149 *Objective*

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18 150 There are a few guideline reporting documents in other fields of medicine,^{18,19}
19
20 151 however a scoping literature review by our group has not identified any document to
21
22 152 inform guideline development and reporting in the field of surgery. Our aim is to
23
24 153 develop an extension of the AGREE II instrument that is specific for surgery through
25
26 154 an evidence-informed and consensus-based approach.
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32 156 **METHODS AND ANALYSIS**

34
35 157 We have formed an international multi- and inter-disciplinary collaborative
36
37 158 research working group, that consists of surgeons, guideline developers, evidence
38
39 159 synthesis experts, GRADE methodologists,²⁰ biostatisticians and a lead member of
40
41 160 the AGREE collaboration. This is a tripartite project named *Guideline Assessment*
42
43 161 *Project: Filling the GAP in Surgical Guidelines*. A summary of the project is outlined in
44
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46
47 162 **Fig. 1.** The project is a result of a partnership between an international team of
48
49 163 surgical research experts and two of the AGREE research team leads (IF and MB). The
50
51 164 AGREE research team is currently under a membership renovation process, and,
52
53 165 therefore, neither of the authors can speak on behalf of the entire AGREE group.
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57 166 However, both AGREE research team leads state that AGREE has supported the
58
59 167 project from its inception. Furthermore, they have agreed to support dissemination
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3 168 activities by making this new tool available in the AGREE website
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6 169 (<https://agreetrust.org>).

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11 171 This protocol complies with the Guidance for Developers of Health Research
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13 172 Reporting Guidelines.²¹

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17
18 174 • *Patient and public involvement*

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20
21 175 No patients were involved in the development of this protocol.

22
23 176

24
25 177 • *GAP I Project: Literature review and exploratory analyses*

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27
28 178 We have previously performed a structured review to identify clinical practice
29
30 179 guidelines in the field of surgery published over a 10-year period.²² We have
31
32
33 180 assessed the methodological and reporting quality of the selected guidelines using
34
35 181 the original AGREE II criteria. Domain scores (calculated by summing up all the scores
36
37 182 of the individual items in a domain and by scaling the total as a percentage of the
38
39 183 maximum possible score for that domain)¹⁶ ranged between 0-56%, suggesting
40
41 184 generally inadequate and highly variable guideline quality. The median overall score
42
43 185 was 4 out of a maximum of 7, and 40% of guidelines were not considered suitable
44
45 186 for use based on their quality as assessed using the AGREE II instrument.

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47
48 187 In exploratory analyses, we have found guidelines produced by surgical
49
50 188 organizations with a high (≥ 1 guideline per year) output (odds ratio 3.79, 95%
51
52 189 confidence interval, 1.01–12.66) and those produced by surgical organizations with a
53
54 190 guideline committee (odds ratio 4.15, 95% confidence interval, 1.47–11.77) have
55
56 191 higher odds of reaching sufficient quality and being recommended for use.²²

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6 193 • *GAP II: Statistically calibrating the AGREE II instrument*
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8 194 The second part of this project was focused on statistical calibration of the AGREE II
9
10 195 instrument. We have used quality appraisal data from GAP I and employed a series
11
12 196 of statistical methods to explore reliability, internal consistency and
13
14 197 unidimensionality of the AGREE II instrument when it is applied in surgical
15
16 198 guidelines. We investigated the internal consistency that refers to the extent to
17
18 199 which all items of the instrument measure the same hypothetical construct. We
19
20 200 explored if and how test items are intercorrelated. Large intercorrelations among
21
22 201 test items are indicative of the items measuring the same construct. Using reliability
23
24 202 analysis, Kendall's tau statistics, factor analysis and the item response theory, we
25
26 203 explored whether items of each AGREE II domain are intercorrelated and are,
27
28 204 therefore, indicators of the same construct. Statistical modeling showed that
29
30 205 excluding 5 items from the original tool (items 1, 2, 5, 7 and 8) and re-arranging the
31
32 206 remaining items into 4 domains instead of 6 would enhance the instrument.. We
33
34 207 have finally drafted a modified AGREE II document for guidelines in surgery, on the
35
36 208 basis of the outcomes of statistical models.
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47 210 • *GAP III: AGREE II Extension for Surgical Guidelines*
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49 211 The third part of the project aims to use the information from the previous GAP
50
51 212 projects and other published information on the topic to develop the extension
52
53 213 document using a structured Delphi process involving relevant stakeholders.
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55

56
57 214 The multidisciplinary Delphi panel will include surgical specialists, journal
58
59 215 editors, guideline development bodies, GRADE representatives, and patient
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3 216 representatives. Under consideration of the evidence, stakeholders will be asked to
4
5 217 provide their input through a Delphi process, which will inform the preparation of an
6
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8 218 AGREE II extension for surgical guidelines.
9

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11 219

12
13 220 *Funding*

14
15 221 This third part of the project is funded by United European Gastroenterology and the
16
17 222 European Association for Endoscopic Surgery. The funding bodies did not have any
18
19 223 influence on the previous work and will not have influence on the upcoming process.
20
21
22

23 224

24
25 225 *Participants*

26
27 226 The executive group consists of surgeons (MLC, SRM, GS, GAA, NKF, SAA), members
28
29 227 of surgical quality and research boards (MLC, NKF, SAA), guideline developers (MLC,
30
31 228 IF, MB, GS, NKF, SAA), evidence synthesis experts (IF, GAA, DM, SAA), GRADE
32
33 229 methodologists (MLC, SAA),²⁰ biostatisticians (DM, ST), and 2 leads of the AGREE
34
35 230 Group (IF, MB). It is further divided into 4 working groups with distinct functions and
36
37 231 responsibilities:
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41
42 232 • The strategic steering group is responsible for overseeing the project.
43
44 233 • The methods group coordinates the methodology of the project.
45
46
47 234 • The evidence review group will review the literature for evidence on candidate
48
49 235 new items to be included in the extension document.
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52 236 • The evidence synopsis group will summarize evidence for presentation to Delphi
53
54 237 participants.
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3 238 The group attended a one-day meeting to discuss the findings of previous
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5 239 work, define the methodology and study design, and identify potential stakeholder
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8 240 groups to comprise the Delphi panel.
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13 242 *Delphi process*

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15 243 The Delphi panel will consist of key stakeholders, including; representatives from
16
17 244 different surgical disciplines (general surgery, urology, thoracic surgery, vascular
18
19 245 surgery, pediatric surgery), guideline developers from different continents and
20
21 246 representatives of guideline development organizations. The public will be involved
22
23 247 by participation of patient representatives from the European Patients Forum (**Table**
24
25 248 **1**). We will develop a web-based survey tool to facilitate Delphi exercises. Findings of
26
27 249 previous work (GAP I and GAP II) and further evidence that will be identified through
28
29 250 a scoping literature review will be summarized and presented to Delphi participants.
30
31 251 Summary information will also be available on the project website at [https://gap-
34
35 253 project.org](https://gap-
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33 252 project.org). Online links to full documents for detailed review of the evidence will be
36
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39
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41 provided.

42 254 The first round will include open-ended questions to identify candidate items
43
44 255 for inclusion in the extension document. Responses will be grouped and summarized
45
46 256 by the methods group before the second round is commenced.

47
48 257 The second round will include closed-ended questions in a 5-point Likert
49
50 258 scale to assess participants' opinions and level of agreement on including candidate
51
52 259 items or excluding existing items from the extension document. As per protocol, 1/2
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54 260 indicates strong/moderate disagreement, 3 indicates no opinion, and 4/5 indicates
55
56 261 moderate/strong agreement. Candidate items will have been identified through GAP
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3 262 I and GAP II, and the scoping literature review. We will discard low-scoring items (i.e.
4
5 263 those with a median score of 1/2 on the Likert scale) and use the shortlisted items in
6
7
8 264 a third Delphi round. We will repeat the process until an agreement of 80% (4/5 on
9
10 265 the Likert scale) is reached among Delphi participants.

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13 266 The Delphi panel's contribution will be acknowledged by group authorship in
14
15 267 subsequent publications of the extension document, the elaboration document and
16
17 268 supporting tools.

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23 270 *Qualitative research synthesis*

24
25 271 We will perform qualitative evidence synthesis to identify factors of conceptual
26
27 272 importance to the quality of evidence in surgery. The overarching question will be:

28
29 273 How do clinical practice guidelines in surgery differ from non-surgical guidelines?

30
31 274 Specific thematic questions will be addressed:

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34
35 275 1. Which are the concepts that make surgical guidelines different from guidelines
36
37 276 or summary evidence in other medical fields?

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39
40 277 2. Which are potential items that may be of sufficient importance to be included in
41
42 278 an AGREE II Extension for surgical guidelines?

43
44 279 3. Which are the items of the original AGREE II that might not be relevant to
45
46 280 surgical guidelines?

47
48 281 4. How should items of the original AGREE II instrument be modified to be more
49
50 282 relevant to an AGREE II Extension for surgical guidelines?

51
52
53 283 We will conduct a scoping search of PubMed, Embase and Google Scholar. In
54
55 284 keeping with realist review guidelines,²³ there will be no restrictions on the types of
56
57 285 study design eligible for inclusion. We will consider editorials, letters to the editor,
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3 286 commentaries, opinions and any type of publication that captures the breadth
4
5 287 discussions about development of surgical guidelines. Information will be used to
6
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8 288 identify characteristics that specifically apply to surgical guidelines.
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10 289 The realist review will aim to develop an explanatory understanding of
11
12 290 development and reporting of surgical guidelines, how surgical guidelines differ from
13
14 291 non-surgical ones, and how AGREE II can be modified to reflect the specific aspects
15
16 292 of surgical guidelines. According to the realist synthesis methodology, studies will be
17
18 293 assessed based on criteria of relevance (whether they contribute to the development or
19
20 294 testing of the initial theories)²⁴ and appropriateness for addressing the research
21
22 295 questions.^{25,26}
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24
25
26

27 296 Studies will be entered into ATLAS.ti and coded to identify the specific
28
29 297 features relevant to development and reporting of surgical guidelines. Themes will
30
31 298 be discussed by the research team using an iterative and speculative process (Wong,
32
33 299 Greenhalgh et al. 2010). Adjudication and triangulation will be applied to refine
34
35 300 theories which can be used across the studies to understand findings.
36
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38

39 301 Furthermore, we will invite users of social media through the project account
40
41 302 on Twitter (@GAPProject2) and through communication streams of the sponsoring
42
43 303 bodies (Facebook, Twitter and email newsletters) to nominate parameters of
44
45 304 importance in the development and reporting of guidelines in surgery, and will
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47 305 group and summarize their responses. Evidence identified from the above pathways,
48
49 306 along with information from GAP I and GAP II will be summarized and taken into
50
51 307 account when developing the extension document.
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57 309 *Consensus meeting*
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2
3 310 Following the Delphi process, the executive group will meet to discuss the findings
4
5 311 and compose the first draft of the extension document. We will present new items
6
7
8 312 that will be identified through the Delphi exercise and the qualitative synthesis, and
9
10 313 discuss their plausibility and possible inclusion in the instrument. Similarly, items to
11
12
13 314 be excluded with the respective rationale will be discussed. The group will finalize
14
15 315 the extension document by ordering and allocating items into domains.

16
17
18 316 The executive group will hold a further meeting with the advisory group that
19
20 317 is comprised of journal editors and representatives of surgical associations to discuss
21
22 318 dissemination and implementation processes of the developed extension
23
24 319 instrument.

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30 321 *Pilot-testing and assessment of internal validity*

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32 322 The extension instrument will be pilot-tested by 2 members of the executive group.
33
34 323 One member will apply the instrument on the surgical guidelines which were
35
36 324 identified by the structured search process as described in GAP I²² and on additional
37
38 325 guidelines that will be identified by extending the search to the present date. A
39
40 326 second member will independently follow the same process in a randomly selected
41
42 327 sample of 15 guidelines. The biostatistical team will assess the internal validity by
43
44 328 applying the statistical models of GAP II. Any difficulties encountered with the use of
45
46 329 the instrument will be documented and addressed. Results of the statistical
47
48 330 assessment will be appraised against statistical findings of the appraisal of the
49
50 331 original AGREE II instrument (GAP II).

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59 333 *AGREE II Extension Statement*
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3 334 The extension statement along with an explanation and elaboration (E&E) document
4
5 335 will be composed by the executive group. The E&E document will detail the use of
6
7
8 336 the extension instrument in developing and reporting a new surgical guideline and
9
10 337 appraising an existing surgical guideline.

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14
15 339 *AGREE II Extension Checklist*

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18 340 A checklist including the AGREE II Extension items will be developed with the aim of
19
20 341 this checklist to be used by guideline developers (to summarize development and
21
22 342 reporting parameters), guideline users (to appraise quality), peer reviewers and
23
24 343 journal editors (to assess adequacy of reporting parameters).²⁷

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29
30 345 *Feedback and criticism*

31
32 346 We will invite constructive feedback on the instrument through the dedicated
33
34 347 website (<https://gap-project.org>) and we will consider comments in letters to the
35
36 348 editor and via the social media. An ad hoc team will collect and summarize the
37
38 349 feedback received in 3-monthly intervals for the first year after publication, and the
39
40 350 executive group will discuss and address this information in web-based meetings.

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46 352 *Monitoring, update and future steps*

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49 353 The executive group will monitor the use of the extension document and appraise its
50
51 354 applicability in surgical guidelines for a reasonable period of time after dissemination
52
53 355 and will publish their findings. Following consideration of the outcomes, feedback,
54
55 356 criticism, suggestions and new evidence in the field, we will discuss the need for an
56
57 357 update. The development of further extension instruments for national surgical
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3 358 guidelines and guidelines in distinct surgical or other interventional disciplines will be
4
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6 359 considered following discussions with key stakeholders.
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8 360

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10 361 *Implications for practice and research*

11
12 362 Clinical practice guidelines directly impact clinical practice and healthcare delivery
13
14
15 363 and, as such, development must follow rigorous methodological and reporting
16
17
18 364 standards. The AGREE II instrument has been designed as a generic tool for
19
20 365 development and appraisal of clinical practice guidelines.⁶ It is not intended to
21
22 366 substitute established detailed guidance on guideline development principles,
23
24
25 367 processes and procedures, such as the GRADE approach.¹⁵ It has addressed a vital
26
27
28 368 need to summarize and detail essential development steps and reporting
29
30 369 parameters for high quality guidelines. Furthermore, as an appraisal instrument, it
31
32 370 may be used by healthcare practitioners, policymakers and other stakeholders to
33
34
35 371 inform decisions regarding the use of an existing guideline.

36
37 372 In addition, AGREE II has been shown to be a valuable tool for assessment of
38
39
40 373 guideline quality in several clinical disciplines and evidence
41
42 374 fields.^{22,28,29,30,31,32,33,34,35,36} Such summaries alert the scientific community to the
43
44
45 375 need for improving specific aspects of clinical practice guidelines (corresponding to
46
47 376 the instrument domains) or the overall quality of guidelines. Our previous research
48
49
50 377 has highlighted the need for improvement of the quality of surgical guidelines.²² An
51
52 378 AGREE II extension for surgical guidelines is expected to meet this need.

53
54 379 The outcome of this project will be the first AGREE II extension document.
55
56
57 380 RIGHT (Reporting Tool for Practice Guidelines in Health Care) is another reporting
58
59 381 instrument for clinical practice guidelines.³⁷ We are aware of a planned RIGHT
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3 382 extension for public versions of guidelines and a RIGHT extension for adapted
4
5 383 practice guidelines.^{38,39} An extension document of RIGHT for surgical guidelines
6
7
8 384 would be justified as well. However, in view of the evidenced gap in methodological
9
10 385 quality of surgical guidelines,²² we considered more appropriate to elaborate on
11
12
13 386 AGREE II, as it addresses guideline development, reporting and appraisal.

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18 388 *Strengths and limitations*

19
20 389 This tripartite project is the first to employ statistical models to inform the validity of
21
22 390 an extension, modification or update document on guidelines reporting. We will
23
24 391 correlate statistical findings with conceptual considerations of the need for
25
26 392 adjustments/extension of the AGREE II instrument. The project methods group has
27
28 393 adopted recommendations on developing research reporting guidelines, proposed
29
30 394 by a collaborative team who have developed a significant number of such
31
32 395 guidelines.²¹ The holistic approach to developing an extension document for clinical
33
34 396 practice guidelines in surgery is reflected in the diverse scientific, cultural and
35
36 397 geographical background of experts in the field involved in the project. Similarly, the
37
38 398 Delphi panel will include stakeholders and members from a variety of backgrounds
39
40 399 including clinicians/surgeons, methodologists, guideline developers, policy makers
41
42 400 and the public (patient representatives).

43
44 401 A face-to-face meeting of Delphi participants, instead of a full web-based
45
46 402 Delphi process, might be more efficacious in developing the extension document
47
48 403 allowing direct exchange of opinions, information and ideas. We will encourage a full
49
50 404 participation and exchange of information by developing a user-friendly and
51
52 405 interaction-allowing web-based platform. Furthermore, we will incentivize

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3 406 participation and engagement of potential Delphi members by proposing group
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5 407 authorship and participation in future associated projects.
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9
10 409 **ETHICS AND DISSEMINATION**

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13 410 Research Ethics Committee and Health Research Authority approval was waived,
14
15 411 since this is a professional staff study only and no duty of care lies with the NHS
16
17 412 (National Health Service) to any of the participants. We will request electronic
18
19 413 informed consent from Delphi participants and the responses of the Delphi members
20
21 414 will be anonymized.
22
23
24

25 415 We have obtained conflict of interest forms of all executive group members
26
27 416 and will request electronic and/or written informed consent by Delphi participants
28
29 417 and members of the advisory group. We will deal with potential conflicts of interest
30
31 418 by re-assigning functions or replacing participants who pose interest conflict.
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35 419 We will submit the final paper with the extension document to be considered
36
37 420 for publication in the UEG Journal and Surgical Endoscopy, as defined in the
38
39 421 respective pre-development agreements. We will negotiate simultaneous
40
41 422 publications in other surgical journals for widest dissemination as recommended by
42
43 423 the Guidance for Developers of Health Research Reporting Guidelines.²¹
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47 424 We will make the extension document available in a dedicated website with
48
49 425 links to the original publications. We will encourage surgical organizations with
50
51 426 guideline development activities to use the instrument. We will further pursue
52
53 427 dissemination through the websites of the funding bodies and channels of social
54
55 428 media of major stakeholders, such as the Guideline International Network, GRADE
56
57 429 and EQUATOR.
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3 430 Through direct contact, we will advise international surgical and guideline
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6 431 development organizations, and policymakers to endorse the extension instrument.
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8 432 Furthermore, editors of surgical journals will be advised to provide an extension
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10 433 instrument checklist that authors of clinical practice guidelines should submit along
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12
13 434 with the original manuscript.

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15 435

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18 436 The GAP III study aims to address the need for improvement of the methodology,
19
20 437 reporting and appraisal of surgical guidelines. An extension document specifically
21
22 438 designed for clinical practice guidelines in surgery will further improve the value, use
23
24
25 439 and applicability of the AGREE II instrument in the surgical field with the ultimate
26
27 440 goal of enhancing patient care, experience and outcomes.

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31
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34
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36
37 444 the excellent administrative support to the project.

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41
42 446 **AUTHOR CONTRIBUTION STATEMENT**

43
44
45 447 George A. Antoniou: Conception and design, interpretation of data, drafting the
46
47 448 work, final approval for the work to be published, agreement to be accountable for
48
49 449 all aspects of the work in ensuring that questions related to the accuracy or integrity
50
51 450 of any part of the work are appropriately investigated and resolved.

52
53
54 451 Dimitris Mavridis: Conception and design, analysis of data, interpretation of data,
55
56 452 drafting the work, final approval for the work to be published, agreement to be
57
58
59 453 accountable for all aspects of the work in ensuring that questions related to the
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3 454 accuracy or integrity of any part of the work are appropriately investigated and
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6 455 resolved.

7
8 456 Sofia Tsokani: Analysis of data, interpretation of data, revising the work critically for
9
10 457 important intellectual data, final approval for the work to be published, agreement
11
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13 458 to be accountable for all aspects of the work in ensuring that questions related to
14
15 459 the accuracy or integrity of any part of the work are appropriately investigated and
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17 460 resolved.

18
19
20 461 Manuel López-Cano: Acquisition of data, analysis of data, interpretation of data,
21
22 462 revising the work critically for important intellectual data, final approval for the work
23
24 463 to be published, agreement to be accountable for all aspects of the work in ensuring
25
26 464 that questions related to the accuracy or integrity of any part of the work are
27
28 465 appropriately investigated and resolved.

29
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31 466 Iván Flórez: Conception and design, interpretation of data, drafting the work, final
32
33 467 approval for the work to be published, agreement to be accountable for all aspects
34
35 468 of the work in ensuring that questions related to the accuracy or integrity of any part
36
37 469 of the work are appropriately investigated and resolved.

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40 470 Melissa Brouwers: Conception and design, interpretation of data, revising the work
41
42 471 critically for important intellectual data, final approval for the work to be published,
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44 472 agreement to be accountable for all aspects of the work in ensuring that questions
45
46 473 related to the accuracy or integrity of any part of the work are appropriately
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48 474 investigated and resolved.

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51 475 Sheraz Markar: Interpretation of data, revising the work critically for important
52
53 476 intellectual data, final approval for the work to be published, agreement to be
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55 477 accountable for all aspects of the work in ensuring that questions related to the
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3 478 accuracy or integrity of any part of the work are appropriately investigated and
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6 479 resolved.

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8 480 Gianfranco Silecchia: Interpretation of data, revising the work critically for important
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10 481 intellectual data, final approval for the work to be published, agreement to be
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13 482 accountable for all aspects of the work in ensuring that questions related to the
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15 483 accuracy or integrity of any part of the work are appropriately investigated and
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18 484 resolved.

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20 485 Nader K Francis: Interpretation of data, revising the work critically for important
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22 486 intellectual data, final approval for the work to be published, agreement to be
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25 487 accountable for all aspects of the work in ensuring that questions related to the
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28 488 accuracy or integrity of any part of the work are appropriately investigated and
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31 489 resolved.

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33 490 Stavros A. Antoniou: Conception and design, acquisition of data, analysis of data,
34
35 491 interpretation of data, drafting the work, final approval for the work to be published,
36
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38 492 agreement to be accountable for all aspects of the work in ensuring that questions
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41 493 related to the accuracy or integrity of any part of the work are appropriately
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8 624 **FIGURE LEGEND**
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10 625 **Fig. 1:** Development steps of the Guideline Assessment Project with the ultimate
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13 626 objective to develop an AGREE II extension document for surgical guidelines
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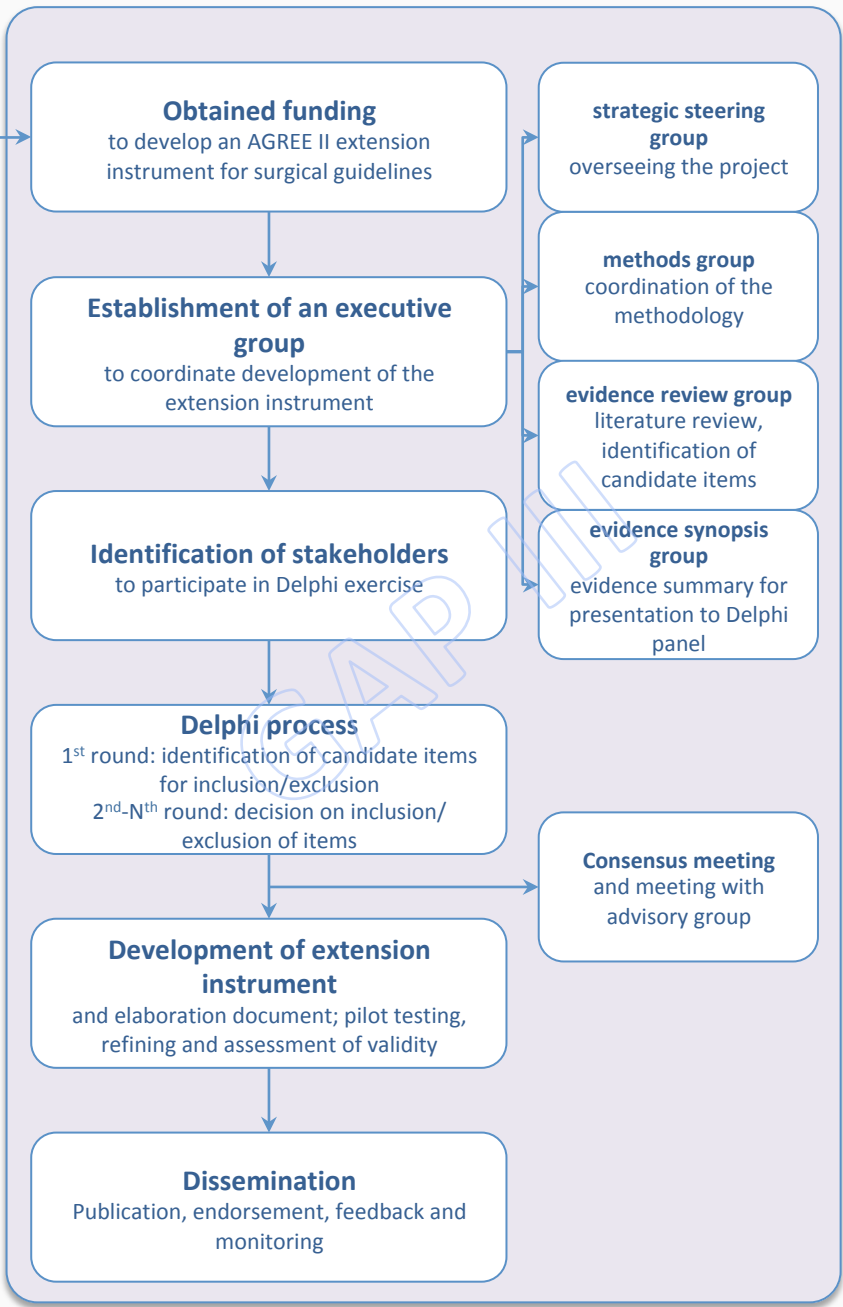
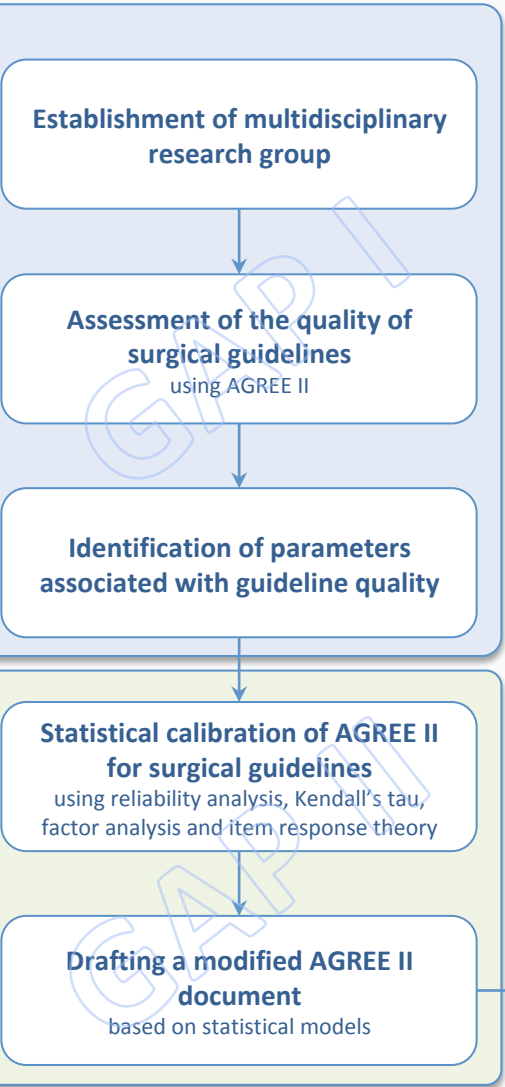
648 **Table 1.** Stakeholders to participate in a web-based Delphi process

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Function
General Surgeon
Urologist
Thoracic Surgeon
Vascular Surgeon
Pediatric Surgeon
Journal Editor
National authority representative
NICE representative
Guideline developer/Representative from Europe
Guideline developer/Representative from North America
Guideline developer/Representative from Asia
Guideline developer/Representative from middle-income country
Healthcare provider representative
Representative from GRADE
Guideline implementer
Patient representative
WHO representative
European Commission representative
GIN representative
EQUATOR representative
NICE: National Institute of Health and Care Excellence GRADE: Grading of Recommendation Assessment, Development and Evaluation WHO: World Health Organization GIN: Guidelines International Network EQUATOR: Enhancing the QUALity and Transparency Of health Research

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APPENDIX

The AGREE II instrument

Adapted from: Brouwers MC, Kerkvliet K, Spithoff K. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. *BMJ*. 2016;i1152.

Domains	Items	Assessment*
I. Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.	1 to 7
	2. The health question(s) covered by the guideline is (are) specifically described.	1 to 7
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	1 to 7
II. Stakeholder involvement	4. The guideline development group includes individuals from all relevant professional groups.	1 to 7
	5. The views and preferences of the target population (patients, public, etc.) have been sought.	1 to 7
	6. The target users of the guideline are clearly defined.	1 to 7
III. Rigor of development	7. Systematic methods were used to search for evidence.	1 to 7
	8. The criteria for selecting the evidence are clearly described.	1 to 7
	9. The strengths and limitations of the body of evidence are clearly described.	1 to 7
	10. The methods for formulating the recommendations are clearly described.	1 to 7
	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	1 to 7
	12. There is an explicit link between the recommendations and the supporting evidence.	1 to 7
	13. The guideline has been externally reviewed by experts prior to its publication.	1 to 7
	14. A procedure for updating the guideline is provided.	1 to 7

IV. Clarity of presentation	15. The recommendations are specific and unambiguous.	1 to 7
	16. The different options for management of the condition or health issue are clearly presented.	1 to 7
	17. Key recommendations are easily identifiable.	1 to 7
V. Applicability	18. The guideline describes facilitators and barriers to its application.	1 to 7
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	1 to 7
	20. The potential resource implications of applying the recommendations have been considered.	1 to 7
	21. The guideline presents monitoring and/or auditing criteria.	1 to 7
VI. Editorial independence	22. The views of the funding body have not influenced the content of the guideline.	1 to 7
	23. Competing interests of guideline development group members have been recorded and addressed.	1 to 7
Overall guideline assessment	24. Rate the overall quality of this guideline.	1 to 7
	25. I would recommend this guideline for use.	<ul style="list-style-type: none"> • Yes • Yes, with modifications • No
* 7 corresponds to the highest possible quality.		