



ORIGINAL RESEARCH ARTICLE

Reproducibility of colposcopy quality indicators—A survey among members of the European Federation for Colposcopy

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Abstract

Introduction: Colposcopy is an important part of the diagnostic work-up of women with an abnormal cervical screening test as it is used to guide the collection of biopsies. Although quality assurance has been used in the evaluation of screening programs, not much is known about quality indicators for the diagnostics and treatment of screen-positive women. Therefore, the European Federation for Colposcopy developed quality indicators aiming to support colposcopy practice across Europe. We performed a survey of colposcopy cases to determine if the quality indicators are understandable, relevant, and reproducible.

Material and Methods: We conducted a survey among all members of the European Federation for Colposcopy Quality and Standards Group from November 2022 to

Abbreviations: CIN, cervical intraepithelial neoplasia; EFC, European Federation for Colposcopy and Pathology of the Lower Genital Tract; QIs, quality indicators.

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March 2023. Members were asked to collect information on a total of 17 quality indicators for 50 women who had been newly referred for colposcopy due to an abnormal screening test between January 1, 2020 to December 31, 2021. Results were reported descriptively.

Results: We included data on 609 cases from 12 members across Europe. The majority of the quality indicators were either achieved or within reach of the agreed standard, often due to few countries with outlying data. One quality indicator had very low performance, although stratified results indicated that two countries had different clinical management of the patient type thereby skewing the results. In addition, discrepancies between the number of cases included in each quality indicator raised concerns regarding potential misunderstanding of the quality indicator and its objective.

Conclusions: Quality indicators on colposcopy must be understandable to those collecting data, highlighting the importance of validating quality indicators before data collection.

KEYWORDS

cervical cancer prevention, cervical intraepithelial neoplasia, colposcopy, health care, quality assurance, quality indicators

1 | INTRODUCTION

Cervical cancer incidence and mortality have declined significantly in many developed countries after the introduction of cervical cancer screening.¹⁻³ Screening enable the identification of women at increased risk of cervical cancer and its precursors who need repeat testing or referral for further diagnostic work-up. A critical component of the management of screen-positive women is colposcopic examination of the cervix, including a collection of colposcopy-directed biopsies from abnormal areas. Colposcopy is subjective and thus a relatively imprecise diagnostic instrument, with a sensitivity of approximately 50%–60% for the detection of cervical intraepithelial neoplasia grade 2 or worse (CIN2+).⁴⁻⁷ Nevertheless, clinical management depends on a combined assessment of cervical cytology, colposcopic diagnosis, and the biopsy result. Hence, colposcopy must be of high quality to reliably triage those women requiring treatment or to provide reassurance for women who are recommended clinical follow-up. Furthermore, it is important that women who have precancerous lesions detected receive adequate treatment.

Most European countries have guidelines on diagnostics and treatment of precancerous lesions formulated by an interdisciplinary group, which colposcopists are obliged to follow.⁸ Even so, quality assurance of colposcopy and biopsy collection has received little attention as most countries have focussed on quality assurance databases for their cervical cancer screening programs, although differing in their data collection and measurement.⁹

Clearly defined standards of care or quality indicators (QIs) are needed for monitoring the quality of colposcopy and for measuring

Key message

Quality indicators may provide a useful measure of colposcopy practice and should be collected and compared by healthcare providers who understand their meaning, both within and across services to facilitate quality improvement.

potential variations of clinical practices. Well-defined and appropriately collected QIs will enable benchmarking of services and produce comparable audit data, potentially resulting in improved patient care.

The European Federation for Colposcopy and Pathology of the Lower Genital Tract (EFC) has an overriding interest in supporting colposcopy services and the clinical management of women with abnormal screening tests. The EFC has developed a set of QIs related to the diagnostic work-up of women with abnormal cervical screening tests and the treatment of precancerous lesions. Therefore, the aim of this survey was to determine the utility of these QIs within colposcopy services across Europe, and the feasibility of collecting information on these QIs.

2 | MATERIAL AND METHODS

From November 2022 to March 2023, we conducted an electronic survey among members of the EFC Quality and Standards Group,

representing general colposcopy practices across Europe. Each member was asked to randomly select 50 women newly referred for colposcopy due to an abnormal cervical screening test taken between January 1, 2020 and December 31, 2021. Members were asked *not* to select patients who had colposcopy performed due to symptoms of vulvar disease, or patients with a previous hysterectomy. Members were asked to select women with low- as well as high-grade cytology, and women with and without treatment. The survey was provided in English only, and survey data were collected and managed using REDCap (Research Electronic Data Capture), a secure web-based software platform designed for constructing and managing research studies, hosted by Central Denmark Region, Denmark.^{10,11} A representative from each member country entered survey data directly onto the designed REDCap database.

2.1 | Development of QIs

In 2017, a set of six provisional QIs and their performance standards were agreed upon by the EFC and its member countries through a lengthy process described in detail elsewhere.¹²

To further refine the QIs, a questionnaire was circulated in 2021 by the EFC Quality and Standards Group to leading colposcopists representing all 38 EFC member countries. A total of 25 responses (66%) were received with most requesting changes to the previously agreed QIs. The largest request was from seven respondents, who recommended additional QIs on follow-up data and replacing margin status with high-risk human papillomavirus (hrHPV) testing as an option for follow-up. In response, the EFC Quality and Standards Group developed five “Core” QIs and a further 10 “Extended” QIs. The standard for achieving each QI was decided by consensus within the group. For the purpose of this survey, we decided to also include margin status. We moved two Extended QIs to a separate section of the survey, named “Structural” QIs, as they did not request patient data, but provided general knowledge on the extent of colposcopy training and access to multidisciplinary team meetings. The Structural QIs were only answered once for each member country. Also, for the purpose of this survey, all QIs were modified to questions and answered as “yes,” “no,” or “not relevant” if the respondent considered the QI of no relevance to the specific patient. The original wording of the QIs is presented in [Table S1](#). Hence, a total of 17 QIs were included in the survey; five Core, ten Extended, and two Structural.

2.2 | Statistical analyses

Results are presented descriptively using numbers and proportions to evaluate overall feasibility according to the EFC performance standards. No formal comparison was made. For the main analysis, we restricted to QIs with yes and no answers (i.e., “not relevant” excluded). This is reflected in a varying number of cases in each QI

([Tables 1](#) and [2](#)). In a secondary analysis, we report results by country and after including “not relevant” answers.

3 | RESULTS

The survey was sent to all 14 members of the EFC Quality and Standards Group, 12 (86%) of whom contributed with data (i.e., Denmark, Estonia, Finland, Germany, Hungary, Italy, Latvia, Lithuania, the Netherlands, Romania, Serbia, and UK). This resulted in the collection of data on 609 women; each country providing data on 50 cases with the exception of Latvia, the Netherlands, Serbia, and Italy (52 cases each) and Lithuania (51 cases). Of note, Estonia, the Netherlands, and the UK did not enter patient data for Extended QIs 9 and 10 regarding margin status. Five countries only included cases who had undergone excisional treatment for cervical precancerous lesions (data not shown).

Overall, the agreed EFC standards were almost achieved for Core QI 2 (i.e., performing colposcopy before treatment), and Core QI 4 on excisional treatment with histologically confirmed CIN2+. A slightly lower performance was observed in Core QIs 1 and 3 (i.e., documenting the type of transformation zone (TZ), and taking diagnostic biopsies in women with TZ1 or TZ2) (90.8% vs. 100%, and 79.8% vs. $\geq 90\%$, respectively). In contrast, Core QI 5 (i.e., the proportion of women with a negative test-of-cure posttreatment) was well above the EFC standard of $\geq 70\%$ ([Table 1](#)). When exploring the distribution across countries, the majority of cases with an undocumented TZ type (i.e., Core QI 1) originated from the UK (34 of 56). With respect to the proportion of women with TZ1 or TZ2 who had a diagnostic biopsy (i.e., Core QI 3), the EFC standard of $\geq 90\%$ was met by eight of the 12 contributing countries. In the remaining four countries, the proportion of cases who had a diagnostic biopsy was about 45%, ranging from 40% in Hungary to 48% in Serbia, resulting in an overall lower performance of Core QI 3 ([Table S2](#)).

For the Extended QIs, the EFC standards were nearly met for QIs 2 and 5, suggesting similar practice for documenting treatment type and histological diagnosis in patient records across countries. Five Extended QIs (colposcopic opinion recorded [QI 1], excision length recorded [QI 3], colposcopy delay due to pregnancy [QI 6], record of treatment failure [QI 8], and proportion with positive resection margins [QI 9]) were considered close or within reach of the EFC standards. This slightly lower performance was mainly because of very low performance or outlying data in a few countries. For example, in Extended QI 1, Denmark reported that 88% of cases did not have the colposcopic opinion recorded in the patient file ([Table S3](#)). For Extended QI 9 on the proportion of cases with positive resection margins, the performance was within reach of the EFC standard despite missing data from three countries. However, the majority of patients with positive margins had histological evidence of CIN2+ in the margins (Extended QI 10). With respect to Extended QIs 4 (i.e., evidence of the SCJ in the cone specimen) and 7 (i.e. repeated treatment in patients with

CORE QIs		Cases	Yes	No	EFC standard (%)
		n ^a	n (%) ^b	n (%) ^b	
1	Has the cervical TZ type (1, 2, 3) been documented?	609	553 (90.8)	56 (9.2)	100
2	Has colposcopy been performed before treatment due to an abnormal screening test?	492	488 (99.2)	4 (0.8)	100
3	Was a diagnostic biopsy taken at colposcopy in patients with TZ type 1 or 2 and minor or major changes?	570	455 (79.8)	115 (20.2)	≥90
4	Did histology from excisional treatment/conization show definitive CIN2+?	452	380 (84.1)	72 (15.9)	≥85
5	Did the patient have a negative test-of-cure within 9 months after treatment?	373	300 (80.4)	73 (19.6)	≥70

Abbreviations: CIN2+, cervical intraepithelial neoplasia grade 2 or worse; TZ, transformation zone.

^aIncludes yes/no answers. Numbers differ because "not relevant" cases were excluded.

^bRow percentage.

glandular disease), the performance was considerably below the EFC standards (73.1% and 22.4% vs 100%) (Table 2). The lower performance of Extended QI 4 was mainly due to two countries, where no cases had the SCJ recorded. In addition, the suboptimal performance of Extended QI 7 was mainly driven by two countries that contributed to the majority of cases with residual glandular disease (31 of 58), and also reported that none of these cases had repeat excisional treatment (Table S3).

When including all options (yes, no, not relevant) for analysis, we found significant differences between countries when classifying a QI as "not relevant" for the case in question, suggesting differences in the interpretation of QIs across countries. However, the number of "not relevant" cases also varied within a country. For example, based on data from Hungary, we found inconsistencies with regards to the number of women undergoing excisional treatment. Based on data for Extended QI 3 on the length of excision, it appeared that 39 had undergone excisional treatment, while 46 cases had evidence of the SCJ in their cone specimen (Extended QI 4). Similar inconsistencies were observed in data from Denmark. According to Extended QI 2 (i.e., was type of treatment recorded), 25 cases had treatment, whereas 48 had excisional treatment according to Extended QI 3 (i.e., length of excision) (Table S3). These discrepancies occur throughout Core and Extended QIs and across all countries.

For the two structural QIs, 10 respondents (83.3%) reported that all colposcopists within their local colposcopy service had either initial training or training updates. Hence, only two countries did not meet this EFC recommendation. Eight countries reported having access to a specialist colposcopy multidisciplinary team meeting, while

four (33%) countries reported not having implemented this EFC recommendation (Table 3).

4 | DISCUSSION

To our knowledge, this is the first survey aiming to assess the utility and feasibility of collecting QIs for colposcopy across European colposcopy services. We found that many of the QIs were achievable across the participating countries, and the QIs that were not met were mainly due to outlying data from a few respondents or differing clinical practices. Nevertheless, stratifying each QI by country and including "not-relevant" responses showed inconsistencies, indicating differences in case selection and possibly a misunderstanding of the QIs.

Core QIs 1 and 3 and Extended QIs 1, 5, and 6 focus on the diagnostic work-up after a patient has been referred due to an abnormal screening test (i.e., documenting the TZ type and the colposcopic opinion, taking diagnostic biopsies when relevant, documenting the histological result, and avoid delay of colposcopy in pregnancy). These components provide the clinician with important information when planning the subsequent clinical management of the woman. Therefore, these QIs are considered most relevant, and although their performance was not the aim of the survey, results indicate good practice for diagnostic work-up across a selected group of colposcopy services in Europe. Core QI 1 and Extended QI 1 on documentation of the TZ type and the colposcopic opinion nearly met the standard. Thus, with minor improvements in documentation practices in countries like Denmark, Finland, and Estonia, these

TABLE 1 Performance of the five Core quality indicators (QIs) across 12 members of the Quality and Standards Group in the European Federation of Colposcopy (EFC).

TABLE 2 Performance of the 10 Extended quality indicators (QIs) across 12 members of the Quality and Standards Group in the European Federation of Colposcopy (EFC).

Extended QIs		Cases	Yes	No ^b	EFC standard (%)
		n ^a	n (%) ^b	n (%) ^b	
1	Was the colposcopic opinion recorded in the patient file?	609	542 (89.0)	67 (11.0)	100
2	Was the type of treatment (if performed) recorded in the patient file?	438	435 (99.3)	3 (0.7)	100
3	Has the excision length ^f (mm) been recorded in the patient file in patients undergoing excisional treatment?	426	373 (87.6)	53 (12.4)	100
4	Was there histological evidence of SCJ ^g in the cone specimen in patients undergoing excisional treatment?	432	316 (73.1)	116 (26.9)	100
5	In patients who had a biopsy, has the histological diagnosis been recorded in the patient file?	481	477 (99.2)	4 (0.8)	100
6	Was colposcopy delayed/postponed due to pregnancy?	86	4 (4.7)	82 (95.3)	0
7	Was repeat excision performed in patients with residual glandular disease ^h after treatment?	58 ^c	13 (22.4)	44 (75.9)	100
8	Is there a record of histological treatment failure at 12 months (i.e., CIN2+)?	319	25 (7.8)	294 (92.2)	≤5
9	Does the patient have positive resection margins?	274 ^d	55 (19.2)	219 (76.6)	≥85
		Cases	≤CIN1	CIN2+	
		n	n (%)	n (%)	EFC standard
10	What is the severity in the positive resection margins?	55 ^e	10 (18.2)	42 (76.4)	None

Abbreviation: CIN2+, cervical intraepithelial neoplasia grade 2 or worse.

^aIncludes yes/no answers. Numbers differ because “not relevant” cases were excluded.

^bRow percentage.

^cRepeat excision was declined by 1 patient (1.7%).

^dResection margin status was not registered in 12 cases (4.2%), and three countries did not enter data.

^eSeverity was not registered for three patients (5.4%).

^fExcision length is the measurement from apex to the base of the loop.

^gSquamocolumnar junction.

^hAdenocarcinoma in situ (AIS) or cervical glandular intraepithelial neoplasia (CGIN).

TABLE 3 Performance of the two Structural quality indicators (QIs) across 12 members of the Quality and Standards Group in the European Federation of Colposcopy (EFC).

Structural QIs		Countries	Yes	No	EFC standard (%)
		n ^a	n (%) ^b	n (%) ^b	
1	Do all colposcopists within the local colposcopy service have demonstrable evidence of initial training or training updates?	12	10 (83.3)	2 (16.7)	100
2	Does your local colposcopy service have access to a specialist colposcopy multidisciplinary team meeting?	12	8 (66.7)	4 (33.3)	100

^aIncludes yes/no answers.

^bRow percentage.

QIs would be considered reproducible and data collection feasible, although it might be worth considering lowering the standard to >95% instead of 100%. Regarding the UK, which had the majority of cases with undocumented TZ types, the visibility of the SCJ was reported instead of TZ type, as this was standard practice at the time of inclusion. A change in practice in alignment with the EFC

recommendations would further underline the reproducibility and feasibility of Core QI 1. Likewise, Denmark contributed to the majority of cases with an undocumented colposcopic opinion, as clinicians did not report this at the time of inclusion.

For Core QI 3, results showed a relatively high number of cases where diagnostic biopsies were not taken when the clinician had

observed minor or major cervical changes. Likewise, a similar number of cases in Extended QI 5 had no documentation of histological results from biopsies in the patient record. It is unclear, whether these results were due to differences in clinical practice across colposcopy services (eg see and treat), or if no biopsies were taken because no abnormalities were detected. Further details on country-specific practices are therefore required to ensure relevance and reproducibility of QIs on diagnostic biopsies.

Core QIs 2 and 4, and Extended QIs 2-4, 9, and 10 focus on treatment aspects (i.e., performing colposcopy before treatment, documenting the type of treatment, and measurements of the cone specimen, the prevalence of the SCJ and CIN2+ in the cone specimen, and resection margin status). Systematic monitoring of these QIs provides clinicians and researchers the opportunity to observe trends in clinical management, such as changes in the proportion of CIN2+ in cone specimens or in the proportion of negative resection margins. This information is relevant for local colposcopy services, as well as for national or international quality assessment in order to continuously evaluate treatment effectiveness and to reduce the risk of overtreatment.

The survey results showed that four of the QIs on clinical management were very close to achieving their standard, whereas two were much below. Overall, documentation practices are well established across Europe, and with additional focus on documenting excision length in, for example, Finland, Romania, and Hungary, data on the Extended QIs 2 (i.e., type of treatment recorded) and 3 (i.e., length of excision) could be reproducible and comparable across countries. Although achieving its standard, Core QI 2 regarding colposcopy before treatment may have been subject to misunderstanding, as discrepancies between stratified results indicate that at least three countries have provided answers on colposcopy in relation to referral and not treatment. Similarly, case numbers in Core QI 4 regarding CIN2+ in the cone specimen, differ for at least four countries from results in Extended QI 2, which provides the number of treated patients for each country. Hence, it is unclear whether countries have provided answers on the prevalence of CIN2+ in the current conization, previous conization, or the diagnostic biopsies.

Extended QI 4 regarding histological evidence of the SCJ in the cone specimen was far from achieving its standard, however, Latvia and Italy included only treated patients, and both countries reported none to have evidence of SCJ in the cone specimen, suggesting sub-optimal documentation practices or different treatment methods, for example, laser ablation or cryo therapy. Thus, by removing data from Latvia and Italy from the analysis, the Extended QI 4 reached 96%, a significant improvement close to the standard.

For Extended QIs 9 and 10 on resection margins and severity of disease in the margins, survey results showed an optimistic tendency toward high numbers of negative resection margins across Europe, and although numbers varied due to missing data from three countries, the reproducibility of Extended QIs 9 and 10 could be high, as both QIs seemed less subjected to misunderstanding. These QIs are of high relevance as negative resection margins substantially reduce the risk of recurrent disease and the long-term risk of cervical

cancer.^{13,14} Hence, thorough monitoring and evaluation of these QIs could provide an excellent indication of treatment effectiveness on a local, national, and international level.

The Core QI 5 and Extended QIs 7 and 8 focus on the quality of follow-up after treatment, specifically HPV testing after 9 months (test-of-cure [TOC]), histology results of biopsies after 12 months, and repeated treatment for patients with residual glandular disease. Evaluation of these QIs is highly relevant, as it provides information on both treatment effectiveness as well as the effectiveness of the follow-up program. In specific, the Core QI 5 regarding test-of-cure after 9 months and Extended QI 8 on repeated treatment of patients with glandular disease, have dual purposes, as their performance relates to treatment effectiveness, while the number of included cases provides information on patient compliance to follow-up after treatment, that is, the effectiveness of follow-up. Thus, it is important to consider that a woman is not at risk of having residual disease if no biopsy is collected. Compared to results on the Extended QI 2 (i.e., type of treatment recorded), which provides the total number of treated cases, results on Core QI 5 indicate that about 85% of treated patients were compliant with follow-up and had a record of HPV testing (TOC) within 9 months after treatment. Even though TOC has a higher sensitivity to predicting recurrent disease compared to margin status, the relatively low compliance among treated patients estimated in this survey might suggest that TOC and margin status should be considered together, particularly because a recent study showed that a positive margin status in HPV-positive women is associated with a higher risk of recurrence compared to HPV-positive women with negative margins.¹⁴ Moreover, margin status is readily available with the histologic results while TOC relies on the patient, their compliance to follow-up, and the availability of free-of-charge TOC. Of note, the compliance rate estimated in this survey may be underreported as some patients may not have had TOC performed yet, or they have had TOC performed elsewhere causing the respondent to have a missing record of follow-up.

Finally, the Extended QI 7 regarding repeat excision of patients with residual glandular disease had the lowest performance of all QIs and was considerably far from reaching its standard. Patients with glandular disease (AIS/CGIN) in the cone specimen and positive resection margins must always be offered repeat excisional treatment due to a higher risk of residual disease and cancer.¹⁵⁻¹⁷ The majority of cases with residual glandular disease came from Hungary and Germany, but when comparing the results from the Extended QI 2, this equals about 50% of the treated patients from these countries being diagnosed with glandular disease. This prevalence differs greatly from the other countries and could therefore indicate that patients had been placed in “no” instead of “not relevant,” thus skewing the results. When removing Hungary and Germany from the analysis, the Extended QI 7 reached 48%, a performance still far from the standard, and with only one patient declining treatment no obvious cause for the low performance was observed.

Regarding the two structural QIs on training and education of colposcopists and the access to MDT meetings, two and four countries did not fulfill these, respectively. The underlying reasons for

these findings remain unclear but may be due to a lack of knowledge regarding the importance of training and MDT meetings for high-quality patient care.

In addition to assessing the relevance and reproducibility of the QIs, the survey also aimed to assess the feasibility of the data collection method and its utility for quality assessment. Overall, the survey distribution and monitoring the data collection by using REDCap® was effective and easily conducted. However, requesting individual clinicians to enter data may have introduced barriers to the feasibility of the survey, as all data were extracted from patient records; a time-consuming effort subjected to entry errors, possibly limited access to patient records from other clinicians, and highly dependent on the clinicians' expertise. Hence, continuous quality assessment on a larger scale would not be feasible with this type of data and data collection, as it would require either standardized patient records and/or database registration.

In addition to the efforts of data entry, language, and misunderstanding were the main barriers to the feasibility of the survey. From the interpretation difficulties, it was evident that the survey and the wording of the QIs should have been further validated, preferably by clinicians outside of the EFC, to ensure a broader understanding of the terminology and the request of each QI. Although efforts were made by participating countries to clarify discrepancies, inaccuracies remained evident. An option for minimizing this could be to simplify the survey and the QIs, for example, by introducing the QIs chronologically (i.e., diagnostic work-up, treatment, and follow-up), and possibly by using a more topic-based phrasing of the QIs in contrast to patient-based. Finally, although barriers made it difficult to achieve the EFC standards of 100% or 0% set for the majority of the QIs, errors and missing data would most likely occur in any data collection method, and an adaption of the QI standards to $\geq 95\%$ and $\leq 5\%$, respectively, could be recommended.

The survey was conducted among a limited number of European countries and without complete participation, therefore, the results may not be representative of colposcopy practices, treatment effectiveness, and follow-up throughout Europe. In addition, patients from each participating country may not be representative of the quality of clinical practice within a country.

5 | CONCLUSION

QIs must be understandable to those collecting data, highlighting the importance of validating QI's before data collection. Moreover, to ensure continuous evaluation of the quality of colposcopy and treatment of precancerous lesions it is important that data retrieval occurs systematically, without the need of manual collection of data from patient records.

AUTHOR CONTRIBUTIONS

All authors contributed to designing the quality indicators. Tina Hovgaard Randrup, Simon Leeson, and Anne Hammer designed the survey. All authors except Tina Hovgaard Randrup and Ahmed Eldib contributed with data entry. Tina Hovgaard Randrup conducted the

analyses with inputs from Simon Leeson and Anne Hammer, and the results were discussed with all authors. Tina Hovgaard Randrup and Anne Hammer drafted the manuscript. All authors reviewed and approved the final manuscript.

CONFLICT OF INTEREST STATEMENT

Anne Hammer has received reagents for free from Roche Diagnostics, Denmark for another study and reports receiving a consulting fee from Exeltis. All other authors have no conflict of interest.

ETHICS STATEMENT

As data were collected retrospectively, anonymized, and for quality-assurance purposes, General Data Protection Regulation (GDPR) restrictions were not relevant, and formal ethical approval for the survey was not required in all countries, except Lithuania (permission obtained on September 11, 2022, reference: BEC-MF-35).¹⁸ Approval was obtained from the hospital administration in Denmark (June 3, 2022, no reference number available) as required. Ethical approval was not needed.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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