

Quality indicators for sentinel lymph node biopsy: Is there room for improvement?

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Background: Eleven quality indicators (QIs) for sentinel lymph node biopsy (SLNB) were previously developed through a consensus-based approach, yet still need to be incorporated into clinical practice. We sought to evaluate the applicability and clinical relevance for surgeons.

Methods: Breast cancer patients undergoing SLNB between 2004 and 2008 at Mount Sinai Hospital, Toronto, were evaluated. Clinical and pathological data were obtained from an institutional database. Information on axillary recurrences was obtained through a retrospective chart review. Adherence to standardized protocols was evaluated in each case.

Results: All 11 QIs were measurable in 300 patients. The identification rate was 100%. More than 1 SLN was identified in 78.6% of patients. The SLNB was performed simultaneously with primary surgery in 96.7% of patients; 61 SLNs harboured metastasis. Of these patients, 80.3% underwent completion lymphadenectomy. Cases complied with protocols for radiocolloid injection and pathologic SLN evaluation/reporting. No ineligible patients underwent SLNB. Of patients with a complete 5-year follow-up ($n = 42$), only 1 had axillary recurrence.

Conclusion: Applying QIs for SLNB was feasible, but modifications were necessary to develop a more practical approach to quality assessment. Of the 11 suggested QIs, those that encompass protocols (nuclear medicine and pathology) should be reclassified as prerequisites, as they are independent of the technical aspect of SLNB performance. The remaining 8 QIs encompass surgery per se and should be measured routinely by surgeons. Furthermore, concise and clinically relevant target rates are necessary for these QIs to be established as widely recognized control standards.

Contexte : Onze indicateurs de qualité (IQ) pour la biopsie des ganglions lymphatiques sentinelles (BGLS) ont déjà été établis par le biais d'une approche consensuelle et pourtant, ils ne sont pas encore été intégrés à la pratique clinique. Nous avons voulu en évaluer la faisabilité et la pertinence clinique pour les chirurgiens.

Méthodes : Nous avons évalué des patientes atteintes d'un cancer du sein ayant subi une BGLS entre 2004 et 2008 à l'Hôpital Mount Sinai à Toronto. Nous avons tirés les données cliniques et anatomopathologiques de la base de données de l'établissement. Les renseignements sur les récurrences ganglionnaires axillaires ont été tirés d'un examen rétrospectif des dossiers. Dans chaque cas, nous avons évalué la fidélité aux protocoles standardisés.

Résultats : Les 11 IQ ont tous été mesurables chez 300 patientes. Le taux d'identification a atteint 100 %. On a reconnu plus d'un GLS chez 78,6 % des patientes. On a procédé à la BGLS au moment de la chirurgie primaire chez 96,7 % des patientes; 61 des GLS hébergeaient des métastases. Parmi ces patientes, 80,3 % ont subi une lymphadénectomie complète. Les cas étaient conformes aux protocoles d'injection de radiocolloïde et d'évaluation et rapport d'anatomopathologie concernant le GLS. Aucune patiente non candidate n'a subi la BGLS. Parmi les patientes pour lesquelles on disposait d'un suivi complet de 5 ans ($n = 42$), une seule a présenté une récurrence ganglionnaire axillaire.

Conclusion : L'application des IQ pour les BGLS s'est révélée faisable, mais il a fallu apporter des modifications pour mettre au point une approche plus pratique d'évaluation de la qualité. Parmi les 11 IQ suggérés, ceux qui concernent les protocoles (médecine nucléaire et anatomopathologie) méritent d'être reclassés parmi les préalables, puisqu'ils sont indépendants de l'aspect technique de la BGLS. Les 8 autres IQ concernent la chirurgie en tant que telle et devraient être mesurés d'emblée par les chirurgiens. En outre, pour que ces IQ en arrivent à être largement reconnus comme normes de contrôle, il faudra établir des taux cibles précis et cliniquement pertinents.

Mammograms are used to diagnose smaller tumours and consequently increase the likelihood of metastasis-free axillary lymph nodes.¹ Therefore, in light of recent trends in which early breast cancer constitutes about 60% of all cases,² axillary lymph node dissection (ALND) is too drastic for node-negative patients. Owing to its lower morbidity and substantial accuracy in predicting the status of other axillary nodes,³ sentinel lymph node biopsy (SLNB) rapidly replaced ALND as a suitable staging technique in properly selected patients.⁴ Because a patient's prognosis is mainly based on optimally staging the axillary lymph nodes,⁵ each patient undergoing SLNB must benefit from the highest standards of care.

Health care authorities and physicians have a substantial interest in monitoring the performance of and establishing a continuous improvement in breast cancer treatment. An example of a tool that allows for high quality care is breast cancer practice guidelines, but in practice these recommendations are not universally implemented and variation among practitioners exists.⁴ More importantly, established breast cancer quality indicators (QIs) focus only on evaluating adherence to recommended care rather than on determining the quality of care being delivered.⁶

Quality assessment of low-risk surgical procedures, such as SLNB, is complex because outcome measures other than morbidity and mortality are necessary.⁷ A reliable QI must have 2 key properties: a quantifiable measure and clinical relevance. A common practice has been for the false-negative rate and the identification rate to act as standard measures of quality.⁸ Nonetheless, after the validation period, ALND is avoided, and it is virtually impossible for surgeons to continuously quantify the false-negative rate. In addition, as newer generations of surgeons learn SLNB while training in centres with an established SLNB practice, they cannot validate their personal technique owing to a lack of ALND. Using just the identification rate as a quality metric deprives a surgeon of additional information that can allow him or her to assure the technique and clinical judgement are competent.

Based on the absence of QIs for SLNB, in 2010 Quan and colleagues⁹ developed a series of quality measures along with proposed potential targets. A multidisciplinary panel of Canadian breast cancer experts convened to develop these indicators using a modified Delphi process. The panel reviewed potential indicators extracted from the literature. A list of 22 candidate QIs were evaluated in 2 rounds of surveys. Through anonymous voting, 11 QIs were ultimately selected and subsequently ranked in terms of importance to measure on a population level. Given that these quality metrics were recently developed, it is pertinent to evaluate how useful they actually are for a surgeon. Therefore, the aim of this study is to evaluate the applicability and clinical relevance of novel QIs for SLNB for surgeons.

METHODS

Study design

After obtaining approval from the ethics committee at University Health Network (UHN) and Mount Sinai Hospital (MSH), Toronto, Ont., we studied a consecutive series of breast cancer patients who underwent SLNB between January 2004 and December 2008 at the Marvelle Koffler Breast Centre at MSH. Patients included in this study were those who had undergone SLNB and had a diagnosis of invasive breast cancer or ductal carcinoma in situ.

Sentinel lymph node biopsy technique

Surgical procedures were performed by an experienced breast surgeon (J.E.) who had previously validated SLNB according to standard recommendations at the time.¹⁰ Radioactive, unfiltered technetium⁹⁹ colloid was injected intradermally and periareolar (dose 1.0 mCi) by a nuclear medicine technician; all patients underwent lymphoscintigraphy. In surgery, 2.0 mL isosulfan blue (1.0%) was injected and followed by a 5-minute whole breast massage. Initially, the injection was peritumoral, but in 2007 the procedure was modified to periareolar subcutaneous injection. A γ probe localized the axillary area with the highest count. A γ count was done for every SLN identified; the background count was accepted to be less than 10% of the highest count. Hot, blue and/or palpable node(s) were excised. Nodes were sent off for frozen section analysis by a breast pathologist who evaluated them according to the College of American Pathologists protocol.¹¹⁻¹³

Data extraction

Using the Princess Margaret Hospital/MSH eClinical Breast Registry, an institutional electronic population database, 2 independent reviewers (S.A.A. and F.A.A.) collected the following data for each patient: date and type of surgery, laterality, histologic subtype, distribution of invasive carcinoma, total number of SLNs, number of positive SLNs, size of largest SLN metastasis, date of ALND, total number of axillary nodes in ALND, number of positive axillary nodes in ALND and the size of the largest axillary node metastasis in ALND. We used the entries collected to calculate the fraction and percentage for each of the 11 QIs, as defined by Quan and colleagues⁹ (Box 1). In the case of the QI for axillary recurrences, we performed a subgroup analysis on a retrospective chart review for those patients who completed 5 years of follow-up post-SLNB. For the QIs that required evaluating, the existence of a protocol at the institution (pathologic evaluation of SLNB processing and reporting as well as radiocolloid injection technique), the Departments of Pathology and Nuclear Medicine provided the necessary documents. For each patient, we reviewed the

synoptic pathologic report to determine the presence of the American Joint Committee on Cancer (AJCC) reporting criteria, specifically the category of histologic lymphatic metastases and the tumour pattern.

RESULTS

In this 4-year study period, 300 patients met our inclusion criteria. The mean patient age was 60 (range 30–92) years. Mean invasive tumour size was 1.8 (range 0.1–5.5) cm; tumours were invasive in 89% of cases. Other major characteristics of the study population are summarized in Table 1.

An average of 60 (range 42–75) SLNBs was performed annually. In all 300 procedures, the identification rate (proportion of patients in whom a SLN was detected and excised) was 100% (Table 2). The false-negative rate (proportion of patients with axillary nodal metastases who had negative SLNs) was not calculated, as the technique had already been validated. On average, 2.7 (standard deviation [SD] 1.6) SLNs were harvested per patient: 61 (20.3%) of the SLNs identified harboured metastatic disease (N1mi, N1 or greater), and 6 only had isolated tumour cells. From the former group, 49 patients underwent ALND, and a

mean of 13.8 (range 3–42) axillary nodes were removed in this group. In this same group, 32 (65.3%) patients had no additional positive axillary nodes. All 12 patients with positive SLNBs who did not undergo ALND had micrometastasis (N1mic). After discussing these cases in a multidisciplinary panel of breast cancer specialists and taking into account the Memorial Sloan-Kettering Cancer Center

Table 1. Clinical and pathological characteristics of the study population

Characteristic	No. (%) of patients
Primary tumour stage	
Tis	28 (9.3)
T1mic	2 (0.7)
T1a	19 (6.3)
T1b	31 (10.3)
T1c	139 (46.3)
T2	78 (26.0)
T3	2 (0.7)
Not documented	1 (0.3)*
Case laterality	
Unilateral	279 (93.0)
Bilateral	21 (7.0)
Histologic subtype	
DCIS	28 (9.3)
DCIS + microinvasive	2 (0.7)
Invasive ductal carcinoma	247 (82.3)
Invasive lobular carcinoma	2 (0.7)
Invasive ductal carcinoma with lobular features	20 (6.7)
Not documented	1 (0.3)
Distribution of the invasive carcinoma	
Unifocal	219 (73.0)
Multifocal	51 (17.0)
Not documented	2 (0.7)
Type of surgery	
Lumpectomy	230 (76.7)
Mastectomy	70 (23.3)

DCIS = ductal carcinoma in situ.
*Patient with a core biopsy with invasive ductal carcinoma; final pathology did not report additional invasive tumour.

Box 1. Sentinel lymph node biopsy quality indicator definitions³

- 1. Pathologic evaluation protocol**
Proportion of patients in whom the SLNs were examined using a recognized serial sectioning protocol.
- 2. Pathologic reporting by AJCC guidelines**
Proportion of SLNB final pathology reports that report the category of metastases identified and the patterns of tumour present according to AJCC criteria.
- 3. Protocol for injection of radiocolloid**
Proportion of patients having radiocolloid injected at an institution that has defined nuclear medicine protocol for SLNB for breast cancer.
- 4. Proper identification of SLN**
Proportion of patients in whom SLNs were identified as “hot” and/or “blue” and/or “clinically suspicious” in the chart or operative note.
- 5. SLNB performance in eligible patients**
Proportion of patients undergoing SLNB in the setting of breast conserving surgery for T1 tumours.
- 6. SLNB concurrent with lumpectomy/mastectomy**
Proportion of patients who underwent SLNB and lumpectomy or mastectomy concurrently.
- 7. Completion ALND for positive SLNB**
Proportion of patients with a positive SLNB (as defined by micrometastasis > 0.2 mm) who received a completion ALND.
- 8. SLNB performance in ineligible patients**
Proportion of patients who undergo SLNB as a stand-alone axillary procedure who are “ineligible” based on preoperative disease characteristics (i.e., inflammatory breast cancer, etc.).
- 9. Axillary node positivity rate**
Proportion of patients undergoing SLNB in whom SLNB was identified and found to be positive.
- 10. Number of nodes removed**
Proportion of patients who underwent SLNB in whom the number of nodes removed is greater than 1.
- 11. Axillary recurrence rate**
Proportion of patients with a negative SLNB who develop an axillary recurrence.

AJCC = American Joint Committee on Cancer; ALND = axillary lymph node dissection; SLN = sentinel lymph node; SLNB = sentinel lymph node biopsy.

Table 2. Sentinel lymph node biopsy quality indicator results

Quality indicator	Proposed target rates ²¹	No. (%) of patients
Pathologic evaluation protocol	> 90%	300 (100)
Pathologic reporting by AJCC guidelines	> 90%	300 (100)
Protocol for injection of radiocolloid	> 90%	300 (100)
Proper identification of SLN	> 90%	300 (100)
SLNB performance in eligible patients	> 80%	189/242 (78.1)
SLNB concurrent with lumpectomy/mastectomy	> 80%	290/300 (96.7)
Completion ALND for positive SLNB	> 75%	49/61 (80.3)
SLNB performance in ineligible patients	< 5%	0 (0)
Axillary node positivity rate	25%–34%	61/300 (20.3)
Number of nodes removed	60%–70%	236/300 (78.6)
Axillary recurrence rate at 5 years	< 3%	1/42 (2.4)

AJCC = American Joint Committee on Cancer; ALND = axillary lymph node dissection; SLN = sentinel lymph node; SLNB = sentinel lymph node dissection.

(MSKCC) nomogram,¹⁴ further treatment was either not recommended or was declined by the patient. In all 300 patients, radiocolloid injection and pathologic evaluation of the SLNB were performed in accordance with departmental protocols. Pathologic reporting of metastases and tumour pattern followed AJCC guidelines.

The medium overall duration of follow-up was 51.2 weeks. Out of the 52 patients who completed 5 years of follow-up, 42 (80%) had available follow-up data. Axillary recurrence was documented in 1 (2.4%) patient, who underwent bilateral SLNB. She presented 1 year later with right-sided axillary recurrence and was treated with completion ALND.

DISCUSSION

Sentinel lymph node biopsy is currently the preferred method of axillary staging for early breast cancer. Delivering high-quality care is a priority for stakeholders in breast cancer management; therefore, having a set of suitable QIs for SLNB is important to guarantee optimal survival rates. Assuring optimal axillary staging can be achieved by practising evidence-based medicine, adhering to protocols, applying QIs and undergoing accreditation with periodical reassessment of the results.

The aim of this study was to evaluate the applicability of a set of novel QIs for SLNB by using our breast cancer centre's data as a means of exercise. By not limiting our data collection to cross-sectional chart review, but also including a longitudinal review of patients who completed 5 years of post-SLNB follow-up, we were able to measure all 11 criteria. Overall, our SLNB performance complied with almost all the indicators, similar to the first study that reported using these QIs.¹⁵ The study by Wells and colleagues¹⁵ was also carried out in Toronto, yet neither cohort used the same patient population. However, the content in that research group's registry limited their study. Both that study and ours described optimal patient selection, proper technique results and adequate compliance with protocols.

During the course of our study, we found that some of the QIs required modifications to make their applicability more relevant. For example, correct pathological interpretation of the SLN is important for correct staging, yet it does not depend on the surgical technique per se. Before offering SLNB, cancer centres must secure a trained pathology staff with a pathological evaluation/reporting protocol in accordance with AJCC guidelines. Therefore, having a pathological evaluation protocol and pathological reporting by AJCC guidelines should be reclassified as structural components of the hospital. This is also suggested for the QI regarding protocol for injection of radiocolloid. The remaining QIs allow surgeons to track individual performance, but we also suggest that some of these QIs need more precise definitions and more inclusive target rates because they fall short of what has been published in the literature (Table 3). For example, the QI regarding the number of nodes removed should set an upper limit to the number of nodes excised, as studies show no benefit when more than 4 SLNBs are excised. Also, the QI of SLNB performance in ineligible patients requires a clearer definition. There are specific situations in which SLNB is indicated (e.g., mastectomies for high-risk ductal carcinoma in situ [DCIS], prophylactic mastectomies in very high-risk patients, and prior axillary procedures). Given the complex method in which this group of QIs was developed, we suggest the modifications and outline of the personal SLNB registry be done in the same fashion.

The only indicator that had results below the suggested target was the percentage of SLNB performance in eligible patients (78.1% v. $\geq 80\%$). To calculate the percentage, Quan and colleagues⁹ proposed that only T1 tumours be used, excluding other eligible cases (e.g., T2N0, TisN0). Although SLNB is indicated for most T1 tumours, only 60% of them undergo this type of axillary staging.¹⁶ Sentinel lymph node biopsy is feasible and accurate in T1–T3 tumours, and this QI appears to be irrelevant. Higher percentages of T2 or T3 tumours in a surgeon's series may

Table 3. Suggested issues for improvement in sentinel lymph node biopsy quality indicators

Quality indicator	Comments/suggestions
Pathologic evaluation protocol	Prerequisite, but does not speak of the surgeon's skill.
Pathologic reporting by AJCC guidelines	Prerequisite, but does not speak of the surgeon's skill.
Protocol for injection of radiocolloid	Prerequisite, but does not speak of the surgeon's skill.
Proper identification of SLN	No changes necessary.
SLNB performance in eligible patients	Target rates should be redefined. Preoperative assessment of axilla by MRI and ultrasound can decrease the number of eligible patients. Patients other than those with T1 tumours should be included (e.g., T2, T3).
SLNB concurrent with lumpectomy/mastectomy	Lack of strong evidence against nonconcurrent breast primary surgery and axillary staging procedure.
Completion ALND for positive SLNB	Requires redefinition given the fact there is evidence that ALND can be avoided patients with micrometastasis and isolated tumour cells.
SLNB performance in ineligible patients	Better definition of ineligible patients is necessary.
Axillary node positivity rate	No changes necessary.
Number of nodes removed	Requires an upper limit to the target rate.
Axillary recurrence rate at 5 years	No changes necessary.

AJCC = American Joint Committee on Cancer; ALND = axillary lymph node dissection; MRI = magnetic resonance imaging; SLN = sentinel lymph node; SLNB = sentinel lymph node biopsy.

reflect their case mix rather than a selection bias. In addition, the frequent use of preoperative magnetic resonance imaging (MRI), ultrasonography and fine needle aspiration identifies suspicious axillary nodes, reducing the number of patients eligible for the technique.

In our cohort, the axillary node positivity rate was 20.3% for patients with in situ carcinoma and invasive carcinoma. The expected percentage of positive SLNs in patients with invasive breast cancer ranges from 17% to 35%.^{17,18} Ideally, this QI should be strictly followed because it speaks of each surgeon's capacity to select patients appropriately. Higher positivity rates may imply bias in the selection of patients with more advanced disease (e.g., T3N0), and lower rates may be due to a greater proportion of high-risk DCIS or prophylactic mastectomy cases. Stratifying our cohort by tumour size exposed a predominant number of patients with tumours smaller than 2 cm (63.6%) and a substantial proportion of high-risk patients with DCIS (9.3%). Currently, patients undergo additional preoperative work-up (e.g., axillary ultrasound, fine needle aspiration of suspicious nodes, and/or preoperative MRI), which filters the patients with positive nodes before surgery and consequently reduces the probability of finding positive SLNs during surgery.

In terms of the number of nodes removed, our performance also met current standards. In all, 206 (68.7%) patients had 2–4 nodes removed. Studies suggest that the false-negative rate decreases when more than 1 SLN is harvested, yet removing more than 4 nodes provides no additional benefit.¹⁹ Therefore, we consider that this particular QI requires a more detailed definition, specifically in setting the upper limit of number of SLNs to remove.

Current evidence in the literature shows that selected cases of micrometastasis may have such a low probability of additional positive non-SLNs that ALND can be avoided without compromising overall survival in patients receiving adjuvant therapy.²⁰ A lower compliance rate in this parameter could be accepted if the MSKCC nomogram¹⁴ is applied, but we consider that this QI should also be redefined to take into account the current evidence regarding micrometastasis and isolated tumour cells.

On subgroup analysis of patients completing 5 years of follow-up ($n = 42$), only 1 (2.5%) had axillary recurrence. This analysis may overestimate the actual axillary recurrence rate (ARR). Our whole cohort's ARR could not be calculated because most surgeries were recently performed. The reported ARR in the literature is 0%–1.4%.^{21–23} A meta-analysis of 14 959 SLN-negative breast cancer patients followed for a median of 34 months reported an average ARR of 0.3%.²⁴ Lower ARR's have been associated with the following factors: performing SLNB in cancer centres, probably reflecting volume and expertise of the surgeons; using 99mTc-sulfur colloid; using a superficial injection technique; or evaluating the harvested sentinel nodes with hematoxylin/eosin and immunohistochemistry staining.²⁴ In practice, this

QI should fluctuate over time, eventually decreasing as more patients complete 5 years of follow-up. Ultimately, the ARR is a strong QI because it directly correlates with the false-negative rate and is the end product of proper patient selection, training and surgical technique.

In our series, patients in whom SLNB was not concurrently performed with primary surgery were those treated for DCIS but who were later found to harbour invasive disease. This QI was suggested without any significant published evidence; despite some authors suggesting that performing primary surgery before SLNB alters the pattern of lymphatic drainage and increases the false-negative rate, others have not shown this relationship to exist.²⁵

Though not included in the set of QIs, postoperative complication rates must be a part of quality assessment because the rationale to use SLNB over ALND is its major impact in reducing morbidity (e.g., surgical site infection, seroma formation, permanent lymphedema, nerve injury, arm weakness, restriction in shoulder mobility).²⁶ Most of these sequelae are difficult to treat satisfactorily, creating impaired function and emotional distress and increasing cost of treatment.²⁷ We propose that shoulder–arm symptoms (e.g., lymphedema, nerve injury, range of motion) be included as a QI. Other less dramatic arm-related symptoms (e.g., nerve damage, limited shoulder movement) should be incorporated because they speak of the surgeon's skill.

The purpose of using QIs is to improve performance. Bearing in mind that most institutions and individual reporting surgeons are above quality standards, there really is little room to improve. Consequently, this exercise should be carried out to monitor performance. Quality indicators are useful if they can be continuously and easily applied so that necessary measures can be taken promptly. Despite the fact that Wells and colleagues¹⁵ and our study show how feasible it is to extract data from an institutional database, we propose that every surgeon do this exercise individually. Cancer registries are usually an asset of large centres, but as SLNB becomes available in private practice settings, these QIs should be accompanied by a structured guide of how to create and maintain a simple, prospective personal SLNB registry.

The quality of SLNB must also be assured on every level of complexity of breast cancer management, including for surgeons with small caseloads. General surgeons practising in rural settings and small hospitals are less likely to perform SLNB.²⁸ In addition, rural regions have only recently validated and adapted SLNB into practice.²⁸ In this setting, these QIs for SLNB will certainly play an important role in improving performance, but achieving benchmarks will take time owing to the limited number of eligible cases. Therefore, it may be necessary for these QIs to be adapted for surgeons with small caseloads, so that the actual progress made is not underestimated. Setting targets well above reality allows for inappropriate, unintended decisions to occur in patient care.

Despite being a highly studied medical topic, breast cancer treatment needs further study to establish standard QIs. In the past, organizations developed quality programs that provided assessment of different aspects of breast care.^{8,29-32} Participating in these programs implies substantial use of resources and time.³² The generic QIs suggested by these groups reduced SLNB assessment to only measuring percentage of SLNB use in eligible patients, SLNB use in mastectomy for DCIS, and pathology frozen section SLN false-negative rates.³³ Other efforts, such as those of the Spanish Society of Senology and Breast Pathology have been more inclusive, focusing on 3 major areas: complexity of care and patient volumes, processes of care and academic activity.³²

CONCLUSION

After a careful retrospective study, novel QIs for SLNB were easily applied to a uniform cohort. Comparison of our results with the proposed QIs' target rates revealed optimal performance. However, in this process, we found that some aspects of this tool require modification to be more clinically relevant. These modifications will allow an easier and more realistic approach to quality assessment of SLNB. Because breast cancer patients are treated by multidisciplinary teams, each team requires specific QIs. Sentinel lymph node biopsy performance levels depend on the criteria and methods used by radiologists and the way sentinel nodes are processed and evaluated by pathologists. To control and optimize performance, each team should account for their own QIs because it is not feasible for one group to monitor the outcomes of other teams. Furthermore, concise, relevant definitions must be offered to busy surgeons wanting to participate in quality initiatives. Long-term outcomes are mandatory to validate and establish QIs for SLNB as widely recognized control standards.

Competing interests: None declared.

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