THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

# SUPPLEMENT TO CHAPTER 6: *QUALITY MANAGEMENT*

*LICπ Clinical Practice Parameters and Standards – Sleep Medicine 4th Edition, October 2016*

# Supplement to Chapter 6 - Quality Management

**Guide to Selecting and Preparing Sleep Studies for Internal and External Review**

***General comments***

This guide is to assist internal and external programs reviewing sleep study collection, scoring, and interpretation.

***Summary of Requirements***

The following table summarizes the percentage/ number of studies to be reviewed internally by the facility, and to be reviewed externally by another sleep lab. In the case of any contradiction, the requirements detailed in the Quality Management chapter of the IHF standards available on line has precedence.

*1)* Studies done in the IHF

| Standard | Review of: | Review by | internal /external | Number for review: |
|---|---|---|---|---|
| S6.3.9 | Study indications and overall conduct | not specified | not specified | at least 10 studies |
| S6.3.11 | All technologists scoring at the facility | board registered sleep technologist | internal | the greater of: 1% of total studies, or 10 studies |
| S6.3.11 | All technologists scoring at the facility | external program as per the standard | external | satisfactory participation in an external program as per the standard |
| S6.3.11 | All physicians reporting studies at the facility | sleep medicine physician | internal (not required if only 1 physician at the facility reports studies) | at least 5 diagnostic studies, AND at least 5 therapy or split night studies, AND at least 1 study reported by every physician reporting studies at the facility |
| S6.3.11 | All physicians reporting studies at the facility | sleep medicine physician | external | at least 10 studies |

2) Home Sleep Apnea Testing (if performed by the facility)

| Standard | Review of: | Review by | **internal /external** | Minimum # |
|---|---|---|---|---|
| S6.3.10 | Study indications and overall conduct | not specified | not specified | the greater of: 1% of total studies, or 10 studies |
| S6.3.11 | All technologists scoring at the facility | board registered sleep technologist | internal | the greater of: 1% of total studies, or 10 studies |
| S6.3.11 | All technologists scoring at the facility | external program as per the standard | external | satisfactory participation in an external program as per the standard |
| S6.3.11 | All physicians reporting studies at the facility | sleep medicine physician | internal (not required if only 1 interpreting physician at the facility) | at least 10 studies |
| S6.3.11 | All physicians reporting studies at the facility | sleep medicine physician | external | at least 10 studies |

***Covering the full range of studies and staff at the facility***

In addition to the current minimum requirements for the quality management program, facilities should systematically assess:

a) the work of *all technologists/ technicians collecting studies, and initiating/titrating therapies*.
b) the indications, conduct, scoring, and reporting of
    a. daytime testing , e.g. multiple sleep latency tests (MSLTs);
    b. extended montage studies, e.g. REM sleep behaviour (RBD) studies; seizure montages;
    c. special therapy studies, e.g. split diagnostic/ treatment studies; BiPAP titration; adaptive servo ventilation (ASV).

These areas will be assessed during an IHF assessment visit, and including them in routine quality management will enhance the work of the centre and facilitate meeting the standards.

***Study selection:***

a) Use a worksheet–log to determine what type of studies is needed, and inclusions/ exclusions. An example is appended (Worksheet – Log for Sleep Study Reviews)

b) Use a random number generator (e.g. https://www.random.org/) to generate a number between 1-200. Ensure that unusual charts or procedures not routinely performed be included in the QA to ensure those are not missed using the random number generator.

c) Count back that number of studies from the most recent study in the sleep lab log. Record the details in a study review log.

d) Create and record a unique code for each selected study. (e.g. IHF initials - review date - study type - sequential #)

e) Repeat to select all the studies needed.

A study that is selected to fulfil one standard can also be used to fulfil another. For example: A study selected to fulfil standard S6.3.9 might also be suitable to fulfil the internal technologist scoring review standard (S6.3.11) or to fulfil the external sleep medicine review standard (S6.3.11).

***File preparation***:

a) Record the relevant details in a secure log

b) Print the following from the chart:
   i) consult and most recent follow-up note
   ii) sleep study scored summary and graphics
   iii) sleep study interpretation report
   iv) if the study under review is a PAP titration, also print the score summary from any recent dx study

c) Write the unique code for the review on each page (see Study Selection (d) above)

d) Although all involved staff are bound by both PIPEDA (the federal Personal Information Protection and Electronic Documents Act) and PHIPA (the Ontario Personal Health Information Privacy Act), anonymization of patient data is suggested for all studies being reviewed, and is **required** for any data sent for external review.

   Using a permanent marker, obliterate all identifiers in the notes:
   i) Patient Name;
   ii) Leave the birth year visible, but obliterate birth day and month;
   iii) All health care provider names (MD/NP/DDS).

e) Collate the file, and, generate as many copies as needed. Keep the original for the QA records.

f) Add a scoring sheet. Examples are appended (Physician Quality Assurance Scoresheet; Tech Quality Assurance Scoresheet)

g) For internal technologist scoring reviews, select representative epochs encompassing at least 2 hours. Several epoch ranges can be specified – the interval to be assessed does not need to be continuous. Write this on the score sheet.

h) For external reviews consult technical support at the sleep software company re how to copy and anonymize a scored data file. Copy the anonymized scored data file onto suitable media (such as a CD or DVD)

***File distribution***

a) Internal Reviews: Distribute a copy of the file to every technologist participating in the review.

b) External Reviews: Mail the anonymized, collated, code-labeled, file with an appropriate score sheet, media, and cover letter to the facility that has agreed to participate

***Finding an IHF to act as an external reviewer***

The quality management standard S6.6.3.11 requires each IHF to arrange an external review of the physician record review and reporting for in-lab sleep studies, and, if applicable, home sleep apnea tests. This is to be done by a sleep medicine physician from another facility.

It is suggested that facilities staff contact IHF sleep medicine facilities and enter into a reciprocal arrangement to fulfil the IHF requirements.

A list of all independent health facilities, including sleep facilities, is available on the Ontario Ministry of Health and Long-Term Care website, with contact information. http://www.health.gov.on.ca/en/public/programs/ihf/facilities.aspx

***Acting as an external reviewer***

On entering into an agreement with another facility, staff should log receipt of the file, and assign review as directed by the QA.

The reviewing physician should look at the file identify any missing information to be submitted before doing the review and direct staff to obtain it.

It is expected that submitting facilities will supply a score sheet. If one is not provided, the IHF can use one of the appended scoresheet examples.

On completion the scoresheet should be faxed back to the originating facility, and the scoresheet retained by the reviewing centre as evidence of participation in the process.

***Continuing Professional Development (CPD)***

Preparing studies, reviewing studies, and discussing outcome of such reviews, qualify as continuing professional development for the Royal College of Physicians and Surgeons of Canada under section 3 – assessment activities – chart audit and feedback. Such activity may qualify for similar credit for other healthcare providers – check with each regulatory agency. Retain a copy of relevant score sheets and feedback sheets as documentation.

***File storage for accreditation***

Maintain a copy of the:

a) worksheet/log;
b) entire review file;
c) completed score sheets;
d) minutes of meetings between the QA and any individual staff members;
e) minutes of any relevant QA meetings.

Ensure that you have ready access to the data files which can be presented during an accreditation visit.

***Worksheets, logs, and score sheets***

Examples are appended, and can be modified to suit the needs of each facility:

a) Worksheet – Log for Sleep Study Reviews
b) Log for Incoming Sleep Study Reivews
c) Physician Quality Assurance Score Sheet
d) QA Feedback for Physician Quality Assurance.
e) Tech Quality Assurance Score Sheet
f) QA Feedback for Tech Quality Assurance.

# APPENDIX A:

*Worksheet – Log for Sleep Study Reviews*

Sleep Study Review Worksheet/ Log Internal — IHF - Sleep Medicine

□ Lab Studies □ HSAT — confidential when completed

Selected by: _____ Date: _____ Review year: 20 _ _ page ____ a

| **reason(s) for this review** | **minimum /year** | **# done to date** | **# to do at this date** | **# done after this set** |
|---|---|---|---|---|
| □ study indication/ OA conduct | 10 | | | |
| □ technologist scoring – internal | greater of 1% of studies and 10 = | | | |
| □ physician review and reporting - internal | dx = 5<br>tx = 5<br>1 / MD = | | | |
| □ physician review and reporting - external | 10 | | | |

# of studies for this review: □ dx ___ □ tx ___ □ other _____

Required inclusions this cycle: physicians : ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

technologists: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Desired inclusions this cycle: □ MSLT □ MWT □ BiPAP □ other:

Random number list : ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ (count back from last study in lab log)

| *random number pulled* | *Patient name file code* | *study type epoch range* | *collection date file read* | *collection tech sent to* | *scoring tech date sent* | *interpret-ing MD date returned* | *Rejected because* | *Accept to QA* |
|---|---|---|---|---|---|---|---|---|
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Sleep Study Review Worksheet/ Log part 2 Example Sleep Disorders Centre

Date: _____ page ____b

Collecting techs: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___
Scoring techs: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___
Interpreting MDs: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Circle RPsgTs. Cross off MD & tech staff who will have completed their review requirements as of this cycle.

Other Notes:

# APPENDIX B:

*Log for Incoming Sleep Study Reivews*

External Sleep Study Review Worksheet/ Log IHF - Sleep Medicine

Review year: 20 _ _

| Submitting facilities | Fax | Contact Name | Phone |
|---|---|---|---|
| | | | |
| | | | |

| *Received on:* | *Originating Facility* | *Study code:* | *Assigned to* | *Done* | *Ret'd* | *notes* |
|---|---|---|---|---|---|---|
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# APPENDIX C:

*Physician Quality Assurance Score Sheet*

**Quality Assurance Score Sheet – Physicians** Independent Health Facilities – Sleep Medicine

| | | | |
|---|---|---|---|
| Originating IHF | | Study code | |
| Reviewing IHF | | Study type | □ Dx □ split Dx-Tx □ Tx<br>□ MSLT □ MWT □ other: |

The review is to assess if the study:

a) was appropriate to the problems/ issues the presented by the patient and identified by sleep medicine
b) followed the appropriate protocol (montage, therapy setup and titration when appropriate)
c) was reported and interpreted correctly
d) interpretation report gave clear and appropriate recommendations and suggestions, including follow-up

To complete: **write:** n/a no yes …or **check: √** in appropriate column and write comments below

**A. Reviewing the requisition, referral, and consultation note:**

| | YES/NO/NA | Minor issues | Major issues |
|---|---|---|---|
| 1. Study and montage ordered is appropriate to problems/ issued identified? | | | |
| 2. Reason for study is an approved indication? | | | |

**B. Reviewing the above and the interpretation report:**

| | YES/NO/NA | Minor Issues | Major Issues |
|---|---|---|---|
| 1. Did the interpretation address the problems/issues identified pre-study? | | | |
| 2. Were there appropriate comments made re:<br>a. sleep structure/ EEG? | | | |
| b. respiratory events? | | | |
| c. other significant events? | | | |
| d. therapy choices or optimal Rx? | | | |
| e. how any of the above, or other issues, impact diagnosis./ therapy? | | | |
| 3. Were any diagnoses made in the summary supported by the data? | | | |
| 4. For ALL of the major issues noted in a-f above were appropriate remarks made in the interpretation? | | | |
| 5. Were suggestions and/or prescriptions clear and appropriate? | | | |
| 6. Was there a clear statement re follow-up, and responsibility for actions? | | | |

**minor vs major**

errors or omissions are **major** = if they clearly violate standards or affect study outcome/ usefulness

are **minor** = if they fall below optimal performance but do NOT affect study outcome/ usefulness

Comment on all major issues below by section and #. e.g. "G2. - no comments made about low sleep efficiency making respiratory indices less accurate"

For other issues deemed important briefly comment below.

**C. How difficult was the study?**

| technical problems | sleep scoring | respiratory scoring | limb scoring | pressure titration | interpretation |
|---|---|---|---|---|---|
| hard average minimal | hard average easy | hard average easy | hard average easy | hard average easy | complex average easy |

**Comments:** □ see attached page □ all areas at or above standards

**Summary:** □ see attached page

a. What would you have done differently, and why? □ nothing

b. What areas might the facility consider reviewing? □ no areas appear to need review

□ as above

Reviewer's Initials: ____ MD Date: _____

Reviewing Facility QA initials: ____ MD Date: _____

| | | | |
|---|---|---|---|
| Originating Facility | QA initials: | □ score sheet reviewed: ___ | Date: _____ |
| | | □ discussed with MD ___ | Date: _____ |
| | | □ finalized ___ | Date: _____ |

# APPENDIX D:

*QA Feedback for Physician Quality Assurance*

## Quality Advisor Feedback Sheet – Physicians

| | | | |
|---|---|---|---|
| Physician | | Study code | |
| QA | | Study type | □ Dx □ split Dx-Tx □ Tx<br>□ MSLT □ MWT □ other: |

The review was to assess if the physician:

a) was appropriate to the problems/ issues the presented by the patient and identified by sleep medicine
b) recommended the appropriate montage/therapy/therapy instructions (e.g. starting pressures for BiPAP titrations
c) was reported and interpreted correctly
d) interpretation report gave clear and appropriate recommendations and suggestions, including follow-up

□ **No areas were identified as needing discussion**

□ **The following areas were identified as needing discussion:**

| | |
|---|---|
| 1. Appropriate indication for study | |
| 2. Appropriate study type and montage recommended | |
| 3. Approved indication for study | |
| 4. Interpretation addressed the problems/ issues identified pre-study | |
| 5. Appropriate comments made re: | |
| a. sleep structure/ EEG | |
| b. respiratory events | |
| c. other significant events | |
| d. therapy choices or optimal Rx | |
| e. how any of the above, or other issues, impact diagnosis./ therapy | |
| 6. Diagnoses supported by the data | |
| 7. Appropriate remarks about major issues in study | |
| 8. Suggestions and/or prescriptions clear and appropriate | |
| 9. Follow-up plan | |

**Physician Comments:** □ also see attached page

**QA comments** □ also see attached page

Physician signature: _____ Date: _____

QA signature: _____ Date: _____

# APPENDIX E:

*Tech Quality Assurance Score Sheet*

# Quality Assurance Score Sheet – Collecting and Scoring Technologists/ Technicians

| | | | |
|---|---|---|---|
| Scoring Tech | | Study code | |
| Reviewing PRsgT | | Study type | □ Dx □ split Dx-Tx □ Tx<br>□ MSLT □ MWT □ other: |

To complete: **write:** n/a no yes …or **check:** √ in appropriate column and write comments below

| **A. Requisition:** | Yes/No/Na | Minor Issue | Major Issue |
|---|---|---|---|
| 1. Requisition complete and signed? | | | |
| 2. Clear reason for study? | | | |
| 3. Reason for study is an approved indication? | | | |
| 4. Study type requested is appropriate? | | | |
| 5. Special setup or special needs appropriately documented? | | | |

| **B. Technical quality & documentation:** | Yes/No/Na | Minor Issue | Major Issue |
|---|---|---|---|
| 1. Montage as ordered and correct? | | | |
| 2. Calibration performed and accurate? | | | |
| 3. Biocals complete and correct? | | | |
| 4. Full quality SpO2 signal documented in raw data | | | |
| 5. Were any major technical faults identified | | | |
| If yes : a. Were reasonable steps taken to correct them? | | | |
| b. Corrective steps documented in data file? | | | |
| c. Do uncorrected faults interfere with study results? | | | |
| 6. If there were equipment issues, was a worksheet/ appropriate form done | | | |

| **C. Study documentation**: | Yes/No/Na | Major Issue | Major Issue |
|---|---|---|---|
| 1. Medications noted appropriately? (including 'none taken') | | | |
| 2. Appropriate episodic tech notes in the data file during the study? | | | |
| 3. Did the collection tech write an appropriate summary after the study? | | | |

| **D. Positive Airway Pressure studies** □ not applicable | Yes/No | Minor Issue | Major Issue |
|---|---|---|---|
| 1. Starting pressure(s) including EPR, modality, well documented? | | | |
| 2. Pressure adjusted reasonably for events and hypoxemia? | | | |
| 3. Pressure decreased after stable intervals? after REM/ supine increases? | | | |
| 4. Starting mask documented (type; brand; size; other) | | | |
| 5. Mask changes documented? (reason, type, brand, size, other) | | | |
| 6. Leaks documented regularly (routinely every 30 min and as needed) | | | |
| 7. Mouth and mask leaks managed appropriately? | | | |
| 8. Central events/ CSB/ CxA managed appropriately? | | | |
| 9. Appropriate steps taken for PAP failure? (eg treatment emergent events) | | | |
| 10. Optimal pressures documented (supine/ lateral ; REM/ nREM; & overall) | | | |

## minor vs major

errors or omissions are **major** = if they clearly violate standards or affect study outcome/ usefulness

**minor** = if they fall below optimal performance but do NOT affect study outcome/ usefulness

For all **major issues** and scoring rated **"often not":**
- briefly comment on the next page
- note section & #
e.g. "A1 – no requisition"
e.g. "E8 – many OAs labelled CAs"

For **scoring issues**, note **representative epoch** ranges.

For any other issues deemed important, briefly comment on the next page.

| **E. Scoring:** Epochs in review; _____ to _____ were the following scored or identified correctly? | Not seen | Almost always | Usually | Often not | Relevant epochs for comment: |
|---|---|---|---|---|---|
| 1. sleep onset | | | | | |
| 2. NREM staging | | | | | |
| 3. REM staging | | | | | |
| 4. microarousals and awakenings | | | | | |
| 5. alpha / beta frequency intrusion | | | | | |
| 6. sharp or epileptiform activity | | | | | |
| 7. artifact and movement time | | | | | |
| 8. respiratory events a. OA MA OH RERAs | | | | | |
| b. CA CSB Chaotic breathing | | | | | |
| c. hypoxemia | | | | | |
| 9. limb movements a. in wake (RLS, parasomnia, other) | | | | | |
| b. periodic limb movements | | | | | |
| c. abnormal EMG or movement in REM | | | | | |
| 10. cardiac arrhythmias aside occasional PACs PVCs and HR variation | | | | | |
| 11. other notable findings (e.g. bruxism, drug spindles, etc.) | | | | | |
| 12. Did the scoring tech write a reasonable summary? | | | | | |

**F. Incidents and Adverse Events**

| | | | |
|---|---|---|---|
| 1. Were incidents managed & documented appropriately - including but not limited to early departure, any other significant event. | n/a | yes | no |

**G. How difficult was each aspect of the study?**

| technical problems | sleep scoring | respiratory scoring | limb scoring | pressure titration |
|---|---|---|---|---|
| hard average minimal | hard average easy | hard average easy | hard average easy | hard average easy |

**Comments:** □ all areas at or above standards
by section A-G □ see attached page

**Review Summary:** □ also attached page
a. What would you have done differently, and why? □ t would not have made anything differently

b. What areas might the facility consider reviewing? □ as above

Reviewer's Initials: ____ RPsgT □ MD □ other: _____ Date: _____

QA initials: □ score sheet reviewed _____ Date: _____
□ discussed with tech _____ Date: _____
□ finalized _____ Date: _____

# APPENDIX F:

*QA Feedback for Tech Quality Assurance*

## Quality Advisor Feedback Sheet– Collecting and Scoring Technologists

| | | | |
|---|---|---|---|
| Tech | | Study code | |
| QA | | Study type | □ Dx □ split Dx-Tx □ Tx<br>□ MSLT □ MWT □ other: |

**□ No areas were identified as needing discussion**
**□ The following areas were identified as needing discussion:**

| | |
|---|---|
| 1. Requisition | |
| 2. reason for study | |
| 3. approved indication | |
| 4. Study type requested was appropriate | |
| 5. Special setup or special needs appropriately documented | |
| 6. Montage as ordered and correct | |
| 7. Calibration performed and accurate | |
| 8. Biocals complete and correct | |
| 9. Full quality SpO2 signal documented in raw data | |
| 10. Technical faults identified | |
| a. reasonable steps taken to correct them | |
| b. corrective steps documented | |
| c. uncorrected faults interfered with study results | |
| 11. Equipment issues led to worksheet/ appropriate form | |
| 12. Medications noted appropriately (including 'none taken') | |
| 13. Appropriate episodic tech notes in the data file during the study | |
| 14. appropriate summary after the study | |
| 15. Starting pressure(s) including EPR, modality, well documented | |
| 16. Pressure adjusted reasonably for events and hypoxemia | |
| 17. Pressure decreased after stable intervals or after REM/ supine increases | |
| 18. Starting mask documented (type; brand; size; other) | |
| 19. Mask changes documented re reason, type, brand, size, other) | |
| 20. Leaks documented regularly (routinely every 30 min and as needed) | |
| 21. Mouth and mask leaks managed appropriately | |
| 22. Central events/ CSB/ CxA managed appropriately? | |
| 23. Appropriate steps taken for PAP failure (eg treatment emergent events) | |
| 24. Optimal pressures documented (supine/ lateral ; REM/ nREM; & overall) | |
| 25. Sleep onset | |
| 26. NREM staging | |
| 27. REM staging | |
| 28. Microarousals and awakenings | |
| 29. Alpha / beta frequency intrusion | |
| 30. Sharp or epileptiform activity | |
| 31. Artifact and movement time | |
| 32. Respiratory events | |
| a. OA MA OH RERAs | |
| b. CA CSB Chaotic breathing | |
| c. hypoxemia | |
| 33. Limb movements | |
| a. in wake (RLS, parasomnia, other) | |
| b. periodic limb movements | |
| c. abnormal EMG or movement in REM | |
| 34. Cardiac arrhythmias aside occasional PACs PVCs and HR variation | |
| 35. Other notable findings (e.g. bruxism, drug spindles, etc.) | |
| 36. Reasonable summary of scoring | |
| 37. Were incidents managed & documented appropriately | |

**Tech Comments:** □ also see attached page

**QA comments** □ also see attached page

Tech signature: _____ Date: _____

QA signature: _____ Date: _____