Clin-IQ Trainee Preparation Workbook

by

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Clin-IQ Process Description

1. **WHAT Clin-IQ IS and IS NOT.**
   - Clin-IQ (Clinical Inquiries) is a scholarly activity process that can results in a publication or presentation ready document.
   - A brief, 1,000 word paper that answers a clinically relevant questions by evaluating published evidence from the medical literature.
   - Clin-IQ is **NOT** a case report. Clin-IQ seeks to answer questions of general clinical interest.

2. **WHY do it?**
   - Meets all ACGME\(^*\) scholarly activity requirements.
   - Increases scholarly activities and productivity for faculty and trainees.
   - No IRB.
   - Not a Case Report.
   - Clin-IQ answers are publishable.

3. **WHO participates in Clin-IQ?**
   1) Trainees at all levels of clinical education.
   2) Academic faculty.
   3) Community-based faculty.
   4) Practicing community clinicians of all disciplines and specialties.
   5) Medical librarians.

4. **HOW does it work?** Steps to Implementing Clin-IQ
   1) **START SMALL WITH QUESTIONS OF BROAD INTEREST AND RELEVANCE.**
   2) Form faculty/trainee teams.

\(^*\) Accreditation Council for Graduate Medical Education
EDUCATIONAL GOALS AND OBJECTIVES

OVERVIEW

Clin-IQ (Clinical Inquiries) was developed by the University of Oklahoma (OU) College of Medicine Department of Family Medicine Research Division to promote research and scholarly collaboration for the OU Family Medicine Residency Program. Since it’s inception in 2003, the process has been tuned and refined into the process described in this workbook.

The process has yielded 55 publications, 42 indexed in PubMed (an important marker for the residency program); 5 are currently submitted or in press. Residents and faculty has presented 28 posters at local meetings and a workshop at a national meeting.

For the trainee interested in a fellowship or a career in academic medicine, Clin-IQ – a 1,000 word paper that answers a clinically relevant question – can add publications to your resume. Most importantly, answers to relevant clinical questions can result in better patient care.

GOALS

1. Involve trainees in clinically relevant, scholarly research.
2. Develop a collaborative learning community between trainees, faculty and interested community physicians.
3. Create opportunities for presentation and publication of scholarly research.
4. Meet accrediting body requirements for trainee research.
5. Establish a database of clinically relevant research questions.

OBJECTIVES

1. Recognize and construct well-formulated, clinically relevant questions.
2. Access appropriate current literature of the highest level of evidence relevant to a clinical question.
3. Utilize Medical Reference Library consultants effectively.
4. Interpret the results from published literature.
5. Appraise the validity and strength of evidence of the literature selected.
6. Summarize the results for an audience of their peers, faculty mentors, and community clinicians.
7. Synthesize the literature in a written document.
8. Follow instructions for authors for scholarly writing.
9. Produce a publication ready document of their findings.

WHERE DO QUESTIONS COME FROM? Questions arise in clinical practice every day. Each program and clinician should develop a method for collecting questions. Talk to your program director or faculty mentor.

1. During clinic.
2. On hospital rounds.
3. From board exams or readings.
4. Listening to lectures.
5. In discussion with other clinicians.
6. From the medical literature and texts.
FACULTY/TRAINEE COLLABORATION. TRAINEES SHOULD BE PAIRED WITH A FACULTY MENTOR TO:
1. Demonstrate the importance of the research process to the trainee.
2. Build a collegial relationship between faculty and trainee.
3. Support the trainee as he/she learns and works through a scholarly research process.

EVALUATION OF CLIN-IQ PROJECTS:
1. Each document should be peer-reviewed and revised as indicated.
2. Faculty mentors should serve as advisor and co-author in the process to assure accuracy, completeness, and readiness for publication.
3. A Clin-IQ faculty scholarly activities director should review each completed Clin-IQ and help the authors find a suitable presentation or publication source.

FOLLOW THE GUIDELINES BELOW CLOSELY. These Guidelines for Authors were designed based on Instructions for Authors from medical journals. By following these guidelines, you will complete a document that is close to publication ready. Publication will depend on relevance and importance as determined by journal editors.
# Clin-IQ Guidelines for Authors

## General Format
- Double space the entire document.
- Indent the first line of each paragraph. Do not use extra blank lines between paragraphs.

## Citing Abbreviations
- The first time you use an abbreviation you must write the complete phrase first and follow the phrase with the abbreviation in parentheses. From then on, use only the abbreviation.

### Examples
- The Residency Review Committee (RRC) is the entity that accredits residency training programs. The RRC requires program to conduct faculty/residency collaborative research for accreditation.

## Numbers in Text
- Spell out numbers one through nine.
  - Except percents (9%)  
  - Medication dosages (15 mg BID)  
  - Laboratory values (162.4 ml/min)  
  - Dates (June 30, 2014)  
  - Time frame (39 weeks, 3 years)  
  - Ages (individuals 13 yrs or older).  
  - More than one number in a sentence

### Examples
- In this study, nine children aged 4 months to 2 years received ear tubes.
- In this study, the first 8 children received ear tubes and the second 8 were placed on Bactrim for 2 weeks.

## Articles from the Medical Literature
- **Recent** review article(s), no more than 2, on which to base your summary of issues.
- **Recent** evidence articles, 2, on which to base your Summary of Evidence and your answer.
- **All articles should be from medical journals preferably published in 2008 or newer.** If you have problems, **consult a trained medical librarian. Be sure to bring this workbook and your Clin-IQ question with you when you consult with the librarian.** (Some libraries offer online “Ask a Librarian” assistance. An example of an “Ask a Librarian” form is included on page 7.)

### Examples
- **Review article:**  

- **Evidence article:**  
### In Text Citations

If you cite, paraphrase, mention or quote directly from a published article, book, website, etc., you must cite the material in the text (and include the citation information in the Reference List). **Failure to do so constitutes plagiarism and copyright infringement.**

### Examples

Use of combined oral contraceptives increases the risk of venous thrombosis two-to-six fold.\(^1\,^2\) Both the estrogen and progestogen of combined oral contraceptives contribute to the increased thrombotic risk.\(^1\) On top of this, smoking doubles the risk of venous thrombosis.\(^2\) Women over age 35 who smoke should not use combined oral contraceptives due to the risk for cardiovascular disease.\(^3\)

### Reference Lists

Reference lists are placed at the end of the paper. References are listed **in the order in which they are cited in the text of your article.**

**TIP:** Reference 1 is always \(^1\) no matter how many times it is cited in the text.

### Examples

Both the estrogen and progestogen of combined oral contraceptives contribute to the increased thrombotic risk.\(^1\)

... in these 56 women when APC resistance was re-tested 3 months later (mean baseline 2.75 vs. mean three months later 2.47; difference -0.29; 95% CI -0.04 to -0.53).\(^1\)

### Complete Reference Examples

**(based on the Uniform Requirements for Articles Submitted to Biomedical Journals)**

#### Journal Article Example


#### Book Chapter Example


#### Website Example


**Acknowledgment:** “This [document, paper, presentation, etc.] was supported in part by Oklahoma Shared Clinical & Translational Resources, grant number NIGMS U54GM104938, NIGMS/NIH.”

A sample completed Clin-IQ, which meets the style, formatting and publication requirements, can be found beginning on page 18.

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* A guide to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals can be found at [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3142758/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3142758/)
Sample “Ask a Librarian” Form

Ask a Librarian Form

Please fill out as much information as possible. This will make it easier for us to quickly and accurately answer your question.

First Name: ______________________ Last Name: ______________________

Email: ______________________ Phone: ______________________

Status: ______________________ College: ______________________

Department: ______________________

Question: ______________________

Challenge Question: 3 + 5 = ______________________ [Send Question]

Other Library Consultations Services

More Research Support Forms

Instruction Request

Set up one-on-one or group instruction with one of our Reference Librarians for in-depth targeted presentations on library resources...

Search Request

Get started on the right foot with a targeted search on your topic...

Purchase Request

Recommend material for the library to add to its collection...

Theses & Dissertations Request Form
TEMPLATE: BUILD A CLIN-IQ

1: **CHOOSE A QUESTION.**

Write the question you have selected on the following lines.


2: **DETERMINE IF THE QUESTION IS IN PICO FORMAT; REWRITE IT IF IT IS NOT.**

**PICO** is an acronym for the components of a well-built clinical question.

\[ \text{P} = \text{patient, always your primary focus.} \]

\[ \text{I} = \text{intervention, what are you proposing to do (not do, e.g., watchful waiting).} \]

\[ \text{C} = \text{compared to what? Some questions (e.g., causation) won’t have a comparison.} \]

\[ \text{O} = \text{outcome, what do you want to happen.} \]

Read the two questions below.

**Before – Not Specific**

Do myringotomy tubes help children with recurrent otitis media?

**After – Very Specific, Well-Built**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant or preschool child; chronic otitis media</td>
<td>myringotomy tubes</td>
<td>episodic or prophylactic antibiotics</td>
<td>Incidence or severity or side effects</td>
</tr>
</tbody>
</table>

Re-write the question you have selected on the following lines.

P

I

C

O

3: **DEVELOP SEARCH TERMS, LIMITS AND INCLUSION/EXCLUSION CRITERIA**

Based on your PICO formatted question (above), select search terms for your literature search.

**PICO Literature Search Strategy Example**

*Adapted from Kerr J. Abdominal Imaging 33 (Sept): 31-33, 2008*
Search Terms:

Limits: (e.g., Human, English, Infants or Pre-School Children review, RCT)

Inclusion and Exclusion Criteria: A brief discussion of which articles you chose to include, e.g., all clinical trials in humans that compared tubes with other treatments or with watchful waiting that were published in the past 6 years and included an n (number of subjects) of XX or greater) and articles you chose to exclude (children over age 5, adolescents, adults).
(See Sample of Completed Clin-IQ, page 18)

4: SEARCH THE MEDICAL LITERATURE

Consulting with a Medical Reference Librarian: Consulting with a medical reference librarian before you do a literature search is most likely to yield the highest level of current evidence with the least amount of irrelevant materials. You may consult with a librarian or you perform the literature search yourself. If you choose to consult with a librarian, here are some tips to make that interaction more productive.

- Conduct the consultation face-to-face. Medical reference librarians are trained in “reference interviews” and will ask you questions about your topic that you may not have considered. Or, fill out the “Ask a Librarian” help request from the library webpage if available (see sample, page 7). You may have to do both to get the materials you need.
- Bring your project workbook with you to the consultation. The librarian will then understand the limited nature of your search and be better able to assist you.
- Medical librarians will be able to readily locate relevant review articles as well as evidence articles.
- Medical librarians are well-versed in evidence-based medicine, levels of evidence and study types. They can assist you in identifying which type of study (or studies) will best answer your question.
- You may also consider consulting with a medical librarian about
  a) Inclusion and exclusion criteria
  b) Search terms and limits

The medical librarian must become an author on a Clin-IQ if he/she:
  a) Performs the literature search that yields the articles used for the Clin-IQ, and
  b) b. Reads the final document for publication.
5: **Locate 1 or 2 Review/Background Articles.** Based on search terms, locate 1 or 2 current (preferably 2008 or newer) review/background article available (you can do the search yourself or work with a librarian). Your review article should include:

- Clinical significance of the problem.
- Prevalence.
- Relevant issues.

6: **Write a Draft of the Summary of Issues (Word Count = 200-300)**

Should include how prevalence and clinical significance relate back to your question. You have two examples to work from (see Sample of Completed Clin-IQ, page 18, and Example of Published Clin-IQ, page 22).

7: **Locate 2 Current (preferably 2008 or newer) Highest Level Evidence Articles.**

You can do this search yourself or consult with a trained medical librarian (item 4 above). Be sure to identify which type of study qualifies as the highest level of evidence. See Figure 1, pages 15, and Figure 2, page 17, for a discussion of levels of evidence.

- Find at least 2 articles relevant to your question that meet the highest level of evidence available as shown on Figures 1 and 2.
- Read the articles
- Send the articles to your faculty mentor

8: **Write a Draft of the Summary of Evidence (Word Count = 500-700)**

- number of patients or papers, if meta-analysis or systematic review
- type of studies (include data on a table for clarity)
- statistical significance.*
- intervention of interest
- outcome(s) of interest (morbidity, mortality, quality of life, etc.)
- weaknesses or conflicts
- cite references

*An excellent Statistics tutorial can be found at http://web.med.unsw.edu.au/QMP/QMPHome.htm
9: **DETERMINE LEVEL OF EVIDENCE OF YOUR BODY OF LITERATURE** (See Figure 1, page 13 and Figure 2, page 15)

Level of evidence for the answer (A, B, or C, see figures): __________________________

10: **ANSWER THE QUESTION.**

   **Answer:** (Circle one): Yes  No  Inconclusive or 1-2 sentences if that is more responsive.

11: **OPTIONAL BUT RECOMMENDED** ADD AN ORIGINAL TABLE, FIGURE, CHART OR GRAPH

   • Tables, figures or charts can be added to elucidate data in the Summary of Evidence
   • Tables, figures or charts must be original, created based on data available from the articles.
   • Place an citation within the text indicating the context of the graphical material (e.g., Figure 1, Table 2),

12: **WRITE A DRAFT CONCLUSION (WORD COUNT = 50-100)**

   • Conclusions (1-2 sentences), to include:
     - Summary of issue (relevance) linked to
     - Summary of evidence, linked to
     - The answer and how you would change your practice based on what you have learned.

13: **ADD REFERENCE LIST:** You must cite all the materials (books, journal articles, website, etc.) that you used to answer your question. You should only need 1-2 review articles and 2 evidence articles.

   1. Review article #1
   2. Review article #2 (optional)
   3. Evidence article #1
   4. Evidence article #2
14: **COMPLETE CLIN-IQ CHECK LIST.** Have you:

- ☐ Answered the question
- ☐ Prepared the reference list in proper format.
- ☐ Cited sources properly as shown in this Guidelines for Authors (above).
- ☐ If you included a table, figure or graphic, is it original or adapted sufficiently from the source to avoid potential copyright violation or plagiarism (see A Word About Plagiarism below).
- ☐ If you included a table, figure or graphic, have to noted in the text where the table materials is discussed (Table 1, Figure 2, etc.).
- ☐ Shared your draft with your mentor and addressed all comments and suggestions.
- ☐ Requested a review from additional faculty or peers as suggested by your mentor (review form, page 16)
- ☐ Revised draft until mentor feels it is publishable.

**A WORD ABOUT PLAGIARISM:** Plagiarism and copyright infringement occur when an author extracts large portions of materials from a published document. Tables, figures, charts and graphs of any kind must be significantly altered or, preferably, created from data within a published study. Brief material (generally a sentence or two, less than a paragraph) may be quoted provided adequate citations are provided for the sources.

A consult with a medical librarian can help you be re-assured that you have not exceeded copyright limitations or plagiarized material.

**REQUIRED SUPPORT ACKNOWLEDGMENT STATEMENT**

Any materials, papers, presentations, etc., developed based on this document must acknowledge the grant. A copy of the material(s) should also be submitted to OSCTR (OSCTR@OUHSC.EDU) for the grant archives and reporting.

Please use the following statement:

“This [document, paper, presentation, etc.] was supported in part by Oklahoma Shared Clinical & Translational Resources, grant number NIGMS U54GM104938, NIGMS/NIH.”
1. **Systematic Review: Level 1 Evidence**
   a. A comprehensive survey of a topic in which all the primary studies of the highest evidence (e.g., randomized controlled trials, prospective cohort studies; see below) are identified, appraised and summarized using explicit inclusion and exclusion criteria.
   b. Results should be reproducible.

2. **Meta-analysis: Level 1 Evidence**
   a. Similar to a systematic review in that a comprehensive search of the topic is conducted.
   b. If the results of the review of all included studies are similar enough statistically, the results are combined and analyzed as if they were one study.
   c. Results should be reproducible.

3. **Randomized Controlled Trial (RCT): Level 1 Evidence**
   a. 2 groups: 1 treatment group and 1 control group. Treatment group received treatment under investigation. Control group receives either no treatment (placebo) or gold standard treatment.
   b. Patients are randomly assigned to each group.
   c. Best type of study to answer questions about therapy.
   d. Sometimes there can be 3 or even 4 groups (called arms) depending on the study question. Example of a 4-arm RCT: Allergy treatment.
      i. Claritin alone
      ii. Flonase alone
      iii. Claritin + Flonase
      iv. Placebo
4. **Cohort Study**: Level 1 or 2 Evidence based on question and study design
   a. A study in which patients who presently have a condition and/or receive a particular treatment are observed over time and compared with another group who do not have the condition being studied.
   b. Example:

   ![Cohort Study Diagram]

   Examples adapted from SUNY Downstate Medical Center ([http://library.downstate.edu/EBM2](http://library.downstate.edu/EBM2))
Figure 2.
Algorithm for determining level of evidence for an individual study

Is the study a key citation for an important point of evidence under discussion?

Yes

Is the key outcome of the study based on patient-oriented evidence (i.e., an improvement in morbidity, mortality, symptoms, quality of life, or cost)?

No

Yes

Is the study based on opinion, bench research, a consensus guideline, usual practice, clinical experience, or a case series?

No

Is the study one of the following?

1. Systematic review/meta-analysis of high-quality studies with consistent findings.
2. High-quality randomized controlled trial
   - Allocation concealed
   - Blinding, if possible
   - Intention-to-treat analysis
   - Adequate size
   - Adequate follow-up (>80%)
3. High-quality cohort study for prognosis (prospective, with >80% follow-up)
4. Validated clinical decision rule in a relevant population
5. High-quality diagnostic cohort study
   - Adequate size
   - Adequate spectrum of patients
   - Blinding
   - Consistent reference standard

Levels of Evidence

A = Consistent level 1 studies
B = Consistent level 2 or 3 studies or extrapolations from level 1 studies
C = Level 4 studies or extrapolations from level 2 or 3 studies
D = Level 5 studies or troubling inconsistent or inconclusive studies of any level

Clin-IQ Peer Review Form

Reviewer: ____________________________________________

Authors: ____________________________________________

Brief Title (first few words) ____________________________________________

General Instructions to Reviewers

• Objective is to help authors improve the manuscript.
• Suggest how to make the manuscript more clear, concise and relevant.
• Identify possible areas of confusion for the reader and make specific suggestions.
• Verify that at least one reference is accurately interpreted.
• Identify any glaring grammatical or format problems, in a supportive manner.
• Sprinkle PRAISE along with recommendations for change.

Answer:

Does the answer accurately represent the evidence given? [ ] Needs improvement  [ ] Yes

Reviewers Comments:

Level of Evidence:

Does the level of evidence accurately represent the references cited?

[ ] Needs improvement  [ ] Yes

Reviewers Comments:

Summary of Issues: Clinical significance, prevalence and relevance based on recent review article(s).

Is the writing clear and logical? [ ] Needs improvement  [ ] Ready to publish

Is the length appropriate (200-300 words)? [ ] Needs improvement  [ ] Ready to publish

Reviewers Comments:
Clin-IQ Peer Review Form

Summary of Evidence: Describes studies, outcomes, interventions. A figure or table will be added. Evidence articles should be cited.

Is the writing clear and logical? [ ] Needs improvement [ ] Ready to publish

Is the length appropriate (500-700 words)? [ ] Needs improvement [ ] Ready to publish

Review at least one evidence article and comment:

- Is the information appropriately represented in the text? [ ] Needs improvement [ ] Yes
- Have the statistics been accurately represented and explained? [ ] Needs improvement [ ] Yes
- If present, do the figures or tables accurately present the data and contribute to your understanding of the material? [ ] Needs improvement [ ] Yes

Reviewers Comments:

Conclusions: Conclusion should be clinically relevant and wrap up evidence.

Is the writing clear and logical? [ ] Needs improvement [ ] Ready to publish

Is the length appropriate (50-100 words)? [ ] Needs improvement [ ] Ready to publish

Does the conclusion state clearly how the answer will impact practice? [ ] Needs improvement [ ] Yes

Reviewers Comments:

Reference List:
Are all references cited in the body of the report according to the instructions in the Workbook (superscripted numbers)? [ ] Needs improvement [ ] Yes

Is the reference list in order numerically according to the order the articles are cited in the text? [ ] Needs improvement [ ] Yes

Reviewers Comments:

Additional comments to the author

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Sample of Completed Clin-IQ

Clin-IQ Project

Clinical Question: In women over 35 years of age who smoke, does Mirena (levonorgestrel-releasing intrauterine system) reduce the risk of DVTs compared to oral contraceptives?

Authors: M. M., MD (PGY-3) and K. J., MD (PGY-2)

Faculty Mentor: J. L. B., MD

Residency Program: [YOUR PROGRAM NAME HERE]

Answer: Yes

Level of Evidence for the Answer: B

Search Terms: intrauterine device, venous thrombosis, oral contraceptives

Date Search was Conducted: September 2012

Inclusion and Exclusion Criteria:

Inclusion Criteria: Published systematic reviews/meta-analysis, cohort studies, and clinical research trials comparing risk of venous thrombosis in women using a levonorgestrel-releasing intrauterine device versus oral contraceptives.

Exclusion Criteria: Women less than 18 years of age

Summary of the Issues

Use of combined oral contraceptives increases the risk of venous thrombosis two-to-six fold. Both the estrogen and progestogen of combined oral contraceptives contribute to the increased thrombotic risk. On top of this, smoking doubles the risk of venous thrombosis. It has been established that women over age 35 who smoke should not use combined oral contraceptives due to the risk for cardiovascular disease. Therefore, in this subset of patients, other forms of contraception with other routes of administration are being evaluated to see if they have reduced risks.
The levonorgestrel-releasing intrauterine device (LNG-IUD) is a T-shaped plastic contraceptive that is inserted in the uterine cavity where it continuously releases the progestogen levonorgestrel. More than eight million women have used the LNG-IUD worldwide. Plasma levels of levonorgestrel during use of a LNG-IUD are lower than during the use of progestogen-only pills. Studies of progestogen-only pills suggest that there is little or no increased risk of venous thrombosis, therefore it is expected that LNG-IUD will have little thrombotic risk. The thrombin generation-based activated protein C (APC) resistance assay is a global coagulation test that enables quantification of the net prothrombotic effect of combined oral contraceptives and can also be used to predict the thrombotic risk of the LNG-IUD.

Summary of the Evidence

A 2009 study assessed the thrombotic risk of the LNG-IUD. In this study, the thrombotic risk was evaluated by comparing the APC resistance before and after insertion of a LNG-IUD in 56 women. High resistance to APC is associated with an increased risk of thrombosis. In contrast to combined oral contraceptives which increase APC resistance, it was observed that the use of the LNG-IUD slightly decreased the resistance to APC in these 56 women when APC resistance was re-tested 3 months later (mean baseline 2.75 vs. mean three months later 2.47; difference -0.29; 95% CI -0.04 to -0.53). In women who switched from a combined oral contraceptive to the LNG-IUD, there was an even larger decrease in resistance to APC (difference -1.48; 95% CI -0.85 to -2.11). This decrease in APC resistance suggests that the LNG-IUD does not have a prothrombotic effect and suggests that it does not increase the risk of venous thrombosis. The non-randomized design is possibly a limitation of this study. In this study, researchers compared resistance to APC before and after insertion of an IUD in the same women so the comparison groups were equal except for the studied intervention which
is the IUD. However, due to the non-randomized design, the observed decrease in APC resistance after insertion of the LNG-IUD can only be attributed to the intrauterine device.¹

In 2010, analyses were done on a large case-control study on risk factors for venous thrombosis. Risk factors for venous thrombosis associated with non-oral contraceptives including injectable depot-medroxyprogesterone acetate (DMPA) and LNG-IUDs were evaluated for this specific analysis. The original study was a large population-based case-control study on risk factors for venous thrombosis where patients younger than 70 years with a first episode of deep venous thrombosis or pulmonary embolism were analyzed from the files of six anticoagulation clinics in the Netherlands. For this specific study, premenopausal women were selected, aged 18 to 50 years, who were not pregnant nor within four weeks postpartum and were not using oral contraceptives. In this study, 446 patients and 1146 controls were included. The use of injectable DMPA contraceptives was associated with a 3.6-fold increased risk of venous thrombosis compared with nonusers of hormonal contraceptives. The use of a LNG-IUD was not associated with an increased risk (odds ratio 0.3; 95% CI, 0.1 to 1.1). Further adjustment for BMI, positive family history of deep venous thrombosis, or smoking habit only marginally affected the risk estimates. It was concluded that LNG-IUD seems to be the safest option regarding the risk of venous thrombosis; however the study was limited to first thrombotic events.²

A 2012 cohort study was done to assess the risk of venous thrombosis in users of non-oral hormonal contraception. Participants included all Danish non-pregnant women aged 15-49 free of previous thrombosis or cancer who were followed from 2001 to 2010. In this study, 1,626,158 women contributed to 9,429,128 woman years of observation, during which time 3,434 first ever venous thrombosis events were confirmed. Risk of thrombosis of users of transdermal, vaginal, intrauterine, and subcutaneous hormonal contraception was compared to users of oral contraceptives and non-users of contraception. It was concluded that
compared to non-users of hormonal contraception, transdermal patches increase the risk of venous thrombosis eight times, vaginal rings increase the risk of venous thrombosis 6.5 times, but the LNG-IUD did not cause any increased risk of venous thrombosis and may even be protective (relative risk 0.6, 95% CI 0.4 to 0.8) (see Table).4

<table>
<thead>
<tr>
<th>Contraception type</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-use</td>
<td>1.00 (reference)</td>
</tr>
<tr>
<td>COC with levonorgestrel and oestrogen</td>
<td>3.21 (2.70 to 3.81)</td>
</tr>
<tr>
<td>COC with norgestimate</td>
<td>3.57 (2.98 to 4.27)</td>
</tr>
<tr>
<td>Levonorgestrel IUD</td>
<td>0.57 (0.41 to 0.81)</td>
</tr>
<tr>
<td>Patch</td>
<td>7.90 (3.54 to 17.65)</td>
</tr>
<tr>
<td>Vaginal ring</td>
<td>6.48 (4.69 to 8.94)</td>
</tr>
</tbody>
</table>

*Adapted from Lidegaard and Hougaard, 2012.4

(For all results above, p<0.05.)

Conclusion

Based on our research of literature, we conclude that in women over 35 years of age who smoke, Mirena (levonorgestrel-releasing intrauterine device) reduces the risk of deep vein thrombosis compared to oral contraceptives. The LNG-IUD was found to decrease the resistance to APC which indicates that this device does not have a prothrombotic effect. In all studies reviewed, the LNG-IUD did not cause any increased risk of venous thrombosis. This information will indeed change the way we practice; we will advise women over age 35 who smoke to consider Mirena for contraception.

Reference List:


Example of Published Clin-IQ

Are at-home sleep studies performed using portable monitors (PMs) as effective at diagnosing obstructive sleep apnea (OSA) in adults as sleep laboratory-based polysomnography (PSG)?

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Answer: In patients with suspected OSA, it is reasonable to use PMs if the patient has a high pretest probability (based on an Epworth Sleepiness Scale (ESS) ≥10 and clinical symptoms*) without significant co-morbid heart disease or other sleep disorders and he/she is able to prove competency in setting up the home equipment properly without assistance. However, if the patient has a negative PM, it is standard to perform PSG as it appears approximately 20% will have a false negative PM.

(*Clinical symptoms include snoring, witnessed apneas, obesity, pulmonary hypertension, refractory hypertension, morning headaches, increased neck circumference — >17 inches in men, >16 inches in women — daytime sleepiness)

Level of Evidence for the Answer: A

Search Terms: obstructive sleep apnea, polysomnography, portable home monitors, efficacy

Inclusion Criteria: polysomnography, ambulatory, adults, humans

Exclusion Criteria: children

SUMMARY OF THE ISSUES
Sleep apnea is a medical condition that, untreated, can exacerbate and possibly cause a multitude of medical conditions, such as hypertension, heart disease, stroke and many others.1 Sleep apnea is defined as episodes of involuntary pauses of breathing (apnea) or a decreased respiratory rate (hypopnea) during sleep. This review focuses on obstructive sleep apnea (OSA), the most common form of sleep apnea, which is caused by upper airway obstruction. It is difficult for patients to monitor their own OSA symptoms because they are asleep during the apneic events. Their significant others, however, often notice episodes when the patients stop breathing or experience significant snoring.

The gold standard for diagnosis is with a laboratory-based, technician attended polysomnography, also known as a PSG or Type I monitor. PSGs are effective at diagnosing OSA due to the controlled environment and multiple monitors recording brain waves, heart rhythm, eye movements, respirations, leg movement and oxygen and carbon dioxide levels. However, PSGs can be very expensive and cause a less than optimal night’s sleep.

A possibly less expensive and more comfortable alternative to a PSG is a home sleep study, or unattended portable monitor (PM). There are several classes of home monitors: Type II records identical information as a PSG, but is done without the monitoring of a technician and is done outside of a controlled sleep lab; Type III measures four physiologic variables including at least two respiratory variables, but cannot tell whether the patient is awake or asleep; Type IV monitors are defined differently by different organizations. The American Academy of Sleep Medicine defines Type IV monitors as devices that record one or two variables (e.g., arterial oxygen saturation and airflow) and can be used without a technician. This review evaluates the effectiveness of home PM studies versus in-laboratory PSGs in diagnosing OSA in adults.2

SUMMARY OF THE EVIDENCE
Masa et al. sought to demonstrate that PM studies were non-inferior in diagnosing OSA compared to PSGs. Three-hundred forty-eight participants from eight sleep study centers in Spain underwent both PMs and PSGs, but were randomized to which order the tests were performed (PSGs vs PMs first). Subjects were referred for the study based on “suspected” OSA supported by witnessed apneas, snoring, or daytime somnolence. Subjects with significant heart disease, other sleep disorders or inability to set up the PM were disqualified. Sensitivities and specificities were calculated for various apnea-hypopnea indices (AHI) in the PM study group in order to obtain cutoff values. AHI
is calculated by adding the number of apneic and hypopneic episodes and dividing by the total sleep time. In this study, apneas were defined as "the absence of airflow (≥90% reduction) for ≥10 seconds"; hypopnea was defined as measurable reduction in airflow (≥30% and <90%), also for ≥10 seconds, "with a ≥3% drop in oxygen saturation or arousal." Results suggested that a higher AHI was needed to support an OSA diagnosis in the PM group versus PSG group. For an AHI cutoff ≥5 for PSG with a high pretest probability (PTP, 90%), a PM AHI ≥10 successfully confirmed the diagnosis due to a positive likelihood ratio (+LR) of 6.25. A PM AHI <5 excluded OSA as the PTP was lowered from 90% to 39%. The indeterminate zone also increased as the severity of OSA increased, suggesting more repeat PSGs would be required if PM was used to diagnose only mild to moderate OSA (Figure 1). However, +LR increased in each PM group with increasing OSA severity.3

The second article evaluated was a multicenter, randomized study sponsored by the American Sleep Medicine Foundation and aspired to prove home PMs and autoPAP are non-inferior in diagnosing and treating OSA when paralleled to sleep laboratory PSG and continuous positive airway pressure (CPAP) titrations. Participants included in the study were adults from a pool of seven different academic sleep centers in five different cities that had a high PTP of carrying the diagnosis of moderate to severe OSA (AHI of ≥15). This was established by an "adjusted neck circumference" of ≥43 cm, along with an ESS of ≥12. Participants were randomized into either the PSG or PM group and were considered "eligible" for the study if an AHI ≥15 was reported via either PSG or PM. In the PSG group only 49% remained eligible for the study. In the PM group, 45% from initial PM and 12% from a crossover PSG remained eligible. In the PM group 27% became ineligible due to a final AHI <15. Of the people who had an inadequate initial PM study due to AHI <15, 20% who completed the PSG crossover proved to have moderate to severe OSA based on an AHI ≥15.4

Additional outcomes important to note include almost equal dropout rates and increased overall quality of life in treated patients of both groups. In regards to treatment, there was an equal percentage (10%) in both PSG and PM subjects who had to repeat their titration studies. Based on the 2011 Medicare Fee Schedule, this study estimated a 25% lower cost for home diagnosis and treatment of OSA than in laboratory testing. This study agreed with the Masa study5 in who approximately 20% of PM patients with severe OSA may require repeat testing. However, once a patient was diagnosed with OSA via PM, a PSG was not performed for comparison of AHI values.4

The Agency for Healthcare Research and Quality released a systematic review in 2011 examining the best methods for diagnosing and treating OSA. After reviewing 99 articles, the reviewers determined that Type III and IV PMs are as accurate as PSGs in diagnosing OSA with a "moderate" level of evidence. One interesting finding revealed was that "the American Academy of Sleep Medicine uses an AHI threshold of 15 to define OSA, with or without OSA clinical symptoms or AHI ≥5 with clinical symptoms." Clinical symptoms include snoring, witnessed apneas, obesity, pulmonary hypertension, refractory hypertension, morning headaches, increased neck circumference (>17 inches in men, >16 inches in women), and daytime sleepiness. However, the diagnosis of OSA between different studies fluctuated significantly from 5 to 20 AHI. Overall, Type III PMs were best at diagnosing OSA with AHI ≥5.3
CONCLUSION
The debate between using home PM versus sleep laboratory PSG as a less expensive but reasonably accurate diagnosis for OSA has been under fairly intense scrutiny over the past several years. We concluded it is reasonable to use PMs for diagnostic purposes in patients with a high PTP of having OSA based on an ESS ≥12 and clinical symptoms only if they are without severe co-morbidities and the patient proves competent in setting up home equipment properly without assistance. Further investigation should be sought regarding patient compliance with treatment, cost-effectiveness and reimbursement of PSGs versus PMs.

ACKNOWLEDGMENT
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REFERENCES