

DECEMBER 2011

HWPP #171 Quarterly Data Update

(Ongoing study; data collected and reported quarterly. Data reported here current as of December 2011.)

In an effort to expand the pool of educated, trained, and skilled California abortion providers, the Advancing New Standards in Reproductive Health (ANSIRH) program at the University of California, San Francisco Bixby Center for Global Reproductive Health has sponsored Health Workforce Pilot Project (HWPP) #171 to evaluate the safety, effectiveness and acceptability of nurse practitioners (NPs), certified nurse-midwives (CNMs) and physician assistants (PAs) in providing aspiration abortion. HWPP #171 operates under the auspices of California's Office of Statewide Health Planning and Development (OSHPD) to improve health care access. Data is collected and reported quarterly.

Study aims

- Evaluate the safety, effectiveness, and acceptability of NPs, CNMs, and PAs in providing aspiration abortion.
- Evaluate the implementation of a standardized, competency-based curriculum in provision of aspiration abortion care.

Study design

This multi-site prospective study is collecting data from 8,000 patients whose first-trimester aspiration abortion is provided by a NP, CNM or PA ("clinicians"), and an equal number of patients seen by physicians (for a total sample size of 16,000 patients), to compare their outcomes to published standards for abortion safety and across provider groups. Approximately 60 clinicians recruited from five organizations (including Planned Parenthood centers and Kaiser Permanente) across California will be trained to competency and evaluated on safety and competency post-training.

Patients are women aged 16 or older who are seeking a first-trimester aspiration abortion at a participating clinic. Patients review a consent form prior to their abortion and are asked whether they agree to have

their procedure performed by a NP, CNM or PA. Patients who decline this provision have the option of being a part of the physician comparison group. All patients who consent to participate in the study receive an anonymous satisfaction survey immediately following their abortion procedure, participate in a four-week post-procedure survey, and have their medical chart abstracted for demographic, clinical and safety data.

To assess the safety of NP, CNM and PA provision of early aspiration abortion, we have developed a standardized method of documenting immediate and delayed abortion-related complications based on national patient safety and adverse event reporting for non-abortion procedures (diagnosis, treatment, outcomes). Published data on first-trimester aspiration abortion-related complication diagnoses and treatments range from 1.3% to 4.4% ($\pm 1\%$) are based on data from nine peer-reviewed papers with a combined sample size of 180,710 aspiration abortion procedures published between 1990-2009.^[1-8]

Study results as of December 2011

Clinician training

- 41 NPs/CNMs/PAs have been trained to competency in aspiration abortion care.
- Clinicians participate in a comprehensive didactic and supervised clinical training program, which includes a written exam and competency-based evaluation process.
- Trainee competency is evaluated daily and at the end of the training phase on confidence, procedural performance, patient care, communication/ interpersonal skills, professionalism, practice-based learning, and clinical knowledge.

Patient sample selection, enrollment and consent

- 8,036 first-trimester aspiration abortion procedures were completed by NPs/CNMs/PAs and 6,533 procedures were completed by physicians, for a total of 14,569 abortion procedures.
- 14,670 patients agreed to participate in HWPP #171 and less than 20% (n=3,636) of study patients declined having a NP/CNM/PA perform their abortion procedure.

Procedure and patient outcomes:

Patient safety & satisfaction

- We rigorously monitor patient safety and track complications that occur on the day of the abortion procedure or up to four weeks afterwards, including any emergency room or hospital visit.
- The primary safety measure is abortion-related complications, as determined by the project's Data and Clinical Safety Monitoring Committee (DCSMC).
- A complication is identified at the time of the procedure (immediate) or after the procedure (delayed) and classified as either major (defined by the DCSMC as "complications requiring abortion-related surgeries, transfusion or hospitalization") or minor.

Abortion-related complications summary

- Overall abortion-related complication rate: 1.5% of all procedures (197 of 14,569) have abortion-related complication diagnoses; this falls well below the expected rate of 5% for total complication diagnoses. No deaths have been reported during the study period at any of the clinic sites.
- Group-specific abortion-related complication rate: 1.6% for NPs, CNMs, and PAs (128 out of 8,036), and 1.1% for physicians (66 out of 6,533); this variation in complication rates between the two groups is within an acceptable clinical margin of difference.
- 97% (191 out of 197) of abortion-related complications have been minor and completely resolved without adverse outcomes; 6 cases have been classified as major complications and were successfully managed and resolved with appropriate treatment.
- The most common type of minor abortion-related complication diagnoses reported for both provider groups were incomplete abortion, hematometra, failed abortion, and symptomatic intrauterine material. Major abortion-related

complications include incomplete abortion, infection, and uterine perforation.

- For both provider groups, less than 0.5% of the minor abortion-related complications were immediate and the remaining were delayed (n=157) with 1.3% in the clinician group and 0.8% in the physician group.

Patient satisfaction

- 10,195 patient satisfaction surveys have been submitted as of December 2011.
- Patients reported an average rate of satisfaction well above 9.0 on a scale of 0-10 (0=Completely Unsatisfied, 10=Completely Satisfied), whether they were seen by a NP, CNM and PA (mean=9.4) or a physician (mean=9.3).
- Patients in both provider groups reported being treated well on a scale of 1-5 (1=Poor, 5=Excellent) with a mean score of 4.9.

Conclusions

- Study results from the HWPP program confirm that NPs, CNMs, and PAs can provide early abortion care that is clinically as safe as physicians.
- NPs, CNMs, and PAs can be successfully trained to competence in aspiration abortion care.
- Outpatient abortion is very safe whether it is provided by a NP, CNM, PA or a physician.

Endnotes

- ¹ Goldberg, A.B., et al., *Manual versus electric vacuum aspiration for early first-trimester abortion: a controlled study of complication rates*. *Obstet Gynecol*, 2004. 103(1): p. 101-7.
- ² Goldman, M.B., et al., *Physician assistants as providers of surgically induced abortion services*. *American Journal of Public Health*, 2004. 94(8): p. 1352-7.
- ³ Hakim-Elahi, E., H.M. Tovell, and M.S. Burnhill, *Complications of first-trimester abortion: a report of 170,000 cases*. *Obstet Gynecol*, 1990. 76(1): p. 129-35.
- ⁴ Westfall, J.M., et al., *Manual vacuum aspiration for first-trimester abortion*. *Arch Fam Med*, 1998. 7(6): p. 559-62.
- ⁵ Macisaac, L. and P. Darney, *Early surgical abortion: an alternative to and backup for medical abortion*. *Am J Obstet Gynecol*, 2000. 183(2 Suppl): p. S76-83.
- ⁶ Paul, M.E., et al., *Early surgical abortion: efficacy and safety*. *Am J Obstet Gynecol*, 2002. 187(2): p. 407-11.
- ⁷ Bennett, I.M., et al., *Early abortion in family medicine: clinical outcomes*. *Ann Fam Med*, 2009. 7(6): p. 527-33.
- ⁸ Warriner, I.K., et al., *Rates of complication in first-trimester manual vacuum aspiration abortion done by doctors and mid-level providers in South Africa and Vietnam: a randomised controlled equivalence trial*. *Lancet*, 2006. 368(9551): p. 1965-72.