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HWPP #171 Final Data Update

(Data reported here represent final results from the HWPP #171 study.)

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 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 operated under the auspices of California's Office of Statewide Health Planning and Development (OSHPD) to improve health care access. Study recruitment and data collection were completed in December 2013 and the final results are presented here.

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 sought to collect data from 11,000 patients whose first-trimester aspiration abortion was provided by a NP, CNM or PA ("clinicians"), and a comparable number of patients seen by physicians (for a total sample size of approximately 20,000 patients), to compare their outcomes to published standards for abortion safety and across provider groups. Approximately 50 clinicians recruited from five organizations (including Planned Parenthood centers and Kaiser Permanente) across California were trained to competency and evaluated on safety and competency post-training.

Patients were women aged 16 or older who were seeking a first-trimester aspiration abortion at a participating clinic. Patients reviewed a consent form prior to their abortion and were asked whether they agreed to have their procedure performed by a NP, CNM or PA. Patients who declined this provision were given the option of being a part of the physician comparison group. All patients who consented to participate in the study received an anonymous satisfaction survey immediately following their abortion procedure, participated in a four-week post-procedure survey, and had 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 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% ($\pm 1\%$) and 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]

Final study results

Clinician training

- 47 NPs/CNMs/PAs were trained to competency in aspiration abortion care.
- Clinicians participated in a comprehensive didactic and supervised clinical training program, which included a written exam and competency-based evaluation process.

- Trainee competency was 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

- 11,284 first-trimester aspiration abortion procedures were completed by NPs/CNMs/PAs and 8,389 procedures were completed by physicians, for a total of 19,673 abortion procedures.
- 19,791 patients agreed to participate in HWPP #171 and less than 20% (n=2,839) of study patients who were present on a day when a participating NP/CNM/PA was available declined having the NP/CNM/PA perform their abortion procedure.

Procedure and patient outcomes:

Patient safety & satisfaction

- We rigorously monitored patient safety and tracked complications that occurred on the day of the abortion procedure or up to four weeks afterwards, including any emergency room or hospital visit.
- The primary safety measure was abortion-related complications, as determined by the project's Data and Clinical Safety Monitoring Committee (DCSMC).
- A complication was 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: 1.4% of all procedures (272 of 19,673) had abortion-related complication diagnoses; this falls well below the expected rate of 5% for total complication diagnoses. No deaths were reported during the study period at any of the clinic sites.
- Group-specific abortion-related complication rate: 1.6% for NPs, CNMs, and PAs (155 out of 9,444), and 1.1% for physicians (92 out of 8,389); this variation in complication rates between the two groups is within an acceptable clinical margin of difference.
- 96.7% (263 out of 272) of abortion-related complications were minor and completely resolved without adverse

outcomes; 9 cases were 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 included incomplete abortion, infection, hemorrhage, hematometra, and uterine perforation.
- For both provider groups, less than 0.5% of procedures resulted in immediate complications and the remaining complications were delayed (n=219) with 1.3% of all clinician-performed procedures and 0.9% of all physician-performed procedures.

Patient satisfaction

- 12,269 patient satisfaction surveys were submitted.
- Patients reported an average rate of satisfaction 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=9.4).
- 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/PAs can provide early abortion care that is clinically as safe as physicians.
- NPs/CNMs/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.
- Patients report high satisfaction during their abortion experience whether they are seen by a NP/CNM/PA or a physician.

References are provided online at www.ansirh.org/_documents/research/pci/HWPPupdate-June2012references.pdf