

Declaratory Ruling 2005-1
Replaces Declaratory Ruling 97-2

RE: The permitted role of unlicensed surgical assistants (“assistants”) in taking of the saphenous vein during coronary artery bypass graft (“CABG”) surgery.

INTRODUCTION

On March 26, 1997, the Maryland Board of Physician Quality Assurance (renamed the Board of Physicians effective July 1, 2003, “Board”) issued Declaratory Ruling 97-2 regarding the permitted role of unlicensed surgical assistants in taking of the saphenous vein during coronary artery bypass graft (“CABG”) surgery. The Board concluded:

“... a surgeon may delegate to an assistant the harvesting of the saphenous vein by the open method (this is, non-laparoscopic) during a CABG procedure as long as the surgeon is present, scrubbed, and personally performing the CABG procedure.”

In 2001 the Practice of Medicine Committee of the Board reviewed the issue of expanding this ruling to allow delegation of the endoscopic harvest of the saphenous vein to an assistant. At that time, the Committee decided not to recommend a change in the ruling, based on the relative newness of the endoscopic technique in CABG.

On July 7, 2004, R. C. Stewart Finney, M.D., Chief, Division of Cardiac Surgery at St. Joseph Medical Center requested, by letter to Carol Samuels-Botts, M.D., Chairperson of the Licensure and Practice of Medicine Committee (“Committee”), that the Board reconsider the issue of expanding the declaratory ruling by permitting delegation to an assistant of saphenous vein harvest utilizing endoscopic techniques. During the period of August 2004 through December 2004, the Committee reviewed the request and relevant materials submitted by Dr. Finney and met with him on several occasions. In January 2005, the Committee submitted to the full Board a recommendation that the Declaratory Ruling be revised. At its January 26, 2005 meeting, the Board voted to proceed to revise the Declaratory Ruling and delegated responsibility for drafting the ruling to the Licensure/Practice of Medicine Committee.

The Board is authorized to issue a declaratory ruling pursuant to State Government Article §§ 10-301 et seq.¹ and Code of Maryland Regulations (hereinafter COMAR) 10.32.16 Petition for Declaratory Ruling.²

RULING

The Board has determined that a surgeon may delegate to a properly trained unlicensed surgical assistant the harvesting of the saphenous vein by either the open method or the endoscopic method during a CABG procedure as long as the surgeon is present, scrubbed, and personally performing the CABG procedure. The chest and the legs of the patient comprise the surgical field for the CABG procedure.

The surgeon may delegate this act only to assistants who have been credentialed by the hospital by a process that contains the minimum qualifications specified within this ruling. The surgeon shall obtain the informed consent of the patient for the intended delegation. The consent form shall name this delegated act, the individual or individuals who will perform it, and their licensure status. The surgeon shall directly supervise the assistant at all times during the harvesting of the vein. The surgeon shall

¹§10-301 et seq., State Government Article, Annotated Code of Maryland.

² Code of Maryland Regulations Title 10, Subtitle 32, Chapter 10.32.16.

provide the Board, upon request, verification that the hospital has credentialed the assistant for harvesting the saphenous vein.

The minimum qualifications for an assistant harvesting a saphenous vein shall include extensive education and experience in the operating room sufficient to demonstrate knowledge of the procedure and the acquired dexterity and skills to accomplish the task.

For harvesting by the endoscopic method, the assistant shall follow the standard training requirements described below.

- Review an instructional video of the procedure.
- Dry leg model training to understand the equipment and conduct of the procedure.
- Case observation in the operating room for 5 cases.
- 20 cases performed under the instruction and direct supervision of an experienced operator

who has performed at least 100 cases.

- Annual competency review.³

The surgeon, upon request of the Board, shall show documentation that the assistant is subject to a hospital credentialing process with regular performance assessments.

At all times, the surgeon is responsible for the acts of the assistant. If the assistant is allowed to act beyond the scope of permitted delegation, the surgeon thereby is aiding in the unauthorized practice of medicine. The surgeon must determine whether to delegate this act based on the surgeon's judgment about the abilities of the assistant and may elect not to delegate the act even if the hospital has credentialed the assistant.

ANALYSIS

Section 14-306 of the Health Occupations Article, Annotated Code of Maryland, states:

³ Standard Training Procedure submitted by Stewart Finney M.D. at the request of the Committee.

“To the extent permitted by the rules, regulations, and orders of the Board, an individual to whom duties are delegated by a licensed physician may perform those duties without a license as provided in this section.”

There have been numerous studies in the past decade comparing the open versus the endoscopic methods for harvesting the saphenous vein. These studies have found that patients undergoing endoscopic harvest have fewer problems with wound healing, pain, etc. Davis *et. al.*⁴ found that endoscopically harvested saphenous veins compared favorably to traditionally harvested veins at one year and three years and concluded the endoscopic vein harvesting does not result in a higher graft failure rate.

Major cardiac centers throughout the country use surgical assistants for endoscopic vein harvest. Letters documenting positive outcomes using surgical assistants for endoscopic harvest of the saphenous vein were submitted from The Cleveland Clinic Foundation⁵, the Mayo Clinic⁶, and Washington Regional Cardiac Surgery, P.C.⁷ Union Memorial Hospital Heart Institute⁸ and Johns Hopkins Cardiac Surgery⁹ submitted letters supporting the request of the Heart Institute at St. Joseph Medical Center that the declaratory ruling be expanded to allow delegation of endoscopic harvesting of the saphenous vein by an assistant.

The Board previously acknowledged that taking of the saphenous vein during CABG is a technical repetitive procedure which does not require the person performing the procedure to exercise independent medical judgment. The Board believes that harvesting the saphenous vein endoscopically is also a technical procedure requiring no medical judgment and that it can therefore be safely delegated to

⁴ Davis Z. Garber D. Clark S. Roth H. Bufalino V. Budoff MJ. Mao S. Jacobs HK. Longterm patency of coronary grafts with endoscopically harvested saphenous veins determined by contract-enhanced electron beam computed tomography. *Journal of Thoracic and Cardiovascular Surgery*, 2004; 127:823-8.

⁵ Letter from A. Marc Gillinov, MD to Stewart Finney, MD, dated September 24, 2004.

⁶ Letter from Kenton J. Zehr, MD, to Stuart Finney, MD, dated October 12, 2004.

⁷ Letter from Jorge M. Garcia, MD, to Dr. Stewart Finney, dated October 14, 2004.

⁸ Letter from Michael Fiocco, MD dated September 16, 2004.

⁹ Letter from David D. Yuh, MD to Carol Samuels -Botts, dated September 16, 2004.

an unlicensed surgical assistant with appropriate training and supervision by a surgeon present, scrubbed, and performing surgery at the chest.

CONCLUSION

The Board recognizes that the practice of medicine develops and evolves over time. The Board reviews and considers developments in the practice of medicine within the context of its duty to protect the public. Allowing surgical assistants to harvest the saphenous vein endoscopically may result in faster recovery and fewer post-operative problems (e.g., wound healing, pain) for patients. Therefore, the Board's previous ruling is amended to allow delegation of the taking of the saphenous vein by either the traditional or endoscopic procedure during a CABG, but only within the parameters set out in this ruling.



Harry C. Knipp, M.D., FACR
Chairman

October 26, 2005

Date