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ORIGINAL RESEARCH & CONTRIBUTIONS

# Analysis of Mitral Valve Replacement Outcomes is Enhanced by Meaningful Clinical Use of Electronic Health Records

John C Chen, MD; Thomas Pfeffer, MD; Shelley Johnstone, APRN; Yuexin Chen, MA; Mary-Lou Kiley, MBA; Richard Richter, MD; Hon Lee, MD

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## Abstract

**Objective:** Cardiac surgical mortality has improved during the last decade despite the aging of the population. An integrated US health plan developed a heart valve registry to track outcomes and complications of heart valve operations. This database was used for longitudinal evaluation of mitral valve (MV) outcomes from 1999 to 2008 at four affiliated hospitals.

**Methods:** We identified 3130 patients in the Apollo database who underwent 3180 initial MV procedures. Internal administrative and Social Security Administration databases were merged to determine survival rates. Electronic health records were searched to ascertain demographics, comorbidities, and postoperative complications. Cox regression was used to evaluate mean survival and identify risk factors.

**Results:** The procedures included 1160 mechanical valve replacements, 1159 tissue valve replacements, and 861 annuloplasties. The mean age of patients undergoing these procedures was 58 ± 11 years, 69 ± 12 years, and 62 ± 12 years, respectively. Mean survival was 8.9 ± 0.1 years for mechanical valve replacement, 7.0 ± 0.1 years for tissue valve replacement, and 7.7 ± 0.1 years for annuloplasty.

Early in the study, there was a preference for implanting mechanical MVs. Beginning in 2003, more patients received tissue valve replacements rather than mechanical valves. Over time, there was an increasing trend of annuloplasty. Cox regression analysis identified the following risk factors for increased ten-year mortality: tissue valve implantation; advanced age; female sex; nonelective, nonisolated procedure; diabetes; postoperative use of banked blood products; previous cardiovascular intervention; dialysis; and longer perfusion time. Hospital location, reoperation, preoperative anticoagulation, and cardiogenic shock were not statistically significant risk factors.

**Conclusions:** When controlling for other risk factors, we observed a lower long-term survival rate for tissue valve replacement compared with mechanical valve replacement. Integrating electronic health records with existing electronic databases provided near-real-time analysis of longitudinal cardiac surgical outcomes.

## Introduction

A new federal initiative offering bonus payments to physicians who successfully implement electronic health records (EHR) launched January 2011. The premise of this initiative is that health information technology improves quality of care and lowers costs, and early signs indicate that it will successfully encourage adoption of such technology.[1,2] The Health Information Technology for Economic and Clinical Health Act offers incentive programs that pay physicians for using health information technology to improve patient care. The federal government recently issued regulations detailing how physicians and hospitals can meet standards for "meaningful use" of the technology. Physicians who meet the criteria are eligible to receive up to $44,000 over 5 years under the Medicare program or $63,750 in 6 years under the Medicaid program. Eligible hospitals could receive millions of dollars, according to the Centers for Medicare and Medicaid Services.[1-6]

Officials in the Office of the National Coordinator for Health Information Technology recently released two surveys showing that more than 40% of office-based physicians and 81% of hospitals plan to seek federal incentives for the adoption and use of EHR under Medicare and Medicaid. Of the early EHR adopters, about 80% said that they plan to enroll during the first stage of the program, from 2011 to 2012.[1]

In stage 1, physicians using certified EHR technology and participating in Medicare or Medicaid must report to the Center for Medicare and Medicaid Services 3 core measures for each patient—height, weight, and blood pressure—as well as 3 additional measures from a list of 38 options. The second stage of the 3-phase program, introduced in February 2012, is focused on improving communication among clinicians and between clinicians and patients.[7] During the next few years, the program will expand into stage 3, with additional requirements for data reporting. Incentive payments to physicians and hospitals will continue for several years and will then be gradually phased out.[2,4] Medicare proposes exercising penalties beginning in 2016 for clinicians who fail to achieve meaningful use of certified EHR technology.[2,3,5]

In our study, an integrated health care delivery system developed a registry to track outcomes and complications of heart valve operations at four affiliated hospitals located in three geographic regions. By combining patient data in a shared registry,

**John C Chen, MD,** is a Cardiothoracic Surgeon at the Honolulu Medical Center in HI. E-mail: john.c.chen@kp.org. **Thomas Pfeffer, MD,** is a Cardiovascular Surgeon at the Los Angeles Medical Center in CA. E-mail: thomas.a.pfeffer@kp.org. **Shelley Johnstone, APRN,** is an Advance Practice Registered Nurse in Thoracic Surgery at the Honolulu Medical Center in HI. E-mail: shelley.johnstone@kp.org. **Yuexin Chen, MA,** is a Surgical Outcomes Analyst for the San Diego Medical Center in CA. E-mail: yuexin.chen@kp.org. **Mary-Lou Kiley, MBA,** is a Group Leader for Surgical Outcomes and Analysis in San Diego, CA. E-mail: mary.lou.kiley@kp.org. **Richard Richter, MD,** is a Cardiovascular Surgeon at the San Francisco Medical Center in CA. E-mail: richard.richter@kp.org. **Hon Lee, MD,** is a Cardiovascular Surgeon at the Santa Clara Medical Center in CA. E-mail: hon.lee@kp.org.

our health care system was able to promote improved interregional communication among clinicians pertaining to patient outcomes and indications of best practices. The robust, integrated database was an important resource for surgeons evaluating and communicating about treatment outcomes.

## Objectives

The purpose of our study was to evaluate the feasibility of using EHRs to ascertain demographics, comorbidities, postoperative complications, and ten-year survival of patients undergoing mitral valve (MV) replacement or repair. We used our Health Plan's internal administrative databases and the Social Security Death Index to corroborate long-term patient survival after MV operations performed between 1999 and 2008.

## Methods

We retrospectively reviewed records in the Apollo Data Repository (versions 4.2.16 and 4.5.9) of patients who underwent MV surgeries between January 1, 1999, and December 31, 2008. Apollo Advance is a cardiology and vascular clinical data repository that contributes to databases of the American College of Cardiology and the Society of Thoracic Surgeons. It was developed by LUMEDX Corporation (formerly Seattle Systems, Inc) based in Oakland, CA.

The patients we studied were treated in three regions at four hospitals affiliated with Kaiser Permanente Cardiac Surgical Centers. Institutional review board approval was obtained in order to access the data and create a valve registry.

Demographic data, comorbidities, perioperative information, and postoperative complications were verified by querying the EHR. Patients undergoing initial MV surgeries were followed-up until December 31, 2009. The failure event was defined as death after the initial MV procedure. Mortality information was obtained and cross-checked between the Social Security Death Index, internal administrative databases, and EHRs.

Pearson $\chi^2$ test was used to assess differences in geographic regions of affiliated hospital, patient demographics (age, sex, body mass index, and diabetes status), and clinical variables (elective procedure, isolated procedure, preoperative anticoagulant use, use of banked blood products, preoperative cardiogenic shock, previous cardiovascular intervention, dialysis, and type of MV implant) between failure and nonfailure groups.

Cox regression analysis was applied to estimate the risk of death, adjusted for implant type, geographic region, demographic variables, and clinical characteristics. Two-sided p values less than 0.05 were considered statistically significant. Analysis was performed with SAS statistical software (SAS version 9.1.3 SP4; SAS Institute; Cary, NC).

### Study Sample

We identified 3130 patients in the Apollo database who underwent 3180 MV replacement or repair procedures: 1160 mechanical valves, 1159 tissue valves, and 861 annuloplasties. Only the first MV procedures performed were included in the analysis. Mean age was 58 ± 11 years for patients receiving mechanical valves, 69 ± 12 years for those receiving tissue valves, and 62 ± 12 years for those undergoing annuloplasty.

### Results

We identified trends in valve selection and surgical behavior during the ten year follow-up period (median follow-up period was just over five years). There was an increasing trend toward MV repair. For patients undergoing MV replacement, there was

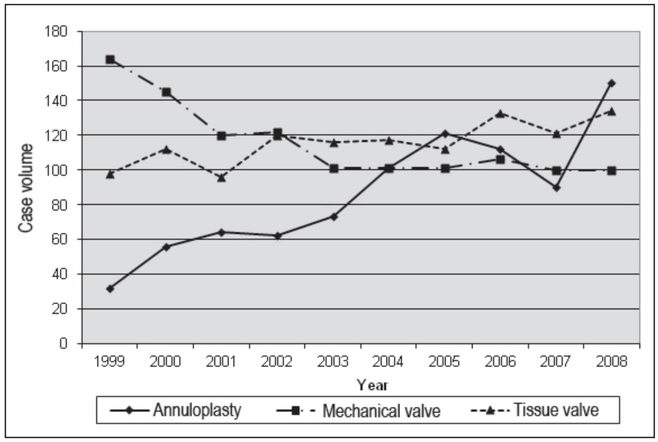


Figure 1. Annual volume of valve repairs and replacements.

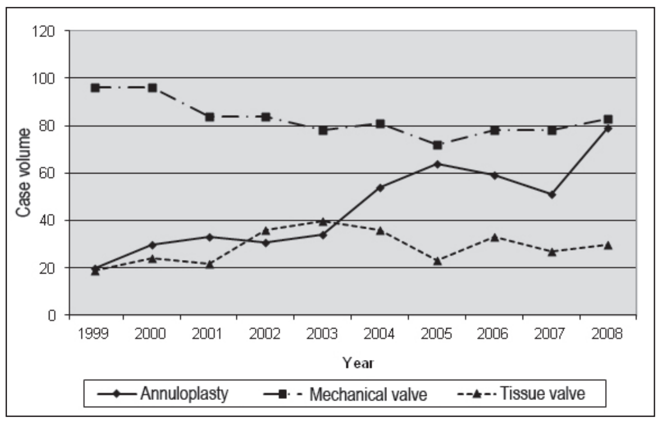


Figure 2. Annual volume of valve repairs and replacements in patients younger than age 65 years.

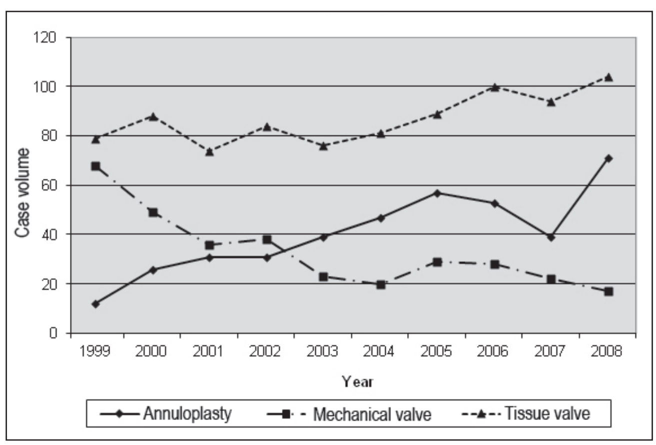


Figure 3. Annual volume of valve repairs and replacements in patients age 65 years or older.

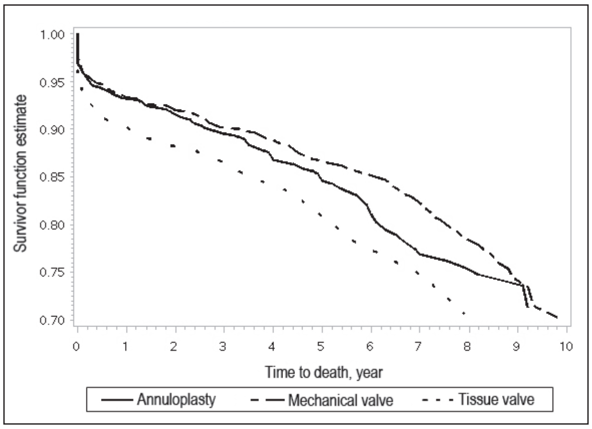

Figure 4. Cox proportional hazards regression for repair or implant type (all ages).

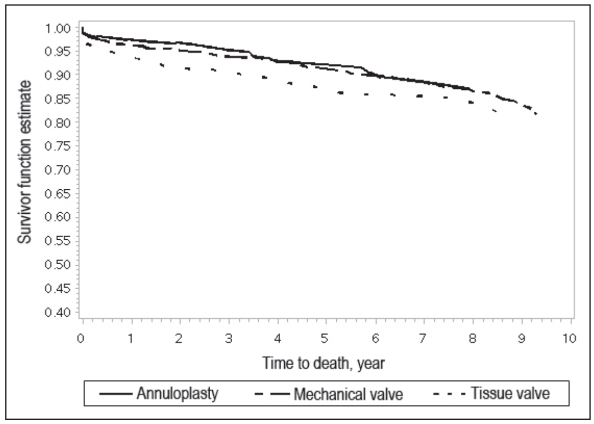

Figure 7. Cox proportional hazards regression for adjusted survival: overall death in patients younger than age 65 years.

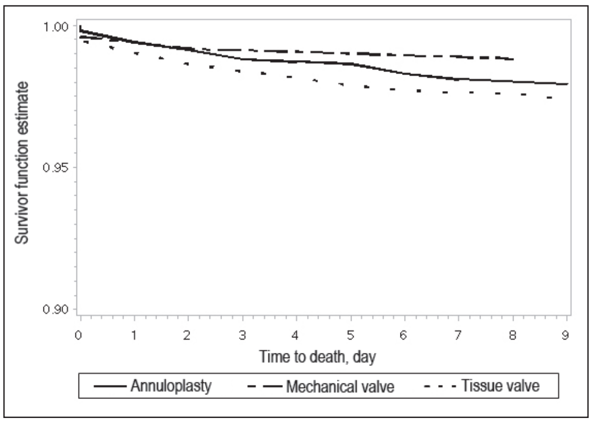

Figure 5. Cox proportional hazards regression for adjusted survival: operative death.

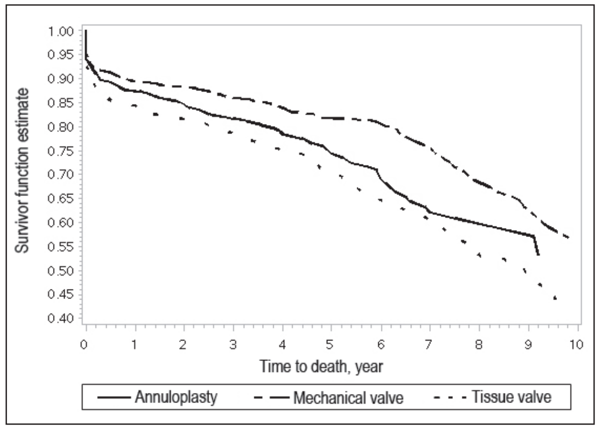

Figure 8. Cox proportional hazards regression for adjusted survival: overall death in patients age 65 years or older.

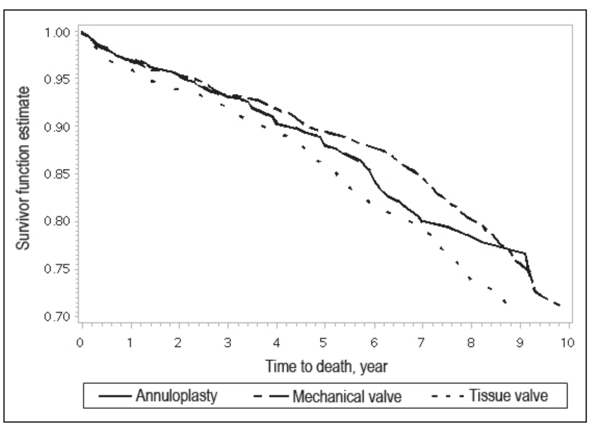

Figure 6. Cox proportional hazards regression for adjusted survival: late death.

a shift beginning in 2002 and continuing to the end of the study period, from a predominance of mechanical valves to tissue valves (Figure 1). Using our integrated database to monitor longitudinal outcomes, we were able to identify changes in the use of valve implants over time and to track patient survival.

The dominant choice for valve implants in patients younger than age 65 years has been mechanical prosthesis (Figure 2). In those age 65 years or older, there is a preference for tissue valves (Figure 3). Older patients contribute substantially to the overall increase in tissue valve use. We saw a decline in mechanical valve use in both age groups, but more so in the cohort age 65 years or older. An increasing overall trend in valve repair was seen across both age groups. We found a statistically significant difference in implant survival when comparing mechanical and tissue valves across all ages (Figure 4).

We analyzed the risk of operative death, defined as death within 30 days of operation or within the same hospitalization, for each valve procedure (Figure 5). In addition, we analyzed the risk of late death, 30 days or more after operation, for each valve type (Figure 6). There was a statistically significant increase in both operative and late death in patients receiving tissue valves, compared with those receiving mechanical valves. The difference in operative death between mechanical valve replacement and MV repair did not reach statistical significance. Patterns in overall mortality rates, defined as death at any time from the date of operation, remained consistent throughout the study period. In both age cohorts (those < 65 years and those ≥ 65 years), overall mortality was significantly higher for patients with tissue valves compared with mechanical prostheses and was not significantly different when MV repair was compared with mechanical valve replacement (Figures 7, 8).

Cox regression analysis identified the following risk factors as being associated with increased ten-year mortality: tissue valve implantation, advanced age, female sex, nonelective, nonisolated procedure, diabetes, postoperative blood bank use, previous cardiovascular intervention, dialysis, and longer perfusion time (Table 1, Figure 9). Location of hospital, reoperation, preoperative anticoagulation, and cardiogenic shock were not statistically significant (Table 1).

## Discussion

Treatment options in patients with valvular heart disease have expanded significantly in the last decade to include stentless tissue valves, homograft MVs, and more widespread use of MV repair.[8] Despite these newer procedures, valve replacement with a prosthetic mechanical valve or with porcine or pericardial xenograft valves remains the predominant procedure for patients with severe valvular heart disease.[8,9] Although several randomized studies examined differences in outcomes between patients with tissue valves and mechanical valves,[10,11] valve selection is not random in clinical practice. The appropriate type of prosthetic valve is selected primarily on the basis of patient age, comorbidities, valve position, and the risks and benefits of anticoagulation.[8] Significant insights into the performance of tissue and mechanical prosthetic valves in real-life settings can be gained through analysis of a large group of patients in whom these valves have been implanted. The primary objective of this retrospective review was to evaluate long-term survival data from a contemporary cohort of patients undergoing MV surgery during a ten-year period.

We found that the placement of mechanical MVs in patients with degenerative MV disease was associated with better long-term, risk-adjusted survival compared with tissue valve replacement. The pattern of survival benefit was unexpected, with statistically significant differences noted in operative and overall mortality. There seems to be a survival advantage of mechanical valve prostheses when we control for the factors outlined above. This benefit tends to increase over time, with the magnitude of survival difference appearing small at 30 days but clinically significant at 5-year (median) follow-up. Tissue valves are known to have durability problems when they are placed in the mitral position, requiring more late reoperations.[12-14] Mechanical valves are associated with higher rates of bleeding and thromboembolic complications.[8,15] All valve prostheses are associated with as much as a 10-fold greater incidence of endocarditis, compared with MV repair.[16]

This study had several strengths, one of which is the large sample of patients undergoing different MV operations. Another

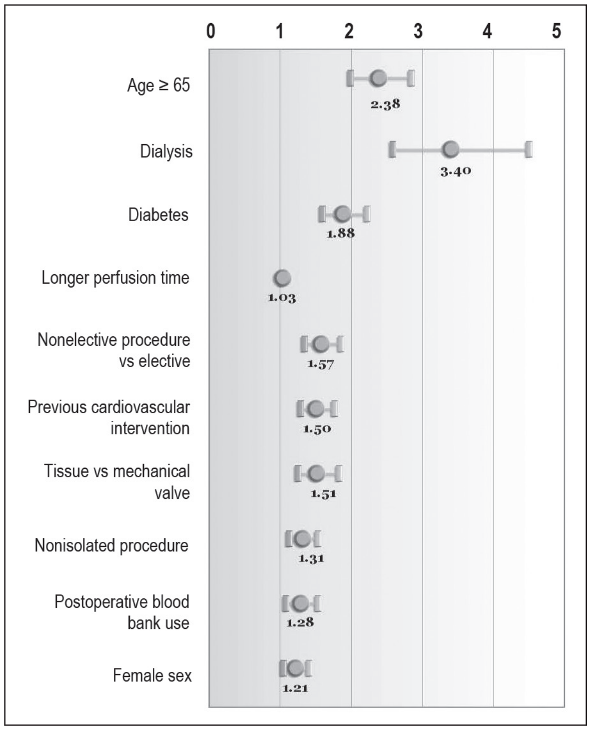


Figure 9. Hazard ratios and 95% confidence intervals of risk factors for mitral valve postoperative mortality.

**Table 1. Cox proportional hazards regression for mortality**

| Variable | Comparison | Hazard ratio | 95% CI | p value |
|---|---|---|---|---|
| Region | NCA vs SCA | 0.98 | 0.83-1.15 | 0.7975 |
| | HI vs SCA | 1.28 | 0.88-1.84 | 0.1941 |
| Age, years | ≥65 vs <65 | 2.38 | 1.99-2.84 | <0.0001 |
| Sex | Female vs male | 1.21 | 1.04-1.40 | 0.0110 |
| Elective | No vs yes | 1.57 | 1.34-1.85 | <0.0001 |
| Isolate | No vs yes | 1.31 | 1.12-1.53 | 0.0009 |
| Reoperation | Yes vs no | 1.02 | 0.63-1.66 | 0.9382 |
| Diabetes | Yes vs no | 1.88 | 1.59-2.22 | <0.0001 |
| Preoperative anticoagulant use | Yes vs no | 1.18 | 1.00-1.40 | 0.0520 |
| Postoperative blood bank use | Yes vs no | 1.28 | 1.08-1.53 | 0.0057 |
| Cardiogenic shock | Yes vs no | 1.27 | 0.84-1.93 | 0.2631 |
| Previous CV intervention | Yes vs no | 1.50 | 1.28-1.76 | <0.0001 |
| Dialysis | Yes vs no | 3.40 | 2.58-4.50 | <0.0001 |
| Perfusion time | 10-minute increments | 1.03 | 1.02-1.04 | <0.0001 |
| Repair or implant type | Tissue vs mechanical valve | 1.51 | 1.25-1.82 | <0.0001 |
| | Annuloplasty vs mechanical valve | 1.12 | 0.90-1.40 | 0.3211 |

CI = confidence interval; CV = cardiovascular; HI = Hawaii; NCA = Northern California; SCA = Southern California.

strength is the conveniently even distribution of patients across mechanical valves, tissue valves, and repairs. However, because this was an observational study of outcomes associated with treatments delivered outside a randomized trial, we cannot fully exclude residual selection bias and unexplored confounding variables, despite adjustment for a large number of established covariates. Another limitation is that, although the longitudinal ten-year outcomes were tracked, MV repairs must be carefully considered. MV repairs lack the same ten-year follow-up that is available with valve replacements. Retrospective analyses, like most observational studies, need to be interpreted within this context.

**… the placement of mechanical MVs in patients with degenerative MV disease was associated with better long-term, risk-adjusted survival compared with tissue valve replacement.**

These trends in treatments, coupled with long-term outcomes data, raise the question as to why there is an increase in tissue valve use despite what appears to be longer overall survival with mechanical valves. It is apparent that this topic needs to be investigated further. The relative merit of various prosthetic valves may become less important over time because, as our results indicate, there is a growing trend of successful MV repairs. A differential benefit of repair has been discussed in several papers[9,16] but was difficult to demonstrate in this series.

The current study did not include information pertaining to how valve choice was made, but it may be that patients within this cohort had anatomy that rendered repair difficult, such as severe Barlow valves or bileaflet prolapse. However, repair techniques continue to evolve,[9,16] and now many degenerative valves can be repaired satisfactorily so that more patients may be candidates for repair rather than replacement.

## Conclusion

We observed a lower long-term survival rate with tissue valves compared with mechanical valves when controlling for age, sex, diabetes, dialysis, isolated procedure, prior surgery, blood usage, and cardiopulmonary bypass perfusion time.

There has been a recent increasing trend in implantation of tissue valves rather than mechanical valves. Additionally, there is an overall increase in valve repair. Integrating EHR data with existing implant registry databases, supplemented by the national Social Security Death Index, allows for meaningful analysis of longitudinal outcomes. As early adopters of EHR technology in an integrated health care delivery system, we have been able to analyze recent trends in MV surgery. This method can be used by other institutions.

In the future, real-time evaluation of outcomes will provide essential guidance for treatment choices. Our increasingly educated patients and outcomes-oriented regulatory agencies expect current and accurate data to guide clinicians' recommendations. The status quo of health care in America is not sustainable; medical groups will need near-real-time measures of quality, safety, and resource use to influence best practices in an effective manner. We support the initiatives of the Centers of Medicare and Medicaid Services that recognize the value of EHR systems and foster meaningful application of this technology. ❖

**Disclosure Statement**

*Richard Richter, MD, is on the Advisory Board of Medtronic Corporation. The author(s) have no other conflicts of interest to disclose.*

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