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# ADOPTION DECISIONS FOR MEDICAL DEVICES IN THE FIELD OF CARDIOLOGY: RESULTS FROM A EUROPEAN SURVEY

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## ABSTRACT

Decisions to adopt medical devices at the hospital level have consequences for health technology assessment (HTA) on system level and are therefore important to decision makers. Our aim was to investigate the characteristics of organizations and individuals that are more inclined to adopt and utilize cardiovascular devices based on a comprehensive analysis of environmental, organizational, individual, and technological factors and to identify corresponding implications for HTA. Seven random intercept hurdle models were estimated using the data obtained from 1249 surveys completed by members of the European Society of Cardiology. The major findings were that better manufacturer support increased the adoption probability of 'new' devices (i.e. in terms of CE mark approval dates), and that budget pressure increased the adoption probability of 'old' devices. Based on our findings, we suggest investigating the role of manufacturer support in more detail to identify diffusion patterns relevant to HTA on system level, to verify whether it functions as a substitute for medical evidence of new devices, and to receive new insights about its relationship with clinical effectiveness and cost-effectiveness. © 2017 The Authors. *Health Economics* published by John Wiley & Sons, Ltd.

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## 1. INTRODUCTION

The adoption of innovations is a major topic of interest for decision makers in the area of health technology assessment (HTA) (Bryan *et al.,* 2014). One of the basic concerns of these decision makers is to balance cost containment pressures and ensure the access to innovative and effective technologies (Rye and Kimberly, 2007; Feder and Umali, 1993; Gopalakrishnan and Damanpour, 1997; Robert *et al.,* 2010). This trade-off implies a system perspective; however, in many European countries, the decisions to adopt medical technologies take place at the hospital level (Sorenson and Kanavos, 2011). In the hospitals, technology adoption is a process involving various stakeholders (Stefanidis *et al.,* 2014). These include hospital managers and (senior) physicians, where the latter play a major role in priority setting and technology adoption (Robert *et al.,* 2010; Boriani *et al.,* 2013; Gurtner, 2014; Barasa *et al.,* 2015). Understanding the factors that lead to the adoption of medical devices is especially important for health care decision makers in Europe because the regulatory barriers to market access are considerably lower for medical devices than for pharmaceuticals. European marketing authorization

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for pharmaceuticals requires a rigorous assessment of quality, safety, and efficacy, while marketing authorization for medical devices requires only a CE mark and an evaluation of clinical data for high-risk devices (Greenberg *et al.,* 2005; Robert *et al.,* 2010). As the market access barriers at the EU level are rather low, the emphasis is on understanding the mechanisms behind adoption decisions at the hospital level. In the past, one of the main questions addressed in the literature was which factors actually drive the adoption process (European Commission, 2015; Vinck *et al.,* 2007). These results were multifaceted (Vinck *et al.,* 2007), leading to the view that the answer to that question is not straightforward. Theoretical models suggest that the adoption of innovations is driven by factors on various levels (Wisdom *et al.,* 2014), and papers summarizing the available empirical evidence confirm this assertion (Ghodeswar and Vaidyanathan, 2007; Wisdom *et al.,* 2014; Straub, 2009; Greenhalgh *et al.,* 2004; Rye and Kimberly, 2007). Four different levels were identified to be especially important across studies: the environmental level, the organizational level, the individual level, and the technological level. The majority of empirical studies did not account for all of these levels, examining only one or two (Wisdom *et al.,* 2014). This led to a call for broader analyses and multilevel models considering the more complex nature of the adoption process (Fleuren *et al.,* 2004; Robert *et al.,* 2010; Rye and Kimberly, 2007). In addition to the need to allow for the complexity of adoption, there are research gaps concerning the influence of certain variables. For example, Rye and Kimberly (2007) suggested that more research is needed to clarify the role of marketing by manufacturers, the interconnectedness of adopting organizations (i.e. of people within the organizations), and the roles of physicians' values, norms, and interests.

We believe that an increased knowledge about how adoption decisions are made at the hospital level has important implications for the adoption and diffusion of medical devices for HTA on system level as well as for health economic evaluations of such devices after their initial introduction to the market (Williams and Bryan, 2007).

Therefore, the aim of this study is to conduct an extensive analysis incorporating environmental, organizational, individual, and technological factors to determine whether they influence the adoption and utilization of medical devices. Moreover, our aim is to investigate the characteristics of organizations and individuals that are more inclined to adopt medical devices; to study the role of perceived medical evidence and financial criteria at the time of the adoption decision; and to examine the role of manufacturer support and physician motivation—variables which are assumed to be important but were hardly addressed in research studies to date.

## 2. METHODS

### 2. 1. Survey development and data collection

Seven implantable cardiovascular devices/procedures were selected for the analysis: Implantable Cardioverter Defibrillator (ICD), Cardiac Resynchronization Therapy (CRT), Drug-eluting Stent (DES), Transcatheter Aortic Valve Implantation (TAVI), Renal Denervation (RD), Left Atrial Appendage Closure Device (LAA), and MitraClip (MC). These devices were chosen after consulting medical experts based on their relevance and different profiles of medical evidence and stages in the diffusion process. CE mark approval dates were used to proxy for the latter (see Table II). We referred to all devices with CE mark approval dates before 2007 as 'old' devices. All devices with CE mark approval dates since 2007 were termed 'new' devices. According to our experts, medical evidence for RD, MC, and LAA was weak or unclear. In contrast, they described the medical evidence supporting the other devices as strong or good.

The data were collected using an online survey that was incorporated into the regular ESC newsletter. The newsletter was sent to 85 568 members and affiliates of the European Society of Cardiology (ESC) with selected fields of interest (e.g. Acute Coronary Syndromes, Heart Failure, Interventional Cardiology). The factors included in the online survey were selected based on a review of the available literature. Our pre-selection was obtained from an extremely large number of potentially important drivers of the adoption and utilization of medical devices that have been identified in the literature. This pre-selection of factors was validated by a



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subsequent pilot study with 17 cardiologists from four European countries (Germany, Italy, England, and Slovenia). The pilot study was conducted via face-to-face or telephone interviews. The interviewees were asked to go through the online survey and were questioned using a semi-structured field manual. The field manual included questions on survey content, item selection/relevance, survey structure, and item wording. The interviews were audio recorded, and the answers were entered into standardized collection forms. Both the responses and feedback provided during the interviews were evaluated, and the questionnaire was revised accordingly.

The final online survey included between 6 and 54 items, depending on the path that the respondent followed through the survey (see Appendix). Respondents who indicated that they use at least one of the devices on our list were defined as adopters. Respondents who indicated that they do not use all of the devices on our list were asked whether the requirements to utilize the remaining devices are fulfilled in their hospitals. Respondents who agreed with this question were defined as non-adopters, and respondents who did not agree with this question were defined as 'excess zeros'. As a result, we compared adopters and non-adopters that had the possibility to adopt the devices on our list in our study.

The independent variables consisted of individual respondent characteristics (e.g. sex, age group, specialty, experience in cardiology or similar department), device-related factors (e.g. quality and quantity of medical evidence, trialability, costs), a validated scale with 20 items to measure four dimensions of motivation (hedonic, functional, social, cognitive) (Wisdom *et al.,* 2014), organizational factors (e.g. hospital size), and environmental factors (e.g. regional location of the hospital). The device-related factors, motivation factors, and some of the organizational factors were measured using a 5-point Likert scale with an additional 'don't know' option. That is, we measured the physicians' perceptions of these factors. Other factors were measured using yes/no answer options, choice lists, or open fields. We incorporated the number of devices utilized as a dependent variable, which made it possible to separately analyse the factors that influence adoption and utilization decisions. The online survey was distributed as a part of the ESC newsletter to ESC members and affiliates on 26/09/2014. The initial invitation to participate in the survey was followed by three reminders (sent on 23/10/2014, 19/11/2014, 09/01/2015), and the data collection phase was completed on 19/01/2015.

Additional environmental-level (i.e. country level) data were collected. The data for GDP and out-of-pocket payments in health systems were obtained from publicly available databases: World Bank Open Data, OECD Health Statistics, and WHO World Health Statistics. All data were obtained for 2012, as this was the latest available. Where necessary, currencies were transformed into US dollars using currency exchange rates dating to 01/07/2012.

### 2. 2. Data refinement and missing values

This analysis focused on hospital physicians and therefore excluded non-physicians, students, retired physicians, and physicians without hospital affiliations. Unrealistic entries (e.g. 100 years of experience) and responses from individuals who did not report a country of origin were excluded as well.

We conducted exploratory and confirmatory factor analyses to test the validity of the motivation scale. The results were satisfying and are available from the authors upon request.

Respondents were given the option to select 'don't know' answers in addition to the 5-point Likert scale options. These answers were treated as missing values (missing at random (MAR)). To avoid loss of information because of case deletion, multiple imputation was conducted (Simpson, 2002). Markov Chain Monte Carlo simulation was used for the multiple imputation procedure because no monotone missing patterns were identified via visual inspection using PROC MI (SAS Institute, Cary, NC). The literature suggests at least five imputations to produce results that appropriately reflect the uncertainty related to the imputation of missing values (Lansisalmi *et al.,* 2006). Because the optimal number of imputations is still unclear, we conducted 10. This number balanced more appropriate estimates with acceptable computing times. All analyses were conducted using PROC MI and PROC MIANALYZE in SAS 9.4 (SAS Institute, Cary, NC, USA), and Stata 13 SE (StataCorp LP, College Station, TX, USA).



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### 2. 3. Data analysis

As suggested by the literature (Vandecasteele and Geuens, 2010; Rubin, 1996), we assume that adoption and utilization decisions reflect two separate, consecutive processes. The adoption decision is made first on basis of certain factors, and the number of devices utilized is subsequently decided. Therefore, we employed count data hurdle models to analyse each of the seven cardiovascular devices. Count data hurdle models combine a binary model with a zero-truncated model (Johnson and Young, 2011; Rye and Kimberly, 2007). The flexibility of these two-part models (i) addressed more zero counts than are predicted by a standard Poisson count data model and (ii) differentiated between the adoption and the implementation decisions (Greer, 1981).

In the first part of the model, we used a logit regression to estimate the likelihood of device adoption. In the second part of the model, we used a truncated negative binomial model (type II) to estimate the number of devices utilized. The Akaike Information Criterion (AIC) and the Bayesian Information Criterion (BIC) indicated that the negative binomial model outperformed the Poisson model (Mullahy, 1986; Winkelmann and Zimmermann, 1995; d'Uva, 2006). Furthermore, the negative binomial model can handle overdispersion (i.e. the variance exceeds the mean), which we observed in our data (Saffari *et al.,* 2012). The hurdle models included 37 variables in the logit regression and 14 variables in the truncated negative binomial model. The data set was divided into seven sub-sets, one for each cardiovascular device, which formed the basis of the analyses. This was done because the cardiovascular devices in our data set did not represent substitutes or complements; hence, we assumed no interdependencies between the devices.

We accounted for the hierarchical structure of the data in all models, allowing for correlation between observations within the same country using random intercepts. The random effects were assumed to be normally distributed and to be uncorrelated with other explanatory variables. The choice of random effects over fixed effects was based on the structure of our data. Our sub-sets included a large number of singletons (i.e. countries with a single observation). The percentage of singletons in the data set ranged between 18% (for ICD) and 38% (for MC). Countries with five or fewer observations accounted for more than one-half of the observations (between 52% for ICD and 59% for MC). In a fixed effects model, such a data structure would cause problems because of small within-country variation. Random effects models are preferable in that case, even when the assumption of zero correlation between the independent variables and the random effects is violated (Burnham and Anderson, 2004). Regarding the accuracy of the parameter estimates and their corresponding standard errors, the proportion of singletons is only problematic when the number of level-two groups is too small (Kuha, 2004). For example, a low number of level-two groups (<30) and a high proportion of singletons (>30%) can cause imprecise confidence intervals for level-two predictors. However, it will not impact the precision of the confidence intervals of the first-level predictors (Min and Agresti, 2005). Although we had a relatively high proportion of singletons in some of our sub-sets, the number of groups on the second level never dropped below 60. Therefore, the estimates and standard errors obtained by these random effects models should not be biased. Empirical sandwich estimators of the covariance matrix were used to obtain robust standard errors. We used Gauss adaptive quadrature to estimate the models. All estimations were conducted using SAS PROC NLMIXED (SAS Institute, Cary, NC, USA).

The adoption and utilization of these cardiovascular devices were analysed using the following hurdle model. Let $y_{ij}$ be the number of devices adopted by the $i^{th}, i = 1, \ldots, n_i$ individual in the $j^{th}, j = 1, \ldots, mj$ country:

$$Pr\left(Y_{ij} = y_{ij}\right) = \begin{cases} w_{ij}, y_{ij} = 0 \\ \left(1 - w_{ij}\right) \dfrac{g}{1 - \left(1 + \alpha\mu_{ij}\right)^{-\alpha^{-1}}}, y_{ij}, > 0 \end{cases}$$

where $\mu_{ij} = \exp(x_{ij}\beta)$, $\alpha(\geq 0)$ is a dispersion parameter, and $x_{ij}$ is a vector of explanatory variables. Suppose that $0 < w_{ij} < 1, w_{ij}$ is modeled using a logit link function



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$$\text{logit}(w_{ij}) = \log\left(\frac{w_{ij}}{1-w_{ij}}\right) = z_{ij}\delta$$

where $z_{ij}$ is a vector of explanatory variables and

$$g = g\left(y_{ij}, \mu_{ij}, \alpha\right) = \frac{\Gamma\left(\alpha^{-1} + y_{ij}\right)}{\Gamma(\alpha^{-1})\Gamma\left(y_{ij}{}^{+1}\right)}\left(\frac{\alpha^{-1}}{\alpha^{-1}\mu_{ij}}\right)^{\frac{1}{\alpha}}\left(\frac{\mu_{ij}}{\mu_{ij}+\alpha^{-1}}\right)^{y_{ij}}$$

is the likelihood function of the negative binomial function. The hurdle models were specified as follows.

Logit part:

$$\log(w_{ij}) = \log\left(\frac{w_{ij}}{1-w_{ij}}\right) = \alpha_0 + dev_{ij}\alpha + ind_{ij}y + org_{ij}\delta + env_{ij}\zeta + country_j\eta + b_{1j}$$

where $\text{dev}_{ij}$ is a vector of covariates at the technology level, $\text{ind}_{ij}$ is a vector of covariates at the individual level, $\text{org}_{ij}$ is a vector of covariates at the organizational level, and $\text{env}_{ij}$ and $\text{country}_j$ are vectors of covariates at the environmental level. Here, α, γ, δ, ζ, and η are the corresponding vectors of parameter estimates, and $b_{1j}$ represents a random variable that is independently and normally distributed, $b_{1j} \sim N(0,\sigma^2)$.

Truncated negative binomial part:

$$\log\left(\mu_{ij}\right) = \beta_0 + dev_{ij}\beta + hosp_{ij}k + env_{ij}\xi + country_j\tau + b_{2j}$$

where $\text{dev}_{ij}$ is a vector of covariates at the device level, $\text{hosp}_{ij}$ is a vector of covariates at the organizational level, and $env_{ij}$ and $\text{country}_j$ are vectors of covariates at the environmental level. Here, β, κ, ξ, and τ are corresponding vectors of parameter estimates, and $b_{2j}$ represents a random variable that is independently and normally distributed, $b_{2j} \sim N(0,\sigma^2)$.

Additional sensitivity and subgroup analyses were conducted. In the first sensitivity analysis, we estimated the models using country fixed effects instead of random effects. To estimate the models (i.e. to ensure enough within-country variance), the singletons and countries with fewer than 20 observations were eliminated. After reducing the data sets, very few non-adopters were left for ICD, CRT, and DES, which consequently did not allow country fixed effects to be estimated in the logit parts of these models. In these cases, the model distribution was changed to a negative binomial including fixed effects. Comparing the results of the fixed effects models to our benchmark models was problematic because different data sets were used to estimate the models (the full data sets vs. the reduced data sets). Therefore, we also estimated random effects models using the reduced data. In the second sensitivity analysis, we estimated our models based on a sample restricted to complete cases to test the influence of the multiple imputation procedure. Finally, we conducted an additional subgroup analysis in which the random effects models were estimating including only the observations from the EU28 countries.

## 3. RESULTS

### 3. 1. Descriptive results

Across all mailings, 56 255 people clicked on the ESC newsletter. A total of 4922 of these clicked on the link to our survey, and 1773 people completed our questionnaire. The response rate based on the number of people who clicked on the ESC newsletter was 3%. The response rate based on the number of people who clicked on the link to our survey was 36%. After data cleansing, our final data set consisted of 1249 observations. Descriptive statistics for all of the included variables are presented in Tables I and II. Overall, the observations were clustered into 89 different countries, including all of the EU28 countries. Our sample included 81 countries (91%) which are included in the ESC members and affiliates lists. As expected, approximately 61% of



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Table I. Descriptive statistics for the included environmental-, organizational-, and individual-level covariates

| Covariates | Category/(measurement) | Mean (SD)/percentage |
|---|---|---|
| Environmental level | | |
| GDP | (US-$/10 Billion) | 143.30 (196.29) |
| Out-of-pocket payments in health system | (US-$/10 Billion) | 2.41 (3.62) |
| Hospital location | Urban | 82.23% |
| | Suburban | 12.17% |
| | Rural | 5.60% |
| Organizational level | | |
| Exp. ch. in human resources | (Likert 1–5) | 3.45 (0.84) |
| Exp. ch. in work flows | (Likert 1–5) | 3.47 (0.79) |
| Exp. ch. in the planning of activities | (Likert 1–5) | 3.37 (0.79) |
| Exp. ch. in organizational structure | (Likert 1–5) | 3.42 (0.85) |
| Relative department size | (Likert 1–5) | 3.46 (1.04) |
| Budget pressure | (Likert 1–5) | 3.80 (0.94) |
| Competitive pressure | (Likert 1–5) | 2.95 (1.01) |
| Size (beds) | 1–199 | 20.26% |
| | 200–499 | 32.35% |
| | 500–999 | 32.11% |
| | 1000–2499 | 13.93% |
| | >2499 | 1.36% |
| Individual level | | |
| Experience | (years) | 15.39 (9.64) |
| Number of visits of scientific conferences | (per year) | 6.27 (7.00) |
| Number of visits of manufacturer exhibitions | (per year) | 2.60 (3.37) |
| Number of salesman visits | (per year) | 7.13 (10.62) |
| Hedonic motivation | (score 5–25) | 19.27 (3.69) |
| Functional motivation | (score 5–25) | 20.83 (2.61) |
| Social motivation | (score 5–25) | 14.81 (4.86) |
| Cognitive motivation | (score 5–25) | 18.15 (3.56) |
| Sex | Male | 75.98% |
| Age | <36 years | 20.26% |
| | 36–45 years | 29.62% |
| | 46–55 years | 29.06% |
| | 56–65 years | 17.61% |
| | >65 years | 3.44% |
| Medical specialty | Int. car. | 23.62% |
| | Elec. | 29.14% |
| | Int. car. and Elec. | 5.20% |
| | Heart surgeon | 2.48% |
| | General cardiologist | 31.47% |
| | Other physician | 8.09% |
| Position in hospital | Chief | 19.14% |
| | Senior physician | 42.19% |
| | Attending physician | 28.66% |
| | Physician | 10.01% |
| Additional economic qualification | With qualification | 9.85% |

Likert items: higher values indicate higher agreement (1: strongly disagree; 5: strongly agree). Motivation dimensions: higher values indicate higher agreement (scores are sums from five Likert items). All values are based on complete cases.
SD: standard deviation; Exp. ch.: expected change; Int. car.: interventional cardiologist; Elec.: electrophysiologist.

physicians in the sample were chiefs of cardiology departments and senior physicians. The size of each sub-set was determined by the sum of adopters and non-adopters per device, which ranged from 459 (MC) to 1141 (ICD).

### 3. 2. Results of the hurdle models

Comparing the significant results ($p$-value $<0.05$) in the logit parts of the hurdle models across devices, three patterns were identified: significant results for the 'new' devices, that is, TAVI, RD, MC, and LAA; significant results for the 'old' devices, ICD, CRT, DES; and significant results across these two groups of devices. In the



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Table II. Descriptive statistics of the dependent variable and included covariates at the technology level

| | ICD | CRT | DES | TAVI | RD | MC | LAA |
|---|---|---|---|---|---|---|---|
| Covariates | | | | Mean (SD) | | | |
| Technology level | | | | | | | |
| Quality of medical evidence | 4.64 (0.59) | 4.53 (0.65) | 4.62 (0.59) | 4.20 (0.69) | 2.69 (0.98) | 3.50 (0.75) | 3.56 (0.86) |
| Quantity of medical evidence | 4.44 (0.73) | 4.37 (0.75) | 4.52 (0.68) | 3.93 (0.79) | 2.60 (1.01) | 3.17 (0.93) | 3.23 (0.96) |
| Manufacturer support | 4.23 (0.82) | 4.23 (0.82) | 3.90 (0.98) | 4.31 (0.77) | 3.83 (0.91) | 4.09 (0.82) | 4.09 (0.82) |
| Costs from hospital perspective | 3.88 (0.98) | 3.84 (0.98) | 3.62 (0.99) | 4.36 (0.76) | 3.92 (0.95) | 4.19 (0.82) | 4.00 (0.84) |
| Profitability | 3.87 (0.92) | 3.88 (0.91) | 3.95 (0.88) | 3.54 (1.06) | 2.80 (0.99) | 3.23 (0.98) | 3.30 (0.93) |
| Cost-effectiveness | 4.09 (0.79) | 4.10 (0.81) | 4.15 (0.80) | 3.58 (0.94) | 2.53 (1.01) | 3.18 (0.91) | 3.28 (0.90) |
| Dependent variable | | | | | | | |
| No. of devices (adopters only) | 90.3 (148.70) | 60.13 (89.35) | 691.08 (756.84) | 44.59 (63.53) | 14.12 (22.60) | 18.76 (43.87) | 14.27 (23.23) |
| No. of adopters (absolute) | 1069 | 1015 | 1059 | 474 | 396 | 227 | 356 |
| No. of non-adopters (absolute) | 72 | 92 | 32 | 136 | 225 | 232 | 256 |
| CE mark approval date (year) | 1985[†] | 2001 | 2002 | 2007 | 2008 | 2008[‡] | 2008 |

[†]The FDA approval date was used instead, as the CE mark for implantables was introduced in the EU in 1990.

[‡]We used the CE mark approval date for the Amplatzer Cardiac Plug III (St. Jude Medical; Saint Paul, Minnesota, USA) instead of the CE mark approval date of the Watchman device (Boston Scientific; Marlborough, Massachusetts, USA) because the latter was not commercialized in Europe before 2009.

All covariates at the technology level were measured using Likert scales: higher values indicate higher agreement (1: strongly disagree; 5: strongly agree). All values are based on complete cases.

ICD: implantable cardioverter defibrillator; CRT: cardiac resynchronization therapy; DES: drug-eluting stent; TAVI: transcatheter aortic valve implantation; RD: renal denervation; MC: MitraClip; LAA: left atrial appendage closure device; SD: standard deviation.





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group of 'new' devices, manufacturer support was associated with an increase of the log odds of adoption. Furthermore, physicians had higher log odds of adoption compared to chief physicians for TAVI, MC, and LAA (and for ICD). In the group of 'old' devices, higher budget pressure in the context of adoption increased the log odds of adopting ICD and CRT (the opposite result was found for LAA). Across devices, larger hospitals (ICD, CRT, DES, TAVI, MC) and urban hospital locations (ICD, CRT, DES, RD, LAA) were associated with higher log odds of adoption. Electrophysiologists had higher log odds of adoption compared to interventional cardiologists for ICD, CRT and TAVI. Better medical evidence (as perceived by the physicians) was associated with an increase in the log odds of adoption for ICD and TAVI. The parameter estimate for hospital-level costs was significant for TAVI. There were very few findings for the motivation variables and the variables capturing the expected impact of the adoption decision. Many of the other estimates were significant for only one or two devices without producing coherent patterns across devices or were not significantly different from zero.

Further results were identified in the truncated negative binomial parts of the hurdle models. In the group of 'old' devices, greater hospital size (size3: ICD, size4: ICD and DES, size5: ICD) and greater relative size of the cardiology department (department size) (ICD, CRT, DES, and LAA) were significantly associated with a higher number of devices utilized. Across devices, urban hospital location (ICD, DES, TAVI, MC), higher GDP (ICD, CRT, TAVI), and lower out-of-pocket payments (CRT, TAVI) were also associated with a higher number of devices utilized. Regarding the covariates at the device level, better perceived medical evidence increased the number of CRTs and LAAs utilized. In addition, the absence of manufacturer support increased the usage of the same devices and MC. The results for cost-effectiveness were mixed, as better perceived cost-effectiveness increased the number of DES and decreased the number of LAAs used. Tables III and IV display all results of the random intercept hurdle models.

### 3. 3. Sensitivity and subgroup analyses

First, we re-estimated the models allowing for fixed effects. Thus, a reduced data set was created to increase within-country variation. All data sets were restricted to include only countries with at least 20 observations. This reduced each data set to approximately 50% of the observations. In addition, the number of hospital size categories was reduced from five to four, as there were very few observations left in size category five, and the GDP and out-of-pocket payments variables were excluded. All logit models were estimated using cluster-robust standard errors. It was not possible to estimate logit models with country fixed effects for DES, CRT, or ICD because the number of non-adopters was too small, that is, in some countries, there were no non-adopters. For these devices, truncated negative binomial models with fixed effects were estimated. Because the comparison of the fixed effects and the random effects models was problematic because of the large differences in the sample size, the random effects models were re-estimated based on the reduced data sets. All of the findings of the fixed effects models (except the significant results for hospital size3 (ICD) and size4 (ICD, RD) in the truncated negative binomial models) were confirmed by the random effects models. However, as expected, the standard errors of the random effects models were smaller than those of the fixed effects models.

Second, we estimated the models based on complete cases to test the influence of the multiple imputation procedure on our results. Case deletion reduced the number of observations used for the analysis by a minimum of 8% (truncated negative binomial part of ICD) up to a maximum of 41% (logit part of MC). In general, the number of observations lost was higher for the new than for the old devices. Overall, it cannot be concluded that the multiple imputation procedure had a clear tendency to increase or decrease $p$-values (i.e. both occurred). As highlighted in Tables III and IV, most of our main findings remained unchanged (i.e. the effects were in the same directions and $p$-values $<0.05$). Substantial changes were observed in the logit parts of the models for the variables medical evidence, costs, cognitive motivation, senior physician, competitive pressure, expected change in work flows and in the planning of activities, suburban region, hospital size5, department size, and urban region. For these variables, our



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Table III. Results of the random intercept hurdle models (logit part)

| | Devices | | |
|---|---|---|---|
| Covariates | ICD | CRT | DES |
| Technology level | | | |
| Intercept1 | −3.35 (2.18) | −2.04 (1.58) | 3.63 (5.15) |
| Medical evidence | **0.19 (0.09)**** | 0.2 (0.11)**.** | 0.14 (0.24) |
| Man. support | 0.15 (0.16) | 0 (0.19) | −0.36 (0.27) |
| Costs | −0.04 (0.15) | −0.1 (0.16) | −0.4 (0.32) |
| Profitability | 0.24 (0.18) | 0.16 (0.15) | −0.04 (0.22) |
| Cost-effectiveness | −0.03 (0.21) | −0.14 (0.2) | 0 (0.29) |
| Individual level | | | |
| Hedonic mot. | −0.04 (0.06) | −0.08 (0.05) | .†**−0.14 (0.06)**** |
| Functional mot. | 0.12 (0.07)**.** | 0.1 (0.07) | 0.15 (0.12) |
| Social mot. | −0.01 (0.04) | −0.01 (0.04) | 0.03 (0.07) |
| Cognitive mot. | −0.08 (0.05) | −0.04 (0.04) | −0.06 (0.07) |
| Experience | 0 (0.01) | 0.02 (0.02) | 0.01 (0.03) |
| Scientific conf. | 0.05 (0.04) | 0.03 (0.02) | 0.02 (0.05) |
| Sales visits | −0.01 (0.02) | 0.01 (0.02) | 0.04 (0.03) |
| Senior phy. | 0.42 (0.33) | **0.67 (0.29)**** | −0.38 (0.61) |
| Attending phy. | 0.87 (0.53)**.** | 0.78 (0.45) | **.**0.55 (0.66) |
| Phy. | †**1.18 (0.58)**** | 0.62 (0.6) | 0.59 (1.04) |
| Elec. | †**1.45 (0.59)**** | †**1.65 (0.49)***** | −1.22 (0.76) |
| Heart surgeon | 0.88 (1.27) | 0.4 (1.04) | 0.92 (0.88) |
| Elec. and Int. car. | 1.68 (0.99)**.** | 0.53 (0.55) | 1.54 (1.29) |
| General cardio. | −0.56 (0.38) | −0.11 (0.33) | −1.31 (0.71). |
| Other physician | †**−1.05 (0.51)**** | 0.13 (0.55) | −1.04 (1.06) |
| Sex (male) | −0.03 (0.35) | 0.16 (0.25) | −0.33 (0.47) |
| Additional qual. | −0.35 (0.39) | −0.49 (0.29) | .0.55 (0.93) |
| Organizational level | | | |
| Hosp. size2 | 0.28 (0.36) | −0.18 (0.32) | 0.75 (0.46) |
| Hosp. size3 | 0.13 (0.39) | −0.02 (0.39) | 0.91 (0.61) |
| Hosp. size4 | **1.69 (0.62)**** | **1.22 (0.59)**** | †**2.07 (0.98)**** |
| Hosp. size5 | †**1.74 (0.67)**** | −0.64 (1.03) | 1.56 (1.88) |
| Department size | −0.05 (0.15) | 0.11 (0.11) | 0.41 (0.21). |
| Budget pres. | †**0.45 (0.16)**** | †**0.36 (0.13)**** | 0.12 (0.24) |
| Competitive pres. | 0.24 (0.21) | 0.08 (0.14) | 0.39 (0.25) |
| Exp. ch. hum. res. | −0.14 (0.18) | −0.23 (0.21) | 0.06 (0.35) |
| Exp. ch. work flows | −0.1 (0.23) | −0.03 (0.26) | −0.02 (0.34) |
| Exp. ch. plan. | −0.01 (0.23) | 0.11 (0.24) | 0.12 (0.41) |
| Exp. ch. org. | −0.01 (0.25) | −0.1 (0.21) | †**−0.82 (0.39)**** |
| Environmental level | | | |
| Suburban region | 0.45 (0.69) | 0.64 (0.46) | 0.59 (0.83) |
| Urban region | †**0.84 (0.4)**** | †**1.08 (0.39)**** | **1.66 (0.69)**** |
| GDP | 0 (0) | 0 (0) | 0 (0) |
| Out-of-pocket pay. | †**0.52 (0.26)**** | −0.13 (0.13) | 0.38 (0.25) |
| ICC | 0.25 | 0.14 | 0.01 |

(*Continues*)

previous findings were (partly) not confirmed (i.e. $p$-value $>0.05$), or the results occurred only in the sensitivity analysis (i.e. $p$-value $<0.05$). In the truncated negative binomial parts of the models, substantial changes were observed for the variable manufacturer support and hospital size3. The other results remained mostly unchanged.

Third, the major findings of the first subgroup analysis (only EU28 observations) were identical to the base case random effects models for greater hospital size, electrophysiologists and budget pressure (i.e. the effects were in same direction and had p-values $<0.05$). Fewer results were found for the role of manufacturer support (which was significant only for TAVI and LAA), urban hospital location (only



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Table III. (Continued)

| | Devices | | | |
|---|---|---|---|---|
| Covariates | TAVI | RD | MC | LAA |
| Technology level | | | | |
| Intercept1 | †**−5.36 (2.03)**** | **−3.27 (1.44)**** | †**−6.44 (1.69)***** | **−3.35 (1.26)**** |
| Medical evidence | **0.29 (0.11)**** | 0.12 (0.07) | 0.14 (0.09) | 0.05 (0.08) |
| Man. support | †**0.55 (0.2)**** | †**0.37 (0.15)**** | †**0.47 (0.17)**** | †**0.47 (0.13)***** |
| Costs | **−0.39 (0.19)**** | 0.28 (0.14)**.** | 0.06 (0.16) | −0.17 (0.13) |
| Profitability | 0 (0.16) | 0.11 (0.14) | 0.15 (0.15) | 0.11 (0.15) |
| Cost-effectiveness | −0.04 (0.19) | −0.09 (0.16) | −0.14 (0.19) | −0.03 (0.17) |
| Individual level | | | | |
| Hedonic mot. | †**−0.1 (0.05)**** | −0.01 (0.03) | 0.01 (0.04) | −0.02 (0.03) |
| Functional mot. | 0.05 (0.07) | 0.03 (0.05) | 0.04 (0.05) | 0.02 (0.04) |
| Social mot. | †**−0.07 (0.04)**** | −0.05 (0.03) | −0.01 (0.03) | 0 (0.03) |
| Cognitive mot. | 0.08 (0.05)**.** | 0.02 (0.04) | −0.06 (0.06) | 0.03 (0.03) |
| Experience | 0.03 (0.02) | 0.01 (0.01) | 0.03 (0.02) | 0.01 (0.02) |
| Scientific conf. | 0.01 (0.02) | −0.01 (0.01) | −0.01 (0.01) | 0 (0.01) |
| Sales visits | −0.01 (0.01) | 0 (0.01) | −0.02 (0.01) | 0 (0.01) |
| Senior phy. | 0.5 (0.32) | **−0.55 (0.23)**** | 0.05 (0.29) | 0 (0.35) |
| Attending phy. | †**1.48 (0.42)***** | −0.21 (0.29) | 0.78 (0.41)**.** | 0.63 (0.4) |
| Phy. | †**1.58 (0.64)**** | 0.42 (0.44) | †**1.35 (0.5)**** | †**1.12 (0.48)**** |
| Elec. | **0.82 (0.33)**** | −0.19 (0.42) | 0.59 (0.5) | −0.09 (0.37) |
| Heart surgeon | 1.49 (0.84) | −0.86 (0.73) | 0.68 (0.55) | 0.33 (0.55) |
| Elec. and Int. car. | 0.04 (0.54) | −0.03 (0.46) | −0.4 (0.38) | 0.2 (0.58) |
| General cardio. | 0.39 (0.48) | −0.77 (0.41). | 0.49 (0.35) | 0.17 (0.43) |
| Other physician | 0.98 (0.57) | −0.22 (0.56) | †**1.06 (0.44)**** | −0.06 (0.57) |
| Sex (male) | 0.27 (0.31) | −0.27 (0.29) | 0.15 (0.26) | 0.01 (0.23) |
| Additional qual. | −0.23 (0.39) | −0.02 (0.27) | 0.36 (0.39) | 0.27 (0.49) |
| Organizational level | | | | |
| Hosp. size2 | 0.2 (0.39) | 0.52 (0.34) | 0.57 (0.39) | 0.43 (0.26)**.** |
| Hosp. size3 | 0.6 (0.49) | 0.52 (0.4) | 0.84 (0.44)**.** | **0.7 (0.34)**** |
| Hosp. size4 | †**1.51 (0.41)***** | 0.57 (0.4) | †**1.34 (0.36)***** | 0.66 (0.39)**.** |
| Hosp. size5 | 1.52 (0.82)**.** | 1.1 (0.72) | 1.54 (0.88)**.** | 1.32 (0.9) |
| Department size | −0.03 (0.16) | 0.13 (0.13) | 0.18 (0.16) | −0.06 (0.12) |
| Budget pres. | 0.12 (0.15) | −0.15 (0.14) | −0.1 (0.1) | **−0.18 (0.09)**** |
| Competitive pres. | 0.2 (0.14) | **0.3 (0.12)**** | −0.15 (0.16) | 0.04 (0.09) |
| Exp. ch. hum. res. | 0.12 (0.19) | †**−0.38 (0.17)**** | −0.06 (0.16) | −0.26 (0.18) |
| Exp. ch. work flows | 0.27 (0.22) | −0.04 (0.16) | **0.37 (0.15)**** | **0.27 (0.13)**** |
| Exp. ch. plan. | −0.09 (0.22) | 0.25 (0.18) | 0.11 (0.19) | 0.1 (0.14) |
| Exp. ch. org. | −0.13 (0.23) | −0.06 (0.19) | −0.31 (0.2) | −0.13 (0.14) |
| Environmental level | | | | |
| Suburban region | −0.17 (0.53) | **1.05 (0.5)**** | 0.06 (0.55) | **0.96 (0.47)**** |
| Urban region | 0.57 (0.4) | **0.79 (0.39)**** | 0.44 (0.58) | **0.82 (0.41)**** |
| GDP | 0 (0.01) | 0 (0) | †**0.01 (0)***** | 0 (0) |
| Out-of-pocket pay. | −0.07 (0.28) | −0.11 (0.19) | †**−0.64 (0.14)***** | −0.13 (0.21) |
| ICC | 0.33 | 0.15 | 0.14 | 0.21 |

Significance: '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1. Values displayed are parameter estimates with standard errors in parentheses. A positive value indicates a positive relationship of the variable with the likelihood of device adoption.
†These results were also significant ($p$-value $<0.05$) when using complete cases only to estimate the models
ICD: implantable cardioverter defibrillator; CRT: cardiac resynchronization therapy; DES: drug-eluting stent; TAVI: transcatheter aortic valve implantation; RD: renal denervation; MC: MitraClip; LAA: left atrial appendage closure device; Man.: manufacturer; mot.: motivation; conf.: conference; Phy.: physician; Elec.: electrophysiologist; Int. car.: interventional cardiologist; qual.: qualification; Hosp.: hospital; pres.: pressure; Exp.: expected; ch.: change; hum. res.: human resources; plan.: planning of activities; org.: organizational structure; pay.: payment; ICC: intraclass correlation coefficient (the proportion of between country variance of the total variance).

significant for CRT), costs (only significant for RD), and medical evidence (significant for TAVI and CRT but no longer for ICD). The former results for the physician and suburban location variables disappeared. In the truncated negative binomial models, greater hospital size, greater relative department size,



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Table IV. Results of the random intercept hurdle models (truncated negative binomial part)

| | Devices | | |
|---|---|---|---|
| Covariates | ICD | CRT | DES |
| Technology level | | | |
| Intercept2 | †**2.36 (0.52)***** | †**1.63 (0.48)***** | †**4.77 (0.35)***** |
| Medical evidence | 0 (0.06) | †**0.12 (0.05)**** | 0.05 (0.04) |
| Man. support | −0.01 (0.05) | **−0.12 (0.06)*** | −0.03 (0.04) |
| Costs | 0.01 (0.04) | 0.07 (0.04) | −0.03 (0.03) |
| Profitability | 0.04 (0.05) | 0.02 (0.05) | 0.02 (0.05) |
| Cost-effectiveness | 0.03 (0.07) | 0.06 (0.06) | †**0.11 (0.04)**** |
| Organizational level | | | |
| Hosp. size2 | 0.1 (0.14) | −0.12 (0.11) | 0.14 (0.11) |
| Hosp. size3 | **0.29 (0.15)*** | −0.06 (0.17) | 0.09 (0.11) |
| Hosp. size4 | †**0.45 (0.19)*** | 0.2 (0.16) | †**0.36 (0.14)**** |
| Hosp. size5 | †**0.69 (0.24)**** | 0.43 (0.23). | 0.49 (0.25)**.** |
| Department size | †**0.13 (0.05)**** | †**0.14 (0.04)***** | †**0.12 (0.04)**** |
| Environmental level | | | |
| Suburban region | 0.05 (0.19) | 0.05 (0.27) | 0.05 (0.12) |
| Urban region | †**0.62 (0.17)***** | 0.47 (0.25). | †**0.31 (0.09)***** |
| GDP | **0.01 (0)*** | †**0.01 (0)*** | 0 (0) |
| Out-of-pocket pay. | −0.25 (0.13)**.** | †**−0.26 (0.1)**** | −0.13 (0.08)**.** |
| ICC | 0.45 | 0.42 | 0.41 |

| | Devices | | | |
|---|---|---|---|---|
| Covariates | TAVI | RD | MC | LAA |
| Technology level | | | | |
| Intercept2 | †**2.69 (0.64)***** | 1.03 (0.7) | **1.75 (0.68)*** | 1.1 (0.72) |
| Medical evidence | 0.05 (0.03) | 0.07 (0.05) | 0.09 (0.06) | †**0.18 (0.04)***** |
| Man. support | −0.09 (0.1) | 0.06 (0.08) | **−0.28 (0.13)*** | †**−0.21 (0.1)*** |
| Costs | −0.02 (0.07) | 0.06 (0.08) | −0.02 (0.08) | −0.05 (0.07) |
| Profitability | 0.07 (0.05) | −0.06 (0.06) | 0.1 (0.11) | †**0.17 (0.07)*** |
| Cost-effectiveness | −0.06 (0.05) | −0.03 (0.09) | 0.06 (0.11) | †**−0.21 (0.1)*** |
| Organizational level | | | | |
| Hosp. size2 | −0.05 (0.25) | 0.13 (0.2) | −0.2 (0.25) | 0.31 (0.2) |
| Hosp. size3 | 0 (0.28) | 0.12 (0.27) | −0.07 (0.25) | 0.13 (0.25) |
| Hosp. size4 | 0.06 (0.29) | 0.29 (0.29) | −0.08 (0.22) | 0.11 (0.16) |
| Hosp. size5 | 0.31 (0.36) | 0.12 (0.43) | †**−1 (0.4)*** | 0.13 (0.28) |
| Department size | 0.02 (0.04) | 0.1 (0.07) | 0.02 (0.09) | **0.13 (0.06)*** |
| Environmental level | | | | |
| Suburban region | 0.13 (0.2) | −0.07 (0.46) | 0.89 (0.5)**.** | 0.27 (0.55) |
| Urban region | **0.3 (0.15)*** | 0.23 (0.36)† | **0.9 (0.33)**** | 0.6 (0.5) |
| GDP | †**0.01 (0)***** | 0 (0) | 0 (0) | 0 (0) |
| Out-of-pocket pay. | †**−0.45 (0.13)***** | −0.12 (0.15) | −0.18 (0.18) | −0.14 (0.1) |
| ICC | 0.38 | 0.36 | 0.41 | 0.20 |

Significance:'***' 0.001'**' 0.01'*' 0.05 '.' 0.1. Values displayed are parameter estimates and standard errors in parenthesis. A positive value indicates a positive relationship of the variable with device utilization.
†These results were also significant ($p$-value $<0.05$) when using complete cases only to estimate the models.
ICD: implantable cardioverter defibrillator; CRT: cardiac resynchronization therapy; DES: drug-eluting stent; TAVI: transcatheter aortic valve implantation; RD: renal denervation; MC: MitraClip; LAA: left atrial appendage closure device; Man.: manufacturer; Hosp.: hospital; pay.: payment; ICC: intraclass correlation coefficient (the proportion of between country variance of the total variance).

urban hospital location, and higher GDP were also associated with higher device utilization, while there were fewer results for the role of medical evidence (only significant for LAA). The results for manufacturer support and GDP remained unchanged.



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## 4. DISCUSSION

This study represents a comprehensive analysis of factors driving the adoption and utilization of cardiovascular medical devices. We investigated drivers at four different levels (i.e. environmental, organizational, individual and technological) and identified patterns across devices, although the results of the random effects hurdle models were multifaceted. Our data were predominantly based on responses from chief and senior physicians but also included responses from attending physicians and physicians (39%). Readers might wonder how adoption decisions can be influenced by attending physicians and physicians. Although it is probably true that chief and senior physicians have a higher formal impact on the adoption decision, lower ranking physicians do influence adoption priority setting processes (Barasa *et al.,* 2015; Wernz *et al.,* 2014). Therefore, we are convinced that the responses from attending physicians and physicians added substantial value to our adoption study and should not be disregarded.

The devices that were chosen for this study differed by stage in the diffusion process. The hurdle models revealed that certain factors are associated with a higher adoption probability for some devices in our sample but not for others. This finding leads to the assumption that there are differences in the adoption and utilization behaviours of physicians according to the length of time that the cardiovascular device has been on the market. In the group of 'new' devices, better manufacturer support (as perceived by the physicians) was associated with a higher probability of adoption. In the group of 'old' devices, there were no significant findings for manufacturer support. With manufacturer support, physicians might be able to 'test' a new device that seems promising for the treatment of patients (Harrington and Califf, 2010; DiPaola *et al.,* 2014). This implies that manufacturers' activities might even function as some kind of substitute for (strong and unambiguous) medical evidence which is often not available for new devices (Clark and Linzer, 2014; Maas and Hox, 2005).

We did not find that perceived medical evidence was a major driver of adoption. Its association with adoption was only significant for ICD and TAVI (and this result was not stable in all of our sensitivity analyses). However, this does not mean that medical evidence is irrelevant to cardiovascular device adoption. Instead, our finding is largely a matter of our research question. In the survey, we asked adopters and non-adopters to state the reasons for adopting or not adopting a specific device. We found that adopters and non-adopters had similar perceptions of the devices' medical evidence, respectively. If we had asked the respondents to state the reasons for adopting one of the devices in our list instead of another, they probably would have chosen one of the devices with better perceived medical evidence (e.g. ICD; CRT, DES instead of RD, MC, LAA). This makes clear that our finding holds for comparisons of adopters and non-adopters regarding a particular device but that it cannot be extended to settings in which different devices are compared.

When examining the factors that influence the number of devices utilized, there were two significant findings for medical evidence (CRT, LAA). In both cases, an increase in the perceived medical evidence supporting these devices was associated with an increase in the number of devices adopted. Again, the assumption that medical evidence is a major driver of adoption was only weakly supported.

Manufacturer support was associated with a lower number of CRTs, MCs and LAAs utilized. However, this result was not confirmed for CRTs and MCs in the sensitivity analysis based on complete cases and should therefore be treated with care.

Economic and financial aspects of the device (i.e. costs, profitability and cost-effectiveness) are often suggested to be important drivers of device adoption and utilization (Bell *et al.,* 2010; Barasa *et al.,* 2015; Greenberg *et al.,* 2005; Mylotte *et al.,* 2013); however, our findings do not support this assumption. So far, this is consistent with the results of other empirical studies (Henschke *et al.,* 2010; Greenhalgh *et al.,* 2004). The only significant estimate for costs in the context of initial adoption (logit models) was found for TAVI, and it disappeared in our sensitivity analysis. Cost-effectiveness was significant for DES and LAA for device utilization, but the parameter estimates had opposite signs. A reason for these results might be that physicians are uncertain about financial figures. This was indicated by the high percentage of missing values (based on



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the percentage of 'don't know' answers) for the financial criteria (up to 26%). In contrast, the percentage of missing values for medical evidence was much lower (the maximum was 7% missing values for the quality of medical evidence for MC), which indicates that physicians are much more confident about their perceptions of clinical information.

Other organizational- and environmental-level factors were found to be significant and associated with adoption and utilization across several devices, including budget pressure for ICD, CRT, and LAA. If budget pressure is influencing the adoption decision, the adoption probability of ICD and CRT is higher. We interpret this result as a reflection of the economic reasoning of the physicians. Physicians who are under budget pressure might be more inclined to adopt established devices such as ICD and CRT because they are less expensive and the corresponding reimbursement is predictable. Over time, patent expiry and manufacturer competition lead to lower device prices and reimbursement systems have had time to fully incorporate device costs. In contrast, low budget pressure might foster the adoption of new devices which are rather expensive and for which reimbursement might not yet be fully established (we found a significant relationship for LAA in the base case model and the subgroup analysis ($p$-value $<0.5$) but not in the sensitivity analysis based on complete cases). This is in line with the assumption that budget pressure is related to the availability of 'slack resources' in a hospital, which were found to be associated with a higher adoption probability of new, and therefore more experimental, devices (Boriani *et al.,* 2013; Cappellaro *et al.,* 2011; Damanpour and Schneider, 2009; Rye and Kimberly, 2007). However, readers should note we did not model a potential adoption trade-off across devices. Instead, one has to interpret the effect of budget pressure on device adoption on a single devices basis.

Variables such as greater hospital size and urban hospital location (compared to rural location) were associated with an increased adoption probability (ICD, CRT, DES, TAVI, MC and ICD, CRT, DES, RD, LAA). In terms of device utilization, these variables, as well as relatively larger cardiology departments, higher GDP and lower out-of-pocket payments, were related to higher device utilization, especially in the group of 'old' devices. Although the sensitivity analysis based on complete cases slightly weakened these findings, they generally confirm what is known from the literature. That is, relatively larger departments in larger hospitals that are located in more urban regions, which are often academic teaching institutions or university hospitals, are more likely to adopt and utilize a higher numbers of devices (Greenhalgh *et al.,* 2004; Ghodeswar and Vaidyanathan, 2007; Nystrom *et al.,* 2002; Wisdom *et al.,* 2014).

The organizational impact of adoption (i.e. expected changes in human resources, work-flows, planning activities, and organizational structures) did not appear to be relevant to the adoption of devices. For TAVI, it has been argued that organizational impact is of paramount importance to the diffusion of the technology and cannot be neglected (Sorenson *et al.,* 2011). However, our results reveal that clinicians either do not consider or are unaware of this challenge. Another reason might be that the organizational impact of adoption was measured on organizational and not on device level. This decision was based on considerations related to the feasibility of the survey (i.e. we incorporated four questions instead of 28) and on the assumption that the organizational impact of implantable and catheter based cardiovascular devices (i.e. DES, TAVI, RD, MC, LAA) is comparable.

Physicians' motivation to adopt was not found to be a relevant factor of cardiovascular device adoption. A reason could be that physicians' personal motivation is superimposed by the interests of hospital managers. If hospital managers exert their influence on adoption decisions, physicians might have to make compromises which might decrease the relevance of physicians' motivation to adopt. However, we believe that this depends on the decision-making processes in hospitals and that a closer look at this topic is necessary to fully understand the role of physicians' motivation to adopt medical devices.

Some readers might wonder about the implicit similarities of our study design and established social cognitive theories such as the theory of reasoned action (TRA) (Fishbein and Ajzen, 1975), the theory of planned behaviour (TPB) (Ajzen, 1985), the Technology Acceptance Model (TAM) (Davis, 1986; Venkatesh



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and Davis, 2000; Venkatesh and Bala, 2008), and the unified theory of acceptance and use of technology (UTAUT) (Venkatesh *et al.,* 2003). All of these theories were developed to explain behaviour, behavioural intention to use, or use behaviour on individual level. Although a relationship between the variables included in our study and the mentioned theories can be found, we did not base our study on one of these theories because they were not designed to capture the specific characteristics of the health care context. For example, TAM and UTAUT were developed in a consumer context to explain information technology acceptance, the theories include individual level variables only, and they do not consider the important characteristics of physicians' adoption situations (e.g. the trade-off between physicians' and patients' interests, the divergence between adopter and end user, the possibility of group decision making in hospitals, the strong impact of health care system conditions on adoption decisions such as market access restrictions and reimbursement etc.). Therefore, we decided against building our study upon the mentioned theoretical frameworks. However, we are convinced that a new or adapted theoretical framework would add value to adoption research in health care.

Taken together, the results of this study contribute to the literature regarding several important aspects. To the best of our knowledge, this study is based on one of the largest surveys available (Ghodeswar and Vaidyanathan, 2007), covering up to 89 countries and seven cardiovascular devices. Answering the call for broad analyses (Bech *et al.,* 2009; Arribas *et al.,* 2014; Fleuren *et al.,* 2004; Berta *et al.,* 2005), our study considered factors at four different levels. This includes factors at the innovation level, which have rarely been studied (Robert *et al.,* 2010). Furthermore, gaps in the literature, such as the role of manufacturer activities (included as the manufacturer support variable) and the role of physician motivation in the adoption of medical devices, have been addressed by our paper. Overall, our results were multifaceted, but they offered new insights into the roles of some major variables (i.e. medical evidence, financial aspects, manufacturer support) while confirming findings from other studies (e.g. the relevance of organization size, hospital location and GDP for the adoption of medical devices).

This study is also subject to limitations. First, our response rate was rather low if one includes the number of people who clicked on the ESC newsletter in the denominator (3%). However, the response rate was much higher if considering the number of clicks on the link to the survey in the denominator (36%). We recommend using the latter number because physicians who have not noticed the link to our survey in the ESC newsletter do not represent potential participants. Nevertheless, a low response rate might be a source of non-response bias. Therefore, we conducted visual inspection to compare our data to the ESC data. We compared the numbers of observations from the different countries in our data set to the numbers of members in the ESC member and affiliate societies as published on the ESC website. Although our data set contained more responses from some ESC member societies (e.g. Italy, Spain) and fewer responses from ESC affiliate societies (e.g. Japan, Brazil, Chile, Argentina), the overall differences between both data sets were small which lowers the probability of a substantial non-response bias. A possible explanation for the differences might be found in existing language barriers especially in the ESC affiliate societies. Second, our data structure did not allow for the estimation of fixed effects models using the original data set; only a fraction of the overall observations were used. This complicated the comparison with our base case random effects model. However, estimating the fixed effects models was still useful in the sensitivity analysis because the comparison of these fixed effects models and random effects models based on the reduced data sets revealed that both types of model yield similar results. Therefore, a general advantage of fixed effects models, that unobserved sources of variation are allowed to correlate with the explanatory variables in the model (Lansisalmi *et al.,* 2006), did not seem to be overly important. Third, the percentage of missing values (the proportion of 'don't know' answers) was rather high for some device-related factors, especially for the financial variables for RD, MC, and LAA. This indicates that physicians are uncertain of these figures. Although we corrected for this bias using multiple imputation, we did not find a clear pattern concerning the influence of financial variables on the adoption or utilization of cardiovascular devices. However, it is possible that these findings change when a target



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population with more certainty about financial aspects (e.g. hospital managers) is used to study adoption. Therefore, future studies should discuss this topic in the context of our results. Fourth, the scale used to measure physicians' motivations for adoption was originally developed in a consumer context. We incorporated the scale developed by Vandecasteele and Geuens (2010) because, to the best of our knowledge, no specific scale has been developed and validated in a medical context to measure physician motivation. Although results of the factor analyses were satisfying, we recommend that future researchers use more specific and validated scales for measuring physicians' motivation, if these are available.

## 5. CONCLUSIONS AND IMPLICATIONS FOR HTA OF MEDICAL DEVICES

In this study, we used a broad approach to analyse the effects of selected factors on the adoption and utilization of cardiovascular devices.

Our findings have several implications for HTA of medical devices. We found evidence that the role of external stakeholders (i.e. through manufacturer support) is highly important and should be further investigated. Manufacturer support was identified as a major driver of physicians' decisions to adopt new devices. We assume that manufacturers conduct activities targeting certain physicians or hospitals (Brennan *et al.,* 2006) that are the starting point for subsequent diffusion processes. Furthermore, manufacturers probably target the hospitals that are of greater size and located in urban areas. We recommend investigating the types and forms of such activities in more detail and across different kinds of medical devices to help decision makers to get a better understanding of the diffusion patterns of newly introduced medical devices and about the relationship between manufacturer support and key individuals or hospitals in the diffusion process.

The role of manufacturer support is also relevant for the health economic evaluation of medical devices. Assuming that manufacturer support is provided in the form of hands-on tests, educational, and learning activities (Harrington and Califf, 2010; DiPaola *et al.,* 2014; Steinman *et al.,* 2012), it functions as a substitute for medical evidence and reduces uncertainty. This refers especially to medical devices that were recently introduced to the market because sufficient medical evidence, that is, data on efficacy and effectiveness, are often not available for such devices (Avorn and Choudhry, 2010; Schreyogg *et al.,* 2009). Thus, manufacturer support may impact the effectiveness of a medical device through learning and therefore also has an effect on cost-effectiveness analyses. Quantifying these effects could provide new insights into the relationship of manufacturer support with learning effects and cost-effectiveness.

Although our findings supporting the relevance of medical evidence are scarce, its role should not be disregarded. Our descriptive results demonstrate that physicians differentiate between the quality and quantity of medical evidence of the different cardiovascular devices. However, we also found that adopters and non-adopters do not have different perceptions of the medical evidence regarding a particular device (i.e. both groups assess a device's medical evidence to be equal). A reason might be that published results are likewise available to adopters and non-adopters (although this does not seem to hold for information in the form of manufacturer support). If adopters and non-adopters have similar perceptions of this evidence, then it cannot be a relevant factor for the adoption decision of a particular device on individual or organizational level. Instead, it might rather function as a 'threshold' factor and a factor influencing the adoption rate in the system. We suppose that a similar mechanism explains the results for the financial criteria. Decision makers could use this information to prioritize other variables (e.g. manufacturer support) if they want to know why some physicians or hospitals adopt medical devices and others do not and to identify diffusion patterns. However, to forecast the adoption rate and extent of diffusion throughout the system of a particular device, medical evidence and financial criteria (and especially their changes over time) will need to be considered.



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## APPENDIX: MEDTECHTA QUESTIONNAIRE

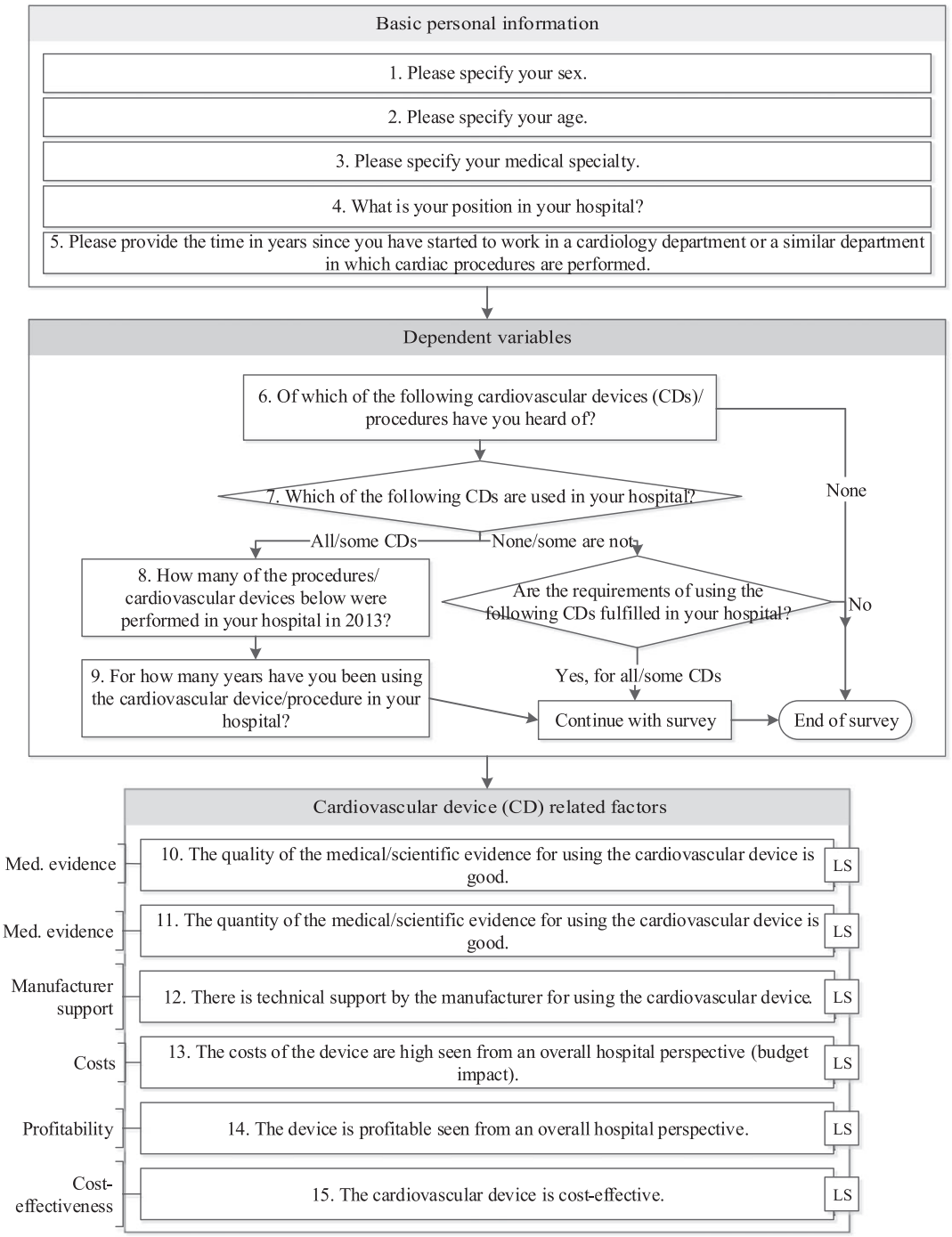


**Figure** Schematic representation of the MedtecHTA survey

LS=This item was measured on a 5-point Likert scale with an additional "don't know" option



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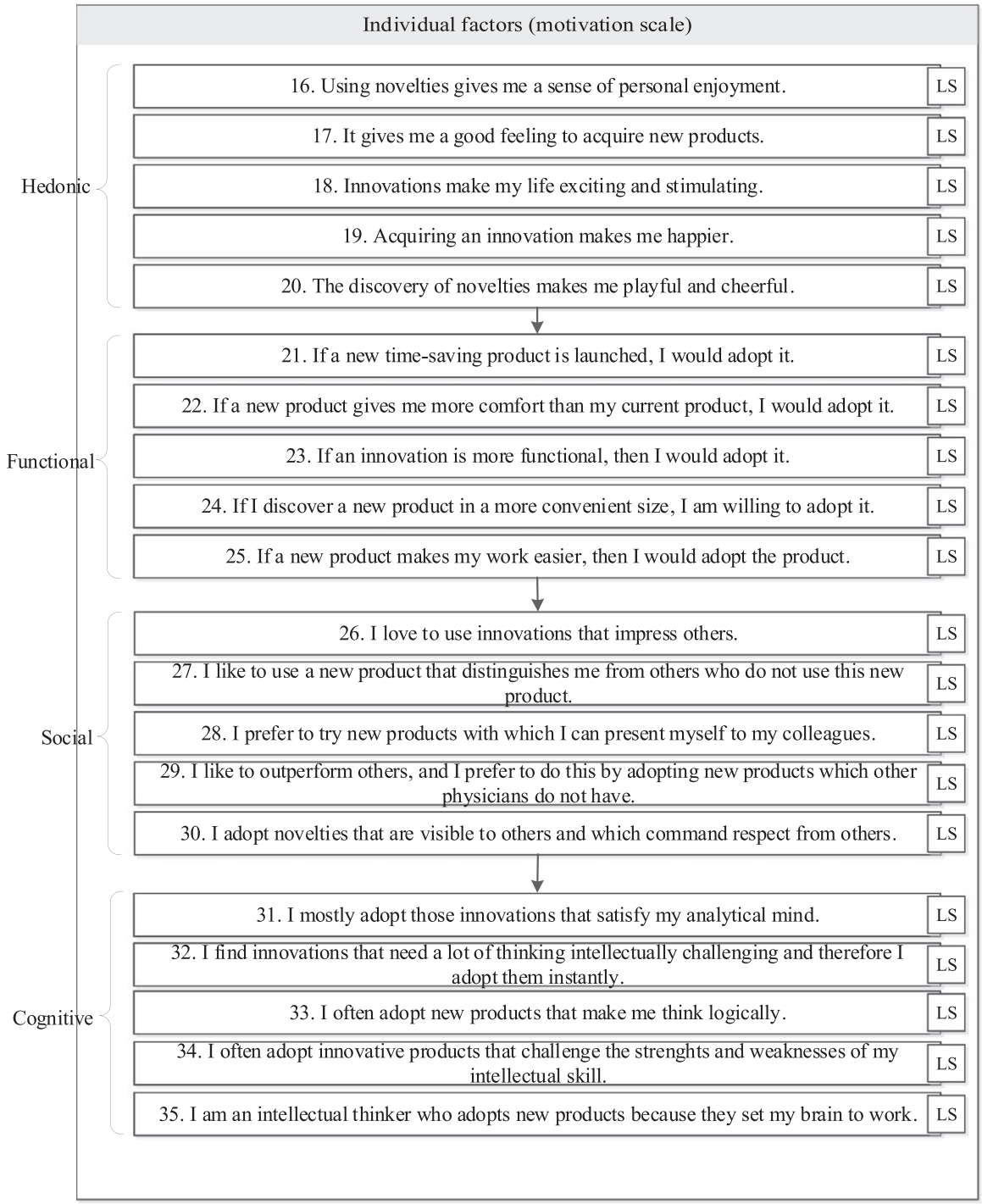


**Figure continued** Schematic representation of the MedtecHTA survey

LS=This item was measured on a 5-point Likert scale with an additional "don't know" option



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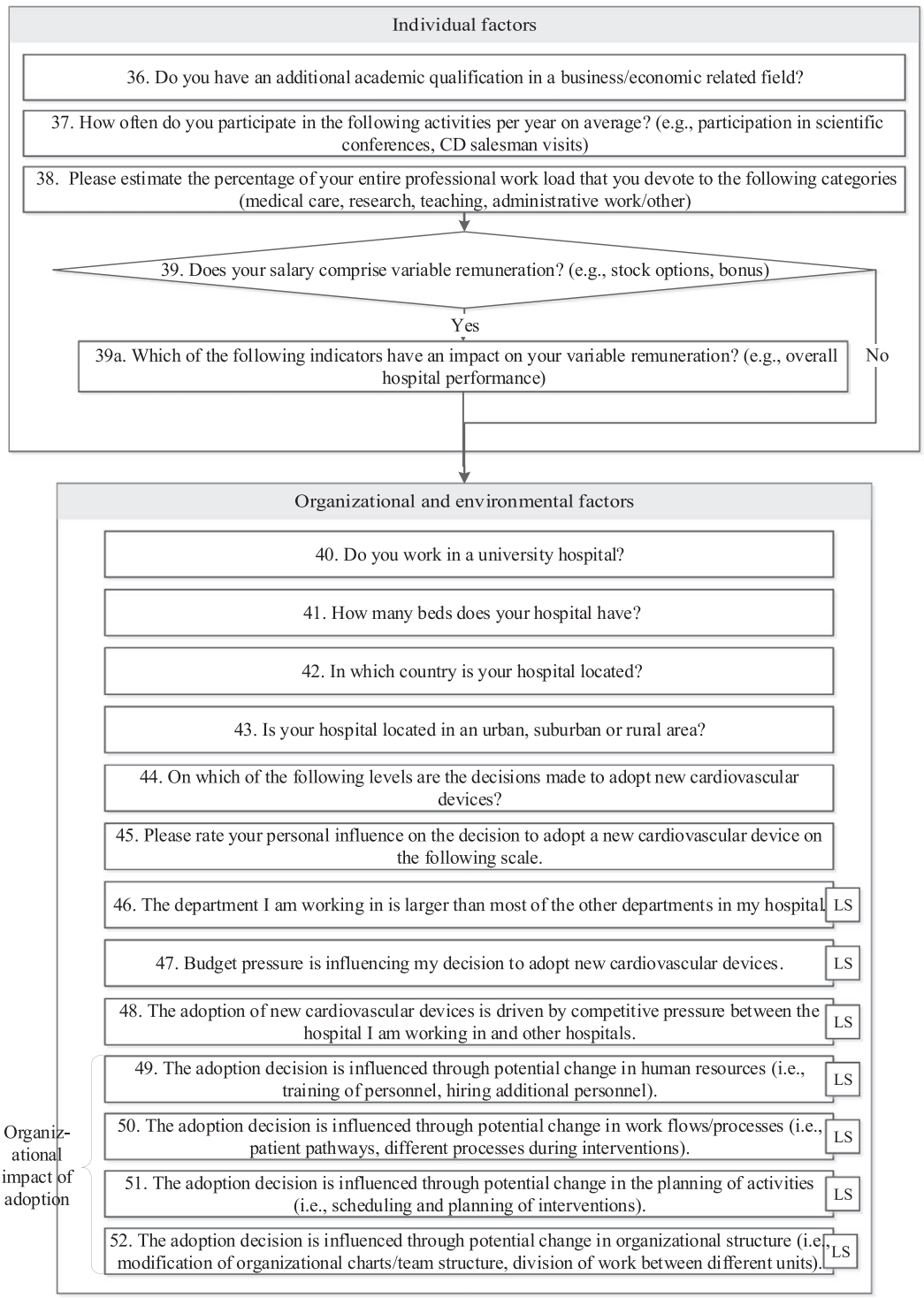


**Figure continued** Schematic representation of the MedtecHTA survey

LS=This item was measured on a 5-point Likert Scale with an additional "don't know" option



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## CONFLICT OF INTEREST

The authors have no conflicts of interest.

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