Variations in the Medical Device Authorization and Reimbursement Landscape: A case study of two cardiovascular devices across four countries

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Abstract

Background:

The authorization process and coverage/reimbursement mechanisms for medical devices play critical roles in device adoption and usage. However, international variation in these processes remains poorly characterized.

Methods:

This study examined publicly available data from the United States (US), Canada, the United Kingdom (UK), and the Netherlands to compare the authorization processes and coverage/reimbursement mechanisms for two novel cardiovascular devices: the Watchman left atrial appendage occlusion device and the Impella percutaneous ventricular assist device.

Results:

Authorization data were easily accessible for the US and Canada but extremely limited for the UK and the Netherlands. Chronologically, authorization occurred earlier in the UK and the Netherlands than in the US and Canada for both devices. The US was the only country where the principle public payor (Medicare) explicitly reimbursed both procedures and was also similarly notable for more rapid adoption and higher utilization of both devices than the other countries.

Conclusions:

This research provides insights into how differences among countries in authorization and reimbursement mechanisms may impact the adoption and usage of medical devices, and may inform future policies on these processes.

Introduction

In an era of continual technological advancements, countries' regulatory authorization processes and reimbursement/coverage mechanisms for medical devices must balance timely and safe access with the imperative for maintaining fiscal sustainability of public healthcare systems. Technological innovation, including the introduction of new medical devices, is an important driver of healthcare spending growth, but also has the potential to lead to improved patient outcomes and population health.(1)

Between 2012 and 2022, the United States (US) Food and Drug Administration (FDA) approved approximately 341 new higher risk medical devices annually through the premarket approval process, which involves rigorous testing to ensure safety and effectiveness before the device is approved for use. Thousands of lower-risk devices were also approved through the 510k pathway, which allows a device to enter the market if it can demonstrate "substantial equivalence" to an existing approved device.(2,3) Medical devices accounted for approximately 5% of US national health spending in 2019.(4) By 2030, the Centers for Medicare and Medicaid Services (CMS) estimates that US healthcare spending on medical devices will reach $300-400 billion (USD) annually.(5) Beyond the cost of devices themselves, their use affects future healthcare spending by changing the trajectories, outcomes, and subsequent spending for device recipients.(6,7)

In the US, the regulatory approval process for devices (governed by the FDA) is separate from decisions about whether the principle public payor (the Medicare program) will pay for devices. The "Breakthrough Device Program," authorized under the 2016 21st Century Cures Act, provides an exception by linking approval and coverage for a small subset of devices that

address unmet medical needs. For most devices, however, determining coverage/reimbursement under Medicare (the largest single insurance program in the US) is not explicitly linked to the regulatory approval process and relies on separate criteria. While private insurers and state Medicaid programs frequently follow CMS's lead, each payer determines coverage and reimbursement independently.(8,9)

From an economic perspective, even devices that are effective and provide good value (i.e., cost-effectiveness below commonly accepted thresholds of $50,000-$150,000 (USD) per quality adjusted life year [QALY]) typically add to overall healthcare spending. Importantly, the value of many medical innovations may erode when new therapies initially approved for use in a narrow subgroup of patients are used for off-label indications or in broader populations where the benefit is less than in the originally target population.(10) To combat decreased value from broadened device use, countries considering new therapies could theoretically limit use to authorized indications and populations. For example, in countries with national health insurance and "government run" healthcare, policy makers may find it easier to restrict the use of devices to their approved indications and populations because policy makers directly oversee both the approval and reimbursement processes. However, in the fragmented U.S. system, where there are multiple payers (e.g., Medicare, Medicaid, private insurers) and no unified mechanism to oversee device use across payers, it becomes difficult to limit the use of a device once it has entered circulation. Thus, the initial authorization and coverage/reimbursement process serves as a crucial mechanism for balancing access to new therapies with budgetary restraints.

Understanding how the authorization and coverage/reimbursement processes differ across countries can identify best-practices and provide opportunities for shared-learning. Although several studies compare how different countries regulate pharmaceuticals, there are limited data comparing countries with respect to processes for establishing medical device regulatory approval, public funding and/or payment policies.(11–13)

In this study, we compare medical device approval and reimbursement pathways for two cardiovascular devices (Watchman and Impella) across four different, high-income countries: the US, Canada, the United Kingdom (UK), and the Netherlands. These countries were selected for their representation of two major medical technology markets (North America and Europe),(14) their varying health insurance models,(15) and their differing device approval and coverage/reimbursement processes. While the US and Canada generally perform poorly in international rankings of health system performance, the Netherlands and UK generally have been considered among the top-ranked healthcare systems.(16) Finally, all four countries actively participate in the International Health System Research Collaborative (IHSRC)(17), a research network dedicated to improving understanding of costs, quality, and patient outcomes across high-income countries. We focused on cardiovascular conditions because cardiovascular disease represents the highest burden of disease in high income countries(18), technological innovation is embraced, and IHSRC is actively working in this area.(19–21)

First, we examined the public availability of information regarding the initial approval and reimbursement processes for each device in each country at the time of first approval. We then used available data to describe the approaches, benefits, and limitations of the regulatory

and reimbursement/coverage strategies employed by each country. Second, we describe uptake and utilization of each device in each country and how utilization may reflect the authorization and reimbursement policies employed.

Methods

All available data is presented in the manuscript, most of which is publicly accessible with citations given.

Countries and Devices

We characterized the medical device regulatory approval and funding pathways in four countries: the US; Canada (represented by Ontario, the most populous province); the UK; and the Netherlands.

We selected two relatively new cardiovascular devices as case studies: the Watchman left atrial appendage occlusion device for patients with atrial fibrillation (AF) (Atritech / Boston Scientific), which was introduced during the early-2000s; and the Impella 2.5 for patients with cardiogenic shock (Abiomed), which was introduced in the late-2000s. We selected these devices because both treat common clinical conditions, but with variable guideline recommendations, and both are costly. Moreover, while each device was initially approved for narrow indications – the Watchman as a nonpharmacologic stroke prevention alternative to pharmacologic anticoagulation, and the Impella for short-term circulatory support in the setting of cardiogenic shock, shown in Appendix A (22) – both have the potential to be used in much larger populations (e.g., all patients with AF with sufficient thromboembolic risk and all patients undergoing high-risk percutaneous coronary interventions, respectively). We limited the scope

of our analysis to the initial approval of the first generation of each device to more clearly follow initial approval pathways.

For each country and device, we collected information on two distinct but related processes: device regulatory authorization, which permits the device to be sold and used; and decisions wherein the device is approved for coverage and reimbursement by each country's public insurance program. For the US, we focused on Medicare, its largest payor of healthcare, which provides public insurance to all adults age ≥65 years and often sets the standard for coverage decisions for other payers. For Canada we focused on the Ontario Ministry of Health; for the UK, the National Health Service (NHS); and for the Netherlands, the 'basisverzekering' (i.e., care financed by the Healthcare Insurance Acts compulsory for all inhabitants).

We framed our study design and data collection by drawing upon prior studies of the drug approval process. Data elements related to device approval included: date of first regulatory review; time from submission to review completion; device approval date; agency approval requirements; number of review cycles (i.e., each new submission required by the manufacturer whether an initial submission or a revised submission responding to requests for more information); and whether relevant post-approval studies were required or collected, as shown in Appendix B(22).

Data elements related to device funding specifically pertained to each country's primary public funder. Key data elements for each country included: date of funding decision; final funding decision (payment yes/no); device coverage requirements (e.g., required associated diagnoses).

Two members of our team (MW and NS) reviewed official websites and databases hosted by relevant regulatory bodies and funding agencies in each country. Often, regulatory and funding information was not available from a primary source and required use of supplementary sources, such as archived press releases from the device manufacturers or the gray literature. Quantitative data elements were collected using a standardized data collection form, shown in Appendix C(22). We obtained additional details from practicing clinicians in each of our four countries (US: JR, BL, PC; Canada, DK; England, MM, MM, AB; Netherlands, CdU).

Results

Description of the Approval and Funding Processes

All the countries examined utilize a risk-based system to determine the regulatory pathway and evidentiary requirements, with higher-risk devices (such as the Impella and Watchman) undergoing more rigorous review. The implementation of this review and options to expedite it based on either health impact or substantial equivalence to previous devices vary by country.

United States

In the US, the Medicare program has traditionally paid for virtually all devices approved by the FDA with few restrictions, though in recent years Medicare has demonstrated greater willingness to limit approved devices to narrower populations or require that recipients be included in post-approal clinical registries to monitor effectiveness.(23,24) The agency may issue a National Coverage Determination (NCD) regarding a device, however in the absence of an NCD this general principle guides Local Coverage Determinations (LCDs) by Medicare

Administrative Contractors (MACs) as they adjudicate claims. Private insurers in the US may make their own coverage decisions but generally follow Medicare decisions.(8,9)

Canada

In Canada, a national government agency, Health Canada, is responsible for regulating medical device approval for the entire country. Funding approval, while often guided by Canadian Agency for Drugs and Technologies in Health (now Canadian Drug Assessment) recommendations, is determined separately by each of Canada's provinces and territories.

The United Kingdom

The UK previously followed the European Union (EU) and Conformité Européenne (CE) marking system, but transitioned to a similar, independent regulatory framework in June 2023 (the United Kingdom Conformity Assessed (UKCA) marking) after exiting from the EU.(25) Funding decisions in the UK for "first -n-class" devices are guided by the recommendations of the National Institute for Health and Care Excellence (NICE), and typically include a formal cost-effectiveness analysis. If a first-in-class device is deemed cost-effective, subsequent similar devices are typically assumed to be cost-effective. The NHS and its hospitals are legally obligated to fund medicines and treatments recommended by NICE,(26) however regional NHS trusts may independently fund devices not recommended by NICE using local budgets on a case-by-case basis.

The Netherlands

In the Netherlands all devices undergo formal EU review and receive CE marking as evidence of compliance with European Union regulations (Medical Device Regulation [MDR]). Once EU approval is granted, the Netherlands National Health Care Institute (Zorginstituut

Nederland/ZIN)- an organization similar to NICE in the UK – provides supplemental review. In a recent change driven by Regulation (EU) 2017/745, the Ministry of Health, Welfare and Sport (VWS) now requires proof of efficacy for devices to be reimbursed by health insurers in the Netherlands, (27) while the National Health Care Institute (ZIN) – an independent administrative body - recommends for or against providing funding at the national level. Individual hospitals then negotiate annual budgets with private health insurers whom they bill for health services covered under the 'basisverzekering' basic, mandated insurance package.

Additional details on approval and public funding processes for each country are described in Appendix D(22).

Watchman and Impella Approval and Payment by Country

Watchman Approval

The Watchman device received regulatory approval in the Netherlands and EU in 2005, in the US in 2015, and in Canada in 2016 (Table 1); dates of regulatory approval were not available for the UK but should be similar to the Netherlands as the UK was in the EU at that time (Table 1). The Watchman device underwent priority review in the US and was approved in 457 days and underwent standard review in Canada and was approved in 980 days.(28–31) For the UK and the Netherlands, Watchman's manufacturer received the CE mark (i.e., EU regulatory approval) in 2005, well before applications were submitted in the US or Canada, but no further information on the CE mark's review cycles, timelines, or exact date of application submission was available.(31–33)

Table 1. Regulatory approval for the Watchman and Impella Devices in the US, Canada (Ontario), England, and Netherlands.

Device & Country	Data source	Date of submission	Date of first review completion	Approval Date	Time from submission to review completion (days)	Review Cycles
Watchman						
US	Devices@FDA(28)	5/14/13	12/11/13	3/13/15	457	2
Ontario, Canada	Health Canada(29)	5/14/13	12/18/14	1/19/16	980	6
England	Press Release(32)	N/A	N/A	CE Mark: 2005, NICE: 6/23/10	N/A	N/A
Netherlands	Press Release(32)	N/A	N/A	CE Mark: 2005, IGJ: 3/13/15	N/A	N/A
Impella						
US	Devices@FDA(30)	12/15/06	2/12/07	5/30/08	532	4
Ontario, Canada	Health Canada(18)	3/28/06	5/8/06	6/27/07	456	2
England	Various studies(34,35)	N/A	N/A	2005	N/A	N/A
Netherlands	Various studies(34,35)	N/A	N/A	Approved for trial: 1/1/04, CE Mark: 2005	N/A	N/A

Watchman Coverage and Payment

In the US, the Watchman device is covered by Medicare (based on a NCD) for patients meeting specified criteria (Table 2), including required documentation in the medical record of shared decision-making with an independent second physician, though this vague requirement has garnered criticism lately, partly due to inconsistent enforcement.(36–38) In 2017, investigators estimated that the US utilized 3.4 Watchman devices per 100,000 adults per-year

(Table 2).(39) Hospitals in the US bill the Watchman procedure under the same diagnosis related group (DRG) as atrial fibrillation ablation, however the Watchman procedure typically takes only 34%-59% of the time required for ablation, depending on ablation technique used (either cryoablation, radiofrequency ablation, or pulsed frequency ablation).(40–43) The cost to the hospital for atrial fibrillation ablation and Watchman implantation are comparable (median $24,500 vs $25,100 [USD]), and thus Watchman devices are potentially more lucrative for US hospitals than ablation given that the procedure can be performed more quickly, thus freeing up procedure room time for additional revenue generating procedures.(44,45) Physicians in the US receive a greater number of relative value units (RVUs) – a measure of work used to define physician reimbursement in the United States – for ablation (17 RVUs) than for Watchman placement (14 RVUs), which could give the impression that US physicians would prefer to perform ablation.(46) However, given that Watchman devices can be implanted more quickly, physicians may prefer the Watchman over ablation despite lower RVUs as they have time for more billable procedures. In the US, financial incentives appear aligned for physician and hospitals in a way that favors the Watchman device for both(47).

Table 2. Funding approval for the Watchman and Impella Devices in the US, Canada, England, and Netherlands.

Device & Country	Data source	Date of funding decision	Publicly Funded?	If funded, reimbursement criteria different from regulatory use criteria?
Watchman				
US	CMS(36)	2/8/2016	Y	Must be implanted by an interventionalist with specific requirements.
Ontario, Canada	Health Quality Ontario, Ontario Health Data Branch, related studies(48–51)	Spring 2020	Y, limited	Additional facility and patient eligibility requirements.

United Kingdom	NHS(52)	7/9/2018	Y, limited	Funded for patients meeting specific requirements (and only at selected health centers).
Netherlands	Various(53,54)	2015	No	Unknown.
Impella				
US	CMS, related studies (55)	10/1/2015	Y	Funded for patients meeting specific requirements.
Ontario, Canada	Health Quality Ontario(56)	February 2017	Rarely, by hospital	N/A
United Kingdom	NHS(57)	11/6/2018	Y	Only as a bridge to transplant.
Netherlands	Various(58,59)	7/26/2012	Y	Unknown

In Canada, the Ontario Ministry of Health, Ontario's public funder of medical devices, recommended funding for the Watchman device based upon estimated costs and benefits.(48) Still, actual funding of the device is infrequent, requires strict patient and facility eligibility criteria to be met,(49) and, generally, use of Watchman in Ontario requires hospitals to either reallocate funds from within their limited global budgets or raise outside philanthropic funds, neither of which would support utilization of the Watchman at scale.(50,51) Based on data from Ontario's Health Data Branch, only 0.98 devices per 100,000 persons were implanted in FY2022/23.(60)

In the UK, NICE issued guidance on appropriate indications for the Watchman device in June 2010, noting that the device is cost-effective in some situations and they would make the treatment available, yet it appears that funding for the device is limited.(61) While the NHS has established a registry of Watchman implant procedures to facilitate post-approval evaluation of effectiveness, there is limited literature from the UK describing uptake or outcomes.(62,63)

Additionally, few hospitals are commissioned to provide the device, significantly limiting its availability.(64) Based on the available literature, use seems rare; we were unable to find data describing Watchman utilization rates in the UK.

In the Netherlands, Watchman was considered for funding in 2015, but not endorsed by the National Health Care Institute (ZIN) based upon review of the available evidence (Table 2). Subsequent articles in the lay-press from 2018 suggest that Watchman use in the Netherlands continues to be limited by funding.(54) The ZIN began funding a 6-year trial (COMPARE-LAAO) of the Watchman device and other LAAO closure devices in 2020, but this study ended prematurely in 2023, in part due to low recruitment.(65) Absent explicit funding, hospitals are still permitted to use the Watchman and do so periodically, but they must fund this from their own global budgets negotiated with health insurers, or through financial arrangements made with the device manufacturer. We were unable to find estimates of Watchman utilization rates in the Netherlands.(53)

<u>Impella Approval</u>

The Impella device received regulatory approval in the US in 2008 and Canada in 2007 (Table 1). It underwent standard review in both countries, and time from submission to review completion was similar for the Impella in the US (532 days) and Canada (456 days). In both the UK and Netherlands, Impella received regulatory approval under the CE mark in 2005, well before the US and Canada.(34,35)

Impella Coverage and Payment

In the US, Medicare approved funding coverage of Impella via a NCD for circumscribed indications in 2016, listed in Appendix A(22).(55) A 2019 study based on the Premier Healthcare Database records through 2016 found that Impella use rates increased over time, with 31.9% of patients undergoing percutaneous coronary intervention (PCI) with mechanical circulatory support (either intra-aortic balloon pump or Impella) receiving an Impella device in 2016(66). These findings are supported by studies showing other types of mechanical circulatory support are overtaking intra-aortic balloon pump during PCI.(67,68) Approximately 3.5% of all US PCI procedures included an Impella in 2016.(66) Assuming 3.5% of PCIs utilize an Impella from among 690,000 PCI procedures annually in the U.S., we estimate that approximately 7-8 Impellas are implanted per 100,000 people in the US yearly just for this indication.(69) Under the US's DRG-based reimbursement system, the Medicare program pays hospitals approximately 300% more for a PCI with Impella (DRG 215) than for a PCI with stenting alone (DRG 246).(70,71) Looking at Medicare's physician reimbursement, implanting an Impella device during high-risk PCI earns the physician an additional 6.75 RVUs (CPT 33990) relative to the PCI procedure alone as compared to 4.84 additional RVUs (CPT 33967) for an intra-aortic balloon pump.(46,72) The alignment between financial incentives for hospitals and physicians may help explain the rapid uptake of Impella in the US.

In Canada, despite regulatory approval, the Ontario Health Technology Advisory Committee recommended against public funding of Impella by OHIP in 2017. The committee stated that "given the price of the technology and the limited evidence of clinical benefit, Impella devices do not appear to provide good value for money."(56) Absent dedicated Ontario Ministry of Health funding, Impella use in Canadian hospitals is infrequent and typically involves

purchasing the devices using philanthropic funds or donations from the device manufacturer and there is no explicit additional reimbursement for physicians placing them.(73–75)

In the UK, NICE published a briefing regarding the Impella device in 2016 and did not recommend its use due to limited clinical benefits combined with the high cost.(76) According to British Cardiovascular Intervention Society reports, 68 Impella-assisted PCI procedures were performed in the UK in 2021/2022, and 98 in 2022/2023, or approximately 0.1% of total PCI cases, as compared to use in 10% of high-risk PCI procedures in the US.(77,78) Use in the UK is likely limited by lack of reimbursement amid ongoing debate about Impella's clinical effectiveness and may be driven mostly by recruitment to industry-sponsored clinical trials investigating its use.(79)

In the Netherlands, Impella has been reimbursed by health insurers since 2012(58) and a national funding review in 2015 suggested that funding of both left ventricular assist devices (LVADs) and Impella was "in line with the current state of science and medical practice" for people with end-stage heart failure and should be reimbursed.(59) A recent study found that, between January 2017 and September 2021, 133 Impellas were implanted in the Netherlands, or 5.7% of all patients during that time period who had acute myocardial infarction complicated by cardiogenic shock and were treated with PCI.(80) In contrast to the US, physicians in the Netherlands are generally salaried and thus lack financial incentive to deploy an Impella.

Discussion

In this analysis of the authorization and coverage/reimbursement processes for two novel cardiovascular devices in four high-income countries, we found several commonalities,

but also important differences. While the Watchman and Impella devices received regulatory authorization from all countries, utilization was limited in all but the US, where uptake of both devices was rapid, facilitated by explicit reimbursement mechanisms. Importantly, utilization of both devices in the US was incentivized by incremental payments to both physicians and hospitals, creating a powerful alignment of financial interests.

Several of our findings merit careful consideration. First, it is important to consider the timeliness of the regulatory approval process in Europe relative to the US and Canada. Consistent with prior research, both the Watchman and Impella devices were authorized for use approximately 10 years earlier in Europe than in the US and Canada.(81) The approval processes in the UK and the Netherlands have historically been more decentralized than in the US or Canada, with multiple pathways to receive CE mark approval, although this is beginning to change with recent changes to EU and member-country regulations(82,83). Importantly, the CE mark indicates that a device complies with Europe's laws requiring devices to demonstrate safety and that they likely perform as designed; the CE Mark did not signify efficacy until May 26, 2021 when EU regulation 2017/745 went into effect, requiring more stringent clinical evidence.(27) Some countries, like the Netherlands, may choose to implement additional requirements including clinical trials before devices are used and reimbursed. Device approval requirements in the US and Canada – outside of expedited mechanisms for substantially similar devices like the 510(k) pathway – are generally more stringent, requiring evidence of clinical efficacy in addition to safety.(23,82,84) Thus, it is plausible that, at least prior to the 2021 shift in EU regulations, the less stringent approval requirements in Europe facilitate earlier authorization than in the US and Canada.

Second, it is important to consider how funding impacted adoption and uptake of the devices. Under Medicare's DRG-based reimbursement system, hospitals receive additional reimbursement for using an Impella device during a PCI procedure, while hospitals do not receive incremental reimbursement for a Watchman device; given the cost to implant the Watchman device (approximately $24,500 [USD]) and the lack of incremental hospital reimbursement for the device, using a Watchman might seem financially disadvantageous to US hospitals.(44) However, to the extent that Watchman devices reduce the time required in the electrophysiology laboratory allowing greater "throughput" and efficiency, hospitals may have financial incentive to perform these procedures relative to ablation alone depending upon the efficiency gains for Watchman versus ablation and the relative costs of the two procedures. Moreover, the US Medicare program provides incremental payment to physicians who use these devices above and beyond older legacy therapies. Thus, there is alignment between hospital and physician financial interests, likely contributing to greater device uptake in the US.(85) In contrast, the Netherlands approved hospital funding for the Impella device but uptake in the Netherlands has been modest, possibly due to a lack of direct reimbursement to physicians. Neither Canada nor the UK approved public funding to hospitals for either device. Hospitals in these countries operate largely under a global budget meaning that increased utilization of these costly devices would not result in greater payment and thus must be absorbed by the hospital's budget. Because the Watchman did not receive funding in the Netherlands, it too relied on funding from the global hospital budget rather than insurers.

The different decisions by insurers in the US, Canada, England, and the Netherlands align closely with differences in how the US approaches Healthcare Technology Assessment

(HTA) relative to these other countries. HTAs synthesize information about the relative costs, effectiveness, and value of health care interventions to inform health policy decision-making. Canada, the UK, and the Netherlands all utilize some form of HTA to inform their decisions around public funding of medical devices. While certain US entities conduct HTAs(86), no formalized processes exist for integrating HTA into Medicare funding decisions.(87–90)

Finally, our study highlights important differences in the availability and transparency in medical device authorization and funding pathways in each country. The US and Canada demonstrated the greatest efforts to maintain transparency; in the EU, little information was accessible beyond the date an application is received or a device is certified. No centralized, publicly available source currently exists containing CE mark review and approval data. The forthcoming European Database on Medical Devices (EUDAMED) aims to address these transparency issues by centralizing and making publicly available information on medical devices within the EU, including details on clinical investigations, market surveillance, and device safety. This database could significantly improve data transparency and availability, although it will not be fully operational until 2026, and the extent of information it will provide remains unclear.

We acknowledge several limitations. First, the endpoints examined by this study represented only several among many that would be worth investigating. Our analysis of device reimbursement, for example, represents only the public piece of the insurer landscape in each country. While in health systems such as the UK this composes nearly all of reimbursement, the US relies more heavily on private payors which may have different criteria and tendencies for reimbursement. Second, our study is focused on two devices, both of which are high-risk,

cardiovascular devices, and should be generalized to other devices with care; similarly, our study was limited to four countries and other countries may well have regulatory processes and patterns of utilization of Watchman and Impella that warrant study.(91,92) Third, we focused on initial approval of the initial devices and did not study subsequent iterations or next-generation devices. Fourth, attempting to compare reimbursement for devices among different countries is difficult because of underlying differences in physician reimbursement (e.g., salaried versus fee-for-service) and hospital reimbursement (e.g., per-admission versus global budget), each of which may transform regulation, reimbursement and usage differently than we account for here. Additionally, during most of our study period the UK followed the EU CE marking system which limits the diversity of our regulatory analysis, though the UK's medical device adoption and reimbursement behave differently. The UK regulatory environment is continuing to adapt after their exit from the European Union.

Fifth, certain measures such as precise country-specific measures of utilization of the Watchman and Impella were not available; while it was evident that uptake was higher in the US than in Canada, the UK, and the Netherlands, additional studies are needed to better characterize these differences. Finally, indications for coverage and reimbursement are dynamic. For example, more recent research showing benefit for the Impella in those with AMI and cardiogenic shock might influence coverage and reimbursement and thus use of these devices in the future.(85)

In conclusion, in this analysis of the regulatory and funding approval processes in the US, Canada, the UK, and the Netherlands, while all countries granted regulatory approval for both the Watchman and Impella devices, only the US authorized public funding to both hospitals and

physicians for both devices. Consequently, the US was the only country with widespread utilization of both devices. In aggregate our study provides important insights into how different high-income countries approach medical device regulation and funding, and unveils the impacts that such approaches have upon uptake and utilization.

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Supplemental Materials:

Appendices A-D

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