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Preliminary feasibility assessment of CDM-based active surveillance using current status of medical device data in medical records and OMOP-CDM

Soojin Choi¹, Soo Jeong Choi², Jin Kuk Kim², Ki Chang Nam³, Suehyun Lee⁴, Ju Han Kim⁵✉ & You Kyoung Lee¹✉

In recent years, there has been an emerging interest in the use of claims and electronic health record (EHR) data for evaluation of medical device safety and effectiveness. In Korea, national insurance electronic data interchange (EDI) code has been used as a medical device data source for common data model (CDM). This study performed a preliminary feasibility assessment of CDM-based vigilance. A cross-sectional study of target medical device data in EHR and CDM was conducted. A total of 155 medical devices were finally enrolled, with 58.7% of them having EDI codes. Femoral head prosthesis was selected as a focus group. It was registered in our institute with 11 EDI codes. However, only three EDI codes were converted to systematized nomenclature of medicine clinical terms concept. EDI code was matched in one-to-many (up to 104) with unique device identifier (UDI), including devices classified as different global medical device nomenclature. The use of UDI rather than EDI code as a medical device data source is recommended. We hope that this study will share the current state of medical device data recorded in the EHR and contribute to the introduction of CDM-based medical device vigilance by selecting appropriate medical device data sources.

Medical devices play important roles in disease diagnosis, prevention, and treatment. However, they also carry potential risks of serious injuries and even fatality^{1,2}. Therefore, postmarket medical device vigilance (MDV) is crucial for public health protection, and medical device adverse event (MDAE) information should be collected, evaluated, analyzed, and disseminated through a timely and reliable method³. Current MDV methods rely on passive reporting, which is a combination of mandatory and voluntary adverse event reporting systems used by patients, physicians, manufacturers, and healthcare organizations. For a long time, these reporting systems have been useful for identifying unexpected and unique adverse events⁴. However, passive surveillance is limited by the voluntary nature of reporting, the strong inherent bias associated with spontaneous reports, underreporting, and the lack of denominator data on comprehensive exposure⁴⁻⁷. To overcome these limitations, an active surveillance system via common data model (CDM) could be helpful. CDM is a logical and semantic data model that can be used to standardize multiple data sources into a common format. It has been effectively implemented with pharmaceutical products (including vaccines)⁸. In addition, applying passive and active surveillance simultaneously using electronic health records (EHR) could augment sample size, increase population heterogeneity, and cross-validate results⁹.

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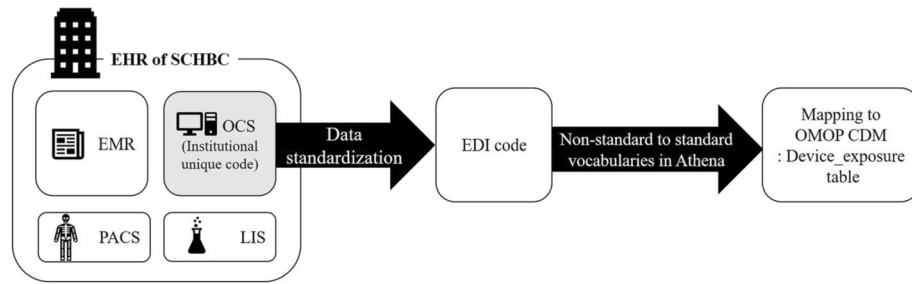


Figure 1. Current CDM mapping process of medical device data in Korea and scopes of this study. Among medical device data recorded in each medical institution's EHR, the institutional unique code recorded in the OCS is converted into a national insurance electronic data interchange (EDI) code. EDI codes are mapped using an OMOP CDM standard vocabulary. The standard vocabulary for medical device data is SNOMED. *EHR* electronic health records, *CDM* common data model, *SCHBC* Soonchunhyang University Bucheon Hospital, *OCS* online charting system, *EDI* electronic data interchange, *EMR* electronic medical record, *PACS* picture archiving and communication system, *LIS* laboratory information system, *MDV* medical device vigilance.

In recent years, there has been an emerging interest in the use of claims and EHR data for evaluating medical device safety and effectiveness¹⁰. Attempts have been made to implement MDV active surveillance through a web-based platform for sharing the experiences on medical device incidents¹¹ and through a multicenter, prospective, observational research study¹². However, both studies used a centralized method with patient data entered into the database as a common language agreed between network organizations. Studies of CDM-based MDV have not been reported yet. There is a difference between pharmacovigilance and medical device. Pharmacovigilance uses CDM to analyze adverse events associated with the use of a drug while medical device vigilance analyzes adverse events associated with the use of a medical device. This study was conducted to identify the current situation and derive improvements, assuming that medical device information deficiencies in EHR or CDM could become a hurdle for CDM-based MDVs.

Results

Soonchunhyang University Bucheon Hospital (SCHBC) in Bucheon, Gyeonggi Province, Republic of Korea is covered by Federated E-health Big Data for Evidence Renovation Network (FEEDER-NET)^{13,14}. According to the user manual provided by FEEDER-NET¹⁵, institutional unique prescription codes were used as medical device data sources and converted into electronic data interchange (EDI) codes used by national insurance claims in Korea. The EDI code is registered in Athena. It can be entered into the CDM as it is. However, since it is a non-standard term, it is converted to the standard term, Systemized Nomenclature of Medicines—Clinical Terms (SNOMED-CT), and entered into the CDM if possible (Fig. 1). Global Medical Device Nomenclature (GMDN) terms are the basis of SNOMED CT medical device content¹⁶.

Analysis of medical device data recorded in EHR. Among the 2112 medical devices posted by the Ministry of Food and Drug Safety (MFDS), 433 posts had MDAE occurrence. Fifty-five medical devices were reported to have health effects on patients. Of the remaining 379 medical devices whose health effects were not reported, 101 had moderate or high potential risks. A total of 155 medical devices were finally enrolled to investigate medical device data in EHR (Fig. 2a). Medical device information from SCHBC EHR was classified into four groups (Fig. 2b). Ninety-one medical devices (91/155, 58.7%) were prescribed by code (EDI code linked) on online charting system (OCS) when used in patients. Fifty devices without other information recorded other than OCS prescriptions were classified into group 1. Forty-one medical devices (41/155, 26.5%) recorded as barcode data in the surgical nursing record on EMR were classified into group 2. Ten medical devices (10/155, 6.5%) recorded model name on picture archiving and communication system (PACS) were classified into group 3. Nine of them had model names displayed separately from the image without serial number or lot number. The other one, a gastroscope, had model name and serial number of the device displayed as part of the image. Fifty-four medical devices without direct device data were classified into group 4. Twenty-two of them did not have any records. Nineteen of them did not have a direct record. They were assumed to be used medical devices needed for treatment or surgeries. Thirteen had a number assigned by the user in the electronic medical record (EMR). However, they were considered as group 4 because such user given number had been assigned to a new device without any comments when replacing the device.

Figure 3 shows changes of implanted medical device records in our institution. Prior to the introduction of EMR, OCS prescriptions using the National Insurance EDI code and scan images of barcode stickers for devices were recorded. Initially, the device name was interlinked with the OCS prescription and the barcode data was replaced by a keyboard entry lot number instead of a scan image. In 2019, barcode readers were introduced to improve barcode data recording. When the barcode is read, the entire barcode data and some distinguished data (lot or serial number and expiration date) are entered at a specified location.

Focus analysis of medical device data. National insurance has 31 and 28 codes for metal and ceramic femoral heads, respectively. There were a total of 11 codes registered in our institute's OCS (Table 1). On the

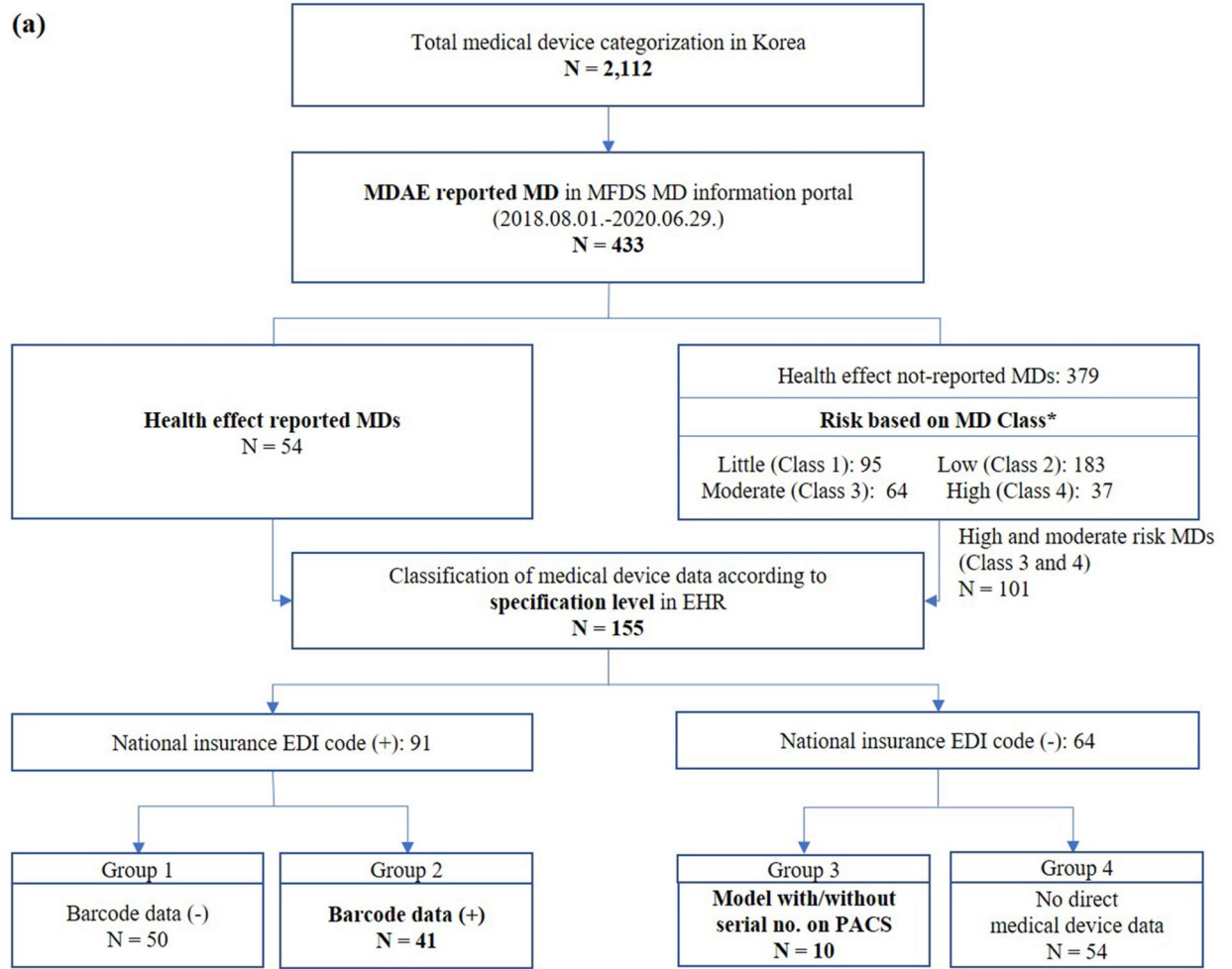


Figure 2. A total of 155 medical devices were finally enrolled for the investigation of medical device data on EHR (a). Medical device information EHR was classified into four groups (b). *MDAE* medical device adverse event, *MD* medical device, *MFDS* Ministry of Food and Drug Safety, *EHR* electronic health records, *EDI* electronic data interchange, *PACS* picture archiving and communication system, *EMR* electronic medical record.

(b)

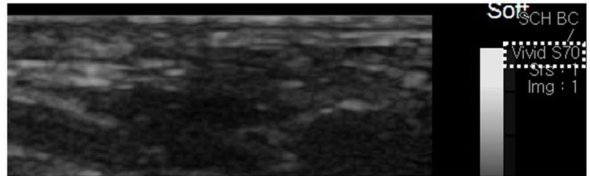
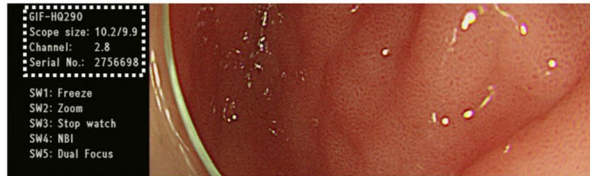

Group	Description	Data format	No. of MD	Example																																										
1	OCS record using national insurance EDI code without barcode	Structured	50	<table border="1"> <thead> <tr> <th></th> <th>Hold Memo</th> <th>Item code</th> <th>Item name</th> <th>DSC</th> <th>Amount</th> <th>Unit</th> </tr> </thead> <tbody> <tr> <td>1</td> <td><input type="checkbox"/></td> <td>E7230</td> <td>Thumb oxymeter (Percutaneous Blood</td> <td><input type="checkbox"/></td> <td>1</td> <td>-</td> </tr> <tr> <td>2</td> <td><input type="checkbox"/></td> <td>JUCSD07</td> <td>Ultrasonography</td> <td><input type="checkbox"/></td> <td>1</td> <td>-</td> </tr> <tr> <td>3</td> <td><input type="checkbox"/></td> <td>MMAN001011</td> <td>ANGIO INSYTE CATHETER [24G*0.75]</td> <td><input type="checkbox"/></td> <td>1</td> <td>EA</td> </tr> <tr> <td>4</td> <td><input type="checkbox"/></td> <td>MSK7203007</td> <td>Q Sterilized elastic bandage 3" [7.5CM*215</td> <td><input type="checkbox"/></td> <td>1</td> <td>EA</td> </tr> <tr> <td>5</td> <td><input type="checkbox"/></td> <td>MTB0011005</td> <td>BLACK SILK 4/0 75CM NON NEEDLE</td> <td><input type="checkbox"/></td> <td>10</td> <td>EA</td> </tr> </tbody> </table> <p>Catheter, Drape, Suture, Dressing</p>		Hold Memo	Item code	Item name	DSC	Amount	Unit	1	<input type="checkbox"/>	E7230	Thumb oxymeter (Percutaneous Blood	<input type="checkbox"/>	1	-	2	<input type="checkbox"/>	JUCSD07	Ultrasonography	<input type="checkbox"/>	1	-	3	<input type="checkbox"/>	MMAN001011	ANGIO INSYTE CATHETER [24G*0.75]	<input type="checkbox"/>	1	EA	4	<input type="checkbox"/>	MSK7203007	Q Sterilized elastic bandage 3" [7.5CM*215	<input type="checkbox"/>	1	EA	5	<input type="checkbox"/>	MTB0011005	BLACK SILK 4/0 75CM NON NEEDLE	<input type="checkbox"/>	10	EA
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3	Model with/without serial number on PACS*	Structured	9	 <p>Diagnostic X-ray device, Ultrasound imaging system</p>																																										
		Unstructured	1	 <p>Speculums</p>																																										
4	No record		22	<p>Medical software, Water purification system, Centrifuge , Refrigerator for medical use</p>																																										
	MD use can be indirectly guessed through treatment or surgical records	No direct data	19	 <p>Defibrillator, Ventilator, Electrocardiograph, Anesthesia system, Bed, Incubator, Infusion pump</p>																																										
	MD number assigned by the department was recorded on EMR		13	<p>Hemodialysis Nursing Records</p> <table border="1"> <tr> <td>Patient ID</td> <td>MN</td> </tr> <tr> <td>Patient name</td> <td>1221</td> </tr> <tr> <td>YYMMDD*****</td> <td>M/66</td> </tr> </table> <table border="1"> <tr> <td>Total dialysis no</td> <td>60</td> <td>Dialyzer</td> <td>1.4</td> <td>Helixone</td> </tr> <tr> <td>Dialysate</td> <td>HD EVC</td> <td>Education</td> <td></td> <td></td> </tr> <tr> <td>Hemodialyzer no</td> <td>E02</td> <td>Classification</td> <td></td> <td></td> </tr> <tr> <td>Dialysis site</td> <td>Kidney center</td> <td>General HD</td> <td></td> <td></td> </tr> </table> <p>Hemodialysis system, Electrosurgical system, Surgical drill handpiece</p>	Patient ID	MN	Patient name	1221	YYMMDD*****	M/66	Total dialysis no	60	Dialyzer	1.4	Helixone	Dialysate	HD EVC	Education			Hemodialyzer no	E02	Classification			Dialysis site	Kidney center	General HD																		
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Figure 2. (continued)

CDM of SCHBC, three of those 11 femoral head codes were mapped to the standard concept of SNOMED-CT (code mapping was provided as Supplementary Table S1), while the other eight EDI terms were mapped to the non-standard concept of SNOMED-CT as shown in Fig. 4.

Both metal and ceramic femoral heads were used most frequently by Howmedica Osteonics Corp (Mahwah, NJ, USA). Thus, they were selected as focus groups: E1012001, E1012102, E1011031, and E1011231. E1011002 was not included as a focus group because it had a prescription record currently excluded from national insurance.

Various medical device data sources used in this study provided different medical device classifications and data (Table 2). The national insurance EDI code was commonly used by MOHW and MFDS data sources. Because EDI codes were applied without distinction to medical device specifications, the four EDI codes selected as focus groups were reclassified using the MFDS's medical device classification criteria. Models were available from the

MFDS, the manufacturer's catalog, and Access Global Unique Device Identification Database (GUDID). EDI data were found from the MFDS and Access GUDID. There were 31 EDI codes registered as metal femoral head in national insurance (Fig. 5). Each of 32 models registered under the E1012102 code was given a unique device identifier (UDI). The manufacturer's catalog categorized 32 models as Exter femoral head stainless steel and Orthinox V40 chemical head. The 32nd model (6364-2-628) of the E1012102 was registered with the MFDS as 07613327298239, but was not registered with the Access GUDID. The 81 models registered under the E1012001 code were categorized under five brand names depending on the type of taper (Morse, C and V40) and Low Friction Ion Treatment (LFIT) application. The first model to the 12th model were listed in the catalog as LFIT Morse taper head and Access GUDID as Morse head femoral head. By searching for Morse head femoral head in Access GUDID, 22 additional UDIs were identified that were not in the MFDS. They were classified under three brand names by the manufacturer. The 27th to 34th models were classified as C-Taper CoCr LFIT heads in the catalog, but were classified as C-Taper heads in Access GUDID. There were 30 EDI codes registered as ceramic femoral head in national insurance. The nine models registered with E1011031 code had a single brand name. Thirty-nine models were registered in E1011231, with six models (from 15th to 21st) being adapter sleeves, not femoral heads. The remaining 33 models were classified as three in the catalog and four brand names in the Access GUDID. Figure 6 presents ceramic femoral head hierarchies according to manufacturer, ceramic type, and head diameter. The 48 models registered in codes E1011031 and E1011231 were reclassified for the hierarchies presented.

Discussion

MDV is currently performed through a variety of voluntary and mandatory reporting mechanisms to report events, not rates¹⁷. The calculation of the latter requires a denominator, that is, the total number of the used devices. For drugs, the situation is different. Sentinel Initiative monitors the safety and comparative effectiveness of drugs by leveraging national drug codes recorded at the point of care or the point of sale and transmitted to payers via insurance claims¹⁸. In Korea, the MFDS is required to record and preserve usage of some medical devices such as implanted medical devices for more than a year in order to track patients. However, medical institutions tend to write this as a dedicated document for medical management rather than recording it in EMR (personal communication). Mapping these data to an OMOP CDM is hard to expect. Therefore, national insurance EDI code has been used as a medical device data source in OMOP CDM (Fig. 1), similar to the Sentinel Initiative. However, there has been no approach or feasibility assessment on whether CDM established by Korean institutions is suitable for MDV. Based on EHR record and OMOP CDM conversion status of medical device data, this study performed preliminary feasibility assessment of CDM-based MDV.

- Adequacy of medical device EDI code for MDV purpose

As of 2016, 97.1% of Korea's population are covered by national insurance. Health Insurance Review and Assessment Service (HIRA) has developed the EDI code system to classify and identify drugs, medical services, and devices. It also maintains the EDI code system. HIRA mandates the use of EDI vocabulary in the claim system. For this reason, every Korean EHR system uses the EDI vocabulary for most drugs, medical procedures, and devices. It has advantages as a data source in that it is structured and domestic standardized. However, EDI term has not been acknowledged as a standard vocabulary in the way that the Current Procedural Terminology, fourth edition has in the United States because its quality has never been audited¹⁹. Instead, there were several attempts to map the EDI term to SNOMED-CT^{20–22}. Nevertheless, the EDI code as a medical device data source showed several limitations in the present study. First, only a few codes were mapped to standard terms (Table 1). Second, it excluded non-claimed medical devices (groups 3 and 4 in Fig. 2a,b). Third, medical devices might be unintentionally intermixed in a single EDI code even if all EDI codes are mapped to standard terms (Fig. 5).

- Candidates for medical device data source other than EDI code

EHR data capture is critical to device-tracking efforts²³. For this purpose, the structure of the data and the presence of records on EHR are both important. EHRs are recorded as either unstructured keyboard entry narrative data or structured coded data²⁴. Structured data enable the reuse of data collected in the course of clinical care. However, structured data systems are typically difficult to use, time consuming, and often inflexible for expressing complex clinical concepts. Previously reports have indicated that 80% of medical data are unstructured data while only 20% of medical data are structured data used mostly for disease diagnosis²⁵. As shown in Fig. 2b, structured medical device data include prescription code modified national insurance EDI code (50 devices), barcode entry (41 devices) including UDI, and model (9 devices) recorded in PACS. Other medical devices without charging patients have been recorded in an unstructured form for management or not recorded. These unstructured data cannot be processed by algorithm directly. Additional data mining, natural language processing, and text analytics would be needed. In the Veteran Administration's Cardiovascular Assessment, Reporting, and Tracking (CART) initiative using free text and limited structured data entry, a dataset of questionable validity for surveillance efforts has been observed²⁶. Tradeoffs between structured and unstructured data recording observed in Fig. 3 complicate the reuse of data. Which medical device data should be captured was discussed considering the existence of EHR records, the structure of the data, and the potential for standardization.

The first option was brand name. It has advantages of easy verbal communication. However, it is not recorded in EHR. Considering the discrepancy in brand name recorded in the manufacturer's catalog and Access GUDID with only a few brand names registered in the MFDS (Table 2), it is considered difficult to standardize brand

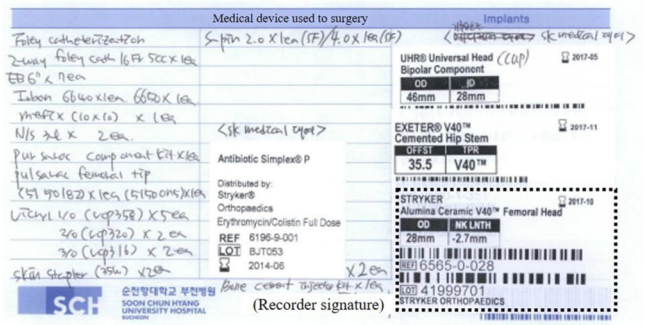
Phase 1: Before electronic health records (EMR) (2002 ~ 2015)
 Name and amount of medical devices used in surgery were hand-written, and bar code stickers were attached on medical charts.



Phase 2: Initial medical device recording on EMR (2015 ~ 2019)
 After the introduction of EMR, the name of the medical device corresponding to the electronic data interchange (EDI) code prescribed in online charting system (OCS) was linked to the medical record. However, other information such as standard and lot number were still recorded by keyboard entry unstructured form.



Phase 3: Medical device records using barcodes (2019 ~)
 Starting in the second half of 2019, barcodes displayed in medical device packaging can be recorded in EMR by barcode entry. As a result, medical device information is recorded accurately in structured form. The program will be improved so that unique device identification (UDI) is recorded separately.



Set	Device name	Standard	Amount	Unit
	EXETER STEM	37.5-2	1	EA
	V40 ALUMINAR FEMORAL HEAD	32(0)	1	EA
	E-POLY HIP LINER	32mm size 23	1	EA
	SIMPLEX ANTI-BIOTIC BONE CEMENT	406* antibiotics	3	EA

Comments: BIOMET RINGLOCK HIP SYSTEM ACETABULAR LINER HEAD 32MM, LINER 23 - LOT: 658250 ANTIBIOTIC SIMPLEX 3EA - LOT: 6N2005 - LOT: 6N2005 - LOT: 6N2005 STRYKER EXETER CEMENTED HIP STEM 37.5 INCH 150MM V40 - LOT: 62279630 STRYKER ALUMINA CERAMIC V40 FEMORAL HEAD 32MM, NK LINTH DMH - LOT: 68384022 S-PIN 4.0 IE A SF

Date	Item code	Item name	Bar Code	Lot	Serial	Exp. date
20201015	HTE1001001	EXETER STEM	0104546540153319172410 091097720570	67720570	-	241009
20201015	HTE1011031	V40 ALUMINAR FEMORAL HEAD	0104546540608499172503 221078464302	78464302	-	250322
20201015	HTE1031075	BONE POLY LINER	8803373830433			
20201015	HTE5002002	SIMPLEX ANTI-BIOTIC BONE CEMENT	0107613327128758			

Barcode: 01 04546540608499 17 250322 10 78464302

UDI	Lot	Expiry date (17) Manufacture date (11)	YYMMDD
04546540608499	78464302	17	250322

Figure 3. Changes of implanted medical device records in our institution.

National insurance EDI code		SCHBC CDM			
Code	Code name	Concept ID	Name	Vocabulary	Record count
E1012001	Osteonics femoral head (Howmedica Osteonics Corp, Mahwah, NJ, US)	42097997	Osteonics femoral head	EDI	0
E1012004	VerSys femoral head (Zimmer, Inc, Warsaw, IN)	42103020	VerSys femoral head	EDI	6
E1012020	ic-head (Implantcast GmbH, Buxtehude, Germany)	42094220	ic-head	EDI	10
E1012102	Exeter femoral head (Howmedica Osteonics Corp, Mahwah, NJ, US)	42092029	Exeter head	EDI	177
E1011008	Ceramic head (DePuy Synthes Companies, Marwah, Indiana, US)	42089833	Ceramic head	EDI	84
E1011029	Ceramic ball head (Plus Orthopedics AG, Rotkreuz, Switzerland)	42089827	Ceramic ball head	EDI	38
E1011031	V40 Alumina femoral head (Howmedica Osteonics Corp, Mahwah, NJ, US)	42102799	V40 Alumina femoral head	EDI	334
E1011231	BioloX Delta Ceramic V40 femoral head (Howmedica Osteonics Corp, Mahwah, NJ, US)	42088730	BioloX Delta ceramic V40 femoral head	EDI	0
E1011023	Femoral head, ceramic (Lima Corporate Spa, Udine, Italy)	45761725	Ceramic femoral prosthesis	SNOMED-CT	35
E1011002	Ceramic head (Howmedica Osteonics Corp, Mahwah, NJ, US)				
E1011204	Ceramic femoral head (CeramTec AG, Plochingen, Germany)				

Table 1. List of 11 national insurance EDI codes registered in our institute and their concept ID used to map to the CDM. CDM common data model, SCHBC Soonchunhyang University Bucheon Hospital, EDI electronic data interchange, SNOMED-CT systematized nomenclature of medicine clinical terms. Among metal and ceramic heads, EDI codes E1012102 and E1011031 represent the largest record count (bold).

names and record them in EHR. It was predicted that CDM conversion of brand name level might increase the loss of data integrity. In pharmacovigilance, brand name level CDM conversion showed 6 to 7% information loss to drug exposure^{8,9}. The second option was model (catalog number). The model is familiar to users as it is recorded in the catalog as well as in the MFDS. It gives specifications, enabling detailed classification of medical devices. The International Consortium of Orthopaedic Registries (ICOR)²⁷ is using models of devices for their identification. However, there has been no worldwide consensus on the encoding of part numbers²⁸. Different prostheses have been identified with the same model and different models have been used for the same prosthesis. In addition, variations in models within and between different companies' products are possible. For example, in Fig. 5, the LFIT Morse taper head is named 01-xxx. However, Morse taper femoral head is named S-1399-HHxx, although the two have the same manufacturer. Additional EHR records would be required to use

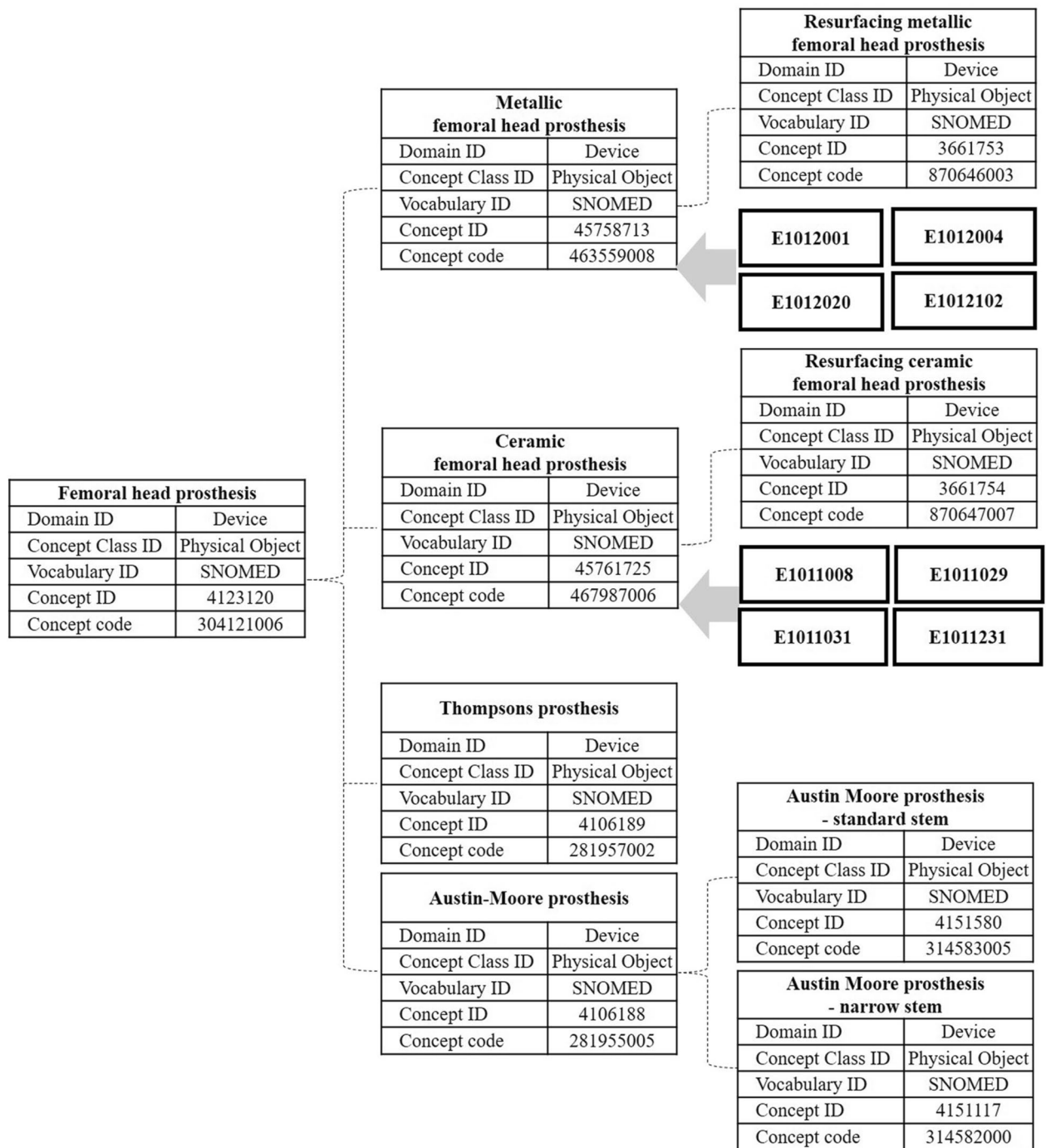


Figure 4. Femoral head hierarchy of SNOMED-CT. Only three of 11 EDI codes registered on the SCHBC CDM are mapped to the concept ID 45761725, while the remaining eight are mapped to concept ID 4558713 or 45761725 depending on the material. CDM common data model, SCHBC Soonchunhyang University Bucheon Hospital, EDI electronic data interchange, SNOMED-CT systematized nomenclature of medicine clinical terms.

the model because only 10 medical devices' model were recorded in our EHR (Fig. 2a, group 3). The last option was UDI. UDI includes device identifier (UDI-DI) and production identifier (UDI-PI). The UDI-DI should be globally unique²⁹. It should identify the specific version or model of a device and its manufacturer. The UDI-PI identifies one or more of the following when present on the label of the device: the lot or batch within which a device was manufactured, the serial number, the expiration date, and the date on which a specific device was manufactured³⁰. Manufacturers must label medical devices with UDI code in a machine-readable format, such as a barcode, radiofrequency identifier (RFID), and human-readable text. The United States Food and Drug Administration (FDA) released a proposed rule in July 2012 that medical devices distributed in the US should be fitted with UDI³¹. Manufacturers must submit key product to GUDID that can be accessed by both patients and providers³². The European Union (EU) medical device regulations also require fitting of UDI to all medical

	Ministry of Health and Welfare	Ministry of Food and Drug Safety	Manufacturer's global catalog	Access GUDID
Target device	National insured devices	Devices licensed for sale in Korea	Stryker's devices on the market	Devices licensed for sale in USA
Category	O (own taxonomy)	O (own taxonomy)	NA	GMDN
Class (1–4)	X	O	NA	NA
License number	X	O	NA	NA
Bander/manufacturer	O	O	O	O
Brand name	O	O or X	O	O
EDI	O	O*	NA	NA
Model	X	O	O	O
UDI	X	O	X	O
Lot number	X	X	X	X

Table 2. Various medical device data acquired from multiple sources. *GUDID* global unique device identification database, *GMDN* global medical device nomenclature, *NA* not available, *EDI* electronic data interchange, *UDI* unique device identifier. *In case of insurance coverage.

devices sold in the EU. This requirement came into effect from 2015 to 2019³³. European Database on Medical Devices (EUDAMED) is expected to have UDI coding³⁴. In Korea, mandatory UDI attachment was implemented by the MFDS in July 2019. All medical devices should have UDI attachment by 2022. To efficiently manage them, an integrated information system for medical device is also in operation³⁵. Although it is introduced after 2019, UDI is recorded in the EHR as a barcode entry in our institute (Fig. 3). It can be easily structured as it is generated in accordance with regulations. Therefore, the authors determine that UDI is the most appropriate medical device data source to be mapped to CDM.

Health systems may benefit from UDI adoption for several reasons other than postmarket surveillance. The UDI establishes a standard identifier to track the device that can be captured by barcode scanning already widely used for many purposes³⁶. Scanning this single UDI barcode is easier than individually capturing several fields, such as manufacturer, product type, and serial number. It can improve inventory management systems to monitor inventory, enable automatic reordering, and ensure that devices are used before their shelf life expires³⁷. Moreover, knowledge of a patient's implanted devices or those used previously can improve clinical care. If issues are identified or the device is recalled, they could be notified quickly³⁸. As with barcode e-MAR (electronic drug administration records), which significantly reduces medication errors, barcode scanning in medical devices can improve patient safety³⁹. For UDI adaption, hospitals need to upgrade their EHR and supply-chain management programs to capture UDIs and train staff. Although some large health care systems have successfully implemented UDI for implantable devices²⁶, UDI has had limited effect because it is available in neither EHR nor claims³⁸. The Office of the National Coordinator for Health Information Technology has ruled that EHRs must have the capability to record UDIs to receive certification. However, this capability is not mandatory¹⁸. Requiring the UDI in claims is expected to prompt EHR integration³². It has the potential to greatly enhance postmarket surveillance and provide essential data for performing research using real-world evidence. CMS has previously expressed concern about such a requirement because the cost and complexity of changing operating and technical systems to include the UDI in claims. The current proposal shortens claims requirement to include only UDI-DI, meaning that specific models could be identified if UDI-PI is not available. A partial implementation that uses only UDI-DI could decrease the utility of the UDI because important information about a faulty device's production may be missing³⁸. Additionally, even if all providers modify their EHR related to claims and if payers modify their claims-processing systems to accept UDIs, MDV system will not automatically emerge. In the MDV system, some unique characteristics of medical devices should be considered⁴⁰. Medical devices consist of multiple components with complex interactions among devices. The effect of device-specific learning⁴¹ and differences in experience between providers can influence clinical outcomes⁴². Mechanical failure, even software error, could be a potential cause of failure. None of these issues is usually a problem with drugs^{7,43,44}. A functioning medical device evaluation system would be needed.

Although UDI can make unique identification of medical device possible⁴⁵, it is only useful for identifying an issue with a specific device from one manufacturer. Generic device grouping of UDI would enable systematic problem to be identified early. Global Medical Device Nomenclature (GMDN) code fulfils requirements of a generic device group⁴⁶. The GMDN is a list of generic. It was specified as the naming convention for the device portion of the UDI by FDA. The Preferred Term in GMDN is the valid description of a group of devices. It does not differentiate between device models or those from different manufacturers with the same intended use and technology. Therefore, GMDN system enables early identification of a systematic problem not limited to one manufacturer, but shared by other products that use the same technology or materials. In SNOMED-CT system, the only medical device standard vocabulary considered in OMOP CDM, the concept of device is mapped to a subset of GMDN codes. However, various analyses were considered difficult with stratification of SNOMED-CT. Work to expand the GMDN content in SNOMED-CT is required to satisfy wider purposes of SNOMED-CT linked to the use of medical devices. To support its further development, developing medical device descriptions in clinical terminology, linking to additional clinical data, and adding more layers of more specific medical device terms would be needed¹⁶. For example, the authors identified two EDI codes from ceramic femoral heads

Medical device classification according to the MHW E1: Hip prosthesis and cable system		UDI Device identifier			Catalog		Device description on Access GUIDID	
		MFDS	Access GUIDID	Model	Brand name			
Metal	E1012004 E1012020 23 UDI codes	1)	04546540153845	04546540153845	0586-0-022	Exeter femoral head, stainless steel	Exeter, femoral head	
		2)	04546540153890	04546540153890	0586-0-326			
		3)	04546540153852	04546540153852	0586-0-026			
		4)	04546540153937	04546540153937	0586-5-026			
		5)	04546540153906	04546540153906	0586-0-328			
		6)	04546540153869	04546540153869	0586-0-028			
		7)	04546540153944	04546540153944	0586-5-028			
		8)	04546540153913	04546540153913	0586-0-330			
		9)	04546540153876	04546540153876	0586-0-030			
		10)	04546540153951	04546540153951	0586-5-030			
		11)	04546540153920	04546540153920	0586-0-332			
		12)	04546540153883	04546540153883	0586-0-032			
		13)	04546540153968	04546540153968	0586-5-032			
		14)	04546540273307	04546540273307	6364-2-122			
		15)	04546540402158	04546540402158	6364-2-322			
	Other 27 codes	E1012102 32 UDI codes	16)	04546540273260	04546540273260	6364-2-026	Orthinox V40 femoral head	Orthinox, V40 femoral head
			17)	04546540273314	04546540273314	6364-2-126		
			18)	04546540273369	04546540273369	6364-2-226		
			19)	04546540402165	04546540402165	6364-2-326		
			20)	04546540273277	04546540273277	6364-2-028		
			21)	04546540273321	04546540273321	6364-2-128		
			22)	04546540273376	04546540273376	6364-2-228		
			23)	04546540402172	04546540402172	6364-2-328		
			24)	04546540273291	04546540273291	6364-2-032		
			25)	04546540273345	04546540273345	6364-2-132		
			26)	04546540273390	04546540273390	6364-2-232		
			27)	04546540402189	04546540402189	6364-2-332		
			28)	04546540273383	04546540273383	6364-2-230		
			29)	04546540273284	04546540273284	6364-2-030		
			30)	04546540273338	04546540273338	6364-2-130		
			31)	07613327124033	07613327124033	6364-2-222		
			32)	07613327298239	NA	6364-2-628		
Femoral head	E1012001 Other 27 codes 81 UDI codes 347 UDI codes (3-42 UDI codes for each EDI codes)	1)	07613327016086	07613327016086	01-2200	LFIT Morse Taper head	Morse head, femoral head	
		2-12)	07613327016093	07613327016093	11 other 01-xxxx			
		NA	07613327016628	S-1399-HH32	9 other			
		NA	07613327016611	S-1399-HHxx	9 other			
		NA	07613327016765	S-2722-2210	1001-3299			
		NA	07613327016451	1001-3299	11 other 1001-xxxx			
		13)	07613327016208	07613327016208	06-2200			
		14-26)	07613327016680	07613327016680	13 other 06-xxxx			
		27)	07613327016680	07613327016680	S-1400-HH22			
		28-34)	07613327016475	07613327016475	7 other S-1400-HHxx			
		35)	07613327016475	07613327016475	6001-2200			
		36-46)	07613327032291	07613327032291	11 other 6001-xxxx			
		47)	07613327032291	07613327032291	6260-9-036			
48-60)	07613327032604	07613327032604	13 other 6260-9-xxx					
61)	07613327032604	07613327032604	06-4099					
62-81)	07613327032604	07613327032604	20 other 06-xxxx					
Ceramic	E1011008 E1011031 E1011029 9 UDI codes	1)	04546540402127	04546540402127	6565-0-028	V40 Taper Alumina ceramic head	Alumina ceramic V40 femoral head	
		2)	04546540390462	04546540390462	6565-0-128			
		3)	04546540390493	04546540390493	6565-0-228			
		4)	04546540402134	04546540402134	6565-0-032			
		5)	04546540390479	04546540390479	6565-0-132			
		6)	04546540390509	04546540390509	6565-0-232			
		7)	04546540402141	04546540402141	6565-0-036			
		8)	04546540390486	04546540390486	6565-0-136			
		9)	04546540390516	04546540390516	6565-0-236			
Other 24 codes	E1011231 E1011023 E1011002 E1011204 39 UDI codes 292 UDI codes (6-104 UDI codes for each EDI codes)	1)	07613154166527	07613154166527	18-28-3	C-Taper Biolox delta ceramic head	Biolox, Ceramic C-Taper femoral head	
		2)	07613154187256	07613154187256	18-2800			
		3)	07613154187270	07613154187270	18-2825			
		4)	07613154187263	07613154187263	18-2805			
		5)	07613154166534	07613154166534	18-32-3			
		6)	07613154187287	07613154187287	18-3200			
		7)	07613154187300	07613154187300	18-3225			
		8)	07613154187294	07613154187294	18-3205			
		9)	04546540608291	04546540608291	18-36-5			
		10)	07613154166541	07613154166541	18-36-3			
		11)	07613154187317	07613154187317	18-3600			
		12)	07613154187331	07613154187331	18-3625			
		13)	07613154187324	07613154187324	18-3605			
		14)	04546540608307	04546540608307	18-3675			
		15)	04546540608314	04546540608314	19-0000T			
		16)	04546540608321	04546540608321	19-0005T			
		17)	04546540608338	04546540608338	19-0025T			
		18)	04546540608345	04546540608345	19-0325T			
		19)	04546540608383	04546540608383	6519-T-025			
		20)	04546540608390	04546540608390	6519-T-100			
		21)	04546540608406	04546540608406	6519-T-204			
		22)	04546540608413	04546540608413	6519-1-028			
		23)	04546540608420	04546540608420	6519-1-032			
		24)	04546540608437	04546540608437	6519-1-036			
		25)	04546540608444	04546540608444	6519-1-040			
		26)	04546540608451	04546540608451	6519-1-044			
		27)	04546540608468	04546540608468	6519-1-048			
		28)	04546540608550	04546540608550	6519-1-052			
		29)	04546540608499	04546540608499	6519-1-128			
		30)	04546540608529	04546540608529	6519-1-228			
		31)	04546540608475	04546540608475	6519-1-032			
		32)	04546540608505	04546540608505	6519-1-132			
		33)	04546540608536	04546540608536	6519-1-232			
		34)	04546540608482	04546540608482	6519-1-036			
		35)	04546540608567	04546540608567	6519-1-436			
		36)	04546540608512	04546540608512	6519-1-136			
		37)	04546540608574	04546540608574	6519-1-536			
		38)	04546540608543	04546540608543	6519-1-236			
		39)	04546540608581	04546540608581	6519-1-736			
Universal adapter sleeve - Titanium	E1011231 E1011023 E1011002 E1011204 39 UDI codes	19)	04546540608383	04546540608383	6519-T-025	Universal adapter sleeve - Titanium	Universal C-Taper adapter sleeve	
		20)	04546540608390	04546540608390	6519-T-100			
		21)	04546540608406	04546540608406	6519-T-204			
		22)	04546540608413	04546540608413	6519-1-028			
		23)	04546540608420	04546540608420	6519-1-032			
		24)	04546540608437	04546540608437	6519-1-036			
		25)	04546540608444	04546540608444	6519-1-040			
		26)	04546540608451	04546540608451	6519-1-044			
		27)	04546540608468	04546540608468	6519-1-048			
		28)	04546540608550	04546540608550	6519-1-052			
		29)	04546540608499	04546540608499	6519-1-128			
		30)	04546540608529	04546540608529	6519-1-228			
		31)	04546540608475	04546540608475	6519-1-032			
		32)	04546540608505	04546540608505	6519-1-132			
		33)	04546540608536	04546540608536	6519-1-232			
V40 Taper Biolox delta ceramic head	E1011231 E1011023 E1011002 E1011204 39 UDI codes	19)	04546540608383	04546540608383	6519-T-025	V40 Taper Biolox delta ceramic head	Biolox, Universal Taper femoral head	
		20)	04546540608390	04546540608390	6519-T-100			
		21)	04546540608406	04546540608406	6519-T-204			
		22)	04546540608413	04546540608413	6519-1-028			
		23)	04546540608420	04546540608420	6519-1-032			
		24)	04546540608437	04546540608437	6519-1-036			
		25)	04546540608444	04546540608444	6519-1-040			
		26)	04546540608451	04546540608451	6519-1-044			
		27)	04546540608468	04546540608468	6519-1-048			
		28)	04546540608550	04546540608550	6519-1-052			
		29)	04546540608499	04546540608499	6519-1-128			
		30)	04546540608529	04546540608529	6519-1-228			
		31)	04546540608475	04546540608475	6519-1-032			
		32)	04546540608505	04546540608505	6519-1-132			
		33)	04546540608536	04546540608536	6519-1-232			

Figure 5. Analysis of various medical device data for the chemical head selected as a focus group. MHW Ministry of Health and Welfare, UDI unique device identifier, MFDS Ministry of Food and Drug Safety, GUIDID global unique device identification database.

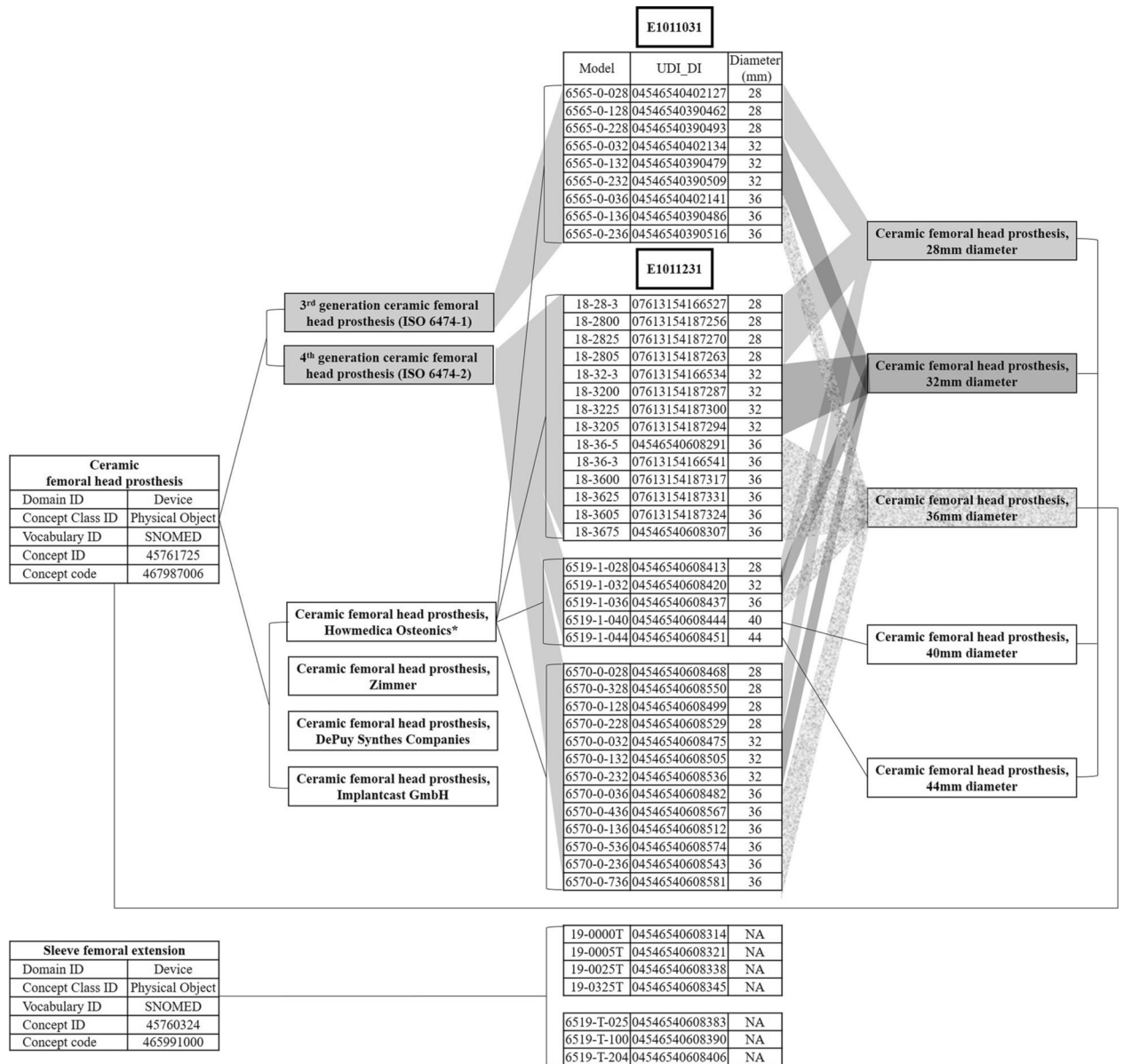


Figure 6. Ceramic femoral head hierarchy was applied to Stryker’s products registered with national insurance EDI codes E1011031 and E1011231. EDI electronic data interchange, SNOMED systematized nomenclature of medicine clinical terms, UDI unique device identifier, DI device identifier.

as examples of UDI for medical devices and sub-grouped them into materials, manufacturers, and specifications based on opinions of orthopedic experts (Fig. 6).

This study has several limitations. First, since a single institution status was investigated, the situation might be different for other countries or institutions. Second, only representative devices in each medical device category were analyzed. Therefore, the EHR recording status for devices not directly identified might differ from this study, even if they are included in the target medical device category.

OMOP CDM, which is built in our institution, uses EDI code as a medical device data source. Despite its advantages of structural and standardization, EDI is matched in one-to-many with UDI, including devices classified as different GMDNs. Therefore, it is difficult to ensure the accuracy of surveillance results if all medical devices corresponding to a single EDI code are considered to have a single characteristic. To communicate safety information of medical devices, it is recommended to use internationally accepted UDI rather than EDI code as a data source. To introduce UDI, each institution needs to have a barcode reader, develop EHR, and train users. To compensate for the vulnerability of UDI to systematic problem identification, analysis of generic device groups using GMDN is necessary. In this respect, SNOMED-CT that reflects GMDN is appropriate for CDM-based MDVs. However, since analysis according to various device characteristics is difficult with current classification, adding more specific layers is essential. Finally, even if UDI is recorded in EHR and converted to CDM, additional MDV systems are needed to analyze it.

Methods

We conducted a cross-sectional study at Soonchunhyang University Bucheon Hospital (SCHBC) in Bucheon, Gyeonggi Province, Republic of Korea. This study was approved by the Institutional Review Board of SCHBC. Informed consent was waived (SCHBC 2020-08-028-001).

Analysis of medical device data recorded in EHR. To evaluate the adequacy of EDI for MDV purposes and to determine the existence of medical device data other than EDI, the target medical device was selected and medical device records of EHR were grouped.

Selection of target medical devices: According to the Ministry of Food and Drug Safety (MFDS) notice in May 2020, medical devices in Republic of Korea are classified into 2112 categories. The following three criteria were applied to select medical devices to evaluate the frequency of MDAE and their risk to patients:

- (1) Medical devices with MDAEs posted on the MFDS medical device information portal. MDAEs reported in the Republic of Korea have been posted on the MFDS medical device information portal since October 2016 (<https://udiportal.mfds.go.kr/>). Since posts before August 2018 did not include details of MDAE, this study was conducted using information posted after 2018.
- (2) Medical devices with patients' health effect caused by MDAE posted on the portal.
- (3) Although MDAEs posted on the portal did not show their effects on patients' health, medical devices were classified as moderate (class 3) or high (class 4) potential risk according to the classification of medical devices in the Republic of Korea.

According to data format, data were classified as unstructured narrative text and structured coded data⁴⁷. The number and percentage of medical devices corresponding to each information level and data format were obtained. Microsoft Excel 2019 (Microsoft, Redmond, WA, USA) was used for statistical processing.

Focus analysis of medical device data. To provide a detailed example of medical device data, focus group analysis was conducted using single item: femoral head. Medical device data related to the focus group were retrieved and collected from the MOHW's medical device price list notice⁴⁸, the MFDS's Information Portal⁴⁹, and the U.S. national library of medicine's Access GUDID⁵⁰.

To analyze SNOMED-CT conversion status of medical device data, Observational Health Data Sciences and Informatics (OHDSI) open-source software and OMOP CDM version 5.3 database were used. EHR of SCHBC was converted to source name of cdmpv531_0920_bucheon. Central vocabulary service Athena (<http://athena.ohdsi.org>) was used to assess the hierarchy of SNOMED-CT.

Ethics approval. This study was approved by the Institutional Review Board of Soonchunhyang University Bucheon Hospital (SCHBC) (approval number: SCHBC 2020-08-028-001).

Consent to participate. Informed consent was waived by the IRB.

Data availability

Data are available from the corresponding author upon reasonable request.

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Competing interests

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Additional information

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