Moon Care and Preliminary Benefit Program in South Korea: Innovative Strategies in Post-Market Evidence Generation for Medical Devices

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Objectives: The President Moon administration was launched in May 2017. The “Benefit Expansion” of the National Health Insurance (NHI) system has emerged as the core policy of the new government. It provides an overview of the health policies and programs announced by the Moon administration and suggests health policy operation for a successful and effective “Preliminary Benefit” program specific to medical devices which is one of the main drivers in the new health policies.

Methods: A description of the new health policies, namely “NHI Benefit Enhancement Measures” and “Preliminary Benefit” program and a review of foreign strategies in post-market evidence generation for medical devices which provides insight for evidence generation applicable in South Korea.

Results: Registries are strategic instruments to generate evidence under “Preliminary Benefit” for those medical devices which do not have sufficient evidence at the time of market entry and subsequent post-market stage. As demonstrated in the transcatheter valve therapy registry and Micra coverage with evidence development study, there are even more effective and cost-saving methods for evidence generation. There are several strategies and elements that can be considered in performing efficient medical device registries: 1) quality measure and pay-for-performance, 2) registry linking with claims datasets, 3) funding and resource provision for registry, and 4) participation in international registries.

Conclusion: The “Preliminary Benefit” program under “Moon Care” is epoch-making in the benefit expansion history of NHI system. Registries are one of the promising strategies to pursue health technology reassessment required in the “Preliminary Benefit” program. The success of “Preliminary Benefit” depends on the reassessments, and the evidence generation of medical devices required for reassessment can be resolved by registries. The development of and investment in registries, and even more innovative evidence generation approaches as seen in the foreign cases, should be made for the “Preliminary Benefit” program.

Key Words Moon care · Preliminary benefit · Medical device · Registry · Coverage with evidence development · Claims datasets · South Korea.

Introduction

On May 10, 2017, the new government in South Korea was launched with the election of President Moon Jae-in. Diverse pledges were presented during the presidential election campaign. The pledge in the health care sector has attracted much attention from the public, and the “Benefit Expansion” of the National Health Insurance (NHI) system has emerged as the core policy of the new government. Since 2005, the Korean government has been heavily investing in strengthening the “Benefit Expansion.” Despite the huge investment of about 29 trillion Korean won (26.4 billion US dollars) from 2005 to 2016, the NHI coverage rates remained at 63.4% as of 2015.a) In the past 10 years, the NHI coverage rates have stagnated at levels slightly above 60% (e.g., 61.3% in 2004, 63.6% in 2010, and 63.4% in 2015). Moreover, catastrophic medical costs (e.g., medical expenses exceed 40% of disposable family income).

The coverage rate is calculated by [total medical expenses-patient-out-of-pocket (non-covered medical expenses plus patient copayment)]/total medical expenses.
come) reached 4.49% in 2014 (vs. 3.68% in 2010) and continue to increase. According to an analysis by the National Health Insurance Service (NHIS), it is estimated that non-covered medical expenses reached 11.2 trillion Korean won (10.2 billion US dollars) as of 2014. The non-covered medical expense ratio to total medical expenses rose from 13.7% in 2009 to 17.1% in 2014 while NHI covered 63.2% of medical expenses along with 19.7% statutory patient copayment in 2014. Eventually patients have to bear 36.8% of the medical expenses, which is a considerable financial burden on patients, much higher than the Organization for Economic Cooperation and Development average (19.6%) in 2014.

On August 9, 2017, three months after the presidential inauguration, President Moon announced the “NHI Benefit Enhancement Measures” to drastically lower the burden of medical expenses on citizens and to prevent the collapse of households due to high medical expenses. It creates coverage enhancement measures through sizable investment of 30.6 trillion Korean won (27.8 billion US dollars) until 2022 and an increase of the NHI coverage rates of up to 70%. The government aims to completely transition all medically necessary non-covered services and items into NHI benefits except certain medically unnecessary services and items (e.g., cosmetics and plastic surgeries, etc.), replacing the former gradual transition approach of the non-covered services and items. For items and services determined to have low cost-effectiveness, the non-covered services and items will be designated to new program called “Preliminary Benefit” that applies differentiated patient copayment rates such as 30%, 50%, 70%, and 90%. The “Preliminary Benefit” is a transitional program to raise the NHI coverage rates in a current situation where non-covered services and items are prevalent. The “Preliminary Benefit” services and items will be reassessed after 3 to 5 years to determine whether to transit into full benefit coverage. At present there are about 3800 non-covered services and items and they will be assigned to full coverage benefit or “Preliminary Benefit” by 2022 on the basis of the implementation roadmap. While the government cannot control the prices or utilization for the non-covered items and services, it becomes possible to manage and control the prices and utilization with “Preliminary Benefit” program, thereby mitigating the financial burden on patients.

HTR Under “Preliminary Benefit” Program

The government plans to provide patients with “Preliminary Benefit” for 3 to 5 years and then perform health technology reassessment (HTR) based on clinical evidence generated throughout clinical practices. The two government agencies, the Health Insurance Review and Assessment Service (HIRA) and the National Evidence-based Healthcare Collaborating Agency (NECA) take responsibility for HTR by undertaking systematic health technology assessments (HTA). The HIRA is expected to carry out initial reassessment and request external in-depth reassessment to the NECA if necessary. Multiple elements including safety, effectiveness, cost-effectiveness, and social demands, etc., will be assessed by referring to the evidence which has accumulated during the period.

The reassessment is not new. It has previously been implemented for the “Selective Benefit” program of the past government which is similar to the “Preliminary Benefit” program. The “Preliminary Benefit” program differs from the “Selective Benefit” program in that patient copayment rates are limited to 50% or 80% covers only four major conditions—cancer, cardiovascular diseases, cerebrovascular diseases, and rare diseases. Previously 51 services and items were covered by the “Selective Benefit” program. Of the 51 covered items and services, three were subject to the conditional “Selective Benefit” program which requires more rigorous reassessment of the clinical evidence [transcatheter valve therapy (TVT), percutaneous left atrial appendage occlusion, and next generation sequencing]. Recently the reassessment process for the services and items covered by the “Selective Benefit” program initiated and TVT has been selected for reassessment in 2018. The prioritization criteria for reassessment are: 1) posing safety issue, 2) uncertain effectiveness or ineffectiveness issues are raised, 3) sufficient amount of clinical evidence is available, 4) high burden of diseases, 5) the greatest potential impact of reassessment, 6) high frequency of utilization, and 7) needs for cost-effectiveness analysis.

Currently reassessment has been sequentially implemented for the “Selective Benefit” services and items which the previous government has determined 3 to 4 years ago. While most of “Selective Benefit” services and items have been in the market for at least three years, it is difficult to say that high quality clinical evidence has been generated for medical devices, particularly for locally-manufactured devices. In addition, it is hard to expect that clinical evidence would be naturally generated over this period of time. It is important to ensure the safety and effectiveness of medical devices through real-world evidence in clinical practices. For medical devices with a high priority for reassessment as described above, a new approach is needed to create clinical evidence. It is necessary to establish an modern approach to accelerate evidence generation while minimizing administrative burden, adopting ideas which are in use in other developed countries.
Registry: Evidence Generation of Medical Devices for HTR

A registry is defined as "organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes." Along with global emphasis on measuring and improving the quality and efficiency of healthcare services particularly under the value-based health care era, clinical registries proliferate to enhance real-world evidence generation on the basis of clinically enriched data for better outcomes and patient-centered care. Registries for medical devices can enhance our understanding of medical device performance beyond what is learned in highly refined premarket clinical trials. They gather clinical information in broad practice setting, which represents the real-world use of therapies including patient and operator characteristics that are not limited by protocol mandated treatments and restrictive trial inclusion criteria of premarket trials. Registries have stronger external validity than premarket trials, and generally gather data in a larger set of patients over a longer-term follow-up, which can increase the ability to detect adverse events that happen infrequently and enhance understanding of longer term benefits. In general, registries capture information across five domains: 1) indicated procedure, 2) patient characteristics, 3) details on procedure and physicians, 4) details on medical device, and 5) patient outcomes.

In addition, registries contribute to medical device innovation by collecting outcome data and identifying quality or performance improvement areas for next generation medical devices. Registries can be executed in a more cost-efficient manner as demonstrated by the Thrombus Aspiration during ST-Segment Elevation Myocardial Infarction (TASTE) trial. The TASTE trial is designed with multicenter, prospective, randomized controlled open-label study. Its patient enrollment was made from the national comprehensive Swedish Coronary Angiography and Angioplasty Registry and also the data were collected from other national registries. The cost of this registry-based trial was less than 1 percent of a conventional randomized trial. It is important to note that registries have several weaknesses as well. It is difficult to control and identify all sources of bias and confounding. It is also more challenging to analyze outcomes than randomized controlled trials (RCTs) due to more variability in treatment, patient population and clinical settings, etc., changing practice over time and variable time intervals between patient visits.

State of the Art Registry Design: STS/ACC TVT Registry

In the United States, the Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) TVT registry (TVT registry) is a national partnership-based clinical registry program enrolling all patients receiving market released transcatheter heart valve devices. Its novel features represent the state of the art in registry design. It was developed through a partnership of the STS and the ACC, in collaboration with the US Food and Drug Administration (FDA), the Center for Medicare and Medicaid Services (CMS), and the Duke Clinical Research Institute, with input from the Society for Cardiovascular Angiography and Intervention and the American Association for Thoracic Surgery (Table 1). This unique collaboration among multiple stakeholders enables the registry to serve numerous purposes: 1) to meet the CMS coverage with evidence development (CED) requirement for transcatheter aortic valve replacement and transcatheter mitral valve repair procedures, 2) to allow for hospital and healthcare provider benchmarking against national data, and 3) to advance the evidence base for transcatheter valve procedures including strengthening post-market device surveillance through embedded post-approval studies, advancing scientific research through other nested sub-studies, and providing data for consideration of expanded indications.

The TVT registry represents a paradigm shift in continuous evaluation and monitoring of safety and effectiveness of transcatheter valve devices and represents an evolution in approach as compared to traditional registries such as the National Cardiovascular Data Registry Implantable Cardioverter Defibrillator registry. The TVT registry requires close partnership and collaboration covering multiple stakeholders (e.g., regulatory and reimbursement authorities, healthcare providers, specialty societies, patient representatives/advocacy groups, researchers and medical device industry). The careful definition of terms and data elements resulting from this collaboration is expected to enable linkages from this registry to other registries, pivotal trials, and datasets such as CMS administrative claims data. The registry also provides comprehensive and detailed patient-level data gathering/analysis repository (e.g., more than 300 pre- and post-procedure data elements) and reporting infrastructure. Implanting hospitals are responsible for electronic data entry and will be provided with quarterly performance benchmarking reports at the hospital and provider level, both against volume-based peer groups and the overall national experience.

The TVT registry has several innovations not commonly found in previous registries (Table 2). It includes the use of unique device identifiers (UDIs) to better monitor the safe
and effective use of transcatheter valve devices. Short-term objectives are included to address clinical issues that have been observed in pivotal trials (e.g., stroke, paravalvular regurgitation, etc.). Linkage with CMS administrative claims data is pre-planned to better understand long-term patient outcomes. Patient-reported outcomes (via validated tools to measure symptom burden and quality of life) are designed into the data collection and analysis.

**Innovative Evidence Generation Beyond Registry: CED of Micra Leadless Pacemaker**

The longitudinal prospective study is a new method for

### Table 1. TVT registry™ overview

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composition and enrollment</td>
<td>Prospective enrollment of all patients in the United States receiving FDA-approved transcatheter heart valve devices</td>
</tr>
<tr>
<td>Registry data elements, analysis, and reporting</td>
<td>Standardized and comprehensive data elements: indications, patient characteristics, periprocedural results, and complications, in-hospital, 30-day, and subsequent yearly outcomes, and patient health status measures</td>
</tr>
<tr>
<td></td>
<td>Harmonization of elements and definitions with national and international registries, pivotal trials, and consensus groups (e.g., Valve Academic Research Consortium whenever possible)</td>
</tr>
<tr>
<td></td>
<td>Unique device identification</td>
</tr>
<tr>
<td></td>
<td>Long-term outcomes with linkages to Center for Medicare and Medicaid Services administrative claims data with adjudication of pre-specified adverse outcomes relevant to individual devices</td>
</tr>
<tr>
<td></td>
<td>Implantation hospitals responsible for data entry using web-based data entry interface from the NCDR</td>
</tr>
<tr>
<td></td>
<td>Completeness and accuracy of data entry monitored and audited both internally - e.g., NCDR and the STS - and externally - FDA</td>
</tr>
<tr>
<td></td>
<td>Protection of confidential health care information and utilization of patient informed consent when appropriate</td>
</tr>
<tr>
<td></td>
<td>Quarterly benchmarking reports for hospitals to compare the institution’s performance with that of volume-based peer groups and the national experience</td>
</tr>
</tbody>
</table>

**Governance and structure**

Steering committee
- Research and publications subcommittee
- Stakeholders advisory group

**Analytic centers and research**

Contracted analytic center: Duke Clinical Research Institute
- FDA-mandated post-approval study nested within the registry with the ability of industry to use this infrastructure to meet their condition of approval requirements
- Investigational device exemption studies sponsored by professional societies
- Future linkages with other professional society registries and other national registries
- Other substudies nested within the TVT registry

**Funding**

The STS, American College of Cardiology, TVT registry site fees, medical device industry, FDA, and research grants

### Table 2. Aspects of different study approaches

<table>
<thead>
<tr>
<th>Example</th>
<th>Traditional registry</th>
<th>Partnership-based registry program</th>
<th>Prospective longitudinal study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data collection</td>
<td>NCDR ICD registry</td>
<td>TVT registry</td>
<td>Micra CED study</td>
</tr>
<tr>
<td>Follow-up</td>
<td>None</td>
<td>30 days, 1 year</td>
<td>All available claims</td>
</tr>
<tr>
<td>Patient characteristics</td>
<td>Detailed</td>
<td>Detailed</td>
<td>Broad (coded)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Claims-based</td>
<td>Claims-based, PROs</td>
<td>Claims-based</td>
</tr>
<tr>
<td>Cost</td>
<td>High (per patient)</td>
<td>High (per patient)</td>
<td>Moderate (per analysis)</td>
</tr>
<tr>
<td>Effort/coordination</td>
<td>Hospital/moderate</td>
<td>Hospital/high</td>
<td>Analysis entity/low</td>
</tr>
<tr>
<td>Data definition basis</td>
<td>Registry specific</td>
<td>Collaborative</td>
<td>Reimbursement codes</td>
</tr>
<tr>
<td>Subgroup research</td>
<td>Detailed</td>
<td>Detailed</td>
<td>Limited by codes</td>
</tr>
<tr>
<td>Embedded sub-studies</td>
<td>No</td>
<td>Yes (new CRFs)</td>
<td>Yes (new analysis plan)</td>
</tr>
<tr>
<td>Linkages to other data</td>
<td>Retrospective</td>
<td>Prospective</td>
<td>None</td>
</tr>
<tr>
<td>Comparators</td>
<td>None</td>
<td>None</td>
<td>Concurrent cohort</td>
</tr>
</tbody>
</table>

NCDR: National Cardiovascular Data Registry, ICD: Implantable Cardioverter Defibrillator, TVT: transcatheter valve therapy, CED: coverage with evidence development, CRF: case report form, PROs: patient-reported outcomes
generating evidence to that has been used to satisfy CED requirements for some health technologies in the United States. The first protocol approved by CMS of this type is the Longitudinal CED Study on Micra Leadless Pacemakers (Micra CED study), which applies to the first market released leadless pacemaker in the United States. This study leverages the data generated by billing claims activity and requires no additional data collection activities. This type of study has the potential to answer questions about new technologies without imposing the cost and resource burdens of a traditional registry, which would be borne by hospitals, device manufacturers or payers requiring the evidence.

The primary research questions posed by CMS for leadless pacemaker technology are related to complications, long-term outcomes, and impact of patient characteristics on the use and health effects of leadless pacemakers. Because of the specificity of diagnosis and procedure codes required for billing submissions, the relevant information to answer these questions is already present in administrative claims databases. Leveraging the claims data will enable a comparison of leadless pacemaker performance with a concurrent cohort of traditional pacemakers, enhancing the evidence in a manner that would not be possible in a traditional registry without virtually doubling the expense and effort.

There are advantages and disadvantages of this new form of study as compared to a traditional registry. It enables an untainted “real world” assessment of performance, free of any influence from inclusion criteria or data collection activities. The sample size is virtually unlimited within the covered population, which can give very precise estimates of performance as well as enabling the characterization of rare occurrences. It will enable complete longitudinal information on patients, unaffected by changes in healthcare providers. Information is standardized and relevant to the payer. It is reliant on the billing codes for specificity, however the broad questions being asked are adequately served by existing codes, especially after the advent of International Classification of Diseases-10. It is also not possible to collect patient-reported outcomes, thus is applicable only to cases where these are not of primary interest.

The value of a claims analysis as described above is dependent on the validity of billing claims data to represent clinical variables and outcomes. Outcomes research of which claims analyses is one form is an established methodology used throughout healthcare to the extent that standards for quality have been proposed by independent organizations. The Micra CED study has been designed with these standards in mind. The protocol for the study pre-specifies the measures for clinical variables, outcomes and analysis methods. The protocol is also informed by a literature review of landmark studies in traditional and leadless pacemakers. The study will engage an independent adjudication committee, which has provided substantial input during the protocol development. A summary comparing the different aspects of the study approaches discussed above is given in Table 2.

**Discussion**

The reassessment under the “Preliminary Benefit” program has a critical role to evaluate safety, effectiveness, and cost-effectiveness of medical devices. However, the reassessment cannot be effectively performed without efforts to generate post-market real-world evidence. Registries generate novel real-world evidence to supplement premarket studies, which enables reassessment of already marketed medical devices. The primary purpose of registries includes the reassessment of safety and effectiveness of medical devices in the market. Both the TVT registry and the Micra CED study suggest the possibility of reassessment through the generation of new clinical evidence. The revision or expansion of indications for use of already marketed medical devices is possible through real-world evidence obtained through registries. In addition, the aggregation of real-world data obtained through registries is useful for post-market control. This enables ongoing medical device safety surveillance as well as providing additional evidence of effectiveness, ultimately becoming the basis for reassessment. In the end, registries provide a useful tool for reasonable assurance of safety and effectiveness of medical devices. As demonstrated in the above-mentioned foreign cases, registries could be critical solution for evidence generation in the pursuit of a successful “Preliminary Benefit” program.

There is growing need for post-market studies for medical devices because it is challenging to sufficiently establish safety and effectiveness with pre-market studies. In addition, there may be more efficient ways to generate evidence beyond conventional registry as seen in the Micra CED study example. As understanding the ‘rational dispersion’ of TVT procedure is the key objective of the TVT registry, registries can contribute the ‘rational dispersion’ of new medical technologies under “Preliminary Benefit” program. Registries could play an important role in long-term medical device surveillance, appropriate use measurement, comparative effectiveness research, and potentially estimation of cost-effectiveness. However, while registries have multiple advantages to gather superior health outcomes data, the selection and initiation of registries should be made with caution due to challenges in implementation in clinical setting. It is appropriate to initiate registries in the specific cases when they can provide answers to research questions in unique or more efficient.
ways. In selecting and operating registries in South Korea, criteria similar to the afore-mentioned prioritization criteria for reassessment can be applicable. The rationale for the TVT registry and the Micra CED study implementation is the lack of sufficient real-world safety and effectiveness evidence in the premarket study. For studies like these, it is desirable to select a technology that requires further evidence because it is at an early stage, has a great impact on the public health in terms of patients’ burden of disease, has uncertain safety and effectiveness, and has a high frequency of utilization.

Registries can serve to align with the regulatory authority’s efforts to enhance medical device quality management. As a more efficient way to operate a registry, a unique device identification system can be used to ensure the safe use of medical devices through enhanced traceability of medical devices. The unique device identification system was initiated by US FDA in September 2013 as a means of national surveillance system to track medical device distribution and usage, and similar systems have spread all over the world including South Korea. The system in South Korea will be phased in over a few years depending on device classification (class 4 devices in January 1, 2019; class 3 devices in January 1, 2020; class 2 devices in January 1, 2021; and class 1 devices in January 1, 2022). It is anticipated to improve medical device safety management by providing earlier identification of any adverse events related with medical devices and encouraging more efficient and timely recalls. All medical device manufacturers shall place a UDI on the product label in human and machine-readable format as mandated. The UDI has the potential to identify a patient treated with a specific medical device by searching electronic health records (EHRs) and also to support a national device registry as primary data source. It enhances the key role of registries in post-market surveillance. When a registry is linked with UDI information, it can maximize the medical device quality measure reporting system across the nation.

South Korea is in a good position to implement registries under its single payer NHI system. Unlike United States and other countries which have fragmented healthcare systems with multiple payers, the universal healthcare system with single payer in South Korea enables streamlined processes for registries with lower administrative and operating costs. Several specialty society or hospital-driven registries are underway and access to the registry data is limited to sponsoring entities. As seen in the TVT registry, the collaboration with all related stakeholders starting from registry development stage is strategically critical to bring maximum benefit to all stakeholders. For patient care and public health improvement across the nation, the findings of registries should be transparent and available to all stakeholders. There are several strategies and elements that can be considered in performing efficient medical device registries for successful “Preliminary Benefit” program in South Korea.

Quality measure and pay-for-performance

Registries can encourage the adoption of quality measures driven by the “care quality assessment” and “Healthcare Benefit Appropriateness Assessment Program” which are designed to improve healthcare quality. For instance, as seen in several care areas in South Korea, the CMS in United States operates “Physician Quality Reporting System” which utilize both incentive and disincentive payments to promote reporting of quality information. To maintain and support the value of registries, it is worthwhile to develop an incentive program for healthcare providers who participate in registry and report quality measure data to HIRA. The current Korean health authority’s policy drive for pay-for-quality measure or pay-for-performance is exactly aligned with the potential reward for participating healthcare providers in registry as they collect quality data and share their knowledge to improve quality of care. With active participation from specialty societies and healthcare providers, registries can boost patient outcomes by transparently reporting on performance by healthcare providers, medical devices and potentially clinicians. In addition, transparency in data access can improve professional and public confidence in the validity of scientific registry data. All stakeholder engagement can maximize the output of registry. For instance, the Agency for Healthcare Research and Quality in United States began to establish online registry of patient registries in order to provide searchable patient registry database in 2012.

Registry linking with claims datasets

While some data elements in a registry are easily and reliably gathered from participating hospitals’ EHRs, other important data are not easy to capture from it. Registries can be made more efficient and generate more useful evidence when other data sources such as EHRs or NHI claims datasets are fully integrated. Those data from other sources can provide long-term patient’s health status (e.g., regular follow-up monitoring and hospital revisit due to revision surgery or complications, etc.) which cannot be captured by a premarket study or a clinical study designed with short-term follow-up. The claims datasets and EHRs are useful data sources which provide answers to the unforeseen questions about long-term medical device performance. Although registries can provide longitudinal long-term patient data with extension of outpatient follow-up, many registries are generally operated with limited setting (e.g., in-hospital or 30 day outcomes, etc.) due to practical challenges such as ‘selection bias’ incurred by di-
rect patient contact for longitudinal follow-up, costs and difficulty in obtaining complete follow-up data for large size of registry population. Furthermore, there are often limitations to gathering longitudinal long-term data beyond the acute episode of care. As an alternative to the limited nature of registry, administrative claims datasets can be effectively used. Administrative claims datasets have several strengths: large size, comprehensive inclusion of patient's entire care experience, and unique patient identifiers possibly creating longitudinal patient care record. However, the claims datasets have disadvantages (e.g., lack of accurate and detailed clinical information) (Table 3).27) Administrative claims datasets with patient identifiers can track the records of patient episodes of care extended into outpatient care.

By linking this claims datasets with registry data, more meaningful and enriched data can be produced to help better quality care and patient outcomes.28) Such an analysis would have advantages over an analysis based on claims datasets alone. Administrative claims datasets are developed for non-regulatory purposes and are typically used for reimbursement billing and payment for medical care. While patient baseline conditions and outcomes can be imputed from the claims analysis adequately for most purposes, a more rich and granular understanding is possible when combined with registry data. When the evidence needs demand a more deep understanding, such as with new indications or novel medical therapies with no obvious comparator, it makes sense to use this more comprehensive approach.

Unlike foreign countries which have primary challenge in linking registry and claims datasets due to lack of direct patient identifiers, all Korean patients have their own unique “resident registration number” and it makes much easier to link the claims datasets and registry data. While privacy information protection issues exist, the technical deidentification to block patient identification can solve the issue. Also the justified data utilization for public interest purpose (e.g., health policy instrument for quality care and patient outcomes) could be supported by the general public.

### Funding and resource provision for registries

Although registries have various advantages, they require significant investment of resources to initiate and maintain. The data collection in a registry requires significant effort and costs. The funding and resources are one of critical elements to operate registry in South Korea. Not only initial funding to create a registry but also continued funding should be provided to maintain independent, impartial, and scientifically credible registry governance and daily operation. As seen in the case of the TVT registry in the United States, multiple sources of funding and resources from stakeholders (e.g., site fees, and grants from specialty societies, research institutes and device manufacturers) can help make a registry successful.16) While healthcare providers, specialty societies or commercial entities (e.g., medical device manufacturers) need to invest and collaborate to initiate and maintain registry, it is essential for health authority to invest in registry infrastructure development.

As seen in the government announcement for “Moon Care” program, a significant investment of 30.6 trillion Korean won will be poured into “Benefit Expansion” program. Unfortunately there is not a specific investment plan to support evidence generation for HTR aligned with “Preliminary Benefit” program. While it is very critical to invest in the “Benefit Expansion” program, investment for evidence generation such as registries can enable a bigger benefit for efficient and cost-effective management of NHI. When the findings from a registry become transparently available to all stakeholders, it can ultimately improve patient care and also save unnecessary spending of NHI funds. The recent government announcement for a health technology development plan indicates the benefits of clinical evidence generation investment. It highlights the huge saving effect of the national health expenditure

**Table 3. Administrative claims datasets: advantages and disadvantages for research and analysis**

<table>
<thead>
<tr>
<th>Advantage</th>
<th>Disadvantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real world outcomes and utilization</td>
<td>Not randomized</td>
</tr>
<tr>
<td>Large sample size</td>
<td>Collected for payment not research</td>
</tr>
<tr>
<td>Ability to study rare conditions and events</td>
<td>Reliance on what is coded (omission bias)</td>
</tr>
<tr>
<td>Longitudinal and complete data on patient</td>
<td>Reliance on coding systems for specificity</td>
</tr>
<tr>
<td>Population-based</td>
<td>Procedure level instead of product level</td>
</tr>
<tr>
<td>Same data payers use to internally</td>
<td>Lack of clinical results/data</td>
</tr>
<tr>
<td>Generalizability</td>
<td>Patient adherence unobserved</td>
</tr>
<tr>
<td>Continuous eligibility for longitudinal designs</td>
<td>Disenrollment</td>
</tr>
<tr>
<td>Ability to construct relevant outcomes and predictors</td>
<td>Lack of explanation for “why”</td>
</tr>
<tr>
<td>Relatively inexpensive</td>
<td>Inability to contact patient</td>
</tr>
<tr>
<td>Relatively standardized information</td>
<td>Time delay</td>
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</table>
through public clinical research. It is expected that registries under “Preliminary Benefit” program may produce a similar effect of the saving of NHI spending.29,30

Under the “Preliminary Benefit” program, it is also very important to select the entity that constructs and operate registries linked to administrative claims datasets. It is expected for the NECA, Korea’s HTA agency to play a leading role in the construction and operation of registries with respect to health policy direction and environment. This would ensure proper publicity, objectivity, transparency, evidence generation-required resource, expertise, infrastructure, and also access to administrative claims datasets as needed. NECA has a mission to promote the efficient use of medical resources and the improvement of the health of the people through the provision of scientific evidence. It is also meant to be a specialized agency leading the generation of healthcare evidence. Since its establishment in 2009, NECA has been supporting the development of evidence-based research for establishing a nation-wide evidence-based healthcare system. It has accumulated research capacity and expertized researchers for the past 10 years. In addition, it has been selected as the research institute of national health clinical research, which supports clinical studies in accordance with policy needs such as scientific clinical evidence generation and establishment of basis for appropriate medical services in order to effectively respond to the healthcare issues. Based on proven and accumulated research capability, expertise, and contribution to building an evidence-based health care system, it can lead and cooperate with various stakeholders in the healthcare field. Through cooperation with the HIRA, it can secure and link administrative claims datasets for more effective registry operation. Furthermore, as a public entity operating registries, it can be justified for securing public funding.

The outcomes data derived from registries can be used as a basis for full benefit coverage decision beyond transitional benefit coverage, and registry outcomes data associated with administrative claims datasets can provide important information for cost-effectiveness analysis. Based on the outcomes data, it is possible to establish optimal reimbursement payment guidelines. By applying care to the correct patient population, unnecessary expenditures in NHI can be avoided which helps to manage efficient NHI finances. In addition, registry outcomes can not only be used for benefit coverage purposes, but also can be shared with the regulatory authority, the Ministry of Food and Drug Safety, to improve the labeling (i.e., revision or addition of indications for use or labeling update to include new information on safety and effectiveness) and to further enhance the safety and effectiveness of medical devices.

**Participation in international registries**

It is desirable to join international registries and to perform global comparative effectiveness research for more robust evidence generation purpose. The International Consortium of Orthopedic Registries was created in 2011 and combined 29 orthopedic registries from 14 countries covering more than 3.5 million patients undergoing either total knee or hip arthroplasty surgeries around the world.31 Considering multiple challenges to perform RCTs with medical devices particularly used in surgical procedures, registry and even further internationally networked registry can fill the gap in the required clinical evidence and answer the questions about safety and effectiveness. In particular, multinational, longitudinal and large scaled registries for implantable devices can provide comprehensive datasets to perform comparative effectiveness research and find adverse events related to specific devices quickly and efficiently.32 This best practice led to similar efforts to develop the International Consortium of Transcatheter Valve Registries participating from 5 nations (United States, Germany, UK, Canada, and the Netherlands) in 2013.33,34

Sweden is well known for top ranking position in international comparison of health outcomes and operating more than 100 care registries covering the majority of the national burden of diseases. Behind the scene, Swedish national effort to capture comprehensive outcomes data about major diseases causing national health expenditures attributes this strong presence of high quality with less-spending in healthcare system. For instance, the National Quality Registry for Diabetes (NDR) program comprehensively collects care outcomes data on more than 5 million diabetes patients. The NDR data are available online allowing healthcare providers to compare their own care results with national statistics. Therefore, a registry can trigger healthcare providers’ behavior change.35 It is recommended to design a registry under the “Preliminary Benefit” program with opportunity of the international registry participation.

**Conclusion**

The “Preliminary Benefit” program under “Moon Care” is epoch-making in the benefit expansion history of NHI. The huge amounts of investment to implement “Preliminary Benefit” for covering all medically necessary services and items are unprecedented. While the investment of coverage for non-covered services and items is important, the efficient and effective management of the NHI funds under ongoing coverage expansion is critical. In this respect, the infrastructure and funding for evidence generation activities is necessary to effectively undertake HTR. Registries are one of the
promising strategies to pursue HTR in the “Preliminary Benefit” program. Registries provide healthcare providers, patients and other stakeholders with valuable information to support the decision-making to optimize care pathways for patients. It gives opportunity for transparent and objective comparison about the performance of healthcare provider relative to patient outcomes and resource use. Registries are more powerful when they are linked with EHRs and administrative claims datasets. As demonstrated in the TVT registry and Micra CED study in the United States, there are even more effective and cost-saving methods in post-market evidence generation than conventional registries.

2018 is the beginning year of the implementation of “Preliminary Benefit” program. It is the right time to design a strategy and detailed action plan for “Preliminary Benefit” program aligned with an evidence generation roadmap. Such a plan can properly balance the need for current access to innovative health technologies with the ongoing need for evidence-based assessment of safety and effectiveness. The investment in registries and even more innovative evidence generation approaches as seen in the foreign cases should be reflected in the strategy.

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