



Survey on Value Elements Provided by Artificial Intelligence and Their Eligibility for Insurance Coverage With an Emphasis on Patient-Centered Outcomes

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Objective: This study aims to explore the opinions on the insurance coverage of artificial intelligence (AI), as categorized based on the distinct value elements offered by AI, with a specific focus on patient-centered outcomes (PCOs). PCOs are distinguished from traditional clinical outcomes and focus on patient-reported experiences and values such as quality of life, functionality, well-being, physical or emotional status, and convenience.

Materials and Methods: We classified the value elements provided by AI into four dimensions: clinical outcomes, economic aspects, organizational aspects, and non-clinical PCOs. The survey comprised three sections: 1) experiences with PCOs in evaluating AI, 2) opinions on the coverage of AI by the National Health Insurance of the Republic of Korea when AI demonstrated benefits across the four value elements, and 3) respondent characteristics. The opinions regarding AI insurance coverage were assessed dichotomously and semi-quantitatively: non-approval (0) vs. approval (on a 1–10 weight scale, with 10 indicating the strongest approval). The survey was conducted from July 4 to 26, 2023, using a web-based method. Responses to PCOs and other value elements were compared.

Results: Among 200 respondents, 44 (22%) were patients/patient representatives, 64 (32%) were industry/developers, 60 (30%) were medical practitioners/doctors, and 32 (16%) were government health personnel. The level of experience with PCOs regarding AI was low, with only 7% (14/200) having direct experience and 10% (20/200) having any experience (either direct or indirect). The approval rate for insurance coverage for PCOs was 74% (148/200), significantly lower than the corresponding rates for other value elements (82.5%–93.5%; $P \leq 0.034$). The approval strength was significantly lower for PCOs, with a mean weight \pm standard deviation of 5.1 ± 3.5 , compared to other value elements ($P \leq 0.036$).

Conclusion: There is currently limited demand for insurance coverage for AI that demonstrates benefits in terms of non-clinical PCOs.

Keywords: Artificial intelligence; Insurance; Coverage; Reimbursement; Payment; Value; Value-based healthcare; Patient-centered outcome; Patient-reported outcome measure; Survey

INTRODUCTION

With its progress and application in medicine continually

advancing, artificial intelligence (AI) holds the potential to enhance every facet of healthcare. Numerous algorithms have already gained approval as medical devices from

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regulatory authorities—such as the U.S. Food and Drug Administration (FDA), the European CE marking, and the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea (ROK) [1-7]. The depth of discussion on the clinical implementation of AI is steadily expanding [8-15]. However, the integration of AI into everyday clinical practice beyond the research domain is lagging [16,17]. One significant factor influencing the clinical adoption of health technology concerns financial considerations, such as reimbursement and return on investment [16]. Similarly, a significant hurdle to the widespread adoption of AI in practice is the issue of payment and coverage policies [18]. While many countries already have pathways and systems for AI coverage by medical/health insurance (for example, the “Guidelines for the Evaluation of Innovative Medical Technologies for Coverage by National Health Insurance: Artificial Intelligence-Based Innovative Medical Technologies” by the ROK government [19]) and instances of insurance coverage for AI are emerging, there are currently only a small number of global examples of AI insurance coverage, many of which are temporary [20-22].

Securing insurance coverage for the use of AI in healthcare hinges on demonstrating its value in improving ultimate patient clinical outcomes when compared to traditional care [21,23]. This tenet aligns with the fundamental principles of value-based healthcare [24]. Initially, AI was hyped for its potential to substantially enhance the clinical outcomes of patients. However, as knowledge and experience accumulated, the predominant strengths of AI often lie in improving productivity and efficiency in hospital workflows and among healthcare professionals, as well as enhancing non-clinical patient-centered outcomes (PCOs) rather than clinical outcomes. Two good examples of the enhanced

productivity and efficiency enabled by AI technology are AI that microscopically examines lymph nodes for metastasis in oncologic patients, substantially saving time and reducing cognitive burden for pathologists [25], along with AI that segments the target lesion contour for radiation therapy, thus enormously reducing time for the practice and patient waiting list [26]. Insurance reimbursement is generally not considered regarding such AI applications, as institutions or personnel already reap benefits from improved productivity and efficiency [20,27]. PCOs are distinguished from clinical outcomes measured by biomarkers and clinical parameters and focus on patient-reported experiences and values such as quality of life, functionality, well-being, physical or emotional status, and convenience (Table 1; PCOs related to imaging tests as examples are also summarized in Supplements [Section B of survey questionnaire]). Despite their significance in enabling a more holistic healthcare approach, PCOs have been neglected in traditional value-based healthcare, where the primary emphasis is on improved clinical outcomes [28]. Consequently, PCOs have typically not yet been considered in insurance coverage decisions. A recent study by Maruszczuk et al. [29] reported the absence of guidance on utilizing patient-reported outcome measures (PROMs), which are similar to PCOs, for real-world evidence generation in the context of reimbursement consideration, indirectly indicating the current state of limited consideration of PCOs in insurance coverage.

With a growing awareness of PCOs, as demonstrated by the activities of organizations like PCORI (<https://www.pcori.org/>), their importance in holistic healthcare is gaining recognition. Simultaneously, AI’s role in improving PCOs is also highlighted. AI tools’ ability to reduce the radiation dose for computed tomography (CT) examinations

Table 1. Value elements offered by artificial intelligence and their beneficiaries

| Value element | Beneficiary | Definition or examples |
|------------------------|--|---|
| Clinical outcomes | Patient | Diagnostic accuracy or treatment outcomes - Diagnostic/predictive performance: sensitivity, specificity, and ROC curve area - Impact on the rates of disease/health-related states or mortality - Survival rate, therapeutic efficacy/effectiveness, or side effects |
| Economic aspects | Insurer | Macroscopic healthcare cost - Nationwide healthcare cost for a particular disease - Frequency of medical service utilization, e.g., number of imaging tests needed |
| Organizational aspects | Healthcare institution/ medical personnel | - Efficiency or healthcare operations-related expenses of an institution - Fatigue, workload, or efficiency of medical personnel |
| Non-clinical PCOs | Patient | Quality of medical services from the patient’s perspective—such as quality of life, functionality, well-being, physical or emotional status, and convenience |

ROC = receiver operating characteristic, PCO = patient-centered outcome

and decrease the scan time required for magnetic resonance imaging (MRI) examinations through quality improvements in image acquisition exemplifies the technology's positive impact on imaging test-related PCOs [30]. A more recent example, especially with the rapid advances in large language models based on the transformer architecture and foundational model technique [31-33], is the use of AI to enhance information exchange with patients in patient care—an important component of PCOs [34,35]. Unlike AI tools that improve the productivity and efficiency of hospital workflow or healthcare professionals, the positive effects of AI on PCOs directly contribute to patient benefits. When compared to improving productivity and efficiency, this distinction may make AI tools that improve PCOs more eligible for insurance coverage, although it is not currently recognized as such. Therefore, this study aims to survey the opinions of various stakeholders regarding AI insurance coverage, as categorized according to the different value elements provided by AI, with a specific emphasis on PCOs.

MATERIALS AND METHODS

The present study was approved by the Institutional Review Board of the National Evidence-based Healthcare Collaborating Agency (NECA) (IRB No. NECAIRB23-010).

Survey Design

To lay the groundwork for our survey, we revisited the outcomes of a previously conducted systematic literature search [36]. The literature search sought to more broadly gather the aspects needed for a clinical evaluation of AI models in medicine. Carried out on December 18, 2022, and spanning the preceding five years, the search utilized PubMed with the query “(checklist OR guide OR guideline OR tip) AND (reader OR reviewer OR user) AND (“artificial intelligence” OR “machine learning” OR “deep learning”).” Drawing from the systematic literature review, we categorized the value elements offered by AI into four dimensions: clinical outcomes, economic aspects, organizational aspects, and non-clinical PCOs, as shown in Table 1. This categorization is similar to that of the Model for ASsessing the value of Artificial Intelligence in medical imaging (MAS-AI) [37]. It proves practical in addressing insurance coverage, as each category has a distinct group of stakeholders as beneficiaries.

We subsequently developed the survey questionnaire. Given that the survey targeted Korean respondents, the

questionnaire was originally crafted in Korean (an English translation and the original Korean version are provided as Supplements). The survey comprised three sections: the first section focused on respondents' experiences with PCOs concerning an evaluation of medical AI technology; the second section aimed to gauge opinions on the eligibility of insurance coverage for the four value elements provided by AI; and the third section sought to collect information about the characteristics of the respondents. Questions related to insurance coverage were designed in alignment with the National Health Insurance of the ROK. To address potential unfamiliarity with PCOs among some respondents, we provided a concise and explicit explanation of PCOs in the survey, focusing particularly on PCOs as related to imaging tests (Section B of survey questionnaire in Supplements) [30]. Furthermore, to avoid confusion among the respondents, the survey also included explanations of the four value elements provided by AI, as outlined in Table 1. Within the section on respondent characteristics, we included a specific question inquiring about the nature of the respondents as stakeholders for AI insurance coverage. This question was designed as a multiple-choice query with seven options (DQ3 in Supplements). We employed seven options during data collection to ensure precise information gathering. However, in the subsequent analysis phase, these options were condensed into four categories (see ‘Statistical Analysis’ below).

Conducting the Survey

The survey was administered through the expertise of the survey research firm Hankook Research (Seoul, ROK), utilizing a web-based online survey method. The survey spanned from July 4 to 26, 2023, encompassing the time required to reach the target of 200 respondents. The selection of the target number for the respondents was primarily guided by the research budget. Given the survey's exploratory nature, along with the absence of relevant prior data for sample size calculations, we opted not to conduct formal sample size calculations regarding the number of respondents.

Recognizing the need to provide meaningful responses to the survey concerning AI in medicine might necessitate a certain level of experience or familiarity with the subject, we did not open the survey to random respondents; instead, we officially announced the survey through NECA to nine representative professional societies or associations in the ROK related to AI in medicine. These included medical and

hybrid medicine-informatics/computer science academic societies (the Korean Academy of Medical Sciences, the Korean Society of Radiology, the Korean Society of Pathologists, the Korean Society of Artificial Intelligence in Medicine, the Korean Society of Medical Informatics, and the Korean Society of Health Informatics and Statistics) as well as industry associations (the Korea Medical Devices Industry Association, the Korea Smart Healthcare Association, and the Korea Digital Health Industry Association). We further reached out to relevant departments dealing with AI in medicine and digital healthcare within government agencies of the ROK, such as the MFDS, NECA, and the Health Insurance and Review Assessment Service (HIRA). We explained the survey's purpose to the representatives of these organizations and requested that these organizations encourage their members to participate in the survey. However, we did not have control over the specific methods used to encourage survey participation—such as email notifications to individual members or posting announcements on the organization's website. To promote participation, we incentivized respondents by offering a mobile gift voucher worth 30,000 KWR to those who completed the survey.

Supplementary Literature Analysis

We conducted an additional literature analysis to gain insight into the relative frequencies of clinical research studies on AI technology by exploring the four value elements provided by AI. This analysis aimed to produce objective data complementing the subjective survey results. We specifically focused on two journals—*Radiology* and the *Korean Journal of Radiology*—for several reasons. First, we aimed to align the literature analysis with the National Health Insurance of the ROK. Consequently, only research studies conducted by Korean authors were considered. Second, these journals are highly regarded publications within the field of radiology, which is the most dominant clinical field regarding AI in medicine. Not only do Korean researchers actively publish in these two journals, but both publications have a particularly strong presence in the West and East, respectively, in addition to a strong global recognition. We opted not to include *European Radiology*, another journal of a similar nature representing Europe. This decision was made to prevent potential skewing of results, as it had a significantly higher publication volume and was known to publish AI studies more prominently [38]. Acknowledging the vastness of AI literature, focusing on these two specific journals may offer a more

practical approach and provide pilot data—even though a comprehensive analysis was not feasible. To identify eligible articles, we conducted a manual search of the two selected journals from 2021 to the most recent update on December 5, 2023. We screened all articles published within the specified period, without utilizing any search queries. The full text of eligible articles was carefully reviewed to assess whether they presented results on clinical outcomes, economic aspects, organizational aspects, or PCOs associated with AI. Clinical outcomes were further categorized into diagnostic accuracy and post-accuracy outcomes, with diagnostic yield considered as a post-accuracy outcome parameter [39].

Statistical Analysis

The survey results were analyzed independently by Hankook Research. Categorical results are presented as percentages, while continuous data are expressed as mean \pm standard deviation. In the analysis of survey results, respondents were categorized into four distinct stakeholder groups: a) patient/patient representative (comprising patients, caregivers, and NGOs), b) industry/developer, c) medical practitioner/doctor, and d) government health personnel (encompassing experts in government health policy/administration from the MFDS, NECA, or HIRA). The PCOs results were compared with those for each of the other three value elements using the McNemar and paired *t*-tests, as appropriate. The analysis was conducted for the entire respondent pool and separately for each of the four stakeholder groups. *P*-values < 0.05 were considered to be statistically significant. Given the exploratory nature of the study, we did not adjust for multiple comparisons. Statistical analysis utilized MedCalc Statistical Software version 22.016 (MedCalc Software bv, Ostend, Belgium).

RESULTS

Characteristics of Survey Respondents

The summarized characteristics of the 200 survey respondents are presented in Table 2. Notably, the distribution of respondents across various stakeholder categories was fairly balanced. However, industry/developer participants and medical practitioners/doctors comprised 32% and 30% of the respondents, respectively, while government health personnel accounted for a smaller (16%) proportion compared to the other categories. The complete survey results, independently compiled by Hankook Research and including aspects not featured in the main paper, are available in the Supplements (in Korean).

Table 2. Characteristics of survey respondents

| Characteristic | n (%) |
|---|------------|
| Sex | |
| Male | 93 (46.5) |
| Female | 107 (53.5) |
| Age, yr | |
| 20–39 | 96 (48) |
| 40–49 | 63 (31.5) |
| ≥ 50 | 41 (20.5) |
| Stakeholder category | |
| Patient/patient representative | 44 (22) |
| Industry/developer | 64 (32) |
| Medical practitioner/doctor | 60 (30) |
| Government health personnel* | 32 (16) |
| Experience in AI in medicine, yr | |
| < 3 | 101 (50.5) |
| ≥ 3 and < 6 | 48 (24) |
| ≥ 6 and < 9 | 28 (14) |
| ≥ 9 | 23 (11.5) |
| All | 200 (100) |

*Encompassing experts in government health policy/administration from the Ministry of Food and Drug Safety, National Evidence-based Healthcare Collaborating Agency, or Health Insurance and Review Assessment Service.
AI = artificial intelligence

Experience with PCOs in the Evaluation of Medical AI Technology

The experience of the respondents with PCOs in the evaluation of medical AI technology is outlined in Table 3. Overall, respondents exhibited a low level of experience, with only 7% (14/200) having had direct experience and 10% (20/200) having had any experience (either direct or indirect). When individual stakeholder groups were considered separately, all groups—except for government health personnel—demonstrated low levels of experience. Government health personnel, who likely had work-related encounters with PCOs, exhibited a relatively higher level of experience (direct experience being 21.9%).

For those without prior exposure to PCOs in the evaluation of medical AI technology, 85.6% (154/180) believed that PCOs would be important in future AI medical technology assessments. Specifically, 78.0% (32/41) of patients/patient representatives, 86.4% (51/59) of industry/developers, 94.5% (52/55) of medical practitioners/doctors, and 76% (19/25) of government health personnel expressed this view.

Table 3. Respondents’ experience with patient-centered outcomes in the evaluation of medical AI technology

| Stakeholder group | Direct experience | Acquaintance without direct experience | No acquaintance |
|---|-------------------|--|-----------------|
| Patient/patient representative (n = 44) | 2.3 (1/44) | 4.5 (2/44) | 93.2 (41/44) |
| Industry/developer (n = 64) | 6.3 (4/64) | 1.6 (1/64) | 92.2 (59/64) |
| Medical practitioner/doctor (n = 60) | 3.3 (2/60) | 5 (3/60) | 91.7 (55/60) |
| Government health personnel* (n = 32) | 21.9 (7/32) | 0 (0/32) | 78.1 (25/32) |
| All (n = 200) | 7 (14/200) | 3 (6/200) | 90 (180/200) |

Data are presented as the percentage of respondents in each row, with the nominal value in parentheses. The sum of percentages may not be exactly 100% due to rounding.

*Encompassing experts in government health policy/administration from the Ministry of Food and Drug Safety, National Evidence-based Healthcare Collaborating Agency, or Health Insurance and Review Assessment Service.
AI = artificial intelligence

Table 4. Respondents’ approval of coverage of AI technology by the National Health Insurance, categorized according to the value elements provided by AI

| Stakeholder group | Value element provided by AI with proven positive effects or benefits | | | | | | |
|---|---|------------|------------------|------------|------------------------|------------|-------------------|
| | Clinical outcomes | <i>p</i> * | Economic aspects | <i>p</i> * | Organizational aspects | <i>p</i> * | Non-clinical PCOs |
| Patient/patient representative (n = 44) | 97.7 (43/44) | 0.013 | 86.4 (38/44) | 0.371 | 84.1 (37/44) | 0.724 | 79.5 (35/44) |
| Industry/developer (n = 64) | 92.2 (59/64) | 0.027 | 90.6 (58/64) | 0.080 | 81.3 (52/64) | 0.803 | 78.1 (50/64) |
| Medical practitioner/doctor (n = 60) | 93.3 (56/60) | < 0.001 | 83.3 (50/60) | 0.044 | 86.7 (52/60) | 0.031 | 66.7 (40/60) |
| Government health personnel [†] (n = 32) | 90.6 (29/32) | 0.078 | 75 (24/32) | 1.000 | 75 (24/32) | 1.000 | 71.9 (23/32) |
| All (n = 200) | 93.5 (187/200) | < 0.001 | 85 (170/200) | 0.003 | 82.5 (165/200) | 0.034 | 74 (148/200) |

Data are presented as the percentage of respondents in each row who expressed agreement with the insurance coverage, with the nominal value in parentheses.

*Comparison with non-clinical PCOs, [†]Encompassing experts in government health policy/administration from the Ministry of Food and Drug Safety, National Evidence-based Healthcare Collaborating Agency, or Health Insurance and Review Assessment Service.
AI = artificial intelligence, PCO = patient-centered outcome

Eligibility for Insurance Coverage of AI: PCOs vs. Other Value Elements

The percentage of respondents who expressed agreement with granting AI technology the coverage provided by the National Health Insurance, based on the specified value elements, is detailed in Table 4. The findings reveal that when AI is proven to have positive effects or benefits, the overall approval rate for non-clinical PCOs was at 74% (148/200), a figure significantly lower than the corresponding rates for other value elements ($P \leq 0.034$). This trend remains consistent across all individual stakeholder groups. It is worth noting that conducting robust statistical comparisons in individual stakeholder groups was not plausible due to the limited sample size in each group. Nevertheless, based on the sample values, respondents exhibited the lowest rate of agreement with insurance coverage for non-clinical PCOs, ranging from 66.7%–79.5%. Contrastingly, the results were notably more favorable for clinical outcomes, recording an overall approval rate of 93.5% (187/200) and ranging from 90.6%–97.7% across individual stakeholder groups.

Table 5 displays the weights assigned by respondents to each value element, ranging from 0–10, with 0 indicating non-approval and 10 indicating the strongest approval for insurance coverage. The overall strength of approval, reflected by the weights, was significantly lower for non-clinical PCOs, with a mean weight \pm the standard deviation of 5.1 ± 3.5 , compared to other value elements ($P \leq 0.036$). While robust statistical testing for each stakeholder group was not feasible, the difference remained consistent across all individual stakeholder groups, where the sample mean weight values for non-clinical PCOs were smaller than those for clinical outcomes and economic aspects and either

smaller or equal to those for organizational aspects.

Relative Frequencies of Clinical Research Studies on AI, Examining the Four Value Elements Provided by AI

The supplementary literature search identified 48 eligible studies (Fig. 1) [40-87]. Table 6 shows the count of studies that addressed the four value elements provided by AI. The literature analysis reveals that only a smaller proportion of studies explored non-clinical PCOs compared to the much larger number of studies investigating clinical outcomes. Specifically, only 10.4% (5/48) of the studies evaluated non-clinical PCOs and reported on reduced radiation exposure during CT examinations, whereas 60.4% (29/48) addressed clinical outcomes. The frequency of studies exploring non-clinical PCOs (10.4% [5/48]) closely mirrors the percentage of survey respondents who reported any experience (either direct or indirect) with PCOs in the evaluation of medical AI technology in the survey (10% [20/200]).

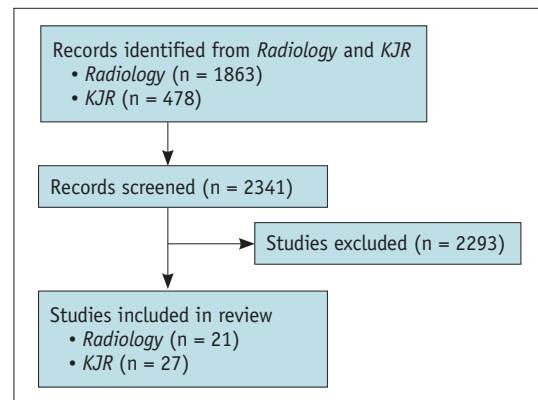


Fig. 1. Flow diagram for the supplementary literature analysis. KJR = Korean Journal of Radiology

Table 5. The strength of respondents’ approval (ranging from 0 for no approval to 10 for the strongest approval) of coverage of AI technology by the National Health Insurance, categorized according to the value elements provided by AI

| Stakeholder group | Value element provided by AI with proven positive effects or benefits | | | | | | |
|---|---|---------|------------------|---------|------------------------|-------|-------------------|
| | Clinical outcomes | p^* | Economic aspects | p^* | Organizational aspects | p^* | Non-clinical PCOs |
| Patient/patient representative (n = 44) | 7.6 \pm 2.4 | < 0.001 | 6.1 \pm 3.3 | 0.425 | 5.7 \pm 3.2 | 1.000 | 5.7 \pm 3.6 |
| Industry/developer (n = 64) | 7.0 \pm 2.8 | 0.001 | 6.4 \pm 2.7 | 0.029 | 5.7 \pm 3.3 | 0.454 | 5.3 \pm 3.2 |
| Medical practitioner/doctor (n = 60) | 7.2 \pm 2.5 | < 0.001 | 5.9 \pm 3.1 | 0.009 | 6.4 \pm 3.1 | 0.006 | 4.6 \pm 3.7 |
| Government health personnel [†] (n = 32) | 7.0 \pm 3.0 | 0.007 | 5.4 \pm 3.5 | 0.566 | 5.0 \pm 3.5 | 0.919 | 5.0 \pm 3.6 |
| All (n = 200) | 7.2 \pm 2.7 | < 0.001 | 6.0 \pm 3.1 | < 0.001 | 5.8 \pm 3.2 | 0.036 | 5.1 \pm 3.5 |

Data are presented as the mean weight \pm standard deviation.

*Comparison with non-clinical PCOs, [†]Encompassing experts in government health policy/administration from the Ministry of Food and Drug Safety, National Evidence-based Healthcare Collaborating Agency, or Health Insurance and Review Assessment Service.

AI = artificial intelligence, PCO = patient-centered outcome

Table 6. Relative frequencies of clinical research studies conducted by Koreans on AI, examining the four value elements provided by AI

| Clinical outcomes | Economic aspects | Organizational aspects | Non-clinical PCOs |
|-------------------|------------------|------------------------|-------------------|
| 29* (60.4) | 1 (2.1) | 5 (10.4) | 5 (10.4) |

Data are presented as the number of studies, with the percentage (of the total 48 studies) in parentheses.

*Four studies addressed post-accuracy outcomes in addition to diagnostic accuracy.

AI = artificial intelligence, PCO = patient-centered outcome

DISCUSSION

This study investigated the opinions of various stakeholders regarding insurance coverage for AI, as categorized according to different value elements provided by AI, with a specific emphasis on PCOs. Our results indicated that there is currently limited demand for insurance coverage for AI technology that yields positive effects or benefits in terms of non-clinical PCOs. The overall approval rate for insurance coverage for non-clinical PCOs was 74% (148/200), a figure significantly lower than the corresponding rate for organizational aspects at 82.5% (165/200), not to mention the rate for clinical outcomes at 93.5% (187/200). Even among patients/patient representatives, the approval rate for non-clinical PCOs was only 79.5% (35/44). Similarly, the semi-quantitative results concerning the strength of respondents' approval of insurance coverage for AI technology showed that the strength was significantly lower for non-clinical PCOs (5.1 ± 3.5) than for other value elements, and specifically for organizational aspects (5.8 ± 3.2). Considering insurance reimbursement is generally not considered for AI that brings positive effects or benefits in terms of organizational aspects [20,27], the results indicate that granting insurance coverage for improvement in non-clinical PCOs would likely not be warranted at present.

The results align with the observation that PCOs have been neglected in traditional value-based healthcare, where the primary emphasis is on improved clinical outcomes [28]. Perhaps this neglect is somehow related to PCOs still currently being in its early stages—at least in the field of the clinical evaluation of AI in medicine. The first comprehensive attempt to define the PCOs of imaging tests, to which the majority of AI tools currently available after regulatory approval belong, was made only recently [30]. According to a recent systematic evaluation of research protocols for clinical trials for AI technology registered in ClinicalTrials.gov up to 2022 by Pearce et al. [88], the use of PROMs in the assessment of AI health technologies as trial endpoints was observed in only 7% of clinical trials for

AI technology. The rate falls behind the 17% rate of using PROMs as trial endpoints across all clinical trials registered on ClinicalTrials.gov between 2007 and 2013 [89]. Our survey and supplementary literature analysis reveal similar patterns, showing that only 10% (20/200) of survey respondents reported any experience (either direct or indirect) with PCOs in the evaluation of medical AI technology, and only 10.4% (5/48) of the clinical studies of AI conducted by Korean authors and published in select representative radiology journals addressed non-clinical PCOs.

On the other hand, it might be worth mentioning that the difference in approval strength for AI insurance coverage among the value elements was small, with differences of 2.1 or less on the semi-quantitative 0–10 scale. Although interpreting these numerical values precisely is challenging as the scoring does not conform to a ratio or interval scale, they appear modest. Additionally, despite the lower approval rate for non-clinical PCO compared to other value elements, a substantial level of approval (74%) was still evident. Considering these results and the importance of PCOs in achieving more holistic healthcare and the potential of AI in improving PCOs, further research to accumulate clinical evidence in this area is crucial. Fortunately, data from the systematic analysis by Pearce et al. [88] also indicated a rapid growth in the number of trials of AI health technologies incorporating PROMs. With an increasing awareness of PCOs as vital components of healthcare outcomes, and as more data accumulate regarding PCOs associated with AI use, it would be worthwhile to explore whether the perception of the value associated with AI use changes in future research studies.

In contrast to PCOs, insurance coverage for positive effects or benefits in clinical outcomes was essentially universally agreed upon. The approval rate, slightly falling short of the 100% mark, likely reflects the understanding that improvements in diagnostic or predictive performance do not guarantee enhanced ultimate patient outcomes [90,91]. Therefore, data directly demonstrating improvements in clinical patient outcomes with the use of AI are regarded more highly for deciding insurance coverage than data

merely indicating improved accuracy [92].

This study has several limitations. First, as the study was designed and conducted in alignment with the coverage provided by the National Health Insurance of the ROK, the results may not be entirely generalizable to other countries. The opinion regarding the different value elements provided by AI may vary according to the healthcare system, including the health insurance system and the sufficiency/scarcity of healthcare resources in a country [93-99]. Therefore, the results should be interpreted in conjunction with the healthcare system/status in a particular country. Second, our survey was a small-scale survey due to budget constraints and our intention to conduct a pilot study. Fortunately, our survey had a fairly balanced distribution of respondents across the four stakeholder categories. Therefore, we believe it provides useful pilot results. We recommend follow-up research at a larger scale with the accumulation of more experience with PCOs associated with AI. Third, it would have been ideal to analyze the results according to the level of sufficiency/scarcity of healthcare resources, especially human resources, in the respondents' practice setting, considering the unique value of AI in mimicking and assisting human health professionals. This factor should be considered in any future large-scale studies.

In conclusion, our study results indicated that there is currently limited demand for insurance coverage for AI technology that provides positive effects or benefits in terms of non-clinical PCOs. However, our study also revealed that considerations of PCOs are at an early stage in the field of clinical evaluation of AI in medicine. Therefore, it would be worthwhile to investigate whether the opinions regarding the value associated with AI use change in future research studies as more data accumulate regarding PCOs associated with AI use.

Supplement

The Supplement is available with this article at <https://doi.org/10.3348/kjr.2023.1281>.

Availability of Data and Material

The datasets generated or analyzed during the study are included in this published article and its supplements.

Conflicts of Interest

Hye Young Jang and Seong Ho Park, who hold respective positions on the Assistants to the Editor and Editor-in-Chief

of the *Korean Journal of Radiology*, were not involved in the editorial evaluation or decision to publish this article. The remaining author has declared no conflicts of interest.

Author Contributions

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