

Reducing the Tendency for Over- and Under-Provision of Health Services at the Point of Care: The Roles of Evidence-Based Medical Education and the Patient-Centered Clinical Method*

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Abstract

In order to reduce ever-increasing social security expenditure, the Government of Japan is attempting to improve the efficiency of healthcare services. The premise of these efforts is that there exists a high degree of waste in the present system. However, the problem lies not only in over-provision of health care, but also extends to under-provision. To redress over- and under-provision of healthcare services and promote the right care, it is necessary to gain the awareness of and secure action from healthcare providers, users, and government officials. Because this is an area that involves human cognition and the modification of behavior, it is not a simple task. However, many other countries have been tackling this problem of low-value care through trial and error. Three forces that govern the de-adoption of low-value care have been previously described: *evidence* that a current practice provides little or no value, *eminence* that comes from professional societies issuing practice guidelines or recommendations against a low-value service, and *economics* (financial incentives) that can be used to catalyze de-adoption. In addition, *education* for primary health care professionals is important to enable them to fully understand the patient-centered clinical method and to implement it within their healthcare practice by taking users' *emotions* and the cost-effectiveness of care into consideration.

By following the examples of other countries' efforts to reduce over- and under-provision in their respective healthcare systems, considerable fiscal benefits can be expected in Japan. This paper revisits the definitions of medical screening, examines over- and under-provision of health care by taking lung cancer screening as an example, introduces overseas attempts to de-adopt low-value care, and outlines the patient-centered clinical method.

Keywords: over-provision, under-provision, right care, low-value care, medical screening, primary care, primary health care, evidence-based medicine (EBM), patient-centered clinical method

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I. Introduction

It is said that medicine is advancing rapidly, and that the development of medical technology—in essence, the practical application of medicine—also shows no signs of stopping. It is difficult to construct a sustainable system that ensures that safe, high-quality health care is provided to all those who need it. However, there have been, and continue to be, cases of over-provision of health care.

In 2015, the *British Medical Journal* (now officially the *BMJ*) began its awareness-raising series ‘Too Much Medicine,’ focusing on the theme of over-provision of health care (BMJ, 2022). Many years beforehand, the legendary *BMJ* Editor-in-Chief Richard Smith co-authored an article in the *BMJ* with *Australian Financial Review* journalist Ray Moynihan entitled ‘Too much medicine? Almost certainly’ (Moynihan & Smith, 2002). The authors argued that although there might not be many people who could agree with the words of social critic Ivan Illich—best known for his books ‘*Deschooling Society*’ and ‘*Medical Nemesis*’—that “The medical establishment has become a major threat to health” (Illich, 1976), many people would agree with American economist Alain Enthoven’s message that “Increasing medical inputs will at some point become counterproductive and produce more harm than good.”

Over- and under-provision of health care is happening all over the world. To rectify this issue and to implement the appropriate level of care (hereafter, the right care) in as many cases as possible, it is essential to gain the awareness of and secure action from healthcare providers, users, and government officials. However, as an area that relates to human cognition and behavioral change, this is by no means a simple task.

In the United States, the continued use of medical tests that have little benefit—performed almost routinely as part of doctors’ medical practice—has become a serious problem. It is estimated that excessive tests of this type waste USD \$67 billion annually (Shrank et al., 2019). For example, the US spends over USD \$274 million per year on carotid artery disease screening for asymptomatic patients, and more than USD \$111 million per year on cervical cancer screening for women aged over 65 years (Schwartz et al., 2014).

In order to curb such low-value medical practices, three key principles (‘three Es’) have been previously raised as important: *evidence* that a current practice provides little or no value, *eminence* that comes from professional societies issuing practice guidelines or recommendations against a low-value service, and *economics* (financial incentives) that can be used to catalyze de-adoption (Powers et al., 2020). Furthermore, because these principles primarily relate to engendering behavioral change among healthcare providers, we believe that there are two further ‘Es’ that are important: *education* for primary health care professionals to enable them to fully understand and implement the patient-centered clinical method (PCCM), and, in doing so, taking users’ *emotions* and the cost-effectiveness of care into consideration as part of their healthcare practice.

In this paper, we review the definitions of the terms ‘health check-up,’ ‘health examination,’ and ‘screening’ in the Japanese context, and, on that basis, we examine the issues of

over- and under-provision of health care by using lung cancer screening as a real-life example. In addition, we introduce examples of other countries' efforts to reduce over- and under-provision in their respective healthcare systems, and we outline PCCM and explore its role in achieving the right care.

II. Definitions of health check-up, health examination, and screening in the Japanese context

The Japanese healthcare system uses several terms to refer to the processes of checking people's health status and testing or examining for diseases, and it is, in fact, difficult to define these individual terms in a meaningful way. 'E-health net'—the Ministry of Health, Labour and Welfare's (MHLW) health information website for the prevention of lifestyle-related diseases—refers to both *kenshin* (健診) and *kenjin* (検診), which despite being phonetically identical in Japanese are written using subtly different characters and therefore contain subtly different nuances of meaning. MHLW's website defines the former as having the purpose of examining the state of health of the whole body, while it defines the latter as clinical tests performed to detect specific diseases (MHLW e-health net). The same website also provides its own English approximations of the Japanese terms, which are listed as 'health examination/health check-up' for the former, and 'case-finding'¹ for the latter. We believe that these English terms are not entirely consistent with those largely recognized overseas to correspond to the given definitions above; therefore, we hereafter differentiate the two Japanese terms in this paper by referring to the former as 'health check-up' and the latter as 'health examination.'

Outside of Japan, the term 'screening' is commonly used to capture the combined meaning of both health check-up and health examination in the Japanese context. However, as described below, there are various different conditions and qualifications that are fixed into the definition of screening, making its meaning rather multilayered.

In the United Kingdom, in 1994, the UK National Screening Committee published the following definition (Wald, 1994): "Screening is the systematic application of a test or enquiry to identify individuals at sufficient risk of a specific disorder to warrant further investigation or direct preventive action, amongst persons who have not sought medical attention on account of symptoms of that disorder." In 2000, the Committee changed the definition to: "[Screening is] a public health service in which members of a defined population who do not necessarily perceive they are at risk of, or are already affected by, a disease or its complications are asked a question or offered a test to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of disease or its complications."

¹ The traditionally accepted meaning of 'case-finding' is the medical practice of diagnosing the cause of symptoms in patients who are already displaying symptoms, which is wholly different from a screening or examination process that targets people without symptoms. The use of this word on e-health net is therefore potentially misleading (refer to continuation of this section).

Wald, who had conceived the original definition in 1994, criticized the new definition as “unwieldy and unclear” in an editorial for the *Journal of Medical Screening*, making the following comments regarding the change (Wald, 2001): (1) if feasible, it is best to provide screening to a defined population, but it is not necessary to include this in the definition; (2) there is no reference to the fact that people who already have symptoms and thus are seeking medical attention are not eligible; (3) because awareness of the risks of contracting a particular disease or disorder is complex and difficult to identify, the statement that screening should be applied to individuals “who do not necessarily perceive they are at risk” is irrelevant and inaccurate; and (4) the intention to “identify those individuals who are more likely to be helped than harmed by further tests or treatment” is relevant to all medical care, not just screening.

The Oxford Textbook of Medicine (6th Ed.) includes a chapter on medical screening, which was co-authored by Wald. Its definition of medical screening is as follows (Wald and Law, 2020): “Medical screening is the systematic application of a test or inquiry to identify individuals at sufficient risk of a specific disorder to benefit from further investigation or direct preventive action (these individuals not having sought medical attention on account of symptoms of that disorder).” Furthermore, their commentary states the following: “Key to this definition is that the early detection of disease is not an end in itself; bringing forward a diagnosis without altering the prognosis is useless and may be harmful. [...] Before a potential screening test is introduced into practice it must be shown to prevent death or serious disability from the disease to an extent sufficient to justify the human and financial costs.”

The UK National Health Service (NHS) defines screening as follows: “Screening is a way of finding out if people have a higher chance of having a health problem, so that early treatment can be offered or information given to help them make informed decisions.” Meanwhile, ‘Health’—the health information website of John Hopkins University in the US—provides the following definition of a screening test: “A screening test is done to detect potential health disorders or diseases in people who do not have any symptoms of disease. The goal is early detection and lifestyle changes or surveillance, to reduce the risk of disease, or to detect it early enough to treat it most effectively. Screening tests are not considered diagnostic, but are used to identify a subset of the population who should have additional testing to determine the presence or absence of disease.”

Considering the above, we propose to use Wald’s 1994 definition as the basis for our definition of screening in this paper, but with the addition of some important extracts from other definitions, as shown in Table 1. The health check-ups and health examinations practiced in Japan represent fundamentally the same approach, with their only point of difference being the health problems that they target.

To operate any system more effectively, it is necessary to regularly review what that system was designed to achieve in the first place and to continuously make improvements to it. If the definition of screening is not also viewed as an active process of continuous improvement, there is a danger that adjusting to individual foreground circumstances becomes the priority, thus creating a system that is superficially easy to operate, but expensive and lack-

Table 1. Definition of screening

“Screening is the systematic application of a test or enquiry to identify individuals at sufficient risk of a specific health problem to warrant further investigation or direct preventive action, amongst persons who have not sought medical attention on account of symptoms of that health problem.”

Notes:

1. Screening is a way of finding out if people have a higher chance of having a health problem.
2. The early detection of disease is not an end in itself.
3. Bringing forward a diagnosis even though the prognosis cannot be improved may be harmful.
4. It is for offering early treatment and making informed decisions.
5. It must be shown to prevent death or serious disability from the disease to an extent sufficient to justify the human and financial costs.
6. It is not for diagnostic purposes. It is to identify whether the individual belongs to a subset of the population who should have additional diagnostic testing.

Source: Created by the authors based on Wald (1994); Wald & Law (2020); NHS; and John Hopkins Medicine

ing in real benefits.

III. Problems with health check-ups and health examinations in Japan

As pointed out in a report by the Organisation for Economic Co-operation and Development (OECD, 2019), public health policy in Japan is highly decentralized. Responsibilities for policy planning and service provision are separated between national and municipal governments, and between ministries, public health centers, and workplaces, and there is little cooperation with medical institutions. For example, during the COVID-19 pandemic, there were numerous cases of patients whose symptoms suddenly worsened while they were isolating at home. The information held by public health centers on COVID-19 cases and people recovering at home from their infections is legally-protected administrative information, and is therefore not supposed to be released to medical institutions without the consent of the individuals involved. As a result, even for patients who have a doctor whom they consult on a regular basis, it was not possible for their doctor to be informed of their situation to enable action to be taken at an early stage. Such highly decentralized healthcare services are prone to both over- and under-provision of care.

In Japan, there is a heavy reliance on population-based health check-ups and health ex-

aminations for early detection and early treatment of diseases. Over the past few decades, the scope of items included in health check-ups and the group of eligible recipients has been expanding. There are many different health check-up and screening programs, including legally required health check-ups for full-time employees, ‘specific health check-ups’ for people aged 40 to 74 to tackle lifestyle-related diseases, and non-compulsory check-ups delivered by medical care providers and insurers, such as municipalities, health insurance associations, and mutual aid associations (Nawata, Ii, and Kassai, 2022; Figure 13). In addition, private medical providers also offer voluntary health check-ups and health examinations, known in Japan as ‘*ningen dock*.’ These vary in quality, and the benefits and harms are unclear. Such an extensive range and coverage of screening and testing is unique among OECD countries, and far from the international standard.

Unlike the majority of OECD countries, cancer screening in Japan is also not provided nationally in a standardized manner. Although there is a national guideline for cancer screening and health education focused on cancer prevention (MHLW, 2013; partially revised in 2021), the target populations and screening intervals vary by municipality, insurer, and medical institution. Municipalities distribute notices of their respective screening programs to local residents, often on the sole basis of age criteria, with no regard for individual degree of risk. Furthermore, many municipalities carry out cancer screenings that are not one of the five types (gastric, cervical, lung, breast, and colorectal cancer screening) recommended in the national guideline above. In 2015, it was reported that 85% of municipalities conducted cancer screenings that were not recommended by national government (MHLW, 2016).

In Japan, because public health policy is decentralized, employers also play a major role in the provision of health check-ups and health examinations. However, it is mainly full-time employees at large companies that receive access to occupational health physicians and cancer screening programs. For that reason, part-time workers, unemployed people, retired people, and older people are often excluded from such health services.

Japanese guidelines for cancer screening often deviate from international standards, such as those for target population and screening frequency. For example, while there is an upper age limit of 69 years for breast, cervical, and colorectal cancer screening programs in many OECD countries, there is no upper age limit in Japan. In most OECD countries, cervical cancer screening is conducted every 3 years, whereas in Japan, it is more frequent, at intervals of 2 years. Additionally, as detailed later in this paper, lung cancer screening guidelines have been created on the basis of case-control studies in Japan, but they contain no recommendations for low-dose computed tomography (CT) for high-risk target populations, as are recommended internationally.

In Japan, the emphasis in gastric cancer screening is on 2-yearly barium swallow imaging tests or endoscopy for those aged 50 years and above, which are uncommon practices in other OECD countries. Although the impact on gastric cancer screening in Japan is unclear, the Cochrane Database of Systematic Reviews recently published a review of research primarily conducted in Japan, China, and South Korea that found moderate evidence that test-

ing for and eradication of *Helicobacter pylori* reduces gastric cancer incidence rates and mortality (Ford et al., 2020).

Although there are many different cancer screening programs—including those provided by local governments and workplaces, and *ningen dock* voluntary screenings offered privately to individuals at medical institutions—data on screenings from municipalities, employers, and medical institutions are not integrated. A national cancer registry was launched in 2016, for which nationwide data are still being compiled; however, in terms of cancer screening numbers and coverage, even the National Cancer Center does not have an accurate grasp of the situation. Under such circumstances, being unable to gain the full picture of costs at the national level, it is extremely difficult to evaluate the effectiveness and value for money of cancer screening.

There exists no mechanism for guaranteeing the quality of cancer screening programs, including their scope and frequency, not only in screenings undertaken voluntarily by individuals but also in those provided by municipalities and workplaces. Therefore, there is the possibility of unnecessary radiation exposure, health risks, and psychological stress due to undergoing superfluous further testing and treatment following a false positive test result (over-provision of care), and necessary medical care not being provided following a false negative test result (under-provision of care). Even when individuals voluntarily undergo cancer screening, there are cases in which screening costs are partially subsidized by health insurance associations and private health insurance providers. For most insurers (national, municipal, and private-sector insurers), disease prevention is important in curbing the ever-increasing costs of medical and nursing care, and therefore, for early detection and treatment, they are pushing forward with measures that increase the rate of cancer screening. However, if policy decisions were made on the basis of information relating to the disadvantages of cancer screening², such as that described above, it would also reduce the related physical and psychological effects on individuals, contribute to improved health, and be possible to reduce the financial burden of such programs.

IV. Over- and under-provision of health care: The example of lung cancer screening

IV-1. International comparison of lung cancer screening

We compared the main guidelines for cancer screening outside of Japan with the current initiatives of the Japan Cancer Society (Table 2). From this international comparison, it is evident that international approaches differ from those of the Japan Cancer Society in the

² In the interim report of the ‘Investigative Committee for Cancer Screening’ (2019 Edition; MHLW, 2020), false positives, false negatives, overdiagnosis, and complications were raised as disadvantages of cancer screening in the ‘Current situation and issues’ section. There are some people who welcome the signs that Japan has finally begun to address the problem of overdiagnosis. However, the literature from which these disadvantages were cited was the ‘*Cancer Screening Handbook for Kakaritsuke-i*’ (MHLW, 2010), published over a decade ago. It is hoped that information that contributes to disease prevention, and maintenance and improvement of personal health, will be shared more quickly and proactively in the future.

Table 2. Major guidelines for lung cancer screening

Society / Organization	Target population	Interventions / Investigations	Interval
Japan Cancer Society	Age 40+ *Sputum cytology is for those age 50+ with a smoking index (number of cigarettes smoked per day × years of smoking) of 600+	Inquiries, chest X-ray, sputum cytology*	Once per year
National Comprehensive Cancer Network (NCCN) (Wood et al., 2020)	High-risk individuals age 50+ with smoking history of 20+ pack-years (number of packs of cigarettes smoked per day × years of smoking) *Risk assessment: smoking history, radon exposure, occupational exposure, cancer history, family history of lung cancer, history of COPD and/or pulmonary fibrosis, passive smoking *Those with symptoms of lung cancer, a history of lung cancer, or a general condition or comorbidity that would interfere with treatment are ineligible for screening	Shared decision making including discussion of benefits and harms, low-dose CT, standardized low-dose CT reporting (e.g., American College of Radiology 'Lung-RADS')	Follow-up interval suggested by standardized low-dose CT reporting
US Preventive Services Task Force (USPSTF) (Krist et al., 2021)	Age 50–80 with smoking history of 20+ pack-years. Current smoker or quit smoking within previous 15 years	Shared decision making Low-dose CT Smoking cessation program for current smokers	Once per year Follow-up interval suggested by standardized low-dose CT reporting
American College of Chest Physicians (ACCP) (Mazzone et al., 2021)	Recommended for asymptomatic individuals who meet all the following criteria: age 55–77, smoking history of 30+ pack-years, current smoker or quit smoking within previous 15 years Suggested for asymptomatic individuals who meet all the following criteria: age 50–80, smoking history of 20+ pack-years, current smoker or quit smoking within previous 15 years	Before screening: • Counseling and shared decision making • If symptoms are present, send for diagnostic tests Low-dose CT Chest X-ray and sputum cytology not recommended Smoking cessation guidance/treatment for smokers	Once per year Follow-up interval suggested by standardized low-dose CT reporting
American Cancer Society (ACS) (Wender et al., 2013)	Asymptomatic, age 55–74, smoking history of 30+ pack-years, current smoker or quit smoking within previous 15 years	Shared decision making Low-dose CT Smoking cessation program for current smokers Chest X-ray not recommended	Once per year
American Association for Thoracic Surgery (AATS) (Jaklitsch et al., 2012)	Age 55–79, smoking history of 30+ pack-years. Long-term lung cancer survivor up to age 79. Age 50–54, smoking history of 20+ pack-years, 5-year lung cancer risk 5%+	Low-dose CT	Once per year
Canadian Task Force on Preventive Health Care (CTFPHC, 2016)	Asymptomatic, age 55–74, smoking history of 30+ pack-years, current smoker or quit smoking within previous 15 years	Low-dose CT Chest X-ray and sputum cytology not recommended	Once per year, for up to 3 consecutive years

Source: Created by the authors based on Japan Cancer Society; CTFPHC (2016); Jaklitsch et al. (2012); Krist et al. (2021); Mazzone et al. (2021); Wender et al. (2013); and Wood et al. (2020)

following respects: (1) international guidelines set upper and lower age limits for the target population; (2) they narrow down high-risk individuals on the basis of smoking history; (3) they consider non-smokers who only quit smoking within the past 15 years to be at risk; (4) they clearly specify that chest X-ray and sputum cytology are not recommended; (5) they recommend annual low-dose CT and standard follow-ups; (6) they promote efforts to help smokers to quit; (7) they include the stipulation that screening subjects should be asymptomatic; and (8) they practice shared decision making (described in more detail later).

Among these international guidelines, the latest are those of the American College of Chest Physicians (ACCP) and the US Preventive Services Task Force (USPSTF), which were both published in 2021 (Mazzone et al., 2021; Krist et al., 2021). The latter is a revision of the USPSTF lung cancer screening guidelines previously published in 2013, with its updates focusing on reviewing the accuracy of low-dose CT, the benefits and harms caused by screening, the optimum age for commencing and terminating screening, the optimum screening frequency, and comparisons with other screening methods. The detailed evidence review process used in updating the guidelines was also described in two research papers published at the same time (Jonas et al., 2021; Meza et al., 2021).

The USPSTF releases numerous guidelines, each of which is immediately published on the USPSTF website and app, and also as an academic paper in *JAMA* (Journal of the American Medical Association) alongside formal editorials by experts in the field. In addition, their guidelines are further disseminated via *JAMA* podcasts, social media, and various other methods, ensuring that anyone can gain immediate access to the latest and best evidence from anywhere in the world, and freely give feedback and comments on the content, whether they agree or disagree with it. Such a timely, easily accessible, and feedback-welcoming style of guideline publication is commonplace internationally, including for all the main guidelines listed in Table 2, and is highly enviable compared with the situation in Japan.

In Japan, the majority of clinical guidelines are prepared by the relevant academic societies; however, owing to the costs involved in their creation, most guidelines are sold as printed publications. Some or all of the guideline content may be published on the academic society's website, but this is often only made available to members of the society or only after a certain period has passed following sales release.

A Ministry of Health, Labour and Welfare consignment project by the Japan Council for Quality Health Care, a public interest foundation, to promote the dissemination of evidence-based medicine (EBM), known as Minds (derived from 'Medical Information Distribution Service'), for which one of the authors of this paper serves as a member of the steering committee, evaluates the quality of clinical practice guidelines published in Japan and then makes them easily accessible to all in the Minds Guideline Library, free of charge (Japan Council for Quality Health Care, 2022). One of the problems that has arisen in this project is a difference of opinion among academic societies on the public release of clinical guidelines. Some societies do not consider medical scientific knowledge to be public property and thus still refuse to publish the latest version of their clinical guidelines, instead only permitting older versions to be released on Minds. This creates unfair access to information, including published evidence relating to medicine, further contributing to knowledge asymmetry, which, in turn, makes shared decision making extremely difficult, as we discuss later. It can also become an underlying cause of over- and under-provision of medical care.

IV-2. *Problems with lung cancer screening in Japan: Evidence of over- and under-provision of care*

Compared with lung cancer screening in other countries, Japan's screening program may include both over- and under-provision of care (Table 3). Hereafter, we introduce some evidence of this.

Table 3. Problems with lung cancer screening in Japan

As over-provision of care:

1. Annual chest X-ray is performed on all people over the age of 40
2. Annual sputum cytology is conducted on people at high risk over the age of 50
3. There is no upper age limit at which lung cancer screening should be terminated

As under-provision of care:

1. Low-dose CT is not performed on people at high risk
2. Shared decision making is not part of the process in carrying out screening

Source: Created by the authors

First, let us consider chest X-ray and sputum cytology, which are routinely performed as part of lung cancer screening in Japan. Manser et al. (2013) conducted a meta-analysis of nine controlled trials (453,965 participants in total), including eight randomized controlled trials (RCTs), as a review project for the Cochrane Library. They found that there was no reduction in lung cancer mortality among smokers and non-smokers by conducting annual chest X-rays compared with the usual level of medical care (relative risk [RR], 0.99; 95% confidence interval [CI], 0.91-1.07), and that there was no significant reduction in lung cancer mortality by conducting both chest X-ray and sputum cytology compared with conducting chest X-ray alone (RR, 0.88; 95% CI, 0.74-1.03). Additionally, regarding low-dose CT, which is not used for screening in Japan, Manser et al. found that there was a significant reduction in lung cancer mortality among high-risk smokers and ex-smokers by conducting annual low-dose CT compared with conducting chest X-ray (RR, 0.80; 95% CI, 0.70-0.92). On the basis of such evidence, most countries outside of Japan do not employ chest X-ray or sputum cytology in their lung cancer screening programs.

However, it is often difficult to use the evidence obtained from clinical studies to make clear judgments on the benefits and harmful effects of screening. We present some examples of this below.

The National Institute for Health Research (NIHR), the largest funder of clinical research for the UK government, published a series of health technology assessment studies carried out by Snowsill et al. (2018), which included a systematic review of 12 RCTs examining the clinical effectiveness and cost-effectiveness of the use of low-dose CT for lung cancer screening in high-risk populations (Snowsill et al., 2018; Chapter 3, pp.13-61). Four of the RCTs examined lung cancer mortality, finding overall that low-dose CT was associated with a non-statistically significant reduction in lung cancer mortality with up to 9.8 years of follow-up, compared with the control group (pooled RR, 0.94; 95% CI, 0.74-1.19). How-

ever, owing to the moderate heterogeneity in the magnitude of the effect on mortality ($I^2 = 43.3\%$), the authors advised caution in interpreting these results. In fact, after excluding one low-quality study, the revised results showed that low-dose CT was associated with a statistically significant reduction in lung cancer mortality (pooled RR, 0.85; 95% CI, 0.74-0.98), and the heterogeneity decreased ($I^2 = 6.9\%$).

In an investigation of all-cause mortality as part of the same review, low-dose CT was associated with a non-statistically significant increase in all-cause mortality with 9.8 years of follow-up (pooled RR, 1.01; 95% CI, 0.87-1.16). Again, there was considerable heterogeneity in the effect on mortality ($I^2 = 57.0\%$), and the results should therefore be treated with caution. However, after again excluding the same low-quality study, the revised results showed that low-dose CT was associated with a non-statistically significant reduction in all-cause mortality (pooled RR, 0.95; 95% CI, 0.89-1.00), with a substantial reduction in heterogeneity ($I^2 = 0\%$). When multiple RCTs are reviewed in this way, the inclusion or exclusion of a single RCT in the analysis can produce very different results. This is something that can also occur in the process of combining multiple pieces of evidence to create guidelines.

Regarding the number of cases of lung cancer detected by screening, low-dose CT was associated with a statistically significant increase in detection with at least 5 years of follow-up (pooled RR, 1.38; 95% CI, 1.02-1.86). Furthermore, low-dose CT was also associated with a significant increase in early-stage (stage I and II) lung cancer detection (pooled RR, 1.73; 95% CI, 1.27-2.37) and a significant decrease in advanced-stage lung cancer detection (pooled RR, 0.85; 95% CI, 0.73-1.00). The shift towards an increased number of cancers being detected in the early stages may be one of the clinical benefits of low-dose CT.

In terms of cost-effectiveness, Snowsill et al. (2018; Chapter 5, pp.69-73; Chapter 6, pp.75-113) examined a combined total of 48 cancer screening programs with varying frequencies (once, three times, annually, or every 2 years), ages of commencement (55 or 60 years of age), ages of termination (75 or 80 years of age), and risk thresholds (3%, 4%, or 5%). A single lung cancer screening using low-dose CT for smokers aged 60 to 75 years with at least a 3% risk of developing lung cancer cost GBP £28,000 per quality-adjusted life year (QALY). Because the UK threshold for cost-effectiveness is usually taken to be GBP £20,000-£30,000 per QALY, it can be said that low-dose CT also provides value for money. However, the setting of the cost threshold per QALY is only arbitrary, and how to apply these results within policy making therefore presents other issues³.

IV-3. Shared decision making

It is clear from Table 2 that all of the main international guidelines for cancer screening, with the exception of those of the American Association for Thoracic Surgery and the Cana-

³ Refer to Ii, Igarashi, and Nakamura (2019) for a detailed discussion on thresholds for evaluating cost-effectiveness.

dian Task Force on Preventive Health Care, specify shared decision making as one of the screening interventions. Shared decision making has been defined as “an approach where clinicians and patients make decisions together using the best available evidence” (Elwyn et al., 2010). Patients are encouraged to consider the available care options and their respective potential benefits and harmful effects, and to inform their medical practitioner of their preferences, and are then given support to choose the course of action that best suits them. Shared decision making respects patient autonomy and promotes patient engagement (Elwyn et al., 2010).

At the foundation of shared decision making is the idea that medical practitioners and patients should be equal partners. Although this point has been made for some time, it is interesting to note that it gained more emphasis in the early 2000s through its inclusion in health policy recommendations in the US, Canada, and the UK. This is due to the modern recognition of the ethical obligation to properly include patients in decision making about their own care, and the growing body of evidence pointing to the benefits of this approach. During this period, this trend was also bolstered by the construction of a database of clinical evidence on treatments, finally enabling medical practitioners to access and use this evidence to inform decision making.

The principles of shared decision making were well understood—seeking to break away from medical paternalism and the ‘doctor knows best’ approach to revolutionize medical care while respecting the rights of patients—but a concrete model was needed to accomplish it within routine clinical practice. Elwyn et al. (2012) proposed the ‘three-talk model,’ which was revised in 2017, comprising ‘team talk,’ ‘option talk,’ and ‘decision talk.’ Team talk refers to the medical practitioner supporting the patient and eliciting goals, and discussing choices with the patient before moving forward together; option talk is the process of weighing up and comparing options, including their relative benefits and harms; and decision talk is the act of making informed decisions that reflect what is most important to the patient (Elwyn et al., 2017).

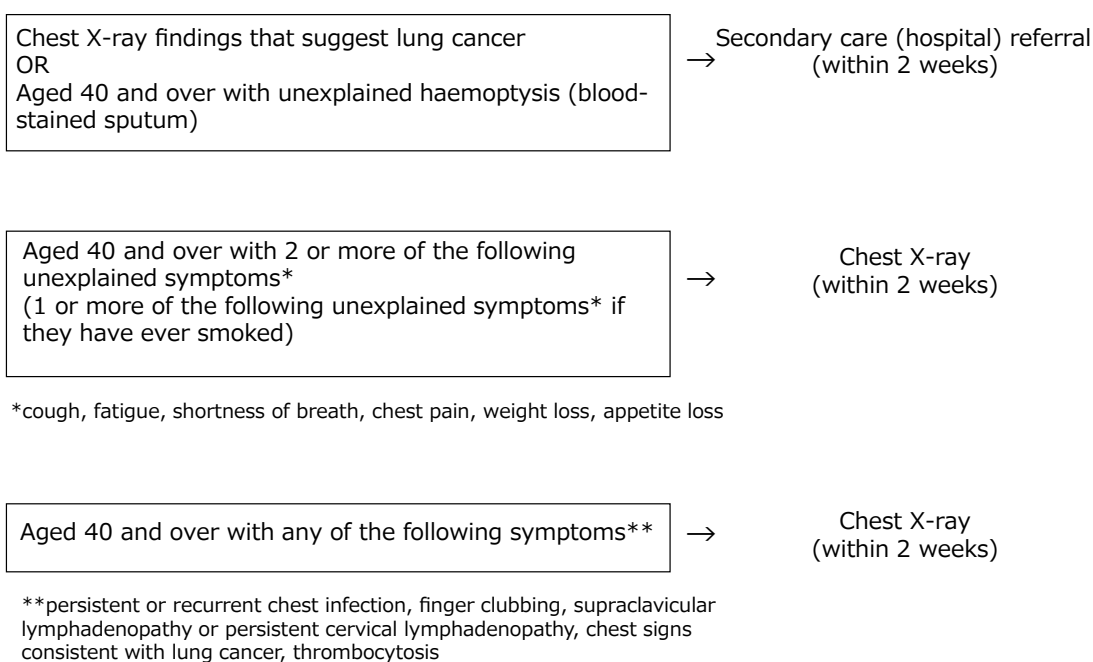
In the UK, the National Institute for Health and Care Excellence (NICE) places such importance on shared decision making that it has produced guidelines for that sole purpose (NICE, 2021). The guidelines, focusing on how to make shared decision making a part of routine practice in all healthcare settings, include recommendations on training for healthcare professionals in making shared decisions, how to communicate risks, benefits and consequences by using patient decision aids, and how to integrate shared decision making into the culture and working practices of healthcare organizations. Such educational initiatives and related reforms are highly effective and can instill a culture whereby shared decision making and seeking appropriate, cost-effective care become a matter of course.

IV-4. The unique approach taken by NICE in the UK

Following the publication of a new NICE guideline in 2015 entitled ‘Suspected cancer: recognition and referral,’ the UK terminated its lung cancer screening program (although it

continues its screening programs for colorectal, breast, and cervical cancer, which have been shown to be beneficial). The guideline covers: (1) identification of children, young people, and adults with symptoms that may be caused by a variety of cancers; (2) appropriate responses and investigations in primary care; and (3) recommendations on the right timing for referral to secondary (hospital) care⁴. Because NICE guidelines are made publicly available, this also helps people to better understand what to expect from medical providers (in both primary and secondary care) when cancer is suspected. The NICE recommendations for lung cancer are presented in Figure 1.

Figure 1. NICE (UK) recommendations for suspected lung cancer investigation and referral



Source: Created by the authors based on NICE (2015; Section 1.1)

The guideline recommends taking appropriate action, such as diagnostic testing or referral to secondary care, when the risk levels of symptoms caused by different cancers in different parts of the body exceed a set threshold value. A positive predicted value (PPV) is used to determine this threshold. PPV is defined as the proportion of people who are positive for a specific symptom and also actually have the disease (e.g., the PPV for blood-stained sputum is equal to the proportion of people with blood-stained sputum who also have lung cancer). In previous guidelines, the set values of PPV varied but were rarely less than 5%.

⁴ In the UK, the division of medical roles and functions is well advanced, and it is necessary for patients to receive referrals from their general practitioner (GP, or family doctor) at the clinic where they are registered in order to make use of specialist care in hospital (called 'secondary care'), excluding emergency care. The scope of health care provided by GPs is called 'primary care' (refer to Section 6.1 for more details).

Setting a lower PPV reduces the number of missed cancers, but results in more patients being referred for further testing and secondary care, which in turn increases healthcare costs. Because the number of referrals for people who do not actually have cancer will increase, this means that the number of unnecessary tests and referrals (over-provision of care) will also increase. Conversely, if the PPV is set at a higher level, there will be fewer tests and referrals to secondary care, resulting in a reduction in healthcare costs; however, the number of people who actually have cancer but are not given the necessary tests or referrals (under-provision of care), and thus the number missed cancers, will inevitably increase. Deciding where to draw the line for thresholds is complex, but the group that produced the latest guideline say that they set the PPV at 3% after considering the financial and clinical costs that would result from expanding their recommendations further.

In the UK, most people first consult a general practitioner (GP, or family doctor) about any medical problems, and people with symptoms that possibly relate to cancer therefore also usually first visit the local GP clinic at which they are registered. Because a vast amount of data has been built up from the primary care setting linking those initial symptoms with the final disease diagnosis made during the course of medical care that follows, it is possible to calculate PPV, which forms the cornerstone of the NICE cancer guidelines.

Another element that makes the UK's approach so effective is the quality of GP care. The gatekeeping function of GPs, whereby they establish symptoms with 3% PPV through interview and physical examination and then make appropriate referrals, relies on standardization. What makes this possible is the high-quality education of GPs and a continuous process of information sharing. As has become clear during the COVID-19 pandemic in Japan, even if a patient with a suspected case of COVID-19 first sees his/her *kakaritsuke-i* ('usual doctor,' i.e., a doctor whom the patient sees regularly in relation to a particular healthcare need or medical condition), there is no standardized threshold for symptoms to refer the patient to a hospital. This indicates that the education provided to and information shared with the *kakaritsuke-i* was not sufficient. With too low a referral threshold, hospitals will become overwhelmed with patients with mild and moderate symptoms, hindering the treatment of patients with serious cases who are in true need of intensive-level care.

V. Overseas initiatives to promote the right care

Table 4 presents a summary of the major overseas initiatives promoting the need for the right care for patients. Many are led by influential general clinical medicine journals and academic societies, who have the advantage of being able to readily build up databases of high-quality evidence.

In order for such initiatives to gain momentum in Japan, it is necessary for Japan's general clinical medicine journals and academic societies to show greater awareness of the issue of over- and under-provision of medicine and to have a stronger sense of mission toward promoting EBM as a means of achieving the right care for patients. It is hoped that this would enable a project team to be established to push for continued provision of suitable,

Table 4. Major overseas initiatives promoting the need for ‘the right care’

Name	Parent organization	Content	Website
Too Much Medicine	BMJ	<ul style="list-style-type: none"> Published first <i>BMJ</i> special issue on ‘Too Much Medicine’ (editor: Dr Richard Smith), April 13, 2002 Includes series of papers on over-provision of care (chronic obstructive pulmonary disease [COPD], bone fragility, mammography, mild hypertension, pre-diabetes, gestational diabetes, low mood, attention deficit hyperactivity disorder [ADHD], predementia, thyroid cancer, chronic kidney disease, pulmonary embolism, polycystic ovary syndrome [PCOS]) Lists and publishes related papers on digital theme issue ‘Overdiagnosis’ Hosted international scientific conference ‘Preventing Overdiagnosis’ as a media partner Promotes ‘Better medicine: shared decisions, best evidence’ campaign with Royal College of General Practitioners (UK) 	https://www.bmj.com/too-much-medicine
Less is More	American Medical Association	<ul style="list-style-type: none"> Published <i>JAMA Internal Medicine</i> series Includes series of papers on how over-provision of care fails to improve outcomes, harms patients, and wastes resources Has published 108 papers from July 2017 onwards 	https://jamanetwork.com/collections/44045/less-is-more
Right Care	The Lancet	<ul style="list-style-type: none"> <i>The Lancet</i> Group (UK) advocated Right Care in special issue, 2017 Targeted not only over-provision but also under-provision of care Focuses on Universal Health Coverage (UHC), the central issue in the UN’s 2015 Sustainable Development Goals (SDGs), emphasizing optimal access to and provision of health care, sustainability, and the pursuit of fairness and equity 	https://www.thelancet.com/series/right-care
Choosing Wisely	ABIM Foundation	<ul style="list-style-type: none"> Began when American Board of Internal Medicine (ABIM) appealed to medical societies across the US in 2012 Facilitates dialogue between patients and clinicians and supports patients to choose care that is evidence-based, does not overlap with previous care, is harmless, and is really needed Each society publishes a list of the most commonly conducted tests and treatments in their field that should have their necessity reviewed ‘Choosing Wisely Japan’ launched in 2016 	https://www.choosingwisely.org
Value-Based Health Care	Harvard Business School	<ul style="list-style-type: none"> Provides resources to implement the framework for restructuring and reforming healthcare systems, based on research of Prof. Michael Porter (Harvard Business School), author of ‘<i>Competitive Strategy</i>’ Defines ‘value’ as the outcomes that matter to patients, and the cost required to achieve those outcomes (Porter, 2010) An important approach to improve patient health outcomes and curb runaway healthcare costs 	https://www.isc.hbs.edu/health-care/value-based-health-care/

Source: Created by the authors

high-quality EBM educational programs for both medical practitioners and the public.

VI. The patient-centered clinical method

VI-1. Primary health care and primary care

Although it received little attention in Japan, the World Health Organization (WHO) and

UNICEF played a central role in holding international conferences on primary health care (PHC) in September 1978 and October 2018, where the ‘Declaration of Alma-Ata’ (WHO, 1978) and the ‘Declaration of Astana’ (WHO, 2018) were adopted, respectively, each receiving its name from the location where the conference took place. The latter declaration reaffirms the importance of the former and emphasizes PHC as essential to achieving universal health coverage (UHC) and sustainable development goals (SDGs). Furthermore, it highlights the importance of specialist education to guarantee the quality of PHC providers. The definition of PHC has evolved over time, but we currently define it as described in Table 5 (Kassai, 2021).

Table 5. Definition of primary health care

“Primary Health Care not only provides patient-centered solutions to most of the commonly encountered illnesses and health problems, but also functions as a hub of coordination with a range of related services within and outside the community, while building continuing partnerships with users to ensure they receive the right medical and long-term nursing care, to prevent disease, and to maintain and promote health. In addition to providing efficient, cost-effective services that take into account family and community context, it is also a system whereby multidisciplinary health teams share responsibility for comprehensive improvements in the health of the entire community.”

Source: Kassai (2021)

In Japan, owing to the influence of the US, the term ‘primary care’ (PC), whose nuance strongly implies medical care provided specifically to individual patients and their families, is commonly used (Kassai, 2018). However, it should be noted that even in countries that have had historically strong PC systems, such as the UK, Denmark, and the Netherlands, the overall meaning of PC has expanded in recent decades, transforming into a model in which multidisciplinary health teams share responsibility for comprehensive improvements in the health of the entire community, i.e., the PHC model that forms the objective of the Declarations of Alma-Ata and Astana (van Weel and Kidd, 2018). A good example of this expanded PC role in action was during the COVID-19 pandemic, whereby GP and family doctor clinics not only cared for patients with mild-to-moderate symptoms but also functioned as public health institutions, putting themselves on the front line of infection prevention, carrying out vaccinations and monitoring of case numbers in the local community (Noknoy et al., 2021). Taking this into account, we believe the terms PC and PHC to be interchangeable, and hereafter use ‘PHC’ to denote both.

VI-2. *The patient-centered clinical method*

It is hoped that the papers published in this special issue will further recognition and un-

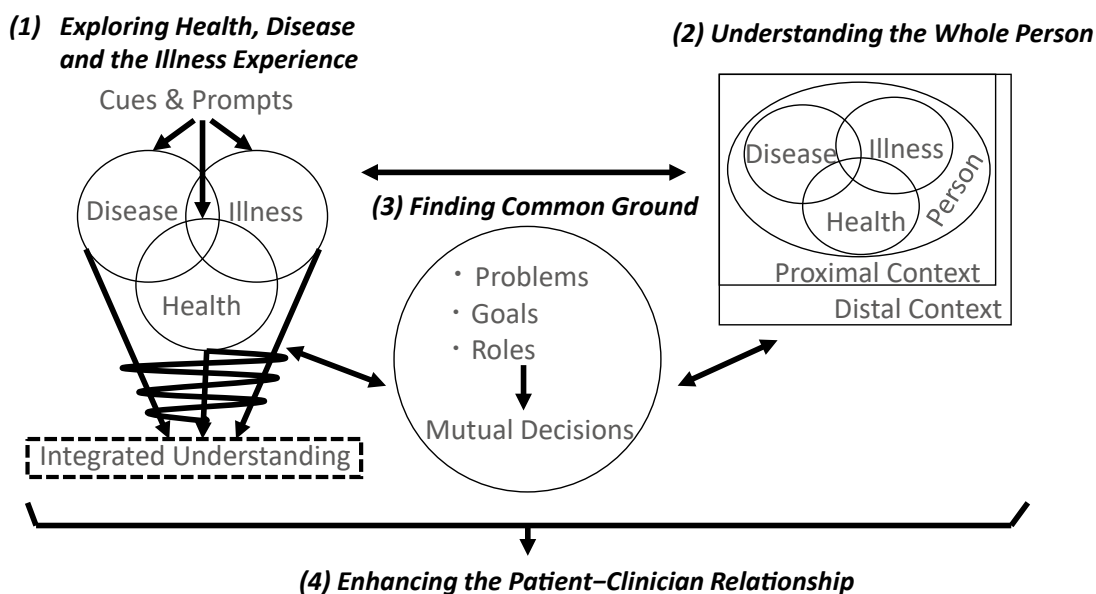
derstanding among experts that over- and under-provision of medical care is a major problem. However, without behavioral change among doctors at the point of care, any proposals and recommendations are simply wishful thinking.

Over the last 30 years, as the specialism of family medicine has become established, family doctors around the world have used trial and error to develop the best methods to maintain and improve the health of their patients, their families, and the entire communities that they are responsible for. The most sophisticated approach that exists at present—which is actually possible to teach, has been evaluated on the basis of patient outcomes, and is undergoing continuous improvement—is the ‘patient-centered clinical method’ (PCCM) (Stewart et al., 2014). This method should be mastered as core expertise by all family doctors who specialize in PHC (also known as *sogoshinryo-senmon-i* in Japan), but it should also form part of the education of all other healthcare professionals involved in PHC.

PCCM is not only a method that aims to reduce over- and under-provision of care, but it is a foundation for superior PHC professional development, and could be the secret weapon in reforming Japan’s healthcare system to promote the right care. For these reasons, we hope that the development of PCCM will be given priority as an agenda for health policy, and we therefore include an overview of the model in this paper.

PCCM consists of four interactive components (Figure 2), which are described in more detail under the headings below.

Figure 2. Patient-centered clinical method



Source: Created by the authors based on Stewart et al. (2014)

VI-2-1. Exploring health, disease, and the illness experience

This component focuses on exploring disease and understanding patient perceptions of

health and illness, whereby the PHC professional actively seeks to enter into the world in which the patient lives. Health in this context refers to its meaning to the patient and his/her aspirations or life goals. Disease is a theoretical label used to describe a specific pathological process or disorder. Exploring disease includes carrying out critical appraisals of the latest and best scientific evidence and clinical practice guidelines on that condition. Illness is the patient's own personal experience of physical or psychological sickness or discomfort; therefore, even among patients with the same disease, the illness experience is unique to each patient, and thus requires understanding at an individual level. Great importance is attached to the subjective side of care, such as how hard or painful things are for the patient, and full consideration is also given to the patient's emotions. The PHC professional weighs up the health, disease, and illness experience elements in a balanced manner.

By way of example, if a patient (Mr. A) is considering undergoing cancer screening and consults his family doctor about it, the doctor will first confirm the presence or absence of symptoms (and if symptoms are found, will perform the related medical examinations) and check his physical and mental condition as required. The doctor will then assess the risk (and discuss smoking cessation, if Mr. A is a smoker) and ask detailed questions that include his reasons for wanting (or not wanting) to undergo lung cancer screening, any history of previous screening, whether Mr. A has any particular worries or concerns, what he wants (and does not want) his healthcare provider to do, and what effect there would be on his life, his work, and his family if he undergoes the screening, tests positive, and then subsequently has to undergo detailed follow-up tests and treatment.

VI-2-2. Understanding the whole person

A person's health, disease, and illness experience are influenced by the many different factors that surround that person, and this combination of factors is referred to as context. The second component of PCCM is integrating the patient's health, disease, and illness experience into a holistic understanding that includes the context in which the patient lives.

Clinical information only becomes useful once placed within the context of the world of that individual patient. Many health problems cannot be fully understood unless they are viewed within their wider context. This also includes gaining an understanding of the individual's social determinants of health (SDH).

Continuing the example of Mr. A above, the following points will be important to understand as context: what interactions he has had with medical services since his childhood, his major life events, whether he has any family members or relatives who have had lung cancer or other cancers (and if so, what their experiences were), his current family situation, his work and living situation, his social life and relationships, and whether he has any other health concerns. It is also important to understand what kind of support Mr. A can obtain from his family and local community if and when he needs it.

VI-2-3. Finding common ground

This component comprises three key areas: (1) defining the problem; (2) determining

treatment goals and priorities; and (3) identifying the respective roles of the patient and the PHC professional. Together these make up the process of achieving mutual understanding and consent between the patient and clinician. Finding common ground is a process of integrating all four components of PCCM, considering the cost-effectiveness for the patient and settling on a care plan that does not fall into the realms of over- or under-provision. This is where the ability of the PHC professional to act as the patient's agent and to put the patient's best interests first is demonstrated. All the elements of shared decision making are contained within this component. However, in PCCM, because the elements of shared decision making can be naturally incorporated into the process of applying the four interactive components, rather than implementing shared decision making in isolation, this makes it easier for both the patient and the PHC professional.

In the example of Mr. A, the family doctor will fully discuss and make shared decisions about the following points relating to lung cancer screening: what Mr. A considers to be most important, what he thinks the problems are, whether he understands the benefits and harms of each lung screening option (including no screening), what the advantages and disadvantages of each option will be for him, what next steps would he like to take after receiving his lung cancer screening result (both for positive and negative results), and what roles Mr. A, his family, and the medical care team will play.

VI-2-4. Enhancing the patient-clinician relationship

In the traditional patient-doctor relationship, the doctor is an observer placed at a distance from the patient (even though the relationship has been described as non-hierarchical). Conversely, showing too much empathy has the risk of leading to compassion fatigue and transference or countertransference. PHC professionals should self-reflect and show self-awareness, building lasting patient partnerships that include compassion, caring, empathy, trust, power sharing, continuity, permanence, healing, and hope, while at the same time consulting with colleagues to further deepen their own insight.

For example, Mr. A's family doctor may already be providing ongoing care to Mr. A and/or his family. Even if Mr. A's consultation about lung cancer screening is his first visit to this particular doctor, the family doctor's role is to ensure that not only Mr. A but also members of his family can continue to freely discuss health-related problems, no matter what the issue might be. In terms of the current COVID-19 pandemic, the doctor will also provide Mr. A with information on vaccinations and how to respond to symptoms or any other concerns he has about the virus, as required.

Overall, PCCM has been shown in clinical studies to be beneficial in improving indicators such as patient satisfaction, treatment adherence, patient concerns, health self-assessment, test results for hypertension and diabetes, and favorable outcomes for patients with depression (Stewart et al., 2014). Furthermore, regarding PCCM's cost-effectiveness, clinical studies have also demonstrated that the method is associated with the use of fewer diagnostic tests and referrals to specialists, and that higher-quality family medicine/general practice is associated with lower healthcare costs (Stewart et al., 2014).

VII. Conclusions and recommendations

The Japanese government is also aware of the problems regarding how to implement standardized cancer screening, and has convened a range of investigative and advisory committees to look at the issue. For example, in 2012, the ‘Investigative Committee for Cancer Screening’ was established at the Ministry of Health, Labour and Welfare. Its objectives were to gather relevant knowledge from Japan and overseas to examine evidence-based screening methods, to investigate the effectiveness of existing policies and measures implemented in Japan to increase the take-up rate for screening programs, and to consider ways of making screening measures more efficient and effective (MHLW, 2012). An interim report of the committee’s findings was published in 2020 (MHLW, 2020)⁵. Regarding Japan’s health check-up program in general, a special committee for health check-ups and health examinations was set up in 2015, which released a report in 2019 (MHLW, 2019).

Unfortunately, many people are not even aware that such reports exist, despite the fact that anyone can, in principle, freely access them from the MHLW website. While some may have been published as academic papers, most others are difficult to find through standard academic literature searches. Even as experienced researchers, we have probably not been able to find all reports related to cancer screening in our literature searches conducted while writing this paper. It does not appear that the information in such reports is reflected in the relevant guidelines nor on the websites of the Japan Cancer Society and the National Cancer Center, which are easily accessible to members of the public (including medical professionals). Assuming that the findings of the reports are intended to be used by patients and medical care providers, such as in the shared decision-making process, the means by which this information is made available needs to be reviewed to make it far more user-friendly.

In addition, all information provided should be the latest and best available at the time of publication. As mentioned in Footnote 5, the most recent data referenced in the Investigative Committee for Cancer Screening’s interim report is from literature from over 15 years ago; this information would be too old to inform a discussion about whether or not to perform the examination (in this case, low-dose CT) right now. Incidentally, as described in our international comparison of lung cancer screening in Section 4.1, the current latest international guidelines for lung cancer screening were published in 2021. The evidence that was used in the analysis to develop the 2021 ACCP guideline came from a meta-analysis of 10 RCTs. The oldest of these was published in 2007, while the other nine were published between 2011 and 2020. The 2021 USPSTF guideline analyzed evidence from 26 different papers, published between 2004 and 2020, with only two papers being published before 2005. Compared with the interim report published in Japan in 2020, in which all the evidence was from

⁵ On page 4 of the interim report, low-dose CT is listed as a grade I recommendation (i.e., at present, its benefits in terms of reducing mortality are not clear, and thus its disadvantages, such as false-positive test results, complications, and overdiagnosis, may outweigh its benefits) for lung cancer screening. The basis for this recommendation grade appears to be the lung cancer screening guideline produced by a research group aiming to establish appropriate cancer screening methods and evaluations, funded by a 2006 MHLW cancer research grant, for which the evidence was drawn from literature published up to July 2005. Therefore, the interim summary is based on evidence dating back 15 years or more.

2005 or earlier, this is an astonishing difference. A national project is needed to appraise evidence from clinical research as rapidly as possible and to provide this information in a way that is easy for medical practitioners and patients to use in the shared decision-making process. Only when such a database is developed and made available will it become possible to have a more evidence-based debate on health care and health policy in Japan. It is a critical piece of information infrastructure for moving toward a healthcare system that avoids the pitfalls of over- and under-provision of care.

As discussed by Nawata, Ii, and Kassai (2022), cost-effectiveness is hard to measure in Japan because the costs of health check-ups and health examinations are integrated into and hidden within broader budgets. For this reason, it is difficult to build a picture of costs of cancer screening at the national level and to evaluate its effectiveness and value for money. Furthermore, because the key organizations that hold health-related information are fundamentally disjointed and fragmented, there has been neither the cooperation nor the will to achieve the scale of information sharing that would be required to support broader health promotion initiatives. As a result of legal reforms in 2021, insurers are finally able to gather health-related information such as data concerning health check-ups carried out at workplaces (MHLW, 2021). It is hoped that such information will become better consolidated and integrated, allowing more accurate evaluations of health check-ups and health examinations to be conducted.

Efforts to reduce the over- and under-provision of health care, which the Japanese healthcare system is particularly prone to, are expected to have considerable financial benefits. In order to promote such efforts, there is an urgent need to provide education that allows doctors to practice cost-effective, evidence-based medicine, to create a database that makes clinical practice guidelines available in a timely manner and guarantees good access to medical information, and to develop and support family doctors/*sogoshinryo-senmon-i* and PHC professionals who can understand and put into practice the patient-centered clinical method. To improve the quality of PHC, it is also important to promote clinical research that uses data from the field of PHC to provide answers to clinical questions and problems. Comprehensively pushing forward with these initiatives in an attempt to optimize medical costs while maintaining quality of care will bring Japan into line with the health policy direction of many other countries around the world (van Weel and Kassai, 2017; Kassai et al., 2020; Noknoy et al., 2021⁶).

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⁶ There have been numerous reports published on this subject in countries with advanced PC/PHC systems, in Europe and the US; however, recently, there have also been reports published in the Asia-Pacific region, which we have included as references.

of this manuscript.

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Conflict of interest statement

There are no conflicts of interest to declare.

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