E-Learning Material of Evidence-Based Medicine for Laypersons

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ABSTRACT

Background: There is a need for evidence-based medicine (EBM) education for laypersons. However, there are few materials or opportunities to learn EBM for Japanese laypersons. Objective: The aim of this study was to develop and test the usability of e-learning material on EBM for health-conscious laypersons in Japan. Methods: This study was conducted in two steps. First, content elements for the material were identified using purposive evaluation and a prototype of the e-learning material was developed. Following this, usability testing of the material was conducted. A questionnaire survey and qualitative semi-structured focus group interviews were conducted with health-conscious laypersons. Subsequently, the material was refined and finalized. Key Results: A total of 217 descriptions related to EBM were extracted from 12 materials and were integrated into 56 major elements. Each element was rated from the viewpoint of usefulness for laypersons and reviewed by four expert panelists, and finally 18 elements were confirmed, most of which were critical appraisal skills related to critical health literacy. For the usability testing after constructing the material, 25 laypersons participated, and 19 (76%) felt very/rather much interest in the contents of the material in the questionnaire. The results of five focus group interviews showed that the effectiveness of the e-learning material was influenced by the story and characters, and whether the contents of the material were consistent with interviewees’ daily interests. Conclusions: The e-learning material on EBM was found to be of interest to health-conscious laypersons and appeared to be useful in participants’ daily lives. This study successfully developed novel e-learning material on the essential components of EBM for laypersons in Japan. [HLRP: Health Literacy Research and Practice. 2022;6(4):e290–e299.]

Plain Language Summary: This study developed and tested the usability of e-learning material to encourage health-conscious laypersons in Japan to learn the fundamentals of evidence-based medicine. Most of the contents of the material are related to critical health literacy. The usability testing showed that the material was of interest to non-health professionals and useful for dealing with health information in their daily lives.

Evidence-based medicine (EBM) emerged in the 1990s to improve and evaluate patient care. It is the knowledge, skill, and behavior that can assist in making clinical decisions by integrating best research evidence, patients’ clinical state and circumstances, and their values and preferences with the expertise of health care professionals (Haynes et al., 2002; Torpy et al., 2006). Clinical decisions require an understanding and consideration of patients’ clinical and physical circumstances to establish the problem and identify available treatment options. The research evidence is necessary to be evaluated the efficacy and effectiveness of the treatment. In addition, patient preferences, such as religious beliefs, must be considered. Health care professionals are required to combine these considerations and recommend the most appropriate treatment (Haynes et al., 2002). The basic steps of EBM include: (1) converting the need for information into an answerable question, (2) uncovering the best evidence related to the study, (3) critical appraisal of the evidence, (4) integrating the critical appraisal with clinical expertise and with the patient’s unique biology, values, and circumstances, and (5) evaluating the effectiveness and efficiency in executing the step (Straus, 2011). Although EBM is taught to medical doctors and other health care professionals (Kyriakoulis et al., 2016; Maggio et al., 2013), there is a need to provide EBM education to laypersons (Stock et al., 2015), as laypersons are often required to make clinical and health care decisions not only jointly with clinical professionals but also independently. First, as stated above, EBM has become the standard
strategy used to solve clinical questions (Berger et al., 2010; Carter, 2010). It is sometimes desirable for laypersons to understand research evidence and appraise it critically to communicate better with health care professionals at the clinical situation (Hoffmann et al., 2014). For example, clinical professionals sometimes show research evidence to the patients and their family members to choose the treatment options for the patients with them. Laypersons who master the basic knowledge of EBM are likely able to perform more skilled shared decision-making with clinical professionals. Second, the internet has improved dramatically, and laypersons frequently search the Internet for health information (Berger et al., 2010). As such, when laypersons make decisions regarding their health and medical care without advice from health care professionals, they require skills to critically appraise and integrate the obtained information, their health condition and circumstances, and their preferences by themselves. These skills are included in EBM. Learning EBM can help laypersons discern and appropriately interpret information in daily life, allowing them to independently perform better decision-making. Third, opportunities for laypersons to participate in health care policy-making and clinical practice guidelines development have increased (Berger et al., 2010; Lancaster et al., 2017). Laypersons participating in policymaking often face research evidence related to health policies, and presenting their opinions requires an appropriate grasp of the evidence. Laypersons participating in guideline development also often encounter and read research evidence, such as evidence regarding treatments. Therefore, learning EBM would help laypersons take an active part in health care policymaking and guideline development (Baicker & Chandra, 2017; Facey et al., 2010; Santesso et al., n.d.). Therefore, there is a clear need for EBM education for laypersons and patient advocates.

Some reports from Western countries indicate that EBM lectures and workshops for laypersons have been implemented (Berger et al., 2010; Dickersin et al., 2001; Gibson et al., 2015; Odierna et al., 2015; Steckelberg et al., 2009). These lectures and workshops were provided in a classical lecture style and requires considerable time (from a 1/2 to 5 days) to complete. Recently, the United States Cochrane Center has been provided an e-learning material, “Understanding evidence-based health care: a foundation for action” (Consumers united for evidence-based health care at the Johns Hopkins Bloomberg school of public health, n.d.; Han et al., 2020). Web-based learning materials are typically more convenient for laypersons, as they allow people to learn anywhere and at any time, and are usually less expensive (Van Nuland et al., 2017). However, this material is not widely used in Japan due to the language barrier and difference in health care systems.
between the U.S. and Japan. Moreover, as it is also provided in a classical lecture style and requires about 6 hours to complete, it may be too formal for laypersons.

Therefore, this study aimed to develop a novel and approachable web-based learning (e-learning) material and assess its usability in assisting health-conscious laypersons in Japan to learn essential components of EBM.

METHODS

This study was conducted in two steps. First, content elements for the e-learning material were identified through purposive evaluation and an e-learning material prototype was developed. Following this, usability testing of the material was conducted with health-conscious laypersons and the material was revised (Figure 1). This study was approved by the Kyoto University Ethics Committee (C1373).

Development of the Prototype of the E-learning Material

For the material, we applied the five principles of programmed learning advocated by Skinner (1968), an American psychologist and founder of behavioral analysis: (1) active learner response indicated to what extent learners could understand, which was judged by asking them questions, with the extent of a learner's understanding ascertained from the responses; (2) immediate feedback immediately informs learners whether their answers were correct or incorrect, followed by providing the subsequent question; (3) setting small steps prevents learners from experiencing difficulty learning and eliminates the risk of being labeled a failure; (4) self-paced allows the learners to learn at their own pace, as the appropriate speed varies between learners; (5) learner verification, which indicated the value of the program, was judged not based on specialists' opinions but on whether learning was accomplished. As such, it is necessary to have learners with no knowledge of the subject matter to try the program under development and improve the material as necessary based on the trials (Skinner, 1968). This study adopted true/false quizzes, and the users were required to select their answer actively. An optional page was included to allow learners to learn more if they desire (principle 1). The correct answer and explanation for each quiz were shown to the learners immediately after answering (principle 2). True/false quizzes were created for each element, and correct answers with explanations were demonstrated for each element. The users could learn the material one by one in small steps (principle 3). The materials allowed the users to return to previously learned material if necessary or desired (principle 4). Usability testing by the users without experience of learning EBM was conducted, as described below (principle 5).

Relevant materials, such as books, websites, and journal articles, that described EBM for laypersons were collected using the online search engine PubMed, manually searching on Google, and consulting EBM and epidemiology experts. Collected materials were carefully reviewed and evaluated for properties that should be introduced in the e-learning material. Following this, all descriptions and information related to EBM were extracted from the collected materials, and similar and related descriptions were integrated into major elements. Subsequently, two researchers independently rated the materials from 1 (least important) to 5 (most important), considering (1) understandability for laypersons, (2) usefulness for critical appraisal of health information that is encountered in daily life, and (3) usefulness for decision-making in self-care.

In addition, four panelists (one health care provider, one patient advocate, one health care policymaker, and one health care journalist) were consulted regarding the appropriateness of the selected elements. All panelists received sufficient EBM training and were familiar with laypersons who would use the e-learning material. Based on the panelists' suggestions, two researchers and two supervisors discussed and finalized the elements to be included in the e-learning material.

Usability Testing of the E-learning Material

Usability of the e-learning material was evaluated using a questionnaire and qualitative semi-structured focus group interviews conducted with laypersons. Survey respondents and interviewees were laypersons assumed to be the main users of the e-learning material. Participants were recruited using purposive sampling in Japan. The inclusion criteria were being at least 20 years of age, interested in health/medicine, an Internet user, and a Japanese speaker. The exclusion criterion was being a health care professional. Written informed consent based on their free-will was obtained from all participants.

First, the participants were asked to use the e-learning material on their personal computers. They were then asked about their age, gender, occupation, highest level of education, interest in health information, and social activities related to health/medicine, such as belonging to patient advocacy groups. In addition, they were asked to rate usability (International Organization for Standardization, 1998), usefulness, effectiveness, and satisfaction with the e-learning material using a 5-point Likert scale. At the end of the questionnaire, the participants were asked to provide additional suggestions in free format to further improve the material. Thereaf-
ter, qualitative semi-structured focus group interviews were
carried out with the same participants that completed the
questionnaires. Each session took approximately one hour to
complete. The number of interviewees per group was four to
five (Kitzinger, 2006), with participants divided into groups
of university office workers; members of a health promo-
tion class; participants of a health policy group consisting of
patient advocates, policymakers, health care providers, and
journalists; and participants of a patient-advocate workshop.
The respondents were asked to provide feedback regarding
usability to further improve the material. All interviews were
recorded.

Responses to the questionnaire were quantitatively sum-
marized, while focus group interviews were qualitatively
analyzed (Kitzinger, 2006). The interviews were transcribed
with all the information anonymized, and the context was
interpreted and assigned special codes. Overarching catego-
ries were developed from similar codes. The interviews were
conducted before reaching the theoretical saturation of cat-
egories. The results were discussed among the authors using
the triangulation method to test the validity and corroborate
the analysis.

RESULTS
Development of the E-learning Material
A total of 12 existing materials (four Japanese books, six
websites [four Japanese and two English], and two journal ar-
ticles in English [Berger et al., 2010; Sutherland et al., 2013])
that included contents regarding essential components of
EBM, epidemiology, and critical appraisal of literature for
laypersons were collected from November 2014 to January
2015. In reviewing them, the properties that should be intro-
duced in the e-learning material as per Skinner’s principles
were determined to be as follows; the material (1) can be used
independently by the user, (2) is composed of one scenar-
io with familiar health issues encountered in everyday life,
(3) uses plain language without technical terms, (4) includes
user-friendly figures and illustrations, (5) can be completed
within approximately 30 minutes, and (6) explicitly shows
the points that users learn.

From the collected materials, 217 descriptions related to
EBM were extracted. Similar and related descriptions were
integrated into 56 major elements (Table A). Of the major el-
ements, 18 elements received high scores (eight to ten points)
by researchers’ rating: characteristics of health information,
evaluation of information on the Internet, evidence, impor-
tance of comparison, numerator and denominator, relative
risk and absolute risk, framing effect, biases (selection bias
and measurement bias), reverse causation, randomized con-
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Figure 1. The process of this study

trolled trial, risk and benefit, limitation of information, acting
on information, conflict of interest, 2 × 2 table, sample size,
confounder, and true/surrogate outcome. These elements
were selected as candidates for material content (Table 1).

Of the four panelists consulted regarding the appropriateness
of the selected elements, the health care provider and
the health care policy maker were in favor of decreasing the
number of elements, as they thought some of the elements
were too difficult for EBM beginners. On the contrary, the
patient advocate and the journalist were in favor of increas-
ing the number of elements. However, all panelists agreed on
the necessity of the 18 elements and required no further ele-
ments. As such, these 18 elements were selected as essential.

A scenario consisting of 18 elements was created for the
e-learning material. In this scenario, three characters (a
40-year-old man and his wife and daughter) learn the funda-
mentals of EBM to solve their own health problems or ques-
tions. All elements consisted of four pages (topic, true/
false quiz, answer to the quiz, and detailed commentary
that users can optionally select to learn), which could be
turned as pages of a book, allowing users to complete the
learning the material around 15 minutes, maximumly 30
minutes.

Usability Testing of the E-learning Material
A questionnaire and five focus group interviews were
conducted from February to March 2016. The characteris-
tics of the participants of usability testing are shown in
Table 2. A total of 25 individuals between ages 30 and
70 years participated in the assessment of the e-learning
material. Fourteen participants graduated college or
more, six graduated junior high school, and five gradu-
ated senior high school. All participants were interested in health and medicine. Eighteen participants often or sometimes participated in social activities related to health and medicine.

The results of the questionnaire are presented in Table 3. Most participants (19; 76%) were interested or very interested in the contents of the material. Further, 22 participants (88%) evaluated the material as easy to follow, and 18 (72%) evaluated it as useful in their daily lives. All participants older than age 70 years were interested in the e-learning material, found it easy to follow, and evaluated it as being useful in their daily lives. Four participants (one in their 30s, two in their 40s, and one in their 50s; two men and two women) were not interested in the material.

Ten categories and twenty-six codes were generated from the five focus group interviews (Table 4). The effectiveness of the e-learning material was heavily influenced by the story, characters, and whether the contents of the material were consistent with interviewees’ daily inter-
ests. In addition, the interviewees stated that the material was useful, as each scene that the characters experienced was likely to be encountered in daily life. Regarding efficacy (difficulties and readability), the participants found the true/false quizzes to be relatively easy; however, the detailed descriptions were difficult to follow, as they contained many technical words. Although the figures and illustrations appeared friendly, the accompanying sentences were too long. Most of the participants were satisfied with the true/false quizzes and intended to introduce the material to their friends; however, some participants desired more detailed descriptions.

Feedback from the focus group interviews included adding information before using the e-learning material to explicitly demonstrate the learning objectives and the time required to complete them, providing additional expressions for easy understanding without technical terms and shortening text length, modifying the structures to equalize the ratio of true to false answers in quizzes and showing a summary of what the users learned, updating the contents to include an older character and cover a wide age range of users, and using various health issues as examples of explanations regarding EBM elements.

Following this, the e-learning material was revised to reflect the feedback from the focus group interviews. The final version of the story characters is shown in Figure 2. An older woman character was added, totally resulting in four characters. An example of the final version of the four pages of one section is shown in Figure 3. The last page in each element of e-learning was changed from a detailed commentary using academic explanations to daily life examples to check what the user learned.

**DISCUSSION**

This study developed a novel web-based EBM learning material for use by laypersons in Japan. This study reviewed existing materials and addressed the limitations of previous methods, particularly the lack of adequate EBM education for laypersons in Japan and the use of lecture-based and time-consuming educational materials, by creating a new material. A usability test based on a questionnaire and focus group interviews demonstrated that the e-learning material was easy to follow and useful for the daily lives of health-conscious laypersons in Japan.

Overall, EBM’s five steps, described above, were considered and evaluated in the selection of material elements. However, most elements included in the e-learning material were concerned with step three (critically appraising the evidence) (Gigerenzer et al., 2007; Sutherland et al., 2013). In addition, these elements were related to critical health literacy, which is one of the three dimensions of health literacy suggested by Nutbeam (2000). Critical health literacy is a more advanced cognitive skill to critically analyze and use information to better control life events and situations (Nutbeam, 2000). There is a significant amount of misinformation and disinformation on the internet, social media, and other sources (Suarez-Lledó et al., 2021; Wang et al., 2019). Laypersons must be careful to recognize and distinguish misinformation and disinformation using critical health literacy. If laypersons acquire critical health literacy, they should be able to critically assess health information and research evidence and use them appropriately. They would be more likely to appropri-

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**TABLE 3**

| Characteristic | n (%) |
|----------------|-------|
| Did you feel interested in the contents of the materials? | |
| Very interested | 5 (20) |
| Interested | 14 (56) |
| Neutral | 2 (8) |
| Not interested | 0 (0) |
| Not interested at all | 4 (16) |
| Did you feel difficulties in understanding the material? | |
| Very easy | 3 (12) |
| Easy | 11 (44) |
| Not too easy, not too difficult | 7 (28) |
| Difficult | 4 (16) |
| Very difficult | 0 (0) |
| Do you think the material is easy to follow? | |
| Strongly agree | 18 (72) |
| Agree | 4 (16) |
| Neutral | 1 (4) |
| Disagree | 1 (4) |
| Strongly disagree | 1 (4) |
| Do you think the material is useful in daily life? | |
| Strongly agree | 8 (32) |
| Agree | 10 (40) |
| Neutral | 4 (16) |
| Disagree | 3 (12) |
| Strongly disagree | 0 (0) |
| Would you like to use the material? | |
| Strongly agree | 3 (12) |
| Agree | 13 (52) |
| Neutral | 5 (20) |
| Disagree | 4 (16) |
| Strongly disagree | 0 (0) |
An appropriate understanding of research evidence would allow laypersons to participate in discussions on health policy and the development of clinical guidelines. Therefore, critical health literacy is likely to influence laypersons’ actions and promote, enhance, and encourage appropriate behaviors for themselves and for society (Abel & McQueen, 2020). The material developed in this study could help laypersons critically consider information before trusting it and may have the potential to empower not only laypersons’ daily lives and decision-making regarding self-care but also their health-related social and political activities.

The results indicated that the content of the e-learning material was of interest to non-health professionals because the story, characters, and contents were consistent with their daily interests. In addition, participants believed that the e-learning material would be useful in their daily lives. These findings are consistent with results from prior studies examining the interests and needs associated with EBM for non-health professionals (Berger et al., 2010; Stock et al., 2015). However, for users who already have sufficient knowledge, the contents might seem rather superficial and unsatisfactory. Therefore, it may be

| Table 4 |
|------------------|------------------|
| **The Categories and Codes of Usability from Focus Group Interviews** |
| **Category** | **Code** |
| **Theme I: Effectiveness (interest/usefulness)** |
| Effects of the story and characters | 1. I could get into the material due to the story  
2. I could get into the material because the character in the story was the same age as me |
| Consistent with daily interests | 3. As I get older, my interest in health issues is increasing, so I was interested in the material  
4. I was interested in the material because I am always interested in health  
5. I was interested in the material because I want to be healthy by any means  
6. I was interested in the material because the contents were what I am always thinking |
| The scene in the material seemed to be useful | 7. This material would be useful to think and reduce impulse purchases when watching advertisements of seemingly attractive products on TV  
8. This material would be useful to decide whether we should intake the foods advertised as healthy  
9. This material would be useful for avoiding being swayed by rumors  
10. This material would be useful for a patient representative  
11. This material would be useful to remind people that information can be good or bad |
| **Theme II: Efficacy (difficulties and readability)** |
| Difficulties of quizzes | 12. The true/false quizzes were easy  
13. It was easy to guess the answer of the quiz because of the character’s personality |
| Difficulty of explanations | 14. Technical terms were difficult  
15. Detailed descriptions were difficult |
| Easy to follow | 16. The material was easy to follow  
17. Illustrations were reader friendly  
18. The whole design was good |
| Length | 19. There were too many words  
20. The sentences were too long. Shorter sentences would be better for a good reading tempo |
| **Theme III: Satisfaction** |
| Gamification | 21. I could learn as if playing a game  
22. The feedback from the score evaluation was interesting |
| Intention to introduce | 23. I would like to introduce the material to friends who easily buy products after seeing advertisements  
24. I can introduce the material incidentally, but it is not worth it to introduce it actively |
| Contents | 25. I hope the elements of the contents will include more detailed explanations  
26. I would like to know how to practically perform using what I have learned in real life |
beneficial to create and provide more detailed optional content. In Japan, informatics classes have gradually begun to be offered as part of school education, and it has become a required subject for students entering high school in 2022 (Ministry of Education, Culture, Sports, Science and Technology, 2018). This subject deals with scientific views and ideas about information in general. Although it does not specifically focus on how to read and understand information on health and medicine, in the future, it may be necessary to brush up on teaching materials for those who have studied informatics in high school.

Furthermore, the results indicated that the e-learning material, which included a story that was tailored to laypersons with cartoon illustrations and true/false quizzes, was enjoyable in a way similar to a game. It has been reported that gaming, as part of e-health applications, is effective for knowledge acquisition, memory, attention, processing speed promotion (Lumsden et al., 2016), implementation motivation, usage satisfaction, and self-efficacy (Sardi et al., 2017). Although the gaming procedure used in this e-learning material was simple, such as true/false quizzes and scoring correct answers, it may have led to increased feelings of satisfaction.

In addition, feedback from a questionnaire and focus group interviews varied and addressed several points, from information before the lesson, such as the objective of the material and required time, to web-design and readability of the contents, such as headlines, plain language without medical terminology, and shorter sentences. These findings were consistent with other materials evaluated for suitability and readability for patients and the public (Finnie et al., 2010; Okuhara et al., 2015; Williams et al., 2016; Wolf, 2011).

This material was intended to assist laypersons in understanding the basic components of EBM and epidemiology and did not address the issues around which opinions may differ, such as vaccinations. Recently, patient decision aids have been gradually developed in various specific conditions (The Ottawa Hospital, 2020). Decision aids are interventions that support patients by making their decisions explicit, providing information about options and associated benefits/harms, and helping clarify congruence between decisions and personal values (Stacey et al., 2017). All the information provided within decision aids to the patients are connected to the elements of EBM. However, this material does not focus on some specific topic which requires making decisions in it. This material is more basic than decision aids, but to learning the material can help the use and understanding of decision aids.

This study had some limitations. First, the focus group interview and the questionnaire sample sizes were small. However, groups that were expected to give proactive opinions and critically evaluate the material were selected from expected users rather than groups that averaged the distribution of various users. Moreover, theoretical saturation of codes was reached. However, further investigations with a wider audience are required to determine whether this material is appropriate for broader distribution. Second, this study did not evaluate the effectiveness of using this material for laypersons. A randomized controlled trial to evaluate effectiveness has been conducted and we will report it in the near future. Third, this study was conducted in 2016. Unfortunately, the publication of this article took considerable time. Much has changed in these years. However, we find that the basic components of EBM and epidemiology for laypersons remain the same. At the same time, due to societal growth, we recognize that additional developmental materials will need to be created in the future.
CONCLUSION

This study developed a novel e-learning material to encourage health-conscious laypersons in Japan to learn the fundamentals of EBM. The preliminary usability test indicated that the material was of interest to non-health professionals and useful for participants’ daily lives. Further investigations are needed to determine whether this material is effective for health-conscious laypersons, and whether it is applicable for broad distribution to a wider audience.

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| Characteristics of health information | Information sources | Evaluation of information on the Internet |
|--------------------------------------|---------------------|------------------------------------------|
| Animal experimentation and clinical research | Expert opinions | News on the media |
| Advertisements | Patients’ narratives | Expression (conjecture, highlight) |
| Evidence of information | Information from the research paper | Structure of the research paper |
| Google search | Medical literature search | Systematic review |
| Definition of EBM | Five steps of EBM | Research ethics |
| Conflict of interest | Drug development (Phase1 to 3) | The others (including supplements) |
| Basics of numeracy | Comparison | Numerator and denominator |
| 2 by 2 table | Relative risk/absolute risk | Number Needed to Treat |
| Causal relationship | Reverse causation | Regression to the mean |
| Measurement error | Bias | Publication bias |
| Confounder | Framing effect | Research design |
| Level of evidence | Randomized controlled trial | Descriptive epidemiology |
| Observational research | Qualitative research | Method of critical appraisal for medical literature |
| Outcome | True/surrogate outcome | Chance and certainty |
| Sample size | Confidence interval, P value | Significant difference |
| Screening test | Important points when interpreting research results | Selection of information |
| Risk and benefit | Limitation of information | Act on information |
| Research question | Emotion | |