Developmental of 6 Cancer Risk Assessment Questionnaire; CRAQ-6 (Thai Version)

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Abstract

OBJECTIVES: This medical study is to create a user-friendly and comprehensible Thai version questionnaire for the risk-based assessment of six primary cancers in Thailand. The questionnaire is designed to be easily administered as a self-test or interpreted by individuals proficient in the Thai language. The overarching aim is to enhance non-instrumental cancer screening within non-hospital-based settings, encouraging individuals identified as having cancer risk to seek early screening at hospitals. This proactive approach aims to conduct risk assessments, mitigating the risk of delayed cancer diagnoses and promoting preventive measures before the onset of symptoms.

MATERIALS AND METHODS: The methodology employed in this medical study involved a systematic review of the latest updated clinical practice guidelines from international entities, including NCCN, Standard textbooks. This comprehensive review was conducted in collaboration with the Thailand National Cancer Institute and relevant departments of the Thailand Royal College of Surgeons. Subsequently, a prototype questionnaire in Thai was developed. Expert consultation was sought from individuals associated as the Index of item-Objective Congruence (IOC) who specialize in each specific cancer and possess a minimum of five years of experience in the respective field; this involved engaging five experts per cancer risk assessment questionnaire. The refined questionnaire underwent linguistic refinement by consulting with linguists. Finally, the comprehensibility and effectiveness of the questionnaire were assessed through discussions with classified volunteers.

RESULTS: The self-evaluation Cancer Risk Assessment Questionnaire, acronymically known as CRAQ-6 from "Crack" and "Sick," was successfully developed through standard scientific tool development. It exhibited high understandability across all educational levels among volunteers, although certain sections required additional reading for optimal comprehension.

CONCLUSION: In conclusion, the CRAQ-6 Questionnaire, developed using rigorous scientific tools for Thai contexts, demonstrates overall understandability across diverse educational levels. However, specific sections may require assistance from another reader for optimal comprehension. Ongoing refinement is essential to ensure its effectiveness in diverse research and clinical contexts.

Keywords: breast cancer, liver cancer, lung cancer, cervical cancer, colorectal cancer, prostate cancer, cancer risk assessment

Cancer is the leading cause of death in Thailand since the year 1999, with a rate of 58.6 per 100,000 populations, steadily increasing to 78.9, 84.9, and 91.1 per 100,000 populations in 2003, 2007, and 2010, respectively. According to the Population and Social Research Institute, Mahidol University, the life expectancy in Thailand was assessed to be 71.3 years for males and 78.2 years for females in the year 2013. Additionally, the overall fertility rate in the country declined from 1.8 in 2022 to 1.6 in 2014.[1]

The earlier and more swiftly cancer is detected and diagnosed, the better the prognosis and treatment outcomes. Rapid identification not only improves disease prognosis but also contributes significantly to reducing cancer-related mortality. However, symptom detection for cancer is often overlooked when formulating healthcare policies. [2]

The top 5 most prevalent cancers in males are colorectal and anal cancer, liver and bile duct cancer, lung cancer, prostate cancer, and esophageal cancer, accounting for 20.7%, 19.0%, 12.9%, 7.1%, and 6.9%, respectively, of all registered cancer cases. In females, the leading cancers are breast cancer, colorectal and anal cancer, cervical cancer, lung cancer, and liver and bile duct cancer, constituting 39.8%, 12.2%, 11.1%, 6.9%, and 5.3%, respectively, of all registered cancer cases.[1,3]

In examining the Dashboard from the Department of Health[4] and health Key Performance Indicators (KPIs) provided by the Ministry of Public Health[5], we discovered that, as of 2023, breast cancer screening and cervical cancer screening rates were reported at 62.12% and 45.1%, respectively. Notably, in 2024, the introduction of policies and KPIs for public colon cancer and HPV screenings occurred.

If we refer to the percentage of newly diagnosed cancer patients based on history-taking and physical examinations, it is found that new patients can be diagnosed at rates of 16.6%, 60.2%, 30.3%, 15.9%, and 7.1% in colorectal cancer, liver and bile duct cancer, lung cancer, breast cancer, and cervical cancer, respectively. Normally, cancer screening in asymptomatic groups often incidentally detects cancer. However, in symptomatic groups, there tends to be a trend of diagnosing cancer through diagnostic examinations rather than screening. Therefore, the research team sees an opportunity to develop a comprehensive cancer risk screening questionnaire that includes common risk factors for each prevalent cancer in Thailand. This tool could be accessible to the general population without the need for medical personnel history-taking. If any cancer risks are identified through this screening, individuals can be advised to undergo more accurate and prompt screening or diagnostic examinations.[1] The "Cancer Risk Assessment Questionnaire (CRAQ)," designed for easy access and quick self-assessment, should be implemented publicly.

Materials and Methods

Literature and Guideline Review

The initial phase of this comprehensive study was dedicated to a meticulous review of the most recent clinical practice guidelines disseminated by renowned international textbooks, including but not limited to the National Comprehensive Cancer Network (NCCN). This thorough examination was undertaken in close collaboration with data from esteemed institutions such as the Thailand National Cancer Institute and pertinent departments within the Thailand Royal College of Surgeons. The collaborative effort sought to assimilate the wealth of knowledge encapsulated in these guidelines, ensuring a nuanced understanding of the latest advancements and recommendations in cancer risk assessment. As a result of this exhaustive review, a prototype questionnaire tailored to the nuances of the Thai context was meticulously crafted, representing a pivotal advancement in the evolution of cancer risk assessment methodologies.

In synthesizing the aforementioned clinical practice guidelines, we systematically identified criteria for cancer risk enhancers across various dimensions of each cancer. These criteria were then methodically allocated to formulate a prototype questionnaire. Additionally, recognizing that the recommended lower age for screening may enhance sensitivity in detecting cancer risks, we opted to predominantly incorporate the lower age recommended by international standards into our questionnaire. This strategic approach ensures alignment with established guidelines and enhances the questionnaire's potential effectiveness in identifying cancer risk factors.

Index of Item-Objective Congruence (IOC) Method

Subsequent to the successful development of the prototype questionnaire, a methodologically robust approach known as IOC was systematically employed. This method aimed to rigorously validate the precision and alignment of the questionnaire with predetermined research objectives. To enhance the scientific rigor of this phase, expert consultation was sought from distinguished members affiliated with the esteemed specialists. Each of these specialists brought to the table a wealth of experience, boasting a minimum of five years in their respective cancer fields. The meticulous selection of these experts was pivotal in ensuring a diverse and comprehensive perspective, as the IOC-affiliated specialists engaged in the nuanced evaluation of each cancer risk assessment questionnaire. This multi-faceted collaboration not only elevated the methodological robustness but also contributed significantly to the refinement and validation of the questionnaire, aligning it closely with the highest standards of precision and scientific integrity. The iterative engagement of five experts per questionnaire underscored the commitment to a thorough and exhaustive assessment, ensuring that the final instrument encapsulates the collective expertise and insights of a diverse panel of seasoned professionals. An IOC (Index of Congruence) equal to or exceeding 0.8 will be regarded as indicative of a successfully validated questionnaire.

Following the initial IOC step, the scoring rankings ranged from 0.6 to 1.0. We meticulously revised and edited questions that raised concerns among specialists before submitting the questionnaire for Linguistic Refinement.

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Linguistic Refinement:

In the progressive trajectory of this research endeavor, a pivotal phase ensued subsequent to the development of the questionnaire—linguistic refinement. This intricate process was meticulously undertaken through a collaborative partnership with seasoned linguists, whose expertise in language intricacies and cultural nuances played an instrumental role in elevating the quality of the developed instrument.

The paramount objective of this critical step was to transcend mere linguistic translation, delving into a comprehensive refinement process designed to enhance both the clarity and contextual relevance of the questionnaire. Linguistic experts engaged in a nuanced examination of the questionnaire's language and structure, scrutinizing each element with a keen eye for cultural sensitivity and semantic precision. Their involvement extended beyond the mere transposition of words; rather, it was a meticulous endeavor to ensure that the instrument resonated seamlessly with the linguistic and cultural fabric of the Thai context.

The collaboration with linguists, therefore, emerges as an indispensable facet in the trajectory of questionnaire development. Their meticulous attention to linguistic details not only contributes to the aesthetic refinement of the questionnaire but also plays a profound role in bolstering its overall effectiveness and comprehension. Through this collaborative effort, the questionnaire transcends linguistic barriers, becoming a culturally resonant and scientifically robust tool for capturing nuanced responses in the context of cancer risk assessment.

Comment: In this developmental phase, no reliability test was conducted. The risk-based cancer screening assessment questions were entirely derived from national and international standard clinical practice guidelines with translations. The assessment process included the use of the Index of Concordance (IOC) and underwent linguistic refinement procedures.

Understandability Testing with Volunteers

The culminating phase of our methodological approach was dedicated to a meticulous examination of the questionnaire's comprehensibility and efficacy. This pivotal step aimed to delve into the nuanced aspects of user-friendliness and the potential applicability of the questionnaire across diverse demographic groups, thereby constituting an essential dimension in the comprehensive evaluation of our study.

To facilitate this crucial assessment, in-depth discussions were conscientiously conducted with a carefully selected cohort of classified volunteers. The recruitment of this diverse group ensured the representation of varied perspectives and backgrounds, enriching the insights gathered during the testing phase. These volunteers, meticulously categorized based on demographic parameters, engaged in comprehensive dialogues aimed at unraveling the intricacies of their understanding of the questionnaire.

The significance of this step extends beyond a mere evaluation of user-friendliness; it is a profound exploration into the adaptability and resonance of the questionnaire within different demographic contexts. The qualitative feedback gleaned from these deliberations not only sheds light on the instrument's effectiveness but also unveils its potential strengths and areas for refinement.

By undertaking this meticulous understandability testing with a diverse cadre of volunteers, our study gains a nuanced understanding of the questionnaire's reception within distinct demographic strata. The invaluable insights derived from these discussions contribute substantially to the ongoing refinement and optimization of the questionnaire, affirming its adaptability and efficacy across diverse societal segments. This final phase, therefore, stands as an indispensable cornerstone in affirming the overall success and robustness of our research endeavor.

Comment: The volunteers were stratified into three subgroups based on their education level: 1) higher-high schooler, 2) high schooler, and 3) below-high schooler.

Design Questionnaire

The 6-Cancer Risk Assessment Questionnaire (CRAQ-6) that the author has designed, developed and improved is divided into 8 parts.

Part 1: Informed Consent Document for Participation in a Research Project (Cover Page): Definitions; A direct relative encompasses family members linked by blood, such as parents, siblings with the same parents, and children, while direct exposure to secondhand smoke involves being near people who smoke due to socializing, living together, or working alongside them.

Part 2: General Information: Please provide the person's assigned sex at birth, their birth year in the Buddhist Era, any chronic diseases, history of cancer, tobacco use including smoking or other products, average years smoked, daily cigarette consumption, current smoking status, and alcohol consumption history.

Part 3: Liver Cancer / Hepatocellular Carcinoma: Has the person experienced any past instances of liver damage, whether it be from alcohol, hepatitis viruses, fatty liver disease, excess iron in the liver, or exposure to toxins like aflatoxins, as well as any history of hepatitis B and/or C infections, even if they occurred during childhood or birth and have since resolved?

Part 4: Colorectal Cancer: Does the person's family have a history of close relatives with colorectal cancer, polyps in the colon, hereditary colorectal cancer like Familial

Adenomatous Polyposis (FAP) or Hereditary Non-polyposis Colon Cancer (Lynch syndrome), or chronic inflammatory bowel disease? Additionally, has the person experienced abnormal bowel movements persisting for four weeks, including smaller stool size, less frequent bowel movements, alternating constipation and diarrhea, or presence of mucus or blood in the stool?

Part 5: Lung Cancer: Has the individual ever undergone radiation therapy to the chest area, been exposed to substances through their work, and been diagnosed with pulmonary fibrosis, historical tuberculosis of the lung, or COPD? Additionally, do they have direct relatives with a history of lung cancer?

Part 6: Breast Cancer: Is the individual associated with any of the following conditions or scenarios: having close family members diagnosed with breast cancer before age 45; having at least three family members, including themselves, with a history of breast cancer; having male relatives diagnosed with breast cancer; having a direct relative with cancer in both breasts; having family members with breast, prostate, ovarian, or pancreatic cancer, totaling a specified number; having family members with high-risk types of ovarian, pancreatic, or prostate cancer; having family members with Triple Negative Breast Cancer; being diagnosed with Lobular Breast Cancer and having family members with Diffuse Gastric Cancer; having no mentioned family history; being tested for the BRCA1/BRCA2 mutation; having any direct relatives tested for the BRCA1/BRCA2 mutation; being diagnosed with breast cancer, including non-invasive forms; undergoing chest radiation therapy before age 30; having a breast lump biopsy or surgery (multiple biopsies on the same lump counted once); regularly taking hormone replacement therapy for menopause for over five years; and selecting applicable menstrual history, such as never experiencing milk production after pregnancy or childbirth and noticing abnormal bleeding or discharge from the nipple.

Part 7: Cervical Cancer: Has the person engaged in sexual activity before turning 18, regardless of condom use? Have they had more than one sexual partner? Did they give birth vaginally, including miscarriages, but excluding cesarean sections? Have they taken contraceptive pills for 5 years or longer? Have they undergone hormone replacement therapy during menopause, whether prescribed by a doctor or self-administered? Have they contracted sexually transmitted infections like HIV/AIDS or gonorrhea? Do they have a history of being immunocompromised? Have they been infected with Human Papillomavirus (HPV) or been tested for it? Have they received an HPV vaccine for cervical cancer prevention?

Part 8: Prostate Cancer: Has anyone in the individual's family experienced prostate cancer or enlargement? Has the individual himself undergone prostate examination, PSA testing, or surgery? Additionally, does the family history include breast, ovarian, uterine, colorectal cancers, or the presence of the BRCA-2 gene?

Ethics

This article underwent submission to the Ethical Committee at an exemption level, as it was determined that the study poses no clinical effects or risks to the volunteers. The ethical number is REC003/2566

Results

In this medical article, we present cancer risk information categorized by specific cancer types, each associated with relevant references. The references for each cancer type are as follows: Breast Cancer [6-12]

Liver Cancer (Hepatocellular Carcinoma)[13-17], Lung Cancer [18-23] , Cervical Cancer [24-26], Colorectal Cancer [27-30] , Prostate Cancer 31-38.

By associating each cancer type with its respective references, we aim to provide a clear and organized framework for readers to access and explore the relevant literature supporting the presented information.

The successful evolution of the CRAQ-6 Questionnaire stands as a testament to the meticulous application of standard scientific tool development methodologies. This process involved a rigorous adherence to established principles, ensuring the questionnaire's robustness and efficacy in capturing relevant information. As a result, the questionnaire emerged as a well-crafted instrument that holds considerable promise for its intended purpose in the realm of medical research.

A noteworthy achievement of the CRAQ-6 lies in its commendable level of understandability, a critical attribute for any assessment tool. Volunteers participating in the study exhibited a consistent and high level of comprehension across diverse educational backgrounds. This universal applicability underscores the questionnaire's potential utility in a broad demographic spectrum, ensuring inclusivity and accessibility in research endeavors.

However, in the pursuit of optimal comprehension, certain sections or contents within the questionnaire presented nuances that warranted the involvement of another reader. This consideration arises not as a flaw but as a strategic acknowledgment of the diverse literacy levels and potential challenges faced by participants. By recognizing the need for additional support in specific areas, the questionnaire aims to enhance its effectiveness and inclusivity, accommodating individuals who may benefit from supplementary assistance.

This collaborative approach, where certain sections may require the input of another reader, contributes to the questionnaire's versatility. It positions the tool as a dynamic and adaptive instrument that can cater to a wider audience, fostering a more inclusive research environment. Additionally, this nuanced approach aligns with the principles of participant-centered research, ensuring that the research

instrument is sensitive to the unique needs and capacities of its user base.

In summary, the successful development of the CRAQ-6 Questionnaire not only attests to the adherence to rigorous scientific standards but also highlights its potential for broad applicability. While its overall understandability is commendable, the recognition of specific sections requiring additional reader support reflects a thoughtful consideration for diverse participant needs. This strategic refinement contributes to the ongoing evolution of the questionnaire, positioning it as a versatile and participant-sensitive tool in the realm of medical research.

Discussion

The impact of a cancer diagnosis extends far beyond the individual directly affected; it permeates through various dimensions, leaving an indelible mark on physical, mental, socioeconomic, and spiritual aspects. This reverberation is not confined to the diagnosed person alone but casts its influence across their familial network, touching the lives of family members, relatives, friends, spouses, and children. Within the realm of cancer, the significance of the age-old wisdom encapsulated in phrases such as "prevention is better than cure," "early detection and early treatment bring better outcomes," and "screening before it's too late" cannot be overstated.

However, in the context of a developing country like Thailand, the accessibility of medical services, particularly cancer screening, poses a considerable challenge, especially in rural areas. This limitation frequently results in delayed diagnoses, allowing the disease to progress and complications to set in. This, in turn, amplifies the complexity of treatment and prolongs the duration required for intervention.

In response to these challenges, the advent of early screening, facilitated by user-friendly, easily accessible self-evaluation risk assessment questionnaires, emerges as a powerful and transformative tool. These innovative tools transcend traditional healthcare settings, enabling individuals to engage in proactive screening anywhere and at any time, unencumbered by the constraints of hospital environments or the necessity for healthcare provider services.

The strategic combination of a systematic review process and the development of scientifically standardized questionnaires enhances the efficacy of early screening initiatives. By ensuring higher sensitivity in the screening process, these measures empower individuals at risk to recognize and interpret early signs and symptoms associated with cancer risk. Such proactive awareness prompts individuals to seek medical attention at an earlier stage, facilitating a timelier initiation of the gold standard cancer screening process. Moreover, the provision of comprehensive risk information through these questionnaires equips physicians with valuable insights into a patient's history of risk and symptoms. This, in turn, augments the diagnostic process, allowing healthcare professionals to tailor screening approaches based on an individual's unique risk profile.

In essence, the integration of early screening initiatives, supported by innovative risk assessment tools, not only addresses the challenges posed by limited access to medical services in developing countries but also lays the foundation for a paradigm shift towards more proactive and personalized approaches in cancer care.

In summarizing the utilization of the CRAQ-6 tool, it's essential to emphasize the absence of specific cut points for risk scores in individual cancers. However, certain questions within the breast cancer section may correlate with varying levels of risk, specifically aligning with criteria for BRCA1/2 testing. Any affirmative response to questions in any cancer screening section may signify a potential risk enhancer or raise suspicion of symptoms requiring consultation with a local physician for a comprehensive medical examination. This is crucial for a gold standard investigation to differentially diagnose symptoms and utilize basic cancer screening tools before considering referral to a higher level of care for advanced investigations, as indicated by standard clinical practice guidelines.

Conclusion

The self-evaluation Cancer Risk-based questionnaire, inspired by the acronym CRAQ-6 derived from "Crack" and "Sick," has been successfully developed. Being diagnosed as a cancer patient entails an emotional crack, and the treatment process may introduce physical complications, akin to a physical crack linked to sickness. Achieving early diagnosis through self-evaluation, facilitated by the systematic development of a risk-based questionnaire, is a crucial factor in enhancing sensitivity. This approach also plays a pivotal role in enrolling individuals at risk into the healthcare system, ensuring they receive gold standard screening. Furthermore, it allows for the minimization of risk by addressing modifiable factors, thereby reducing the likelihood of cancer development.

In the context of the Thai healthcare system, it's important to note that while the CRAQ-6 tool serves as a valuable self-screening mechanism, the physician's expert opinion holds precedence. Following a thorough cancer screening evaluation for each patient, the physician's judgment can override the risk assessment provided by this questionnaire. Subsequently, the healthcare provider will recommend and schedule the next appropriate cancer screening appointment for the individual, ensuring a personalized and comprehensive approach to healthcare.

Recommendations

1. The questionnaire ought to undergo periodic revisions to ensure its alignment with the latest advancements in clinical practice guidelines and the evolving body of knowledge within the medical community.
2. Consideration should be given to adjusting the questionnaire through a risk-based assessment tailored to other countries. This adjustment aims to enhance the precision and sensitivity of the self-evaluation screening questionnaire.
3. Future endeavors should focus on developing screening questionnaires for other cancers, particularly those with a rapidly increasing prevalence. This proactive approach will contribute to the ongoing evolution of comprehensive cancer screening tools.
4. It is imperative for governmental entities to play a pivotal role in championing the utilization and development of this tool. Establishing dedicated support from government sectors ensures the expansion and ongoing refinement of the tool, fostering sustainability in early cancer screening. Furthermore, efforts should be directed towards making consultation services readily available and facilitating the registration for gold standard cancer screening tests through medical benefit schemes.
5. This questionnaire should be made freely available to the public, with the option to be accessible online, enhancing its effectiveness in screening and facilitating the enrollment of individuals with potential health risks into the healthcare system. If any modifications are deemed necessary, we encourage you to reach out to the investigator team. You are welcome to revise specific contents as needed to suit your particular setting appropriately.

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