Generating a decision support tool to aid early detection of pancreatic disease: A Delphi study

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study which aims to develop a tool to aid in the early detection of diseases of the pancreas. Although many symptoms are associated with pancreatic diseases, such as pancreatic cancer and chronic pancreatitis, most are non-specific and may also be indicators of other conditions. Deciding who should undergo testing to diagnose pancreatic conditions and which tests should be used is thus challenging in primary care. Consequently, patients might experience incorrect or delayed diagnosis, or have undiagnosed disease. This may be at least partly due to a lack of clear guidance in terms of criteria for identifying patients at high risk of pancreatic disease. A number of guidelines exist, including from the National Institute for Health and Care Excellence (NICE), the American Pancreatic Association, the United European Gastroenterology group, and the Australasian Pancreatic Club. Despite this, most guidelines stop short of providing clear guidance. We aim to develop an easily accessible decision support tool for pancreatic disease diagnosis by combining and weighting multiple risk factors and symptoms.

You have been invited to participate in this study because you are a primary care clinician who is likely to see patients with symptoms that are possibly related to pancreatic disease, or a specialist involved with the diagnosis and treatment of pancreatic disease. By participating in the study, you will provide your expert opinion about the symptoms and risk factors that should be included in a decision support tool for pancreatic disease.

We have completed a comprehensive review of the literature to identify risk factors and symptoms associated with pancreatic cancer, chronic pancreatitis, and pancreatic exocrine insufficiency. We are using this evidence to guide a “Delphi process” to harness expert opinion about items that should be included in a decision support tool. The Delphi process involves a series of 2-3 online surveys, followed by a face-to-face meeting of sub-group of participants to finalise the tool. Further details about the process are included in section 3.

When we have completed the study, we will use the information to develop a tool for implementation into primary care practice. We will also publish the results in a peer-reviewed journal.

Your responses to the survey questions will remain confidential. Results from the survey will be aggregated for each question. Results may be stratified by clinician experience, country/state, or primary care provider versus specialist, but we will ensure anonymity of respondents in these results.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read the content and ask questions about anything that you don’t understand or want to know more about.

Participation in the study is voluntary.

By completing the survey you are telling us that you:

✔ Understand what you have read.
✔ Agree to take part in the research study as outlined below.
Agree to the use of your personal information as described.

(2) **Who is conducting the study?**

The study is being carried out by the following researchers and clinicians:

**Chief Investigators**
- Professor Rachel Neale, Group Leader, QIMR Berghofer Medical Research Institute
- Dr Stephen Philcox, Gastroenterologist, John Hunter Hospital

**Working Group**
- Mr Daniel Coagh, Hepatobiliary Surgeon, Monash University
- A/Prof Andrew Metz, Gastroenterologist, Royal Melbourne Hospital
- Professor John Windsor, General and Laparoscopic Surgeon, University of Auckland
- A/Prof Benedict Devereaux, Gastroenterologist, Royal Brisbane and Women’s Hospital

**Project Manager**
- Dr Bridie Thompson, Project Manager, QIMR Berghofer Medical Research Institute

(3) **What will the study involve for me?**

You will be asked to complete two to three online surveys.

In the first round, you will be provided with a list of symptoms and risk factors. We will ask you to score each of these in terms of importance to be included in a decision support tool for pancreatic disease.

In the second and third surveys, you will receive a summary of responses, and a revised series of questions formulated based on the results of the previous survey. The questions will be in the same format, asking you to rate symptoms and risk factors, or combinations of these, according to their importance for inclusion in a decision support tool. The third survey may not be required if there is high consensus in the second survey.

We will ask for information specific to your clinical experience, the state/provincial district in which you practice and whether you hold a public hospital appointment. Your name and contact details are solely for the purpose of contacting you for the follow-up survey/s and these will be stored separately to the survey response data.

The first survey will be completed by in December 2019. We will send you the second survey around February 2020 and a third survey (if required) in April 2020.

In order to allow timely conclusion of the study we would respectfully request your response within 2 weeks for each survey.

(4) **How much of my time will the study take?**

Each survey will take approximately 15 minutes to complete.

(5) **Do I have to be in the study? Can I withdraw from the study once I've started?**

Participation in this study is completely voluntary and you do not have to take part.
Submitting your completed survey is an indication of your consent to participate in the study. You can withdraw your participation any time without giving a reason before you have submitted the survey. You can also request that your contact details be removed from our database. Please note that de-identified data already collected until the withdrawal point will be retained to ensure data integrity for this study. Please contact the project manager (please see section 9 for contact details) if you wish to withdraw from participation.

(6) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

(7) Are there any benefits associated with being in the study?

We cannot guarantee that you will receive any direct benefits from being in the study. Participants of the study will be acknowledged in any peer-reviewed publications, documentation or literature resulting from the study. See the Publication Policy for more details [https://www.qimrberghofer.edu.au/wp-content/uploads/Publication_policy_V1.0.pdf](https://www.qimrberghofer.edu.au/wp-content/uploads/Publication_policy_V1.0.pdf).

(8) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement.

The online surveys will be administered using Qualtrics. Your responses will be stored on the Qualtrics data storage systems that meet the best security practices for access control, cryptography and network security. Only study researchers will be access your survey responses. Once accessed from Qualtrics, the information collected about you during this study will be stored on the secure network at QIMR Berghofer Medical Research Institute and your identity/information will be kept strictly confidential, except as required by law. Only members of the research team will have access to this information.

Your name and contact information will be removed from your survey responses and a unique identifier corresponding to your contact details will be allocated. Your survey responses will therefore be re-identifiable to research staff. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future projects. Your survey responses will de-identified and stored for future use. We will retain your contact information in a separate database. Access to all data (survey and contact details will be restricted to the study group). By providing your consent you are allowing us to use your information in future projects. We don’t know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects.
(9) **Can I tell other people about the study?**

Yes, you are welcome to tell other people about the study. Please ask them to contact the Project Manager on the details below, if they wish to participate in the study.

Project Manager: Bridie Thompson  
bridie.thompson@qimrberghofer.edu.au  
+61 7 3362 0296

(10) **What if I would like further information about the study?**

Please contact the Project Manager, Bridie Thompson, on the contact details above.

(11) **Will I be told the results of the study?**

We will share the overall results of the study in a summary report to the Australasian Pancreatic Club and Royal Australian College of General Practitioners. This summary will be provided after the study has been completed.

(12) **What if I have a complaint or any concerns about the study?**

The ethical aspects of this study have been approved by the HREC of QIMR Berghofer Medical Research Institute (P3503). As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*. This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the reviewing HREC using the details outlined below. Please quote the study title and protocol number.

<table>
<thead>
<tr>
<th>Reviewing HREC name</th>
<th>QIMR Berghofer HREC</th>
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</thead>
<tbody>
<tr>
<td>Telephone</td>
<td>07 3362 0117</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:HREC.Secretariat@qimrberghofer.edu.au">HREC.Secretariat@qimrberghofer.edu.au</a></td>
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This information statement is for you to keep
Declaration by Participant

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project.
- I understand that I will be able to save an electronic copy of this document to keep.
- I understand that this research may have some commercial potential in the future, and that my questionnaire will be stored and may be considered for use in future research that may or may not be related to this research project. I understand that use of this kind can only be undertaken subject to separate review by the Human Research Ethics Committee.
- I understand all information gathered during this research project will be treated in a strictly confidential manner in accordance with the National Health and Medical Research Council (NHMRC) Guidelines and the Commonwealth Privacy Act.

Agree and continue to survey [Date and time automatically recorded]