Participant information sheet

To gain wound care practitioner consensus on the clinical signs, symptoms and/or biomarkers likely to indicate presence of biofilm in chronic wounds: an electronic Delphi study.

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Introduction

There are clinical signs and symptoms reported in the literature as being indicative of biofilm in chronic wounds, but none have been scientifically proven, and clinicians are currently advised to assume that all non-progressing chronic wounds have biofilm present. We suspect however that this assumption may result in overuse of antimicrobial agents without necessarily improving patient outcomes.

We have carried out a comprehensive scoping review of the literature and derived a list of signs and symptoms thought to be indicators of biofilm presence in chronic wounds.

We would like to invite you to participate in an electronic Delphi process that aims to gain consensus from a group of internationally based wound care clinicians on which of a series of signs and symptoms selected from this list are most likely to be indicators of biofilm in chronic wounds.

We would advocate that you take at least 24 hours to consider whether or not you would like to participate in this study.

Procedures

Participation is expected to require 15 – 20 minutes of your time for each round of the survey. You have the right to decline to offer any information asked by this survey should you so wish.

Round 1:
Following a series of eligibility/consent questions you will be asked to provide demographic information i.e., years of experience, country of practice, specialty (nursing, medicine, podiatry etc.), practice area (general practice, gerontology etc.) and setting.

You will then be presented with a list of 26 items reported in the literature as being indicative of biofilm presence in chronic wounds. You will be asked to rate each item along a 9-point Likert scale (1-3 = not likely to be indicative of biofilm in chronic wounds, 4-6 = somewhat likely to be indicative of biofilm in chronic wounds & 7-9 = very likely to be indicative of

biofilm in chronic wounds). You will be asked to provide a brief justification for your score in a text box associated with each item, but this step is optional. This anonymous information will be provided as feedback to all participants between rounds. The duration of this round will be approximately 21 days. You will receive a single reminder to complete email from the gatekeeper of your organisation 1 week from receiving this invitation.

Round 2:
Within 6 weeks of completing round 1 you will receive an email from the study investigators containing a link to round 2 of the survey in which you will be provided with aggregated feedback and a summary of the data analysis from round one, and you will be asked to rate items from that round deemed to have no consensus along the same 9-point Likert scale as outlined above. This round will not have an open question for each item, and you will not be asked to provide feedback regarding your score.
You will receive a single reminder to complete email from the study investigators 1 week after receiving the link.
The duration of this round will be 21 days maximum.

Benefits

There are no direct benefits from participating in this study. However, its findings will contribute toward determining if an appropriate diagnostic tool for determining presence of biofilm in chronic wounds at the bedside can be developed. Such a tool would be of significant, direct benefit to wound care clinicians.

Confidentiality

Confidentiality of information cannot be absolutely guaranteed by the research team and can only be protected within the limits of the law.

Because this is a two-round Delphi study, it will be necessary to record your email address in round 1 for the purpose of sending a link to round 2 of the survey and a single reminder to complete email. All email correspondence will be blind carbon copied. Email addresses will only be used for the purposes described above and will not be shared with any other entities in any location. We do not intend to follow up with you at any time in the future regarding this current project or any future research.

Your survey responses will be kept confidential and identifiable information will not be directly linked to individual responses at any time during or after the study. The QuestionPro platform upon which the questionnaire and survey data will be held is firewall protected and data will only be accessed by allocated researchers who must provide usernames and passwords. All data will be analysed per group rather than per individual case. Physical documents (if any) will not have associated identifiers and will be stored in a locked cabinet with access strictly restricted to the allocated researchers. Printed documentation will be shredded immediately

after use. Apart from web-stored data (see above), all computerised data/information will be stored on a password protected hard drive in a locked office with restricted access.

Risks

There are no risks anticipated from participating in this study. Participants will not meet face-to-face at any stage during the process and will be anonymous to each other and to all members of the research team except the project coordinator. All confidentiality procedures will be strictly adhered to as outlined above.

Voluntary participation

Participation in this research is entirely voluntary. You may withdraw from this study without penalty at any point and you will not be required to complete both rounds of the survey if you do not wish to. Participating in or withdrawing from this study will not impact your relationship with your current organisation/employer. You may request to have your data deleted from the study up until the point of its aggregation with all study data for processing and analysis.

Permission to participate.

This study has received ethical approval from the University of Galway Research Ethics Committee. Queries about the study or procedures can be directed to the email address listed in the contact details below.

We would like to thank you for providing us with your time and support. If you volunteer to participate in this study, clicking on the link provided in the invitation email will take you to a series of yes/no questions that will determine your eligibility and ask if you are willing to consent to participate. If you answer 'no' to any of these questions you will receive a message of thanks and will not be able to proceed any further.

You may withdraw any time without penalty or waiving of any legal rights. You may also request to have any data that you input into the study withdrawn up until the point of its aggregation with all study data for processing and analysis without penalty or waiving of any legal rights.

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Contact details

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Please feel free to contact Mr. Ivory for any questions you may have about this study.