Signs, symptoms and/or biomarkers reported to indicate biofilm in chronic wounds: an eDelphi consensus protocol

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ABSTRACT

Background Chronic wounds secondary to conditions, including venous insufficiency, diabetes or unrelieved friction/shear, are a significant burden to patients and healthcare systems. Biofilms are estimated to occupy 60–78% of these wounds. However, they are difficult to detect macroscopically and have no definitive clinical markers. Clinicians are thus advised to assume biofilm presence in all stalled wounds. Incorrect diagnosis of biofilm presence may result in sub-optimal care provision and inadvertent, inappropriate administration of medical interventions.

Hypothesis/aim To achieve clinical consensus on which signs, symptoms and/or biomarkers (items) currently reported in the literature are most likely to indicate presence of biofilm in chronic wounds.

Methods design, sample, data collection, data analysis An international steering committee of researchers and wound clinicians convened to develop this protocol for a 2-round electronic Delphi process that will recruit ≥30 active clinicians with ≥3 years' clinical experience, ≥50% of which must be in wound care. Participants will rate items on a 9-point Likert scale. Consensus to include items requires ≥70% of participants rating 7–9 and ≤15% rating 1–3.

Conclusions The integrity of research findings depends on methodological rigour. Concerns exist regarding the consistency of methods in Delphi studies. Given these concerns, we decided that a review of Delphi methodological dilemmas by a group of experienced clinicians and researchers would be the most appropriate means to optimise the methods for this particular project.

Implications for clinical practice Findings will consolidate current clinical opinion on what signifies biofilm in chronic wounds. Delphi methodology should be standardised to develop its rigour.

Keywords chronic wounds, biofilm, signs, symptoms, eDelphi, consensus

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KEY MESSAGES

- Biofilms, capable of delaying healing and thought to be present in 60–78% of chronic wounds, are difficult to detect macroscopically.
- This protocol describes an eDelphi process that aims to gain clinical consensus on which signs, symptoms and/or biomarkers currently reported in the literature are most likely to indicate presence of biofilm in chronic wounds.
- Uniformity and standardisation of Delphi methodology would improve validity and credibility of findings.

INTRODUCTION

Biofilms are groupings of microbial cells that enclose themselves in a matrix of polysaccharide material and adhere to surfaces such as indwelling medical devices, water system piping or living tissue[1–3]. Indeed, it is assumed that 99.9% of the total microbial biomass on earth exists in the biofilm phenotype[2].

Chronic wounds are vulnerable to occupation by multiple microbial species presenting in the biofilm phenotype; its prevalence in these wounds is estimated to range from

60–78% and the consensus is that pathogenic biofilm types contribute to delayed healing[4–6]. These pathogens may halt the wound in the inflammatory phase, impair granulation tissue formation, and reduce epithelialisation[4,6].

Biofilms can be challenging to detect in a wound at the macroscopic level. There are some features on the wound surface such as extensive fibrinous slough, visible to the naked eye, that may be mistaken for biofilm. Additionally, it has been reported that biofilms may not present uniformly across the wound bed and may also be located below the wound surface, although evidence to support this hypothesis is limited[5,7–10]. Erroneously diagnosing biofilm may lead to suboptimal provision of care[5]. Currently, there are no clinical markers that can definitively indicate the presence of biofilm on biotic surfaces and clinicians are advised to assume that all chronic wounds demonstrating delayed healing have biofilm present[5,11]. We suspect that this may result in unintentional misuse of antimicrobial agents, adding more cost and increased risk of developing multi-drug resistant bacterial strains without necessarily improving patient outcomes.

The Delphi technique is a structured consensus method originally developed by the Rand Corporation in the 1950s that is commonly applied in areas such as education, environmental science, management and healthcare for the purposes of priority determination, problem solving or ideas generation[12–14]. It has been defined in one instance as "an iterative process designed to combine expert opinion into group consensus"[15] and it permits large numbers of individuals across a wide range of expertise and settings to be included in an anonymous fashion. The technique helps to reduce negative effects of group interactions such as dominance by one or more individuals[15–18]. Consenting participants or panel members engage in multiple rounds of a questionnaire and receive feedback after the closing of each round. This feedback can constitute information in terms of descriptive statistics on how questions were answered by individual participants and/or by the panel, and facilitates reconsideration of opinions by participants in light of the whole group[14–19]. Typically, the process continues until group consensus is reached[15].

This paper reports a protocol for an eDelphi method to gain consensus from an international sample of experienced wound care clinicians/clinician–researchers on which clinical signs, symptoms and/or biomarkers (defined characteristics that are measured as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention[20]) that can be measured at the bedside and are currently reported in the literature are the most likely to indicate presence of biofilm in chronic wounds.

METHODS

An international steering committee comprised of nine experienced wound care clinicians and researchers convened to finalise the methodology for this project.

We took eleven areas of Delphi methodology reported in *The COMET handbook: version 1*[12] and used them to structure the agenda for this exercise. These areas are: 1) Number of panels; 2) Group size; 3) Participant information; 4) Number of rounds; 5) Questionnaire structure; 6) Scoring methods; 7) Between-round feedback; 8) Criteria for outcome retention; 9) Attrition; 10) Definition of consensus; 11) Means for assessing consensus.

Sample size

We wish to recruit ≥30 clinical personnel actively engaged in wound care practice, including nursing, podiatry and medicine, to form a single participant panel for the eDelphi process[21,22]. We will incorporate a snowballing sampling technique into the recruitment process, meaning that we cannot predict a final sample size at this point[21]. Sample size for a Delphi exercise is not decided on the basis of statistical power and it can vary considerably between projects with, for example, anywhere between 12 and >300 participants recruited. Deciding on the number of participants to recruit can often be a matter of practicality[12].

Finalising the sample size and choosing a minimum rather than a maximum number was achieved through discussion between steering committee members that centred around factors of representativeness, best estimate of external validity, attrition, participant appropriateness and practicality, in conjunction with our mixed recruitment strategy (see below).

Eligibility

We will include adults (≥18 years old) based on their involvement and experience in wound care clinical practice or wound care research in conjunction with clinical practice[23].

Participants may be from any geographical region worldwide and must possess ≥3 years; clinical experience, ≥50% of which has been spent in a wound care environment. Participants must be experienced and proficient in assessing wounds in accordance with guidance such as the wound bed preparation paradigm[24] and have at least basic, self-declared microbiological knowledge of biofilm development, management and control in the wound care context. Eligible participants may or may not have published on the topic of biofilm in chronic wounds.

In round one of this exercise we will capture the following demographic data from consenting participants – gender, age, country of practice, specialty (e.g. nursing, medicine, podiatry etc.), practice area (e.g. primary care, gerontology, etc.) years of clinical wound care experience and number of relevant publications (if any)[23].

We considered four possibilities regarding appropriate participants for this process: a single participant group of biomedical researchers; a single participant group of clinical personnel; a mixed research/clinical participant group; or two separate clinical and research participant groups. This eDelphi work is concerned more with clinical experience and opinion than academic/laboratory expertise, yet it could also benefit from research input. The steering committee thus decided that the best way to balance both would be to choose clinically experienced participants who may or may not have research experience in this field.

Recruitment strategy

An invitation to participate email will be drafted. This email will contain a link to the online survey, contact details of the research lead and a participant information leaflet describing the nature and background of the study, expectations of participants and their rights, and a description of how data will be collected and managed[25].

We will identify a list of national and international organisations involving wound care clinicians and contact

their gatekeepers with a request to distribute the email invitation to members. We will then ask recipients of the invitation email to forward it to potentially eligible colleagues on their contact lists. We will also seek to recruit participants through our own Alliance for Research and Innovation in Wounds (ARIW) twitter account (@ariw_1) and via social media accounts of steering committee members.

Round one

We will create a questionnaire containing a randomised list of clinical signs and symptoms thought to be indicative of biofilm in chronic wounds (items) derived from a scoping review of the literature[26]. Participants will be asked to rate each item on the list along a 9-point Likert scale split into three domains of choice[12]:

- 1–3: Unlikely 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.

Finally, participants will be asked to provide a brief justification for their scores in a text box associated with each item. This will be an optional step and information provided will be included as part of the feedback presented to participants at the end of round one (see feedback between rounds below). This should contribute to the comprehensiveness of the feedback and may facilitate convergence of opinion on items presenting in round two.

The questionnaires will not have an open question option as this may introduce an excess of data managed differently from that which has passed through the scoping review process. Additionally, such questions may lead to an influx of unique items that are not encountered in clinic on a regular basis.

The duration of this round will be 21 days maximum[12].

Round two

Items with a 'no consensus' decision (see definition of consensus below) at the end of round one will be collated and participants will be asked to rate each item on the list on a 9-point Likert scale split into three domains of choice as reported for round one above[12].

This round will not have an open question option. Participants will not be asked to provide feedback describing the reasons for their decisions at the end of this round. Items with a clear 'excluded' decision will be discarded and items with clear 'included' or 'no consensus' decisions will be retained (see definition of consensus below).

The duration of this round will be 21 days maximum[12].

All items from rounds one and two designated 'include' and items from round two designated 'no consensus' (see definition of consensus below) will be collated into a list of potential signs and symptoms of biofilm in chronic wounds. This list will be subject to testing against clinical samples as part of a biofilm diagnostic project.

Definition of consensus

We will define consensus on each included item on the list as follows[25,27]:

- Include: ≥70% of participants rate item 7–9 and ≤15% rate item 1–3.
- Exclude: ≥70% of participants rate item 1–3 and ≤15% rate item 7–9.
- No consensus: any item not meeting the criteria above.

Only items with a 'no consensus' decision will be carried forward to round two of the process[28].

Feedback between rounds

At the end of round one an analysis of the ratings will be presented in tabular/graphical formats. This will include the group median (IQR) score and percent agreement among participants for each item. Any justifications provided by participants for scores will be summarised into brief statements and added to items intended for circulation in round two[12,25,28].

Assessment of consensus

Williamson et al recommend that researchers examine the degree of consensus in each round to ensure that the Delphi process is working as intended. They suggest examining changes in individual's scores between rounds[12].

We will assess consensus in this research by means of a Bland Altman analysis[29]. The Bland Altman method creates statistical limits of agreement using the mean and standard deviation of the differences between two measurements to quantify agreement between two methods of measurement. This is represented by a plot of the difference between paired measurements on the y-axis versus the mean of both measures on the x-axis. The method recommends that 95% of data points lie within ±2 standard deviations of the mean difference. Expected limits of agreement will be determined *a priori* and normality of distribution will be determined graphically. If differences are not distributed normally, appropriate transformation will be used to satisfy the normality assumption.

Strategy to maintain response rate

Attrition bias occurs when participants who do not respond in subsequent rounds have different views from peers who continue to participate. If feedback suggests that a participant is in the minority with respect to scoring of items, they may be more likely to drop out, with a resultant over-estimation of the degree of consensus in results[12].

A single group email will be sent midway through the 21-day response period of each round as a reminder to participants to complete their questionnaires.

Pilot exercise

This eDelphi exercise will be piloted by members of the steering committee who meet study eligibility criteria. The methodology may be revised after the pilot exercise[28].

Protocol deviations

Deviations from the protocol during execution of the eDelphi process will be documented in the final report with justifications.

Ethics

Ethical approval for this work will be sought from the University of Galway's College of Medicine, Nursing & Health Sciences (CMNHS) Research Ethics Committee (REC). Potential participants will be fully informed about the background and nature of the study, their rights, and expectations of them via

an invitation email. The first questions in the survey will ask if the potential participant is over 18 years of age, if they have read and understood the participant information leaflet, if they are willing to consent to participate and, if yes, to proceed to the next question. If the answer to any of these questions is no, they will receive a message of thanks and may not proceed any further.

Participants have the right to withdraw from the survey at any time without the expectation of an explanation, but once responses have been submitted to either round of the survey, those responses cannot not be withdrawn from the analysis since data will have been pooled anonymously. This will be outlined in the information leaflet. Contact details of participants will be retained by the study investigator only for the purpose of sending reminder emails to complete survey rounds if necessary. The study will be conducted in accordance with GDPR requirements.

DISCUSSION

This proposed eDelphi exercise comprises one phase of a project that will determine if a clinical signs, symptoms and/or biomarkers tool to predict presence of biofilm in chronic diabetic foot ulcers (DFU) can be developed.

The Delphi technique has been adopted by many healthcare fields and is often modified to the degree that a uniform method is used by few researchers[15,30,31]. This has been criticised as a threat to the validity and reliability of Delphi research findings, with an editorial commentary from 2021 proposing that strict adherence to methodology could result in lower agreement between participants and more acceptance of Delphi findings[15,32]. Furthermore, a systematic review from 2017 reported that "Clear recommendations on conduct of Delphi studies and a reporting standard for their publication in peer-reviewed journals to date are not available"[33].

Other authors also report issues with the Delphi process. Keeney et al wrote that "there are no universally agreed criteria for the selection of experts, and no guidance exists on the minimum or maximum number of experts on a panel; rather it appears to be related to common sense and practical logistics"[34]. Falzarano et al state that "The literature does not suggest a set percent agreement; however, many studies use 80%"[35]. Williamson et al write that "The issue of the impact of panel composition on Delphi performance has seldom been investigated in general"[12].

We convened a steering committee of nine internationally based wound care clinicians and researchers to apply collective knowledge and research experience to resolving Delphi methodological dilemmas and optimise the rigour of this project. The following is an illustration of our discussion and decision-making process for finalising the number and nature of panels to be included in our project.

In the context of core outcome sets, Williamson et al[12] argue that one homogenous participant group will produce outcomes relevant to one stakeholder group only. If heterogeneity is introduced into that group, there is a risk that resulting outcomes will reflect the relative proportion of stakeholders in the panel or on weightings that may be used for different groups. They advise a multiple participant-group approach comprising distinct stakeholder groups when differing stakeholder opinions are expected[12]. Our committee had to choose between recruiting a single participant group of biomedical researchers, a single participant group of clinicians, a single participant group of biomedical researchers and clinicians, or two separate clinical and biomedical research participant groups.

A series of arguments for each scenario were presented as follows: it was proposed that a single participant group of biomedical researchers would be familiar with the relevant literature and have a perspective that clinical personnel might not. The committee was then asked how immersion in relevant literature or research data might shape biomedical researcher perspective, for example, it is generally reported that biofilm in chronic wounds is difficult to visualise[5]. Finally, the committee was asked to consider the applicability of laboratory-based biofilm research knowledge involving *in vitro* and/or pre-clinical (animal models) to the day-to-day clinical management of wounds involving biofilms.

In terms of recruiting a clinical participant group, it was presented that the outcome of this research is intended exclusively for clinical personnel. In addition, clinicians are grounded in a clinical environment, but biofilm research is quite a niche area and clinicians might not be up to date on relevant literature. Finally, given that the overall project hopes to minimise clinical error, the committee was asked whether clinical involvement at the eDelphi phase would align more with this objective than would biomedical researcher involvement.

Regarding a single, mixed group of participating clinicians and biomedical researchers or two separate (by background) groups, it was proposed that both perspectives would be considered and that there would be potential for divergence between both due to differing perspectives.

Initially, the steering group split along a fault line of clinical vs. biomedical research perspectives and focused on whether a single clinical participant group or two separate clinical and biomedical research groups should be created.

Those in favour of a clinical group proposed that it can be difficult to apply academic/laboratory knowledge to a clinical context without relevant experience. Secondly, the research project of which this eDelphi exercise is a component pertains to clinical experience, and so the population should emphasise the clinical. Finally, the product of this research, if successful, will exclusively serve clinical personnel. Conversely, it was argued that while two separate biomedical research and clinical groups may result in divergence of opinion, all opinions matter and should be captured to reduce the risk of important information being omitted. The debate then evolved into a discussion on how researchers should be defined for the purpose of this project, and if perhaps they should be seen as clinical personnel who engage in research. However, clinicians who engage in biomedical research are a minority in the wound care community and so there is a risk of having too small a sample size.

Ultimately it was agreed that we recruit a group of participants populated predominantly by clinicians with experience in treating wounds but that we also be open to wound care clinicians with interest and experience in research. The committee unanimously agreed that this was the best course

of action to ensure that a participant group capable of meeting our research needs could be created.

Ambiguities within each of the 11 Delphi methodological areas reported by Williamson et al[12] were discussed by the steering committee in a similar fashion and finalised into the methodology reported herein.

CONCLUSION

Internal validity of research findings is contingent on the rigour within the methodology giving rise to those findings. A rigorous methodology reduces the risk of introducing bias into research through systematic error. Concerns have been expressed regarding uniformity of methodology across Delphi studies and the cost that this may bring in terms of reliability and validity of study findings. In light of these concerns, we finalised the process for this eDelphi protocol through review and discussion of methodological dilemmas as well as experiential contributions from clinicians and researchers, believing this to be the most prudent and balanced approach given the current state of the Delphi art.

We conclude as a group that the Delphi method would greatly benefit from in-depth review and quantitative examination to develop a more uniform, standardised and rigorous process.

IMPLICATIONS FOR CLINICAL PRACTICE OR FUTURE RESEARCH

- When completed, the findings of this work will help conceptualise current clinical opinion on what does or does not constitute a clinical sign, symptom and/or biomarker of biofilm in chronic wounds.
- There is potential to review and research the Delphi process to develop a more standardised, rigorous and uniform methodology.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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AUTHOR CONTRIBUTIONS

Conception and design: JDI, DS, PMC, CH, JVS, JPO, DG, GG. Data analysis and interpretation: JDI, DRS, JVS. Manuscript draft: JDI, GG. Critical revision of the manuscript: JDI, DS, PMC, DRS, CH, JVS, JPO, DG, GG. Final approval of the manuscript: JDI, DS, PMC, DRS, CH, JVS, JPO, DG, GG.

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