The development and feasibility testing of a community pharmacy-based guidelines for the assessment and management of acne vulgaris.

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THE DEVELOPMENT AND FEASIBILITY TESTING OF A COMMUNITY PHARMACY-BASED GUIDELINE FOR THE ASSESSMENT AND MANAGEMENT OF ACNE VULGARIS

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Executive Summary

The following describes a research study commissioned by Galderma to explore the development of guidelines for community pharmacists on how to assess and manage patients who present with acne.

Background

Acne vulargis (or simply acne) is an extremely common skin condition affecting up to 85% of teenagers and which, for a small proportion of individuals, can persist into adulthood. The majority of patients have mild to moderate disease which is amenable to treatment with topical acne therapies. Community pharmacies have been advocated as a first port of call for minor ailments, which includes skin conditions such as acne. While acne treatments are available over-the-counter, there is an array of different products available which can lead to confusion amongst patients and pharmacy team members. Furthermore, acne can be associated with psychosocial co-morbidities and lead to problems such as scarring hence the importance of a holistic assessment to ensure that patients are effectively managed and referred, where appropriate, to other healthcare providers.

There are currently no pharmacy-specific guidelines published in the public domain to support UK-based pharmacy teams in the assessment and management of those seeking advice and or treatment for acne. The purpose of the present study was, therefore, to develop and feasibility test such a guideline to help support pharmacy teams to appropriately assess and manage patients seeking advice on acne.

Method

The study was conducted in three separate phases: semi-structured interviews with consultant dermatologists; an online Delphi study; and, a quantitative evaluation. The semi-structured interviews were used to gather information for the development of the initial statements for the Delphi and the final phase was used to

evaluate, from the perspectives of community pharmacists and patients, the guideline developed from the Delphi.

Results

Interviews were conducted with five consultant dermatologists with an interest in acne. Emergent themes from these interviews were used, together with the literature, to develop the statements for the first round of the Delphi. A total of 49 statements were developed relating to patient consulation (7), clinical management (10), treatment (4), referral (9), lifestyle factors (16) and monitoring (3).

The Delphi was conducted for three rounds with 19 panellists representing an interprofessional mix of dermatologists, GPs with a special interest in dermatology, specialist dermatology nurses, community pharmacists with an interest in dermatology, and expert patients. The response rate was 79% (n=15/19) and stable for all three rounds.

Consensus level was set at 80% summative of strongly agree and agree. This was achieved for 21 out of the 49 statements, relating to: patient consultation (2/7) ; clinical management (4/10) ; treatment (1/4) ; referral (7/9) ; lifestyle factors (4/16) ; and, monitoring (3/3). In many instances, there was strong sense among panellists that assessment of acne was a role for the pharmacist rather than suitably qualified non-pharmacist staff.

The final guideline was evaluated in 9 community pharmacies on 35 patients seeking advice on acne. Though limited in size, the median rating for the helpfulness of the guideline was 4 out of 5 (interquartile range 4-4) which suggested that it potentially was of value to pharmacists.

Conclusion

The Delphi process, utilising an interprofessional expert group, was successfully used to create a novel pharmacy-specific guideline to support pharmacy teams when

dealing with patients seeking advice on acne. Although the guideline was piloted with a small number of pharmacies, it appeared to be of value though further work with a larger number of pharmacies and patients is required to more fully evaluate the usefulness and value of the tool.

INTRODUCTION

In the United Kingdom (UK), a number of potential new roles for community pharmacists were outlined such as in England in the 2008 White Paper, *Pharmacy in England*.[1] The White Paper also made clear that the Government was committed to increasing the number of medicines available for purchase through pharmacies to further strengthen pharmacists' clinical advisory role in helping to facilitate effective self-care.

One area in which pharmacists have a potentially important role is in supporting self-care in the management of skin problems. Although limited, the available literature highlights patient preference for self-care over medical care with regard to skin problems. For instance, one qualitative exploration of why patients with undiagnosed skin problems sought advice in pharmacies, identified that the accessibility of professional advice, the potential for triage to GP care and the perceived minor nature of the problem, were some of the factors leading to patients' choice of community pharmacy as the primary source of healthcare advice on their skin problem.[2]

Acne vulgaris is the eighth most prevalent disease worldwide with around 9.4% of the world's population affected.[3] Furthermore, one European study of over 10,500 individuals aged 15 to 24 year old demonstrated a prevalence of 57%.[4] Acne mostly occurs in adolescence, reportedly affecting 95 to 100% and 83 to 85% of 16 to 17 year old boys and girls respectively.[5] The condition is characterised by non-inflamed lesions (open and closed comedones) together with inflamed lesions (papules and pustules). In more severe cases, nodules and cysts, which represent more severe papules and pustules are also present. Acne severity is generally considered as either mild, moderate or severe and although there are no universally accepted grading systems, the Leeds Acne Grading Scale (which ranges from grade 1 (mild to moderate) to 8 (severe)) is often used to delineate disease severity.[6]

A further complication of acne is scarring. Precise figures are not widely available, however, one study in over 2000 Brazilian 18 year old males, observed a prevalence

of 22%.[7] In addition, acne is associated with considerable psychosocial impact: it has a negative effect on self-esteem,[8] can lead to suicidal ideation,[9] and may have an adverse effect on quality of life.[10] These potential long term consequences highlight the need for effective treatment and management.

Although the diagnosis of acne is relatively straightforward, due to its obvious presence, there is a wide array of over-the-counter (OTC) treatments available. As a consequence of their convenience and accessibility, community pharmacies are an ideal setting for acne patients to seek advice and treatment. Nevertheless, marketing surrounding OTC treatments and the social consequences of acne such, as embarrassment and shame, may result in patient demands or perceived preference which may influence the recommendations of pharmacy staff yet be inappropriate. Indeed, several studies in different settings have identified poor knowledge among sufferers with respect to the causes of acne and there is even some evidence that community pharmacists lack sufficient knowledge about the condition.[1-15]
Current European acne guidelines do not consider the role of community pharmacy teams or provide any information on the use of OTC topical acne treatments[16] yet a recent European survey of just over 3,000 individuals, aged 15 to 24, found that the most common source of acne treatment was an OTC product chosen with the help of a pharmacist.[17] Similarly, in a telephone survey of 1,566 young French people, aged between 12 and 25, 51% had not sought medical help for their acne but 10% had sought the advice of a pharmacist.[18] It is therefore important to ensure that pharmacists possess the necessary skills to assess and provide suitable management advice to those seeking treatment for acne.

One means of supporting pharmacy teams when dealing with patients seeking advice about acne is the development of community pharmacy-specific guidelines. This would offer an opportunity to more clearly define the position of both pharmacists and OTC treatments in the acne patient pathway to:

1. serve to improve the care of patients by enhancing the role of pharmacists in OTC management of acne or referral to other professionals

2. enable the development of standards for assessment of acne in clinical practice

Therefore, the purpose of the present study was to use the Delphi process to develop, and feasibility test, consensus-based guidelines for the community pharmacy-based management of patients presenting with acne vulgaris and to explore the value of the guideline with practicising community pharmacists.

Aim

To develop a guideline on community pharmacy assessment and management of acne vulgaris and to evaluate the usefulness of the guideline in practice.

Objectives

1. To utilise the expertise of consultant dermatologists to inform guideline development
2. To determine agreement amongst experts on the content of the guideline, specifically around:
    a. The severity of acne to be managed in community pharmacy
    b. The most appropriate management options for community pharmacy
    c. The criteria for referral of patients from community pharmacy to their GP
    d. The impact of various lifestyle factors on acne severity
3. To evaluate the usefulness of the guideline from the perspective of community pharmacists.

METHODS

Design

This study was a mixed methods design comprising three distinct phases: qualitative interviews; a consensus-based Delphi study and an evaluation of the developed guideline in practise.

Phase 1

Design

Semi structured interviews.

Setting

Secondary care consultant dermatologists, based in England, with an interest in the management of acne vulgaris.

Recruitment

Potential dermatologists were identified by a member of the research team with expertise in acne (AML). A total of five individuals were selected and approached to participate in the interviews.

Semi-structured telephone interviews were conducted with these five dermatologists by the same member of the research team (RT). This phase was primarily conducted to aid the development of the statements for the planned Delphi, hence data saturation was not a consideration. Interviewees were provided with full study information (Appendix A) and informed consent (Appendix B) was obtained by the researcher prior to conducting the telephone interview.
A topic guide for the interviews was developed and reviewed by members of the research team and piloted with one dermatologist, not included in the final analysis (see Appendix C). Questioning focused on pharmacists' assessment of acne, potential treatment options, criteria for referral to a GP and the impact of lifestyle factors on acne severity.

Analysis

Interviews were audio recorded, transcribed verbatim and analysed thematically using NVivo 11 software (QSR International) to facilitate data management.

Phase 2

Design

Consensus-based Delphi study.

There are three main consensus methods: nominal group technique[19], Delphi[20] and the consensus development conference.[21] The Delphi technique is appropriate for the development of guidelines or policies where there is limited evidence[22] and typically comprises a series of rounds whereby agreement between panel members is determined anonymously. The viewpoints of all panel members and consensus levels were fed back iteratively upon the conclusion of each round in an effort to refine statements towards further consensus. A six-point Likert scale was used for participants to rate levels of agreement with statements (strongly agree to strongly disagree). This scale was used to determine consensus and although different definitions of consensus have been reported in the literature, there is no agreement on the most appropriate level.[23] Given the lack of current guidance on the community pharmacy management of acne and the potential importance of such a guideline, a level of agreement was arbitrarily set at 80% (summative strongly agree and agree) for each of the statements.

Setting

The study was conducted online.

Statement development

The statements for the Delphi were developed based on information derived from the dermatologist interviews also the existing research and guideline literature . These were reviewed by members of the team for readability then 'think aloud' and

pilot tested with one dermatologist independent of the research team. The final version of the statements were uploaded in SurveyMonkey® and the study conducted online to facilitate effective communication.

Recruitment

Members of the research team contacted potential panel members, making use of professional networks to identify specialists with an interest in acne who in turn were able to identify expert patients. Ideally, the aim was to recruit a panel of 20; five doctors, five pharmacists, five nurses and five expert patients. All who were approached agreed to join the Delphi panel. Each panel member was sent, via email, a participant information sheet (Appendix D) detailing study specifics and a consent form. Panel members were asked to sign and initial the consent form (Appendix E) if they agreed to participate and return it to the research team.

Delphi rounds process

At the start of the process, each panel member was sent an email with a link to the online Delphi questionnaire. A two week deadline was set for panel members to rate their level of agreement with each statement. An open comments box was provided alongside each statement, allowing members to justify their responses, where they felt it necessary, and the opportunity to add any additional comments.

The second round included only those statements which had not achieved consensus in round one. Alongside each round two statement were the collated anonymous open comments provided by panel members from the first round . As with the first round, a two week deadline was set for completion and return of responses and the level to determine consensus maintained, 80% (summative of strongly agree and agree).

The third and final round proceeded as in the second round and, if no further consensus was achieved, the statements were deemed as non-agreement.

Panel members received a £50 fee for participation in each of the Delphi rounds up to a maximum of £150.

Analysis

Data collected after the initial round was exported from SurveyMonkey © into Microsoft Excel and then SPSS version 24 (IBM SPSS Statistics) for descriptive analysis (frequencies and percentages) to determine whether or not consensus had been achieved for each of the statements. A content analysis approach to the open text responses was agreed between two members of the research team, performed by one and sample checked for confirmation by the other member of the research team.[24]

Phase 3

Design

Quantitative evaluation.

Based on results of the Delphi study, the research team developed a guide on the assessment and management of patients who present with acne to be used in community pharmacy. One member of the team drafted the guideline and this was circulated to the others for review and modification. A copy of the final guideline can be found in Appendix F.

The final guideline consisted of a single page of statements that included only those for which consensus was achieved in the Delphi. The statements were categorized into “patient assessment”, “patient treatment”, “self-care” and “referral to the GP”. In an effort to help community pharmacy staff to recognise the level of acne severity that was appropriate for management in the community pharmacy, the guideline included (with permission) the first 4 images from the Leeds Acne Severity Scale.[1] The guideline specified that community pharmacy management was appropriate for only grades 1 to 3 and the fourth image served to help teams identify the level of disease severity that warranted GP referral.

Setting

Nine community pharmacies in the South West of the UK (Cornwall and Devon).

Recruitment

The clinical research network (CRN) circulated information on the study to community pharmacies within their database, asking for expressions of interest.

In order to provide some feedback on the value of the guideline, community pharmacists were asked to complete an evaluation form for each of the patients who they encountered seeking advice on acne. The form (see Appendix G) recorded the following information:

1. Patient demographics (i.e., gender, date of birth, years with acne)
2. Type of acne present (i.e. comedonal, inflammatory, mixed, extent)
3. Treatment provided by the community pharmacist
4. If referral to the GP was warranted, the reason for referral, i.e. evidence of scarring, psychosocial co-morbidities, multiple treatment failure, truncal acne
5. Community pharmacists were also asked to record how useful they had found the guideline when dealing with the patient, on a scale from 1 to 5, where 1 represented “not very helpful” and 5 “very helpful”

Analysis

Data from the evaluation forms were input to SPSS version 24 (IBM SPSS Statistics for Mac) for descriptive analysis (frequencies and percentages).

Governance approvals

The study was approved by the Ethical Review Panel at the School of Pharmacy & Life Sciences, Robert Gordon University, the Office for Research Ethics Committee Northern Ireland (ORECNI) and by the Health Research Authority (HRA).

RESULTS

Phase 1

All five dermatologists who were approached agreed to participate in the telephone interviews which lasted for approximately 25 minutes. The participating dermatologists had been qualified for between 20 and 29 years.

Analysis of the interview data generated several main themes and associated sub-themes which are given in Tables 1 to34.

Table 1. 'Patient assessment' as an area for inclusion plus details to include

Area	**Patient assessment**
Details	**Illustrative quotes and dermatologist identifier**
Use of a photographic assessment scale	*The pictures [on the Leeds scale] … are really helpful because you can get the patient to grade themselves (D1)* *If they [pharmacists] can get familiar with the Leeds scale, it's a visual scale, so you can have a look at the patient, have a look at the pictures that grade the acne and then make a guess-timate"(*MD4)
Types of lesions present	*They [pharmacists] ought to be able to distinguish between non-inflamed lesions, inflamed lesions and larger nodular lesions. Because if they're going to advise about treatments, they need to know whether [lesions] are mainly comedonal or inflammatory* (D2) *Spot count, so the number of papules and pustules you have* (D4)
Impact of the acne	*They [pharmacists] should be focusing on the psychological impact, impact on daily functioning* (D4) *Need to ask about the quality of life, how they feel about what's going on with their acne* (D5)
Extent of the disease	*[Assess] the areas of the body that are affected, so does it affect the chest, back and face* (D3)

Table 2. 'Over the counter treatment' as an area for inclusion plus details to include

Area	Over the counter treatment
Details	**Illustrative quotes**
Benzoyl peroxide (BPO)	*Benzoyl peroxide is a fantastic agent, it's under-utilized because of the irritancy and the bleaching effect but it's a very effective agent* (D3) *I tend to use it [BPO] for almost everybody … benzoyl peroxide would be something that is safe in pregnancy so that's an issue compared to other topical treatments.* (D4)
Salicylic acid	*There are some studies that have demonstrated that salicylic acid has some benefits in the comedonal lesions... if you've got very mild disease you might want to start off with salicylic acid* (D5) *Salicylic acid may be very good if they've [patients] got a lot of comedones, it can help unblock the comedones so if they've got bumps, sand paper acne, that sort of thing that might be helpful* (D2)
Nicotinamide	*It's certainly got a role if they've more inflammatory acne then that [nicotinamide]might be helpful* (D1) *I personally don't use it because I've not found it very useful* (D5)
Cosmetic acceptability	*It's about being something that's cosmetically acceptable to the patient, something that isn't going to sting, be actually sticky, something that's pleasant to use* (D3) *It [the vehicle] needs to be something that patients find that they can rub into their skin, that's pleasant to use that's not sticky…doesn't leave any kind of visible residue on the skin* (D4)
Duration of therapy	*If patients have responded by 6 to 8 weeks then they were going to respond to some degree, if they hadn't it was unlikely that they were going to respond to that agent* (D3)
Use of emollients	*They can use an emollient as well [as acne therapy] often at the opposite end of the day so I normally recommend a non-comedogenic moisturiser* (D4)

There was agreement among the five dermatologists that community pharmacists should refer patients with:

- Scarring
- Widespread or severe disease
- Treatment failure
- Psychosocial co-morbidity

Other factors mentioned included a family history of acne, early-onset (before the age of 12) disease and those with a high level of seborrhoea (very greasy skin).

Table 3. 'Lifestyle modification' as an area for inclusion plus details to include

Area	**Lifestyle modification**
Details	**Illustrative quotes**
Diet	*If you look at the strength of evidence they're moderate for glycaemic index and milk but they're low for other foodstuff so I think those are the two things we might advise them about* (D3) *There is some evidence that high carbohydrate diets [high glycaemic index diet], may have an effect on acne, it's not a very strong effect...and the same with dairy produce* (D1)
Smoking	*There may be some correlations between current comedonal acne in mature women with a history of smoking but otherwise we haven't found any clear correlation* (D3) *Smoking definitely makes acne worse. So I would ask about smoking and say it's a good idea to think about stopping or cutting down at least* (D5)
Stress	*There's been a lot of work looking at stress…my observation is that we definitely see young people who seem to get deteriorations around the times of exams, I think stress does play a part* (D3) *I think stress is an issue, emotional stress does play a factor in worsening [acne]*(D4)
Cosmetics	*We tend to go for oil-free, non-comedogenic properties and there are a lot of them about* (D3) *It's important to ensure that the make-up is some kind of non-oil based, non-greasy and women should avoid comedogenic make-ups* (D4)
Sunlight	*We know short term that ultraviolet light can help but long term that doesn't have an impact* (D3) *In terms of actually improving the acne, it [sunlight] can disguise acne to some extent but it's generally not advised because of the risk of skin cancer* (D1)
Sleep	*There is a couple of papers that have looked at that [sufficient sleep] but there's only a little bit [of evidence] for it* (D3)
Humid environments	*Saunas and steam rooms and facials are generally not great for acne* (D5) *If they're sweating a lot and humid environments and that sort of thing [is bad for acne*] (D2)

Phase 2

A series of 49 statements were developed for the first round based on information gathered from the dermatologist interviews in Phase 1. Statements were grouped into six categories: patient consultations (7 statements); clinical management (10 statements); treatment (4 statements); referral (9 statements); lifestyle modification (16 statements); and monitoring (3 statements).

Nineteen experts participated in the Delphi including: eight doctors (five consultant dermatologists; three dermatology specialist GPs); three pharmacists with an interest in dermatology; four dermatology specialist nurses; and four patients.

Participation across the three rounds is shown in Table 4 although one panelist (patient) did not respond to any of the rounds. Fifteen people from the total panel of nineteen participated in each of the three rounds of the Delphi (but not the same fifteen each time). The majority of respondents across round 1 were doctors (n=6) and each of the remaining rounds, nurses (n=4) and doctors (n=5).

Table 4. Delphi participant distribution across the three rounds

Delphi participants	Round 1 – n (%)	Round 2 – n (%)	Round 3 – n (%)
Patients	3 (20.0)	3 (20.0)	3 (20.0)
Nurses	4 (26.7)	4 (26.7)	4 (26.7)
Pharmacists	2 (13.3)	3 (20.0)	3 (20.0)
Doctors	6 (40.0)	5 (33.3)	5 (33.3)

As shown in Table 5, consensus (at least 80% summative of strongly agree and agree) was achieved for 21/49 statements.

Table 5. Delphi statements achieving consensus

Statements which achieved consensus	Strongly disagree (n)	Disagree (n)	Somewhat disagree (n)	Somewhat agree(n)	Agree (n)	Strongly agree (n)	% Consensus
Statements relating to patient consultations (2 out of 7)							
Acne consultations should be recorded on the pharmacy medication records (n=15, Round 2)	0	2	1	0	7	5	80.0
Pharmacists should consult with acne patients in a private consultation room (n=15, Round 2)	0	0	0	1	3	11	93.3
Statements relating to clinical management (4 out of 10)							
Pharmacists should assess the clinical severity of acne prior to managing with over-the-counter treatments (n=15, Round 1)	2	0	0	1	5	7	80.0
Pharmacists should only manage mild/moderate acne with over-the-counter treatments (n=15, Round 1)	2	1	0	0	2	10	80.0
Based on the pictorial guide, pharmacists should only manage mild/moderate acne (n=15, Round 1)	1	0	1	0	4	9	86.7
Pharmacists should assess the number and type of acne lesions prior to managing with over-the-counter treatments (n=15, Round 2)	0	1	1	1	3	9	80.0
Statements relating to referral (7 out of 9)							
Patients with evidence of scarring should be referred to a GP (n=15, Round 1)	0	1	1	0	4	9	86.7
Patients with psychological and social comorbidities (e.g. depression, anxiety or suicidal ideation) should be referred to a GP (n=15, Round 1)	0	0	0	0	2	13	100
Patients who have tried multiple over-the-counter treatments without success should be referred to a GP (n=15, Round 1)	0	0	1	1	5	8	86.7
Patients with moderate/severe acne should be referred to a GP (n=15, Round 1)	0	0	1	2	1	11	80.0
Patients with larger acne lesions (cysts or nodules) should be referred to a GP (n=15, Round 1)	0	0	1	1	2	11	86.7
Patients with early-onset acne (less than 12 years of age) should be referred to a GP (n=15, Round 2)	0	0	1	2	3	9	80.0
Patients with truncal acne should be referred to a GP (n=15, Round 2)	0	0	1	1	7	6	86.7

contd.

Table 5 (contd). Delphi statements achieving consensus

Statements which achieved consensus	Strongly disagree (n)	Disagree (n)	Somewhat disagree (n)	Somewhat agree(n)	Agree (n)	Strongly agree (n)	% Consensus
Statements relating to treatment (1 out of 4)							
Patients should be offered a choice of formulation (e.g. lotions, gels or creams) that they find cosmetically acceptable (n=15, Round 1)	0	0	0	2	4	9	86.7
Statements relating to advice (4 out of 16)							
Pharmacists should advise against the use of ultraviolet treatments (n=15, Round 1)	0	0	1	2	6	6	80.0
Suitably-trained non-pharmacist pharmacy staff should advise against the use of ultraviolet treatments (n=15, Round 1)	1	0	1	1	6	6	80.0
Pharmacists should advise acne patients to use oil-free, non-comedogenic (e.g. does not block pores) make-up products (n=15, Round 1)	0	1	0	2	4	8	80.0
Suitably-trained non-pharmacist pharmacy staff should advise acne patients to use oil-free, non-comedogenic (e.g. does not block pores) make-up products (n=15, Round 1)	1	0	0	1	4	9	86.7
Statements relating to monitoring (3 out of 3)							
Patients should be advised to continue with topical acne treatments for at least 6 weeks unless they experience severe adverse effects (n=15, Round 1)	1	1	0	1	2	10	80.0
Patients should be warned about the bleaching effects of benzoyl peroxide (e.g. bedding, clothing) (n=15, Round 1)	1	0	0	0	2	12	93.3
Patients with acne should be advised to use an oil-free, non-comedogenic emollient alongside their topical treatment (n=15, Round 3)	0	0	0	2	7	6	86.7

The statements for each area **not** achieving consensus are shown in Table 6.

Table 6. Statements not achieving consensus

Statements not achieving consensus (n=15, Round 3)	Strongly disagree (n)	Disagree (n)	Somewhat disagree (n)	Somewhat agree(n)	Agree (n)	Strongly agree (n)	% Consensus
Statements relating to patient consultations (5 out of 7)							
Suitably-trained non-pharmacist staff should consult with acne patients in a private consultation room	3	3	2	3	0	4	26.7
Pharmacists should assess the psychological and social impact of acne prior to managing it with over-the-counter treatments	1	2	1	2	2	7	60.0
Suitably-trained non-pharmacists should assess the psychological and social impact of acne prior to managing it with over-the-counter treatments	3	4	2	2	0	4	26.7
Pharmacists should assess the impact of a patients' acne on their quality of life prior to managing it with over-the-counter treatments	1	3	1	3	1	6	46.7
Suitably-trained non-pharmacists should assess the impact of a patients' acne on their quality of life prior to managing it with over-the-counter treatments	3	5	1	2	0	4	26.7
Statements relating to clinical management (6 out of 10)							
Suitable-trained non-pharmacist staff should assess the clinical severity of acne prior to managing with over-the-counter treatments	3	5	2	1	0	4	26.7
Suitable-trained non-pharmacist staff should assess the number and type of acne lesions prior to managing with over-the-counter treatments	4	5	1	1	0	4	26.7
Suitable-trained non-pharmacist staff should only manage mild/moderate acne with over-the-counter treatments	2	4	0	1	3	5	53.3
Pharmacists should use a pictorial guide to assess the severity of a patients' acne	0	0	0	4	4	7	73.3
Suitable-trained non-pharmacist staff should use a pictorial guide to assess the severity of a patients' acne	5	3	2	0	1	4	33.3
Based on the pictorial guide, suitable-trained non-pharmacist staff should only manage mild/moderate acne	3	5	0	2	1	4	33.3

contd.

Table 6 (contd). Statements not achieving consensus

Statements not achieving consensus (n=15, Round 3)	Strongly disagree (n)	Disagree (n)	Somewhat disagree (n)	Somewhat agree(n)	Agree (n)	Strongly agree (n)	% Consensus
Statements relating to referral (2 out of 9)							
Patients with a family history of acne should be referred to a GP	6	0	1	2	3	3	40.0
Patients with very greasy skin (seborrhoea) should be referred to a GP	1	1	4	2	6	1	46.7
Statements relating to treatment (3 out of 4)							
Benzoyl peroxide is a suitable first-choice treatments for all patients unless they have a known hypersensitivity to the drug	0	2	0	5	5	3	53.3
Nicotinamide can be used as a second-line treatment for patients who fail to respond adequately to benzoyl peroxide	1	9	1	0	3	1	26.7
Salicylic acid should be offered to those with very mild comedonal acne	0	8	0	4	1	2	20.0
Statements relating to advice (12 out of 16)							
Pharmacists should advise acne patients to adopt a healthy diet	0	5	1	2	3	4	46.7
Suitable-trained non-pharmacist staff should advise acne patients to adopt a healthy diet	3	4	0	1	4	3	46.7
Pharmacists should advise acne patients to avoid foods with a high glycaemic index (e.g. Biscuits, cakes, white bread)	2	3	1	3	3	3	40.0
Suitable trained non-pharmacist staff should advise acne patients to avoid foods with a high glycaemic index (e.g. Biscuits, cakes, white bread)	3	4	0	2	3	3	40.0
Pharmacists should advise acne patients to reduce or stop smoking	1	0	1	6	3	4	46.7
Suitable-trained non-pharmacist staff should advise acne patients to reduce or stop smoking	1	1	1	6	2	4	40.0
Pharmacists should advise acne patients to avoid saunas/steam rooms/facials	2	3	5	1	2	2	26.7
Suitable-trained non-pharmacist staff should advise acne patients to avoid saunas/steam rooms/facials	2	3	4	2	1	3	26.7

contd.

Table 6 (contd). Statements not achieving consensus

Statements not achieving consensus (n=15, Round 3)	Strongly disagree (n)	Disagree (n)	Somewhat disagree (n)	Somewhat agree(n)	Agree (n)	Strongly agree (n)	% Consensus
Pharmacists should advise acne patients to try and reduce their stress (e.g. work-related, personal)	0	4	1	5	3	2	33.3
Suitably-trained non-pharmacist pharmacy staff should advise acne patients to try and reduce their stress (e.g. work-related, personal)	2	3	2	4	2	2	26.7
Pharmacists should advise acne patients on the importance of sufficient sleep	0	4	1	4	3	3	40.0
Suitably trained non-pharmacist pharmacy staff should advise acne patients on the importance of sufficient sleep	1	4	2	3	3	2	33.3

Panelist comments

As shown in Tables 7 to 9, panelists often had differing views on statements, and the value of the interventions described in the statements, with respect to advice and management of acne. The quotes are not attributed to a given panelist as no attempt was made to track their participation.

Table 7. 'Patient assessment' area with supporting quotes

Area	Patient assessment
Details	**Supporting quotes**
Psychological assessment	*It is a significant ask for a pharmacist to be making this [psychosocial] assessment.* *I don't think that this [psychological assessment] should be the responsibility of the non-pharmacist staff.* *Patients will not always feel comfortable in bringing up this topic, and so it is important for a pharmacist to initiate this conversation and do an assessment.*
Clinical management	*Clinical assessment should be carried out by a pharmacist [rather than pharmacy staff] due to further training and expertise.* *If a person requires treatment advice and support, they should be seen by a pharmacist.* *Suitably trained non-pharmacist staff should only give OTC advice on mild acne - definitely not moderate, which should be referred to the pharmacist.*
GP referral	*Clearly this [family history] is one marker for potentially more troublesome acne, but by no means the only one and doesn't have that [GP referral] sort of mandate.* *Yes [referral] if the patient has tried a few different OTC treatments without success.* *A useful marker [seborrhoea] of the likelihood that the acne is going to be more resistant / troublesome.*
Pictorial guide	*As a guide [images of acne], but not used as a complete decision aid. Must consider whole presentation & other contributing factors.* *[a pictorial guide] is only really for monitoring progress once the goals of treatment have been established by someone more suitably qualified.*

Table 8. 'Over-the-counter' area with supporting quotes

Area	Over-the-counter treatment
Details	**Illustrative quotes**
Benzoyl peroxide	*Clearly need to be advised HOW to use and side-effects etc. Excellent, non-antibiotic first-line option.* *[good first-line treatment] providing that the patient starts with a low concentration then builds up.* *Evidence points to topical retinoids which are POM so advice to consult GP is the next line of treatment [after benzoyl peroxide].*
Nicotinamide	*Not a great treatment in my experience.* *I've not been too impressed by this [nicotinamide]. It is generally quite a weak alternative and is especially unlikely to be helpful if the acne has already failed to respond to a first-line option.*
Salicylic acid	*There are better options [than salicylic acid] e.g. benzoyl peroxide and topical retinoids.*

Table 9. 'Lifestyle modification' area with supporting quotes

Area	Lifestyle modification
Details	**Illustrative quotes**
Dietary advice	*Dietary advice may be of benefit but it is important also for pharmacists to recognise that diet sometimes has no clear link to acne.* *Unsure if evidence re dietary link is strong enough to specifically target people with acne* *Need to ensure not fueling myths.* *They [pharmacists] could indicate the emerging evidence to support a low GI diet.*
Smoking	*Obviously all patients who smoke should receive this advice, but as its role in acne is not well established, I would not risk alienating the patient by raising this, unless asked.* *General health advice [around smoking] as no evidence that a link to acne.*
Facials/sauna	*Only if [facials/sauna] this is effecting their skin [should patients avoid].* *I am sure patients would be appreciative of this more general advice [avoiding facials/saunas]. Patients may not have thought about these activities having an effect.*
Stress	*Again general wellbeing [advice], not necessarily acne-related.* *Very helpful in terms of acne management and for general wellbeing.* *Little evidence to support this advice.*
Sufficient sleep	*Very helpful in terms of acne management and for general wellbeing.* *All patient need sufficient sleep but no evidence just for acne.* *Generally not relevant - not worth focusing on.*

Phase 3

A total of 9 community pharmacists used the Delphi-derived guideline on a total of 35 patients which comprised 11 (31.4%) males and 24 (68.6%) females, with an overall mean age of 22.6 years (SD = 6.57) with a range 15 to 40 years.

The onset of acne occurred at an average age of 14 years (range 11 to 29). The type of acne was comedonal only (37.1%, n = 35), inflammatory only (20%, n = 35) and a mixture of comedonal and inflammatory acne (40%, n = 35). One patient (2.9%, n= 35)) was described as having both scarring and hyper pigmentation. The treatments provided by pharmacists are shown in Figure 1.

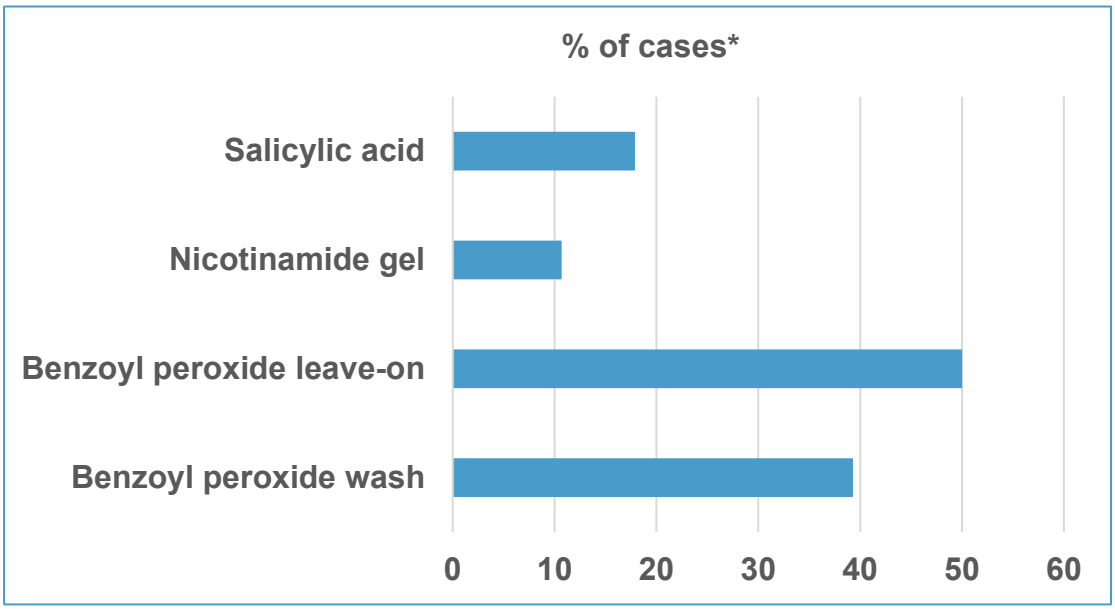

Figure 1. Treatments provided by pharmacists (n = 35)

*Pharmacists were able to supply more than one treatment

In total, 19 patients (54.3%, n = 35) were referred to the GP because of their acne with the reasons for referral shown in Figure 2.

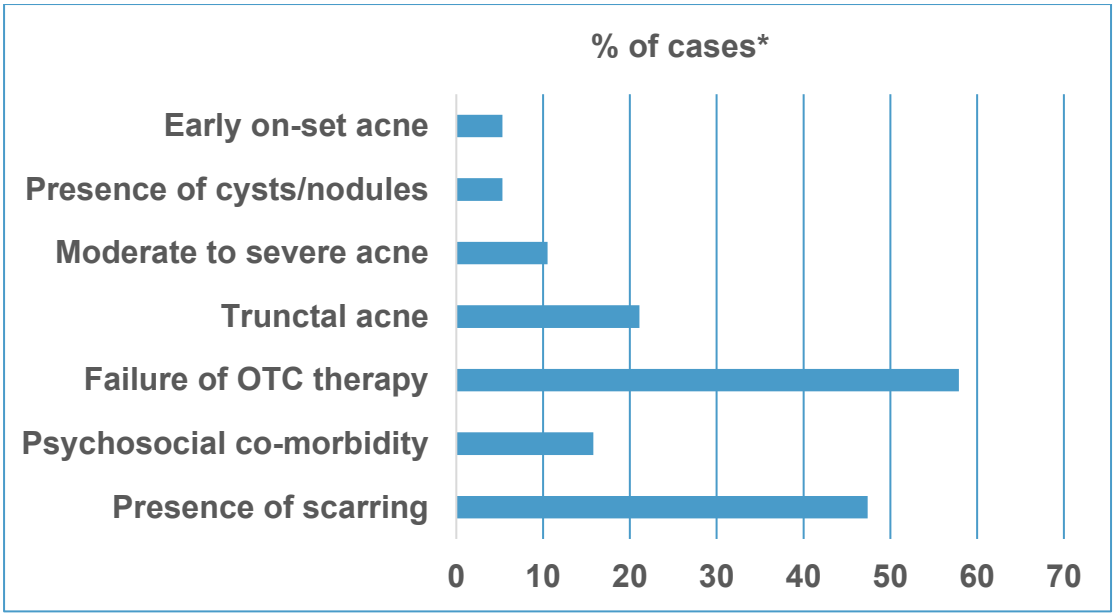

Figure 2. Reasons for acne referrals to a GP

*Pharmacists could refer for more than one reason

Pharmacists were asked to rate the usefulness of the guideline when treating those with acne on a 1 to 5 Likert scale, where 1 = not very helpful and 5 = very helpful. The median rating for all patients was 4 (interquartile range = 0).

DISCUSSION

Key findings

Consensus was achieved for 21 of 49 statements. Since the Delphi was directed at the pharmacy team rather than the pharmacist, many of the statements sought consensus on the role of both pharmacists and what was termed "suitably qualified non-pharmacist staff". However, the results showed how, for some statement categories, the low level of consensus was more a function of the person involved rather than the content of the statement. For instance, consensus was achieved for only four of the ten statements relating to clinical management, each of which was linked to the pharmacist performing the role. For the remaining six statements, all but one made reference to the use of "suitably qualified" non-pharmacist staff. In

other words, there was a strong sense that panelists – expert patients, doctors, nurses and pharmacists - felt clinical assessments should only be undertaken by a pharmacist. This was also apparent in relation to consultations with acne patients. Panellists agreed that pharmacists rather than non-pharmacist staff should conduct private consultations.

Though consensus was achieved in some areas, the implications were somewhat contradictory and liable to generate confusion among pharmacy teams. For instance, although acne is known to be associated with suicidal ideation and social impairment,[9] panelists did not agree that it was appropriate that pharmacy teams assess patients for signs of psychosocial co-morbidities and the impact of acne on quality of life. However, and in contrast, the panel were in agreement that individuals exhibiting psychosocial impairment should be referred to the GP despite a lack of agreement that such an assessment should be undertaken. As a result and to assist pharmacy teams, the guideline included signs and symptoms that were potentially indicative of psychosocial impairment.

There was a low level of consensus for statements related to lifestyle modification, irrespective of whether it was a pharmacist or non-pharmacist practitioner. The sixteen lifestyle modification statements related to eight separate factors, of which consensus was only achieved for two (four in total), irrespective of who offered the advice. Consensus was likely to reflect the lack of convincing evidence that exposure to UV radiation, for instance sunlight[29] or other forms of light therapy are effective in acne.[30] Similarly, the need to advise on the use of non-comedogenic cosmetics arises from work which suggests that many of the common ingredients used in cosmetics are comedogenic and thus potentially able to aggravate acne.[31]

The lack of consensus for other lifestyle modification may be indicative of the lack of robust data for the impact of these factors on acne. For instance, the role of diet remains controversial[32] and evidence for the potential acnegenic effects of a high glycaemic index diet has come from several small scale trials, for instance Smith et al[33] and cross-sectional observational work.[34] Despite evidence of a possible link between stress and acne[35] and an apparent positive association with disease

severity,[36] panelists did not feel that the evidence was sufficient to recommend advice on reducing levels of stress to improve acne. The positive link between smoking and acne has arisen from epidemiological evidence[37,38] although not all studies have detected such an association.[39] There is also evidence that increases in humidity (which can lead to sweating e.g. saunas) can also worsen acne but the data are based on patient self-reporting and thus potentially unreliable.[40] Finally, it has been suggested that lack of sleep triggers the release of stress hormones and since acne may be potentially made worse by stress, lack of sleep may indirectly worsen acne though the available evidence is circumstantial.[41]

An important purpose of the Delphi was to establish consensus on the most appropriate first-line community pharmacy-based treatment for acne. Currently, pharmacy-based acne treatments in the UK are based on either benzoyl peroxide, nicotinamide or salicylic acid. Unfortunately, there was no consensus on a suitable first-line treatment which probably reflects the lack of good quality evidence that is available for either benzoyl peroxide,[42] nicotinamide[43] or wash products that contain salicylic acid.[44] The only statement achieving consensus was on the importance of patient choice in selecting a suitable vehicle. It is assumed that offering patients a formulation that they find to be cosmetically acceptable will improved adherence and hence patient outcomes. Though patient preferences for a topical formulation have been shown to be similar between those with acne, eczema and psoriasis,[45] in a large scale study of the factors affecting adherence in acne, cosmetic acceptability was not found to be an important factor.[46]

Finally, there was a high level of consensus for statements (7/9) related to patient referral. Acne scarring occurs during resolution of lesions and can be a problem for up to 95% of people with acne.[47] Furthermore, it is important to recognise the psychosocial impact of the condition which in the more severe cases can lead to suicidal ideation.[48] There was consensus that GP referral was appropriate for patients with trunctal acne and this is based on the pragmatic view that it is inefficient and often difficult for an individual to self-treat large areas of acne with topical agents.

In an effort to evaluate the final guideline, it was used in 9 community pharmacies on a total of 35 patients. The overall helpfulness of the guideline, which was assessed for each patient, had a median score of 4 out of 5 (range 3 to 5) which possibly suggests that it might represent a useful tool when assessing patients seeking advice on acne.

Strengths and limitations

This appears to be the first time that the Delphi process has been used to develop a consensus-based guideline for the community pharmacy management and assessment of patients with acne. The Delphi process was found to be an effective tool for facilitating a "virtual" discussion amongst panelists and strengthened to some extent because of the multidisciplinary nature of members which allowed for a diversity of opinion and experience. The Delphi response rates were relatively high[23] (75%) and were stable across each of the three rounds. The distribution of respondents across panel member professional category (dermatologist, general practitioner, specialist nurse, community pharmacist and expert patient) varied within each round and hence, any changes in agreement may be reflective of changes in the composition of the expert panel across each of the rounds. As highlighted, there was diversity in the professional category of panel members although their distribution was uneven and therefore, some categories were underrepresented. For example, both doctors and nurses comprised the largest proportions of both recruited panel members and responses. The evaluation is limited in the sense that it is small scale, and hence, the findings are not generalisable. It may be beneficial to evaluate the guideline on a larger scale to determine true effectiveness.

CONCLUSION

The present study successfully utilised the Delphi process for the development of a consensus-based guideline for the community pharmacy management of patients seeking advice on acne. Although consensus was achieved on criteria for assessment and referral, there was a lack of agreement upon a suitable first-line treatment

option or on advice related to lifestyle modification. There was also strong sense that the assessment of patients should be undertaken by community pharmacists rather than pharmacy staff.

There was an appreciation of the final guideline when used in community pharmacy practice but, since this was based on a small number of pharmacies and patients, further work is clearly necessary to fully evaluate the utility of the guideline in a larger sample of community pharmacies and patients.

Acknowledgements

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We would also like to thank the consultant dermatologists, Delphi panel members and all the pharmacists who piloted the final guideline. All efforts are greatly appreciated.

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Appendix A

Research team
Professor Derek Stewart
Dr Rod Tucker
Dr Vibhu Paudyal
Dr Katie Maclure
Dr Alison Layton

Developing and feasibility testing guidelines for the management of acne vulgaris in community pharmacy

Dear Dermatologist

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?
The aim of the study is to develop a guideline to help community pharmacists manage patients who seek advice and treatment for acne.

Why have I been chosen?
You have been chosen because you are considered to be an expert in the management of acne. We want to interview you to get some idea of your thoughts on the the management of acne by patients who visit community pharmacies.

Do I have to take part?
Participation in the study is voluntary and your decision to participate will not influence your relationship with members of the research team.

What will happen to me if I take part?
You will be contacted by a member of the research team to take part in a telephone interview to seek your views on how you believe that acne should be managed in pharmacies.

We would like to record your telephone conversation.

What are the possible benefits of taking part?
We cannot guarantee any direct benefit for you from participation in this study. However, interview data will inform the development of a questionnaire which will be sent to other experts in the subject area to develop guidelines through Delphi/consensus process for the community pharmacy management of acne.

Will my taking part in this study be kept confidential?
Yes, your contact details will be kept secure at the university. You will not be named in any report of the study.

What will happen to the results of the research study?
We hope that the main findings of the study will be published in a health care journal. You may request a copy of the publication or report by contacting Professor Derek Stewart (d.stewart@rgu.ac.uk).

Who is organizing and funding the research?
This project is organized by the research team and funded by the Galderma UK.

Who has reviewed the study?
This study has been approved by the Robert Gordon University and an NHS ethics committee.

If you are interested in participating in the study, please sign the enclosed consent form and return to us in the reply-paid envelope provided. Alternatively, you can sign and scan the enclosed form and email to Dr Vibhu Paudyal (v.paudyal1@rgu.ac.uk)

Thank you in advance

Appendix B

ROBERT GORDON UNIVERSITY ABERDEEN

Dermatologist Consent form

Developing and feasibility testing guidelines for the management of acne vulgaris in community pharmacy

Please initial each box

I confirm that I have read and understand the information sheet dated 30th April 2016 and have had the opportunity to ask questions	☐
I understand that it is up to me whether or not I take part and that I am free to withdraw at any time, without giving any reason.	☐
I agree to take part in this study.	☐

Your Name _____

Signature _____

Date _____

The best telephone number to contact me on is

_____

The best time of day to contact me is

_____

Thank you for all your help
Please return this form in the reply paid envelope

Appendix C

Background

- *Can you tell me about where you work and your current role?*
- *What do you enjoy most about your current role? [probe – do you have any dislikes?]*
- *What other positions/roles have you held before your current post?*

Acne patients

- *What proportion of your workload do you think involves patients with acne?*
- *What are the main factors or issues that you consider when you see a patient with acne for the first time?*
- *What do you consider when assessing the impact of acne on a patient? [probe – is it only physical factors or are other factors important?]*

Acne patients in the pharmacy

- *Do you think that patients with acne should always try to treat themselves before seeking medical advice?*
- *When a patient seeks advice about their acne in a pharmacy, what would you say are the main factors that a pharmacist should consider?*

Severity

- *What level of acne severity do you think is appropriate for pharmacists to manage?*
- *How should pharmacists assess the severity of a patient's acne? [probe – what things should they be looking for or asking about]*

Referral

- *What are the signs or symptoms that should prompt a pharmacist to refer a patient with acne to their GP? [probe - are these only physical or are there other factors that pharmacists should consider and ask about?*

- *Should they suggest an over-the-counter product first or simply refer the patient without any treatment?*

Management

- *What types of currently available over-the-counter treatments do you think would be appropriate to manage patients with acne? [probe −do you there is any value in using cosmetic washes?]*

- *How long should pharmacists recommend that a patient perseveres with an over-the-counter acne treatment before trying something else*

- *What are your thoughts on the availability of topical antibiotics for acne in some European countries?*

- *What, if any, treatments do you think should be available through pharmacies?*

Appendix D

Research team
Professor Derek Stewart
Dr Rod Tucker
Dr Vibhu Paudyal
Dr Katie MacLure
Dr Alison Layton

Developing and feasibility testing guidelines for the management of acne vulgaris in community pharmacy

Dear Panel member

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?
The aim of the study is to develop a guideline to help community pharmacists manage patients who seek advice and treatment for acne.

Why have I been chosen?
You have been chosen because you are considered to have some expertise in the management of acne. We want to get your views on the topics generated from the interviews undertaken with dermatologists on the level of acne severity appropriate for pharmacy management, criteria for referral of patients by pharmacists to their GP and the most suitable treatment options for acne available in pharmacies.

Do I have to take part?
Participation in the study is voluntary and your decision to participate will not influence your relationship with members of the research team.

What will happen to me if I take part?
You will be contacted by a member of the research team to take part in a Delphi panel. This will be delivered in an electronic format and you will be sent a series of statements related to the management of acne in the pharmacy and asked to state your level of agreement with these statements. The statements will be refined and new ones added and we expect that the whole process should be completed over a period of 6 weeks to complete the tasks.

What are the possible benefits of taking part?
We cannot guarantee any direct benefit for you from participation in this study though you will be helping to develop a guideline to be used by community pharmacists for patients who present seeking advice/treatment for their acne.

Will my taking part in this study be kept confidential?
Yes, your contact details will be kept secure at the university. You will not be named in any report of the study.

What will happen to the results of the research study?
We hope that the main findings of the study will be published in a health care journal. You may request a copy of the publication or report by contacting Professor Derek Stewart (d.stewart@rgu.ac.uk)

Who is organizing and funding the research?
This project is organized by the research team and funded by the Galderma UK

Who has reviewed the study?
This study has been approved by the Robert Gordon University and an NHS ethics committee.

If you are interested in participating in the study, please sign the enclosed consent form and return to us in the reply-paid envelope provided. Alternatively, you can sign and scan the enclosed form and email to Dr Vibhu Paudyal (v.paudyal1@rgu.ac.uk

Thank you in advance

Appendix E

ROBERT GORDON UNIVERSITY ABERDEEN

Delphi participant Consent form

Developing and feasibility testing guidelines for the management of acne vulgaris in community pharmacy

Please initial each box

I confirm that I have read and understand the information sheet dated 1st June 2016 and have had the opportunity to ask questions	☐
I understand that it is up to me whether or not I take part and that I am free to withdraw at any time, without giving any reason.	☐
I agree to submit my responses to the Delphi questions when requested by the research team.	☐
I understand that data collected during the study will be used for research purposes including publication of anonymised findings and quotations. I grant copyright permission on the understanding that my confidentiality will be protected.	☐
I agree to take part in this study.	☐

Your Name _____

Signature _____

Date _____

The best telephone number to contact me on is

_____

The best time of day to contact me is

_____

Thank you for all your help. Please return this form in the reply paid envelope

Appendix F

Management of acne in community pharmacy

This guide has been developed by an expert panel of dermatologists, pharmacists, nurses and patients and provides recommendations to assist community pharmacists in the management of acne.

Patient assessment

- *Record all acne consultations on the pharmacy medication record*
- *Consult with acne patients in a private consultation room*
- *Assess the clinical severity of acne prior to managing with over-the-counter treatments*

Patient treatment

- *Only mild/moderate acne (grades 1 – 3 see images) should be managed with over-the-counter treatments*
- *The number and type of acne lesions should be assessed prior to managing with over-the-counter treatments*
- *A choice of formulation (e.g. lotions, gels or creams) that is cosmetically acceptable to patients should be offered*
- *Advise against the use of ultraviolet treatments*
- *Warn about the bleaching effects of benzoyl peroxide (e.g. bedding, clothing)*

Self-care

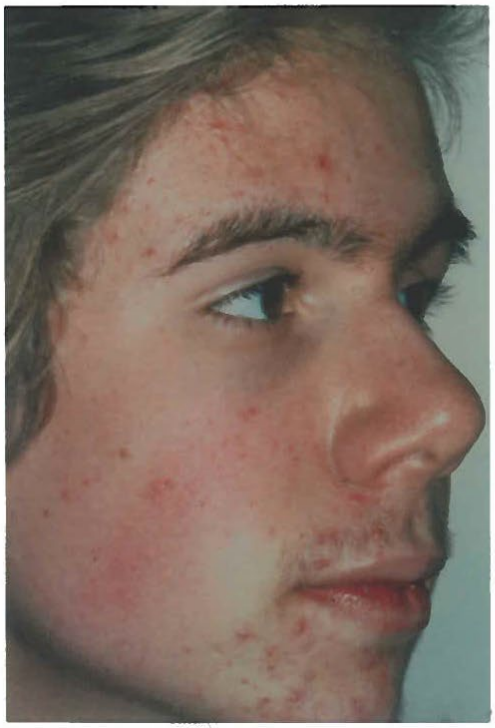
- *Advise acne patients to use oil-free, non-comedogenic (e.g. does not block pores) make-up products*

Referral to the GP

- *Refer patients with evidence of scarring to a GP*
- *Refer patients with psychological and social comorbidities (e.g. apparent low mood, acne affecting lifestyle etc) to a GP*
- *Refer patients who have tried multiple over-the-counter treatments without success to a GP*
- *Refer patients with moderate/severe acne (grade 4 and above) to a GP*
- *Refer patients with larger acne lesions (cysts or nodules) to a GP*
- *Refer patients with early-onset acne (less than 12 years of age) to a GP*
- *Refer patients with truncal acne to a GP*

Grade 1*

Grade 2



Grade 3

Grade 4 REFER

*The revised Leeds acne grading system. O'Brien et al. J Dermatol Treat 1998;9: 215-220

Appendix G

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Developing and feasibility testing guidelines for
the management of acne vulgaris in community pharmacy

PATIENT CONSULTATION FORM

Patient details

Female ☐ Male ☐ Date of birth DD / MM / YY Age acne developed ☐

Acne characteristics

Type of acne: *Tick all that apply*

☐ Comedonal only ☐ Inflammatory only ☐ Comedonal and inflammatory ☐ Widespread and prominent scarring/post-inflammatory hyperpigmentation

Treatment: *Tick all that apply*

☐ Benzoyl peroxide wash ☐ Benzoyl peroxide leave on product ☐ Nicotinamide

☐ Salicylic acid-based product ☐ None

Other, please specify ☐

Reasons for referring patient to GP: *Tick all that apply*

☐ Evidence of scarring ☐ Psychological and social comorbidities ☐ Multiple OTC treatments tried ☐ Truncal acne

☐ Moderate/ severe acne ☐ Presence of larger acne lesions (cysts or nodules) ☐ Early onset acne

Other, please specify ☐

Evaluation

How helpful were the guidelines in dealing with this patient? *Tick one.*

Not very helpful helpful — Very

1 2 3 4 5

Please scan this completed form and return to Dr Kathrine Gibson Smith (k.l.gibson-smith@rgu.ac.uk). Alternatively, once you have completed the intervention, please return the batch of forms via the prepaid envelope provided to:

FREEPOST AB313, ATTN: Dr Katie Gibson Smith, School of Pharmacy & Life Sciences, Robert Gordon University, SIWB, Garthdee Road, Aberdeen, AB10 7GJ

Pharmacist-patient with acne consultation form Version 2. 1st May 2018


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