

Microneedles in Clinical Practice—An Exploratory Study Into the Opinions of Healthcare Professionals and the Public

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ABSTRACT

Purpose Microneedles are being developed to administer vaccines and therapeutics to and through skin. To date there has been no qualitative or quantitative research into public and health professionals' views on this new delivery technique.

Methods Focus groups (n=7) comprising public and healthcare professionals were convened to capture the perceived advantages for, and concerns with, microneedles. Discussions were audio-recorded and transcribed. Transcript analysis identified themes that were explored using a questionnaire identifying consensus or otherwise.

Results Participants identified many potential benefits of the microneedle delivery system, including reduced pain, tissue damage and risk of transmitting infections compared with conventional injections, as well as potential for self-administration (subject to safeguards such as an indicator to confirm dose delivery). Delayed onset, cost, accurate and reliable dosing and the potential for misuse were raised as concerns. A range of potential clinical applications was suggested. The public (100%) and professional (74%) participants were positive overall about microneedle technology.

Conclusions This exploratory research study captured the views of the eventual end-users of microneedle technology.

Microneedle researchers should now reflect on their research and development activities in the context of stakeholder engagement in order to facilitate the transfer of this new technology 'from bench to bedside.'

KEY WORDS clinical practice · healthcare professional · microneedles · perception · public

INTRODUCTION

Microneedles provide a new opportunity for administering a wider range of therapeutics to and through skin. Microneedles are designed to specific dimensions to facilitate piercing of the outer barrier layer of skin, the stratum corneum, to enable drug and vaccine delivery, without impinging on the underlying pain receptors and blood vessels. Since the first demonstration that microneedles were effective in facilitating the delivery of calcein across the skin (1), there has been widespread academic and commercial interest in their development, resulting in extensive research into suitable fabrication methodologies (2–7) and potential pharmaceutical and pharmacological applications (8–21). Those intimately involved in the scientific development and testing of microneedles perceive that this new delivery method will confer many advantages compared with conventional dosage forms. Indeed, the literature lists a number of potential advantages of microneedles, with specific reference to hypodermic injection, including pain-free and blood-free delivery (22–25), minimal skin trauma following microneedle insertion (23,26,27), reduced risk of infection (27–29), appropriateness for non-skilled and/or self-administration (23,30–32), reduced risk of needle-stick injury and cross-contamination (23) and ease of disposal (27,33,34).

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Whilst the majority of the literature concentrates on demonstrating the many perceived advantages of micro-needles, a few concerns relating to this technology have also been raised. It has been questioned whether or not the creation of multiple microscopic holes in the stratum corneum could allow passage of bacteria, fungi, viruses or allogenic macromolecules leading to infection or hypersensitivity reactions (28,35,36). It is not known if minimally invasive delivery methods could provide a risk of inadvertent misuse or intentional abuse (35). On a more technical level, it will also be important to address whether or not microneedle devices will be able to deliver a sufficient dose in a reproducible manner (35–37).

Despite the extensive scientific research in this field, and the aforementioned perceptions of those developing microneedle technology, there has been no qualitative or quantitative research conducted into the opinion of the eventual stakeholders of this new delivery technique, that is, those who will ultimately be prescribing and administering microneedle ‘injections’ and those who will be receiving them. Whilst laboratory research must continue to provide further evidence on the potential clinical applications of microneedles, it is also important to assess and thereafter consider the views of the eventual users of microneedles. It is widely accepted that obtaining public opinion on developing scientific, technological and medical innovation and policy is important and that there should be greater public engagement (38–41). Increased public engagement provides lay citizens the opportunity to express views, concerns and opinions and to actively contribute to decision-making processes regarding scientific advances (42). Public engagement ensures that in the creation of new technologies, the consumers and potential consumers “do not stand at the end of the scientific pipeline passively waiting to consume new products. They are agents in the process of innovation.”(43). The United Kingdom National Health Service (NHS) is currently promoting wider public engagement in, and involvement with, NHS, public health and social care research through the National Institute for Health Research (44).

This preliminary, exploratory study begins to ascertain the views and opinions of the public on microneedles as a new drug delivery system. Hopefully, early public engagement will identify the perceived advantages and limitations of the technology, from the public perspective, and help to inform microneedle development towards producing an end product that is acceptable to the public. In addition to engaging with lay members of the public, this study also captures the opinions of a range of healthcare professionals, purposively sampled from a range of backgrounds, regarding the use of microneedles in clinical settings. As well as providing general opinions and views on the new technology, it is anticipated that those involved in parenteral drug administration will be able to raise more specific and

technical questions than the public through their different expertise and experiences (45–48). For example, the professional healthcare workers may be well placed to comment on the potential clinical applications of microneedles. This group could also provide a contextual perspective on appropriate methods and procedures for administering microneedles in the clinical environment.

In summary, determining the opinions and appropriate suggestions of the public and healthcare professionals at this early stage of development will potentially allow microneedle researchers to recognise and act upon any concerns and realise potential benefits. This will hopefully aid the successful translation of microneedles from the laboratory to clinical practice.

METHODS

Use of Focus Groups

Focus groups can be defined as “group interviews that capitalise on communication between research participants, in order to generate data” (49). The main feature of focus groups, which distinguishes them from other qualitative methods, is participant interaction (50). Rather than interviews, focus groups were chosen, as they enable the collection of views from a larger number of participants and allow individuals to hear and question others’ opinions and develop or modify their individual standpoints. There is greater participant interaction, with less input (and potentially less bias) from the moderator, permitting the group participants to develop and discuss themes that are important to them. Debates and agreement, or disagreement, can prompt participants to justify or expand on their points of view. Thus, focus groups not only allow researchers to examine what people think, but why they think that way (49–51).

Professional Focus Groups

Non-probability purposive convenience sampling was used to recruit 31 health professionals into three focus groups, which were held in a UK NHS Trust. The participants were doctors and nurses from a variety of medical backgrounds, including accident and emergency, paediatrics, outpatients (ambulatory care), dermatology, cardiology, occupational health and general practice. Individual focus groups comprised of healthcare professionals generally working in outpatient (ambulatory care) departments (7 participants), accident and emergency (10 participants) and paediatrics (14 participants) (Table I). Each focus group commenced with a very brief description of microneedles from the moderator as a means of focussing the discussions. This 5 min briefing explained that a) skin has inherent barrier properties; therefore, many drug molecules are not

Table 1 Composition of focus groups

Focus group	Participant profile	Social group / professional expertise	No. in group	Age range	Participant identifier
1	Lay Public	Mothers	7	37–53	FG1, PP1-7
2	Lay Public	Adults without children	6	20–27	FG2, PP8-14
3	Lay Public	Mixed Adults	7	22–37	FG3, PP15-20
4	Lay Public	Fathers	7	26–53	FG4, PP21-27
5	Healthcare Professional	Outpatients (Ambulatory Care)	7	Unknown	FG5, HP1-7
6	Healthcare Professional	Accident & Emergency / Occupational Health	10	Unknown	FG6, HP8-17
7	Healthcare Professional	Paediatrics	14	Unknown	FG7, HP18-31

able to permeate it; b) microneedles are designed to disrupt the outer skin barrier layer without impinging on the underlying pain receptors and blood vessels, i.e. their use may be less invasive than conventional intramuscular or subcutaneous injections; and c) microneedles can be used by coating drug onto the microneedle surface, injecting medicine through hollow microneedles or simply using microneedles to make holes in the skin after which drug is delivered via a topical formulation or transdermal patch. A few images were shown to illustrate the difference in size between microneedles and conventional needles, and an example of a microneedle array (36 microneedles of approximately 300 µm height) was passed around the group. NHS ethical approval and written consent to take part in the study and to be audio-recorded was obtained from participants prior to the focus group commencing.

Public Focus Groups

Purposive, convenience sampling was used to recruit 27 members of the public as four pre-existing social groups. Groups were male-only (7 participants), female-only (7 participants) or mixed (two groups of 6 and 7 participants). The age range was 20–53 years with a 12:15 male:female ratio. Pre-existing social groups were used to encourage interaction and reduce inhibition when challenging the views of others (49,51) (Table 1). A brief description of microneedles from the moderator, images of microneedles and conventional needles and a prototype microneedle array (as described above) were used as a focussing exercise for discussion. Ethics approval and written consent to take part in the study and to be audio-recorded were obtained from participants prior to each focus group.

Focus Group Data Analysis

All audio-recorded discussions were fully transcribed within 24 h of each focus group. Each participant was assigned an anonymised identifier, that is, public participants were identified as PP1 to PP27, and healthcare professional participants were identified as HP1 to HP31 (Table 1).

Focus group transcripts were reviewed, coded and thematically analysed (50,51) to determine the issues to be explored through the subsequent questionnaire. Exemplar quotations are provided in the results section of this paper for each theme. Focus groups are identified as FG1 to FG4 (public) and FG5 to FG7 (healthcare professionals).

Questionnaire Design

Questionnaires were used to further substantiate the outputs from the qualitative focus groups (52,53), allowing individuals to express their own opinions where they may have differed from those of other group members and did not wish to disagree or where they were not able to express their view within the group. The questionnaire was also used to raise issues not fully discussed with all focus groups. The quotations from the focus groups were used to create an item pool of attitude statements. Since the attitude statements were wholly derived from focus group transcripts, this reduced researcher bias. An attitude statement is a single sentence that expresses a point of view, a belief, a preference, a judgement, and emotional feeling or a position for or against something (52). Quotes from the item pool were modified, as illustrated in the example below, to improve clarity and allow subsequent analysis of general agreement or disagreement.

Attitude Statements:

Original transcribed quote from focus group:

“Because, if they’re not as effective I would be prepared to go through pain knowing that I was more likely to be, um, er, effectively treated than, er, you know, I mean, there’s the epidural, there’s no point in having an epidural that’s ineffective, where, so I’d be prepared to go through the pain, to have the pain relief, knowing that it was effective.”

Resulting attitude statement:

“I would still be prepared to go through the extra pain and have an injection, if it was more effective than microneedles”. (Public questionnaire, question 11)

A number of such attitude statements were created in the form of a five-point Likert scale which allowed participants to tick one of the following options for each statement: strongly agree, agree, no opinion, disagree or strongly disagree (52). The attitude statements included statements that were both for and against the use of microneedles to ensure the questionnaire itself was not inappropriately weighted in favour of, or against, microneedles. In addition to attitude statements, participants were also asked for more general views. Questionnaires were provided to all 58 participants approximately 4 weeks after they had taken part in the focus groups.

RESULTS AND DISCUSSION

Focus Group Studies

In this study, qualitative methods were employed to explore the views of the public and professionals on the microneedle drug delivery system. Qualitative methods are more appropriate for initial exploratory research, as they help us understand phenomena in natural settings, giving due emphasis to experiences and views of the participants; provide access to areas not amenable to quantitative research, such as lay and professional health beliefs; lead to the generation of hypotheses, as opposed to the testing of hypotheses; establish the views of those being researched, rather than the views of the researchers; and act as an essential pre-requisite to reliable quantitative research, particularly in areas with little prior investigation. Data from this preliminary qualitative research could therefore be used to supplement larger-scale quantitative research including obtaining the views of those who will be involved in distributing these devices, e.g. pharmacists. Focus groups were identified as the appropriate qualitative methodology for exploratory research into public and professional perceptions regarding microneedle technology and applications (45–51).

The potential advantages of microneedles as a new drug delivery system, identified from comments raised by both public and professional focus group participants, are listed in Table II. Exemplar comments are included below with the focus group and participant identifiers. All of the groups highlighted the fact that, in their view, microneedles would cause less pain on administration, thereby providing an attractive alternative to conventional injection, particularly in situations where injection pain is an important factor, for example, paediatric medicine, needlephobia and for treatment of certain chronic conditions, such as diabetes.

Focus Group (FG)2, Public Participant (PP)10: *If they are just as effective as conventional needles and they are less painful, as long as they are not more expensive, I suppose people would always choose them over conventional needles.*

FG1, PP3: *It would be good for children—wouldn't it—when you are taking your children, knowing that they don't have to suffer the same, suffer as much pain as when the injection goes in.*

FG3, PP18: *I think there's, there's probably quite a number of people who really don't like the pain of injections, and who are scared to go, and therefore will avoid having vaccinations, and I think if they knew it was going to be really pain-free, then hopefully a bigger range of people would actually come and have vaccinations they need.*

FG7, HP20: *We get lots of adults leaving the room because they can't look at needles; they're quite needle-phobic.*

FG5, HP3: *As a GP I would say probably, in the area of chronic disease, painless, empowering patients, certainly things like diabetes, maybe helping people with terminal illness control their own pain.*

FG6, HP10: *It would be better for travelling as well; you wouldn't have to take piles of syringes and needles and everything else there is—you could just take a little box with everything in and just put it on when you, when you have to.*

Table II Potential advantages of microneedles. Potential advantages were identified following thematic analysis of focus group transcripts

Potential advantages of microneedles	Public				Professional		
	FG1	FG2	FG3	FG4	FG5	FG6	FG7
Reduced pain on administration	✓	✓	✓	✓	✓	✓	✓
Good for children	✓	✓	✓	✓	✓	✓	✓
Good for needlephobes	✓	✓	✓	✓	✓	✓	✓
Good for diabetics	✓	✓	✓	✓	✓	✓	✓
Ability to self-administer with minimal training	✓	✓	✓	✓	✓	✓	✓
Reduced needle-stick injuries	✓		✓		✓	✓	✓
Alternative to oral medication			✓	✓	✓	✓	✓
Potential for controlled release and delivery				✓	✓	✓	✓
Reduced apprehension to injection	✓	✓		✓			
More discreet method for delivery		✓		✓		✓	

During each focus group, whether comprising public or professional participants, the potential advantage of self-administration was raised. It is clear that the focus group members believed, without any prompting, that a minimally invasive microneedle delivery device may be able to be administered given very minimal training and that administration would not necessarily be restricted to a clinical environment. It was interesting to note, however, that the public groups raised a number of concerns relating to self-administration. A number of participants indicated some discomfort about the responsibility of using the device properly, on themselves and their children, to deliver an appropriate dose. Public participants also sought reassurance on the appropriate safe disposal of a used microneedle device. The professional participants, however, did not raise any concerns on self-administration, describing only perceived advantages over conventional injections.

FG4, PP23: *Just looking at it, you're not going to have to be as well trained to inject that, so you would have thought Joe-public would be able to do that themselves.*

FG2, PP10: *I would rather have it done by a doctor as well, because I would be thinking that something might have gone wrong, or I hadn't done it completely correctly. I think people still believe in doctors and nurses more than they do their own ability.*

FG6, HP11: *It would be easier for patients to learn to use themselves, you know, perhaps in cases with fertility drugs and things, where patients have got to go home and inject themselves.*

The participants recognised that a current problem with conventional needles is the risk of transmitting infection through needle-stick injury. Whilst both the public and professional groups recognised that microneedles could offer less risk of cross-infection, the professional participants in particular regarded this as a major advantage that potentially addresses a surprisingly common and under-reported adverse event (54).

FG1, PP3: *Also would they be safer, if you accidentally prick or if the person administering it would accidentally prick themselves, would that be a safer way maybe than a traditional type of needle, you know there's these sort of needle-stick injuries aren't there?*

FG7, HP19: *Is there any advantage in needle-stick injuries? Because we get quite a lot of those at the moment.*

FG5, HP1: *Presumably there's no transmissible infection risk because you're not actually being exposed to any blood products, are you?*

Table II shows some additional advantages that were predominantly raised during the professional groups (FG4-7). These advantages were more technical in nature, when compared with public comments, such as the use of microneedles as an alternative to oral medication, especially for

children, and the potential for achieving controlled release via microneedle delivery.

FG7, HP21: *Some children get really cross with oral medication and spit it out, and then they're not taking anything else. I'm looking after a child now and he will NOT take anything in his mouth, and he's like "No medicine," so if you can give it pain-free somewhere else, you know they're getting it.*

FG5, HP4: *One of the major advantages could be the slow delivery of drugs over a period of time.*

The most frequently raised concerns during the focus groups are shown in Table III, which demonstrates that, in general, the public and professional groups raised many similar concerns regarding microneedle technology.

All of the groups required reassurance that microneedle-based drug administration would be sufficiently efficacious and rapidly acting.

FG1, PP1: *Because, if they're not as effective, I would be prepared to go through pain knowing that I was more likely to be, um, effectively treated.*

FG4, PP21: *I wonder whether the microneedle will be as effective with it being injected only on the top layer. Is the microneedle as effective as something that's going to be injected deeper?*

FG4, PP22: *If I was really ill and I had a really nasty disease, I would want whatever got the thing into my system the quicker to make me better quicker.*

FG5, HP2: *Do you actually know how long it's going to take for the drugs to get into the system to act?*

Interestingly, all of the groups mentioned that it would be necessary to include a feedback mechanism into the delivery system that provides the administrator or recipient of the treatment with confirmation that the appropriate dose had been administered. These comments can also be linked to the aforementioned commentary concerning public reservations about self-administration using microneedle devices.

FG2, PP8: *Is there any way to tell it's been used? Is there some sort of coating you'd put on, or something that changes colour or something like that? Just because they are so sensitive you wouldn't know if you had used it or not.*

FG6, HP8: *So you're giving, say, 1 ml of something into a muscle and you know you're going deep, and you can be quite confident that all the volume has been delivered. I just feel a bit uncomfortable with managing a very small volume into the skin, and not being able to see exactly if it's actually being delivered.*

FG7, HP18: *The fluid you were giving, if it was dyed, or something, so it wasn't harmful to the skin, but you could see the point of entry of just tiny dots, then you would know obviously if you'd touched it on yourself, you could see the area.*

Table III Concerns regarding the use of microneedles. Concerns were identified following thematic analysis of focus group transcripts

Concerns regarding use of microneedles	Public				Professional		
	FG1	FG2	FG3	FG4	FG5	FG6	FG7
Lack of efficacy	✓	✓	✓	✓	✓	✓	✓
Delayed onset of action	✓	✓	✓	✓	✓	✓	✓
Inability to confirm delivery of dose	✓	✓	✓	✓	✓	✓	✓
Relatively high cost	✓	✓	✓	✓		✓	✓
Potential for misuse and abuse	✓	✓	✓	✓	✓		✓
Potential for cross contamination		✓	✓	✓		✓	✓
Inter-individual variation in skin thickness			✓		✓	✓	✓
Difficulty in injecting a small volume					✓	✓	✓
Increased risk of infection					✓		✓
Restricted availability			✓	✓			

The potentially higher cost of the device, when compared with existing oral and injectable systems was mentioned within the groups.

FG4, PP22: *You know the health service is, in terms of cost, it's absolutely crucial isn't it, because this could deflect attention from more needed treatments, or other people.*

The public participants were particularly perceptive and inventive when considering ways this new technology may be misused or abused. For example, it was questioned if the risk of accidental cross-contamination may be increased, as the devices would be perceived to be less dangerous than conventional needles and provide a less obvious hazard. Similarly, it was noted that the minimally invasive nature of the microneedle device could allow the devices to be intentionally misused to deliver a harmful substance without the recipient's knowledge.

FG2, PP9: *Do you not think there could be more of a potential risk then of people injuring themselves with them or cross-contamination, say, in the hospital you can see the needles obviously so you are more aware of the risk of hurting yourself or somebody with them, whereas with those you wouldn't necessarily feel that you'd even hurt yourself with them.*

FG2, PP10: *I mean you do worry about the misuse with abusers of drugs and stuff; they'd probably find it easier to get a fix through using one of them than like a proper needle.*

FG4, PP23: *I was always too scared to inject a needle into me, but if I could have had a little pop with something a bit more easy I might have well had had a go.*

FG3, PP17: *You could just, you know instead of having to slip something in someone's drink, and they wouldn't feel it would they, yeah?*

FG3, PP15: *Yeah, like that rape drug, you could have problems with that.*

FG2, PP10: *I know this is going to extremes, though, but like terrorists using them...or you could get crazy doctors giving their patients something and you wouldn't know! And they'd just have it on the end of their finger! And just shake your hand and you're dead!*

Whilst the issue of potential abuse appeared to be of greater concern to the public, there were additional concerns highlighted only by professional participants. Indeed, the healthcare professionals (FG4-7) were found to have a greater number of concerns than the lay public. As with the additional advantages raised by the professional cohort (Table II), the additional concerns raised exclusively during the professional groups were more technical or applied in nature (Table III). These issues included the potential for increased infection through compromising the stratum corneum, inconsistency and irreproducibility of skin puncture and delivery given differences in epidermal thickness between individuals and within individuals at different skin sites and the practical difficulties in delivering small volumes of medicament to restricted biological compartments.

FG5, HP2: *One of the major problems that I can see really is the risk of infection. The skin is a protective layer, and once you breach it, you breach that protective layer.*

FG6, HP9: *Do you have to adjust the needle length to the size of the patient? And would be easy for us to work out, on the shop floor?*

FG6, HP8: *I just feel comfortable giving a bigger volume of something, because it, it seems easier to manage.*

FG7, 7HP19: *But if you were to concentrate drugs, then there would be more potential for error in children with the dose that you're giving them, and that's a big consideration.*

Questionnaires

The use of questionnaires allowed some quantification of the overall consensus, or otherwise, on themes that had emerged during the focus groups, making it possible to

identify whether or not the majority of participants agreed or disagreed with the issues discussed. The use of an additional approach for gathering data on the participants' opinions on microneedles also increased research validity through triangulation (55).

High response rates for questionnaires were achieved, namely 93% for public participants and 74% for the healthcare practitioners. Table IV summarises the public participants' responses to the listed attitude statements. The concerns regarding the technology generally aligned with, and substantiated, those voiced during the focus group sessions. For example, a suggestion arising from the focus groups that an indicator would be needed on the device to show the user that the dose had been delivered correctly was supported (strongly agree or agree) by 100% of the participants. 96% of the participants also agreed that they would prefer a painful conventional injection if it were more effective than microneedles. In total, 80% of the participants were also concerned that drug users could misuse the devices and leave them in public places. Regarding the potential advantages of microneedle use, all of the participants agreed (strongly agree or agree) that microneedles would be particularly useful in needlephobic patients and in patients who have to inject frequently. A high percentage of public participants (92%) also agreed that microneedles would be ideal for the

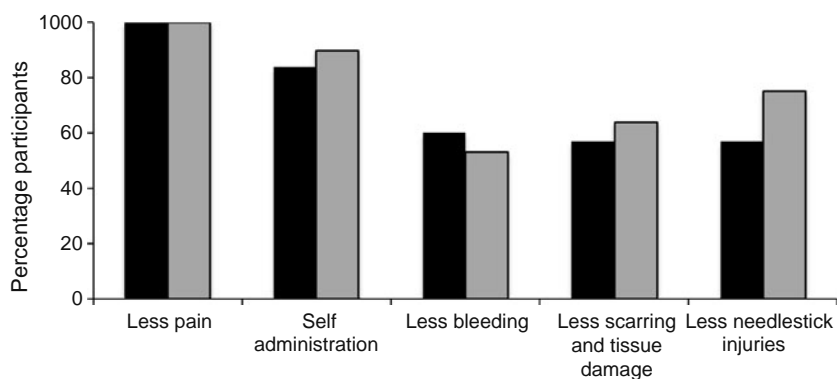
administration of medicines to children. These responses provide strong consensus for focus group observations that children, needlephobes, and those injecting frequently (e.g. diabetics), would particularly benefit from the clinical translation of microneedles.

The focus groups had previously revealed that some members of the public were particularly wary about self-administration. The questionnaire, however, highlighted a more optimistic viewpoint on self-administration, with 88% of participants agreeing that they would be happy to use microneedles on themselves, as long as the instructions provided were clear. Moreover, the majority of participants (80%) disagreed with the statement "*I don't think I would want to administer microneedles to a child in my care,*" suggesting a willingness to administer microneedle 'injections' to children. Providing further evidence of support for self-administration, when public participants were asked to tick the most important advantages of microneedles compared to conventional needles, 84% of participants ticked "*the ability for patients to self-administer*" (Fig. 1). Conversely, however, when public participants were asked to indicate how they would like to see microneedles being used in the future, only 25% wanted the devices to be available from a pharmacy for subsequent use at home and only 8% favoured the general sale of microneedles for home use,

Table IV Public participant responses to attitude statements. Percentage of public respondents who strongly agreed, agreed, had no opinion, disagreed or strongly disagreed with the listed attitude statement

Question	Strongly agree	Agree	No opinion	Disagree	Strongly disagree
If microneedles cost more than conventional needles, I don't think they are a good idea.	8	24	4	56	8
The NHS should not fund the use of microneedles at the expense of other treatments.	12	36	4	48	0
It is a concern to me that drug users could leave microneedles lying around in public places.	20	60	4	8	8
Microneedles will be more open to abuse than conventional needles.	8	36	24	20	12
With microneedles, it might be hard to know whether you have actually administered the medicine.	12	72	8	8	0
Microneedle devices should contain an indicator to show when a dose has been administered correctly.	64	36	0	0	0
I'd be quite happy to use microneedles to administer medicines to myself given clear instructions.	44	44	0	12	0
If asked to use microneedles at home, I would be worried I wouldn't do it right.	0	28	12	56	4
If people could self-administer using microneedles, it could save the NHS time and money.	24	56	12	8	0
I do not trust microneedles to effectively deliver medication at the right dose.	0	16	32	40	12
I would still go through the extra pain and have an injection, if it was more effective than microneedles.	12	84	0	4	0
If given the choice, I would prefer to be injected with microneedles than traditional needles.	24	36	28	8	4
If given the choice I would prefer to take a tablet than use microneedles.	16	32	20	28	4
If given the choice, I would prefer to use a normal patch than use a patch containing microneedles.	8	20	36	32	4
Microneedles would be good for people who need to inject frequently.	64	36	0	0	0
Microneedles would be better than conventional needles for administering medication to children.	48	44	8	0	0
Microneedles would be particularly useful for people who are frightened of needles.	64	36	0	0	0
I don't think that I would want to administer microneedles to a child in my care.	4	8	8	72	8

Fig. 1 Perceived advantages of microneedles. Percentage of public (black bars) and healthcare professional (grey bars) participants who selected the underlying option when asked the following question: *What, if any, would be important advantages of microneedles compared to conventional needles? (Please tick all that apply).*



with 75% and 83% of the public participants favouring the use of microneedles by trained healthcare professionals in either a hospital or surgery, respectively (Fig. 2). This issue may, however, not be restricted solely to 'self-administration' but also relates to concerns raised during the public focus groups (Table II) regarding restricting the availability of the devices to prevent intentional misuse of the device.

Table V shows the healthcare professional responses to the listed attitude statements. Inadvertent cross-contamination with microneedles in the clinical setting was a concern, with 84% of participants agreeing "There could be a risk of health professionals accidentally brushing against microneedles and injecting themselves." All participants therefore recognised that education would be required to prevent cross-contamination with these new devices. Despite these concerns, Fig. 1 shows that three quarters (75%) of the professional participants considered the reduced risk of needle-stick injury with microneedles compared to a hypodermic needle as a key advantage, compared with a lower proportion of public participants (57%). It is perhaps unsurprising that practising clinicians and nurses would consider avoidance of needle-stick injury as more of an advantage than the general public, as the former would be at a greater risk of such adverse events.

In agreement with the public participants, the professional respondents agreed (95%) that an indicator would be required to confirm that an appropriate dose had been administered to patients (Table V). Despite not being extensively discussed during the professional focus groups, 84% of health professionals thought that there could be a risk of infection with microneedle use. The same percentage of participants also agreed that it may be physically difficult to administer liquids through hollow microneedles given their restricted dimensions, whereas 90% of the healthcare professionals confirmed their confidence in conventional intra-muscular injection for delivering appropriate volumes of material. Nevertheless, 95% of the professional participants confirmed that needle-phobia is a significant problem in the clinical setting.

Both the public and professional participants were asked to provide their views on the likely future use of microneedles (Fig. 3). Specifically, the public participants were

provided a number of options (previously identified in the public focus group transcripts) to tick following the question "How would you like to see microneedles being used in practice?". The healthcare professionals were asked to tick up to five listed applications (previously identified in the professional focus group transcripts) for which microneedles would be most useful. It is interesting to note that both public and professional respondents felt that suitable applications for the technology include insulin delivery for diabetes and the minimally invasive delivery of vaccines, although the public participants clearly felt that the advantages were greater for childhood rather than adult immunization.

Both groups were also asked to indicate which microneedle delivery method they would most like to use at home (public participants) or which microneedle delivery method would be of most use in the clinic (professional participants). Figure 4 shows that there was no clear consensus of preference for the method of receiving medication using microneedle technology, although it was noticeable that the healthcare professionals showed more preference for using hollow microneedles in conjunction with a syringe when compared with the public volunteers. It is perhaps understandable that healthcare providers may want a new delivery technology to be closely aligned with conventional, well-practiced and proven delivery methods, such as

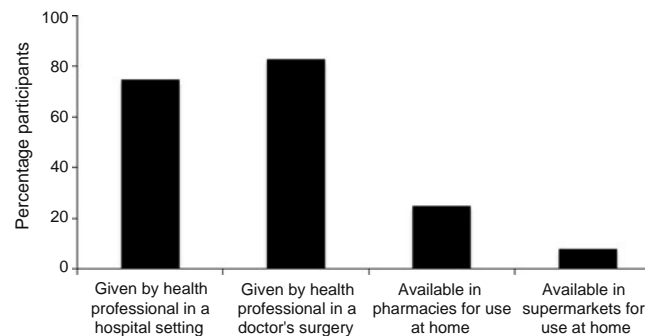
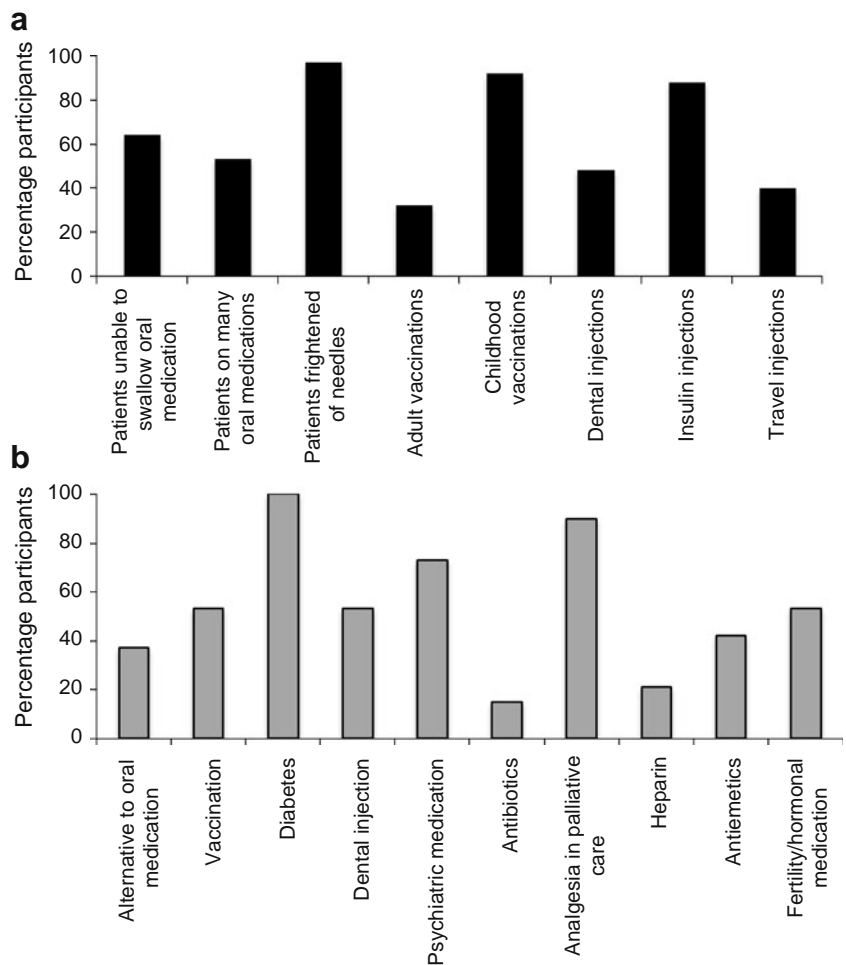


Fig. 2 Future availability of microneedles. Percentage of public participants who selected the underlying option when asked the following question: *How would you like to see microneedles being used in the future? (Please tick all that apply).*

Table V Healthcare professional responses to attitude statements. Percentage of healthcare professional respondents who strongly agreed, agreed, had no opinion, disagreed or strongly disagreed with the listed attitude statement

Question	Strongly agree	Agree	No opinion	Disagree	Strongly disagree
Microneedles will not replace all injections.	63	37	0	0	0
In emergencies, it does not matter if you cause pain to that patient, the important thing is getting the drug administered as quickly as possible.	47	42	0	0	11
It might be harder to physically push liquid through microneedles because the needles are small.	5	79	11	5	0
When you inject deep into the muscle, you can be confident that all the volume has been delivered.	16	74	5	5	0
Compared with normal needles, I would not be confident that I had delivered the correct dose of drug when using microneedles.	26	26	16	26	6
There could be a risk of health professionals accidentally brushing against microneedles and injecting themselves.	37	47	11	0	5
Education would be important to prevent possible cross contamination with microneedle use	74	26	0	0	0
Microneedle devices should contain a visual (or other) indicator to show when a dose has been administered correctly.	79	16	5	0	0
A potential problem of microneedles is the risk of infection as the skin is a protective layer.	11	73	5	11	0
Needlephobia is a significant problem in the clinical setting.	68	27	0	5	0
Microneedles would be particularly useful for people who are frightened of needles.	74	26	0	0	0

Fig. 3 Future clinical applications of microneedles. Percentage of public (A) and healthcare professional (B) participants who selected the underlying option—when asked the following question: Public participants—*How would you like to see microneedles being used in practice? (Please tick all that apply).* Healthcare professional participants—*Please indicate up to FIVE applications which you think would be most useful by ticking the appropriate boxes.*



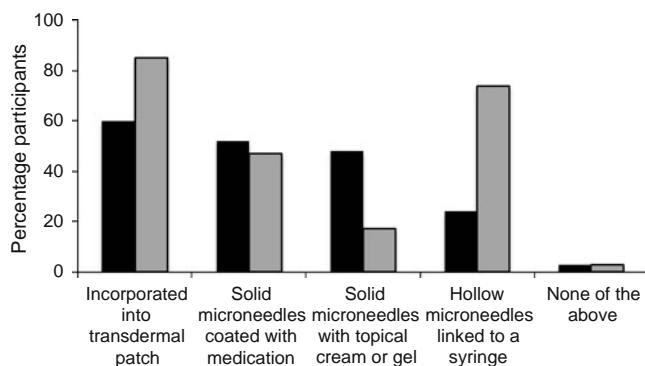


Fig. 4 Method of microneedle administration. Percentage of public (black bars) and healthcare professional (grey bars) participants who selected the underlying option when asked the following question: Public participants—Which of the following delivery options would you most like to use at home? (Please tick all that apply). Healthcare professional participants—Which of the following options would be of most use in clinical practice? (Please tick all that apply).

transdermal patches and needles and syringes. On reflection however, it is also possible that the public groups may not have sufficient technical or experiential knowledge of the suggested delivery methods to make an informed judgement on this particular question.

Finally, both of the groups were invited to provide an overall view on microneedle technology. Figure 5 shows that all (100%) of the public participants were positive about microneedle technology, with 28% being strongly positive. Therefore, despite the many concerns raised, the public appeared to welcome the potential value of this new technology. Whilst the majority of healthcare professionals (74%) were either positive or strongly positive, the remaining 26% were neutral. These neutral participants may see limited value in the technology at present or at least require convincing of its worth as a new drug delivery modality. Importantly, although the results from this exploratory study may not be generalisable, not one participant was negative regarding the concept of microneedle devices as a drug delivery approach.

CONCLUSION

In this study, we sought to determine the views, opinions and perceptions of the public and healthcare professionals relating to the use of microneedles in clinical practice.

The public participants suggested many potential benefits of the microneedle delivery system, including the reduction in pain and potential for reduced tissue damage on administration. These benefits were thought to be particularly important for children and needlephobic patients and for managing chronic conditions, such as diabetes. In addition to these perceived advantages, a number of concerns were also expressed, such as confidence in the

effectiveness of delivery, delayed onset of action, increased cost and reliable dosing. The potential for microneedles to be intentionally misused was also a real concern for the public participants, with participants generally expressing concerns on making the devices freely available.

The public participants regarded self-administration of microneedle treatments as a potential advantage, for example, in reducing hospital or clinic visits. However, many participants were wary of self-administering medications and vaccines, unless an infallible method of administering the correct dose could be developed. Moreover, participants felt that it would be difficult to confirm whether a dose had been administered correctly with microneedles, and, therefore, an in-built dosing indicator would be required to reassure patients.

The healthcare professional participants reported a wide variety of advantages with microneedles when compared with existing delivery techniques. This group also identified a wide range of potential clinical applications for microneedles in both acute and chronic medicine. In common with the lay public, the professional participants perceived that microneedles could be particularly useful in needle-phobic patients and in paediatric medicine. Further, they welcomed the possibility of delivering a wider range of medications at a controlled rate, with a reduced risk of transmitting blood-borne infections.

The concerns raised during professional groups included the need for reassurance regarding the effectiveness of delivery, speed of onset, inter-individual variation and the ability to deliver an accurate dosage. Professionals were apprehensive about the possibility of inadvertently injecting themselves during practice and the inability to determine whether they had actually administered a dose to themselves (inadvertently) or to their patients (intentionally). They also regarded a visual dose indicator to be integral to the finished microneedle product and appeared to welcome

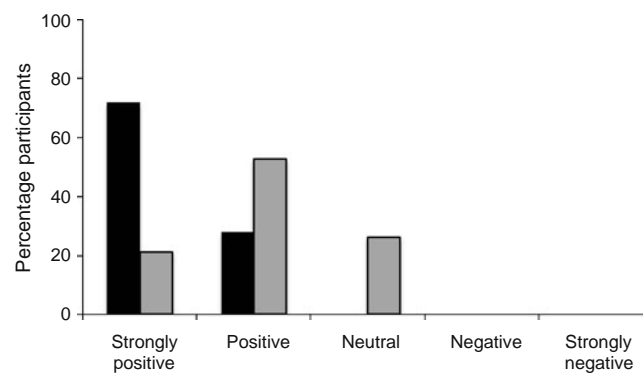


Fig. 5 Overall opinion on microneedle technology. Percentage of public (black bars) and healthcare professional (grey bars) participants who selected the underlying option when asked the following question: What is your overall view of the concept of microneedle technology? (Please tick ONE box only).

a microneedle device that was either incorporated into a transdermal patch or could be linked to a conventional syringe. More practical concerns related to the logistics of injecting a smaller, potentially more concentrated dosage which could be associated with greater risk of error. The risk of infection was also mentioned, as microneedles could compromise the skin's natural defense barrier against foreign bodies. It is fair to say that more professional participants expressed reservations overall, with a quarter of those responding to the follow-up questionnaire having only a neutral view on microneedle technology.

Although this novel, exploratory study involved a relatively small but diverse number of participants, the combination of qualitative with quantitative social science research methods established some of the issues that matter most to the eventual end-users of microneedle devices, that is, the clinical staff that will deliver microneedle 'injections' and members of the public who may receive them. It will be important for the microneedle research community to reflect upon their research-and-development activities to consider these issues in an attempt to encourage stakeholder engagement and facilitate transfer of the concept to the clinic.

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