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Acceptability of microneedle-patch vaccines: A qualitative analysis of the opinions of parents

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ABSTRACT

Introduction: Vaccines incorporated into microneedle-based patch platforms offer advantages over conventional hypodermic injections. However, the success and clinical utility of these platforms will depend on its acceptance among stakeholders. Minimal focus has been placed on determining parents' acceptability of microneedle-patch vaccines intended for paediatric use. This qualitative study probes the perceived acceptability of microneedle technology for paediatric vaccination in a parent population.

Research design and methodology: Focus groups (n = 6) were convened through purposive sampling of Cork city primary schools. Discussions were audio-recorded, transcribed verbatim, anonymised, independently verified and analysed by thematic analysis, with constant comparison method applied throughout.

Results: The opinions of 32 parents were included. All participants declared that their children were fully vaccinated. Five core themes were identified and defined as: (i) concern, (ii) suitability for paediatric use, (iii) potential for parental administration, (iv) the role of the healthcare professional and (v) special populations. Drivers for acceptance include; concerns with current vaccines and vaccination programmes; attributes of microneedle-patch (reduced pain, bleeding, fear and increased convenience) and endorsement by a healthcare professional. Barriers to acceptance include; lack of familiarity, concerns regarding feasibility and suitability in paediatrics, allergic potential, inability to confirm delivery and potential reduction in vaccine coverage.

Conclusion: This is the first study to explore parental acceptance of microneedle-patch vaccines. Capturing the opinions of parents, the ultimate decision makers in paediatric vaccination, is crucial in the understanding of the eventual uptake of microneedle technology and therefore adds to literature currently available. This study has revealed that even "vaccine-acceptors"; parents who agree with, or do not question vaccination, will question the safety and efficacy of this novel method. Participants in this study remained tentative. However, the study has also revealed that endorsement by healthcare professionals could reduce this tentativeness, thereby identifying the role of healthcare professionals in disseminating information and providing support to parents. An increased awareness of developments in microneedle technology is needed to permit informed decision-making by parents.

1. Introduction

Microneedles are micron-sized needles, designed to achieve the efficacy of the conventional hypodermic injection with the simplicity of a skin patch [1,2]. Incorporating vaccines into microneedle-based patch platforms offers the possibility of reducing costs associated with current vaccination programmes: (i) their thermostability eliminates cold-chain transportation requirements, thereby reducing distribution costs [3–5]; (ii) their potential for self-administration would reduce reliance on trained personnel, reducing administration costs [1,6–8] and (iii) their potential dose-sparing characteristics would permit a reduction in vaccine antigen per dose, reducing production costs [9–11]. In addition, microneedles may be fabricated using dissolving polymers, eliminating the biohazardous sharps waste associated with conventional vaccination methods [7,12]. These dissolving microneedle-patches have been developed to successfully incorporate vaccines *in vivo* for multiple disease indications [13]. The ability to penetrate the skin with minimal trauma, in the absence of pain and bleeding [1] has been identified by healthcare users as an important factor in their eventual clinical use [14,15]. Recent

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research assessing the potential cost-effectiveness of microneedle-patches in childhood measles vaccinations reports that while microneedle-patch vaccines may reduce costs, this cost-effectiveness and thus commercial viability will depend on the vaccine recipients' acceptability and the effectiveness of the patches relative to the conventional vaccine-delivery methods [16]. In Ireland, all childhood vaccinations are offered free of charge, thus parental concern regarding vaccination cost will not be an issue in our study.

It is widely accepted that obtaining and evaluating public opinion on developing scientific, technological and medical innovation and policy is important [17,18]. The European Medicines Agency (EMA) recommends that evaluation of patient acceptability should be an integral component of pharmaceutical and clinical development [19]. In their exploratory research study, Birchall et al., captured the perceived advantages of, and concerns with, microneedles, through the convening of focus groups comprising public participants and healthcare professionals [20]. A high percentage of participants suggested that microneedles would be 'ideal' for the administration of medicines to children [20]. In another study, children expressed a favourable viewpoint, suggesting that microneedle-based blood monitoring could offer an attractive alternative to conventional methods [21]. This research was expanded to include parental perception of microneedle-mediated blood monitoring of their infants and, once again, support for the microneedle was evident [22]. Research thus far has focussed on demonstrating safety and efficacy of microneedle-mediated delivery and assessing the acceptability of microneedle technology in general, with minimal focus on determining the acceptability of microneedle-patch vaccine delivery, in particular those intended for paediatric use. Therefore, to address this knowledge gap, this qualitative study probes the perceived acceptability of microneedle technology for paediatric vaccination in a population of parents.

2. Methodology

2.1. Focus groups

The acceptability of microneedle-patch vaccines was explored through a series of focus groups. Focus groups were chosen as they can provide insights into attitudes and beliefs that underlie behaviour and give context and perspective that enable experiences to be understood more holistically [23]. These attitudes, feelings and beliefs may be partially independent of a group or its social setting but are more likely to be revealed via the social gathering and the interactions entailed within a focus group. Focus group methodology was preferred over other qualitative research methods, such as interviews for several reasons: it is a highly efficient method of collecting data, with information from multiple participants being collected in a single session [24]; it is particularly useful when there is a common interest among the group of participants i.e. vaccination of their child(ren); and it is ideal for exploratory research, when little is known about the research question of interest [25]. The optimum size for a focus group is six to eight participants [25], thus this was the advertised group size. Research has shown that 90% of themes are discoverable within three to six focus groups [26] thus a target sample size of 30 participants was set.

A list of primary schools in Cork city, Ireland (n = 50), detailing address, Principal name and contact details was compiled using information freely available from the Irish Department of Education and Skills [27]. A recruitment poster, a copy of the informed consent form and a cover letter detailing study overview, addressed to each Principal, were sent via post. A follow-up email detailing the same information was sent one week later. With the permission of the Principal, contact was made with the Parent Association of those schools that expressed willingness to participate and focus group participants were recruited, using purposive sampling. Inclusion criteria included self-declared satisfactory English language and parent or guardian of a child or children less than 12 years of age, with no limitation placed on age or gender of participant. Focus groups took place within the grounds of the school, often coinciding with pre-arranged Parent Association meetings, to enhance convenience for participants. Written informed consent to take part in the study and to be audio-recorded was obtained from participants prior to each focus group. Information detailing gender, age, highest level of education achieved (according to International Standard Classification of Education (ISCED) [28]), number of children less than 12 years of age in their care and the vaccination status of their children was obtained for each participant.

A brief description of microneedle-patch vaccines, explaining their ability to disrupt the outer skin barrier layer and deliver a vaccine, without impinging on the underlying pain receptors and blood vessels, was provided. The moderator explained how the vaccine was incorporated into tiny microneedles, on a patch system. This patch could be applied to the skin: the microneedles would penetrate, without causing significant pain or bleeding and dissolve, releasing the vaccine into the patient. This provision of information was considered necessary given the likely unfamiliarity of participants with microneedle technology. However, to mitigate against risk of introduction of bias, information relayed was of a factual nature only. A research prototype, placebo microneedle-patch was passed around the groups and a magnifying glass was provided, to permit visualisation of the individual microneedles, to act as a focussing exercise to stimulate discussion and to reduce bias by enabling the independent formation of opinions (Fig. 1). A topic guide with a semi-structured design was used during each focus group, constructed based on a comprehensive literature search [29], providing general probes in an open-questioning style (Table 1). Ethical approval was obtained from the Social Research Ethics Committee, University College Cork. The authors declare that they have no competing interests.

2.2. Focus group analysis

Audio-recorded sessions, using a Dictaphone (OLYMPUS Digital Voice Recorder VN-731PC), were fully transcribed verbatim within one week of each focus group. Data were entered into QSR International's NVivo V.11 software to assist analysis. Each participant was assigned an anonymised identifier; for example, the first participant of the first focus group was assigned FG1P1. Transcripts were verified against audio-recordings with a random sample verified by an independent researcher. Focus groups transcripts were independently coded by co-investigators. Disparities were identified and resolved through discussion. Data were analysed by thematic analysis, with constant comparison method applied throughout.

3. Results

3.1. Focus group participants

Six focus groups were completed from 3rd November 2015 to 12th January 2016, representing an uptake rate of 12%. The opinions of 32 participants (29 female) were compiled. The most commonly reported age range was 30–39 years (46.88%), highest education level was Higher Education (ISCED level ≥ 4) (68.75%) and the number of child(ren) under 12 years in their care was two (46.88%). All participants declared that their children were