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Part 1: a qualitative description of participation in an eight-week infant skin integrity study

Abstract

Background The qualitative phase of the Baby Skin Integrity Comparison Survey (BaSICS) study was designed to address a dearth of information about research recruitment and retention, and how mothers make decisions about neonatal skincare.

Aims The aim of the qualitative phase of the BaSICS study was to explore participants' experience of participating in the research and how this interrelated with the experience of newborn skincare.

Methods Semi-structured, face-to-face or telephonic interviews were used to collect data. Interviews were transcribed verbatim. Data analysis used both software and manual methods.

Findings Motivation included both altruism and personal benefits. The bespoke smartphone application was a convenient and easy tool for data collection, and being afforded full responsibility for observing and recording infant skin condition increased mothers' awareness of skin changes. Family, friends and the internet were the most commonly used sources of information about baby skincare.

Conclusion The qualitative interview component of the BaSICS study provided information that could not have been deduced from the daily survey and final questionnaire alone. This provides valuable guidance for future research in the field of infant skincare.

Keywords

Qualitative description | Recruitment | Motivation | Infants | Skincare information

Part 1 of this paper describes the methods, analysis and findings of the qualitative phase of a larger research project, the Baby Skin Integrity Comparison Survey (BaSICS), and begins a discourse on these factors by a closer examination of the first two major themes identified. Part 2 explores the remaining three themes in greater detail, using the participants' own words and situating these in context by reference to relevant literature.

The primary phase of the study, with a sample of 698 mother/baby pairs, sought to determine whether variations occurred in the incidence of infant diaper dermatitis or nappy rash (IDD) when different brands of baby wipes were used during nappy changes. The brand of nappy was the same across all three arms of the study. The results of the main body of this study, comprising 55 days of maternal observations and surveys conducted using a custom-designed smartphone application, have previously been reported (Price et al, 2020; MacVane Phipps et al, 2021).

To provide a brief summary of the primary phase: three brands of baby wipes advertised as pure or gentle enough to use from birth were compared; one of these (Brand 3) was the industry sponsor's brand. Participants were divided into three groups, each group receiving one brand of wipes to use during the eight-week observation and data-collection period. All participants received the same brand of disposable nappy during the study so that differences in incidence of rash could not be attributed to differences in the type of nappy used. A popular brand, known and trusted by mothers, was selected as the nappy for the study to increase maternal confidence in participation. Brand loyalty will be discussed more explicitly in part 2 of this paper.

On writing up the findings of the entire project, the authors felt that the qualitative data derived from semi-structured interviews with a small sub-sample of the study population was too important to be included in a discussion of the primary study results but should be reported separately. This is an ethical and coherent way of presenting the qualitative data because the hypotheses, methods, and population are not the same as those in

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reports of the primary study. There is no hypothesis in the qualitative study; the study population is a small sub-sample of the entire population and the qualitative phase uses semi-structured interviews, not a smartphone application-mediated survey. The primary phase of the BaSICS study and the final qualitative phase address 'different and distinct questions' (Ethics.Elsevier.com, 2019).

The qualitative phase of the BaSICS study was conducted with a small sub-sample of participants ($n=38$) who were contacted on completion of the primary phase of the study and who agreed to be interviewed. The aim of this qualitative phase was to explore mothers' experience of participating in the research, and how this interrelated with the experience of caring for the newborn's skin, in order to inform future studies about best practice in engagement and retention in research with mothers and infants in the neonatal period. The research team felt that these were important research aims as motivation for consenting to research participation and prevention of attrition are not well-understood phenomena. While self-interest or personal gain (Nappo et al, 2013) and a desire to contribute to the greater good or advance knowledge (Stunkle and Grady, 2011) have been proposed, the balance between these or how potential participants use these in the decision-making process about research participation is less clear.

In addition, the primary phase of the BaSICS study involved a large sample population and requested that participants do daily observations and complete a survey each day using a bespoke smartphone application. This expectation could be considered burdensome over an eight-week period and using a smartphone application as a data-collection tool was a new concept in the field of infant-skin health. Therefore, understanding maternal experience of this process could serve to inform future research with similar population groups.

Background

This paper uses qualitative description (Chafé, 2017) with liberal use of low-inference descriptors to report on the final qualitative phase of the BaSICS study by presenting the experiences of study participants in their own words. Qualitative description, while inherent in all qualitative methodologies, can be considered a research methodology in its own right (Sandelowski, 2000). Qualitative description seeks to describe phenomena accurately, most often with liberal use of participants' verbatim quotes, often termed 'low-inference descriptors' in research terminology. This means that the participants' words are allowed to speak for themselves rather than being subjected to in-depth levels of interpretation by the researchers presenting their findings. This produces a high level of transparency as it enables readers to see the words of the participants without the filter of the researchers' viewpoints.

The qualitative phase of the BaSICS study reported in this paper was conducted through interviewing mothers and was designed to answer two questions: 1) 'what were mothers' experiences of participation in this research project?' and 2) 'how did they access and use information about infant skincare (see *Appendix*)?'.

Regarding the first question, the research team identified understanding why women volunteered to participate in the research and what kept them motivated to complete the study as key questions for researchers working with similar population groups. This question took on greater importance due to the 100% compliance achieved with survey completion and the very low attrition rate. While 722 women commenced the primary phase of the BaSICS study, 12 dropped out due to dissatisfaction with the products received, a desire to use reusable nappies or finding answering daily surveys time consuming and burdensome. These participants left the study within the first weeks. Therefore, the attrition rate was approximately 1.66%. Out of the remaining 698 women who completed the study, 100% completed all 56 days of the skin integrity survey. Understanding more about what motivated women and how such high rates of retention and compliance were achieved will be valuable information for future research studies both for this and other research teams.

The second question was to do with participants' experience of infant skincare. This is discussed more comprehensively in part 2.

Methods

This section presents only the methods of the qualitative phase of the BaSICS study. The methods of the primary phase are discussed in two previous publications (Price et al, 2020; MacVane Phipps et al, 2021)

The final phase of the BaSICS study was designed as a qualitative descriptive study. Qualitative description is often an overlooked research methodology as researchers seek to validate qualitative enquiry by, for example, aligning their work to lived experience of the participants as in phenomenology or by focusing on an aspect of culture and identifying their work as ethnography (Sandelowski, 2000). There are times when these more academic-seeming methodologies are entirely appropriate and accurately address the essence of the research question. At other times, work presented in this way could be more honestly addressed and appropriately evaluated as qualitative description. Neergaard et al (2009) suggest that while qualitative description is often identified as the 'poor cousin' of health research, it is a useful tool in medical and other health research, particularly when researchers want to

gain an understanding of participants' experience with a single topic or with a limited and focused number of topics. The same authors also point to the usefulness of qualitative description in mixed-methodology research studies. Chafe (2017) confirms this point of view, describing qualitative description as an under-used research method which is most valuable in health services and public policy research.

Qualitative description fit seamlessly with what the BaSICS team aimed to achieve. The project involved mixed methodologies, with the primary study data collected through the use of a daily online survey using a smartphone application and a final more extensive survey completed on day 56 of each participant's data submission. Mothers representing 10% of the total BaSICS sample were randomly selected and invited to participate in a semi-structured interview. Although a purposive sample is more common in qualitative research, we assigned invitations using a computer algorithm as we were not seeking to interview women with particular characteristics other than completion of the study. Selecting participants booked at all three participating NHS trusts from the research database provided a balance of ethnic and socioeconomic diversity, although this was not a parameter of the sample. Just over half the women approached agreed to be interviewed ($n=38$). Six members of the research team conducted interviews using the same interview guide (see *Appendix*); participants were given the choice of a face-to-face or telephone interview. Interviews were recorded and then transcribed verbatim. University and National Research Ethics Service approval were awarded for all aspects of the research project including the final qualitative interviews.

Interview data were analysed using NVivo and template analysis (King, 1998; Brooks et al, 2015) with templates derived from the NVivo nodes or categories. Three research assistants completed the initial first-line analysis of the data using NVivo Software. This served to group the data into initial themes or nodes. The principal investigator and co-investigator extended the depth and breadth of analysis by using the template model of manual analysis with templates developed from the initial NVivo nodes. Employing a combination of qualitative analysis software and manual analysis provided greater richness as it facilitated the use of intuitive and creative organisation of the data (Rodriguez, 2002) and contributed to the confirmability of the analytical interpretation (Cope, 2014). However, the strength of this work lies in its qualitative descriptive characteristic, which allows interpretative validity by liberal use of the words of participants themselves (Sandelowski, 2000).

Results

Original templates derived from NVivo nodes developed in the preliminary analysis covered aspects of participants' experiences from their engagement with and experience of participating in the research study, the use of the smartphone application as the data-collection tool, product deliveries, baby skincare advice and practice, and product feedback. These were collapsed into five broad themes:

- Broad theme 1: motivation and recruitment
- Broad theme 2: experience of being a study participant
- Broad theme 3: compliance and completion
- Broad theme 4: advice and choices
- Broad theme 5: product satisfaction

Overall findings were:

1. Two types of altruism described women's motivation for participation. These were banal altruism (Carrera et al, 2018) and conditional altruism (McCann et al, 2010). The fact that the study was midwifery led and compared product brands known to the participants increased their confidence in the research. Curiosity, interest in the topic area and appreciation of products supplied during the study were also important factors in participant motivation to commence and continue the study
2. Women's experience of participation was very positive; they particularly liked the use of the custom-designed, smartphone application to record daily observations of their baby's skin integrity at one selected nappy change. The relationships that developed between the participants and researchers contributed to participants' positive experience of the study. Initial contacts were unrushed and participants felt comfortable about contacting the research team with any questions or issues. Women also appreciated the regular prompt deliveries of the products they received as part of the study. This served to reduce stress during the early weeks of their baby's life
3. The commitment that women made when they agreed to become part of the BaSICS study contributed to their compliance with the study protocol and completion of the data collection. Mothers spoke of feeling as if they had entered into a contract with the research team where each party was giving something of value and receiving something in return
4. Participants sought information on baby skincare and prevention or treatment of nappy rash mainly from family and friends. Even mothers who were doctors and midwives spoke of relying on friends and family rather than their own professional knowledge. The NHS came third despite the fact that postnatal care is part of the package of maternity care provided in the UK. Some women spoke of

postnatal midwife visits as being brief and task-orientated; others were visited by midwives whom they had not met previously and thus felt inhibited in asking questions. When NHS sources were accessed, these were likely to be internet sources. A non-NHS advice web page was also mentioned frequently as women felt this gave credible advice and is staffed by UK health professionals

5. Participants were satisfied with the brands supplied to them, although there were some personal preferences. Some of these were due to previous experience or the functionality of the brand supplied. All mothers preferred using baby wipes during nappy changes to the often-recommended water and cotton wool.

Discussion

The discussion section of parts 1 and 2 of this paper are presented using the words of the participants themselves to illustrate and explore the themes derived from the interview data. This is supported by appropriate use of the literature in this descriptive study which does not aim to develop theory, explore culture or derive deep meaning of experience but instead to legitimately describe women's experiences of participation in the primary phase of the BaSICS study in order to present information which may be helpful for future researchers. Corden and Sainsbury (2006) support this approach in their assertion that experienced researchers and writers often move beyond standardised textbook guidelines by finding creative and innovative ways to present and discuss their research findings. A liberal use of verbatim quotations empowers the study participants by presenting their views in an open and transparent fashion, enabling the reader to form their own interpretations. The first major theme identified was 'motivation and recruitment'. The discussion of this theme and that of 'experience of being a study participant' conclude part 1. The remaining three themes form the content of part 2.

Motivation and recruitment explored women's motivation to participate in the study and the methods used to recruit participants. While the research team anticipated that the study would be attractive to women due to the free products, for many mothers this was not their stated primary reason for participation. Women were curious, wondered about differences between products or just wanted to contribute to the body of knowledge around newborn skincare. One mother, who was a midwife, when asked why she participated in the research, was honest about her dual motivation when she said:

'Because, I suppose, part of my job, I find it quite interesting. I love filling out surveys and stuff. I find it

quite interesting reading about research but also because nappies are quite expensive and my daughter [first child] is still in nappies. So that was a big incentive, having nappies provided and having them delivered was great.' (P1)

Comments such as 'I'm a math teacher, that sort of thing interests me' (P37), 'I'm a scientist, I'm always interested in research studies' (P4), 'I like doing research, to be part of things to make the world a better place' (P24) were common. One participant who came from a medical background said she wanted to participate because, 'I know the importance of research' (P38). Another mother expressed an interest in finding out more about nappy rash, saying:

'Just because there's not a lot of things out there about nappy rash and how to treat it' (P14).

The nappies and wipes were a strong secondary motivation with comments such as 'the offer of free nappies and wipes, it's a big help' (P18) and 'I know you get the nappies and wipes but I didn't want to take advantage of that' (P37), expressing the concept that the products were an important motivation but not the only one. One mother commented:

'The idea that I could get free nappies and wipes and all I had to do was fill in a questionnaire, it felt like a very fair deal' (P6).

The daily survey's 100 % compliance rate and the low attrition confirmed women's engagement with the study; mothers frequently expressed feeling sorry when their participation in the study ended. One mother said she would have been happy for the research to continue longer (P12) while another expressed her feelings in this way:

'But actually, when it stopped, when I did my final report and it said, "Thanks, that's your last one", I was actually a bit sad. It was almost like institutionalism, I like the ritual of it.' (P3)

This was interesting to the research team because an initial proposal for a longer study had been rejected, anticipating that it would be difficult to maintain participants' motivation over an extended time period. Motivation to participate in the research was well balanced between personal gain and desire to contribute to knowledge creation, challenging the findings of earlier research into participants' motivation which found that personal benefit was the main motivating factor, with altruistic motivation a weak secondary factor (Nappo et

al, 2013). However, findings from a systematic review into the reasons why people agree to participate in research studies found that while financial rewards were an important incentive, participants reported many other motivating factors, such as curiosity and contribution to scientific knowledge (Stunkel and Grady, 2011). As these findings came out of analysis of a wide range of research rather than a single study, it may be safe to assume that they represent a more balanced view of motivation as well as supporting the findings of this study.

More recently, Carrera et al (2018) explored the concept of altruism as a motivating factor in research participation and proposed a category of altruism, underlying participants' motivation, which the authors labeled as 'banal altruism'. Banal altruism describes a form of altruism that does not exact a high personal cost. This refers to research studies where participation is not a burden to participants. This is similar to the category of 'conditional altruism' (McCann et al, 2010) which is defined as peoples' consent to participate in research based on a willingness to help others, as long as such participation will also benefit themselves, or at least will not subject them to any potential harm. Women participating in the BaSICS study exhibited banal altruism in their reporting on the simplicity of completing a daily skin integrity assessment survey using an application on their phone or in one instance on a computer. Because of the ease-of-data reporting and the minimal time this demanded of them, many mothers said they had no reason not to participate. Conditional altruism was displayed by women who stated that they liked being involved in research which could help other new mothers make choices about infant skincare, while at the same time valuing the personal benefits of free nappies and baby wipes during the study period. One mother displayed banal altruism when she said:

'Two things: coming from a medical background, I know how important trials are and also when I found out how easy it was to complete. To be honest, if I had had to do lots in those first weeks, then I would not have wanted to carry on. When I heard what I had to do, I thought, "Oh yeah, I'm on my phone all the time anyway, I might as well go to the app and fill in the survey". Sometimes when I was on my phone in the middle of the night when I was feeding her, I would think, "Oh yeah, I'll just go to the app and fill it in". I wanted to complete it.' (P38)

Another expressed conditional altruism in her comment:

'First of all to save some money, 'cause we're saving for a house and I thought it was a great opportunity 'cause they don't come cheap, nappies. And it's for a

study as well, so I thought, I'm helping and I'm on maternity leave so I've got to find something to do [laughs].' (P19)

An important factor influencing the ease of recruitment to the BaSICS study was the 'trusted brands' effect (Todkill and Powell, 2013). This proposes that when a research intervention involves products with which participants are familiar, or the study is being done by a recognised and trusted research group, such as researchers from a university or from the NHS, members of the public will be more willing to take part. The BaSICS study provided triangulation at three points, all of which would have been reassuring to potential participants. The research was carried out by a local university, and perhaps even more important, by a midwifery led research group within that institution. For pregnant women, midwives represent a trusted professional group (Lewis, 2015). Recruitment initially took place in NHS antenatal clinics and was supported by midwives and midwifery managers within those locations. Finally, the brands of both wipes and nappies offered as part of the study protocol were familiar to, and trusted by, women. The fact that women often asked questions about brands in the initial recruitment encounters indicated that knowledge of products was an important consideration in their decision to participate in the study. One mother demonstrated the importance of brands when she said:

'You said when you first came and did the consent that you have to use a brand that people trust, you know, if you'd given us something that I'd never heard of, I might not be as happy, but [nappy brand], it's a big brand, we know it, it's premium nappies, and the same with the wipes.' (P33)

However, each research project is different and individual reasons for participating may be varied and highly personal. In this study, the qualitative interview sample represents only a small percent of the total participants and it may be that mothers who agreed to take part in the final interview were those who already had a positive inclination towards participation in research studies.

Participants reported on their recruitment to the study, giving examples across the span of recruitment methods. Some participants were recruited through meeting with one of the research assistants while waiting for an antenatal appointment (P13); others saw banner advertisements at their booking hospital (P23) or were recruited through posts about the study on different social media group pages (P22). Some women heard about the study from family, friends (P32) or

their midwives (P21), and phoned the research office to self-refer. There were multiple ways in which pregnant women could find information about the study and all of these were demonstrably successful in attracting participants.

Experience of being a study participant examined women's experiences of being involved in the study. All of the participants who were interviewed praised the smart phone application as easy-to-use. Only one mother reported using the web-based version of the application on her desktop computer (P24). Mothers recorded their baby's skin integrity score at a single nappy change each day. If the skin condition was different on a subsequent nappy change during the same day, the score was not altered. Many mothers admitted that the time they remembered to fill in the survey was in the early hours of the morning when their baby woke for a night feed. One mother stated that she deliberately chose the late night nappy change to do the survey because it allowed her to monitor her baby's skin condition over a range of nappy changes. Her explanation was:

'I did it towards the end of the day because it had given me a few nappy changes to think about. So, if anything, I erred on the side of caution 'cause I wanted to get the questions right. I was thinking "Oh, has it definitely been clear?">' (P1)

Mothers described the ease of using the application to record their baby's skin condition. Comments, such as 'I found it [the application] really easy to use, yeah, dead simple' (P16), 'I just used the app 'cause I thought it was the easiest option' (P23) and 'It was really straightforward, took two minutes, maybe not even that to do, nice and straight forward. Just two questions and that was it' (P19) were expressed in almost every interview. One participant's comments were typical:

'I think it was dead simple. The simplicity of it was the easy bit because it literally would take me a minute at night, once everyone was quiet to sit down and do it. I could just do it then. It wasn't too in-depth and the multiple choice answers were enough but not too much so it was really good.' (P9)

The use of the smartphone application, designed for this research study, prevented problems commonly reported with paper research diaries leading to loss of data (Lavender et al, 2012). A paper diary had been offered as an alternative for participants who did not wish to use internet-based tools; out of all completing participants ($n=698$) only a very small proportion ($n=3$) chose to use the paper version of the survey tool. None of these participated in the final qualitative phase of the study.

Key points

- Altruism is as, if not more, important in motivating research participation than concerns about receiving some form of recompense
- A smartphone application is an acceptable data-collection tool, well-liked by research participants, available everywhere and protects against data loss from inadequate storage or transfer of data contained in paper research diaries
- Research participants who feel involved through a participant-as-co-researcher model, with whom the research team have established good relationships, and who feel that they are both contributing and receiving something of value, are less likely to discontinue participation before completion of their data collection journey

If participants forgot to complete the survey, they received an email and then a text message. Mothers reported that they appreciated the reminders and did not find them intrusive. The fact that the survey was short, accessible and had been piloted with pregnant women prior to the start of the study all helped to ensure compliance with completion and followed guidelines for good research practice (Boynton, 2004). The delivery of nappies and wipes to the mothers' homes at approximately fortnightly intervals was also a feature of the study that the participants appreciated. Comments such as, 'It was great having nappies and wipes delivered to your door, really helpful' (P38) were common. One mother described the delivery experience very succinctly as:

'Deliveries were spot on and they were always early. Lots of stock, plenty of supplies and the courier was friendly too' (P18).

Occasional problems, such as an anticipated delivery not arriving when expected, were easily resolved by a phone call or text to the research office. The fact that women felt an ongoing connection to the research team and knew that if any problems occurred, they could email or phone, and receive help was a positive factor in their continuing engagement with the research study. One reason for such positive engagement may have been the groundwork done by the research team. During the recruitment process, researchers took the time to get to know potential participants rather than trying to hurry them through the consent process. If women were not within the recruitment time period, the research assistants making the initial contact asked women to complete a 'consent to contact' form giving them permission to contact the women at a later stage in their pregnancy. If, when they subsequently made contact, the women were still interested in participating, researchers would offer to meet them at home, at a local meeting spot such as a café or at their place of work.

Appendix

Baby Skin Integrity Comparison Survey Qualitative research guide for exit and completion interviews Version 3.0 08.10.2017

The purpose of the exit or completion interview is to collect qualitative data from participants in two areas:

- The experience of participating in the research study
- Infant skincare (beliefs, routines, observations)

Researchers should begin the interview by reminding participants that their participation is voluntary and that they may end the interview at any time.

The interview should commence with the open question: 'Tell me about your experience of being part of this research study.'

Prompts related to this question might be:

- How did you find out about the research and what attracted you to sign up to be a participant?
- Did you use the baby electronic survey tool (phone application or web-based application) or a paper version? What was that like?
- Did you find the nappy area assessment scale and the line drawings related to the appearance of your baby's nappy area?
- Did you find it easy or hard to remember to do the assessment every day?

The next question could be: 'Tell me about caring for your baby's skin. What was that like for you?'

Prompts related to this question might be:

- How did you clean your baby's skin during the first eight weeks of life?
- Did you bathe your baby? If so, at what age did you start giving baby baths?
- What was your main source of information about how to care for your baby's skin?
- How satisfied were you with the products supplied to you?

Some women chose to come to the university to meet with the research team. One mother, in discussing how straightforward all aspects of her participation in the study were, expressed it in this way:

'I met her [research assistant] at the hospital when I was having my glucose test but I wasn't far enough along so she had to get back in touch with me ... then she came around and had a chat about it.' (P19)

Conclusion

The aim of the primary study was to compare brands of wipes to determine if incidence of IDD varied between different study arms. The findings indicated that brand is a determinant of rash incidence. The aim of the qualitative phase of the research reported in this paper was to explore participants' experiences of the research study in greater depth with a small sub-sample. This paper describes mothers' feelings about participating in the study and their motivation for volunteering for and completing the study. Part 2 of this paper explores issues of compliance and completion and describes mothers' experience of seeking information about baby skincare and how they used this information. This information will be useful to other researchers working with similar populations.

Women enjoyed taking part in the study. They felt a connection to the research team, largely due to the time taken by researchers to engage with the women during the recruitment process. This included meeting women when and where it was convenient to them to explain the study and gain consent; offering them a coffee if they met at a café or at the university; and giving them a phone contact if they had further questions. The three data collectors/research assistants carried mobile work phones and another phone used only for the BaSICS study was kept in the research office. Women approved of the phone application as a tool to record their daily observations of their baby's skin condition. They found it easy to use and liked the diagram of stages of nappy rash, which acted as a reminder if they were having difficulty deciding what category to record on the application. More extensive information, including photographs of nappy rash reproduced with permission from a medical dictionary, was included in an information pack given to women when they registered on the study. Furthermore, participants expressed two separate but related forms of altruism in their desire to add to knowledge around infant skincare while acknowledging the benefits they received in the form of nappies and baby wipes. **BJM**

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CPD reflective questions

- Why did the authors feel that a final qualitative phase would add knowledge and value to the 56 days of survey data already collected from the full sample of 698 women?
- What were the advantages of using a smartphone application as the data-collection tool in the first phase of the Baby Skin Integrity Comparison Survey (BaSICS) study rather than using a paper diary tool? Were there any disadvantages?
- What are the differences and similarities between banal and conditional altruism? How did these concepts contribute to women's motivation to participate?
- In what ways did the supply of free products influence women's decisions to participate in the research study? Suggest methods of ensuring added value to participants in research that does not involve product comparison
- Multiple methods of participant recruitment were used in the BaSICS study. Which of these do you feel was most significant in achieving such excellent recruitment levels and why?

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