Institution: The University of Manchester

Unit of Assessment: 3

Title of case study:
Prevention of atopic eczema through appropriate neonatal skin care practices. (*ICS-12*)

1. Summary of the impact

Atopic eczema affects approximately 30% of children, causing suffering at a crucial time in their development. An increasing prevalence has raised concern that newborn skin care may be a factor. University of Manchester (UoM) research explored the effect of a range of products including commercial baby skin care products on skin integrity. We identified harmful practices related to topical oil use; established that a specially formulated newborn cleansing product was safe; and demonstrated increased maternal-reported nappy rash, when cotton wool and water, as opposed to baby wipes, were used. The findings have: changed the attitudes of healthcare professionals to baby skin care practices; informed the guidance provided to parents of newborns, allowing them to make informed choices (a YouTube video featuring the research has been viewed almost 400,000 times); and increased sales of Johnson & Johnson baby skin care products by 15%.

2. Underpinning research

See section 3 for references [1-6]; see section 5 for corroborating sources (S1-S7); UoM researchers are given in bold. In REF3a and REF5 this case study is referred to as ICS-12.

Skin barrier development in babies remains incomplete until around 12 months of age. This is important, as the thin skin barrier in an infant makes it vulnerable to skin diseases such as atopic dermatitis and napkin dermatitis. It has been reported that around 20% of babies develop atopic dermatitis and 50% develop napkin dermatitis. These problems cause concerns regarding skin care routines for parents and health professionals and led to this comprehensive programme of research.

Key researchers:

- **Dame Tina Lavender** (Professor of Midwifery, 2008-date)
- **Christine Furber** (Lecturer, 1996-date)
- **Carol Bedwell** (Lecturer, 2009-date)
- **Ediri O'Brien** (Research Assistant, 2008-2011)

Our research included: a review of the literature, highlighting the dearth of evidence in this field; a national survey [1] and qualitative study [2], which identified diversity in current skin care practices and beliefs, and inconsistencies in information delivered by health professionals; a pilot randomised controlled trial [3] of water alone for baby cleansing (as recommended by NICE) compared to a baby bathing product or fragrance free wipe, which provided proof of concept and directed the main trials; and the first two adequately powered RCTs of skin care interventions in healthy newborn babies [4, 5].

The two main randomised controlled trials (n=583) are the largest and most robust in this field, the results of which have been adopted by midwives, health visitors, paediatricians and dermatologists. These trials [4,5], which were led by Prof Dame Tina **Lavender**, found no evidence of harm when the two specific commercial products were used, thus supporting the notion of choice for parents and challenging NICE guidelines.

Within this programme we have also conducted a controlled mechanistic study [6] which ascertained the effect of olive oil and sunflower seed oil on the biophysical properties of the skin. This groundbreaking study challenges the belief that all 'natural' oils are beneficial to the skin. In contrast to sunflower seed oil, topical application of olive oil significantly damaged the skin barrier, and therefore has the potential to promote the development of, and exacerbate existing, atopic dermatitis. Based on this research we have recommended that the use of olive oil for the treatment of dry skin and infant massage be discouraged.

The research described is the most comprehensive programme exploring the complexities of skin care practices and newborn health. This research has improved understanding of potentially harmful skin care practices and identified practices that can safely be used, thus supporting parental choice. Importantly, this work has produced the strongest evidence to date of the impact of topical applications on babies' skin and the predisposition to subsequent atopic dermatitis.

3. References to the research

1. Cooke A, Cork MJ, Danby S, **Lavender T**. Use of oil for baby skincare: A survey of UK maternity and neonatal units. *British Journal of Midwifery*. 2011;19(6):354-62. URL:http://www.intermid.co.uk/cgi-bin/go.pl/library/article.cgi?uid=84164;article=BJM_19_6_354_362;format=pdf

2. **Lavender T, Bedwell C, Tsekiri-O'Brien E**, Hart A, Turner M, Cork M. A qualitative study exploring women's and health professionals' views of newborn bathing practices. *Evidence Based Midwifery*. 2009;7(4):112-2. DOI: Missing Paper available from UoM on request

3. **Lavender T, Bedwell C, O'Brien E**, Cork MJ, Turner M, Hart A. Infant skin-cleansing product versus water: A pilot randomized, assessor-blinded controlled trial. *BMC Pediatrics*. 2011;11;35**.** DOI:10.1186/1471-2431-11-35

4. **Lavender T**, **Furber C, Campbell M**, Victor S, Roberts I, **Bedwell C**, Cork MJ. Effect on skin hydration of using baby wipes to clean the napkin area of newborn babies: Assessor-blinded randomised controlled equivalence trial. BMC Pediatrics 2012:12:59. DOI: 10.1186/1471-2431-12-59

5. **Lavender T, Bedwell C**, Roberts SA, Hart A, Turner MA, Carter L-A, Cork MJ. Randomized, Controlled Trial Evaluating a Baby Wash Product on Skin Barrier Function in Healthy, Term Neonates. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*. 2013;42(2):203-14 DOI: 10.1111/1552-6909

6. Danby SG, AlEnezi T, Sultan A, **Lavender T**, Chittock J, Brown K, Cork MJ. Effect of Olive and Sunflower Seed Oil on the Adult Skin Barrier: Implications for Neonatal Skin Care. *Pediatric Dermatology*. 2013;30(1):42-50. DOI: 10.1111/j.1525-1470.2012.01865.x

4. Details of the impact

See section 5 for numbered corroborating sources (S1-S7).

Context

Atopic eczema affects approximately 30% of children, causing suffering at a crucial time in their development. An increasing prevalence has raised concern that newborn skin care may be a factor. Research conducted at UoM dispelled the myth that all 'natural' products are safe and all commercial products are harmful, leading to changes in attitudes among healthcare professionals and impacting on the information provided to new parents. The research informed recent communications campaigns run by Johnson & Johnson (J&J) and as a result has brought about increases in sales of J&J baby skin care products. Furthermore, it has highlighted the need for any products, used on babies, to be subjected to the same research gold standard that is recognised for the use of medicines; currently this is not compulsory.

Pathways to Impact

This research programme, partly funded by J&J, provides an exemplar of the impact of working with industry to obtain clinically meaningful results which can have direct impact on practice. Following publication of the two randomised controlled trials [(4,5], J&J conducted large communication campaigns based on the key findings. Separate campaigns targeted healthcare professionals (e.g., conference presence, direct mail) and new parents (e.g., digital and TV

campaigns, maternity wards, parenting press), leading to the impacts described below (S1).

Reach and Significance of the Impact

Impact on attitudes of healthcare professionals

J&J reports that the campaign targeted at healthcare professionals reached 85% of midwives and health visitors and supporting midwifery and health visiting staff via one or more media (S1). For example, syndicated dissemination of the findings via the Bounty Health Network, which provided face-to-face presentations on the research, reached 12,500 maternity and healthcare professionals (S1). [Text removed for publication.]

Further reach is revealed by the fact that the National Eczema Society is using our research to advise parents and health care professionals on appropriate skin care practices (S2).

Impact on guidelines and training

The trials [4,5] challenge current NICE Postnatal Care Guidelines (due for renewal in 2015), which advocate 'water alone' or 'mild soap' for baby cleansing. The mechanistic study [6] alerts parents to the potential harm caused by certain household oils. Findings from our programme of work have been incorporated into a number of international guidelines, in the USA (*Association of Women's Health, Obstetrics and Neonatal Nursing (AWHONN))* (S3) and Europe (*Update of European Round table Recommendations*) (S4). These updates are a direct result of our findings and are changing skin care practices as revealed by changes in information given to new mothers.

Findings from these studies and reviews have become integrated into a number of national training programmes; of note is inclusion of the studies in the British Journal of Midwifery's Continual Professional Development programme (S5).

Impact on information provided to new parents

National provision of parental information has changed as a direct result of our findings. New information leaflets have been produced with direct reference to our research. These leaflets are provided in Bounty packs, which are distributed in maternity units to every new mother in England. Several units (e.g., Southampton, North Berkshire) (S1) now support women's choice to use these tested products within the hospital.

As a direct result of the research, the baby wipes (sensitive) and bathing product (top-to-toe) packaging has been changed to include direct reference to the trial and a web address linking consumers to the research findings. This provides parents with the confidence that their chosen product is based on a pragmatic clinical trial. J&J refers to our work in product information, advertising and health professional training (S1,S6). A recent YouTube film (S7) featuring our research has received nearly 400,000 hits.

Commercial impact for J&J

[Text removed for publication.]

5. Sources to corroborate the impact

Source

S1. Corroborating statement and supporting documents from Professional Communications Manager, Johnson's Baby UK.
S2. Corroborating letter from Chief Executive, National Eczema Society, UK.
S3. Corroborating letter from Science Team Leader, AWHONN Neonatal Skin Care Evidence-Based Clinical Practice Guideline, 3rd edition (2013) and Neonatal Clinical Nurse Specialist, Children's Hospital & Research Center, Oakland CA, USA.
S4. Corroborating letter from Professor, Department of Dermatology and Allergy, Charité-Universitätsmedizin Berlin, Germany.
S5. Letter from British Journal of Midwifery
S6. Johnson's Baby professional resource http://www.johnsonsbaby.co.uk/healthcare-professional

S7. YouTube video: *What's safe to use on newborn baby skin?*
http://www.youtube.com/watch?v=1gUY6CseAyw