Vulval dermatology database BMedSci project: Protocol
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Study Protocol

Title of Study:	**Vulval dermatology database BMedSci project**
Study Centre:	Centre of Evidence Based Dermatology, University of Nottingham
Duration of Study:	4 months
Primary Objective:	This study will develop a national vulval dermatology database
Secondary Objective:	Obtain consensus from national experts which items are critical to collect with in the database
Rationale:	Vulval skin disorders are common and have considerable impact on quality of life. This area has typically been under researched and underfunded leading to deficiency in evidence-based care and even basic information about the natural history of vulval disorders and their response to treatments.
Methodology:	Survey of clinicians with specialist interest in vulval disease (through the British Society for the Study of Vulval Disease, BSSVD), using Delphi technique, followed by development of database in RedCAP.
Sample Size:	The survey will be circulated to the BSSVD membership, which is approximately 300 clinicians.
Statistical Analysis:	Descriptive statistics will be reported; qualitative free text data will be categorised via NVivo software.

Background:

There are many disorders that specifically affect the vulval area including inflammatory disorders, pain syndromes, premalignant/malignant disease, and infections(1). Lichen sclerosus (LS) is the most encountered inflammatory condition (2). It affects up to 3% of women. Vulval skin conditions are common but accurate incidence and prevalence data are not known. However, in a study of UK General Practitioners, it was demonstrated that over half saw more than 3 patients with vulval disease per month (3). A US community survey of 303 adult females reported one fifth with lower genital tract discomfort lasting longer than 3 months (4).

Vulval skin diseases can affect physical, psychological, and psychosexual wellbeing(4-6). Negative impact can lead to self-harm or suicidal thoughts.

In the UK, there is patchy provision of care and no clear ownership of vulval patients. Delay in diagnosis and unsatisfactory clinical experience are frequently experienced. Patient involvement to describe the lived experience of vulval conditions has highlighted that misdiagnosis from non-specialists, ill-defined care pathways and social stigma/embarrassment preventing people seeking help, are ongoing issues (7).

Vulval disease is a relatively neglected area of women's health which historically has been underfunded and under researched.

Vulval clinics have developed to provide specialist care for women with vulval disease. Management of vulval conditions may present a unique set of challenges. The vulval skin is a combination of keratinised epithelium and non-keratinsed mucosa. It is sensitive and at risk of irritation from local friction, heat, lack of moisture and changes in normal flora. Exposure to urine and faeces can also cause irritation and trigger flares of vulval skin conditions, with delayed response to treatment. Vulval skin conditions can be perceived as embarrassing and can interfere with sexual functioning, self-image and interpersonal relationships. Optimising patient care, patient outcomes and service design depend upon robust data which is currently lacking.

This project looks at data which could be collected routinely during standard clinical practice using a proforma which is already in use at Blackburn Hospital.

The Centre of Evidence Based Dermatology (CEBD) is one of the few places worldwide that specialises in vulval disease research. In collaboration with the British Society for the Study of Vulval Disease (BSSVD), we aim to develop a national database that can be used to record long term routine clinical data collection from vulval clinics. These data will ultimately be used to establish response to treatments and long-term outcomes for patients with vulval skin disorders.

Aim:

To develop a database that will be used nationally to collect data from vulval disease clinics.

Methods:

1. **Survey of BSSVD members**:
    a. There is already a data collection proforma in use in Blackburn Hospital which is completed during usual clinical practice. This is very detailed and contains too much information for the potential future database. To establish which items are critical/important but not critical/not important, we will survey members of the BSSVD to obtain professional opinion, using Delphi technique. An online

survey using Microsoft 'Forms' will be developed. The study team will review the Form and agree on its final content.

    b. Information collected in the survey will include:
   - **i.** Consent of health professional to participate
   - **ii.** Speciality type
   - **iii.** Location of practice (primary/secondary care)
   - **iv.** Whether they see adult and/or paediatric patients
   - **v.** Contact details for further information and potential future rounds of the survey
   - **vi.** Free text information on additional items that are perceived to be missing and overall comments on the database.

    c. The purpose of the survey is to narrow down the current 'long list' of items in the Blackburn proforma and establish which of the proforma items are considered 'critical, 'important but not critical' and 'not important' to collect for the purposes of the database. This will create a 'short list' of items to take forward into the database.

    d. 2 rounds of Delphi technique will be performed to narrow the list down. Items which do not reach 75% consensus of either 'critical/important but not critical/not important' will be put into the second round of the survey. Any free text 'additional items' suggested by participants will be qualitatively analysed and added to round 2. This time participants can see the anonymised answers from round one and asked to rate the items again.

    e. The survey responses will be anonymous.

    f. The survey will be circulated via the BSSVD Members mailing list.

    g. Free text data will be analysed by categorising using thematic analysis.

2. **Development of database using REDcap software:** With support of the Clinical Database Support System (CDSS) an online database using REDCap (Research Electronic data Capture) software will be developed. Domains/items established during the clinician survey will be used as the basis for the database.

    a. No clinical data will be entered at this time. Ethical approval will be sought separately for this later and is not within scope of this BMedSci project.

Outputs and dissemination:

Functioning database that can be used in the future to enter routine clinical data from vulval clinics.

Opportunity to present work at National conference and publish work in peer reviewed journal.

Newsletter to participants and BSSVD members detailing the output.

References:

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