Skin in the game:
Skin issues and Diabetes Technologies

Dr Sufyan Hussain **MA MB Bchir MRCP PhD**

Honorary Senior Clinical Lecturer, King's College London (UKRI/MRC CARP scheme)
Consultant Physician in Diabetes, Guy's and St Thomas' NHS Foundation Trust
Honorary Consultant Physician, King's College Hospital NHS Foundation Trust

Joint Vice-chair, Association of British Clinical Diabetologist's Diabetes Technology Network
Director, International Diabetes Federation Europe

@sugarydoc

Disclosures

The content presented is my own work.

I have delivered non-promotional continuing medical education activities, consultancy and advisory boards in the past for Insulet, Medtronic, Tandem, Roche, Abbott, Dexcom, Vertex.

I have unpaid roles in the following organisations which receive industry sponsorship:

Association of British Clinical Diabetologist, Diabetes Technology Network (vice-chair)

International Diabetes Federation Europe (director)

I was the specialist committee lead for the National Institute for Health and Care Excellence (NICE) multiple technology appraisal on hybrid closed loops in England.

I have > 30 years personal experience of living with diabetes.

Summary

Skin issues in diabetes tech

Why do we need to know about them?

What are they?

- Adhesive dermatitis
- Contact dermatitis

How to manage?

How to identify and investigate?

What to do?

Where next?

What to check in consultations

General advice and sensor hygiene

Legislation

Common issues with adhesion and devices

Practical	Clinical
Does not stick	Hypersensitive reactions
Falls off easily - heat and climate	**Allergic reactions**
Pain on insertion	**Contact dermatitis**
Bleeds at insertion site	Pressure induced sensor attenuation (PISA)
Chronic dry ness	Infections
Leaves prolonged red marks	Blistering
	Scaring
	Lipodystrophy

These are barriers to continuing devices

Discontinuation and skin issues can impact glycaemia & emotions negatively

Observational studies and data from trials

Prevalence:

Systematic review: 70% of CGM users experience a reaction at some point

CGM-related issues worse than infusion sets

Reasons for discontinuation:

Adults 42%

Children 40%

Higher odds if:

Prior reaction to adhesive

Longer wear

History of atopy

Issue	*N* trials and participants	*N* complications	% of Each issue
Sensor wear related	complications		
Erythema	Seven trials of 584 people	319 Issues over 38.5 weeks	55.2
Pruritus/itching	Five trials of 548 people	65 Issues over 35.3 weeks	11.2
Induration	Three trials of 549 people	49 Issues over 33 weeks	8.5
Edema	Four trials of 436 people	40 Issues over 29.15 weeks	6.9
Rash	Two trials of 328 people	37 Issues over 32 weeks	6.4
Bruising	Five trials of 552 people	33 Issues over 37.5 weeks	5.7
Allergic reaction	Four trials of 388 people	25 Issues over 65.29 weeks	4.3
Skin infection	Four trials of 170 people	Four issues over 27.1 weeks	0.7
Dry skin	Two trials of 96 people	Three issue over nine weeks	0.5
Cellulitis	One trial of 322 people	Two issues over 26 weeks	0.3
Collection	One trial of 76 people	One issue over eight weeks	0.2

Asarani et al 2019 JDST, Berg et al 2018 DTT, Berg et al 2018 Peds Diab

Contact Irritation (Irritant Contact Dermatitis or ICD)

Direct damage to skin via chemical or mechanical agents

Non-immune inflammatory response

Influenced by temperature, humidity and duration of exposure

Irritant contact dermatitis - presentation

Redness

Excoriation

Burning/ Stinging

Bleeding

Scabbing

Allergic contact dermatitis

Contact allergy

Hypersensitization of the immune system in response to a chemical agent in the adhesive

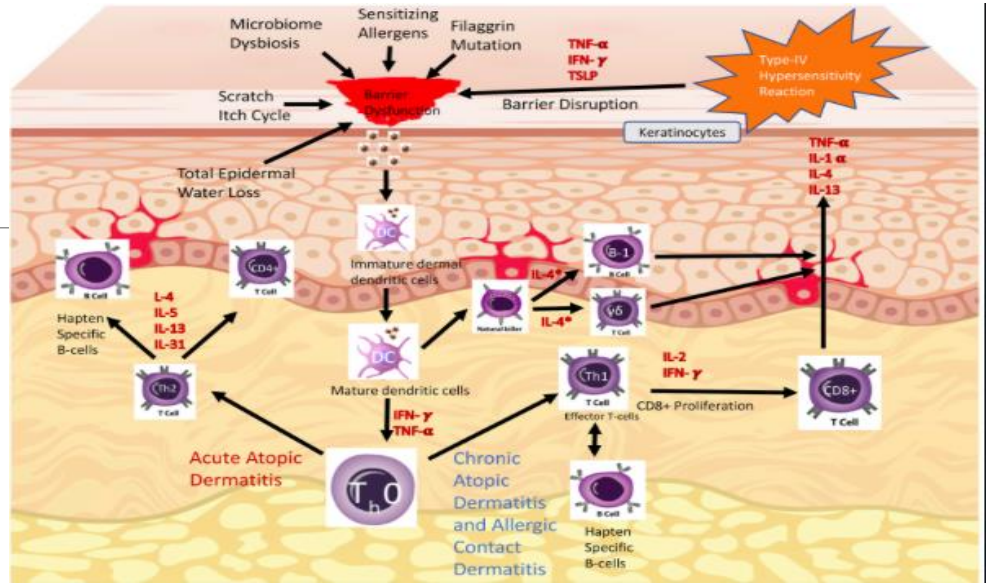
Delayed (type 4 sensitivity T-cell mediated)

Onset can be weeks to years after first exposure

Permanent sensitization

0.7-5% sensor users (estimated perveance)

Hyry et al 2019, Contact Derm



Presentation

Redness

Swelling

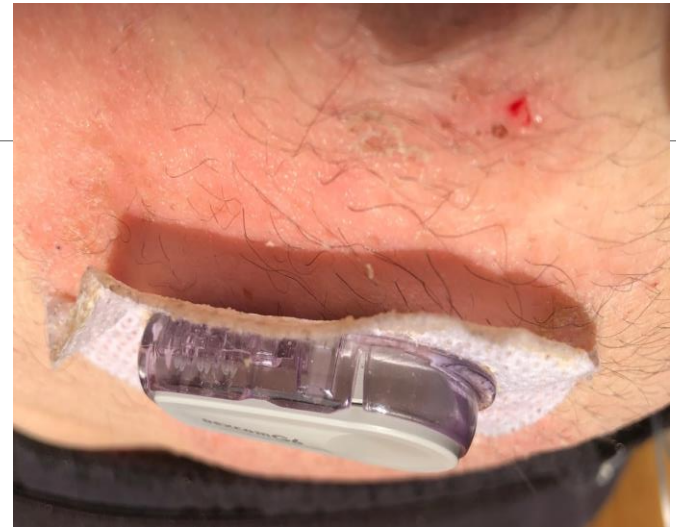
Vesiculating, blistering

Oozing

Intensive itching

Rash/ spreading irritation beyond borders of tape

(different devices contain different agents in their adhesives)



Different devices = allergens

Allergen	Found in…
Colophonium	Tapes, cosmetics, soaps, ink
Isobornyl acrylate (IBOA)	Coatings, adhesives, paints. More recent problem with longer duration of wear
Ethyl cyanoacrylate	Instant glue, eyelash glue, liquid wound closure, acrylic nails
N,N dimethylacrylamide	Coatings adhesives, synthetic fibers
Other: preservatives, fragrances, metals	


CONTACT DERMATITIS
ENVIRONMENTAL AND OCCUPATIONAL DERMATITIS

ORIGINAL ARTICLE

Allergic contact dermatitis caused by glucose sensors in type 1 diabetes patients

Heli S. I. Hyry, Jussi P. Liippo, Hannele M. Virtanen

First published: 17 June 2019 | https://doi.org/10.1111/cod.13337 | Citations: 6

1 Hyry et al (2019) Contact Derm 81:161-166
2 Raison-Peyton (2018) Contact Derm DOI:10.111/cod.12995

CONTACT DERMATITIS

Isobornyl Acrylate and Diabetic Devices Steal the Show for the 2020 American Contact Dermatitis Society Allergen of the Year

Cutis. 2020 June;105(06):283-285 | 10.12788/cutis.0014

By Neel Nath, MD; Margo Reeder, MD; Amber Reck Atwater, MD

IBOA in FL
↑ Duration of use
↑ Use of the devices
↑ Awareness of ACD and allergen

Device	Allergen	Reference
Omnipod	IBOA (pod itself), Colophonium	*doi: 10.1111/cod.12995*
Libre	IBOA (housing), N,N dimethylacrylamide	*doi: 10.1111/cod.13337* *doi.org/10.1111/cod.12866* *doi.org/10.1089/dia.2019.0163*
Dexcom G4	Ethyl cyanoacrylate	*doi.org/10.1177/1932296817738076*
DexCom G5	Early sensors: Ethly cyanoacrylate	*doi.org/10.1177/1932296817738076*
DexCom G6	(Negative for IBOA)	*doi.org/10.1089/dia.2019.0163*
Enlite CGM	Colophonium, IBOA (housing)	*doi: 10.1111/cod.13337* *doi.org/10.1089/dia.2019.0163*
Eversense	(Negative for IBOA)	*10.1111/cod.13392*
Duoderm Extra Thin	Colophonium	*doi: 10.5021/ad.2011.23.S3.S387*
Mastisol	gum mastic, Styrax liquid or methyl salicylate?	*doi: 10.3827/faoj.2008.0102.0002*

Irritant (ICD) vs Allergy (ACD): can you tell the difference?

Hard to tell the difference clinically

80% Irritant

20% allergic

Not mutually exclusive – ICD can increase antigen exposure leading to ACD

Soft features :

-irritant: milder redness, burning (no erosions)

-allergy: intensive itching, tense papules, vesicles, spreading outside adhesive area

- may take months to develop
- Subsequent exposure produces immediate reactions
- Worsens with subsequent exposure
- If barrier adhesive not working, probably ACD

NEED PACTH TESTING for definitive diagnosis

Heinemann et al, 2016, JDST, Aerts et al 2017, Lancet

Patch Testing

Controlled elicitation reaction

Patch tests applied D0 – D2 and D4 readings +/- D7

Positive reaction – palpable erythema +/- vesicles

Standard series +/- additional

Patch testing – Medical device series?

STANDARD SERIES

Colophononium

Epoxy Resin Mix

2-Hydroxyethyl Methacrylate (HEMA)

Nickel

Sesquiterpene Lactone Mix

Fragrances

ADDITIONAL TESTING

IBOA (0.1% +/- 0.3%)

Ethyl Cyanoacrylate (ECA)

N,*N*-dimethylacrylamide (DMAA)

Methacrylate series

Negative patch testing?

Caution re a diagnosis of ICD

- ? Right concentration allergens
- D7 testing
- Components tested as is?
- ? Unidentified allergen (ultrasound bath extraction techniques)

How to assess clinically

A photo

Assess reaction site – cannula entry or adhesive area

Classify the reaction - location, erythema, pain, bleeding, blistering, itch, lump, discharge, systemic symptoms

History of allergies (skin, asthma, hayfever)

When does the reaction occur – immediately or after a time

Review skin preparation

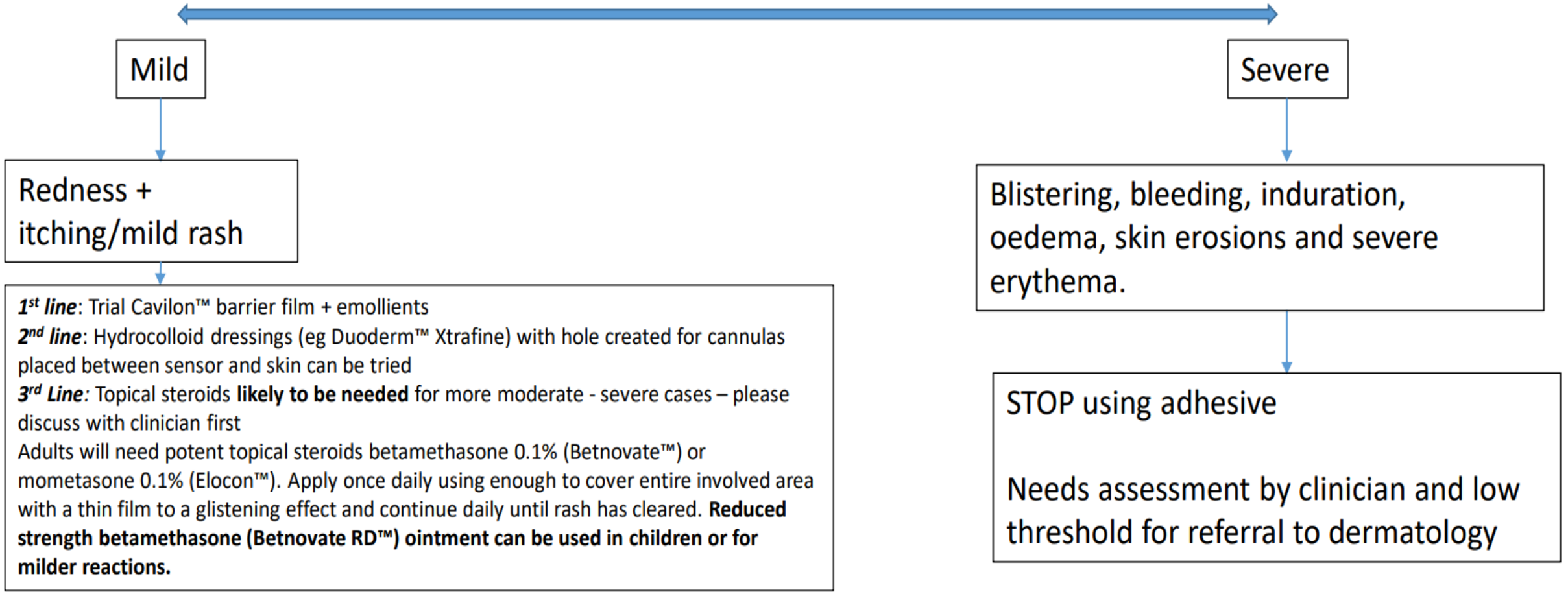
Home treatments?

Have other sites been tried

Report to MHRA via the Yellow Card

Action

3. Management based on severity of reaction:



Jointly developed at GSTT with Diabetes and Dermatology Team

Prevention

- ? Applying a thin hydrocolloid dressing between skin and adhesive part of sensor

Investigation

- Patch Testing:
  - Standard, medical device series, components of the system

Management

- Potent topical cortico steroid
- Allergen avoidance (frequent multiple sensitizations)
- Trial of barrier films (eg Cavilon); Hydrocolloid dressings
- Use testing of adhesives
- Device switching?
  - ❖Degree of sensitization
  - ❖Allergen concentration
  - ❖Duration of contact

Barrier/skin prep

- Topical steroid
  - fluticasone
  - hydrocortisone
- Chemical barrier preparation
  - Skin prep
  - Skin tac
  - Cavilon
- Tips:
  - Let preps DRY completely before insertion
  - Can insert pump/sensor through preps OR leave circle of clean skin for insertion

Skin Adhesive Wipes

- Aid securing the sensor and preventing early detachment
- Apply using bullseye method

Skin Tac– aids adhesion, latex free, hypo allergenic (often used with Tac Away) *(Torbot Group/Mason Labs)*

IV Prep– prepare , aids adhesion, good in humid climates or people who sweat *(Smith and Nephew Inc)*

No Sting Skin Prep– protects from irritation between skin and adhesive *(Smith and Nephew Inc)*

Skin Prep - protects from adhesive irritation between skin and adhesive (Smith and Nephew Inc)

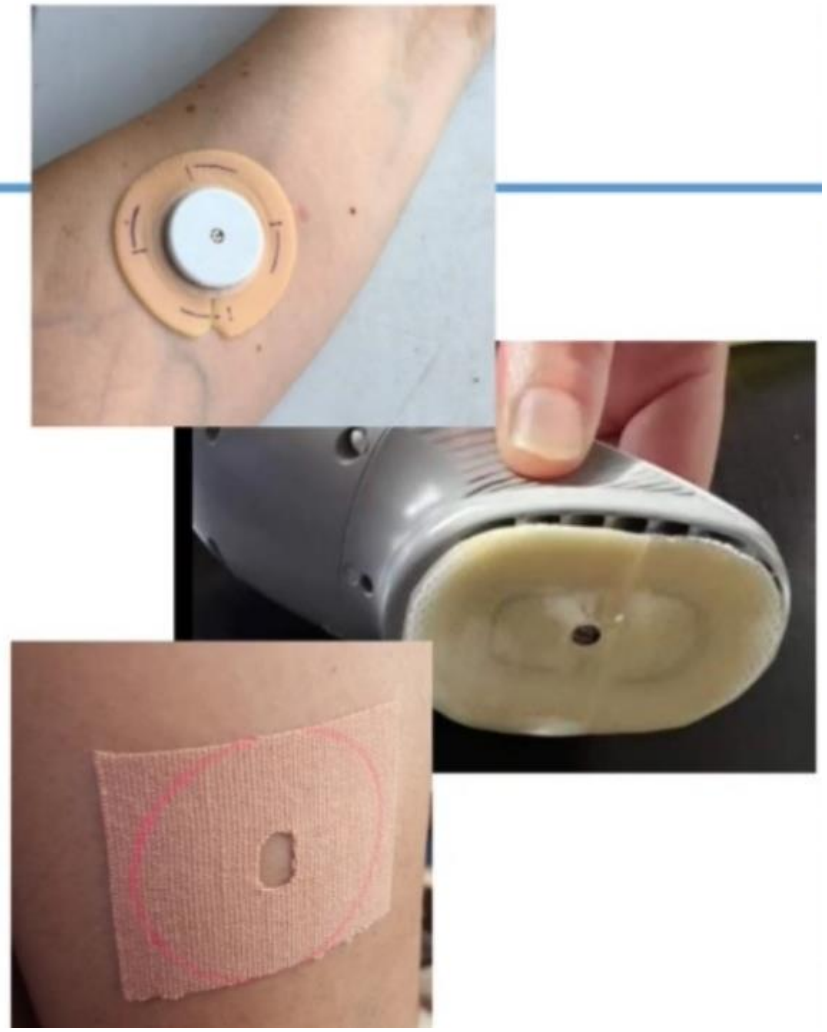
Physical barriers

- Hydrocolloid bandages
- Kinesiotape bandages
- Transparent films

CONSIDER: exposure to more chemicals may increase rick of new hypersensitivity (DuoDerm, mastisol, etc.)

TIPS:

- Many reports of inserting sensor through tape, others cut a hole



Tapes

Hypafix™ Tape *by BSN Medical*	Non-woven fabric made from white polyester material and coatec with hypoallergenic adhesive on quick-release backing paper. **Note:** Not available to purchase through Medtronic.
IV3000™ Tape *by Smith & Nephew, Inc.*	Transparent moisture responsive film dressing.
Infusion Set IV3000™ Tape *by Smith & Nephew, Inc.*	Transparent tape dressing with a customized design to fit around the Quick-set™, Silhouette™, Sure-T™, and Mio™ infusion sets. Made with the same adhesive and film as IV3000™ Tape.
Mastisol ® Adhesive *by Ferndale Laboratories, Inc.*	Clear, non-irritating liquid adhesive. Consider using Detachol® Adhesive Remover with this product.
Polyskin™ II Transparent Dressing *by Covidien*	Moisture Vapor Permeable transparent tape to keep the skin dry and more comfortable at the insertion site.
StayPut™ Patch *by StayPut™ Medical, LLC*	These overlay patches are water-resistant, breathable and flexible to help keep medical devices secured to the body.
Tegaderm™ HP Transparent Film Dressing	Clear tape dressing that adheres well when exposed to moisture.

Source: Medtronic

Supplemental adhesive

- **Kinesiotape tape** (Simpatch, Grifgrips, Rocktape, Rockadex)
- **Cloth tapes** (Hypafix)
- **Elastic bandage** (Ace, coban)
- **Transparent films** (IV3000, Tegaderm, Opsite)
- **Non-adhesive:** (Arm bands, plastic covers)
- Tips:
  - Can cut into strips to supplement sections
  - Dexcom will mail “oval tape” if asked

Switch to another product!

Difficult to know what is in adhesives

Devices need to have fuller disclosure/ better labelling of ingredients AND when ingredients change

Devices should also have different adhesive options eg sensitive skin options

NB

- CSII / HCL funding and issues with switching….
- Cross-sensitisation can also occur

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CASE 1

40 year old female

T1DM since 1997

Medication History:

Humalog via CSII

Irbesartan 150 mg od

Levemir (emergency use)

Other Diagnosis:

Factor V Leiden

Pulmonary Embolism

Reaction to Omnipod Pump, Improved since started using an out-of-warranty Medtronic pump

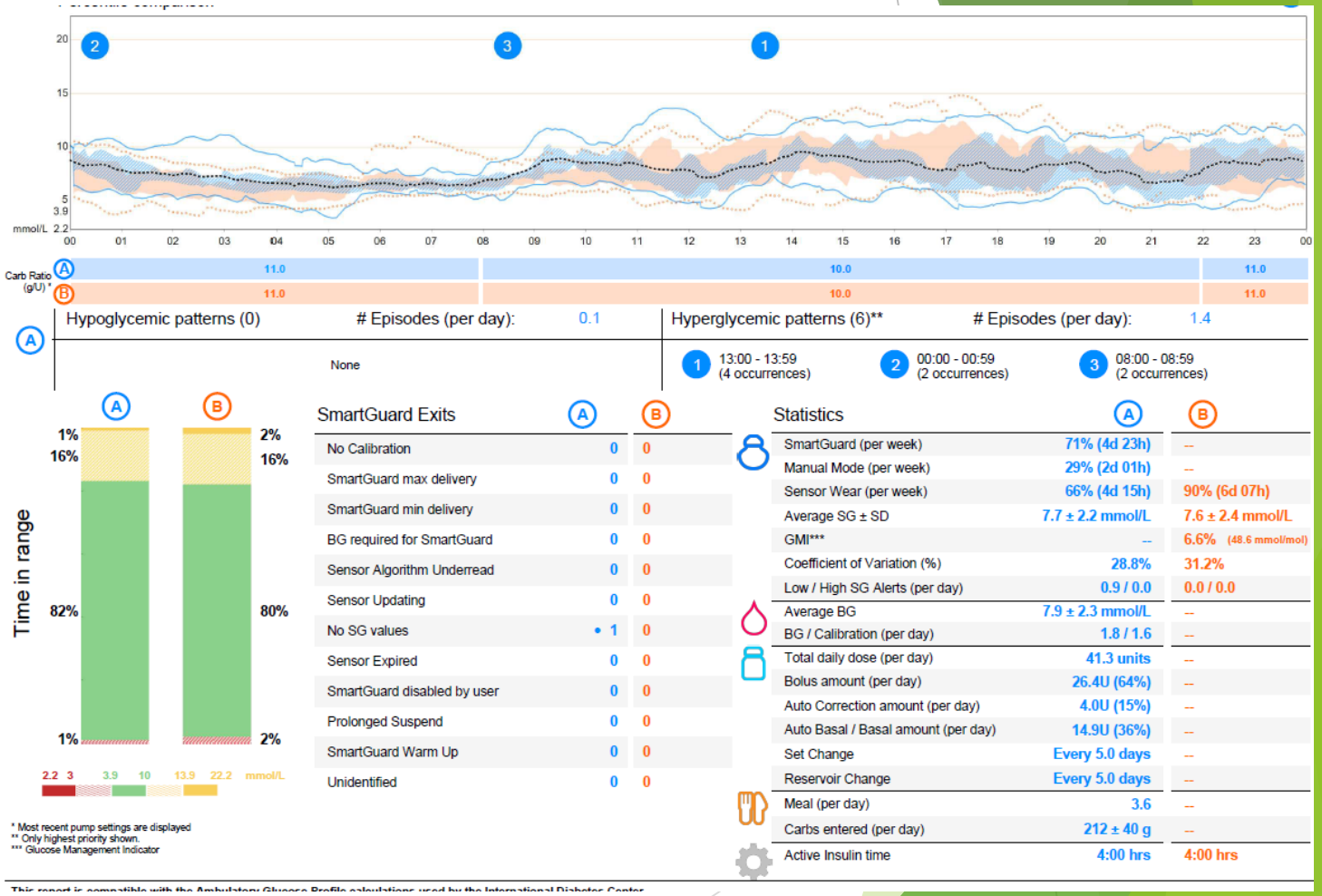
Similar reaction to Free Style Libre and changed to Dexcom G6

Skin reactions ? IBOA (Adhesive)-> Referred to dermatology → patch testing confirmed

- **CASE 2**
- 40 yo T1 DM for 32 years
- Co-morbidities RhA (adalimumab + HCQ); PCOS
- ?Paradoxical psoriasis 2◦ TNFai
- Free style Libre → frequent symptomatic hypos
- Using 640G predictive low glucose suspend with enlite sensors

Next?

- Use of Medtronic GS3 with modifications – mepore, gauze
- Commenced on 780G



General adhesive hygiene and tips

Assess skin at every visit

How do they insert? - Revise technique – correct preparation important

- Sites – avoid natural bends, irritation from clothing, hardened areas, scars, stretch marks, lipos
- Avoid using oils, lotions, alcohol wipes or abrasives
- Body hair trimmed ideally
- Additional adhesives needed? Increase allergen exposure

How do they remove it? – Revise technique

- Do not extend the sensor/ cannula beyond the intended use
- Careful removal: under shower (soften) or use removal agents (oil products), slow and careful removal
  - Baby Oil
  - Tac Away – wipes (Torbot and Masons Lab)
  - Detachol Adhesive remover – liquid (Ferndale Lab inc)
  - UNI-SOLVE Wipes (Smith and Nephew)
- Site rotation to allow healing
- Use cream/ lotions – skin emollients (neutral PH), avoid disinfectants
- (Hydrocortisone only if prescribed otherwise skin atrophy)

Medical devices – Legislation change needed

A medical device (MD) is defined as any instrument, equipment, material, or product intended to be used in humans for medical purposes, the main action of which is not of a pharmacological or immunological nature

Future legislation:

- Mandatory ingredient labelling
- Legal responsibility to use chemicals with lower sensitization capacities
- Switch when threshold prevalence of ACD is identified
- Requirement to provide details of chemical compositions to medical/scientific investigators?

Summary

- Adhesive issues with diabetes devices are COMMON and will be more prevalent as devices are used more often and for prolonged periods
  - Assess sites and insertion/ removal techniques every visit
  - If issues emerge, examine or review a picture, with history
  - Liaise with your dermatology team to form a pathway for patch testing
  - Trial different management options - prolonged exposure makes the problem worse and cross-sensitization can occur
- LEGISLATION CHANGE NEEDED to ensure device manufacturers declare adhesive agents used

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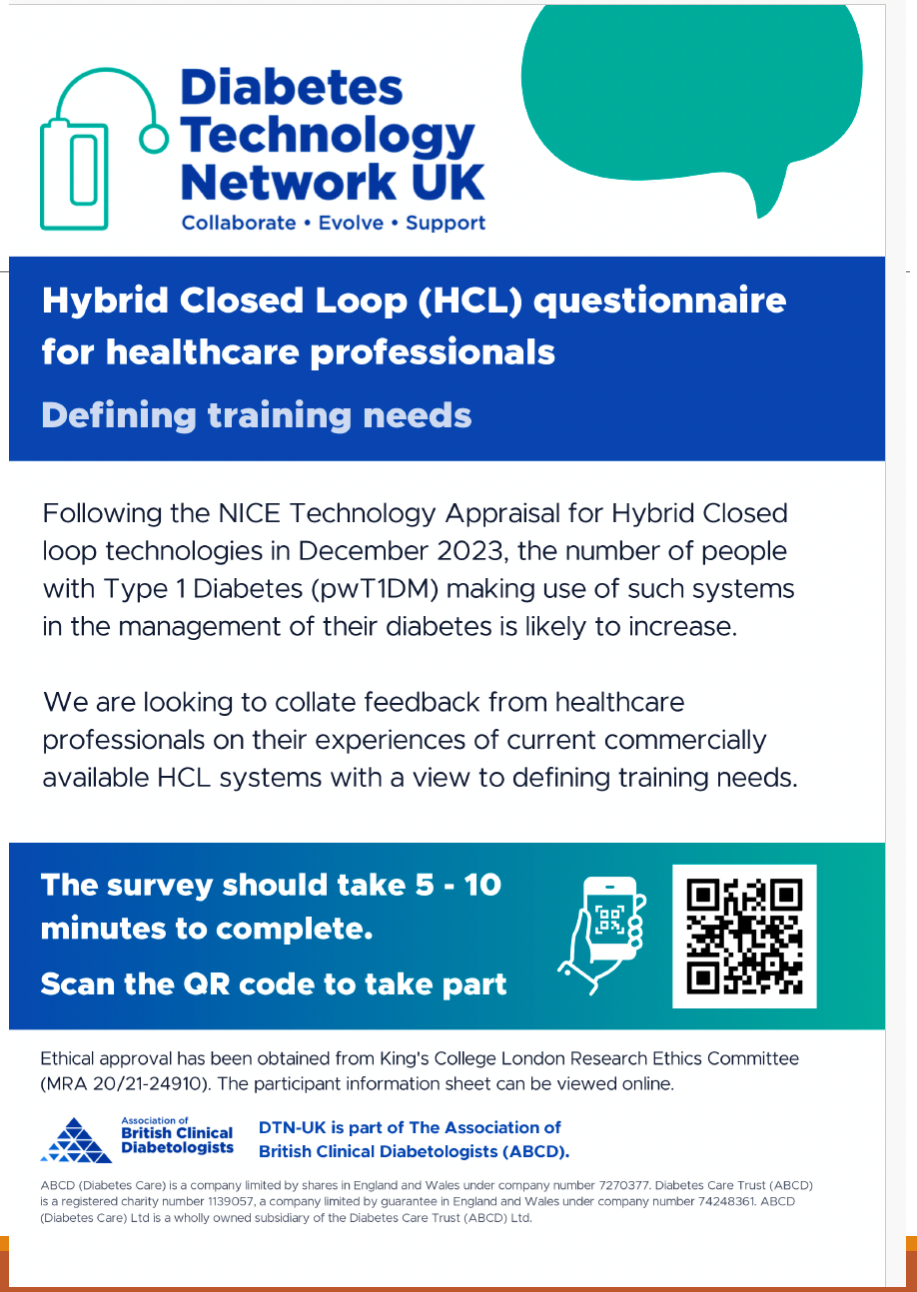
Diabetes Technology Network UK
Collaborate • Evolve • Support
Hybrid Closed Loop (HCL) questionnaire for healthcare professionals
Defining training needs
Following the NICE Technology Appraisal for Hybrid Closed loop technologies in December 2023, the number of people with Type 1 Diabetes (pwT1DM) making use of such systems in the management of their diabetes is likely to increase.
We are looking to collate feedback from healthcare professionals on their experiences of current commercially available HCL systems with a view to defining training needs.
The survey should take 5 - 10 minutes to complete.
Scan the QR code to take part
Ethical approval has been obtained from King's College London Research Ethics Committee (MRA 20/21-24910). The participant information sheet can be viewed online.
Association of British Clinical Diabetologists
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