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Patron: The Rt Hon Lord Fowler

3 October 2012

Mr Ife Akinbolaji Coordinator - Interventional Procedures National Institute for Health and Clinical Excellence MidCity Place 71 High Holborn London WC1V 6NA

Dear Mr Akinbolaji

BHIVA response to NICE on Interventional Procedures Consultation - IP622/2 Deep dermal injection of non absorbable gel polymer for HIV-related facial lipoatrophy

Thank you again for your consideration and the extended deadline for the British HIV Association to make its comments on this consultation. Please see below remarks on the NICE Interventional Procedures Consultation – IP622/2 Deep dermal injection of non absorbable gel polymer for HIV-related facial lipoatrophy.

Treating HIV-related lipoatrophy by injecting a non-absorbable gel polymer BHIVA response: "Specifically the earlier drugs used in treatment, which are rarely used now – failure to mention this may give the reader the impression that this is still a not uncommon problem with newer HIV agents (which it is not)."

- 1.1 Current evidence on the efficacy of deep dermal injection of non-absorbable gel polymer (NAGP) for HIV-related facial lipoatrophy is adequate. BHIVA response: "BHIVA would argue that it is 'limited' and restricted to single centre reports using differing NAGP's, different procedures, and rarely comparing treatment methods. Data on comparisons of NAGP's is rare and there is limited evidence of long-term efficacy and safety."
- 1.1 Therefore, this procedure should be performed only with special arrangements for clinical governance, consent and audit or research. BHIVA response: "Ordinarily, this would only be performed by plastic surgeons with the appropriate specialty certification."
- 1.3 Clinicians using this procedure should be trained in the technique of injecting non-absorbable gel polymers

BHIVA response: "There should be evidence of training as opposed to trained and a competency assessment made as above."

- **1.3** Injection should be carried out with strict aseptic technique in an appropriate environment because patients with HIV are commonly immunocompromised. BHIVA response: "By definition they are immunocompromised – anyway, this comment has no bearing as any injectable procedure should be carried out using universal infection control precautions and under strict aseptic technique.
- **2.1.1 Prolonged treatment with highly active antiretroviral therapy for HIV...** BHIVA response: "Incorporating in particular the thymidines nucleosides."
- 2.1.1 ... central parts the body (predominantly over the abdomen).

BHIVA response: "The process of fat loss and fat accumulation are different – lipoatrophy only relates to fat loss. This is an important distinction to make to avoid confusion."

2.1.1 It usually persists after HIV treatment has stopped.

BHIVA response: "In severe cases, restoration of fat after switching away from the causal drugs is likely to be incomplete. – It's not that the process persists but that the visible return of fat is often imperceptible"

2.1.1 Facial lipoatrophy is commonly seen after HIV treatment.

BHIVA response: "Again, there needs to be specific mention of the responsible drugs otherwise the wrong impression is given to the reader."

- 2.2.2 The procedure is performed under general or local anaesthesia. Non-absorbable gel polymer is injected with a needle or cannula, deep into the subcutaneous tissue. Strict aseptic technique is used and prophylactic antibiotics are given. BHIVA response: "The evidence for this is limited? Advise 'consideration for..' "
- 2.4.1 Infection (confirmed by culture) was reported in 16% (5/32) of patients in the cohort study

BHIVA response: "Should reference Clin Infect Dis 2012 September 24th where infectious complications in 267 patients treated with Polyalkylimide (Bio-Alcamid) and Plast. Reconstr. Surg. 129: 101, 2012 which quotes infectious complications on 141 patients treated with polyacrylamide gel. Also systematic review in AIDS patient care STDS 2009."

Yours sincerely

Professor Jane Anderson Chair British HIV Association (BHIVA)