NHS England

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12th September 2016

Dear Mr. Barkley,

Regulation 28 report: James Michael Hedge

Thank you for your Regulation 28 report of 27 July 2016 regarding the sad death of James Hedge. On behalf of NHS England I would like to express our sympathy to the Hedge family.

NICE has advised[1] that insulin pump therapy should only be started by a trained specialist team and that this team should provide structured education suitable for people using insulin pumps.

NICE's guidance on structured education[2], which has just been updated and reissued, cross-refers to the Department of Health's Patient Education Working Group report[3]. This advises that, in order for insulin pump therapy to be successful, people with diabetes need to understand how to use the technology and how to use insulin management skills, including structured self-testing.

Structured education from a specialist team for those who use insulin pumps should therefore include education on the risk of diabetic ketoacidosis, particularly if the insulin pump should malfunction or the device is not used correctly. More generally, structured education should also cover the management of hyperglycaemia, including supporting individuals to recognise when hyperglycaemia may be arising, when and how to test for it, and what action to take if ketone levels are elevated.

NHS England is currently reviewing how greater take-up and consistency of structured education can be supported and the issues of key content in relation to the risks from incorrect use of insulin pumps and the management of hyperglycaemia will be considered as part of this.

I note that the Medicines and Healthcare Products Regulatory Agency (MHRA)

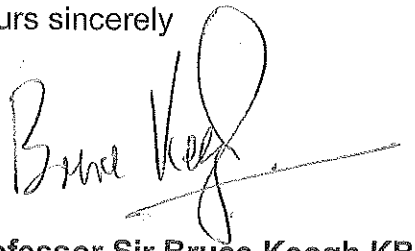
[1] Technology Appraisal 151 https://www.nice.org.uk/guidance/ta151
[2] https://www.nice.org.uk/guidance/qs6/chapter/Quality-statement-3-Structured-education-programmes-for-adults-with-type-1-diabetes
[3] http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4113195

has also been asked to respond to your report. I understand that the MHRA has recently issued a Medical Device Alert in relation to a specific brand of insulin pump[4], advising that 'cartridges inserted incorrectly can leak insulin into the cartridge compartment, resulting in an under-delivery of insulin, which may lead to rapid deterioration of health, diabetic ketoacidosis or death'. The MHRA has advised that this should be brought to the attention of all healthcare workers responsible for patients who use such pumps and has set out a range of distribution routes recommended to those responsible for circulation of its device alerts.

Taken together, the planned actions on structured education and the advice on specific devices should help support a greater awareness of the risks in relation to insulin pumps, and a greater understanding by healthcare professionals and by patients of the steps they need to take.

Thank you for bringing this important issue to my attention. I hope that you are reassured that this organisation is taking appropriate steps to address the concerns as detailed in your report.

Yours sincerely



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[4] https://www.gov.uk/drug-device-alerts/accu-chek-insight-insulin-pump-system-manufactured-by-roche-diabetes-care-with-novorapid-pumpcart-cartridges-risk-of-hyperglycaemia