NICE National Institute for Health and Care Excellence

Surveillance report 2016 – Alcohol-use disorders: diagnosis and management of physical complications (2010) NICE guideline CG100

Surveillance report

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Contents

Surveillance decision

We will plan an update of the following section of the guideline:

- Corticosteroid treatment for alcohol-related hepatitis

Reason for the decision

We found 11 new studies relating to corticosteroid treatment for alcohol-related hepatitis through focused surveillance search of this guideline. New evidence that could affect recommendations in this area was identified. Topic experts advised us about whether the following section of the guideline should be updated:

Corticosteroid treatment for alcohol-related hepatitis

- In patients with acute alcohol-related hepatitis, what is the safety and efficacy of corticosteroids versus placebo?
    - What is the safety and efficacy of corticosteroids for acute alcohol-related hepatitis?

The STOPAH trial (funded by the National Institute for Health Research [NIHR]) was identified which evaluated the effect of treatment with prednisolone or pentoxifylline in patients with alcoholic hepatitis and severe disease in the UK. The results indicated that prednisolone was associated with a reduction in 28-day mortality that did not reach significance but was associated with significantly more serious infections. At 90 days and 1 year there were no significant differences in mortality rates between the treatment groups. This new evidence appears contradictory to the evidence included in the guideline as steroids were associated with a significant reduction in both all-cause mortality at 1 month and 6 months and liver-related mortality follow-up at 1 month in people with severe hepatitis. At the time of development, the Guideline Committee were aware of the ongoing STOPAH trial and had the view that the results of the trial would further inform the best treatment approach for these patients.

The results of the STOPAH trial were considered alongside evidence identified at previous surveillance reviews and from a focused search of the question. Overall, the new evidence available from the recently published STOPAH trial in addition to the studies identified

through previous surveillance reviews suggest that recommendation 1.3.3.1, which states that people with severe acute alcohol-related hepatitis and a discriminant function of 32 or more should be offered corticosteroid treatment, may no longer be justified. Feedback from topic experts indicated that the current recommendation on corticosteroids for acute alcohol-related hepatitis should be revisited in light of the data from the STOPAH trial.

Topic experts also highlighted that the Cochrane Hepato-Biliary group is currently in the process of updating several reviews in this area (focusing on analyses of prednisolone and of pentoxifylline) and that it would be useful to time an update to coincide with publication of these updates. Current information from the Cochrane Hepato-Biliary group indicates that publication of these Cochrane reviews is imminent.

Decision: This review question should be updated. The timing of the update should consider the publication of relevant Cochrane reviews in this area by the Cochrane Hepato-Biliary group.

Other clinical areas

This exceptional surveillance review was carried out to allow us to consider the impact of the STOPAH trial results on the guideline recommendations. We did not search for new evidence relating to other clinical areas in the guideline as part of this focused surveillance.

Overall decision

After considering all the new evidence and views of topic experts, we decided that a partial update is necessary for this guideline.

See how we made the decision for further information.

How we made the decision

Exceptionally, significant new evidence may mean an update of a guideline is agreed before the next scheduled check of the need for updating. The evidence might be a single piece of evidence, an accumulation of evidence or other published NICE guidance. We based the decision on an exceptional surveillance review of corticosteroid treatment for alcohol-related hepatitis to consider the impact of the NIHR-funded STOPAH trial on the recommendations for corticosteroid treatment. Stakeholders informed us that the results of the STOPAH trial had published and felt that this new evidence was significant and could have an impact on guideline recommendations.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual'.

Previous surveillance update decisions for alcohol-use disorders (2010) NICE guideline CG100 are on our website.

New evidence

We found 4 new studies in a search for randomised controlled trials and systematic reviews relevant to corticosteroid treatment for alcohol-related hepatitis published between 1 November 2014 and 21 January 2016.

Evidence identified in previous surveillance 2 and 4 years after publication of the guideline was also considered. This included 7 studies identified by search.

From all sources, 11 studies were considered to be relevant to corticosteroid treatment for alcohol-related hepatitis.

See appendix A: decision matrix for summaries and references for all new evidence considered.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline.

Views of stakeholders

Stakeholders are consulted only if we decide not to update the guideline following checks at 4 and 8 years after publication. Because this was an exceptional surveillance review to consider the impact of the STOPAH trial on the recommendations on corticosteroid treatment for alcohol-related hepatitis, and the decision was to update, we did not consult on the decision.

See ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual' for more details on our consultation processes.

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The NICE project team would like to thank the topic experts who participated in the surveillance exceptional review.