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A Change in the NICE Guidelines on Antibiotic Prophylaxis

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A Change in the NICE Guidelines on Antibiotic Prophylaxis

In Brief:

- NICE guidelines on antibiotic prophylaxis have recently changed
- This change now makes clear that in individual cases, antibiotic prophylaxis may be appropriate.

Abstract:

Since 2008, NICE clinical guidelines have stated "Antibiotic prophylaxis against infective endocarditis is not recommended for people undergoing dental procedures." This put UK guidance at odds with guidance in the rest of the world, where antibiotic prophylaxis is recommended for patients at high-risk of infective endocarditis undergoing invasive dental procedures. Many dentists also felt this wording prohibited the use of antibiotic prophylaxis, regardless of the wishes of the patient or their personal risk of infective endocarditis and made it difficult for them to use their clinical judgment to deliver individualized care in the best interests of their patients. NICE have now changed this guidance to "Antibiotic prophylaxis against infective endocarditis is not recommended routinely for people undergoing dental procedures". This article examines the implications of this small but important change.

Introduction:

This article discusses the implications of this change and provides practical advice about when antibiotic prophylaxis may be appropriate

You would be forgiven for missing it, because it was announced without any fanfare, but in July this year NICE made a small but extremely important change to Clinical Guideline 64 (CG64), "Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures". Recommendation 1.1.3, "Antibiotic prophylaxis against infective endocarditis is not recommended for people undergoing dental procedures" (or other non-dental procedures) has now been changed to "Antibiotic prophylaxis against infective endocarditis is not recommended **routinely** for people undergoing dental procedures". The addition of the word "routinely" is of considerable importance. As pointed out by Sir Andrew Dillon (CEO of NICE) in a letter confirming the change, "This amendment should now make clear that in individual cases, antibiotic prophylaxis may be appropriate".

This is an important and welcome change. Previously, many dentists felt that the wording prohibited the use of antibiotic prophylaxis, regardless of the views of the patient or their personal risk of infective endocarditis. This change makes it clear that in circumstances where the risk of infective endocarditis posed to the patient is perceived to be sufficiently high, or when the patient themselves expresses a preference for it, antibiotic prophylaxis may be appropriate.

This change follows a review of the NICE guidelines in 2015 which was

precipitated by a study published in the Lancet² and concluded that there was insufficient evidence to change the guidance.¹ Several papers and letters published in the BDJ³⁻⁵ subsequently made the case that it was inappropriate to withhold antibiotic prophylaxis from patients at high-risk of infective endocarditis, particularly in light of a recent change in the law concerning informed consent.⁶⁻⁸ This change places an onus on clinicians to identify patients at increased risk of infective endocarditis, explain the risk and ways in which it can be reduced (including antibiotic prophylaxis), and then allow them to decide for themselves if they want antibiotic prophylaxis or not.⁴ In addition, two widows whose husbands died from infective endocarditis following hygienist visits for dental scaling have been petitioning NICE with the support Chris Philp MP for Croydon South. The change in guidance was first mentioned in a letter to Chris Philp on 28th June 2016 and appeared shortly afterwards on the official NICE web site. The change in wording now allows clinicians to comply with the new law on consent and another important statement in the NICE guideline, "Doctors and dentists should offer the most appropriate treatment options, in consultation with the patient and/or their carer or guardian. In doing so, they should take account of the recommendations in this guideline and the values and preferences of patients, and apply their clinical judgement".

As it stands, however, the change poses 3 important unanswered questions for dentists faced with implementing the guidelines:

- 1. How do I determine which patients should receive antibiotic prophylaxis?
- 2. Although NICE now acknowledge that antibiotic prophylaxis may be

- appropriate for some patients undergoing dental procedures, it gives no advice concerning which dental procedures should be covered.
- 3. If antibiotic prophylaxis is appropriate for a particular patient, what antibiotic prophylaxis regimen should be given?

In a recent BDJ opinion piece we proposed how dentists should deal with each of these issues.⁴ In the absence of clear guidance from NICE, we reiterate the key points here with links to tables and figures from the original article that provide more detailed information. Our recommendations are based on the current European Society of Cardiology (ESC) guidelines that are applied in the rest of Europe and provide a sound clinical basis for dealing with these issues. The ESC guidelines have been published in full⁹ and are also available as a smart phone app and a pocket guide at http://www.escardio.org/Guidelines-&- Education/Clinical-Practice-Guidelines/Infective-Endocarditis-Guidelines-on-<u>Prevention-Diagnosis-and-Treatment-of</u>. The ESC guidelines recommend antibiotic prophylaxis is limited to patients at highest risk of infective endocarditis (Link to Table 2 of BDJ 220(2)51-56) undergoing the highest risk dental procedures (Link to Table 3 of BDJ 220(2)51-56) They emphasise, however, that good oral hygiene and regular dental review are even more important than antibiotic prophylaxis in reducing the risk of infective endocarditis.

How do I decide which patients it is appropriate to consider antibiotic prophylaxis for?

The individuals considered to be at high-risk of infective endocarditis (and

therefore recommended for antibiotic prophylaxis by the ESC guidelines) are shown in Table 2 (Link to Table 2 of BDJ 220(2)51-56). Those at particularly high-risk include those with a previous history of infective endocarditis, those with prosthetic or repaired heart valves and those with multiple risk factors e.g. a prosthetic heart valve and previous history of endocarditis. Whilst, the ESC does not currently recommend antibiotic prophylaxis for those at moderate risk (also shown), it does highlight the importance of good oral hygiene and oral care with at least annual dental review for these individuals.

In most cases the risk status of a patient will be clear from the medical history e.g. previous history of infective endocarditis or prosthetic heart valve implantation. For others it may be less clear. Where there is any uncertainty, advice should be sought from the patient's cardiologist (with the patients consent) to clarify their risk status and determine the need for antibiotic prophylaxis (or not). A record of any such communication should be kept with their clinical record.

The new legal framework suggests that the potential consequences of developing infective endocarditis need to be discussed with anyone at increased risk. The differing views concerning the value of antibiotic prophylaxis and small risk of adverse drug reactions related to antibiotics also need to be addressed. We previously published a figure that may be helpful when discussing the issue of risk with patients (Link to Figure 1 of BDJ 220(2)51-56).⁴ Following a clear discussion of the facts, it is then for the patient (rather than the clinician) to decide if they wish to receive antibiotic prophylaxis. GMC/GDC standards and the

advice of the medical/dental defence organisations highlight the need for this discussion (and the patient's decision) to be recorded in the clinical records.

The patient's cardiologist may well be better placed than the dentist to decide on the level of risk posed to an individual patient. In this situation, the cardiologist should provide a letter outlining their advice and the dentist should confirm with the patient that this reflects their wishes before acting on the recommendation.

The risk of infective endocarditis developing in an individual with no risk factors is so low that it would be reasonable (even in the new legal framework) for the clinician to conclude that it is unlikely the patient would attach significance to the risk, and therefore not to inform them of these issues.

Which dental procedures are considered high-risk?

Generally, invasive dental procedures involving the gingival crevice are likely to be high-risk procedures and should therefore be considered for antibiotic prophylaxis. Table 3 (Link to Table 3 of BDJ 220(2)51-56), which is based on ESC recommendations⁹ and closely matches the American Heart Association (AHA) guidelines¹⁰ identifies those dental procedures considered high-risk.

What antibiotic prophylaxis regime should be provided for those requesting it?

The regime recommended by the ESC (Link to Table 4 of BDJ 220(2)51-56) is very similar to that of the AHA 10 but differs in two main respects from that previously used in the UK. First, the oral dose of Amoxicillin used is 2g rather

than 3g. Previously, 3g sachets of Amoxicillin oral powder were used for antibiotic prophylaxis in the UK and are still widely available. Moreover, recent adverse drug reaction data demonstrate a low level of adverse reactions to the 3g oral dose¹¹ and it seems reasonable, therefore, to prescribe this formulation. The other change is that the pre-NICE UK guidance recommended using clindamycin if a patient had received a dose of amoxicillin in the previous month. This is not a feature of either the ESC or AHA guidance and, given the higher risk of adverse reactions with clindamycin,¹¹ the ESC guidance is likely to be safer. That is, amoxicillin antibiotic prophylaxis should be used in those with no history of allergy, even if amoxicillin has been used within the previous month.

Both the ESC and AHA guidance currently recommends clindamycin antibiotic prophylaxis for those allergic to penicillins. Neither the ESC nor the AHA guideline committees have had the opportunity to take account of recent adverse reaction data showing a higher rate of adverse reactions with clindamycin antibiotic prophylaxis. Both are likely to do so in the future and may consider changing their recommendations. In the meantime, however, whilst not as safe as amoxicillin, clindamycin antibiotic prophylaxis is relatively safe and likely to be safer than the risk of developing infective endocarditis, particularly for those at high-risk. As such, it is probably advisable to adhere to ESC recommendations until any change in guidance is announced.

What else should dentists do for patients at increased risk of infective endocarditis?

Dentists should emphasise that good oral hygiene and regular dental review are

as important as antibiotic prophylaxis (if not more so) in reducing the risk of infective endocarditis. The ESC recommend strict dental and cutaneous hygiene with dental follow up at least twice a year in high-risk patients and once a year for all other (i.e. moderate risk) patients at risk of infective endocarditis. They also point out the need to effectively treat foci of infection, adhere to aseptic measures during at-risk procedures and explain the risks of body piercing and tattooing in those at risk of infective endocarditis.

Mortality and morbidity are very high in patients who develop infective endocarditis but are significantly reduced by early diagnosis. Unfortunately, early symptoms are often non-specific, making diagnosis difficult and frequently delayed. A low threshold of clinical suspicion is therefore vital. Patients at increased risk should be advised by their dentists of the signs and symptoms of infective endocarditis (Link to Table 5 of BDJ 220(2)51-56), whether or not they choose to have antibiotic prophylaxis, and the need to see their GP quickly should they occur, particularly if they develop soon after a high-risk dental procedure. Early assessment by the GP (who should be made aware of the patient's risk status and the timing/nature of any risk related procedure) and appropriate onward referral to a cardiologist could be life saving. The British Heart Foundation produce warning cards that can be given to patients – available at: https://www.bhf.org.uk/publications/heart-conditions/m26a-endocarditis-card

What other issues are raised by this change?

This change throws decisions about which patients should receive antibiotic

prophylaxis back into the hands of cardiologists and dentists while decisions about when antibiotic prophylaxis is required (i.e. when a high-risk dental procedure is going to be performed) and the prescription of antibiotic prophylaxis will reside largely with dentists. No longer can dentists and cardiologists ignore this issue because NICE does not recommend antibiotic prophylaxis. Moreover, there is now a new generation of dentists whose training did not incorporate the issues of infective endocarditis and antibiotic prophylaxis. As a consequence, dentists, cardiologists and GPs will need post-graduate training and CPD courses to update them on the implications of this guideline change. Thought will also need to be given to the re-introduction of teaching on infective endocarditis and antibiotic prophylaxis into undergraduate dental and medical curricula.

Finally

Although subtle, this change makes NICE guidance less dogmatic and allows clinicians to use their clinical judgement and provide the care their patients want – it is therefore very welcome. However, it leaves 3 important information gaps for clinicians involved in its implementation. This paper attempts to provide practical advice for dentists (based on the ESC guidelines) while we await the response of professional or official organisations to more formally fill the gap.

References:

- National Institute for Health and Care Excellence (NICE). Prophylaxis against infective endocarditis 2015 [NICE Clinical Guideline No 64]. Available from: http://www.nice.org.uk/guidance/cg64/chapter/Recommendations.
- 2. Dayer MJ, Jones S, Prendergast B, Baddour LM, Lockhart PB, Thornhill MH. Incidence of infective endocarditis in England, 2000-13: a secular trend, interrupted time-series analysis. Lancet. 2015;385(9974):1219-28.
- 3. Thornhill MH, Lockhart PB, Prendergast B, Chambers JB, Shanson D. NICE and antibiotic prophylaxis to prevent endocarditis. British dental journal. 2015;218(11):619-21.
- 4. Thornhill MH, Dayer M, Lockhart PB, McGurk M, Shanson D, Prendergast B, et al. Guidelines on prophylaxis to prevent endocarditis. British dental journal. 2016;220(2):51-6.
- 5. Thornhill MH, Dayer M, Lockhart PB, McGurk M, Shanson D, Prendergast B, et al. Prophylaxis guidelines: Plea to NICE. British dental journal. 2016;221(1):2-3.
- 6. Edozien LC. UK law on consent finally embraces the prudent patient standard. BMJ. 2015;350:h2877.
- 7. Main BG, Adair SR. The changing face of informed consent. British dental journal. 2015;219(7):325-7.
- 8. Southerland L. Montgomery in the Supreme Court: a new legal test for consent to medical treatment: Scottish Legal News; 2015 [Available from: http://www.scottishlegal.com/2015/03/12/montgomery-in-the-supreme-court-a-new-legal-test-for-consent-to-medical-treatment/.

- 9. Habib G, Lancellotti P, Antunes MJ, Bongiorni MG, Casalta JP, Del Zotti F, et al. 2015 ESC Guidelines for the management of infective endocarditis: The Task Force for the Management of Infective Endocarditis of the European Society of Cardiology (ESC)Endorsed by: European Association for Cardio-Thoracic Surgery (EACTS), the European Association of Nuclear Medicine (EANM). Eur Heart J. 2015;36(44):3075-128.
- 10. Wilson W, Taubert KA, Gewitz M, Lockhart PB, Baddour LM, Levison M, et al. Prevention of infective endocarditis: guidelines from the American Heart Association: a guideline from the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee, Council on Cardiovascular Disease in the Young, and the Council on Clinical Cardiology, Council on Cardiovascular Surgery and Anesthesia, and the Quality of Care and Outcomes Research Interdisciplinary Working Group. Circulation. 2007;116(15):1736-54.
- 11. Thornhill MH, Dayer MJ, Prendergast B, Baddour LM, Jones S, Lockhart PB.

 Incidence and nature of adverse reactions to antibiotics used as endocarditis prophylaxis. J Antimicrob Chemother. 2015;70(8):2382-8.