



David Healy <david.healy54@googlemail.com>

FW: Letter to M Hancock

David Healy (BCUHB - Mental Health & Learning Disabilities)
<David.Healy@wales.nhs.uk>
To: David Healy <david.healy54@googlemail.com>

20 December 2019 at
12:34

From: Andrew Dillon [mailto:Andrew.Dillon@nice.org.uk]
Sent: 20 December 2019 12:22
To: David Healy (BCUHB - Mental Health & Learning Disabilities); 'vaughan.gething@gov.wales'; 'richard.pengelly@health-ni.gov.uk'; 'june.raine@mhra.gsi.gov.uk'; Paul Chrisp
Subject: RE: Letter to M Hancock

Dear Professor Healy

Thank you for this and your earlier emails. I am sorry that you didn't receive a response to your letter to David Haslam. He would have referred it to me for action and so the responsibility is mine.

The two main themes in your correspondence touch on the notion of 'bureaucratic medicine' and the provenance of the evidence that NICE takes into account when developing its guidance.

I know that you will be familiar with David Sackett's definition of evidence-based medicine (BMJ 1996; 312:71-72). His description of a "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" and his view that "the practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research" continue to be an important reference for NICE. Our guidelines are just one element of evidence-based care, alongside clinical judgement and the values and preferences of individual patients, a position we capture with these words, which appear in each guideline:

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

The issue of unpublished evidence is a challenge for anyone using evidence to inform treatment options. As you point out, the authors of our Depression in Children guideline drew attention to the problems caused by unpublished evidence some years ago. Since this guideline was published, there has been some progress in addressing the issue of unpublished evidence and positive bias in the published literature. Researchers are expected to follow the Good Publication Practice guidelines, which includes medical writers being named in the acknowledgements of papers. Since 2016, the EMA has made all clinical data submitted to them for the marketing authorisation applications of new medicines available through a dedicated website (<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication>). This means that all clinical data that was used by regulators is accessible to everyone within 60 days of marketing authorisation (after registering for access to the database), whether or not it has been published.

Of course, these procedures were not in place when most SSRIs were approved, but post-marketing surveillance can trigger regulatory action and the EMA completed a referral procedure on SSRIs and suicide in 2005:

<https://www.ema.europa.eu/en/medicines/human/referrals/serotonin-specific-reuptake-inhibitors-serotonin-noradrenaline-reuptake-inhibitors>

We agree with you that it is not NICE's role to 'police' the academic literature, but we take the matter seriously and we are a AllTrials campaign which calls for all past and present clinical trials to be registered and their full methods and summary results reported.

Yours sincerely

Andrew Dillon

Chief Executive

National Institute for Health and Care Excellence

From: David Healy (BCUHB - Mental Health & Learning Disabilities) <David.Healy@wales.nhs.uk>
Sent: 17 December 2019 09:13
To: Andrew Dillon <Andrew.Dillon@nice.org.uk>; 'vaughan.gething@gov.wales' <vaughan.gething@gov.wales>; 'richard.pengelly@health-ni.gov.uk' <richard.pengelly@health-ni.gov.uk>; 'june.raine@mhra.gsi.gov.uk' <june.raine@mhra.gsi.gov.uk>
Cc: 'colleen.bell11@outlook.com' <colleen.bell11@outlook.com>
Subject: Letter to M Hancock

Attached a further piece of correspondence linked to recent correspondence sent to each of you

David Healy

David Healy MD FRCPsych

Professor of Psychiatry

Cymraeg

Rhybudd Ebst (2010) - Bwrdd Iechyd Prifysgol Betsi Cadwaladr

Fech cynhorir i ddarllen rhybydd ebst Bwrdd Iechyd Prifysgol Betsi Cadwaladr (a'i argraffu er mwyn cyfeirio ato yn y dyfodol). Gellir dod o hyd iddo yn y lleoliad canlynol

<http://www.wales.nhs.uk/sitesplus/861/tudalen/47230>

English

Betsi Cadwaladr University Health Board - Email Notice (2010)

You are advised to read (and print for future reference) the Betsi Cadwaladr University Health Board e-mail notice which can be found at this location

<http://www.wales.nhs.uk/sitesplus/861/page/47229>

Betsi Cadwaladr University Health Board is the operational name of Betsi Cadwaladr University Local Health Board

Delivered via MessageLabs
