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# BC DISEASE NEWS

A WEEKLY DISEASE UPDATE

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# Welcome

Welcome to this week's edition of BC Disease News.

In this week's edition, we examine the appeal judgment of *Alpha Insurance A/S v Roche & Anor* [2018] EWHC 1342 (QB) dealing with fundamental dishonesty and QOCS protection where the claimant discontinued 1 day before trial.

In addition, we report on the Recovery of Medical Costs for Industrial Disease (Scotland) Bill consultation, which will close later this month. Members of the insurance industry have been urged to provide responses.

Elsewhere, there are more positive results in non-small lung cancer Keytruda treatment trials.


In this week's feature, we discuss the relevance of the McShefferty papers in NIHL claims, which measured the increase in speech to noise ratio necessary to produce 'noticeable' and 'meaningful' differences in speech intelligibility. We go on to explain how the researchers' findings could have an impact on future hearing aid claims.

Any comments or feedback can be sent to [Boris Cetnik](#) or [Charlotte Owen](#).

As always, warmest regards to all.

## SUBJECTS

Fundamental Dishonesty and QOCS – Recoverable NHS Costs Bill – Keytruda and Non-Small Lung Cancer – Non-Melanoma Skin Cancer and Outdoor Work – Ticks and Insecticide – Screen Time, Cancer and Cardiovascular Disease – Fibromyalgia and Non-Rheumatological Conditions – Road Paving and Lung Disease – McShefferty Papers.



## Fundamental Dishonesty Post-Discontinuance: *Alpha Insurance A/S v Roche & Anor* [2018] EWHC 1342 (QB)

At the High Court, judgment has been handed down in the case of *Alpha Insurance A/S v Roche & Anor* [2018] EWHC 1342 (QB). This concerned an appeal to the High Court, on the basis that the trial judge had erred in not allowing a further hearing on fundamental dishonesty.

The facts of the case were as follows. The defendant disputed that the 2<sup>nd</sup> claimant was present at the scene of a road traffic accident. The defendant alleged fundamental dishonesty. It was argued that the 2<sup>nd</sup> claimant was pursuing a fraudulent claim, whilst the 1<sup>st</sup> claimant's claim was 'ainted' with dishonesty.

Just 1 day before the 1<sup>st</sup> instance trial, a Notice of Discontinuance was filed. Nonetheless, the defendant requested that the trial remain listed, with a view to obtaining a determination on the issue of fundamental dishonesty.

At trial, HHJ Gregory rejected the application.

He began his reasoning by stating that CPR 38.2(1) permits:

*'A claimant may discontinue all or part of a claim at any time.'*

The trial judge perceived 'any time' to encompass the filing and serving of a Notice of Discontinuance.

Ordinarily, under CPR 38.6(1), the default burden on costs is shifted post-discontinuance, such that claimants are made liable for the defendant's costs up to the date of discontinuance. However, this was a case where QOCS applied. As a

result, the defendant required leave of the court to enforce such an order.

Exceptions to QOCS can be found in CPR 44.16, an example of which is where there has been fundamental dishonesty.

The defendant's case on fundamental dishonesty was encapsulated within CPR 44PD 12.4©:

CPR 44PD 12.4 provides:

- "(a) the court will normally direct that issues arising out of an allegation that the claim is fundamentally dishonest be determined at the trial;
- (b) where the proceedings have been settled, the court will not, save in exceptional circumstances, order that issues arising out of an allegation that the claim was fundamentally dishonest be determined in those proceedings;
- (c) where the claimant has served a notice of discontinuance, the court may direct that issues arising out of an allegation that the claim was fundamentally dishonest be determined notwithstanding that the notice has not been set aside pursuant to rule 38.4;
- (d) the court may, as it thinks fair and just, determine the costs attributable to the claim having been found to be fundamentally dishonest."

Following the Practice Direction, HHJ Gregory reasoned:

*'...there is nothing, in my judgment, which suggests that there is any particular exceptional quality about this particular case that should cause me to give further directions and to set aside further court time to allow this particular isolated issue of dishonesty to be ventilated.'*

The defendant appealed the decision of the 1<sup>st</sup> instance judge.

In its grounds of appeal, the defendant argued that HHJ Gregory's ruling was perverse and that he had failed to provide any weight to his reasoning. The main basis for exhausting the appeal, however, was that it was in the interest of the public to maintain the integrity of the legal system and ensure that claimants pay the costs of litigation if they are exposed as dishonest. Further, the defendant submitted that more emphasis should have been put on the 'eleventh hour' discontinuance, and less emphasis on the use of court resources to determine the issue on fundamental dishonesty.

However, the claimant argued that the judge's ambit of discretion, at case management, although unfettered, is still subject to the overriding objective.

Mrs Justice Yip, who gave judgment on appeal, found that HHJ Gregory had made an error in suggesting that CPR 44PD 12.4(c) only applies if there is a 'particular exceptional quality':

*'The relevant sub-section does not require exceptional quality.'*

Therefore, the 'correct approach is to regard the discretion under CPR 44PD 12.4(c) as an unfettered one, requiring the weighing of all relevant considerations in accordance with the overriding objective'.

Consistent with recent case law on fundamental dishonesty, also in relation to strike out applications under the Criminal Justice and Courts Act, the appeal judge maintained that 'each case will depend on its own facts' and exercised her discretion afresh.

She professed that 'the very late stage at which the claim was discontinued and the complete absence of an explanation from the claimants' were factors to consider. She believed that an explanation for discontinuing should be reasonably expected of claimants, given that there are many reasons for discontinuing. Also, she saw that the expense, inconvenience and use of court resources was an important consideration.





On this occasion, Yip J allowed the appeal:

*'On balance, looking at all the circumstances of this case, I consider that it is reasonable for the defendant to be given the opportunity to put forward its evidence and to test the claimants' evidence on the issue of fundamental dishonesty.*

*I do not say that a decision in this case not to direct the determination of the fundamental dishonesty issue would be perverse. I regard the position as quite finely balanced. The defendant's case may well not succeed. It all depends on an assessment of disputed factual evidence. For my part, any reasonable explanation for the late discontinuance may well have tipped the balance the other way'.*

We will endeavour to report on the redetermination of the disputed factual evidence in due course.

The full text judgment, on appeal, can be found [here](#).

## Insurance Industry Encouraged to Contribute in Proposed Recovery of Medical Costs for Industrial Disease (Scotland) Bill Consultation

We last discussed the Recovery of Medical Costs for Industrial Disease (Scotland) Bill proposal in edition 226 ([here](#)), which would *'enable Scottish Ministers to recover, from the party responsible for causing an industrial disease, certain costs incurred by the NHS in providing care and treatment to those suffering from that disease'*.<sup>1</sup>

Diseases contemplated by the Stuart McMillan MSP's draft Bill, would be mirrored on diseases which entitle Industrial Injuries Disablement Benefit (IIDB), including:

- Asbestos-related conditions;
- Skin conditions;
- Respiratory conditions;
- Deafness; and
- Asthma.

In addition, recovery would only be possible if exposure to occupational hazards, responsible for the onset of the industrial disease, occurred after the commencement date of the Bill.

The consultation began on 29 March 2018 and ends on 22 June 2018. The foreword of the consultation states that its aim is to *'elicit views from experts, industry, the public sector and individuals and insurers'*.

As such, the insurance industry has been encouraged to contribute to the debate, as the consultation draws to a close later this month.<sup>2</sup>

After consultation responses are analysed, a final proposal will be launched in the Scottish Parliament. If at least 18 other MSPs from at least half of the political parties represented in the Parliamentary Bureau show support for the Bill proposal, a Member's Bill will be introduced. This would be subject to a 3-stage scrutiny process of amendment or rejection, prior to becoming an enforceable Act of the Scottish Parliament.

Click [here](#) to respond to the consultation.

## Keytruda Offers Benefits for Lung Cancer Patients in Another Trial

Merck, the manufacturer of the immunotherapy drug pembrolizumab (trade name Keytruda), has announced the results of another clinical trial, finding that the drug offers benefits to non-small cell lung cancer (NSCLC) patients<sup>3</sup>. Keytruda has now demonstrated improved survival benefit in advanced NSCLC patients in 5 phase-3 trials.

We have discussed the relationship between Keytruda in lung cancer patients in editions 227, 215 and 186. We have also discussed the relationship between Keytruda and mesothelioma in editions 214, 208, 200, 189 and 176.

In the latest trial, involving 560 patients, known as KEYNOTE-407, Keytruda was given in combination with chemotherapy drugs (either carboplatin-paclitaxel or nab-paclitaxel) as the first line treatment for NSCLC. The patients had not received any prior treatment for their cancer.

An interim analysis has found that treatment with Keytruda in combination with chemotherapy resulted in significantly longer overall survival and progression-free survival than chemotherapy alone.

Merck has reported the findings to the Food and Drug Administration and applied for the drug to be approved for use in NSCLC patients under the combination treatment plan in the KEYNOTE-407 trial. Keytruda is already approved by the FDA for first line use in NSCLC patients in combination with the chemotherapy drugs, pemetrexed and carboplatin<sup>4</sup>. It has also been approved for use in patients with solid tumours that have certain genetic properties which have spread and cannot be completely removed by surgery and in situations where the tumour has progressed following prior treatment<sup>5</sup>.

The main objectives of KEYNOTE-407 were to measure patient survival time and time without disease progression. More details of the results from the trial will be presented at the American Society of Clinical Oncology meeting, later this year.

As previously stated in BC Disease News ([here](#)), in respect of KEYNOTE-189, the use of Keytruda in lung cancer patients is of interest to the mesothelioma community because NSCLC has similar characteristics to mesothelioma. Keytruda has also shown promise in mesothelioma patients, but remains an expensive experimental treatment at this stage.



## New Study on the Risk of Non-Melanoma Skin Cancer in Outdoor Occupations

Non-melanoma skin cancer (NMSC) is the most common cancer worldwide. Exposure to ultraviolet light from the sun is known to be a risk factor and thus, NMSC is recognized as an occupational disease in several countries<sup>6</sup>. Workers most at risk are those who work outdoors and those who work in the agriculture, construction and transportation industries. A new study has found that workers in different industries face different risks of NMSC<sup>7</sup>.

Farmers, gardeners, mountain guides, and office workers participated in the study; the office workers formed the control group. The participants completed a questionnaire, in which they provided information about their UV exposure and how they protect themselves from UV. All test subjects underwent a skin examination conducted by a dermatologist. In total, data was collected from 348 outdoor workers and 215 indoor workers.

NMSC or actinic keratosis (damage to the skin caused by the sun) was diagnosed in 33.3% of mountain guides, 27.4% of farmers, 19.5% of gardeners and 5.6% of indoor workers. The differences between the outdoor occupations were statistically significant. Mountain guides were at a risk of NMSC 2.6 times greater than the risk posed to farmers.

There were also measurable differences in protective behavior among the study groups: 61.4% of indoor workers attended skin cancer screening, compared with 57.8% of mountain guides, 31.9% of farmers and 27.6% of gardeners. In addition, researchers noted that daily occupational UV exposure varied from group to group.

The authors of the study concluded that different outdoor professions have significantly different risks of NMSC and

demonstrate different protective behaviours. Efforts to prevent NMSC could be tailored to different occupational groups, tailored to their particular needs. Lead author, Dr. Alexander Zink, of the Technical University of Munich, said

*'Altitude and number of hours working outside seem to make the difference'*.<sup>8</sup>

This study could be of interest to the current *No Time To Lose* campaign, launched by the Institution of Occupational Safety and Health. The campaign provides resources to employers, with the objective of reducing the numbers of cases of occupational cancers<sup>9</sup>. Skin cancer caused by occupational UV radiation is one of the main focuses of the campaign and efforts have been made to target particular occupational groups, such as those in the agricultural and construction industries<sup>10</sup>.

## Ticks Repelled by Insecticide-Treated Fabric in Latest Study

In the USA, new research, conducted by the U.S. Centers for Disease Control and Prevention (CDC), has found that treating *'Insect Shield fabrics'* with permethrin, an insecticide, reduces the risk of tick exposure.<sup>11</sup> Results were published in the *Journal of American Entomology*.<sup>12</sup>

In edition 227 of BC Disease News ([here](#)), we reported that the number of Lyme disease cases, in England and Wales, has increased steadily since 2001, but decreased between 2012 and 2014. Figures, published by Public Health England in February 2018, showed that in each quarter of 2017, the number of cases of Lyme disease was greater than the corresponding quarter in 2016. In 2017, there were around 1,500 laboratory confirmed cases of Lyme disease.

The latest CDC study involved treating clothing with an insecticide, permethrin, which is derived from the chrysanthemum flower.

In 2011, Thomas Mather, Director of the University of Rhode Island's Center for Vector-Borne Disease, conducted research on the effects of permethrin on tick activity.

The test subjects in Mr Mather's research wore permethrin-treated and untreated clothes (shorts, t-shirts, socks, and shoes) for 2 hours, while they were exposed to pathogen-free ticks. The result of this investigation was that those wearing treated clothes had been bitten by fewer live ticks.

Evidence of contact irritancy and toxicity of permethrin, therefore, has been known to experts for some time.

In the 2018 study, researchers discovered that the effect of permethrin was to repel three types of Lyme disease-causing tick (*Ixodes scapularis*, *Amblyomma americanum*, and *Dermacentor variabilis*). Repellence was observed when ticks fell from fabric, oriented at a 45 –degree angle. After up to 5 minutes of contact with the insecticide, the ticks were immobilized and unable to bite.

Mr Mather reacted to the CDC study's findings, in light of his earlier study:

*'If there's more evidence that permethrin-treated clothing works, the hope is that many more people will use it'*.

In fact, the CDC, World Health Organization (WHO), National Institute for Occupational Health and Safety (NIOSH), American Academy of Family Physicians, and Public Health Agency of Canada has recommended that insect-repellent apparel is treated with 0.5% permethrin.

As discussed in issue 227, in Europe, the most prevalent Lyme disease-causing tick species is *Borrelia burgdorferi*. Given that numbers of Lyme disease cases are rising, it would be worthwhile to conduct further research into the effect of permethrin against the sub-species of ticks which outdoor and agricultural workers are exposed to in the UK.



## Research Associates High Levels of 'Screen Time' With Cancer and Heart Disease

Published in a recent *Bio Med Central* journal article,<sup>13</sup> researchers at the University of Glasgow have identified that an increase in discretionary viewing of television and computer screens almost doubles the negative effects on human health as low fitness levels.

The rationale for this study was that discretionary screen time was thought to be a contributor to sedentary behaviour, which is positively correlated with mortality and cardiovascular disease.

390,089 participants were selected from the UK Biobank and their behaviours were analysed. Researchers were only interested in the amount of time spent watching screens during the test subjects' leisure time. Other factors, such as physical activity, grip strength, BMI, smoking, diet and socio-economic status, were also taken into account.

The test results emphasise that sedentary behaviour, generally, is detrimental to human health. The incidence of 'all-cause mortality', cancer and cardiovascular disease, caused by screen time, was almost double the attributable risk presented by low fitness levels.

Lead author of the study, Professor Jason Gill, stated:

*'Our study shows that the risks associated with sedentary behaviour may not be the same for everyone, with the association between leisure time screen use and adverse health outcomes being strongest in those with low levels of physical activity, fitness or strength. This has potential implications for public health guidance as, if the findings are causal, these data suggest that specifically targeting those with low fitness and strength to reduce their*

*sedentary behaviour may be an effective approach'.<sup>14</sup>*

Somewhat inevitably, Professor Gill implies that risk factors (screen viewing and low fitness) are not mutually exclusive, with the most adverse health effects observed in participants who spent more time watching screens and had low levels of physical activity.

As a result, study author, Dr Carlos Celis, shared in Professor Gill's advisory comments that *'people with the lowest levels of strength, fitness and physical activity could potentially gain the greatest benefit from health promotion interventions aimed at reducing sedentary behaviours'*.

He went on to say that *'grip strength is a quick, simple and cheap to measure, so could easily be implemented as a screening tool in a variety of settings'*.

## How Does Chemical Exposure in Asphalt Road-Paving Affect Lung Function?

A new study has investigated chemical exposures in asphalt road paving and monitored the lung function and respiratory symptoms of affected workers<sup>15</sup>. Work with conventional asphalt or crumb rubber modified (CRM) asphalt (contains recycled rubber tyres) were recruited to take part in the study. Current data on the exposure conditions of those working in proximity to asphalt are limited, meaning that it is difficult to set occupational exposure limits.

The researchers took measurements of dust and various airborne chemicals at the work sites, and blood samples from 116 conventional asphalt workers, 51 CRM asphalt workers and 100 controls. Spirometry tests were then performed to determine lung function on Monday morning before work and on Thursday evening after work. Participants were also asked to disclose any respiratory symptoms suffered.

The air sampling found that levels of dust and various chemicals were highly variable, but there were no overall differences in exposure conditions among conventional and CRM asphalt workers, except for benzothiazole, a mucosal irritant. Concentrations were higher in CRM asphalt work. Air testing found that nitrosamines were present during both conventional asphalt and CRM asphalt work, and although the presence of molecules were expected at the site of CRM asphalt work, the origin of nitrosamines found at the conventional asphalt work site is still unknown. This finding suggests that sources other than rubber tyres may contribute to workers' exposure to nitrosamines.

Moreover, greater proportions of asphalt workers than controls reported eye symptoms after starting their current jobs. The same was found for wheezing and coughing, but the differences were not statistically significant and could have occurred by chance. In both CRM asphalt workers and controls, lung function decreased after spending 4 days at work, but the decrease was not seen in conventional asphalt workers. On analysis of asphalt workers alone, there was a weak increase in change in lung function with number of years worked.

The design of this study, in which workers were followed-up after 4 days of work, provides stronger results than other studies, as the exposure measurements more accurately reflect the true exposures. The researchers tested the participants' lung function themselves, which is an objective measure of lung function, and is more accurate than participant recollection of past symptoms and diagnoses. However, a limitation of this study was that the control group were gardeners. The researchers acknowledge that the control group may have been exposed to organic dusts, which could have triggered similar symptoms to chemicals also found in asphalt.

Asphalt workers are exposed to a range of particles and chemicals, but at highly varied levels. No acute airway irritation was observed during the study, but a reduction



in lung function was observed after 4 days of paving and some workers reported a development of eye symptoms after starting their job. However, the findings should be interpreted with caution, as similar effects were seen in the controls. Irrespective of higher benzothiazole exposure in CRM asphalt paving work, there was no evidence in support of more adverse health effects in CRM asphalt paving workers than in conventional asphalt paving workers.

## Fibromyalgia Contribution to Burden of Ill Health

*'... physicians should be alert to the possibility of comorbid FM [fibromyalgia], and symptoms of FM should be specifically addressed'.<sup>16</sup>*

In new research, published in the *European Journal of Pain*, fibromyalgia was found to have a negative impact on patients suffering with both rheumatological and non-rheumatological conditions.<sup>17</sup>

Fibromyalgia is a widespread musculoskeletal pain disorder that sensitises, or dysregulates general functioning of the nervous system, resulting in heightened perception of pain.

Initially, fibromyalgia was considered to be a uniquely diagnosed disease. However, fibromyalgia has been observed alongside rheumatological diseases and is increasingly seen to coexist with other non-rheumatological diseases.

In edition 185 ([here](#)), BC Disease News reported that fibromyalgia was correlated with subjective hearing loss in test subjects.

The latest article, *'Comorbid fibromyalgia: a qualitative review of prevalence and importance'*, is one of few studies to-date to consider how fibromyalgia affects non-rheumatological primary disease.

In the review, researchers noted that fibromyalgia occurs in 20% to 30% of

patients with various rheumatic conditions. In one study, *'fibromyalgia was found in 21% of patients with rheumatoid arthritis, 37% of patients with systemic lupus erythematosus and 17% of patients with osteoarthritis'*.

In addition, fibromyalgia cases have been reported alongside non-inflammatory musculoskeletal conditions, such as chronic spinal pain and chronic low back pain. Indeed, the authors noted that 23% to 41% of patients with chronic disabling occupational musculoskeletal disorders also had fibromyalgia.

Multiple sclerosis (MS), post poliomyelitis syndrome, neuropathic pain, and Parkinson's disease are 4 neurological disorders with alleged links to fibromyalgia. However, further evidence is required, in respect of primary disease outcome, to fully understand any fibromyalgia association.

There have also been reports of celiac disease and irritable bowel syndrome (IBS) occurring with fibromyalgia. However, reports of gastrointestinal diseases are often conflicting and this inhibits a general consensus.

In two separate studies, the review identified that fibromyalgia was present in 23% of patients with heart failure and in 21% of patients with post-traumatic stress disorder. Chronic pain, therefore, is not a prerequisite for fibromyalgia incidence and nor is the requirement that the primary disease is physical; it can also be psychological.

The authors of this latest study concluded that fibromyalgia may be an unidentified condition, which occurs among many different diseases and may contribute to the overall burden of illness. Coexisting fibromyalgia can result in less favourable primary disease outcome, more severe symptoms and impaired function. Failing to diagnose fibromyalgia where there is a primary disease, therefore, may cause a mismanagement of both conditions.



## Feature:

# Future Hearing Assistance Claims: The McShefferty Papers

In the case of *Evans v Secretary of State for the Department of Energy and Climate Change and Anor* (Unreported, Cardiff County Court, 2017), the judge primarily dealt with expert differences of opinion on quantification of hearing loss where the claimant alleged a loss of speech intelligibility as a result of NIHL. We provided case analysis in edition 216 of BC Disease News ([here](#)).

In *Evans*, the defendant's medical expert, Professor Lutman, cited the McShefferty papers in his medical report, although the significance of the findings were not considered by the trial judge in detail. Within these papers, David McShefferty investigated how the phenomenon of speech-to-(background) noise ratio (SNR) affects the understanding of speech communication in both hearing impaired and non-hearing impaired individuals.

In this article, we review the conclusions reached and consider any foreseeable impact on future claims for hearing assistance devices.

### WHAT IS SNR?

Speech-to-noise ratio (SNR) is the level of speech relative to the level of background noise. It is measured in decibels and is the difference between the sound levels of speech and noise signals. For example, a 2 dB SNR could be achieved by having a 72 dB speech signal in a 70 dB noise signal.

SNR is therefore relevant to our ability to hear and understand speech in the presence of background noise. This is a common admission in claimant witness statements who allege NIHL.

Generally speaking, hearing impaired individuals require higher SNR to achieve the same results in speech intelligibility tests as non-hearing impaired individuals.

Factors that can affect improvements in SNR include distance and spatial location from the speech signal, the type and number of noise sources and the amount of reverberation in the environment.

### DO HEARING AIDS AFFECT SNR?

Technically, the function of hearing assistance devices is not to increase SNR. They simply amplify the combined speech and background mixture.

However, some features of hearing aids, such as directional microphones, can produce more favourable SNR for users. As a result, NIHL claimants often seek future hearing assistance.

### RELATIONSHIP BETWEEN SNR AND SPEECH INTELLIGIBILITY

Increased SNR and, by deduction, the use of hearing aids, can therefore increase speech intelligibility – but to what extent?

It is important to consider that the magnitude of any increase in intelligibility depends on the difference between subjects' responses to physical stimuli in testing.

So, is there a definitive increase in SNR which allows speech clarity to be more *'noticeable'*, or *'meaningful'*? This was the purpose of David McShefferty's two published papers.<sup>18 19</sup>

### PRE-MCSHEFFERTY PAPERS

Prior to the latest work of David McShefferty & others, in a study conducted by Killion, it was found that a 2 dB increase in SNR could yield benefit. However, the author warned that this change was unlikely to be noticed in a real-world setting.



*The Just-Noticeable Difference in Speech-to-Noise Ratio Experiments*

The 2015 study comprised of 4 separate experiments. McShefferty perceived that just-noticeable difference (JND) was crucial to the understanding of how much improvement in SNR is necessary to provide a *'noticeable'* benefit, i.e. a difference in intelligibility that listeners can detect. He also considered it important to analyse whether there was an association between the degree of hearing impairment and JND. Both of these considerations are relevant to the suitability of claims for future hearing assistance.

Of particular relevance was the 1<sup>st</sup> experiment, in which 44 participants were recruited (50:50 male to female ratio). Better-ear, four-frequency (at 0.5, 1, 2, and 4 kHz), pure tone average hearing losses were measured. Among the participants, losses ranged from (-) 2 dB to (+) 71 dB. The criteria for hearing impairment was that average loss over all the frequencies exceeded 25 dB in the better ear. Of the 44 participants, 14 were non-hearing impaired and 30 were hearing-impaired. 23 of the 30 hearing-impaired participants had sensorineural hearing loss, 3 had mixed hearing loss and 4 had conductive hearing loss.

The purpose of the 1<sup>st</sup> experiment was to measure the *'noticeable'* difference caused by changes in SNR. To calculate JND, test subjects listened to two sentences with different SNRs, containing male-talker sentences partially masked by speech-shaped noise. The sentences were separated by a gap of half a second of silence and the participants were asked to decide: *'Which sentence was clearer?'* This procedure was repeated, and the difference in the SNR between the two sentences was gradually reduced as the participants correctly identified the sentence with the higher SNR. When the gap between the two SNRs of the two sentences was small enough that the participant had got several answers wrong, the test was completed, and the size of this SNR gap was the JND for that participant.

Among the 44 participants, the average JND for a change in SNR was 3.2 dB.

Non-hearing impaired test subjects gave an average JND for a change in SNR of 2.9 dB.

Hearing-impaired test subjects gave an average JND for a change in SNR of 3.3 dB.

The study authors observed a relationship between age and JND. However, they did not find any difference between the JND measured in hearing-impaired and non-hearing impaired groups. Any difference was not statistically significant. On average, the JND in SNR of speech in noise was 3 dB across all 44 participants.

The authors concluded that, although the conventional level of JND was considered to be 1 dB, they were confident that their measurement was accurate. Further, the authors stated that Killion's study (referred to above) perceived a 4 dB JND to be 90% correct, compared to a 2 dB JND, which was only 50% correct. Interpolating the JND found in the McShefferty papers, Killion would calculate this finding to be 79% correct.

The significance of the results was phrased, as follows:

*'The SNR JND of 3 dB measured here indicates the lower bound of the minimal clinically important difference for SNR improvement; that is, a change of 3 dB SNR indicates the threshold of the perceptual relevance (as opposed to speech intelligibility improvement) of those features of hearing aids designed to increase SNR. Therefore, regardless of the strategy used to achieve it, the data presented here indicate[s] that a noise reduction scheme—or directional microphone or indeed any feature for increasing SNR—in a hearing aid should provide at least 3 dB SNR improvement in order to provide a reliable and consistently noticeable benefit for HI listeners.'*

The study's *'Discussion'* section does, however, consider that the expected JND could decrease if there are *'changes in listening effort or fatigue, particularly in continuous speech with multiple opportunities for detecting a difference in SNR'*. Alternatively, the expected JND *'might also increase in a real-life scenario with multiple distracters and reverberation present'*. Without more rigorous testing, the necessary benefits that hearing assistance devices need to provide are arguably difficult to quantify.

What is more, McShefferty's findings on *'noticeable'* difference were no indication of how significant a change in SNR has to be to bring about a *'meaningful'* difference, obligating medical intervention. This led to the publication of McShefferty's 2<sup>nd</sup> paper, in 2016.



## The Just-Meaningful Difference in Speech-to-Noise Ratio

In the introduction to the 2016 article, the authors emphasised the importance of carefully distinguishing *'noticeability'* and *'meaningfulness'* of changes in SNR.

Just *'meaningful'* difference (JMD) is the minimum increase in SNR necessary for there to be a medical intervention. This is because JMD strongly resembles clinically important difference (CID). CID is regarded as a *'change in outcome that would be considered meaningful to a patient after some form of intervention'*.

The difficulty with previous investigations involving CID, highlighted by the researchers, is that the perception of beneficial outcome is often not determined by decrease in disease prevalence or statistical inference. Measuring JMD requires a subjective test, not an objective one. JND, investigated in the 2015 McShefferty paper, is objective, i.e. the measurements (in dB) are appreciable to scientists and clinicians, and cannot be influenced by the participants' opinions. By contrast, JMD relies on the opinions of test subjects.

As a result, the 2016 study was an attempt to reconcile the differences between subjective and objective ratings of hearing ability and perceived benefit.

4 separate experiments were devised to measure *'the smallest difference in SNR that would elicit a change in behaviour'*. We will examine the results of the first 3 experiments conducted.

Participants were recruited and better-ear, four-frequency (at 0.5, 1, 2, and 4 kHz), pure tone average hearing losses were measured.

Once again, test methods involved listening to two intervals (target interval and reference interval), containing a corpus of sentences partially masked by embedded speech-shaped noise. The identical choice in stimuli was deliberately chosen to allow for direct comparison with the earlier JND results.

However, unlike the 1<sup>st</sup> experiment of the JND paper, the participants in the 1<sup>st</sup> JMD experiment were not only given a noise discrimination task, but also asked whether the target interval was the same, better, or worse than the reference interval (which was a SNR of 0, so the speech sound level was the same as the background noise level) with an incremental change in SNR. *'Better'*, for the purpose of examination, was defined as *'being clearer or easier to listen to'*. Ratings were measured on an 11-point scale [from (-) 5 (*much worse*), to 0 (the same), to (+) 5 (*much better*)]. Of the 32 participants tested, 14 had sensorineural hearing loss and the remainder were non-hearing impaired.

JND for a change in SNR yielded similar results to the 2015 study (3 dB). JND was measured at 2.8 dB across all participants in the 1<sup>st</sup> experiment of the 2016 paper. On average, benefits were rated as better by 1 unit after a 4 dB increase in SNR and deficits were rated as worse by 1 unit after an 8 dB change in SNR, where units are the increments of the 11-point scale from *'much worse'* to *'much better'*. However, the authors note that it is unclear what *'one unit'* would mean on a clinical level.


The 2<sup>nd</sup> and 3<sup>rd</sup> experiments were designed to give the JMD in SNR measurements more clinical relevance.

In the 2<sup>nd</sup> experiment, the test subjects listened to sentences with a particular SNR, and then other sentences with a different SNR, were told that the first one was the sound from their device and the second one was the sound from a different device, and asked if they would like to swap devices. The JMD was defined as the threshold (in difference in SNR) at which the participant wanted to swap devices. Of the 31 participants tested, 21 were classified as hearing impaired (3 had conductive loss and 17 had sensorineural hearing loss) and the remainder were non-hearing impaired. Results showed that participants said *'Yes'* to switching more than 50% of the time when the increase in SNR was between 4 dB and more than 8 (the highest difference tested) dB.

In the 3<sup>rd</sup> experiment, participants were asked if they would be willing to attend a clinic for a given SNR benefit or deficit, which, again, were presented as pairs of sentences with different SNR's. Of the 21 participants tested, 10 had sensorineural hearing loss and the remainder were non-hearing impaired. *'Yes'* responses only exceeded 50% when the increase in SNR was between 6 dB and 8 dB.

As such, the researchers concluded that a meaningful difference equates to an average increase of 6 dB of SNR. Further, a **6 dB JMD** *'means that a change of 6 dB of SNR needs [to] be supplied for someone, on average, to consider it worth seeking intervention, whether by swapping their devices or attending the clinic'*.

Moreover, the authors were successful in discovering that there is a difference between *'noticeable'* and *'meaningful'* difference in SNR:



*'While participants were able to detect differences in SNR of 3 dB, those differences were not deemed to be clinically important (i.e., participants were unwilling to swap devices or to attend the clinic for differences of that magnitude). Only when differences in SNR reached at least 6 dB did participants find them meaningful enough to consider intervention.'*

Many of the limitations discussed in 2015 were also discussed in the 2016 paper. These were discussed in more detail by a co-author of McShefferty papers, William Whitmer, in the run-up to the *Evans* case.

## CRITIQUE OF MCSHEFFERTY PAPERS

In November of 2017, prior to the *Evans* trial, William Whitmer, co-author of the McShefferty papers, responded to comments made by Professor Mark Lutman in his defendant commissioned medical report and shed light on the continuing limitations of his co-written work.

One limitation discussed, was that the McShefferty papers identify what immediate change in SNR would be *'noticeable'* or *'meaningful'*. As such, thresholds relevant to the perception of long-term changes in SNR are still *'unclear at best'*.

Mr Whitmer further indicated that, while random variation of sound level from one presentation to the next was designed to rule out the use of sound level as a cue, day-to-day realistic listening situations would not be that unpredictable. Consequently, the JND thresholds are relevant to the demonstration of hearing aid features, such as noise reduction, but not necessarily changes in SNR which bring about a *'noticeable'* or *'meaningful'* change of speech clarity.

He also explained that the McShefferty papers measure *'noticeable'* and *'meaningful'* difference on the basis of single sentences, before going on to cite data collected in additional, unpublished research, which showed that discriminating changes in SNR for single words was more difficult than discriminating changes in SNR for sentences. Extending that association, he expected that changes in SNR (especially the meaningful thresholds) would decrease with prolonged listening, *'as occur in daily life'*.

In summary, Mr Whitmer concluded:

*'... it is my strong opinion that the result of the two studies of McShefferty et al. cannot be used to draw valid inferences about the smallest change in audiometric thresholds that would be noticeable in cases of noise-induced hearing loss.'*

## EVANS V SECRETARY OF STATE FOR THE DEPARTMENT OF ENERGY & CLIMATE CHANGE (2017)

In the case of *Evans*, the claimant alleged that he had difficulty in *'several domestic and social situations'*. It was said that he struggled to understand *'... conversation, particularly in the presence of background noise. He not infrequently ... [had] ... to ask others to repeat themselves or to speak up ...'*

In this case, causation was disputed. The experts differed in their quantification of hearing loss, i.e. whether the loss was *'significant or appreciable'*. If the NIHL was insignificant, the claimant would not have been able to advance the claim for future hearing aids.

The defendants were assisted by the instruction of Professor of Audiology, Mark Lutman. They submitted that, on the balance of probabilities, the claimant's noise induced hearing loss should have been treated as *'de minimis'*.

Prior to the case of *Evans*, in edition 111 ([here](#)), we discussed the medical authorities on the effect of NIHL at specific frequencies on speech intelligibility. In *Evans*, the importance of speech intelligibility at 4 kHz were debated.

The judge found in favour of the claimant expert's analysis, ruling that the claimant's calculated losses were *'likely to cause a material and appreciable difference for this claimant in both audibility of sound and resolution of speech'*. Mr Singh, favoured the use of a 4 kHz anchor point, as opposed to a binaural 1, 2, 3 kHz average, suggested in the 2016 LCB guidelines. As such, the claimant's average binaural NIHL, between 3 and 4 kHz, was calculated at 11.2 dB.

The judge accepted, as a result of the method of NIHL calculation, that *'the Claimant's need for hearing aids ... [was] ... brought forwards by 5 years ...'*



Unsuccessfully, he sought to use the McShefferty papers to bolster his argument. At paragraph 50 of the judgment, the judge reasoned:

*'Mr Singh, at page 119 criticises the limitations of the 2 studies – and I do not believe that Professor Lutman has disputed those limitations, but in my judgment, more significantly, he contends that if those papers are accepted, all I am able to conclude is that 3 dB and 6 dB are likely to be of significance in terms of just noticeable and just meaningful levels in terms of speech to noise ... [ratios] ... when considering a relatively broad speech spectrum. Here, however, it is not in dispute between the experts that there is a binaural noise loss of 11.2 dB averaged at 3 and 4 kHz and, even ... [accepting] ... the McShefferty research, that cannot be regarded as insignificant'.*

## CONCLUSIONS

Provided that long-term changes in SNR produce, as McShefferty et al. suggests, a 3 dB JND, the studies dictate that hearing impaired claimants would only 'notice' a difference in speech intelligibility if they were to use hearing assistance which increases SNR by at least 3 dB. The same analogy can be extended to intervention-seeking 'meaningful' difference, at 6 dB. In the conclusion of the 2016 study, the authors advise:

*'... when the JMD was measured as a participant's willingness— 50% of the time—to swap devices or attend clinics for a change in SNR, it was approximately 6 dB for more difficult (lower SNR) situations and 8 dB for less difficult situations ... These latter, less arbitrary JMD values exceed what is currently possible with conventional hearing-aid technology'.*

If this assertion is correct, and the McShefferty limitations are disproven, then noise reduction schemes in modern hearing aids should be enhanced. If they are not, it is likely that hearing aid users are subjected to speech in background noise which has not received an increase in SNR significant enough to produce a reliably discriminable difference, when compared with non-use.





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