Department of Health

National Institute for Health and Care Excellence (NICE) Triennial Review – Call for Evidence

The review team are particularly interested in evidence in support of responses to the 9 questions set out in this Call for Evidence. Wherever possible, please provide evidence in support of your response.

Questions 1-5 focus on NICE's functions and how they are delivered.

Questions 6-9 consider NICE's performance and capability, opportunities for efficiency, and the governance arrangements.

The questions below invite interested stakeholders to consider both together and feed in where they feel appropriate.

*** For all options, you do not have to answer all of the questions – please feel free to answer as many or as few as you like. Where possible, please give specific examples. ***

Name: Charles Lowe

Organisation: Digital Health & Care Alliance (DHACA)

Work Role: Managing Director, DHACA

DHACA currently has 340 members, split approximately 40:40:10:10 across the health & care areas of the public, private, academic and third sectors.

DHACA is funded by Innovate_UK with the objective of encouraging members to pool healthcare innovation funds, such that wheels are only invented once, and to encourage interoperability of healthcare systems. We were established by the UK's Demonstration of Assisted Living Lifestyles At Scale ("dallas") programme, to continue the work started by that programme once it completes in May 2015.

Charles is also President of the Telemedicine & eHealth Section at the Royal Society of Medicine and runs the London Health Technology Forum

Please indicate what interactions you have with NICE / which functions

you use: Currently DHACA's principal interaction with NICE is to promote expansion of NICE's remit to include medical software, notably medical apps.

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Question 1: Is there a continuing need for the functions undertaken by NICE?

Yes

The world is entering a period of increasingly rapid technological change, one effect of which is to deliver new health & care technologies currently at an ever faster rate. If the UK is to take advantage of the enormous potential benefit many of these technologies can offer in improving patient outcomes and dramatically reducing the costs of delivering care – and to winnow out those that do not offer appropriate benefits – an organisation such as NICE is essential, to go beyond the excellent safety gatekeeping role delivered by the MHRA to identify and promote those technologies offering the greatest benefits.

In our many conversations with clinicians at all levels in the NHS, it is crystal clear that they see that NICE provides a vital trusted role guiding advances in treatment and evidencing the efficacy of (in particular) new drugs and medical hardware. A NICE recommendation engenders trust; it promotes improved health & care services and removes any significant liability concerns, including the recommendation/prescription of drugs and medical hardware. DHACA therefore believes that here is an increasing need for the functions provided by NICE.

DHACA's principal reason for responding to this consultation request is a concern that the services offered by NICE are beginning to be outpaced by this rapid period of change in the way health & care services are being delivered. In particular many of our members are concerned that that NICE's service is not currently available for most items of medical software, notably medical apps (by which term we mean medical software downloadable onto portable medical devices that either meets the EU's Medical Devices/In Vitro Devices Directive definition of a medical device (as refined in Meddev 2.1/6)). Excluded from this definition are any 'health & wellness' apps merely giving advice on good health or recording healthcare information eg from 'fitness' wearables.

DHACA believes that this lacuna in NICE's coverage of the health & care sector seriously damages patients, the NHS, and the UK because:

1. It inhibits doctors recommending/prescribing apps for fear of liability and because of absence of efficacy data – this deprives patients of the most effective treatment, particularly those with mental health issues where the effectiveness of some new technologies is very high and coverage of traditional services in the Uk is particularly poor;
2. Doctors are unable to compare or discuss with patients the merits of drug treatment or the (usually much cheaper) app alternative because

they are currently not evaluated on the same basis; again this harms patients who are constrained to taking pills, with potential side-effects and addition problems; it also increases the cost to the NHS as pills typically are significantly more expensive than medical apps;
3. The absence of an agreed standard of evidence for medical apps prevents vendors advertising the benefits of medical apps, reducing sales and undermining the viability of this recently-emerging potential UK export sector;
4. No organisation in the world currently evaluates the efficacy of medical apps in a systematic manner – an opportunity for NICE again to reassert its world-beating status as the first of its kind.

To a lesser extent, our members are also concerned that NICE has little if anything to say about the array of other new technologies that can assist in the delivery of health & care, notably wearable devices for vital signs measurement (aka "wearables", though of course only those with an intended use that offers potential significant medical benefit), point-of-care-testing devices, remote diagnostics systems, electronic health records & electronic patient records, and use of health data.

In summary therefore, DHACA's members are concerned that NICE's programmes are increasingly moving out of alignment with the needs of the rest of the UK's health and care system because they are not tracking the change in available technologies and methods of delivering care.

In the areas it currently covers, NICE makes a significant contribution to wider government policy and constitutes a very justifiable use of public money – as hinted at in the evidence section below, where NICE's remit does not stretch, there is comparative confusion.

Please give evidence for your answer:

If any evidence is required of the increased pace of change, any recent book by Erik Brynjolfssen (eg "The Second Machine Age") or Ray Kurzweil (eg "The Singularity is Near") should provide appropriate evidence, the "second half of the chessboard" being the best simple explanation for exponential growth in data handling capability. The best recent example of a TED talk specifically on how machine learning will quickly deliver an excellent medical diagnosis service, by Jeremy Howard, is here.

Mobihealthnews recently ran an article on the 31 FDA clearances for digital health in 2014 which gives a good idea of the rapid pace of change.

The almost complete absence of NICE guidance on apps and the other technologies mentioned above presumably requires no evidence.

The requirement for evidence on efficacy specifically for medical apps was gathered for DHACA by the author of this consultation, Charles Lowe, in discussion with over 100 people from across the health & care sector primarily in the UK. These included nurses, GPs, hospital doctors (who are typically especially heavy apps users), consultants, health & care managers, social

workers, vendors, managers of app 'curation' sites, industry bodies, lawyers, MHRA and of course NICE itself. The evidence is summarised and is available as Part I, Part II and Part III, with a PS. Alternatively DHACA would be happy to provide it as a single document, if required. Many interviewees requested anonymity, so a full list associated with their comments is not available.

Specifically regarding government policy regarding medical apps – an area of course not currently covered by NICE – there has been very evident incoherence, with Sarah Wollaston MP quoted as claiming that apps are like books so do not require evaluation (they aren't, primarily because books don't compute; apps do), and Tim Kelsey Director for Patients & Information, proposing that apps are 'kitemark ed', seemingly ignoring the existing mechanisms for appraising medical devices. This incoherence is not evident in any area currently covered by NICE: sure there are arguments about whether a drug meets QALY targets, though when exposed to public scrutiny, these are always very clear and precise, unlike the mess about medical apps just now.

Question 2: Assuming that the functions undertaken by NICE are necessary, are there alternative means of delivering them which would be more efficient and effective? See Annex I at the end of this form for the options that might be considered.

Possibly

On the general point of options in Annex 1, DHACA considers it essential that the organisation performing NICE functions remains in the public sector, to ensure maximum trust in its judgement by the NHS and other clinicians.

More specifically, the one area of potential overlap involving NICE that DHACA is aware of is between NICE and the MHRA and specifically relates to evidence: the MHRA needs evidence to prove the safety of a medical device or other technology for CE certification whereas, if NICE's remit were to be expanded, for example to cover medical software, NICE would require evidence to prove the efficacy of the technology.

This whole area will need careful attention when a decision is made to expand NICE's remit particularly as the standard RCT techniques used for drug trials are far too slow for the rapidly changing world that is described in answer to the previous question (for example selection of the hardware for the DH's Whole System Demonstrator trial of telecare and telehealth began in 2006 in LB Newham, where this author won – and ran – the programme for a year, and the final report was delivered to the DH at the end of 2014, a few weeks ago – a total elapsed time of some eight years).

DHACA has a proposal for speeding up evidence gathering specifically for medical apps using a variant of A/B testing used by insurance companies,

online retailers and travel sites, that was developed in conjunction with Prof Jeremy Wyatt of Leeds University, who works extensively in this area, and has previous experience of NICE. It may be more generally applicable to other new technologies.

An additional benefit from NICE opining on appropriate evidence would be to enable responsible technology suppliers to advertise the benefits of their products as the EU's Consumer Protection Directive prevents mentioning benefits when advertising health products unless those benefits can be evidenced; currently there is much uncertainty in the sector as to what constitutes good evidence, so a lead from NICE would be hugely beneficial in terms of raising sales, which would benefit both the NHS and the UK in general.

There would of course also be ramifications for the MHRA which is currently significantly understaffed in this area, and arguably not aligned to handle significant numbers of CE certifications of new technologies, an in particular medical apps – DHACA has already raised similar matters with Ian Hudson, the Chief Executive who is fully aware and working to increase their support for medical apps.

If NICE were to expand its remit in the manner proposed, it would be the only organisation in the world at present offering an unbiased view of the efficacy of medical apps which would therefore represent a significant money-making opportunity for the Institute. (The FDA for example has been active in this area for over ten years, has 'cleared' a little over 100 medical apps, and has yet to opine on the efficacy of any of them.)

It's also worth pointing out that once GPs for example are able to compare the cost and efficacy of medical apps with drugs for those areas where both (or a combination) are appropriate, such as pain relief, anxiety and depression, the NHS stands to save very substantial sums on the drugs bill, as well as having fewer addiction problems to deal with.

However if NICE is unwilling to expand its remit to cover novel healthcare technologies, there are other possible options, such as:

- asking NHS to run a more visible programme of medical apps/technology testing and verification on demand for any medical app whose supplier is willing to pay, and mandatory for CE-certified medical apps/technologies;

- asking Ofcom what provisions they have to license online medical apps stores (eg iTunes, Google Play) or at least regulate their content for consumer protection;

- joining forces with the US Food and Drug Admin (FDA) perhaps including other country/regional organisations too, to save costs by working together more closely on these matters, as these are international issues;

- examining how app curators (http://myhealthapps.net/) can be

licensed/used and promoted as part of or in addition to new regimes for NICE or NICE / MHRA;

- empowering a trade organisation such as the Telecare Services Association in the UK, who already maintains a telehealth & telecare code of practice with associated certification process to provide a technology review service along the lines of the ATA in the USA who now also review remote patient consultations services;

- establish a separate NICE-like organisation specifically to evaluate digital health-related treatments – this might also be combined with how the newly announced NHS genomic medicine centres are going to offer best practice guidelines for genetic information gathering and distribution (these may offer new protocols in this area which should ordinarily contribute to NICE guidelines).

DHACA does not consider that any of these options are very appealing compared with adding incrementally to NICE's remit – an organisation that already has worldwide credibility and expertise in evidence-gathering & determination of the efficacy of rival medical treatments.

Please give evidence for your answer:

With Prozac, to take one example, advertised on the internet at some £175 per 100 pills, it is pretty clear that even if it is necessary to pay the same prices for depression-treating apps as private individuals have to pay for CBT programmes such as Beatingtheblues (currently advertised at £149.95, neither cost of course includes NHS discount), the NHS would save a huge amount of money by encouraging greater use of apps, as well as reducing addiction and side-effect problems.

(To support a comment made earlier in the paper, the evidence from organisations such a Big White Wall and Psychology Online is that online consultations involving app usage are especially beneficial, in part at least because there is a record of the consultation that patients can replay, to embed the learning. Given the surplus of demand over supply for mental health facilities in the UK, and the fact that unlike physical health issues, mental health apps can assist in assessment, diagnosis, monitoring AND treatment, this is a particularly important area that requires prioritising.)

Question 3: How effectively does NICE carry out its functions?

DHACA's dealings with NICE have been exclusively discussions related to medical apps. All NICE personnel spoken with have been extremely supportive and helpful, whilst tactfully making clear the challenges of a seriously cash-constrained organisation taking on what could, if not handled carefully and appropriately, become a large element of their workload.

Clearly to expand to cover new medical technologies would likely require additional DH/NHS funding, or a means of recovering greater costs from potential suppliers, although where these technologies improve care and reduce treatment cost, there would likely be a most attractive payback in terms of faster adoption arising from positive NICE guidance.

Please give evidence for your answer:

In the evidence gathering mode referred to earlier, this author never heard a serious criticism of the Institute – indeed it was time and again that those being interviewed said "we need a NICE for medical apps", or words to that effect. Strong praise indeed!

Question 4: How do NICE's functions impact on users and stakeholders?

Currently the impact that NICE's functions have on users of new technologies and their stakeholders is limited only to those few technologies covered by NICE appraisals.

Otherwise, the only one relevant to DHACA is the last: our members believe that NICE does not currently have the budget to go far enough in terms of evaluating new technologies appropriately, including the efficacy of medical apps.

More generally there is huge confusion, as revealed in the DHACA research by Charles Lowe, mentioned in Q1 (see Part I, Part II and Part III, with a PS) among suppliers, hospital clinicians and GPs as to what the roles of the MHRA and NICE really are especially regarding technology-related services. Patients rarely have any understanding, so the need for GPs in particular to get a better understanding is critical.

Please give evidence for your answer:

We hear occasionally of an app that is said to be being evaluated by NICE although none has yet been publicised.

Question 5: How does NICE engage and collaborate with users and stakeholders?

Sadly DHACA has little practical experience to relate to date; all requests have been responded to politely and in reasonable time, although we feel we have not been able yet to make our case fully to NICE.

Please give evidence for your answer:

Question 6: Could NICE reduce costs or improve performance through efficiencies?

There are always opportunities to reduce costs very marginally in any organisation, though whether the cost involved in the case of NICE would be worth it is not something we know the organisation well enough to judge. Certainly DHACA has seen no evidence to suggest inefficiencies in NICE; indeed we are aware that significant savings have already been achieved over the past few years.

Perhaps more relevant would be to consider a different cost model for NICE – for example could suppliers whose products/services are approved make a greater contribution to the costs of running NICE, or could a micropayment levy be charged every time eg an app is downloaded? These are trivial suggestions, although doubtless with time & expertise, good suggestions can be developed.

Please give evidence for your answer:

Question 7: Is the body, and its approach, sufficiently able to identify and respond to challenges in the Health and Social Care sector?

No

As mentioned earlier, new technologies are emerging at an exponentially increasing rate. For example, medical apps, almost unknown at the time of the previous NICE triennial consultation, are now a significant feature of the health & care sector. Although this author was told recently in a Chatham House Rules-governed debate that NICE can evaluate the efficacy of CE-certified medical apps, this is not the advice given in discussions with senior management in NICE. DHACA is therefore forced to conclude that NICE is constrained by remit and/or budget from being fully responsive to changes in the wider health and care system. This is an extremely serious issue that DHACA considers requires urgent action for the reasons given in Q1, notably:

1. It inhibits doctors recommending/prescribing apps for fear of liability and because of absence of efficacy data – this deprives patients of the most effective treatment, particularly those with mental health issues where the effectiveness of some new technologies is very high and coverage of traditional services in the Uk is particularly poor;
2. Doctors are unable to compare or discuss with patients the merits of drug treatment or the (usually much cheaper) app alternative because

they are currently not evaluated on the same basis; again this harms patients who are constrained to taking pills, with potential side-effects and addition problems; it also increases the cost to the NHS as pills typically are significantly more expensive than medical apps;
3. The absence of an agreed standard of evidence for medical apps prevents vendors advertising the benefits of medical apps, reducing sales and undermining the viability of this recently-emerging potential UK export sector;
4. No organisation in the world currently evaluates the efficacy of medical apps in a systematic manner – an opportunity for NICE again to reassert its world-beating status as the first of its kind.

DHACA therefore considers it essential either to extend the remit of NICE, or explore the options mentioned in Q2 above.

We have seen no evidence of the organisation behaving incoherently.

Regarding the question of skills, DHACA has not encountered many people in NICE who have a good understanding of the finer points of the new technologies, and specifically our current major area of concern, medical apps; this however is a common problem in all but the fastest growing – and highest paying – suppliers, as the skills are still in very short supply.

The exemplar technology used through this response to the NICE consultation is medical apps: it may well be that apps are a transient phenomenon to an as-yet completely different model of health & care so up-to-date NICE guidance will continue to be very relevant. Recent demonstrations of for example the use of machine learning to aid medical diagnosis suggest that NICE will need some very different skillsets to verify the efficacy of that technology.

Please give evidence for your answer:

The TED talk from December 2014 given in evidence for Question 1 on deep learning and its application to health is also here – well worth a watch!

Question 8: Does NICE follow best practice governance arrangements?

Yes

DHACA members have always been impressed by NICE's openness and the quality of its personnel.

Please give evidence for your answer:

Question 9: Are there any other issues or evidence the review team

should take into account?
The points raised by DHACA's members are covered adequately above
Please give evidence for your answer:

Please return completed forms by:

Email to: TR-NICE@dh.gsi.gov.uk

Or Write to:
NICE Triennial Review Team
Department of Health
Richmond House
79 Whitehall
Room 220
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Annex I

Option	Questions
Remain in its current form (Executive Non-Departmental Public Body)	Is the function necessary and carried out effectively? Does the current form support innovation and the wider health and care system? Does it contribute to economic growth? Does the current form provide the right degree of oversight and governance? Are there appropriate incentives to encourage continual improvement?
Merge with another public body?	**This might be with a government department, another arm's length body, or a local government body.** Would this function be better delivered by a government department? Does it need to be conducted at greater arm's length from government than currently applies? Are there other organisations with which synergies could be obtained through merger? Can this function be delivered more effectively by local government? What are the risks and benefits of moving the function? Could efficiencies be made by delivering the function through a different model?
Move into private or voluntary sector?	**This could mean privatisation, mutualisation, a joint venture with a private company, or other potential approaches.** Is there an existing service provider (or providers) in the voluntary or private sector that could deliver this function? Can the function be better (more efficiently) delivered by the private sector, or delivered under contract by the voluntary or private sector? Can the function be delivered by a mutual or social enterprise? (This implies employees having a stake in the success of the organisation (John Lewis is an example).) Could the body increase its revenues through a more commercial approach? What are the risks and benefits of moving to a more commercial model? Are there potential efficiencies that a more commercial model might encourage? Is this function appropriate for private sector activity? What safeguards would need to apply?

*** END ***