



DHACA final response to 'Personalised Health & Care 2020'

Purpose

This document is an updated and more detailed response from the Digital Health & Care Alliance (DHACA) to the NIB regarding its *Personalised Health and Care 2020* framework for action. It replaces our earlier [initial response](#). Its main purpose is to register DHACA's strong support for the initiative and to seek an early audience with appropriate members of the NIB as we believe our members can make a very significant positive contribution to the successful delivery of the plan.

DHACA

DHACA is an organisation sponsored by Innovate UK with a specific remit to encourage interoperability between health & care systems in the UK, and to encourage sharing of innovation development to reduce money wasted on reinvention. The current 360+ members of the Digital Health & Care Alliance ("DHACA") are drawn from across the board of government, academic, large corporate, SME and charity sectors, and include both patient and developer representation.

DHACA operates primarily through (currently) seven Special Interest Groups ("SIGs") which comprise members with particular skills and knowledge relevant to each area. The SIGs are: Benefits & Value, Economic & Business Modelling, Healthcare Education, Information Governance, mHealth Apps, Reference Architecture, and Self-Care.

Summary

DHACA is extremely supportive of the plan described in the paper. As will be apparent from the listing of SIGs above, many areas mentioned are ones where work is already well underway in DHACA, so we do have value that we can add immediately, as well as the ability to bring in a wide range of expertise from our extensive membership; as will be apparent throughout this document, we are very keen to work with the NIB to make it *Personalising Health and Care 2020* a reality.

In more detail

What follows are our more detailed comments and proposals; we welcome the opportunity to expand on them with the NIB.

Chapter 1 – Why do we need to act now?

We were especially pleased to see the recognition that “For care professionals, from social workers to doctors and nurses, the arrival of the digital age has often been experienced not as a force for good but rather as an intrusive additional burden in an already pressured existence.” Many of DHACA’s members, as well as its management, have long experience of successful implementation of health & care change management programmes involving use of new technology essentially as a catalyst to encourage beneficial behaviour change – well implemented telehealth and supported self-care, for example, can transform a culture to one that is patient-centric. In our experience, the single most important prerequisite is a respected clinical champion that has the power to make important systemic changes to support the introduction of technology to change ways of working.

Chapter 2 – Can it be done?

We welcome the reference to the importance of standardisation, be it formal or by evolution and informal adoption, as this is a prerequisite to our drive to improve interoperability between systems.

The challenge, of course, is getting the balance right between enforced adoption of formal standards and allowing innovation. As digital services are in the early stages of evolving, standards should only be enforced where absolutely necessary, as inappropriate enforcement will stifle innovation, as there’s no means to do something different within the strait-jacket of the standards.

Two further considerations are:

- Standards documents must be freely available to read if uptake is to be maximised, especially by SMEs. IEEE, BSI and such like charge very substantial sums to gain access to standards, even as a PDF; this can be a major barrier to someone who wants to have a quick look to see what it’s like.

There is good work currently being undertaken under the auspices of BSI at the moment to produce PAS 277 “Health and wellness apps – Quality criteria across the life cycle – Code of practice”, which the BSI is kindly, exceptionally, making freely available for anybody to download, for it to have the widest possible impact.

- The standards development process needs to be truly open and inclusive. The process currently set out in the Standardisation Committee for Care Information’s (SCCI’s) [Operating Framework](#) is far from this – it is extremely bureaucratic, and assumes that HSCIC staff will do all the work, only taking input and comment from others. We believe this risks stifling development and innovation.

Best practice is to undertake standards development in an open forum (not one with restricted membership rules, or one which requires a substantial membership fee to be paid – DHACA would be delighted to assist) and then, if necessary and when pretty-much stable, ratified by a more formal body such as SCCI. This is the approach that has worked very well in the digital TV and mobile phone sectors – some of the recently most innovative digital sectors.

In short, DHACA believes that the NHS needs to “let go” much more and let industry and health informatics people work collaboratively as peers. Great things will then happen.

Specifically, DHACA would strongly recommend and be happy to assist in:

- a. co-design of all standards (with all stakeholders, including SMEs and local NHS organisations as well as national NHS organisations and larger incumbent suppliers) at all stages;
- b. learning from open-source distributed development methodologies and governance;
- c. not letting HSCIC/NHS England technologists go off into an “ivory tower” to specify anything alone – do everything in the open, working by consensus wherever possible;
- d. publishing everything under an open licence;
- e. basing technical implementations on existing open standards that are agnostic of the business model of actual systems (e.g. the health-related standards [FHIR](#), [OpenEHR](#), [SMART](#), along with standards from the Internet of Things, such as [Alljoyn](#) and [HyperCat](#), and generic standards from W3C and IETF), with only minimal changes to create a UK / English profile;
- f. “rubber-stamping” the eventual technical solution as an NHS Information Standard if needed, but ensuring that there is a means of constant improvement outside of a typical multi-year fixed standards review cycle;
- g. engaging with NHS Scotland, NHS Wales, and HSCNI to try to ensure maximum applicability/compatibility across four UK home nations as possible, to minimise cost of development; and
- h. endeavouring wherever possible to ensure that the open standards on which solutions are based will meet the [GDS definition of an Open Standard](#). Realistically, of course, this may not always be possible but, at the very least, they should be free to view, and the licensing terms for use should not disadvantage/be unreasonable for SMEs.

We note with approval HSCIC’s commitment (in its [draft strategy](#)) to a “strategic shift from top-down delivery of standards to a more open and engaged role (as ‘orchestrators’)”.

Chapter 4 – what needs to change?

We approve very much of the statement that a collaborative approach is necessary to achieve the vision, in which “solutions and services must be defined by the service users, the carers and the care professionals” in a process that “must be open and transparent”. This aligns perfectly with our view, stated above, about the subsequent technical standards approach. In fact, one should lead on to another – no technical standard should be defined without a need being clearly articulated by users.

A recurring theme in our comments is the issue of standards, as we believe that intelligent application when appropriate is the key to rapid innovation. We are therefore very supportive of the comment: “We will be tight on standards and definitions, and clear on expectations regarding interoperability, but we will support local decision-making on systems, programmes, interfaces and applications.”

DHACA’s members have enormous experience in determining and measuring the benefits of digital health interventions; we would therefore be delighted to assist the NIB in developing the road-maps and business cases for the resources required to deliver this plan.

Chapter 5 – Enable me to make the right health and care choices

We welcome the commitment to extend patient/service user access to GP records across all NHS institutions by 2018, and to allow the individuals to write into these records. We welcome the

acknowledgement that patient-supplied data and comments can be of value to clinicians, and can enhance the clinician-patient interaction and ultimately patient experience.

Likewise, we welcome the statement that *NHS Choices* is to become a single point of access for digital transactions for NHS, adopting the GDS Identity Assurance service.

In more detail, we believe that all records access and transactional services must be provided via APIs that are accessible by any/all accredited apps. These APIs must be defined in open industry forum as described above, and the specifications openly available to anyone. In order not to stifle innovation, it is important that *NHS Choices* is not given any special access – it should be required to use only the same APIs as any other app or web service.

We understand that NHS England intends that *NHS Choices* be reworked into a modern web application platform that facilitates the development of different parts of the overall site by a variety of developers. We encourage NHS England to investigate what lessons can be learnt from existing open web application platforms, for example, [that operated by the BBC](#).

We consider that adoption of *GOV.UK Verify* (the brand name for the GDS Identity Assurance service) is the right choice – however it will need to be tailored for the ID assurance requirements of the health and care sector; we understand that work is underway within NHS England, however we would strongly recommend open stakeholder engagement, which DHACA is happy to assist with.

A particular area of expertise in DHACA is mHealth apps. We have already published [guidance](#) pulling-together information from various sources about what apps are and are not likely to be judged by MHRA to be medical devices. Our mHealth Apps SIG is taking this work further, working on flow diagrams to help app developers ensure they have covered all the extensive legal requirements (including those other than medical devices legislation) when developing apps, to help them then navigate the CE certifying process, and to help clinicians understand what they need to do before prescribing or recommending an app. The guidance will:

- Cover regulatory aspects: EU medical devices & data protection directives, consumer protection laws, copyright & licensing laws, patents;
- Attempt as much clarity as possible over what is (and is not) a medical device to ensure developers can be appropriately guided;
- Cover procurement (organisational versus individual versus prescriptions) and suitable reimbursement models.

The SIG would be delighted to work with the NIB to ensure the above guidance is as comprehensive as possible.

We particularly welcome the proposal to “support the development, diffusion and adoption of low-cost, high efficacy apps with a particular priority on mental health services”, as we have been hugely impressed by the mental health apps developed by our members – these have an opportunity not only to enable diseases to be diagnosed & monitored electronically, they can also treat people electronically. Intriguingly many providers claim that treatment gives better results when done online than face-to-face – one reason for this is that there is a record of the consultation that patients can rerun afterwards, should they wish to, to ensure the key messages are absorbed.

We note also in the same proposal a reference to “rapid trial methods”, a topic that DHACA has been working on with Professor Jeremy Wyatt of Leeds University, an acknowledged expert in this field. At our request he has produced a proposal to develop a technique for rapid trials of mHealth apps using the ‘A/B testing’ technique developed by the banking, insurance, travel and online shopping industries for rapid app appraisal. He is all ready to start working with us when we can find the funding, so DHACA would be delighted to discuss appropriate potential funding source with the NIB.

The SIG would also be delighted to provide comment and feedback on the NIB roadmap & plans as they develop.

Charles Lowe, MD of DHACA has already made [a presentation to a NIB workgroup](#). The principal thrust of the presentation was the need for an agreed standard of evidence that providers needed to produce in order for clinicians to have confidence in the efficacy of products, as well as their usefulness, appropriateness, etc., to justify recommending/prescribing them.

A separate point was that there was an urgent need to improve policing of ‘serious’ mHealth apps to prevent a potential disaster, perhaps with an unproven dosage calculator app. Charles proposed that a date be set in the future when all apps used in the NHS should have a basic (eg ISB0129 & subsequent clarifications) safety check, one outcome of which should be to identify all apps that need CE certification. Only CE certified/ISB0129-cleared apps should then be used, much as current regulations cover all other aspects of potentially dangerous materials used in the NHS.

In the context of apps for use by members of the public (rather than healthcare professionals) and which are not specifically prescribed by healthcare professionals, and thus which would not fall under either the ISB0129 regime or any approval scheme overseen by NICE, we wonder whether NHS England could ever realistically have the resources to provide accreditation of such apps itself (as it appears to be trying to do at the moment with the [NHS Apps Library](#)). It seems more sensible that NHS England should develop an accreditation scheme for independent app accreditors which may do things differently, and provide different experiences to members of the public looking for apps, but which all comply with some overarching requirements.

The SIG would also plan to cover alignment to SNOMED CT, testing and evidence building procedures for apps, use of NHS number and integration into electronic care records.

Chapter 6 – Give care professionals and carers access to all the data, information and knowledge they need

As mentioned earlier, we were pleased to see a reference to limiting standards only to where needed.

An underlying theme throughout this chapter is the need for good, widely-used apps that can securely and reliably record and transmit clinical data – as mentioned earlier, the mHealth Apps SIG is working hard on enabling this vision and would be delighted to work with the NIB on this.

DHACA’s Self-Care SIG has a particular interest in the commitment to “drive up adoption and optimisation of mobile technologies that enable healthcare professionals, service users and carers to collaborate effectively”, and would particularly welcome working with the NIB on this topic.

Information sharing and collaboration must extend to informal, as well as formal, carers. DHACA members have significant experience of supporting carers to access and/or control patient data to enhance the effectiveness of service delivery for the patient's benefit.

Chapter 8 – Build and sustain public trust

DHACA welcomes the proposals to build and maintain public trust.

Our Information Governance SIG would welcome the opportunity to be involved in the proposed development of a roadmap for moving to consent-based information sharing; we have already published a framework for digital [identity and consent](#). Our Self-Care SIG is also interested in working with the NIB to remove information governance-related barriers to the innovation encouraged in Chapter 9.

We would suggest that the proposed enhanced data security standards and the associated re-launched IG Toolkit need to take account of the use of apps as a means of citizens interacting with the NHS, be that to book appointments or repeat prescriptions, to view their care records, or as part of a programme of treatment. DHACA could assist with some of this work – specifically the Reference Architecture and Information Governance SIGs. The work within, and outcomes from, Innovate UK's [dallas](#) and [Trusted Services](#) programmes should inform this toolkit update.

Chapter 9 – Bring forward life-saving treatments and support innovation and growth

DHACA greatly welcomes your objective of establishing England as one of the world's leading centres for innovation in digital health and care services. Our commercial members would obviously particularly welcome it, although our public sector and patient representatives would benefit hugely too.

In particular, we would ask that DHACA is invited to join the AHSNs, AHSCs and other government stakeholders in the NIB's work to develop an industry strategy. Our Benefits & Values, Economic & Business Modelling and mHealth Apps SIGs are already working in this area. We are particularly concerned to ensure that a holistic evaluation of redesigned service models is undertaken (rather than current evaluation techniques, which tend to focus on economic benefits at the service component level).

DHACA is already engaged with the Bradford Digital Health Enterprise Zone and the associated Digital Catapult Local Hub. The work being undertaken here would add particular value to the proposals for Technology for Care innovation centres and "test beds".

Our Economic & Business SIG would also be very interested in working with Healthcare UK to explore opportunities to develop international opportunities to exploit digital health and care innovations.

Chapter 10 – Support care professionals to make the best use of data and technology

We consider the choice of Mersey Burns as an exemplar to be a particularly appropriate choice. Rowan Pritchard-Jones, the leader of the Mersey Burns innovation, has addressed DHACA-attended

events three times to date, to enable us to learn as much as possible from the development and marketing of this truly outstanding app.

DHACA's Healthcare Education SIG is exploring ways to support the training of healthcare professionals to enable them to effectively incorporate innovative digital technologies in their workflows and professional relationships with patients. This will include guidance and case studies of how technologies can enhance delivery as part of a service redesign. Our members' experiences of delivering digitally-enabled transformation are likely to provide a useful perspective on the knowledge and skills framework for all levels of the workforce being developed by HEE and HSCIC and we would value the opportunity to review and input on this work.

DHACA's Economic & Business Modelling SIG would especially welcome being involved with the proposal to develop a framework contract.

Chapter 11 – Assure best value for taxpayers

DHACA welcomes the objective of this chapter.

We particularly welcome the proposal to align existing national programmes with the core outcomes of the document to maximise their cost and clinical benefits, and your proposals for the termination of ineffective investments. We would be delighted to assist.

Stressing again DHACA's interest in standards, we welcome the proposed publication of security and interoperability standards for common services to be purchased directly by care providers, such as email, to allow them to connect to the national infrastructure and provide confidence for inter-organisational transactions.

Chapter 12 – How can we make it all happen?

DHACA is dedicated to open systems, so we greatly welcome the commitment to “ensure a level playing-field for open source software” alongside commercial solutions. We would emphasise, once again, however, that the most-important commitment needs to be to open standards and APIs, rather than the source code.

In our discussions with GPs and other clinicians, they have indicated a particular welcome for an efficacy measure for mHealth apps which, as already mentioned above, DHACA has suggested would best be developed by NICE, a suggestion also agreed by senior NICE personnel, and as presented to a NIB workgroup meeting recently by Charles Lowe.

The benefit of this proposal, once implemented is that it would begin to allow clinicians to compare the benefits of apps and drugs in a comparable manner so, say, a GP could decide whether a mental health app or an anti-depressant drug would be more effective for treating depression. Given the relative costs of drugs that treat anxiety, depression and pain, and the cost of a CBT-based app, we would expect that if apps are proven to be as effective as they are cracked out to be, this would yield a significant saving to the NHS as well as improving patient outcomes.

Alongside this, again as suggested to the NIB workgroup already, there is a need to set a date beyond which all apps used in the NHS need to be safety checked to ISB0129 or CE-certified: this is

to avoid problems with potential 'bad apps' that may well be being used now and which risk causing serious harm or death to patients.

Once the above has been established specifically for mHealth apps, it would of course also be appropriate for wearable and implantable health monitoring devices, and indeed any medical innovation with potentially significant risks and benefits. Indeed in our submissions to the triennial reviews of both NICE and the MHRA, DHACA proposed the creation of an 'innovation architecture', to embrace both the above suggestion and related topics, in order to accelerate the adoption of beneficial medical technology. We would be delighted to expand on this if required.

Finally, to close, DHACA would welcome the opportunity to work strategically with the NHS/NIB. In particular we would welcome NIB support to obtain funding for DHACA to undertake some of these activities on a formalised basis, such as the development of a technique for rapidly establishing efficacy evidence for mHealth apps as mentioned in Chapter 5. We strongly maintain that the NHS and NIB stand to be huge beneficiaries from the work of DHACA, so a formalised partnership would be desirable, and beneficial, for all.