

AGENDA ITEM 4**Emerging Science and Bioethics Advisory Committee****Focus Group on Technologies to Optimise Treatment****Proposal to ESBAC****INTRODUCTION**

1. At the second ESBAC meeting, the Committee decided to set up four Focus Groups each to consider one of the four topics selected for possible work. These Groups met twice with the aim of scoping the feasibility of these areas of work.
2. Discussions from the Focus Group on Technologies to Optimise Treatment¹ are reflected in this paper which proposes to ESBAC that a piece of work to *explore using emerging technology to assist and improve patient adherence as a technique to improve healthcare* should be included in ESBAC's workplan.
3. The reasoning behind this proposal is outlined below with reference to ESBAC's topic selection criteria, together with initial scoping information on the proposed approach including potential stakeholders, delivery mechanisms and deliverables. This is in line with Annex E of ESBAC's Code of Practice. The Membership of the Focus Group is included at Annex A.
4. ESBAC is invited to comment on this proposal and collectively agree whether the Committee is supportive of the proposal progressing.

PROPOSED APPROACH

5. The Group proposes focusing on emerging technologies that may assist (rather than 'monitor') patients – often those with complex conditions – to optimise their medicine adherence and plan their healthcare. The work would consider reasons for patients not following the prescribed therapy, recognising that these reasons may vary depending on a number of factors (including the disease type/condition) and may be behavioural (e.g denial, side effects) or as a result of a patient's condition (e.g dementia, schizophrenia). The work would seek to establish which patient scenarios, if any,

¹ The group was originally called the Health Related Behaviour Focus Group, but changed its name to reflect the evolving discussions within the Group.

could be assisted by emerging technologies such as smart pills², recognising no one size will fit all.

6. The emphasis is on improving patients' healthcare and to help people optimise their treatment by adhering to the prescribed regimen. However, it is also envisaged that this proposed work that would consider why people do not adhere to medication and establishing what emerging technology might improve this situation would be of interest to the research community, where patient adherence during participation in research, including clinical trials, is important.
7. Although reference is made in the paper to patient 'adherence', it is recognised that alternative terms in usage include 'compliance' and 'concordance'. If this work is taken forward the terminology can be reviewed to best reflect the context.
8. There are also other potential areas of public interest in improving adherence, such as the appropriate use of public funds, or the social responsibility to continue treatment (e.g. antibiotic resistance and the treatment of TB requiring lengthy courses of medication that may have unpleasant effects (see Annex B).
9. The Group also considered conditions of treatment (which require the patient to comply with certain behaviour or achieve certain goals before being eligible for treatment, (e.g. bariatric surgery, fertility treatment) but recognised some areas lacked an explicit link with emerging technologies.

TOPIC SELECTION CRITERIA

10. The case for how this topic fulfils ESBAC's remit is summarised below:
 - ✓ **Relevant:** Advances are being made in emerging technologies in this area and a range of devices is becoming available. How they are utilised has potential ethical, legal, social and economic implications that it would be helpful to consider before these technologies become more widespread.
 - ✓ **Applicable to policy:** There is a range of potential policy linkages for this work to feed into and be advised from. It will be essential that any work taken forward ties in very closely with the work that the Chief Pharmaceutical Officer of the NHS Commissioning Board (NHSCB) is taking forward on the optimisation of medicines. In

² For example, smart pills that contain a tiny antenna and microchip signalling when the pill has made it to the patient's stomach. Pill bottles wirelessly report to a computer when the cap has been opened and there is a device to dispense the medicine at the right time and for reminding patients to take their medicine

addition, the 'Steering Group to Improve the Use of Medicines' recently published their report ('Improving the use of medicines for better outcomes and reduced waste: An action plan')³. The Steering Group's action plan will also be considered as part of the NHSCB's medicines work programme. Any work ESBAC takes forward in this area would also have to make links with the quality, innovation, productivity and prevention (QIPP) agenda, and in particular, the QIPP work on medicines procurement and supply. Other potential policy linkages include health equality and the health and wealth agenda.

- ✓ **Timely:** No dependencies on timing but consideration would need to be given to the delivery of the NHSCB's work on medicines optimisation and possible alignment issues. There is ongoing debate on adaptive licensing and the possibility of granting marketing authorisation, on the basis of less data than is currently required, to accelerate the availability of important life saving medicines. Patient adherence (and therefore means of improving adherence) is an essential element of adaptive licensing because of the need to reduce uncertainty by collecting post marketing data, and ensuring that the data collected is valid (e.g. patient adherence is high) and that benefit-risk balance can be progressively assessed.
- ✓ **Realistic:** The proposed work relies on the availability of ESBAC and sub-groups that may be set up and stakeholders to contribute.
- ✓ **Unique:** This work could build on from NICE's guidance (Patient care in the future, 2009 No. 76) with the view of exploring, which, if any, non-adherence types could be assisted with emerging technologies. This technology could also be applied in research (e.g. the potential to improve data, not just for patients, but also for those involved in research /clinical trials where patient adherence is not necessarily known). Following the Faculty of Pharmaceutical Medicine's Annual Symposium on drug adherence, there appears to be significant interest in this area, but nobody else seems to have made the connection that the Focus Group has.

TOPIC FRAMING ISSUES

Scoping:

11. The proposed work could focus on technologies (e.g. digital medicines containing a sensor, pill bottles that wirelessly report to a computer when the cap has been opened) that specifically address

³ The Report covers making more effective use of medicines in primary and community care, in secondary care and in care homes and end of life care. It also looks at how patients can be better engaged in decisions about their medicines and how information about medicines can be better provided to patients and health and care professionals.

issues around medicines use, rather than, for example, technology for monitoring vital signs. The emphasis should be on improving patients' healthcare. The scope of this work includes identifying the range of reasons for non-adherence and consideration of the behaviours and conditions that could be addressed by the emerging technology available.

12. An important component of the work would be to explore the ethical aspects of the technology including, for example, issues around whether patients felt that the use of such technologies impacted positively or negatively upon consent to treatment. Some initial consideration of the potential ethical issues has already been undertaken and is attached at Annex B for information.
13. Other considerations include the feasibility of the measures being suggested (e.g. drug re-formulation), data governance, whether some patients might potentially be concerned that they had to use the technology to access the treatment and issues of dignity and autonomy. Economic implications also constitute an area of interest requiring a cost-benefit analysis. This would particularly highlight the benefits of new technologies that both raise patient adherence and provide savings when implementing them.
14. Consideration would also be given to the fact that patients may need more than one intervention for it to be effective. Additionally, interventions may also need to be reinforced to prevent regression to former behaviour.
15. Telehealth⁴ and telecare⁵ are out of scope, except perhaps to the extent that they are used specifically for the purpose of remote monitoring in support of adherence.
16. If this work is progressed additional areas for possible future consideration, (but as yet not considered by the Focus Group) are included in Annex C.

Stakeholders:

17. If the work proposed by this Focus Group were taken forward it would need to be closely aligned with the medicines optimisation work being led by the NHS Commissioning Board, and recognise

⁴ Telehealth – often referred to as remote patient monitoring – refers to services that use various point-of-care technologies to monitor a patient's physiological status and health conditions. Typically, it involves electronic sensors or equipment that monitors vital health signs remotely from home or while on the move. [Source: <http://3millionlives.co.uk/>]

⁵ Telecare is a service that enables people, especially older and more vulnerable individuals, to live independently and securely in their own home. It includes services that incorporate personal and environmental sensors in the home, and remotely, that enable people to remain safe and independent in their own home for longer. [Source: <http://3millionlives.co.uk/>]

the NHSCB as a key stakeholder to consult with at the outset. Close collaborations would also need to be established with the MHRA and industry, including academics and clinicians. The initial identification of stakeholders/collaborators includes:

- NHS Commissioning Board (NHSCB)
- DH Medicine, Pharmacy and Industry colleagues (MPI)
- MHRA
- NICE
- Faculty of Pharmaceutical Medicine
- DH Commercial Medicines Unit (CMU)
- Industry
- Experts in the area
- Patient groups and their carers
- Clinicians/prescribers

Delivery Mechanism:

18. A collaborative approach to the work is proposed engaging with relevant stakeholders as appropriate to maximise resources available and ensure expert input.
 19. One option would be to set up a task and finish group to look in parallel at the emerging technologies available and the evidence of non-adherence. This could include a workshop of stakeholders to establish the state of the art around these emerging technologies, and appraise different approaches to seek a rounded view to inform the work. The group would have to deliver any agreed outputs itself.
- Co-ordinate a piece of work on:
 - identifying and pulling together what the state of the art is in emerging technologies in this area
 - identifying the range of reasons for non-adherence
 - consideration of the behaviours and conditions that could be addressed by the emerging technology available.
 - exploring the ethical aspects of the technology

Deliverables:

20. The tangible output could be a brief report or framework to be placed in the public domain that considers the ethical implications (not necessarily with recommendations) of emerging technologies to assist patients comply with their medication.

Cross cutting themes

21. Overarching themes of particular relevance to this topic that would need to be given consideration if work was taken forward include the impact of regulation, consumer protection/safeguarding patients, governance and good practice, translation and societal impact. Linkages could be made with the Regulations Focus Group through a shared interest in and implications of adaptive licensing.

QUESTIONS for ESBAC:

ESBAC is asked to comment on the proposal with a view to recommending whether or not this work should be taken forwards.

If ESBAC recommends that this work should be taken forwards, then it will wish to comment on the remit, scope and deliverables.

However, if ESBAC considers that this work should not be taken forward at this stage, the Committee will wish to record its reasons for its decision.

Annex A

Health Related Behaviour Focus Group

Members

Prof. Sir Alasdair Breckenridge (Champion)

Dr Rachel Quinn

Prof. Angus Clarke

Prof. Duncan McHale

Mr Hugh Whittall

Dr Julie Maxton

Ms Katherine Littler

Ms Madeleine Colvin

Dr Paula Boddington

Prof. Peter Littlejohns

DH

Dr Mark Bale

Dr Jane Barrett

Annex B

Ethical issues that may be raised and which therefore need to be examined include:

Consent to treatment. Consent to treatment always poses the potential of misunderstanding, gaps in communication and ambivalence. It is possible therefore that technologies to ensure adherence may be experienced as putting pressure on 'consent' e.g. in cases where there is ambivalence about medication, one reason for poor adherence. On the other hand, better data about treatment effectiveness under different regimes of adherence may feed into better understanding of doses and in the longer term address some patient concerns about medication use. It would be of ethical importance to address the question of whether any patients felt that the use of such technologies impacted positively or negatively upon consent to treatment.

Responsibility and blame. Placing of inappropriate responsibility on patients for non-adherence or for their behaviour in general is perennially possible and raises ethical issues. Much depends on context and on individual attitudes as well as on general social attitudes and climates of opinion so it may not be easy to give a 'yes/no' answer. Adherence technologies could potentially be used with individuals and groups in ways that could be construed as blaming or as attributing labels of 'irresponsibility'; or, if they are used routinely and if they help increase adherence without individuals being 'nagged' by professionals, they may help to reduce such labelling.

For some issues, there may be a general social responsibility to continue treatment, e.g. antibiotic resistance and the treatment of TB requiring lengthy courses of medication that may have unpleasant effects.

Relationships between patients and health professionals. Any relationship has many dimensions. At one end, a patient may feel excessively monitored or nagged by a 'nanny' technology and a critic might argue this is a further step in social surveillance. At another end, a patient may feel that technology that is concerned with their health behaviour in between surgery visits extends the sense of being cared for and of an ongoing relationship with their health professionals. These are just initial illustrations of how such technology might be received, but nonetheless illustrate how ethical issues may be raised which deserve attention.

Social inclusion. It is known that the introduction of new technology may have the unintended effect of increasing health disparities because uptake is disproportionately higher in the more advantaged groups. However, if these technologies help to increase adherence, they may assist with improving the health status of the more vulnerable groups, as these groups may have higher rates of non-adherence for a variety of reasons, including lack of stable accommodation, low self-esteem, lack of social support, poorer memory, etc. It would be very interesting therefore to monitor both uptake by vulnerable groups with poorer health status, and impact on health inequalities between different social groups. In the best-case scenarios, impact on the health of the

worst off in society may be an important reason to utilise such technologies. Different reasons for poor adherence may apply in different groups and therefore different technologies might be the most effective at countering their relatively poor health.

Reduction of waste / and improving treatment outcomes for both individuals and for patient groups by the use of better information from knowledge of how patients actually take medications would both of course in themselves be beneficial and to that extent provide ethical reasons for use, other things being equal. Reduction of waste may refer not just to waste of medicines but saving of human resources if some patients are able to be more independent or cut down on doctor visits.

Annex C

Widening the scope – potential future areas for consideration

In an increasing number of conditions, new technologies are being utilised by patients themselves and these are often critical in their management. Not only does this raise the issue of the appropriate use of the technology, but also how these innovations have changed the interface between the patient and the health care professional.

Some examples are suggested below:

Hypertension - This was formerly largely the domain of secondary care, as GPs referred patients to hypertension clinics, which mushroomed in the 1960s as effective treatment became available. However, so large was the problem that GPs had to become more actively involved. The next (and current) phase is to devolve measurement of blood pressure to patients themselves using technology of varying reliability by individuals with varying skill.

Not only may this be a problem, but it may change the relationship between the patient and the health care professional. Should the patient be in charge of altering drug dose? How should the patient communicate his information?

Anticoagulant therapy - It is now relatively common in selected cases that patients are invited to use testing at home to monitor the international normalised ratio or INR. How reliable are the results of this exercise? Should patients also be empowered to change their dose of anticoagulant drug? How should the limits of the responsibility of the patient be set? Does this influence the relationship between the patient and the health care professional?

Diabetes - It has been common practice for many years for patients with type 1 diabetes to monitor urine sugar and more recently to monitor their own blood sugar and adjust the dose of insulin accordingly. In general and if properly supervised, this has been very beneficial to the public health.

But the major problem in diabetes today is type 2 diabetes, where the relationship between blood sugar and efficacy and drug safety is much less clear than in type 1 diabetes. Should similar considerations be applied to type 2 as type 1 diabetes? What is the state of knowledge and medical practice in this area?

There are other examples where it is increasingly the responsibility of patients to use technologies to improve their own management. The question is whether this issue should be considered as part of the remit, especially where there is concern about the reliability and usability of the technology and the influence this has on overall management.