

**A** = Chapter title heading (**Bold Times 14pt**)

**B** = Primary Heading (**Bold Times 12 pt**)

**C** = Secondary heading (**Bold Italic Times 12 pt**)

## **B** Chapter 13

### **A** Evaluating the ethics of health promotion: understanding informed participation

#### **B** Dalya Marks

Ethical issues in health promotion are often overlooked. Interventions are planned, executed and evaluated with little regard to ethical concerns. There is an assumption that health promotion is good for you and compliance is expected. This chapter examines some of the issues surrounding participation in health promotion interventions and considers what is required to acquire informed consent and promote informed decision-making.

Informed consent requires that participants are provided with unbiased information on the risks and benefits of an intervention, and are free to decide whether or not to take part. In addition to practical problems in delivering the information, acquiring informed consent might create conflict between health professionals' desire to achieve a high programme uptake whilst accepting that an informed person might decide *not* to participate. This chapter will suggest that in evaluating a health promotion programme, outcomes should not be measured simply in terms of uptake, but *informed* uptake. Evaluation should include measures of knowledge and empowerment, not simply acceptance or refusal.

#### **B** Current Guidelines

The UK General Medical Council (GMC) guidelines for seeking patients' consent (see Box 1) do not state how much information should be given nor how it should be conveyed to facilitate informed decision-making.

#### **B**Box 1 Guidelines on informed consent for screening procedures

The following should be explained before the test:

- The purpose of screening
- The likelihood of receiving a positive or negative results
- The chance of a false positive or false negative result
- The risks and uncertainties of the process
- The potential for financial and/or social discrimination

The following should be explained after the test:

- Follow up plans
- Availability of support or counselling services

(General Medical Council 1999).

The UK National Screening Committee guidelines (Department of Health 2000) state:

There is a responsibility to ensure that those who accept an invitation (to screening) do so on the basis of informed choice, and appreciate that in accepting an invitation or participating in a programme to reduce their risk of a disease there is a risk of an adverse outcome

Informed choice implies that a decision to refuse a test or an invitation to participate is as valid an outcome as attendance.

### **B Participant involvement in decision-making**

An individual should be able to make an informed choice about whether to participate or not, through provision of the necessary information about the benefits *and* disadvantages of such a decision (Department of Health 2000; Jepson *et al.* 2000). This process has been described as

a reasoned choice...made by a reasonable individual using relevant information about the advantages and disadvantages of all the possible courses of action, in accord with the individual's beliefs (Bekker *et al.* 1999).

Whether this adequately describes what is experienced is unclear. Although it corresponds well with respect for autonomy, little is known about the effectiveness of involving patients in decisions about their care, or the effect that sharing information will have (Entwistle *et al.* 1998).

Informed choice requires a discussion to take place between a participant and the health professional promoting the 'informed' aspect. There is a continuum of where the responsibility for that decision takes place; shared decision-making (SDM) at one end and informed decision-making at the other. SDM involves at least two parties (the client and the professional) and both have to reach consensus (Whelan *et al.* 1997). SDM recognises the importance of participant preference but includes a role for the health professional who is equipped with the technical knowledge, whereas informed decision-making assumes that the participant will make the decision on his/her own (Coulter 1997). With SDM, both the process of the decision-making and the outcome (intervention choice) are shared, requiring joint access to the evidence supporting decisions rather than an abdication of professional responsibility (Coulter 1997). Some commentators caution that SDM cannot bear the entire burden for informing and involving individuals and that population-orientated interventions promoting informed decision-making should be explored (Briss *et al.* 2004).

The introduction of participant involvement in decision-making has led to tensions between traditionalists and those advocating individual choice. Traditionalists fear that the promotion of individual choice may endanger the goal of improving the public's health. For example, in the UK, following a media-led scare about the safety of the combined measles, mumps and rubella vaccination, many parents chose not to immunise their children. As a result, the proportion of children immunised fell to dangerous levels, and there is now concern about both measles and mumps epidemics. However, individual decision-making need *not* be incompatible with broader public interest or 'communitarian' values if the shift in power or decision-making from professional to patient incorporates autonomy, rights and responsibilities (Parker 2001).

The tension between respecting individual autonomy whilst trying to maximise the benefits for the population has been discussed with reference to a population cardiovascular screening programme (Marteau *et al.* 2002). The programme aimed to reduce population level morbidity and mortality, and the information provided was brief, highlighting the health benefits of participation whilst neglecting the potential harms. These 'harms' could be the identification of one's susceptibility to coronary heart disease, which would require long term monitoring, adherence to medication and/or lifestyle changes. The authors argue that attendance might be reduced if a more balanced account of the implications of participation is provided. However, if those participating are more motivated to adopt the recommendations, the longer-term outcomes could be more favourable, and the programme might be more cost-effective.

## **B Problems with delivery**

Little is known about the effects of providing patients with a full account of the risks and benefits of the intervention they have been offered. Not only do we not know how best to provide this information, we know even less about the effect of providing informed decision-making in terms of uptake (Jepson *et al.* 2000). Information may increase knowledge about the intervention, but not acceptability, as was found in a study of parental acceptance of HPV screening (See Box 3) (Dempsey *et al.* 2006). It is assumed that the more a person knows about the condition and the impact of the intervention, the less the psychological distress will be, but this is not supported by evidence.

The ability of the target audience to absorb the information is important. Data from a study assessing the readability of patient information leaflets in general practice estimates that five and a half million people in the UK have reading difficulties and 22% of the working population have low literacy levels (Smith *et al.* 1998). This issue is even more important in low income countries where literacy levels are lower.

The focus of patient information leaflets tends to be on presentation and readability rather than content, which can lead to inaccurate and misleading information, based on unscientific clinical opinion (Coulter 1998). The basic ground rules of effective communication include the exchange of accurate information, exploration of anxieties or concerns, opportunities for expressing empathy, awareness of treatment options and a negotiation of different views.

Problems can arise if the information presented are not tailored to individuals' needs, beliefs and values, but rather have a 'one size fits all' approach (Goyder *et al.* 2000). If individuals' values and competing priorities are not taken into account, both participants and health professionals may be faced with conflicting demands.

Newer technologies such as interactive CD-ROM's, computer decision tools or the Internet may focus attention further onto appearance rather than substance. Few such technological decision aids have been evaluated, but it appears that they can improve knowledge and realistic expectations, enhance active participation in decision-making, and improve agreement between choice and values (O'Connor *et al.* 2003). It may be that such advances in communication lead to greater highlighting of the uncertainties around medical interventions or outcomes, which in turn may make decisions harder to make. A review of the evidence on presenting risk information has suggested that when patients receive information which is more understandable, they become increasingly cautious in deciding whether to accept treatment, comply with interventions or participate in trials (Edwards *et al.* 2001).

Even when stringent consent processes are present, and information is provided orally and in writing, there may still be a discrepancy between a health professional's account and a lay person's understanding of the nature of the condition being screened for (see Box 2).

### **Box 2 – Screening for Familial Hyperlipidaemia: an example of misunderstanding**

A qualitative study of twenty relatives of individuals with FH (a condition which carries a high risk of premature heart disease), found that despite following a carefully established protocol, with a high participation rate, there was still much misunderstanding and confusion after participants had been screened.

Understanding of the condition, risk of transmission to self and family and what lifestyle modifications were effective differed greatly from the information that the nurse thought had been provided.

It cannot be assumed that just because information is provided, and formal consent procedures are undertaken, that people will act in the expected way. Some of the participants who tested negative for FH were left with heightened awareness of their disease risk and lingering fears about whether they were still at risk of developing heart disease. Participation in this screening programme did not allay concerns about disease susceptibility.

This research, using qualitative methods, demonstrated unanticipated effects that had not been considered previously. Regrettably, qualitative research is not often incorporated into programme evaluations or assessments of social ‘costs’ in cost-effectiveness analyses.

(Marks 2004)

### **B Informed participation – potential tensions**

The tension between individual choice, autonomy and what is considered to be in a participant’s best interests is frequently raised. For example, a participant might be well informed (presented with the benefits and risks), and then may make a decision which the clinician, or health professional feels is not the right one, but this decision might be appropriate for the participant (Ashcroft *et al.* 2001). Decisions are made within the context of one’s environment, and this complex interaction must be understood and respected when one course of action is chosen over another. Sometimes a decision not to undergo further tests might be appropriate, and thus the choice *not* to present for screening should be accepted as a positive outcome if the objective of the programme is to encourage *informed* uptake.

A systematic review (see Chapter 6) explored the concept of informed uptake, examining factors associated with participation, and assessing the effectiveness of methods to increase uptake in screening programmes (Jepson *et al.* 2000). The authors found limited evidence on how providing information affects uptake. Only four of the 190 intervention studies reported giving information on the risks and

benefits, and only one study evaluated the effect of this knowledge on the decision-making process. Evidence was inconclusive on how different types of information might affect screening knowledge or uptake. This review concluded that when trying to increase participation, knowledge should be measured as an outcome in the decision-making process, and that future studies should evaluate both informed uptake and actual uptake. Giving a balanced account might result in refusal to participate, which the health professional may not feel is a sensible choice, but it will have to be accepted as a valid outcome.

### **Box 3 – Human Papillomavirus (HPV) vaccination programme in schools**

Thirteen year old girls in the UK are being immunised against HPV, (which causes cervical cancer) through a school-based programme. Because they are aged under sixteen, consent is required from a parent or guardian. This might result in discord between the young person and parent. The vast majority of research in this area has focused on factors relating to parental attitudes and consent, rather than the young people's views.

Young people aged under sixteen can attend a confidential sexual health clinic and access a range of services without parental consent, yet parental consent is required for the girl to have the HPV vaccine. A third of parents who were asked their views about the child's right to consent to HPV vaccination within a sexual health setting without parental consent, insisted that they still be involved in the decision-making process (Brabin *et al.* 2007).

If consent procedures differ from one setting to another, there is the potential for friction within the family unit as parental rights are upheld, over those of the adolescents.

In evaluating health promotion interventions, ethical aspects including the acquisition of consent should be considered; informed participation as well as actual uptake should be evaluated. Individuals make decisions based on their own beliefs and values, as well as their own perception of the risks involved. If an individual makes an informed decision not to participate, it should be regarded as an appropriate decision.

### **Key points**

- Individuals have the right to expect a full explanation of the risks and benefits of an intervention before consenting to participate.
- People have the right to make an informed decision *not* to participate.
- If, after assessing the information, a decision not to participate is made, that needs to be valued.
- In evaluating health promotion interventions, informed uptake rather than throughput should be measured.

## References

- Ashcroft, R., T. Hope and M. Parker (2001). Ethical issues and evidence-based patient choice. *Evidence-based patient choice: inevitable or impossible?* A. Edwards and G. Elwyn. Oxford, Oxford University Press.
- Bekker, H., J. G. Thornton, C. M. Airey, *et al.* (1999). "Informed decision making: an annotated bibliography and systematic review." *Health Technology Assessment* **3**(1): 1-156.
- Brabin, L., S. A. Roberts and H. C. Kitchener (2007). "A semi-qualitative study of attitudes to vaccinating adolescents against human papillomavirus without parental consent." *BMC Public Health* **7**: 20.
- Briss, P. R., B., B. Reilley, R. Coates, *et al.* (2004). "Promoting informed decisions about cancer screening in communities and healthcare systems." *American Journal of Preventive Medicine* **26**(1): 67-80.
- Coulter, A. (1997). "Partnerships with patients: the pros and cons of shared clinical decision-making." *J.Health Serv.Res.Policy* **2**(2): 112-121.
- Coulter, A. (1998). "Evidence based patient information: Is important, so there needs to be a national strategy to ensure it." *BMJ* **317**: 225-226.
- Dempsey, A. F., G. D. Zimet, R. L. Davis and L. Koutsky (2006). "Factors that are associated with parental acceptance of human papillomavirus vaccines: a randomized intervention study of written information about HPV." *Pediatrics* **117**(5): 1486-93.
- Department of Health (2000). Second Report of the National Screening Committee.
- Edwards, A., G. Elwyn, J. Covey, E. Matthews and R. Pill (2001). "Presenting risk information-a review of the effects of 'framing' and other manipulations on patient outcomes." *Journal of Health Communication* **6**: 61-82.
- Entwistle, V. A., T. A. Sheldon, A. Sowden and I. S. Watt (1998). "Evidence-informed patient choice. Practical issues of involving patients in decisions about health care technologies." *Int J Technol Assess Health Care* **14**(2): 212-25.
- General Medical Council (1999). Seeking patients' consent: the ethical considerations. London, GMC.
- Goyder, E., A. Barratt and L. M. Irwig (2000). "Telling people about screening programmes and screening test results: how can we do it better?" *Journal of Medical Screening* **7**: 123-126.
- Jepson, R., A. Clegg, C. Forbes, R. Lewis, A. Sowden and J. Kleijnen (2000). "The determinants of screening uptake and interventions for increasing uptake: a systematic review." *Health Technology Assessment* **14**(14): 1-123.
- Marks, D. (2004). An evaluation of strategies for detecting Familial Hypercholesterolaemia. *Public Health and Policy*. London, University of London. **PhD**.

- Marteau, T. M. and A. L. Kinmouth (2002). "Screening for cardiovascular risk: public health imperative or matter for individual informed choice?" *BMJ* **325**(78-81).
- O'Connor, A., D. Stacey, V. Entwistle, *et al.* (2003). "Decision aids for people facing health treatment or screening decisions [update of a Cochrane Database Syst Rev. 2001;(3):CD001431; PMID: 11686990]." *Cochrane-Database-Syst-Rev.* **2**(CD001431).
- Parker, M. (2001). "The ethics of evidence-based patient choice." *Health Expectations* **4**(2): 87-91.
- Smith, H., S. Gooding, R. Brown and A. Frew (1998). "Evaluation of readability and accuracy of information leaflets in general practice for patients with asthma." *BMJ* **317**: 264-5.
- Whelan, T., A. Gafni and C. Charles (1997). "Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango)." *Soc Sci Med* **44**(5): 681-692.