Monographs of the Víctor Grífols i Lucas Foundation 24

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CONTENTS

PRESENTATION

Public health continues to be characterized by the paternalistic attitudes prevalent when public health services were founded: everything for the people, but without involving the people. As health professionals, we tend to believe that we know what is good for people, even though such knowledge is not always a blessing. However, things are never so simple, not just as a result of general human ignorance and the specific ignorance of doctors and health professionals, but also and above all because “what is good for people” is not simply a technical question.

And yet this is the not so enlightened basis for our decisions to prescribe healthy behaviours and to restrict or ban ‘unhealthy’ ones. In answering the question of why such action is appropriate and for whom, it is somewhat depressing to have to recognize that the only moral justification lies in utilitarianism, which invokes the criterion that what is right is that which produces or contributes to the greatest well-being, happiness and health of society as a whole.

However, while such well-being is important, it would not appear to constitute sufficient grounds for imposing restrictions or treatments on all when many will derive no benefit from such treatments and, even more seriously, some individuals will suffer from undesired effects. And this is in addition to their being subjected to coercion which is, in itself, at odds with the bioethical principle of autonomy, a principle which is an essential element of modern concepts of health which stress well-being or, at least, adequate physical, mental and social functioning, rather than the mere absence of illness. Or, to put it differently, a way of living which is autonomous, compassionate and meaningful.

No health treatment is free from the risk of undesired effects, and while safety has improved, so too has the scope and complexity of medical interventions. There is, therefore, no such thing as a totally harmless treatment when it comes to curing illness or relieving suffering, and the same is true of those measures designed to protect or promote health which are aimed at apparently healthy people. And it is precisely such individuals who have the most to lose in the event that preventive activities cause them any harm, however slight this may be.

This is the focus of this monograph. While ethical considerations should be paramount in the public health sphere, as the first chapter of this publication (on the relationship between bioethics and public health) explains, this area has until now not received the attention it deserves, and has been addressed only tentatively if at all. As the contributions to this monograph make clear, this requires a perspective which acts as a counterbalance to the trend towards the commodification and medicalization of today's health service. As Richard Smith commented in his *BMJ* blog on 1 September 2010, medicine would benefit from suffering defeats which might force it to rethink its purpose. Perhaps such a setback might spark analysis of how basic ethical principles, including the principle of non-maleficence, are affected by preventive programmes.

The potential adverse effects of breast cancer secondary prevention programmes require careful attention and cannot simply be brushed aside by referring to the preventive benefits; in addition to radiotherapy – the effects of which are cumulative – there is the iatrogenic effect of false positives and, particularly, over-diagnosis in the form of the detection of real but irrelevant injuries which pose no risk to the individual's health.

All that remains is for me to express my hope that this initiative is a success, and that it gives rise to further consideration of the ethical implications of collective health promotion and protection initiatives conducted by the public health service. I would also like to acknowledge the commitment of the director of the Víctor Grífols i Lucas Foundation and the director of the Institut d'Estudis de la Salut (IES), without which this event would not have been possible, and to thank all the contributors responsible for the contents of this publication, which I am sure will receive an enthusiastic welcome from its readers.

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The context of public health and ethics

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Introduction

The growing importance of bioethics is a reflection both of long-standing dilemmas in clinical practice and the new problems thrown up by scientific and technological progress. Although applying bioethics to the world of clinical or biomedical science is complex and controversial, ethical analysis helps to raise critical awareness and provides guidelines for professional conduct, in addition to which it enriches decision-making criteria by complementing the classical principles of beneficence and non-maleficence with the concepts of autonomy and justice.

Do we need to incorporate an ethical perspective in public health? What difficulties does such an attempt entail? What should this ethics of public health be like? These are the questions we will attempt to answer, taking as our starting point the clear underdevelopment of this area of ethics when compared to its application to clinical practice.

Let us illustrate the problem with the example of fines for motorcyclists who fail to wear a helmet. If we ask what the reason for this is, the answer usually given is that it is a way of reducing damage to society by preventing death and injury. But what if some foolhardy cyclist, with an insurance policy similar to those held by people who practise dangerous sports, is prepared to accept these risks? Are we entitled to impose socially desirable conduct even when there are no economic 'externalities' (damage to third parties)? What legitimacy do we have to act in such cases?

We need to think about the moral basis of our actions. As Maeckelbergh has argued, "It is, however, only recently that trained ethicists have focussed their attention to population health systematically. This late involvement is surprising because public health is characterized by a huge inherent moral tension: to find the balance between the social good (the public's health) and the rights and goods of the individual." [1]

Here, we will consider a range of issues:

- Firstly, we need at least briefly to locate the conflict between the individual and society within the historical context of the public health service.
- This provides the basis for identifying one of the key issues in the ethics of public health: the implications of 'consequentialist' and 'principlist' ethics.
- Thirdly, it can be useful to draw a comparison with bioethics in the clinical context, an exercise which helps to identify the efforts made to create something similar to the Hippocratic oath in the public health sphere. The search for different ethical frameworks is another area of current intellectual pursuit.
- The need to understand the imperfections and problems of the individual and society leads us, in turn, to explore new virtuous circles within which to locate our interventions.
- One delicate aspect which merits special scrutiny is the role of authority, and in point five we address some of the implications of normative and financial coercion.
- In point six we present some 'softer' approaches to intervention, and identify a range of models for influencing individuals.
- In point seven we outline the specific problems of health information, and the risks and benefits this represents, particularly in the event of scares or emergencies.
- Point eight explores another 'soft' intervention mechanism: the contribution of the new economy to changing behaviour and promoting health through what is referred to as 'asymmetrical paternalism'.
- We end by offering some conclusions designed to stimulate analysis of public health ethics while avoiding 'paralysis by analysis', and we suggest some pragmatic options as a path forward.

1. Divergent traditions in public health: society and the individual

Without entering into the details of the early history of public health, or attempting to provide a detailed taxonomy of its scope or interventions, it can be useful to distinguish between those actions which are designed to modify our environment (physical or social) and others designed to ensure that individuals protect themselves from the risks to which they are exposed. Individual and social initiatives have different purposes, and in different periods the focus has shifted from one to the other.

In practice, in the ancient and medieval world empirically based social actions were dominant in the face of the risk of epidemics, sealing a stable alliance between political authorities and the health authorities (with coercion and punishment as the habitual means of guaranteeing such actions). In the 14th century the Black Death, which reduced the population of Europe by nearly half, illustrates the importance of vigilance and control measures (‘health police’). After the Renaissance (16th century) through to the mid-18th century, an individual model of preventive medicine predominated: based on a rational-observational approach, it regulated every aspect of the healthy person necessary to avoid catching diseases. At the end of the 18th century, the concept of the social genesis of disease gained strength, expressed in the phrase “*De populorum miseria, morborum genitrice*” (“The people’s misery: mother of diseases”) put forward in a speech by Johann Peter Frank in 1790[2].

In essence, we can identify two visions or perspectives: locating the problem in individuals or in society. This dichotomy has not been resolved by the development of public health in the modern era. The scientific basis for public health was developed in the 19th century and the first half of the 20th century. Particular importance was due to advances in four areas: statistics and demographics (the measurement of population variables); experimental sciences (measurement of physical, chemical and biological variables in the laboratory); preventive actions (immunization, prevention and screening) and the social sciences (analysis of social and economic variables).

The two perspectives have a different impact on the three classic spheres of public health interventions (which provided the basis for the United States health plan for the 1990s, titled Healthy People 2000)[3]:

- Health protection seeks to prevent risks which affect broad groups of the population, and relies on the action of the authorities through regulatory actions or interventions which limit the group’s exposure to these risks.
- Health promotion seeks to stimulate the behaviour of individuals and social groups so that their choices and behaviours protect them from risks and improve their health capital.
- Illness prevention is based on technical actions which either occur in or derive from a health setting, with a social perspective but starting from the individual, and taking the form of counselling, immunization, preventive medication and screening. All these measures are designed to reduce the appearance of disease and the harm it causes.

Whether from a social or an individual perspective, one should consider the following issues:

- The environmental context (and its corollary in corrective public policy measures) plays a dominant role in health protection: the weight accorded to environmental or social interpretations has varied depending both on the period and ideology.
- In health promotion, the clearest conflict to arise is between social responsibility (social determinants of individual behaviour) and individual responsibility (freedom and autonomy of the individual to take responsibility for his or her behaviour)
- In the case of prevention, there is also a conflict between society and the individual, although in this case it takes a form similar to that found in clinical bioethics (regarding individual interventions which carry a degree of risk or cost for the patient), but with the differences being that the benefit is for the population as a whole (for example, in the case of quarantine or isolation), and interventionism is a given, even if direct coercion is rare.

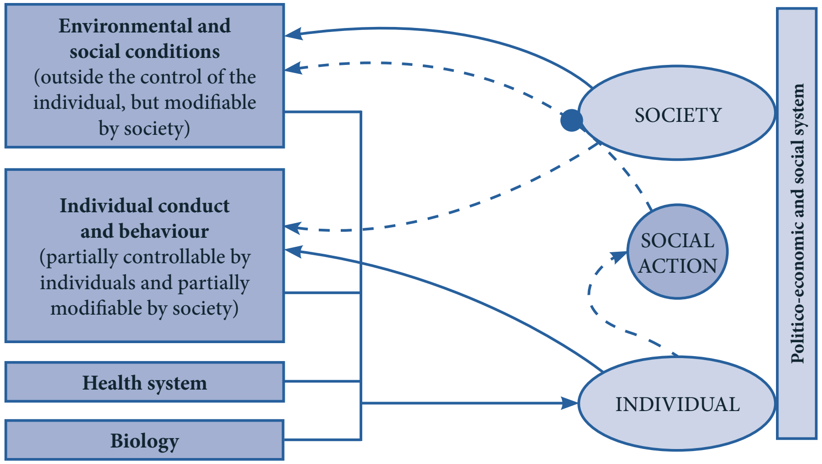
It therefore seems necessary to reflect upon the traditions and perspectives of public health in order to understand how to reconcile this conflict between individual and social preferences.

In practice, the causality of diseases is highly complex, and the physical and social environment interacts with individual factors, as demonstrated by

Díez-Roux with respect to the genesis of cardiovascular disease[4]. Here, it might be useful to quickly review the relationship between the determinants of health, individuals and society, as illustrated in Figure 1:

Figure 1

Relationship between health determinants, society and the individual.



Environmental and social conditions are, by definition, beyond the control of individuals, but they can be modified by social agents (health protection).

Individual behaviours play a key role in exposure to or protection from disease; they are partially controllable by individuals, and partially by society (social or group over-determination of behaviour).

Figure 1 also reflects the role of the health system and of biology (the other classic determinants of health described by Alan Dever). The health system includes both preventive actions promoted for public health purposes and typically delivered via primary care systems (community dimension) and specific secondary and tertiary interventions, generally related to diseases treated by specialists.

The right-hand side of the figure also depicts the relationship between the individual and social agents: individuals, via institutional action (political representation) or social action (campaigns, complaints, advocacy, mobilization etc.) can condition the response of social agents[5].

We can therefore see that, although there is a wide range of options and categories, two actors – the individual and social agents – are the focus of ethical dilemmas in public health. We will now review the main aspects of this debate.

2. Ethical dilemmas in public health: utilitarianism versus principlism

When we move beyond interpreting health problems and seek to take action to address them, there are two possible models of behaviour to be followed:

- Altruistic or “Good Samaritan”: help reflects the wishes of the person receiving it (who is unable to act on his or her own behalf)
- Paternalistic: help is imposed upon the recipient and justified with reference to his or her best interest, even if the recipient does not fully agree with the help received. This is a form of enlightened despotism, where the greater ‘wisdom’ of the guardian takes precedence over the ignorance and short-sightedness of his ward.

The paternalistic model tends towards utilitarianism: seeking the greatest aggregate well-being (for the greatest number of people); this is the habitual bias of social reformers (maximizing the well-being of citizens) and of public health systems (maximizing the health gains for the population). In the words of Hense, “Public health [...] is implicitly directive, in the sense that it strives to restrain the expression of individual wills in order to deliver health gains expected at the community level”[6].

However, utilitarianism (as an economic doctrine) is not contrary to individual liberty: liberals assume that, in order for there to be a wide range of goods and services supplied under conditions of competition and information, the market must allocate scarce resources in a satisfactory manner, and the greatest aggregate utility is obtained by allowing individuals to choose without restrictions. Clearly, the decisions taken by health professionals are precisely those which cannot be managed via the market, and must instead be applied by the state; their utilitarianism, in this sense, refers to the pre-eminence of aggregate health gain as a criterion for social decision-making.

However, in addition to legitimating paternalistic and utilitarian approaches, the focus of such interventions on outcomes tends to be 'consequentialist' (based on the notion that "the end justifies the means"). Health professionals, according to Mackenbach[7], aspire to large-scale altruism. But in reality they tend to be conspicuous paternalists rather than compassionate altruists.

When consequentialism is designed to change individual behaviour, we run the risk of "blaming the victim" or at least severely criticizing him for his lack of intelligence or willpower. This approach frequently manifests itself as puritanism, which is often smuggled into health education policies.

The other ethical orientation is that of 'principlism'. This makes explicit the principles which inform health decisions, on the basis that it is not just the ends or the consequences which are important when judging the morality of an action, but also the means. When a Jehovah's Witness, who is an adult and in full command of his faculties, refuses to receive a blood transfusion, what is ethical – although not necessarily intelligent or reasonable – is to attend to his beliefs and wishes: in this case, the principle of autonomy would prevail. Beauchamp and Childress[8] popularized this approach on the basis of the already widely known principles of beneficence, non-maleficence, autonomy and justice.

Contrast between consequentialist and principlist visions in public health. Figure 2 shows the contrast between the two visions mentioned above:

- Paternalism and consequentialism fit poorly with the concept of individual liberty: while this approach maximizes collective health gains, it raises the problem that the end tends to justify the means, leading to the imposition of decisions on individuals in a way which disregards their own preferences (even if it is "for their own good")
- Principlism makes explicit the principles upon which the legitimacy of decisions is based. While this is its strength, when we explore in greater detail the question of collective health decisions, we find ourselves facing a conflict between principles which can lead to paralysis in the face of ethical dilemmas.

Figure 2

Contrast between consequentialist and principlist visions in public health.

Public Health	**Consequentialism**	**Principlism**
Maximizes	Collective health gain	Takes account of ethical standards
Problem	Infringes individual liberty (the end justifies the means)	Acute conflict between principles in serious dilemmas

It could be argued that public health is inevitably principlist because it is a fundamentally normative discipline (as Masse explains)[9] due to the need to resolve contradictions raised by criteria or rules in at least three situations:

- When we consider how we define health and illness, and how we establish the border between normality and pathology: this problem is shared with clinical medicine
- When determining the concept of risk (factor, groups and risky behaviours): this problem is much more specific to public health and identifies the danger of the risk becoming an illness, causing damage[10]
- And when, faced with conflict between the individual and society, we must establish criteria and values which justify intervention (the key issue which concerns us here).

These three sets of issues together mean that public health is very vulnerable to dominant sociocultural constructs, and can easily be manipulated or used for political ends: we should not forget the phenomenon of Nazi eugenics[11] and the exploitation of public health for purposes of social control by authoritarian regimes.

There are also philosophical approaches (communitarianism or collectivism) which seek a middle path, arguing that communities are not just the sum of individuals, that their preferences are constructed and informed through social interaction (customs, institutions and values shared by people), and that this group of core shared values provides the basis on which moral principles for social action are founded.

3. The contrast with the world of clinical bioethics: is there a "Hippocratic oath" for public health?

If we compare public health with clinical medicine, we will see that, while the Hippocratic oath has been at the core of individual medical ethics for millennia, the first systematic attempts to provide an ethical framework for public health only arose at the end of the 20th century. The separate origins and trajectories of public and individual health also affect the ethical framework of both disciplines[12].

In clinical bioethics, the Hippocratic model is limited to the principles of beneficence and non-maleficence. At the end of the 20th century, the principle of autonomy began to be accepted (despite great resistance to accepting the patient as an active decision-maker), while the integration of the principle of justice is still to be addressed, linked as it is to resource limitations, equity of distribution, and the social opportunity cost of medical decisions.

The American Public Health Association (APHA)[13] supports a code of ethical principles drawn up by public health professionals and academics, set out in twelve points. It proposes addressing the fundamental causes of disease, aiming to prevent adverse health outcomes, by providing information to the community and seeking consent for these interventions, advocating a variety of approaches (values and beliefs), and protecting the confidentiality of individuals and groups.

If the APHA and the Public Health Leadership Society (PHLS) seek an ethical guide for the practical development of public health, then there would appear to be a need to explore the philosophical foundations of public health in greater depth. Jonathan Mann proposes linking it to human rights, given the underlying complementarity between the two, as evidenced by the AIDS epidemic, the humanitarian emergencies in Bosnia and Rwanda, and examples from women's health[14]. This places us within the tradition of Rudolf Virchow (1821–1902): "Medicine is a social science, and politics is nothing more than medicine in larger scale."

But some have questioned whether making human rights so central to public health is not self-defeating, as this means assuming problems which there are no tools to resolve, unless public health bodies become Amnesty International or Human Rights Watch. Hessler[15] argues that the existence of a clear legal context for human rights (the Universal Declaration) means it is misleading to apply it in such a straightforward manner; rather, public health must develop together with other disciplines which study social conditions and well-being; it needs, in other words, to find its own path.

Hessler quotes Rothstein's statement that, "Just because war, crime, hunger, poverty, illiteracy, homelessness and human rights abuses interfere with the health of individuals and populations does not mean that eliminating these conditions is part of the mission of public health". But he also quotes Gostin when he says, "Think about HIV prevention in vulnerable women in resource-poor countries … Public health practitioners may educate them about the risks of sex and drug use. They may even distribute the means for behavior change (e.g., condoms and sterile injection equipment). Yet, if women are culturally and economically dependent on, or physically and emotionally abused by, their husbands, they remain powerless to reduce their risk of HIV." Hessler concludes that if we only focus on immediate causes then we render much of our public health effort irrelevant.

We can see, then, that there is a tension between a sterile pragmatism of immediate actions, based on the tools and technology of intervention, and a social reformism which pulls us away from our professional and scientific identity to embrace a social and political militancy which goes beyond what can typically be delivered through technical and professional practice.

4. The framework for transaction: virtuous cycles between individual and society in public health policies

Human beings are social animals which are only partly socialized; unlike bees, individual humans belong to a collective through a complex process of internalized norms and the membership of institutions (such as the market and the state). Following Nobel laureate, Douglass North[16], what characterizes institutions are the explicit and implicit rules which regulate the interactions between human beings.

As individuals we have a natural tendency towards a certain level of opportunism and dishonesty, which is modulated both by social rules and internalized moral codes (what are sometimes referred to as *meta-preferences* or the *superego*)[17]. Obviously, institutional rules are designed to minimize this tendency, but these cannot prevent the abuse of relationships of mutual trust and cooperation, because codifying such conduct and monitoring strict compliance would be both expensive and impractical. This is why virtuous societies are built on the basis of intangibles (reciprocity, trust etc.) which have been termed 'social capital'[18].

However, human societies have political and civil service structures to manage public affairs, and these generate high levels of entropy and distortion (with respect to the general interest which is, in theory, their *raison d'etre*). Corruption (financial gain and favouritism), authoritarianism (the restriction of individual liberties in favour of discretionary powers) and the occupation of the social space (the domination of informational and collaborative space to perpetuate the position of those in power) are just three typical instances of the high costs of political interference due to democracy being compromised or absent. In a similar regard, public bureaucracies introduce inefficiency costs: corporatism, elitism etc.

If individual and social decision-makers are to engage in successful decision-making about public health issues then they must find a virtuous equilibrium which enables them to design alternatives which allow them to overcome the apparent contradiction between a state which is invasive and paternalistic in health issues and individuals who put their own health and that of others at risk through irresponsible and reckless behaviour. This is not so much a philosophical debate – although it is that as well – as a practical problem: how to design intelligent, sensitive public health interventions which are capable of having positive impacts without giving rise to secondary problems.

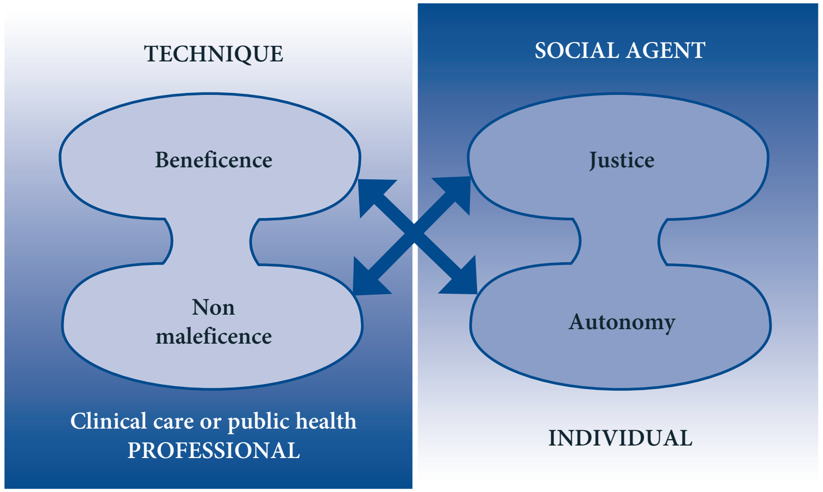
This practical perspective provides a basis for reflecting upon the classical principles of bioethics, two of which, beneficence and non-maleficence, are in reality attributes of the intervention technique itself. As a result, the pros and cons of weight loss surgery, the PSA test for prostate cancer, or breast cancer screening must be assessed on the basis of evidence or, at least, taking into account the best available research.

Because knowledge and skill are safeguarded and administered by health professionals (doctors in clinical medicine, public health practitioners in public health), these are the people who interpret the risks and the benefits in accordance with their own preferences and biases, and under the influence of the settings in which they work. However, the principles of autonomy and justice represent the notion that the individual and society are both stakeholders in public health initiatives. Figure 3 shows this conceptual reorganization of the ethical principles.

Professionals are also interested parties, but because they are at the service of two "principal agents" (the society which pays and hires them, and the patients to whom they are bound by the Hippocratic oath) they must legitimate their arguments and opinions by presenting them as beneficial for the health system or for the health of the patient (they are stakeholders in these

Figure 3

Adaptation of diagram showing relationship between bioethical principles and agents (social, individual or professional).



outcomes). However, there is also a significant difference between clinical professionals and public health practitioners:

- For clinical professionals, the "principal" agent is the individual, but the vast asymmetry of information and power between them means that the relationship is of a paternalistic nature, in which the doctor has more power than the patient (the principle of autonomy is thus 'dominated' by the professional concepts of beneficence and non-maleficence).
- For public health professionals, the "principal" agent is the social agent, which not only contracts his or her services but is also the vehicle of regulatory actions and public health interventions. However, here the asymmetry of power works in the other direction, as politicians and institutions possess both social authority and institutional power, while public health practitioners hold knowledge which in practice is not as decisive as that held by clinical staff when it comes to influencing decisions. Few people tell surgeons how to operate, while lots of people have opinions about screening, vaccination or actions to improve environmental risks.

This last point is very important: the lack of power makes it difficult for public health when dealing with its principal agent (society), and this makes it essential to identify elements which offer scientific and professional legitimacy which support its discourse and give strength to its proposals.

A corollary of these issues is awareness of the professional biases which are likely to exist in each situation. For the majority of clinical practitioners, the principle of autonomy is subordinate, while the principle of justice is simply ignored; public health practitioners tend to demand greater activism by the social subject (principle of justice) to facilitate their interventions, while at the same time neglecting or undervaluing the autonomy of the individual.

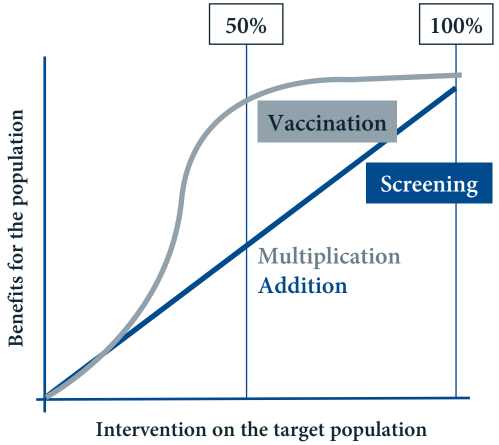
In any event, it is clear that the relationship between the social actor and the individual over-determines the whole ethical debate. It is essential to stress that the more or less interventionist stance of public bodies depends on the degree to which individual problems extend to others (negative externalities) or, alternatively, where interventions directed at individuals may give rise to multiplier effects which have a beneficial impact on the health problems or risk of illness of others. We summarize this issue briefly in figure 4.

Let us consider two examples and situations. If we implement a colon cancer screening programme, the benefit obtained depending on how it is applied to the target population would be, in the best case, the risk prevented for this population; the effect is additive, shown in figure 4 as a straight line.

Now let us imagine a childhood vaccination programme; in this case, as the immunized population grows, the effects start to multiply, because it reduces transmission between children until a herd effect is achieved where, after a threshold has been passed, the whole group is protected. As a result, in this

Figure 4

Extension of benefits to the general population as a function of the cumulative coverage of actions on the target population.



curve we can see that there is a section of rapid increase, due to multiplier effects (or positive externalities of the action) which rapidly saturate the expected benefit: in other terms, with only 50% of the effort we obtain almost the full impact.

Where this multiplier effect or positive externalities exist, it is logical that the social agent is concerned to 'impose' intervention on individuals (or at least to suggest it persistently and offer it free of charge). However, when it is only the individual to whom the measure is applied who benefits from it (and where the aggregate effect for the population is calculated by adding these micro-effects together), there should not be any more tension than that which exists in clinical practice, and the principle of autonomy should therefore have more weight, while imposition or the restriction of individual freedom should be much less acceptable.

When we consider 'externalities' we often realize that our well-being is interdependent: when somebody suffers harm which could have been prevented, those around him are affected and seek to reduce his suffering; in the words of Donne, popularized by Hemingway: "the bells [of death]" also toll for those who hear them, and they startle us all. It is precisely these "caring externalities" which underlie the interventionist impulse which society accepts with regard to individual behaviours which are harmful for health; empirical research appears to demonstrate that this effect is significant, and that it increases with the seriousness of the condition or the risk to the individual[19].

In the next section, we will analyse in more detail the problems which may arise when public bodies take a harder or more coercive approach to intervention.

5. Authority and risks of maleficence: normative coercion (*behaviours*) and fiscal coercion (*consumption*)

One of the ways in which the state can most clearly act to harm individuals is through the use of coercive instruments. The three main categories of intervention by public bodies are regulation, subsidy and provision.

a) Regulation is essentially coercive, as it penalizes certain behaviours: when we refer to compulsory education, we mean that the state imposes an obligation on parents to send their children to school; or if we talk about compulsory health insurance, we mean that companies must include their employees in a system to insure health risks. Violation of these obligations is penalized by the state.
b) Subsidy, and its opposite, taxes and duties, also entails financial or economic coercion by using the power to transfer income from some people to others, or by making some products cheaper and others more expensive. The state can impose a tax on tobacco, on income or on profits, and allocate the revenue to subsidizing the health system

so that this is able to ensure that those on low incomes have access to medical care at low cost or free of charge.

c) In providing services, the state or its institutions or agencies (for example, the Social Security system) act as organizers and producers of services for citizens. This is essential in the case of the classic public goods such as the army, the legal system, epidemiological vigilance etc.

Regulatory or fiscal coercion is usually designed to influence the behaviour of individuals so that it conforms to the standards established by social agents.

The gap between what society demands and what the individual wants is bridged more by authority (in the sense of social legitimation) than by power (in the sense of the capacity to directly compel individuals to act). As a result, education, information and persuasion provide the basis of action and reduce social stress.

When applied to measures related to public health, Hunt and Emslie[20] argued that in the "informal epidemiology" used by most people, what is important is not what causes the incidence of a disease in general, but rather why the individual concerned has caught it at this particular time. For this reason, the link between population risk and individual illness has to be carefully explained so that society accepts the social cost of preventive policies, and individuals accept the costs of changing their behaviour.

However, the debate is complicated by the multiple vectors which act in opposite directions: post-modernism (which undermines the legitimacy of the state to intervene openly when it comes to issuing rules governing individual behaviour); the development of technologies which make it possible to monitor people's private lives (enabling the state to intervene surreptitiously); organized crime and international terrorist movements (which are used as a motive for giving the intelligence services *carte blanche*); global mobility and the chaotic pattern by which epidemics move (which gives rise to the search for new disease control systems), etc.

6. The complex and difficult task of persuasion: models of influence

There is an important ethical and political difference between ensuring compliance with social expectations by coercion and doing so by persuasion. This is why it is essential to limit the use of instruments which restrict individual freedom to those situations where there are public goods which are seriously threatened, or because an individual's behaviour has clearly identifiable negative externalities which cause harm to others. For other situations, it is sufficient to advocate models of persuasion which act by influencing the preferences of the individual. There are a variety of ways in which a person's behaviour can be modified:

a) **Informative**: supplying information and indicators which are relevant and can be clearly understood.

   For example, the life expectancy of those who do not smoke, do not drink too much, are active, and consume a reasonable amount of fruit and vegetables is 14 years longer than for people who do not exhibit these four protective behaviours[21].

b) **Indicative**: using individual or social arguments to reinforce those behaviours which should be adopted or abandoned.

   For example, the campaign by the Spanish Road Safety Department in Easter 2007 to encourage motorcyclists to use helmets: "There are lots of reasons. Choose yours and do it … Because of the penalty points … So your mother doesn't have to leave flowers by the roadside …"[22].

   If trust is to be built, then people must not be manipulated, individual freedom must be respected, and the arguments against any given action must be presented honestly.

c) **Educational**: investing in citizen education so that people are capable of greater autonomy, and have rational and emotional control of their decisions.

This means demanding consistency and continuity in public policy across all sectors; the aim is to reconcile metapreferences (personal beliefs and convictions) with the individual's other preferences (consciously expressed wishes and desires) and with actual conduct (behaviour in daily life). For example, a young person may be a convinced environmentalist, have a stated passion for walking and then, in contrast with the above, use a private vehicle for short trips instead of going by foot or using public transport.

The 2005 campaign run by Spain's Department for the Environment appealed to people's environmental and civic conscience to convince them not to throw bottles away in the countryside, waste water, leave the car engine running, or discard plastic[23].

d) **Exemplification**: as human beings we are great imitators, and this is why consistency between what politicians say and how they behave is so essential. (Do they donate blood? Do they send their kids to state schools? Do they have surgery in public hospitals? Do they use the national health service?) But we also need to demand consistency between different public policies. (If tobacco is harmful, then it would make sense not to subsidize farmers to grow it.)

e) **Selective modulator**: capitalizing on our increased knowledge of the limited or contradictory reasoning which underpins human behaviour, and putting this at the service of health goals in ways that do not damage individual freedom. This has been called asymmetrical paternalism; this asymmetry is a reference to the selective capacity to influence decisions where there is no clearly established individual preference, while respecting those for which such preferences do exist.

For example, in a dining hall we might provide water, only serve wine by the glass if requested and not provide salt (while making it available if requested). As a result, we would reduce the consumption of both wine and salt. And we would do so without violating the firmly established preferences of those who want them; that is, we would preserve their individual freedom.

The models of influence are not exclusive, and they can be combined. Figure 5 shows an image from a campaign promoting the use of condoms in same sex relationships, with the slogan "Between us: use a condom. Not without it!" The message does not work solely at the cognitive level, through information, but also uses the indicative mode (official context of the campaign and general message), together with exemplification, using well-known personalities (presenter, commentator and judge) to contextualize their personal commitment to the preventive behaviour proposed.

Figure 5

Image from the December 2007 AIDS campaign by the Department of Health and the Consumer.

A similar way of tackling methods and degrees of intervention to modulate the behaviour of individuals has been described as the stewardship model by the Nuffield Council on Bioethics, a working group on ethics in public health[24]. According to this scale, there are various levels of limitation of an individual's capacity to choose (options for behaviour or action):

1. Eliminate choice: for example, compulsory isolation of patients with infectious diseases.
2. Restrict choice: for example, removing unhealthy ingredients from foods.
3. Guide choice through incentives (or disincentives): for example, taxes on cigarettes, or subsidies for public transport.
4. Guide choice through changing the default policy: for example, in a restaurant, providing vegetables as standard unless another option is chosen.
5. Inviting a healthy choice: for example, offering participation in a 'stop smoking' programme.
6. Provide information: for example, offer statistics on risk factors.

As can be seen, this gradient (from more to less intervention on individuals' freedom of choice) runs from quite severe restrictions to simple information. In this, it is broadly similar to the models of influence described earlier.

7. Information for the population: Why, when and how to communicate? Can we cause harm by informing people?

If we restrict ourselves to information about preventive interventions performed at the initiative of the health service, we face two rather different issues. Firstly, there is the question of notification and how to ensure participation in the proposed activity by the target population, and secondly there is the question of ensuring that the initiative makes an effective, efficient and fair contribution to improving the health of the population.

With respect to notification, the content of the information provided must enable the recipient to form a reasonably complete idea of both the benefits and the disadvantages which undergoing the treatment could entail. As part of the long-running debate around breast cancer screening, it is worth noting the points put forward by Jorgensen and Gotzsche,[25] including the following: the existence of a conflict of interests, as the people providing the information have a strong interest in achieving the highest possible levels of participation; the fact that none of the invitations include information about the most significant adverse effects of screening; the use of persuasive language, information which does not balance the pros and cons, and does not describe them in a way which is easy to understand.

Evaluation of the positive and negative effects should be published regularly, together with information about costs and other data relevant to the decision as to whether to continue with the intervention or not. Of course, when the aim is for women to participate in a secondary prevention programme, then they must be given the information they need and enough time to allow them to reach a decision. But how we provide this information is a far more delicate matter.

More generally, we must demand that the benefits of public health interventions far outweigh the risks. In other words, the principle of non-maleficence must be amplified. We should also consider the possibility that information may itself cause damage to health: a false positive in a screening, a panic epidemic (bird flu?) or a prediction of risks which is treated as if it were an actual illness. We have only recently become aware of the risks of prevention, but it is something we can no longer ignore[26].

Failure to consider the adverse effects of public health interventions, while all too common, is simply unacceptable. Just as we demand health impact assessments for public policies, we should also require assessment of the potential damage caused by the measures we propose.

Applying the principle of non-maleficence may actually reveal professional malpractice. With regard to the risks associated with our interventions, Gervas uses the harsh term ‘medical malpractice’ to refer to apparently well-intentioned actions which are reckless, are derived from arrogant self-delusion and, very often, cause more harm than good. He also proposes the term ‘quaternary prevention’ as a practice to reduce or ameliorate the medical part of the medicalization of our daily life, in which prevention is playing an ever larger role[27].

8. The contribution of the new economics of behaviour to health promotion and changing behaviour

Recent years have seen a process of cross-fertilization between different scientific disciplines in an attempt to understand some of the paradoxes of human behaviour. In economics, there is growing evidence that we do not act as ‘rational’ consumers; social psychology is identifying new explanations of how individuals’ preferences are formed and how decisions are made; finally, advances in biomedical knowledge and instrumentation mean that many studies have an experimental basis (e.g., functional magnetic resonance imaging) which helps to locate specific processes (calculation, emotions, anger etc.) which influence behaviour and choices.

This field, sometimes called neuroeconomics or behavioural economics, is gaining increasing relevance in two areas of the public health debate:

- As a new method for avoiding the inherent risk of imposition and paternalism associated with public health interventions in general and health promotion activities in particular[28].
- As a process of transferring techniques used in other sectors to apply them to the field of public health, which ultimately are designed to ensure that the healthiest decisions are the easy ones: “Make the healthy choice the easy choice”[29].

Ariely’s book provides lots of examples of how we can be “predictably irrational”, and how this offers an opportunity for anticipating our behaviours[30].

Another way of visualizing this is as a balance between intellectual calculation (frontal) and more primary impulses (subcortical), leading Cassidy to define this field as a “new political philosophy based on the idea of saving people from the vagaries of their limbic regions”[31].

In this regard, Loewenstein[32] has proposed the term asymmetric paternalism to describe this phenomenon: paternalism because in seeking to help people achieve their goals, it protects them from themselves (and does not just prevent potential harm to others); and asymmetric because it assists those who are most prone to irrational decisions, without limiting or harming the autonomy of those who take informed, considered decisions (regardless of the fact that, socially, these may not appear to be the best option).

An illustrative case is provided by the regulation of organ donation for transplant; in countries where consent is assumed (opt-out for people who do not wish to donate) the number of organs donated is far higher than in countries where consent has to be explicit (opt-in for people who want to donate) with rates of above 90% and less than 20%, respectively[33].

9. Conclusions about the ethics of social action to influence the health of the population and individuals

The first major consideration is this: while actions at the population level deliver benefits for the aggregate health of the community, they do not necessarily do so for the individual, whose freedom and capacity to act or choose is restricted, or who has to bear the personal costs of changing his or her behaviour. At the same time, the chances of the individual obtaining health benefits is very low: this is what is known as Rose’s paradox[34]. In such situations, we cannot expect too much of health education, as it is clearly swimming against the tide.

This coincides in essence with the notion that human beings prefer to receive good things as soon as possible, while deferring the costs. The logic of public health involves bringing the individual face to face with future costs in order to ensure that their behaviour incorporates the sacrifices necessary to achieve a healthy, extended and happy life. It is the same approach which leads us to sacrifice consumption today to invest in capital which will deliver greater well-being tomorrow.

However, there are those who question the wisdom of this approach. Spanish writer, Manuel Vicent[35] has argued that the effort to be healthy is something we should enjoy in the here and now:

> If I give up smoking, it is not in order to live for longer but to live better now, and not to huff and puff every time I climb a few stairs.
>
> […] If I eat small quantities of healthy food and don't consume animal fats, hamburgers containing dog food, or chips fried in engine oil, it is not to lose weight or trim my stomach, but because I respect my body and do not wish to submit it to the humiliation of digesting such junk.
>
> […] If instead of slumping in front of the telly for my daily dose of rubbish, I lead an active life, walk for an hour a day or get down to the gym, it is not to impress my lover with my sculpted body or to show my biceps off in the bar, but because I enjoy being flexible and don't want to groan in pain every time I get out of a taxi or get up from the sofa.
>
> […] If I decide to avoid closed spaces which smell of stale breath, and instead fill my lungs with clean, fresh air, it is because in addition to seeking to purify my cells with fresh oxygen, I want nature to be an essential part of my life.
>
> […] Not smoking, eating healthily and exercising are things we do to enjoy the present, because the whole of eternity fits into a single day, without any need to wait until tomorrow. So long as one lives healthily, one remains immortal […].

Despite this wonderfully positive picture (which we should strive to apply to our own lives), overcoming the gloomy, spoilsport tendency which usually characterizes public health is no easy matter.

We also need to consider the ethical implications when we work to address social or environmental factors or the behaviour of individuals; these can provide the basis for new lines of analysis, research and innovation in the practice of public health:

a) **Interventions addressing social variables**: the key components here relate to:

   - human rights philosophy,
   - the principle of minimum intervention (proportionality),
   - the criterion of subsidiarity (not supplanting the individual when
   - he or she is capable of taking responsibility),
   - applying intelligence to the design and development of policies (persuasion rather than coercion),
   - and good governance, democracy and commitment to social capital for public health policies.

b) **Individually based health prevention and promotion interventions to deliver population health gains**: we could use a model similar to bioethical analysis for clinical decisions, with additional emphasis on non-maleficence and autonomy to ensure that we do not cause harm or impose actions without due justification, bearing in mind that the subjects are healthy individuals who may not benefit directly from our intervention.

The Nuffield Council on Bioethics study referred to earlier[24] incorporated a proposed stewardship model designed to help configure public health interventions on the basis of ethical analysis to maximize the positive objectives and minimize restrictions on individual freedom; this is summarized in figure 6.

The final consideration relates to the need to take a proactive approach, avoiding "paralysis by analysis" which often results from the fact that many ethical problems appear to be unsolvable. A number of authors have offered advice in this area:

- Hense argues for a concept of "good governance" in public service which is less ideological, and more pragmatic, democratic and humble[36].

Figure 6

Stewardship Model of the Nuffield Council on Bioethics.

Stewardship model for public health programmes

- **Public health programmes and interventions should ...**
  - Aim to reduce the risks of ill health that people might impose on each other
  - Aim to reduce causes of ill health by regulations that ensure environmental conditions that sustain good health (clean air and water, food, housing)
  - Pay special attention to the health of children and other vulnerable people
  - Not simply provide information but also help people overcome addictions and other unhealthy behaviours
  - Make it easy for people to lead a healthy life (opportunities for exercise)
  - Ensure access to medical services
  - Aim to reduce health inequalities

- **But they should also seek to minimize ...**
  - Attempts to coerce adults to lead healthy lives
  - Interventions without the individual consent of those affected, or without procedural justice arrangements which provide adequate mandate
  - Interventions that are perceived as unduly intrusive and in conflict with important personal values.

Nuffield Council on Bioethics Working Group *Public Health: Ethical Issues* London: Nuffield Council on Bioethics, 2007, p. xvii. Available at: http://www.nuffieldbioethics.org/sites/default/files/Public%20health%20-%20ethical%20issues.pdf

- Miettinen advocates a practical approach, arguing that, "There is no real problem in reconciling respect for individual autonomy with utilitarianism […]. But there is no place in utilitarianism for the obsession of public health practitioners with pursuing the health of populations rather than their happiness."[37]

- Marmot seeks to put the categorical imperative not to violate individual preferences and autonomy into perspective: "The conflict between individual rights and social benefits can be overstated. We pay taxes to fund compulsory education even if we don't have children of school age. This can scarcely be called fascism, just a desire to live in a society characterized by a minimum level of social solidarity. If taxes on the alcohol I consume, or working hour restrictions […] mean a reduction in deaths and suffering, then I am happy to be subjected to a similar restriction of my freedom"[38].
- Another helpful piece of advice is that offered by Mackenbach: "Good Samaritans with a public health inclination can solve their moral dilemmas about health promotion by redirecting their attention at the environmental determinants of behaviours."[39]

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Autonomy, beneficence and maleficence in prevention programmes. Information about breast cancer screening

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General characteristics of prevention programmes based on early diagnosis

Prevention programmes based on early diagnosis through population screening share one key feature: success is measured in terms of high rates of coverage. Whether these programmes are aimed at high-risk populations, defined by some previously identifiable factor, or are universal, maximizing coverage is the usual standard of excellence. And this is why there is an incentive in all of these programmes to ensure the lowest possible levels of refusal to participate. This wish to maximize participation arises from the balance of aggregate benefits and costs, but fails to take into account the possible disagreement of those affected, who may believe that the burden they bear exceeds their portion of any benefits to be gained. The questionable assumption of identical benefits which are shared by all recipients, and which match those identified by the planners, is an obstacle to attempts to convince individuals of the desirability of collective goals.

Prevention programmes based on the early diagnosis of non-infectious diseases differ from other initiatives in one important way. The general absence of externalities, that is the absence of consequences, whether positive or negative, for anyone other than the individual directly affected. In the case of infectious disease, the risk of an individual's behaviour harming others – either as a result of direct or indirect infection, by sustaining a reservoir of infection etc. – may justify depriving individuals of their right to choose in order to submit them to the 'common good': isolation, quarantine, imposed treatment etc. There is also scope for incentives, coercion or imposition when it is not only the recipient who benefits from intervention but also the well-being of others. This is the framework for legislation on immunization, both for the general population and for individuals who encounter particular risks, such as travelling to regions where the endemic diseases differ from those of the individual's country of origin.

Although recently there have been attempts to extend the scope of externalities[1,2], we will focus here on the most widely shared definition. From this perspective, programmes for the early detection of transmissible diseases are based on a "principle of beneficence", a "shared good" which transcends the individual benefit, and this provides the justification for overriding another generally accepted principle, that of autonomy. However, there are many early detection programmes the sole aim of which is to deliver benefits for the individual at whom the intervention is directed, and it is only on the basis of arithmetic aggregation that one can argue that these individual benefits are also benefits for society as a whole, without there being any multiplier effect. In such cases, of which programmes for the early diagnosis of cancer are a clear example, it is difficult to argue that the principle of autonomy should not have absolute priority.

In addition to these basic features, there are often other characteristics of such programmes which are not inherent to them but which, instead, reflect a range of motivations. One of these is the desire to maximize coverage, outstripping the ability to resolve any problems which this may cause, such as systematic delays in resolving difficult cases or the lack of resources to deal with diagnosed cases in a timely manner.

Another feature of these programmes is that the information provided to potential recipients clearly leaves much to be desired. The issue here does not concern the specific problems of information in the health sector identified in Arrow's seminal article[3]. The shortcoming here relates to the need to provide information which constitutes the basis for autonomous decision-making which reflects our own values and individual preferences in the face of a reasonable description of the foreseeable consequences of each course of action. This is just the opposite of supplying data which is biased or deliberately misleading for propaganda or marketing purposes. Although useful information exists and can be easily assimilated by most people, it is rare for this to be made sufficiently widely available and it is often withheld on purpose. This deliberate concealment or distortion of the information which individuals need if they are to reach their own decisions is all-pervasive in the health sphere, both where there are supposed grounds for justification and where no such grounds conceivably exist. But when it affects the healthy population as a whole and may result in preventable damage which individuals might not have experienced (or might have decided not to expose themselves to) if they had had acceptable basic information, then it is particularly important.

On autonomy, non-maleficence and beneficence

Autonomy, information and the "paradox of prevention"

In the case which concerns us here – secondary breast cancer prevention and specifically mass early detection programmes based on breast scans – the most cursory review of the medical literature of the last century reveals alarming deficits in how this information is made available. To quote one of the key works in this area, "Outcomes of screening mammography include benefits (reduced risk of death from breast cancer) and harms (physical and psychological adverse effects from screening and follow-up tests and detection of inconsequential disease). Current information about screening mammography fails to meet women's needs for full and balanced information about these benefits and harms."[4] This is a good point at which to stress that the concept of autonomous decision-making is meaningless if adequate information is not supplied or made available. As we have argued elsewhere, "*Where basic information is lacking, it is impossible to take decisions; all one can do is back one's 'hunches'.*"[5]

The information required to assess the balance between benefit and harm, and for each individual to decide whether or not a given intervention is acceptable in the light of his or her personal preferences, is increasingly available. Indeed, in recent years new information has been generated as to the aggregate effects of such programmes, making the previous absence of such data all the more striking[6]. It is therefore particularly hard to understand why many institutions, both public and private, continue to conceal such information and hinder its dissemination. And even more difficult to accept is the fact that this concealment is motivated by a desire to impose the calculations of certain collective decision-makers as to the desirability of intervention, disregarding the right of those who are directly affected to reach autonomous decisions. In seeking to explain this violation of the right to autonomy, we are faced with a number of potential explanations. One possible explanation is the desire to overcome the so-called prevention paradox.

This paradox was formulated by Geoffrey Rose in an influential article published in 1981,[7] and stated as follows: "A measure that brings large benefits to the community offers little to each participating individual." As a result, "We should not expect too much of individual health education. People will have little motivation to follow our advice because they have little to gain individually, especially in the short and medium term." To which can be added the deterrent effect of having to suffer the inconvenience now while waiting until the future before receiving any benefits. This is the essence of the prevention paradox: the social benefit has little attraction for the individual, because he or she has different preferences with respect to when costs and benefits are to be experienced[8].

The description of this as a paradox may help us to identify the issues. A paradox is "an idea which is strange or contradicts the general opinion and feelings of individuals," but what is described here corresponds precisely to "the general opinion and feelings of individuals". And while it might be argued that we are concerned here with a 'strange' idea, this is only if one also takes exception to the notion that utility might not necessarily be limited to the maximization of the individual's health. This issue has been widely discussed, if we consider the tendency among many public health practitioners to substitute health for well-being, assuming that the two concepts are identical and interchangeable, at least for the decisions they take on behalf of others.

If we expect that individuals will not act on the basis of what we consider to constitute a rational weighting of risks and benefits, and if at the same time we distrust our own powers of persuasion, then the withholding of information is easy to explain. This prepares fertile ground for the very worst expressions of arrogant utilitarianism of which some authors accuse public health practitioners[9]. If we accept that there are limitations to the rationality of the behaviour of some or all individuals, then there is inevitably a danger that some will be tempted to remedy this shortcoming, regardless of the legitimacy of the means employed to do so.

Primum non nocere?

No health intervention is absolutely free of unwanted consequences: "All screening programmes do harm; some do good as well."[10] Failing to provide adequate information about these consequences is a serious breach of the relationship of trust between suppliers and health service users. We will not list these consequences here, because they are recorded in great detail in the paper by Teresa Queiro, which distinguishes between the negative effects associated with breast scans, effects associated with the results, and the consequences in terms of over-diagnosis and over-treatment.

The argument that a detailed description of the drawbacks associated with screening would distort the perception of the benefits and disadvantages does not strike me as providing sufficient grounds for imposing our (socially aggregated) preferences upon all the individuals affected by our decision to withhold this information. This is particularly the case when adverse effects go beyond necessary radiotherapy and involve a high volume of callbacks for further investigation, with the corresponding discomfort and, above all, worry and anxiety. And the alarming rates of false positives and over-diagnosis make such issues even more pressing.

But there is also another sort of adverse effect, less widely recognized, which affects society as a whole and those responsible for screening programmes in particular. I refer here to the effect of justifying practices which violate generally accepted principles, invoking grand principles, the applicability of which is questionable, arguing that the burden of proof should fall upon critics[11-13] and developing principles on an *ad hoc* basis. In particular, it is important to note the undesirable effects associated with the increasingly real risk of creating general distrust with regard to public health interventions *per se*. Certain decisions regarding vaccination – and the unreasonable criticism aimed at it – have encouraged the growth of anti-immunization movements, which did not even exist in Spain until quite recently. The question of the imperfect rationality of individual decisions has already been discussed. The most innovative publication in this area, "Animal Spirits", by Nobel laureate Akerlof[14], identifies the five essential aspects which influence decision-making. And the first of these is 'confidence' and its multipliers.

Beneficence

In light of the above, establishing the net benefit of such programmes is very difficult and depends to a large degree on what value is assigned to the available data and how this is interpreted. Of the different ways of interpreting this data on the efficacy of screening (the scientific evidence), establishing recommendations and transmitting information, it is interesting to note the disagreement between the US Preventive Services Task Force and the American Cancer Society (ACS) after the publication by the former of guidelines[15] opposing the recommendation of routine breast scanning in women aged between 40 and 50 years. This states that, "The decision to start regular, biannual screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms." The response of the ACS has been to recommend generic annual screening from 40 years of age, arguing that every life saved justifies this.

Note that while the Task Force does not advocate a generic approach, and explicitly argues for the need to decide within the framework of the preferences and values of each woman, the ACS establishes a more aggressive approach than the one rejected by the Task Force – annual rather than biannual screening – while omitting any reference to individual decision-making. When one is aware of the scope of the benefits and risks that this 'policy' represents for those affected, it is difficult to know how to respond to the ACS's zeal in overriding the capacity of individual women to reach their own decision as to whether the benefits outweigh the harm. It is not hard to imagine a set of values which would justify imposing a range of sacrifices on the decision-makers at the ACS to prevent them from engaging in any behaviours which could endanger their own lives, which are so valuable for the community. We could start by banning all risks associated with travel by confining them to their homes, before considering a range of dietary, physical and even intellectual restrictions, while also imposing preventive controls to protect them from prostate, colon and other pathologies.

Strategies to maximize the scope of prevention programmes raise important questions as to the nature of the information to be provided, the systematic shortcomings of such information, and the limitations of certain forms of paternalism. Without becoming involved in the complex debate about how to evaluate the harm attributable to screening, it is important to note the general misconceptions about its benefits and the ignorance of the associated risks. Various studies[16,17] have revealed generalized and significant overestimation of these benefits, accompanied by an even greater ignorance of the potential harm associated with participation in these programmes. Estimates of the reduction in mortality as a result of breast cancer screening speak for themselves. While almost 20% of women believed screening would deliver a reduction equal to or less than 10 per 1000 (with 8% estimating it at between 0 and 1 per 1000), 20% expected reductions in the order of 50 for every 1000 participants, and 30% estimated between 100 and 200 deaths prevented for every 1000 women screened. In Spain, there was a similar rate of over-estimation, together with a higher proportion of interviewees who felt unable to respond – 48% as compared to the European average of 31% – in contrast with our usual willingness to offer opinions, suggesting that disinformation is almost absolute.

A review of leaflets inviting people to participate in these programmes in seven European countries[18] found that three quarters failed to quantify the benefits of screening, while none mentioned the greatest risk, that of over-diagnosis. With respect to Spain, I will limit myself to quoting Teresa Queiro: “None of the material analysed referred to the possibility of over-diagnosis (ductal carcinoma in situ) or over-treatment, or to the percentage of false positives, while only one leaflet referred to the percentage of false negatives.” Those who play down some of the negative effects of screening would do well to remember that 37% of women who were re-examined for a false positive defined the period between the two examinations as “very scary” or the “scariest time of my life”[19]. Clearly, without reliable information about the effects of screening, recipients cannot take ‘informed decisions’.

It is easy to ‘sell’ the desirability of screening by inducing fear, exaggerating the risks, and offering unrealistic expectations by magnifying the benefits and ignoring the harms[20]. This is a frankly undesirable trend in which education is replaced by propaganda and marketing replaces information. Generating unrealistic expectations – or consciously contributing to this – and underestimating the associated drawbacks could well be argued to violate the principle of non-maleficence. We need to go from ‘selling’ screening to helping people decide whether this option genuinely reflects their own preferences, and this means that providing the information they need for such decision-making is absolutely essential.

Ethical dilemmas in breast cancer secondary prevention programmes

Ethical dilemmas in these programmes derive from the reasonable suspicion that the aims and means of public health activities may differ from the values held by individuals[21]. A recent document published by the Nuffield Council on Bioethics identifies the framework for these dilemmas: “A great deal of bioethical literature focuses on the way the individual can be protected in the medical context ... Public health programmes, by contrast, extend beyond the clinical context and focus on the population level, affecting the lives of the whole population, or large subgroups of the population. Many of these measures focus on prevention and may have implications for those who would not consider themselves to be ill. As a result they raise issues about the responsibilities and authority of the state and other agents whose policies and actions shape or affect people’s lives.”[22]

Although so far we have been using the Four Principles approach of Beauchamp and Childress[23] – respect for autonomy, beneficence, non-maleficence and justice – differing emphases on these ethical principles lead to different theoretical models and operating frameworks within the public health sphere[24]. As Schramm explains:[25] “Ethical problems in public health are not easily addressed within the existing framework of bioethical thinking, based on the principlist model; in addition to which, the ethical evaluation of health policies, particularly of a preventive nature, can give rise to a form of ‘health promotion tyranny’[26] and ‘preventive fanaticism’,[27] as a result of which we need to identify a specific ethics of public health.”

If we are to work towards a consensus as to how best to act, we need to start by shifting the emphasis away from the discussion of theoretical models, and focusing instead on the operating frameworks which should govern this type of intervention. A simple start would be to answer the questions proposed by Nancy Kass:[28]

- What are the goals of the programme?
- How effective is the programme in achieving its stated goals?
- What are the known or potential burdens of the programme?
- How can burdens be minimized? Are there alternative approaches?
- Is the programme implemented fairly?
- How can the benefits and the burdens be balanced?

Rather than provide my own answers, I will quote the Nuffield Council on Bioethics Report referred to earlier: “An important consideration faced by those responsible for breast screening programmes is how to strike the right balance between types and levels of information and education to support these programmes. The information must be designed to ensure that the women who participate in them understand the purpose of the screening, the possible pain or discomfort it may entail, and the likely consequences of detection (for example, the possibility of being called back for further tests). For example, how much should we know about such issues as false positives and negatives, treatment options if required after screening, or even conflicts between experts as to the possible side effects of analysis or its efficacy in general? Care should be taken to ensure that patient information is balanced and meets the needs and requirements of specific patients. The need to protect the population from alarmist health information must be thoroughly incorporated into professional health culture.”[22]

Starting from this basis, it is possible to establish a set of ‘terms of reference’ so that, in cases such as the one which concerns us here, we can consider:

- the various objectives of these measures, including providing information for individual decision-making and protecting the community as a whole, and the relative priorities;
- the role of autonomy, consent and solidarity;
- the issues raised by decisions regarding risk and how it is perceived.

From the perspective we will adopt, the main dilemma we intend to consider is the conflict – in this case, a false one – between social and individual benefits. This supposed collective ‘beneficence’, which is actually nothing more than the aggregated individual benefits of those involved, without any external or multiplying effect, then provides the basis for forms of paternalism or state control which would entail restricting the conditions which underpin autonomous decision-making. This ‘paternalism’ exists in a strong form which denies the rationality of opt-out decisions, or the production or dissemination of information which supports it; however, it is more frequently encountered in a weaker form, which seeks to intervene ‘at arm’s length’ in individual decisions by exaggerating the benefits of programmes and restricting information about the harms.

During the last five years we have seen cases where not only has information not been made available to those with an interest in receiving it, but also where the information itself has been withheld. There is the famous case of a scientific article which demonstrated the inconsistency between official data and the favourable results attributed to a particular screening programme. Accepted for publication and available in March 2006 on the website of the *European Journal of Cancer*, an operation designed to prevent it from being disseminated was initially successful. Despite having been accepted for publication, the article was withdrawn from the website. In November 2006, *The Lancet* published a description of this unacceptable censorship[29] and, finally, another medical journal[30] published the article. The traces of this scandalous attitude are still to be found on MEDLINE and other electronic resources, which describe the article as having been “withdrawn”[31].

At the same time, we are seeing the emergence of ways of overcoming this dilemma, based on the identification of a general framework to ensure that the necessary information is provided so that decisions about screening are consistent with the generally accepted principles of autonomy, beneficence, non-maleficence ... and even the adoption of the precautionary principles when investigating these processes[32]. Such approaches including the pioneering work by Barratt (cited earlier), together with various subsequent examples of the dissemination of accurate, balanced and comprehensible information. Other at least partially positive developments include the publication of a specific set of guidelines for the design of communication materials provided to breast screening candidates,[33] or the production and translation into Spanish of information material which is careful to respect the autonomy of decision-making on the basis of the relevant information available[34].

It appears, then, that significant progress is being made with regard to the autonomous decision-making capacity of potential participants in breast scan screening programmes. But it should also be noted that these advances are a reflection, primarily, of the unacceptable situation which existed beforehand rather than of the specific initiatives described here becoming generally widespread. And, above all, we are still a long way from today's analysis and debate being taken on board by specialists in bioethics and public health.

Some final considerations regarding autonomy and information

We have seen that it is possible to provide simple, comprehensible and accurate information about the benefits and harms of these programmes, even if this is only rarely done. Models such as Barrett's, the information leaflets developed by the Nordic Cochrane Centre or the Public Health Agency of Canada (http://www.phac-aspc.gc.ca/cd-mc/pdf/Information_on_Mammography-eng.pdf) are a good example of this. The next paper considers in more depth the content of the information provided in Spain, but in the meantime it is possible to state that it is a simple, straightforward matter to provide information of the highest quality, to ensure the autonomy of decisions by women who are candidates for inclusion in screening programmes.

There is one issue which affects all the matters considered here, and requires further consideration. We have mentioned various forms of paternalism, including asymmetric paternalism. However, the provision of good – or better – information is not incompatible with such paternalism, indeed just the opposite. Kranzberg argued that technology is neither good, bad nor neutral. Information can be good or bad – sufficient or not, accurate or false etc. – but never neutral. The way in which information is presented goes a long way towards determining how it is perceived and processed.

There is a significant bibliography on the perception of risks and paradoxes, together with a parallel literature on the 'innumeracy' which affects both the general population and, far more worryingly, health professionals, many of whose decisions and advice must be based on a thorough understanding of the available evidence. So, for example, it has been shown that informing of a 'one in ten chance' is perceived as more 'frightening' than 'a 10% risk'[35]. And when patients with lung cancer were given information so that they could choose between radiation therapy or surgery, when they were told that surgical mortality was 10%, over 40% chose radiation therapy, while when they were told that survival of surgery was 90%, less than 20% opted for radiation therapy.

Health professionals are not immune to these phenomena. Over a decade ago, we reproduced in Spain some studies[36,37] in which doctors undertaking courses in clinical research and management were asked about their intention of prescribing five, supposedly different, lipid-lowering drugs, on the basis of the results of the respective clinical trials. These results were actually different expressions of a single trial. Willingness to prescribe varied significantly in accordance with the manner in which the results were presented, with the presentation of relative risk reduction (RRR) leading to the highest propensity to prescribe the corresponding drug, and the presentation of increased rate of mortality being associated with the lowest propensity to prescribe[38].

It is not easy to know how to take account of such phenomena when choosing how to transmit information for use in decision-making. Some have argued that it is a problem which can be addressed through education and training, together with a commitment to using natural probabilities to present data, rather than less intuitive conditional probabilities. From this perspective, "Everyone who participates in screening should be informed that the majority of suspicious results are false alarms. We face a large-scale ethical problem for which an efficient solution exists yet which ethics committees, focusing their attention instead on stem cells, abortion, and other issues that invite endless debates, have not yet noticed."[39]

However, I am not so convinced that a technical solution is so near at hand. Assessing the benefits and risks of health interventions does not depend solely on the information provided in order to take a specific decision. In large part these are the consequence of general prior conceptions and, in this respect, oncology procedures – some more than others – are not comparable to actions taken in response to infectious agents, inert toxic substances or traffic accidents. There is a well-developed metaphorical framework which associates any action against cancer with an imaginary enemy. This is not the forum in which to consider such issues, but it is worth remembering the importance of cancer metaphors in constructing our imagery and identifying courses of action[40]. It was in this regard that Lakoff argued for the importance of the "metaphors we live by"[41].

In the light of all this, while we debate a 'new' ethical framework for public health interventions, there would seem to be a need to change existing strategies, using some of the approaches analysed here to provide recipients with sufficient information on which to base a decision. Huge efforts are required to reverse the history of disregarding patient autonomy, a history which is epitomized by attempts to circumvent debate with the argument that individuals have always had the right to refuse to participate.

However, the question which arises is whether it is possible to provide information about these or other interventions without to some degree determining the responses which will be received. Clearly it is not, and this may give succour to those who, while respecting the autonomy of individuals, seek to guide their decisions towards their own notions of 'beneficence'. And at the same time, it may disconcert those who trust the autonomous capacity of individuals to decide on the best for themselves in accordance with their own values and preferences.

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Information provided to women invited to participate in prevention programmes

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Screening programmes are a prevention strategy, generally secondary, in which asymptomatic individuals are tested and classified in accordance with their probability of suffering from an illness[1]. In 1968, Wilson and Jungner developed criteria for the implementation of screening programmes[2] with respect to the illness to be screened for, the programme, and the screening test.

According to the Recommendation of the Council of the European Union on cancer screening in 2003,[3] screening should only be performed within the framework of organized programmes, with guarantees of quality at every level, with an appropriate invitation and monitoring system, with fair access and good information about the benefits and risks to the target population. The Council only recommends screening for breast, cervical and colon cancers.

Populational breast cancer screening programmes began to be introduced in the second half of the 1980s[4]. In Spain, the first programme was introduced in the Navarre region in 1990; today, every region of Spain has organized populational breast cancer screening programmes[5].

The purpose of breast cancer screening programmes is to reduce mortality in the target population as a result of early diagnosis of the illness, when treatment is more effective and less aggressive, with consequent gains in quality of life[6]. To achieve this objective, programmes must have a high rate of participation by women in the target population[7], in excess of 70% according to European quality guidelines on breast cancer screening[8]. For this reason, programmes have made a huge effort to promote participation.

One of the limitations inherent to screening programmes is the fact that the majority of women who participate in screening programmes do not suffer from breast cancer when they are examined, and obtain no health benefit from participating in the programme[7,9]. At the same time, screening programmes are associated with adverse affects, both as a direct result of the breast scan process or with respect to the results (as the scan does not provide a definitive diagnosis). These negative effects can affect any woman who participates in a screening programme.

The negative effects of having a breast scan include the pain or discomfort and potential risks associated with radiology (although the real impact of this in inducing breast cancer is unknown)[10].

The adverse effects derived from the results of the breast scan[10] are associated, firstly, with false positives (unnecessary tests, anxiety or depression)[7]. Another key adverse effect is delayed diagnosis and treatment of false negatives and interval cancer (breast cancers which are diagnosed in the time interval between a negative screening test result and the next appointment)[11]. Screening also increases over-diagnosis and over-treatment: that is, the detection and treatment of breast cancers which would never have been diagnosed had the woman not participated in screening programmes[7]. Ductal carcinoma in situ is considered to be the most frequent form of over-diagnosis, and its incidence has increased since the introduction of screening programmes, although the value of early diagnosis and treatment are not adequately understood[7,12]. In Spanish screening programmes, 15% of tumours detected corresponded to the diagnosis of ductal carcinoma in situ[5]. Over-diagnosis is the cause of serious adverse effects in women, including the anxiety associated with a diagnosis of cancer, and complications deriving from treatment.

Breast cancer screening is a complex process, which can be divided into several stages, from invitation through treatment and monitoring of the breast cancer, although not all women have to pass through each of these stages. Organized programmes must guarantee high quality at every stage, with the aim of minimizing adverse effects to ensure that the relationship between benefits and harms is as favourable as possible[13].

In screening, it is the health system which contacts women to invite them to participate in such programmes, not women who request care. Various systems have been proposed for inviting women to participate in screening programmes: personalized letters, telephone or face-to-face invitation, general open invitation or a combination of all of these[8]. The majority of programmes invite women to participate through personalized letters, often accompanied by an information leaflet[14]. And most Spanish programmes also use this method to invite participants and arrange an appointment[15].

When it comes to informing users of screening results, programmes use various methods (personal letters, communication by phone, personal communication via the family doctor). Often, different communication methods are used depending on the result. In Spain, most programmes communicate normal results by letter. However, if it is necessary to perform further tests to confirm the diagnosis, few programmes send the results by mail[15].

Informed participation in screening programmes

People need to be capable of participating in decisions about their health if this is what they want. Decision-making is a process consisting of various stages: information exchange, deliberation and decision-making. Three theoretical treatment decision-making models have been proposed: paternalistic, informed and shared[16].

In screening, the term 'informed decision' or 'informed participation' is used because people are invited to participate and they decide whether or not to do so, without direct contact with health professionals to discuss their decision[9].

For a person to take an informed decision, she must have access to good, high quality, relevant, unbiased information about all the consequences of her decision[17]. In Spain, Act 41/2002, of 14 November, regulating patient's autonomy and rights and obligation with regard to clinical information and documentation[18], states in article 4 of chapter II that, "The right to health information," means that "patients have the right to know all the available information regarding any action affecting their health," and that this information "includes, as a minimum, the purpose and nature of each intervention, its risks and consequences," and also that it must be "accurate, and provided to the patient in a comprehensible manner which is adapted to his needs and helps him to take decisions on the basis of his own free will."

The General Medical Council (GMC)[19] argues that, in order to take an informed decision about screening, individuals need information about the purpose of the screening, the likelihood of positive/negative findings and possibility of false positive/negative results, the uncertainties and risks attached to the screening process, and follow-up plans, including the availability of counselling and support services.

High-quality information is fundamental in helping people to take informed decisions, but individuals also need to be able to understand this information and be capable of choosing freely between different options[9]. There are a series of factors associated with the provider, the communication channel, the nature of the recipient, and the manner in which the information is presented which influence how it is interpreted[20].

The credibility and competence attributed to the provider of the information are critical in determining whether or not the information is accepted[21]. Screening programmes are designed by health organizations and the majority of people consider them to be highly credible, as a result of which the information they issue is accepted uncritically.

Another key issue when providing information is the channel used. Screening programmes primarily use written information, especially when inviting women to participate. One of the advantages of this channel is that it means exactly the same message can be transmitted to all users, while the main drawback is that it means information cannot be personalized to reflect the needs of the individual woman. It has been suggested that written information should be complemented with helpline numbers and the inclusion of new information channels (internet), without neglecting the face-to-face relationship with health staff (programme staff, family doctor, etc.)[22].

Two important elements of written communication are the audience's ability to read (and to understand what one has read) and the readability of the text, defined as the ease of comprehension of the text as a result of the writing style[23]. Various sets of rules regarding the language content, wording and format of the text have been developed, with the aim of ensuring that all written technical documents form a basis for good communication[24-27]. However, in a study by Paul *et al.*, testing out six different designs of a leaflet inviting women to participate in screening for cancer of the cervix, it was found that the design of the leaflets did not influence their efectiveness[28].

Since the middle of the 20th century, a number of tools have been developed to assess the level of difficulty of English texts, based on the complexity of the vocabulary and the length of the sentences used (Flesch, Klare, Dale, Chall, SMOG, FORCAST). These formulae have been used in a number of contexts, including journalism, research, health, law and industry. Although they are not without their limitations, these continue to be used as an objective means of predicting the difficulty of a text[23]. Although these formulae were developed to measure the readability of texts in English, the Flesch scale has been adapted for use in Spanish; however, no assessment of the degree to which it reflects the realities of Spanish readers has been conducted[29].

The decision-making process is also affected by how the results are framed[30]. In screening programmes, the framing effect is related primarily to how the epidemiological information (incidence, sensitivity, specificity, risks, prevented mortality etc.) affects the perception of the advantages and drawbacks of screening. There is no consensus as to whether and how quantitative information should be presented. Those who propose the inclusion of this type of information believe that it is a fundamental element of informed decision-making, while those who prefer to present qualitative information argue that the presentation of quantitative data can be confusing and impossible to understand. There are also some who advocate the inclusion of both types of information (quantitative and qualitative data). In any event, information must be matched to the educational level of users, especially when including information about the risks of screening[31].

In response to the great difficulty of handling epidemiological information, a range of recommendations have been put forward regarding how to present or frame information for users to ensure its comprehension:[31-37]

- Presenting numerical probabilities in percentage form (3 per 100 women).
- Using constant denominators (4 per 1000, 15 per 1000) instead of constant numerators (1 in 25, 1 in 200).
- Providing a timeframe for evaluating a risk (in the next five years, during a lifetime, etc.).
- Presenting data with visual aids (pictograms, bar charts).
- Using dual representation (positive and negative data, profit and loss, mortality and survival) to counteract the influence of framing.
- Providing data about absolute and relative risks.
- If conditional probabilities are used (sensitivity, specificity, predictive values) then the base risk of the illness (prevalence) should be provided, because this data is difficult to interpret.
- Putting the specific probabilities of the illness (or intervention) in context, comparing the risk with other common or rare events (winning the lottery, having a car accident).
- Recognizing the level of uncertainty of estimates, giving confidence intervals or ranges for data.

At the same time, the effect of the communication of individual risk on decision-making has not been studied thoroughly. Edwards, in a systematic review, argues that the communication of individual risk increases overall acceptance of the screening test, but it is not clear that this equates to informed decision-making by users[32].

It is widely accepted that participation in screening programmes should be based on an informed decision; to take a decision, users must have all the relevant information, and this applies to breast cancer screening programmes too. The latest edition of the European guidelines[22] contains for the first time a chapter on the communication of information on screening which stresses the central role of service users in this process.

Programmes are advised to provide information which is accessible, appropriate, complete, comprehensible, honest and evidence-based. The information must be specific to each stage of the screening and must cover both the benefits and the adverse effects. It must be adapted to individual needs and characteristics, in addition to taking account of women's educational levels, and their linguistic and religious differences, and recognizing the importance of race, ethnicity, class and culture[22].

In addition, the guidelines stress the role of health professionals in transmitting information, and highlight the need to educate, train and motivate family doctors, as these play a key role in disseminating information. They also note the role of new technologies as a source of information in the future[22].

Finally, the European guidelines propose potential quality assessment indicators for the information provided to women by screening programmes, with the aim of guaranteeing high-quality communication in screening programmes[22].

Recognizing the importance of high-quality information for decision-making, at *avalia-t* we conducted a project with three objectives: to identify which information to offer and how to offer it (through a systematic review of written information for the users of breast cancer screening programmes); finding out users' opinion of the information they wish to receive (through focus groups of women and health professionals); and analysing the printed material used by different Spanish programmes[15]. The insights gained may make it necessary to reconsider some of the communication strategies used to date.

Analysis of written information in breast cancer screening programmes

Starting with the recommendations identified in the systematic review, a checklist of the content and readability of information materials in Spanish programmes (leaflets, invitation letters and letters informing of results) was drawn up[15].

The information on breast cancer and the screening programme was analysed: objectives, characteristics, organization and logistics of programme, screening test, diagnostic confirmation tests, benefits and adverse effects. Information in other areas was also evaluated, including: programme quality control, patients' rights, information to minimize emotional suffering, scientific bibliography and bodies endorsing the invitation information and letters informing participants of test results[15].

Almost all programmes offer information about what breast cancer is: seven of them inform about risk factors, and six about the incidence of the disease. Other epidemiological data, such as the risk of developing breast cancer or of dying as a result of it, or the survival and mortality of patients scarcely appeared in the information material. Most of the information about the illness is contained in the information leaflets.

In general, fairly comprehensive information is provided regarding the objectives, target population and screening interval. Relevant information is included on such issues as what to do in the event of symptoms appearing in the interval between screenings, something which is important if delays in the diagnosis of interval cancers are to be prevented; this information usually appears in letters communicating negative results.

The invitation material identifies the organization responsible for the screening programme, and the invitation and results letters are signed. The logistical information is concentrated in the invitation letters, and all programmes provide contact methods (usually a telephone number).

Information about breast scans is organized into four categories: information about the procedure, about results, about validity, and about quality control of the process. Detailed information is provided about the procedure, although there is usually no reference to the staff who perform or interpret the breast scan.

Information about the validity of the breast scan is limited to discussing the reliability of the test in qualitative terms, and data about sensitivity, specificity and predictive values is not usually provided. In general, these concepts are not very intuitive, and women who took part in focus groups had serious difficulty in understanding them[15].

The majority of programmes mention the possibility of having to perform diagnostic confirmation tests, although only four of them provide information about the proportion of women who need these. Other important information, such as a brief description of complementary tests or the waiting time before obtaining a final result is not usually included.

The project also analysed the inclusion of information about the benefits and adverse effects of screening. Most of the information focused on the advantages of the programme (the importance of early detection and treatment), while very little information was provided about the adverse effects; the only references were to the discomfort, pain and effects of radiation during the scan. None of the material analysed talks about the possibility of over-diagnosis (ductal carcinoma in situ) or over-treatment, or the percentage of false positives, while only one leaflet referred to the percentage of false negatives.

Other points identified in the review are not reflected in the information material: the voluntary nature of participation, the need for informed consent, or the bibliographical sources on which the information is based.

Stylistic analysis of leaflets issued by breast cancer screening programmes showed that these were generally satisfactory. The issues where the guidelines were not followed included text size (which is not usually greater than 12 points), the fact that text is almost always fully justified, and a failure to use enough relevant illustrations.

In summary, it appears that the content of the information material issued by programmes is designed to promote participation, within a paternalistic decision-making model. Efforts need to be made to ensure that information reflects a balanced decision-making model, including both positive and negative aspects of screening to help women reach an informed decision as to whether to participate in the programme.

As part of this process of adapting the material, it would be important to have the opinions of users as to the written information issued by programmes, and use should also be made of new technologies as an information tool which could be used by many women considering whether to participate in programmes.

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Working group contributions

Initial considerations regarding preventive interventions: population programme or care on demand?

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The initial question is whether a cancer screening programme should be populational and centrally organized, under the model of the state as a benevolent guardian, or whether it should be based on offering information which enables autonomy when deciding whether to participate. This issue affects not just screening for breast cancer, but also the prevention of other tumours which can benefit from early detection, such as bowel or cervical tumours, and even other forms of screening (such as antenatal).

Arguments in favour of centralization include considerations of justice, fairness and accessibility. There is less variability, and the potential risk of abuses such as the performance of smears, PSA tests and breast scans in young women who are not at risk is avoided. However, we also need to recognize the costs of non-prevention, and the benefits for those not affected (positive externality) and the group as a whole. However, the main argument concerns the right to this type of preventive treatment, although it is unclear whether this is the right to health or to healthcare.

Arguments against government screening programmes are related to the rigidity of administrative activities, unresponsiveness, and a failure to modify the design of programmes and recommendations in light of changes suggested by the scientific evidence. Populational programmes face difficulties in ensuring that the target population receives all the information they need, in a comprehensible form, in order to take an autonomous decision. The difficulty increases when it is necessary to include messages about the early detection of different tumours such as bowel, breast and cervical cancer, in women aged from 50 to 69 years.

However, government programmes are more effective so long as they take into account two issues. Firstly, when designing the screening programme it is necessary to decide and specify if the aim of the programme is to:

a) Inform about the early detection of cancer.
b) Persuade of the benefits of early detection of cancer.
c) Impose the early detection of cancer.

Information, in any event and regardless of how complex it is, must always be provided. We must bear in mind, however, that information should not constitute manipulation and that the aim is, rather, to ‘inform to decide’. This means providing candidates for inclusion in screening programmes not just the information which the programme designer deems important, but also all the information which is of relevance when deciding whether or not to accept the invitation to participate. For example, any false negatives or false positives which may occur, the potentially harmful effects of repeated exposure to radiation, the fact that participation in a screening programme does not necessarily mean that any cancer detected will be cured, etc. It does not strike us as acceptable to seek to maximize the number of participants in the screening programme – so that that the programme is deemed effective – through the use of manipulative techniques or by withholding information.

It is also important to distinguish between the design of the programme and a marketing operation: the aim is not to ‘sell’ anything, but rather to invite people to participate, offering the advice and an opportunity for prevention. It is therefore essential to resist the temptation to leave campaign messages in the hands of communication or advertising professionals.

The second issue to consider is that there must be ongoing evaluation of the effectiveness and the results of screening programmes, and these must feed back into them. Programmes should be modified on the basis of the results obtained or changes in scientific knowledge. Decision-making bodies need to be established which are able to promote effective change in response to the results obtained. And the opinions of the participants in screening programmes also need to be taken into account through the use of questionnaires or other techniques which ensure effective feedback.

Basic aspects of professional, institutional and populational involvement

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There are a few basic issues which need to be taken into consideration with regard to the range of professionals involved, the institutions which are responsible for such interventions, and the information which should be provided to invitees:

- Science and pluralism: scientific research and debate must involve all professionals and should also reach out to include ordinary people in the discussion. It is essential that there be an open discussion of the efficacy of breast cancer screening, based on the review of current scientific evidence, and this must incorporate a multidisciplinary approach.
- Institutional involvement: although these programmes are very well established both in the health services and in society as a whole and no one currently questions their usefulness, the institutions responsible for implementing them should constantly analyse their efficacy, effectiveness and efficiency.

Evaluation of these programmes should not be limited to the quantitative results (indicators) but should also incorporate qualitative elements with regard to participants' experience of the programme. An important element of evaluation is the quality of information provided to women throughout the process (invitation, screening, complementary tests etc.) to facilitate informed decision-making. This would make it possible to analyse not just the rate of participation but, better still, the rate of informed participation.

If the efficacy of these screening programmes leads to reductions in mortality from breast cancer, they should be implemented by the public health service and aimed at the whole population in order to avoid inequalities. However, we also need to consider whether such screening programmes should be promoted either in part or in full, if it is not clear that they are contributing to reducing mortality, or if the cost is not justified by minimal benefits.

The information provided by screening programmes to participants must be accurate, personalized and specific, with the function of enabling informed decision-making.

To achieve this, we propose providing generic information as part of the invitation to the initial appointment, followed up by personalized information in the breast scan units, before the scan is performed, so that invitees are able to decide whether or not to participate up until the last moment.

The information should also include those elements of uncertainty which are associated with such programmes. It is important to promote a culture of risk management and to break with the notion of scientific infallibility. Both health professionals and service users need to learn how to handle this uncertainty. For this reason, information should not only be provided to participating women, but should also be made available to the health professionals responsible for implementing the programme at different levels of the health services.

Quality requirements of screening programmes from an ethical perspective

The two working groups which considered this issue were:

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Josep Alfons, *group spokesperson, on behalf of*:

Jordina Capella, Montserrat Casamitjana, Juan Gérvas, Ricard Meneu, Teresa Queiro, José Ramón Repullo, Leonor Taboada and Núria Terribas.

The basic quality requirements affect the whole programme, from invitation to participate through to treatment of any breast cancer detected, passing through the breast scan and additional examinations, irrespective of whether the direct involvement of the screening programme in some cases is limited to invitation and performance and interpretation of the breast scans, with patients then being referred to the usual health service providers if necessary.

Validity of the breast scan

The validity of the test – accuracy and precision – is conditioned, firstly, by technical factors such as the nature and conditions of the breast scanner and, secondly, by other human factors such as the training and experience of the professionals performing and interpreting the scans (radiologists and radiology technicians). Other issues which influence the validity of examinations include the number of readings (independent interpretation of the scans by one or two radiologists) and projections (single or double) for each breast.

The quality criteria for programmes (as a minimum, number of readings or accreditation models of professionals) should be made explicit and publicly available.

Safety of breast cancer screening

The breast scan should be performed with the correct equipment, using the lowest possible dose of radiation possible and the lowest exposure time needed to detect small lesions. And quality control should be performed regularly, as recommended.

To limit as far as possible the harmful effects of ionizing radiation, it is not enough to limit the impact of breast scans. This is because of the cumulative nature of the harmful effects of medical ionizing radiation throughout the individual's life (X-rays, CAT, breast scans etc.). The acceptable doses of radiation for breast scans and control procedures for verification in Spain are established by law. There are two possible ways of controlling the amount of radiation received by each individual: an individual 'radiation card', recording all the examinations with ionizing radiation (something which exists in some countries); or using medical records to record the same information.

Intermediate studies (breast scans performed within two years for women whose previous screening did not produce results which were either clearly normal or showed signs of possible malignity) represent an additional radiation risk. Information about the increased risk from radiation as a result of these practices should be known by participants and professionals.

Repeat examinations due to technical defects in the initial examination or loss of the results also mean that participants receive an additional dose of radiation. Appropriate training of radiology technicians is therefore essential in order to reduce to a minimum the need for repeat examinations due to quality failings. The European guidelines cited earlier also establish maximum values for the repeat of breast scans for technical reasons.

Finally, the gradual introduction of digital breast scans reduces radiation risks.

Waiting times

We need to guarantee waiting times between an initial test with a suspicious result and a follow-up test to confirm diagnosis, and between confirmation of diagnosis and the start of treatment. These screening standards should not be at the expense of treatment for women diagnosed with cancer outside of the screening programme (that is, they should not lead to increased delays for such women). Once a woman has been diagnosed as having cancer, the care process should be the same regardless of whether the cancer has been detected through the screening programme or due to the presence of symptoms.

Information about results

It is essential to monitor, evaluate and disseminate the results in a transparent minor. Evaluation should be performed not simply for the purposes of monitoring, but also to provide a basis for implementing improvements or suspending negative activities.

In this respect, European guidelines propose a set of indicators and standards which the majority of screening programmes monitor. And the cancer strategy of Spain's National Health System also establishes a set of maximum average intervals between the different stages of general oncology care.

Other indicators used include cancer detection rates (employed by all programmes), the state of the cancer at diagnosis, and measures of the adverse effects of intervention such as false positives, interval cancers and overtreatment.

Interval cancers are ones which are detected after a normal breast scan and before the next invitation (for example, at 2 years). Some of these may have begun during the interval, but others may have been present when the first breast scan was performed and may have been missed due to examination or interpretation problems. Studies of interval cancer are very important, although calculating their rates is methodologically very challenging. It is also helpful to have populational cancer records to ensure comprehensive identification of all cancers occurring in the invited population, and determining their prior participation in screening. If access to populational information records is not available, then it is not possible to perform effective validation. European quality guarantee guidelines in breast cancer screening propose a methodology for validation studies, on the basis of which Spain's screening programmes have developed a shared methodology.

Thorough evaluation of screening programmes should include both the direct and indirect tangible costs, and the intangible costs of programmes, and should evaluate efficiency (the relationship between costs, effectiveness and utility) and the opportunity cost. It is also important to include the social impact of programmes in the evaluation.

The final specific outcome which has to be evaluated is the mortality rate from breast cancer in general, and the rate among women who reject screening.

Organized populational screening programmes are easier to study and evaluate than opportunistic screening, and it is easier to compare programmes. Comparison between the results of programmes implemented using different organizational models also makes it possible to evaluate the influences of such models and the differences between them. One possible limitation concerns the distribution of information about the outcomes of the different organizational models and the difficulty of publishing such results.

Information provided to women

The efficiency of screening programmes depends on the participation of the target population, and it is essential to ensure that participants do so on an informed basis.

Information must be objective, clearly explained, and suitable for the population to whom it is addressed: "If information is to be of use, it must be comprehensible." This means that the benefits, risks and drawbacks must be explained. Women who are invited to participate in screening programmes are not ill, and only a few of them will be diagnosed with cancer; it is therefore very important that they understand the pros and cons of a screening test which will be performed regularly every few years. The 4th edition of the European guidelines contains a specific chapter on communication in screening programmes, which defines the requirements of such screening.

The challenge is to ensure that the information offered is relevant not just from the perspective of health professionals but also from the point of view of invitees. At this point we discussed the dynamic of the invitation to participate in the screening programme, which typically refers the woman directly to a breast scan appointment, without any intermediate contact with the system (for example, the family doctor) which could provide more information, clarify doubts or reduce anxiety. Of course, existing resource constraints in the Spanish health system work against the introduction of further demands for apparently non-essential medical consultations, but the priority must be providing the right care to the user, giving her the opportunity to check information and to reach her own opinion. Finally, there is the fact that at 60 years of age a woman may be involved in up to seven different preventive programmes: public or private, institutional or opportunistic, formal or informal, validated or not. And there is no ignoring the impact of these practices on the quality of life of healthy adults.

With respect to the aim of ensuring a level of participation which guarantees the efficacy of the programme while also respecting the autonomy of invitees, we propose including information about this overall objective so that the population can also incorporate such considerations into their decision-making and take responsibility for these outcomes.

The greatest difficulties arise when it comes to informing about some of the potential adverse effects of screening, particularly over-diagnosis and over-treatment.

Information is much more effective when it is provided to educated individuals. If we are to propose different preventive activities to people throughout their lives and to respect their autonomy, we must incorporate concepts of probability, risk and public health in basic education. Even when early detection is possible, this should never be set against primary prevention, based on the health education of society and professionals in all the preventive measures which have been shown to be effective.

If the aim of a prevention programme is to achieve maximum coverage, then we need to facilitate the active participation of ordinary people in designing the programme. Good information is essential to promote participation, but it is not on its own a guarantee of success.

Communication must take account of cultural and educational differences in the target population when supplying information. To avoid information problems for cultural reasons, we need to identify the key information and adapt it to reflect the needs of the target audience. And nor should we forget that the differences between ‘medical culture’ and ‘ordinary culture’ are often larger than differences due to social factors such as religion or class.

The person providing the information and the way in which the information is provided are also important.

We also need to consider how the information is presented in response to the needs of candidates for screening (posters, letter, leaflet, website: from less information to more), using different locations and opportunities to inform (visit to the doctor, radiology technician during breast scan, etc.), building on any positive information initiatives already available (in Canada, Australia) and adapting them to the Spanish context if required.

Organizing workshops with the participation of women who have been through the programme with the aim of identifying the differences between prior expectations and actual experiences could help to identify key messages and the right language in which to express them. This could be similar to the paper presented by Teresa Queiro about written information, but eliciting women’s opinions not just on the suitability of the written information but of the whole process, in which what matters is not just the information people receive but how they are treated. If women are to feel truly involved then they must be treated as autonomous agents who are actually incorporated into the decision-making process, organizing discussion groups with others who have already been through the process, and listening to their suggestions about how procedures could be improved.

It is essential that people participate in decisions about the whole prevention, diagnosis and treatment process, and is particularly important when there is a range of alternative treatments, each with their own pros and cons.

Even so, communication and information about the positive and negative aspects of screening to facilitate informed decisions is no easy matter. Special attention needs to be paid to the tendency to treat screening programmes from a marketing perspective, as if it entailed the sale of a product, and in which advertising is a central element of obtaining acceptance by the target audience. In screening more emphasis must be placed on transparent, accurate information and communication, taking care not to manipulate the decision to participate in the programme but rather to provide the information needed in order to reach a responsible, considered decision.

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- Rafael Cofiño, Head of Populational Health Service, General Department of Public Health and Participation of the Principality of Asturias
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- Josep Alfons Espinàs, screening evaluation manager, General Oncology Plan for Catalonia
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- Màrius Morlans, member of the Professional Ethics Committee of the College of Doctors of Barcelona
- Carmen Natal, Coordinator of the Breast Cancer Early Detection Programme of the Health Service of the Principality of Asturias
- Mercedes Pérez Fernández, doctor, President of the Ethics Committee of the Spanish Primary Care Network, Madrid
- Mercè Peris, doctor, Catalan Oncology Institute
- Celsa Pico, magistrate
- Joan Pons, Programme for Research and Innovation in Health Sciences, Department of Health, Government of Catalonia
- Rosa Puigpinós, Breast Cancer Early Detection Programme, Public Health Agency of Barcelona
- Teresa Queiro, Health Technologies Evaluation Agency of Galicia
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- Gema Revuelta, Assistant Director of the Scientific Communication Research Centre of the Pompeu Fabra University
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Publications

Bioethics monographs:

25. *La ética, esencia de la comunicación científica y médica (Ethics: an essential element of scientific and medical communication)*
24. *Maleficence in prevention programmes*
23. *Ethics and clinical research*
22. *Consentimiento por representación (Consent by representation)*
21. *Ethics in care services for people with severe mental disability*
20. *Ethical challenges of e-health*
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12. *The management of nursing care*
11. *Los fines de la medicina* (Spanish translation of *The goals of medicine*)
10. *Corresponsabilidad empresarial en el desarrollo sostenible (Corporate responsibility in sustainable development)*
9. *Ethics and sedation at the close of life*
8. *Uso racional de los medicamentos. Aspectos éticos. (The rational use of medication. Ethical aspects)*
7. *The management of medical errors*
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Reports:

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3. *Therapeutic Cloning: scientific, legal and ethical perspectives*
2. *An ethical framework for cooperation between companies and research centres*
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