Observations on the Consultation from the European Commission

Discussion Document on a Health Strategy

Health in Europe: A Strategic Approach

Professor Michael Rigby

Professor of Health Information Strategy

Centre for Health Planning and Management, Keele University, UK

This paper comprises observations on the issues raised in the Discussion Document from the Commission on 'Health in Europe: A Strategic Approach'. It is provided from a personal academic perspective, based not least on advisory and research work within Europe for both the European Commission and the World Health Organisation Regional Office for Europe, and citizenship of two Member States.

This paper is in two parts:

A. Issues arising from the Discussion Document
B. Response to the Questions raised

A. ISSUES ARISING FROM THE DISCUSSION DOCUMENT

Whilst the document is clearly argued, there are some issues that arise from the content or the underlying assumptions, which are not specifically reflected in the Questions raised at the end. These are raised here.

Introduction

First, it must be recognised that this discussion paper is innovative and necessary, but enters into a difficult area. As indicated, health services and healthcare delivery are responsibilities of individual Member States, based upon the principle of subsidiary. However, not only do both citizens and health workers have rights of mobility throughout the European Union, but also many environmental and biological threats to health are also unrestrained by national boundaries. Furthermore, both knowledge and telecommunications pass effortlessly through national boundaries and thus citizens will have expectations of the best of health and healthcare being available throughout Europe. Some citizens will convert this expectation into expressed demand through patient mobility. Thus the Commission faces the dilemma on the one hand of ensuring treatment of citizens and health determinants equitably throughout the whole of Europe, whilst concurrently respecting the principle of subsidiarity. Moreover, national systems

of healthcare delivery are not identically structured and managed at national level – they differ radically in philosophy, funding, organisation, and management approaches, probably more so than any other major public or private service, though each is similarly being vital equally to the wellbeing of every citizen. **Thus any European policies and actions proposed as a result of this consultation or otherwise need to be firmly evidence based in order to ensure political and citizen consensus in their support regardless of the local national healthcare system structure.**

Underpinning Values

That said, there are two key values expressed in the first paragraphs of section one of the consultation document that represent an incomplete picture, and are thus hostages to fortune. The first is the unqualified laying of responsibility for health upon governmental and related bodies. The first paragraph states 'People expect to be protected against illness and disease', whilst the third paragraph states 'European Member States have the prime responsibility for protecting and improving the health of their citizens'. Such responsibility in fact cannot and should not rest solely upon member states. **The lead responsibility for protecting health must lie with citizens themselves, and by extension upon parents concerning the health of young children, and the Commission should seek ways of supporting this approach.** It is unfortunate and inappropriate that this consultation document by implication absolves the citizen from personal responsibility for health, not only because this is where prime responsibility should lie, but also because it places an impossible burden upon government and society if they are expected to have to support deterioration of health caused by uninformed or reckless health related behaviour by citizens. This is not just a point of semantics: a key part of the EU responsibility for health must lie in ensuring that salutogenic guidance - based and impartial evidence - is made available accessibly to citizens so that they can behave in health-enhancing ways. **The Commission has rightly adopted forcefully this approach of encouraging informed citizen and organisational behaviour with regards to greenhouse emissions and climate change; a similar philosophy and approach with regards to a societal and individual partnership needs to be taken with regards to health.**

The second principle which needs challenging in its simplicity is the statement that having a population in good health is important to achieving the strategic and economic objectives of the European Union and its Member States. Whilst in the short term this is true, at the same time recognition needs to be paid to the inevitable consequence that maintaining more people into old age will produce increasing economic and burdens of health and social care for society into the future, as will maintaining the life span of persons with chronic diseases. Clearly, this is not to suggest for a moment that these humanitarian and societal objectives should not be pursued vigorously; rather, it is to emphasise that one of the key actions must be to find the most innovative and effective means of providing this support using proven modern concepts – an area where there is considerable scope for European research and innovation. **The Commission strategy should therefore be cognisant of the medium term imperative of supporting a changed ratio of dependent to economically active persons to accommodate the inexorable increase in the proportion of elderly and chronically ill in the population of the future.**

European or Global Values

Given the pertinent comments in the introductory section that though the European Union is a major force, Europe's countries and citizens operate within a global environment, there needs to be a deeper discussion of this dichotomy. There may be conflicts and paradoxes in the health impact of policies, affecting differently European, distant countries', and local interests. For instance, the opening up by air transport of markets in European countries for fresh vegetables grown in African developing countries may have a modest beneficial health impact within Europe through making available more choice of affordable fresh vegetables throughout the year; may have a much greater positive impact on health in the originating developing countries both by generating earned income for poor farmers and also hard currency income for their governments to facilitate development of public services; yet may have a modest negative global health impact through a contribution to carbon dioxide and pollutant generation affecting global warming. **Some recognition of the need for explicit balance between the often separate and possibly conflicting European, external, and global health interests needs to be made explicit, though no magic formula is likely to be possible.**

Effects on Health Services and Health Systems

Much of the attention, not least both press and consumer interest, is on health services at a particular point in time for a particular – often acute – condition. Thus there is increasing interest amongst consumers – supported actively in some instances by Governments – in looking to other service centres for treatments that may be available more quickly, at better quality, and/or at lowered economic cost, elsewhere in Europe. Elective orthopaedic, cardiac care, and dental surgery are particular interests at the moment, along with (for different motivations) innovative or 'alternative' treatments for some chronic conditions. Whilst there is benefit to this, there is inadequate understanding by press and to a lesser by extent consumers of the importance of the integrated balance of the local health system or health economy. Whatever the system of health care provision in a country, a patient or citizen normally needs to be able to attend a local setting for a whole range of conditions from trauma through to low–impact illnesses, such as respiratory or gastric problems, or for first diagnosis of more significant symptoms which may prove to be caused by bigger problems such as cancer or rheumatoid conditions.

When an individual citizen travels to a different location for specific treatments, the remote specialist provider may not be in possession of their full previous medical history, nor subsequently will their local health provider receive adequate clinical details of their specialist elective treatment. The same applies with emergency treatment, where a short discharge note in the native language may be of little illumination to the home health system. This may jeopardise subsequent diagnosis and appropriate treatment. Further, many treatments undertaken in another country may need an element of follow up by local community or primary care services, or may result in sequelae which can only be addressed with a good understanding of the external treatment. **This necessitates a systematic means of transmitting both a summation of the treatment, and a clinical request for any ongoing support, in both a health taxonomy and a natural language totally comprehensible to the recipient health care workers in the**

locality of residence of the citizen; controlled access to previous history is also desirable.

External treatments, (including E health services) may have a destabilising effect on the overall health economy and on its systems of formal and informal post basic education. If significant elements of services such as orthopaedics or dermatology are removed from the local health economy, the ready availability of second opinions, and of in service education, will be diminished. **Future European strategic health policy will therefore have to highlight the importance of a balance between local health economy stability and integrity, and the benefit to citizens and health systems of a degree of external longer–distance service provision.** Such flexibility in modest volumes is an important way of avoiding monopoly providers making available only slow or otherwise poor services, as well as relieving short–term bottle necks, but if unplanned and in regular large volumes will compromise health systems and thus the support of the health of local residents. (It is recognised that in some settings, such as the northern part of Ireland or the Benelux and Franco-German border areas, local health economies may cross boundaries in a planned and managed way).

Health in all Policies

The concept of health in all policies, and of health impact analysis, is admirable and must be encouraged. However, there is a corollary – that some services may need to have their provision modified in order to facilitate health. Provision of information about healthy lifestyles within education; adequate provision for children with particular health–needs; and patterns of housing provision to accommodate the needs of those with disability or age-related frailty, are examples. **Thus there should be a corollary concept of 'policies to facilitate health'; in addition to education and housing components, parks, recreation and sports for all ages and abilities; adequate accessible public transport; safe cycling routes to schools and service centres; and positive encouragement of appropriate voluntary groups including youth activities, and social groups for the isolated or old, are some examples.**

B. RESPONSE TO CONSULTATION QUESTIONS

The consultation questions are slightly difficult to respond to, in that they each contain different components, and at the same time seek responses according to the three broad elements of core issues, mainstreaming health and global health. The following are therefore points which are seen as important in the context of the Commission's consultation, allocated to the questions as far as possible.

1. Prioritisation

It would be easy to spend considerable time on debates about prioritisation, and at the same time these would be likely to raise concerns from some Member States about subsidiarity. Therefore two key prioritisation criteria are suggested:

- those areas where cross-European mobility – of health threats, of health resources, or of patients – is a major factor and thus coordinated action is desirable;
- those areas where health interests are congruent with other active Commission programmes, such as some areas of research including Information and Communication Technologies, E-Health and Health Informatics, and product safety regulations.

The focus should primarily be upon core issues, but where the issues are global the European Union ought increasingly to be seeking to take a global lead. Action on health threats from pollution and global warming, and regulation of international telemedicine and E-Health, are examples.

Regarding the use of Healthy Life Years as an indicator, this may be one appropriate measure but any single measure is likely to have limitations. There should be better understanding of avoidable challenges to ill health, quality of treatment regimes in terms of clinical outcomes, and other factors. Secondly, it is important to recognise that concentrating solely on those Member States with the worst indicators (which in general will tend to be the newer Member States) may indirectly encourage inactivity in those countries with a better baseline, whereas it is important to have a balance between intensive effort to support the most disadvantaged, and ongoing active effort in all Member States to facilitate further improvements in health and longevity wherever possible. – good can get better even while worst is being uplifted to good.

2. 5-10 Year Objectives

It seems important to develop a short list of probably not more than ten key health activities, whilst strictly avoiding in that process the elimination of any interest in other health-related activities as opportunities or problems emerge or policies develop. As for the short list, this might include:

1. **Strengthening of the Health Indicators Programme.** The Commission has in the recent past sponsored a very innovative Health Monitoring Programme, to develop suites of indicators assessing health and health care delivery across Member States. This had the vision of developing a form of indicator assessment covering all dimensions of health and its treatment. In so doing it gained considerable support from specialist health professional and patient communities. However, that programme now seems to be downgrading rapidly, with a potential range of over 300 indicators now manifesting as a short list of probably not more than 25-40, of which a high proportion are indicators already readily available from other sources. It would be a major benefit to Member States and the citizens of Europe, and a major global lead, to reinvigorate the Health Indicators Programme so as to establish a much more ambitious data gathering programme; to refresh the indicators to ensure application to the 27 member states; and to address any remaining gaps such as indicators on health and health care for the elderly. This could be of benefit to national governments, professions, and citizens, as well as a robust global lead in public health information.

2. **Decision support and other health-specific software.** Many health support devices are software based, or include a significant component of embedded

electronic calculations. This includes clinical decision support systems and many diagnostic systems. Perversely, these are not regulated as products being fit for a purpose, escaping both CE-marking and medical device regulations. This gap was identified by the Towards European Accreditation and Certification (TEAC) project under the Fourth Framework[1,2], but still has not been addressed. Rectifying this omission would be a European benefit both for health and for commerce, but would also be a global lead.

3. **E-Health and Telemedicine.** As also identified by the TEAC project[1], it is a major anomaly that E-Health and Telemedicine are unregulated. This puts the citizen at significant risk of either incompetent or malicious services, whilst leaving them in a very weak position with regard to regulation, indemnity, and redress. Models already exist of global activity to protect its citizens in high-risk areas where the client cannot possibly assess the risks or the providers, the examples being civil aviation regulation and the Codex Alimentarius regarding food safety and labelling. It would be an excellent European-led initiative to seek a global framework a similar regulation of E-Health and Telemedicine. The issues are not unduly complex, though requiring some detailed technical preparation – Labelling, and national verification of practitioner registration status, and viable liability and redress systems, are principle issues. Whilst a legal underpinning is vital, a voluntary scheme to international standards would be powerful, as it would inform the citizen and encourage all practitioners to move towards recognised registration. The need for this has been published in the international scientific press[3],[4].

4. **A Professional Scientific Health Office.** In nearly every country, overview of health matters and guidance on specific issues of health care delivery, are conducted by a balanced triumvirate of Minister, senior civil servants, and professional head such as Chief Medical Officer or Director of Public Health. This ensures a sound balance of political leadership including accountability for policy issues to the electorate; guidance on formulation of enduring and viable public policies and regulation including fiscal and cross-central implications; and sound technical leads on the scientific and clinical issues. Moreover, an office of Chief Medical Officer or Director of Public Health provides a stable repository of technical evidence and organisational knowledge. The European Commission has robust and experienced ministerial equivalents, parliamentary supervision, and civil servants. However, by definition all of these are subject to regular rotation, whilst not being technical experts. This lack of a robust central technical office for health within the Commission is at times conspicuous, and it

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[1] Forsström J, Rigby M, Roberts R, Nilssen S-I, Wyatt J, Beier B, Delfosse I. Towards Evaluation and Certification of Telematics Services for Health (TEAC-Health) - Key Recommendations (Final Report of the EU Health Telematics Application Programme project HC 4101, Towards European Accreditation and Certification in Health (TEAC-Health)); University of Turku, Turku, Finland, 1999.

[2] Forsström J, Rigby M. TEAC-Health – Research-based Recommendations for European Certification of Health Telematics Services; in Hasman A, Blobel B, Dudeck D, Engelbrecht R, Gell G, Prokosch H-U: Medical Infobahn for Europe: Proceedings of MIE2000 and GMDS2000, IOS Press, Amsterdam, 2000.

[3] Rigby M, Forsström J, Roberts R, Wyatt J. Verifying Quality and Safety in Health Informatics Services; British Medical Journal, 323, 7312, 552-556, 2001.

[4] Rigby M. Globalisation or Localisation: Common Truths or Local Knowledge?; in Rigby M (ed.) Vision and Value in Health Information; Radcliffe Medical Press, Oxford, 2004, 149-158. (ISBN 1 85775 863 3)

is a major challenge to expect career lay civil servants to master technical briefs on issues ranging from new health threats to scientific evidence for types of treatment, and the staff are in turn likely to move on and be replaced. There is therefore a strong need to establish a central expert office such as a Director of Public Health and Policy, which would be an impartial scientific office providing advice within the Commission.

5. **Public Health Research.** The European Union has a commendable active research programme, and a drive towards the European Research Area. However, within this the focus on health tends to be on the important areas of biological research, new health threats, and health informatics. The amount allocated to public health research is modest compared with its importance. There is scope for significantly increasing the work in true public health, including better gathering an analysis of health information; development of survey and census tools not least in the difficult areas of child health, mental health, and care of the elderly; further research on the balance between income, housing, and health not least in the elderly; and analysis in cost benefit and health outcomes of different treatment modalities not least for chronic conditions. A particular challenge with the mobility of citizens within the EU is that of measuring health outcomes when treatments cross boundaries (whether organisational or national), and of measuring both epidemiology and health outcomes when care is provided by Telemedicine or E-health. These should all be seen as core issues for research yet at the same time would also be a major contribution to concepts and techniques of global public health. At present, much of this work is by default falling to elements of the Health and Consumer Protection Directorate General where a severely inadequate budget normally leads to a ceiling 60% funding contribution which is now severely compromising both goodwill and the ability of many sound research institutions to participate, and this contrasts very unfavourably with the Research Directorate General which can fund good research to 100%.

6. **Create a Synergy with WHO European Regional Office.** The role and responsibility of the World Health Organisation is significantly different from that of the European Commission. However, when it comes to issues of maintaining and protecting health, not least with regard to interpretation of scientific evidence and definition of health issues, the fundamental objectives on both bodies are the same. Particularly now that the European Union is extending to include an increasing number of central and more eastern countries, and countries with low economic baselines, many of the priority issues being addressed by the two bodies are very similar. Though there is a concordat between the two organisations, it has all the appearances of being weak. However, there are many areas where it ought to be possible to harmonise and share the work, and this would include many information issues of data definition and information collection; interpretation of a scientific data to address enduring and new health risks; and aspects of public health research. Given that the WHO does not have the same access to resources to commission studies as does the European Commission, it would seem mutually advantageous to strengthen the synergy between the two bodies, not least with regard to harmonising an increasing proportion of statistical data collection, and to co-ordinating some of the research activities. Indeed, it undermines the position of European Commission to on the one hand claim appropriately that health is a cross-sectoral

issue which should cross all portfolios both within the Commission and national governments, yet at the same time to remain less than harmonised with its partner specialist international health organisation.

3. Issues where Legislation would be Appropriate. Using the broadest and non-technical definition of legislation and regulation, the following would seem to be areas where some form of community regulation would be desirable;

1. **Out of Country Treatment Information.** Mobility of citizens and emergency treatment in another member state raise three issues – sending an appropriate summary of treatment and of ongoing treatment required to the home health system; contributing to epidemiological statistics; and enabling continuation of outcomes measures through development of harmonised reporting systems. To achieve these objectives supported by regulation or legislation would be an important step forward.

2. **Harmonisation of Professional Registration.** The rights of health professionals, and patients, to travel fits uncomfortably with national responsibility for regulation of professions, particularly when it comes to the smaller professions or some subsets of principal professions. It seems desirable to encourage incremental harmonisation of core requirements for registration for the principal clinical professions, and for specialist sub areas such as psychiatric nurses, paediatricians, and the like.

3. **Informatics Product Regulation**. Reference has already being made to the desirability of including e-health, electronic patient records systems, and other clinical software within an appropriate quality regulatory mechanism such as a developed sub set of CE marking or of medical appliance licensing.

4. **E-Health and Telehealth Regulation.** Reference has already being made to the long overdue need for a legally bound regulatory framework for international E-Health and Telehealth. The Commission could be a pioneer in setting a much overdue global lead.

Within each of these, the decision as to which form of legislation or regulation is most appropriate can only be made effectively once the requirements, and the type of sanctions needed for a breach of regulation, have been identified.

4. Combination of Approaches

It is difficult to produce one global answer for this. However, two particular themes come to mind:

1. **Joint Issues.** Whilst there is increasing liaison between Directorates-General where issues cross boundaries, there is arguably much more scope for truly joint initiatives. For instance, Health Informatics research does have a joint steering committee between Directorates General INFSO and SANCO but the appearance is of less than a truly joint activity. Education of health informatics staff is a joint issue between those two directorates and Education and Training, but no shared mechanism exists. Many other examples could be found. Thus better means of true joint programmes is desirable.

2. **Health Scientific Office** **T**he concept raised earlier of a Director of Public Health and Health Services or similar, as a central scientific office, would be a sound means of facilitating integrational approaches as this office would be evidence based rather than with an allegiance to any one Directorate General.

5. Milestones

Milestones should be set and publicised for each programme appropriate to its objectives and timescale.

6. Sharing of Value between the EU and Member States

A number of mechanisms already exist to co-ordinate Member States and the Commission, such as the High Level Group on Health and the Health Systems Working Party, whilst the European Parliament also has a role. This current consultation may provide a suitable opportunity to review, rationalise and strengthen these relationships. A further co-ordination mechanism, which harmonises with an earlier point in this response, is that both the EU and the WHO convene with Meetings of Health Ministers. The Health Ministers should therefore have an important role both in harmonising objectives and added value between Member States and the Commission, and also between EU member states and WHO. Health Ministers might also be further encouraged to think of the importance of the EU becoming a global leader, both in terms of scientific and service delivery achievements, but also in terms of responsible global citizenship by example.

7. Stakeholder Involvement

It has to be recognised that the increasing size and diversity of the European Union makes detailed stakeholder involvement more difficult, with the numbers of interests, languages, cultures, and issues involved. To avoid the build up of a further bureaucratic process, which in turn antagonises a high proportion of citizens, it may be better to take a lean approach. For instance, in policy groups and the like it might be appropriate to insist that 25% of members are brought from stakeholder groups including key health professions and key citizen or disease sufferers groups. It is very important that such representation be adequately funded, not only for attendance at meetings but also to ensure they can operate their own stakeholder group-specific networks.

8. Further Comments

This consultation document is very welcome. At the same time, it faces two challenges; first, the challenge that member states will wish to emphasise subsidiary over and above community cohesion; and secondly that critics of the Commission and its processes will see a Health Strategy as further European bureaucracy and domination. For these two reasons, but above all because it also allies with the core objectives of a health strategy, future work should be strongly bound on research evidence, sharing and interpretation of information, and of demonstration of best practice. In other words, A Healthy Europe should be seen as a primary objective for citizens and the governments, achieved by evidence and example, and not foremost by bureaucratic or regulatory processes.

Other comments were made in Part A in the narrative on the Discussion Document text, but may be summer up here as:

- European policies and actions proposed as a result of this consultation or otherwise need to be firmly evidence based in order to ensure political and citizen consensus in their support regardless of the local national healthcare system structure.
- The lead responsibility for protecting health must lie with citizens themselves, and by extension upon parents concerning the health of young children, and the Commission should seek ways of supporting this approach.
- The Commission has rightly adopted forcefully the approach of encouraging informed citizen and organisational behaviour with regards to greenhouse emissions and climate change; a similar philosophy and approach with regards to a societal and individual partnership needs to be taken with regards to health.
- The Commission strategy should be cognisant of the medium term imperative of supporting a changed ratio of dependent to economically active persons to accommodate the inexorable increase in the proportion of elderly and chronically ill in the population of the future.
- Some recognition of the need for explicit balance between the often separate and possibly conflicting European, external, and global health interests needs to be made explicit, though no magic formula is likely to be possible.
- Patient mobility necessitates a systematic means of transmitting both a summation of the treatment, and a clinical request for any ongoing support, in both a health taxonomy and a natural language totally comprehensible to the recipient health care workers in the locality of residence of the citizen; controlled access to previous history is also desirable.
- Future European strategic health policy will have to highlight the importance of a balance between local health economy stability and integrity, and the benefit to citizens and health systems of a degree of external longer–distance service provision.
- There should be a corollary concept of 'policies to facilitate health'; in addition to education and housing components, parks, recreation and sports for all ages and abilities; adequate accessible public transport; safe cycling routes to schools and service centres; and positive encouragement of appropriate voluntary groups including youth activities, and social groups for the isolated or old, are some examples.

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Professor of Health Information Strategy

Centre for Health Planning and Management, Keele University, Staffordshire, ST5 5BG.

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