Observations on the Communication from the European Commission

Consultation Regarding Community Action on Health Services (SEC) (2006) (1195/4)

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This paper comprises observations on the issues raised by the Communication from the Commission on the implications on European citizens' rights to high quality health care, and the free movement of those citizens and service providers. 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.

The issue of patient mobility for treatment within the European Community raises important benefits and opportunities, but also new risks and challenges. It creates new dimensions, paradoxically both positive and negative, in the key healthcare dimensions of Equity, Choice, Quality, Liability and Redress: it has the potential to improve all these, but without the right facilitating framework and policies it could seriously damage them instead. Further the linking resource of Information is unfortunately little addressed.

This discussion paper comprises three parts:

1. Introductory issues
2. Issues concerning Information, Telecommunication, and E-health
3. Observations on the Commission's nine questions

1. Introduction

The consultation document identifies four broad sets of circumstances in which services are provided within a cross-border set of conditions:

i European citizens temporarily resident in another Member State and needing healthcare.
ii Members requiring non-hospital care, who are entitled to seek it elsewhere without prior authorisation.
iii Members requiring hospital care, who have the right to seek it elsewhere but who first require the authorisation of their Member State health system, and must be given that authorisation if treatment cannot be provided locally within 'a medically acceptable time limit'.
iiii A health service provider from another state offering services within the Member State of residence, including virtual service provision.

1.1. Non-Hospital Care Definitions and Perverse Effects

Whilst these are principles and definitions within which the Commission indicates it is willing to operate, and are given factors in the process of seeking and responding to consultation, it must be recognised that these principles in themselves cause problems. These problems can be summarised as:

A. The terms 'hospital care' and 'non hospital care' as quoted are not defined.

Presumably 'non-hospital care' is intended to mean health treatments not requiring overnight admission, as apposed to 'hospital care' requiring overnight admission.

This is neither explicit nor related to practical realities, and requires clarification. It could be discriminatory against practitioners or service providers who are located on a comprehensive health campus linked to a hospital as apposed to those operating from private consulting rooms or other non-hospital premises. This could also encourage practitioners to move away from health sites that have emergency back up facilities, in order to be classed as 'non-hospital'.

B. The requirement for preauthorisation for hospital treatment but not for non-hospital treatment may lead to an inappropriate pressure for increasing those procedures provided on a day case basis in order to avoid prior authorisation, and thus in certain circumstances put patients at risk.

The boundary between what is locally accepted as suitable for day case treatment and what requires admission varies between Member States, and in each state this boundary is steadily shifting as medical science and health practice develop locally. Pushing patients to receive care outside a hospital in order to avoid the need for prior authorisation is a pressure for increased risk taking. Further, this creates an incentive for practitioners to develop a style of delivery mechanism based on undertaking treatments by a non-hospital procedures route, linked to a period of residential stay in a hotel or apartment with visiting health support. This is already the pattern in at least one Member State for procedures of assisted dying, and it is easy to foresee similar options being offered for other treatments given this regulatory stimulus.

C. It is desirable to harmonise the prior authorisation mechanism for specific conditions so as to avoid these perverse pressures which may increase the risks to citizens.

Harmonisation of definitions of included conditions or treatments would also avoid potential future problems whereby disputes arise between a receiving Member State which accepts a non-hospital procedure to treat a particular condition, and the State of residence which might claim that this should only be provided in a hospital setting and thus required prior authorisation. In such cases the patient would be the victim caught in a technical and political dispute between two Member States, untreated whilst the bureaucracies debate.

Further, some conditions may be amenable to treatment serially in a non hospital setting, but secure in the knowledge that hospital back up is available. Forms of renal dialysis are one strong example. If a citizen feels that an adequate dialysis service is not available in

their country of residence, with modern transport they can easily travel to another member state for outpatient assessment, and then non-hospital dialysis on a regular basis for an indefinite period, but would be in an invidious position if in-patient treatment suddenly became needed.

1.2. Virtual Services

The consultation document also rightly distinguishes between services provided by a physical attendance, and health services provided remotely by telehealth of various kinds. However, a major difference is that the location of the provider of a physical service is clear, and the identity of the providing professional is much easier to establish. With e-health services it is much more difficult to assess the location of the provider, which may be within the European Union area or may be outside. This raises a further challenge

D. The location of the agent of provision of electronic health services – whether personal consultation, reading of forwarded diagnostic data, or email consultation – cannot be identified unequivocally during the remote transaction. Current communications technologies enable enquiries to be electronically forwarded to other locations (the underlying principle of call centres), whilst confirmation of identity and authenticity are also extremely difficult.

As will be discussed in the second section of this paper, the issue of electronically provided services needs much greater attention. European citizens are potentially put at much greater risk if they, or practitioners serving them, seek telehealth remote services. This is primarily because of lack of any serious attempt to address issues already raised through European Commission funded studies [1, 2, 3].

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1.3. Insidious Development of Treatment Norms

A further potential problem created by the issues in the consultation paper is that of the development of pressures upon individual Member States' health systems by the development of externally originating *de facto* norms and guidelines as a result of patient mobility. If each Member State develops a different definition of 'a medically acceptable time limit' for any particular health care condition, in due course the public awareness of these differences will create pressures upon the local health system to conform to the best. It will also create pressures in the 'receiving states', if an 'exporting' state does so on the basis of a time limit less than that in the recipient state. Other issues raised later in this paper concerning definitions of quality will also have similar effects.

E. The effect of Member State definitions of reasonable time limits, and of quality measures, within their own state will, with the mobility of patients for services and related growth of public knowledge, create pressures on each Member State's health system to perform with the standards of the best. This should be considered explicitly and made an open process to avoid tensions both within and between Member States.

1.4. Self-funded Treatment

Finally, however, in referring only to the current criteria for the citizen's right to travel for health care, the Commission's consultation paper omits a major further important category, namely where the patient in their home country would pay the full cost of treatment without any intervention of their Member State, or elects to in the State to which they choose to travel. This appears a major anomaly, for two reasons – first, it is discriminatory between the citizens of different countries, where the availability and threshold of fully reimbursed treatments are different; and secondly, on grounds of patient safety because the citizen is not likely to know the regulatory and quality assurance mechanisms of other states so as to be able to make an informed choice of provider. Services such as dentistry, cosmetic surgery, and a range of what in some countries are considered alternative health regimes are particularly at stake here.

F. In seeking to give the citizen choice whilst protecting them against risks and ensuring they are protected by liability and redress mechanisms, there should be no differentiation between services reimbursed by the citizen's Member State of residence, and services reimbursed in full by the citizen.

2. Information, Telecommunication, and E-health

2.1 E-health and Health Informatics Platform Variations

A vital but under-appreciated part of any health system, and of effective diagnosis and treatment of the patient, is a sound information system. In this context health system is taken to refer both to the information content and to the means of transmission of this information.

The Commission's consultation document makes strong reference to e-health policy, inter-operability, and Electronic Health Cards. These, together with health informatics standards not least as promoted by CEN TC251, are vitally important. However, these can only be effective universally in the long term. The significant number of legacy systems in those health systems with strong e-health applications, and the major level of investment necessary in many of the health systems of less economically developed parts of Europe, mean that none of these important concepts can be universally operational across Europe in under a decade, and many would say a much longer period – a fact conformed by a recent Commission publication [4].

G. Therefore, a development of principles and policies for safe and effective care to citizens across boundaries cannot depend upon e-health or interoperability, and to act thus in the short term would discriminate against those patients whose home or 'receiving' health suppliers are not equipped to these standards.

2.2. Remote Services and Continuity of Care

It is also important to differentiate between remote delivery of services by electronic means – telemedicine, remote diagnostic consultation, and access to reference databases – and communication of information for and about citizens travelling to receive treatment by traditional means. The issues and the solutions are significantly different.

For traditionally provided services the conventional policy hitherto has been for information from the service provider to be made available to health staff providing services to the patient in their normal location of residence. This can be split down into two elements, for each of which issues of language, patterns of treatment, and mutual understanding between practitioners in different countries about ongoing care need urgently to be addressed. The first applies for all cases.

H. There should always be supplied a summary of the procedure(s) undertaken and the immediate outcomes, in a prescribed European standard format, to enable the information to be entered as a part of the patient's health record in their locality of residence, unless the patient requests otherwise for confidentiality reasons.

This may also contain more general information as to what action to take in the event of a particular type of subsequent side effect, or recurrent aspects of the original condition.

The second element may only apply in certain cases.

I. Where specific follow-up treatment needs to be undertaken locally as part of the completion of that episode of illness and treatment, but will not be supervised by the remote treatment provider – such as a specific course of medication, physiotherapy or other rehabilitation, or wound treatment – it must be notified in a prescribed format to a nominated local practitioner.

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Such information needs to be specific as to the actions sought and the parameters of treatment; it needs to be appropriate to the services available in the patient's Member

State of residence; and it needs to indicate firmly who holds clinical responsibility for this treatment and any triggers for reference back to the remote treating clinician.

2.3 Enabling an Informed Remote Provider

However, important though it is to provide post-treatment information to subsequent clinicians, far less attention has been paid to the desirability of a treating clinician having access to a prior clinical history of the patient. Whilst many patients are well informed on their conditions, this cannot be taken as a generalisation. Nor would it be appropriate to expect all patients to be experts about their treatment in this way, or to carry a full medical history dossier.

J. With increasing mobility of patients, there needs to be developed a systematic way of giving 'receiving' health professionals access to previous medical history.

Only the treating practitioner will know what are the significant aspects they need to know, and necessary data may include more general information such as allergies or previous drug reactions. Asking the patient to bring their full medical history with them is impractical in most cases until such time as a common electronic health card format is achieved, in the long term. In the meantime, an interim solution is needed. A standard medical history format might be possible, but has major constraints as the patient will not know what the treating clinician may find. A more innovative solution which could be achieved with limited research and rolled forward incrementally is the concept of the web-based broker. This has been developed to demonstrate this stage in health in the United Kingdom, and could enable any clinician with a duty-of-care interest to access and search any health record system which is electronic and has a web portal interface. This has been written up extensively [5, 6, 7], and is commended as a relevant subject for further practical research.

2.4. Verification of E-health Services

However, regarding services provided electronically, it seems imperative for the Commission to pick up the issues identified in its previously funded Towards European Accreditation and Certification of Health Informatics Services (TEAC-Health) [1, 2, 3] earlier.

One key element of this is Labelling. Labelling is a concept which has been well developed by the European Commission, not least with regard to CE-marking. It is also well developed for food labelling in the *Codex Alimentarius*, which is a joint WHO/FAO agency based in Rome. The Labelling aspect both of CE marking and of the *Codex Alimentarius* specifies the items to be provided in a virtual 'label', the format of presentation, and the terms to be used. Moreover, and vitally important, participating states enshrine the provision of this information within legal protection. Thus it becomes a criminal offence in the country of action to make a false statement.

K. Labelling of e-health services – whether these be consumer consultative services, telemedicine, or diagnostic reference services supporting home-

based clinicians – would provide a significant safeguard against incomplete knowledge, or false or malicious statements.

The Label would require a practitioner to state their name, place of practice for this service, registration, qualifications, and other key data to be developed as part of a European patient mobility facilitation or e-health verification process. Once quality standards or measures are agreed as discussed in the third section of this paper, they too could be developed as Label requirements – such as standardised outcome measures.

A second aspect of services provided remotely electronically is that all boundaries are porous. There is no proof that a provider who gives all the indications of operating within Europe has not in fact had 'forwarded' that service to third country. Moreover, it seems unreasonable to expect the European citizen to be able to ascertain the real location of a virtual service provider.

L. To protect European citizens, and to exploit the Commission's increasing profile in innovation in e-health, it is highly desirable for the European Commission to be the initiator of moves towards international agreement on supervision and safeguards of e-health.

A clear precedent is set by the civil aviation industry, whereby virtually all the countries of the United Nations are part of a process which standardises many operational aspects of civil aviation based on scientific-led political consensus, in the interests of total global mobility matched with strong citizen and professional protection. The same applies with the *Codex Alimentarius*, to protect citizens' food safety and integrity. If this can be achieved for civil aviation and food supply, it is surely important to achieve the same evidence-based policy and regulation benefits for e-health which directly affects the health of every person using it directly or indirectly [8].

2.5. E-health Record Keeping

Effective clinical record keeping is an essential part of ethical healthcare practice. With physical attendance of the clinician to the practitioner, or vice versa, the locus of responsibility for record keeping is clear. However, with virtual services, and especially live real-time consultation telemedicine, there may be ambiguity as to record-keeping responsibilities leading to inadequate records being kept. This issue needs European standardisation to protect all parties – remote practitioner, local practitioner, and patient.

M. To protect all parties, the Commission should specify minimum levels of record keeping for e-health services, and that for interactive services both the remote and the local practitioners should record the evidence they received and the advice and treatment given; this may necessitate video recording of remote consultations (with patient permission).

3. The Nine Consultation Questions

Paper from Professor Michael Rigby

Question 1 – Impact on Local Health Systems

The full effects on local health systems will only emerge with the passage of time. Individual countries are likely to be in the best position to predict possibilities. However, the following may be hypothesised:

a In newer Member States with generally lower economic costs, in the short term treating external residents may stabilise and even strengthen their health systems by bringing in higher income, but possibly at the expense of local residents. In the medium to longer term economic forces are likely to balance this out.

b In higher income Member States, which often have over-stretched health systems, the provision of services elsewhere may provide a welcome pressure relief. This may even lead to moves to reduce further investment in certain areas, if satisfactory arrangements with lower cost external partners can be established.

c The development of centres of special expertise may have one of two effects. For rarer conditions the build up of expertise may strengthen services to all – a principle already enshrined in Community action with regards to Rare Diseases. However, in other areas it would be possible for centres of expertise to develop in a commercially aggressive way, possibly to select less complex cases for very cost effective treatment, leaving home health systems with the complex cases or those with co morbidity, and at the same time leading to extreme competitive pressure to prove optimised measures of success. These latter trends can already be identified in those countries which have moved towards performance indicators – perverse action such as discharging patients half way through their convalescence for further care elsewhere can manipulate mortality and length of stay statistics, whilst the efficiency of data flows such as mortality data or information on enduring side effects will be different in each Member State and very difficult for inter-State care, thus making the playing field uneven by nature and possibly also by design.

Question 2 – Objective Informed Choice

This question raises two separate issues. The first is the medico-legal issue, concerning definition of 'unduly delay', which is likely to vary between Member States and can also form a mechanism for delaying authorisation until such time as local treatment has been arranged. It is important that the Commission seeks to ensure yardsticks are in place whereby delaying tactics cannot be allowed to become effective. This might be through development of local reference criteria that became public knowledge, such as by publication of a reference table for a range of typical conditions. This would need to be drawn up within individual States because of the principal of subsidiarity, but once established it will enable a rapid decision to be made simply by confirmation of the patient's diagnostic condition.

Secondly under the first issue, the consultation paper raises the topic of mechanisms of appeal. This does seem essential both on the grounds of equity, and to prevent intentional malicious delaying tactics from being effective.

The second issue raised is also a vital one, but of a very different nature, namely the citizen's means of choosing treatment services. Two separate elements are required. The first is a means of confirming the legitimacy of a service provider – validating primarily

their professional qualification, but in some form also their ability to provide particular types of service based on the availability of the right type of technical knowledge, equipment, and support services. Developing such a schedule will be challenging, based on an agreed common nomenclature or taxonomy, but without such it lays the citizen open to provision of inadequate quality services albeit by registered practitioners.

The second dimension to this issue is the definition of quality measures. These might relate to health outcomes such as morbidity rates and 'complete cure' rates, though these are particularly challenging to achieve. Also this approach could relate to litigation and complaints rates, but again cultural and other factors are liable to bias these. Once the other issues raised in this consultation have been addressed at the European level and a firmer framework for cross border service provision established, the increased importance of the quality measurement issues should be revisited with the incentive of populating a framework by then established.

It should also be noted that e-health services are very different in this respect. What is often involved here is the quality of advice for diagnostic interpretation to a health professional treating the patient in their State of residence. Different means of assessing the quality and acceptability of these services is needed.

Finally, reference in this particular section to the European Health Card and inter-operability to enable the transfer of health related data issues are largely irrelevant at this point. These initiatives are intended to improve treatment of the individual, not selection of the potential external treating practitioners, as well as being some considerable way off in terms of widespread use.

Question 3 – Authority with Responsibility

For practical reasons it seems important that the Member State in which a health practitioner or the health service operates is responsible for all regulatory mechanisms. The alternative, that a practitioner has to seek authorisation from (currently) 26 additional Member States each of which will be unfamiliar with the practitioner and may only have a few citizens seeking services, would be impractical. Automatic mutual recognition of a national registration by all other Member States would be unsafe, as it would circumvent regulation, accountability, and redress mechanisms.

However, it could be a significant development to differentiate in future the basis of registration, to identify separately registration to provide services within State, and registration to provide services to citizens of other EU Member States. This would give important opportunity to protect quality by ensuring that practitioners have the knowledge and technical means of providing the relevant communication back to the citizen's Member State of residence. Dependent on the services to be provided, this could include appropriate equipment and record keeping where telehealth was in operation, to more simply understanding and complying with a standard form of clinical communication or discharge communication to the local health practitioner in the citizen's locality of residence.

Question 4 – Compensation and Redress

It would seem essential that the lead responsibility for operating any compensation and redress mechanism should be from the Member State of provision, as only they will have ready physical access to the practitioner, their records, and other relevant information. However, commensurate with this it seems desirable to develop a standard compensatory framework, not least indicating the grounds and the mechanisms for seeking redress. A further issue is the compensation levels – it could be argued that the rates applicable to the State of treatment should apply as they will be linked to the rates for which the patient has paid for treatment. However, this could be disadvantageous to citizens living in higher income countries, for whom such financial redress would have significantly diminished real value. Therefore, it seems desirable to develop a form of liability insurance for practitioners and health providers treating patients from other Member States, which would have to be covered by the fees charged to patients, to enable compensation related to the country of patient residence to be applied when a liability case was proved or accepted.

Question 5 – Effect upon "Receiving" Country Health Systems

This would seem an issue for local operational management. A health practitioner or health system is not forced to accept a referral, accept in case of emergency. Thus acceptance of external referrals must be a matter of choice of the service provider, who should be liable under local mechanisms for any adverse effects of local discrimination. However, in locations of over-stretched health systems, a desire to accept outside referrals in order to generate income to avoid a waiting time less than in the receiving country could lead to perceived local inequity and thus disquiet.

Question 6 – Mobility and Registration of Health Professionals

This seems to be rather a confusing issue to raise in this paper. However, more fundamental is that of levels of knowledge and areas of practice within the Member State of treatment. There could be benefit in codifying safety or competence issues such as child health nursing, or delivery of dental anaesthesia, across Europe. A patient from one Member State attending a service provider in another Member State could check on that provider's legitimate registration, but not realise that the level of expertise or patterns of practice for a particular type of treatment or service are very different within their own Member State.

Question 7 – Other Issues Concerning Legal Certainty

One further issue which needs to be clarified as a result of the issues raised by this consultation concerns the responsibility for ongoing treatment. There should be a clear distinction concerning treatment which has been 'completed' and for which the health practitioner or service will provide no further support – in which case they should provide a standardised 'discharge' communication to the citizen's local health provider, explaining what has been done so that they are informed. This is distinct from those areas where the 'receiving State' practitioner accepts ongoing responsibility for a defined period or permanently, such as monitoring subsequent health data and adjusting

medication. In these cases there should be an advisory communication to the local health provider indicating those areas where possibility for continuing care, and therefore by implication a request for consultation over adverse effects or new sequelae when required.

Question 8 – Effect upon Member State Health Systems

This is an important dimension. The issues of centres of excellence have already been referred to earlier in this paper, where it appears important to differentiate strongly between planned European reference centres to pool expertise for Rare Diseases and conditions (which is highly desirable); and the risk that individual centres could create expertise and aggressive marketing to address specific sectors of a more general market and thus destabilise both the local service pattern and the related education and training hierarchies. For instance, a strong remote offering of a dermatology service, widely taken up, may remove from local setting a proficient dermatology presence for secondary consultation and in-service education. It would severely down grade the service available for the balance of dermatology cases, which need direct consultation. The same issue of the balance between relieving overload on local services, or destabilising their cohesiveness, will apply to many other conditions and services.

The other issues raised in sections 3.2.2 – 3.2.4 of the consultation document seem perhaps irrelevant to patient mobility. Work is already in hand through the Commission both in scientific research, and in sharing of evidence of health impact assessment and the creating of a suite of health indicators. The sharing of knowledge is vitally important and needs to be encouraged even more strongly than at present as it benefits all Member States and citizens equally whilst maintaining autonomy of health systems. The creation and sharing of evidence is significantly different from cross border provision of services.

Question 9 – Appropriate Tools to Tackle Different Issues

This question is addressed more in the second section of this response paper. However, specification of formats and content for key referral and discharge messages; research into a broker approach to standardise record searching; sanctions-based Labelling of e-health services of all types; and moves towards initiating global standards and sanctions commensurate with the civil aviation model, are all postulated.

4. Conclusion

The issues of patient mobility, and the separate issues of collaboration between health systems, are essential issues that appear to fit within the principles of subsidiarity. However, the defining of elements necessary for implementing the right to travel for treatment or to enjoy remotely provided virtual services will in their very process start to develop national standards which are likely to become universal public expectations. The division between hospital and the non-hospital services is an increasing artificial one, and runs severe risk of providing services in sub-optimal format in order to make them more readily available for mobile patients, creating unnecessary avoidable risks for patients. Provision of centres of expertise is highly desirable in a planned and coordinated way for rare conditions, but for more common conditions and on a free-market basis could have

adverse effects on holistic integrated health systems in Member States. Sharing of other expertise such as health technology assessment is valuable provided that the scientific evidence is presented in a way that enables mapping to local economies, health systems, and cultures[9].

Finally, and most importantly, e-health visions such as inter-operability cannot be seen as solutions to the information support necessary for patient mobility. The extensive lead time before digitisation and interoperable systems become reality are such that alternative solutions must be sought urgently. Standard message formats and contents for paper communication, standard messages for electronic transmission, and further research into appropriate solutions for pre-treatment record searching, are the priorities. E-health services themselves such as telemedicine and have much to offer, but cannot readily be constrained to within EU providers. The development of a legally backed framework including Labelling and drawing upon the expertise of CE marking is needed. The Commission should also seek to move towards a global infrastructure for these essential means of protecting the citizen.

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