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Theme – ‘E-Health: Challenges and Opportunities’

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GLOBAL E-HEALTH DEVELOPMENTS: FISCAL; LEGAL; INFRASTRUCTURAL and ETHICAL CHALLENGES

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1. EXECUTIVE SUMMARY

1.1 Overview

This paper is one of three commissioned from HealthSystems Consultants Limited by the Commonwealth Secretariat on various aspects of *e-health* under the auspices of the Commonwealth Fund for Technical Co-operation (CFTC).

2. This paper focuses on the fiscal, legal, infrastructure and ethical issues that relate to *e-health*. The reference numbers in brackets identify various previously published papers relevant to *e-health*. These papers are listed in Appendix A.

1.2 A definition of *e-health*

3. A recent *e-health* publication (3) defined the *e-health* market. That definition is restated here and used in this report issued by the European Union.

4. “The *e-health* market can be defined as comprising the following four interrelated major categories of applications:

1. Clinical information systems

- a) Specialised tools for health professionals within care institutions, hospitals for example. Examples are Radiology Information Systems, Nursing Information

Systems, Medical Imaging, Computer Assisted Diagnosis, Surgery training and Planning Systems.

- b) Tools for primary care and/or for outside the care institutions such as general practitioner and pharmacy information systems.
2. Telemedicine and homecare, personalised health systems and services, such as disease management services, remote patient monitoring, tele-consultation, tele-care, tele-medicine and tele-radiology.
3. Integrated regional/national health information networks and distributed electronic health record system and associated services such as e-Prescriptions or e-referrals.
4. Secondary usage non-clinical systems
 - a) Systems for health education and health promotion of patients/citizens such as health portals or online health information services.
 - b) Specialised system for researchers and public health data collection and analysis such as bio-statistical programs for infectious diseases, drug development, and outcome analysis.
 - c) Support systems such as supply chain management, scheduling systems, billing systems administrative and management systems, which support clinical processes but are not used directly by patients or healthcare professionals.
5. *E-Health* can thus be said to cover the interaction between patients and health service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals; it can also include health information networks, electronic health records, telemedicine services and personal wearable and portable communicable systems for monitoring and supporting patients.”

1.3 The common challenges

6. A prior report to Commonwealth Secretariat(ComSec) (1) noted that ‘*e-health* programs are already underway in many of the 53 Commonwealth countries. However, there are currently few mechanisms in place to:

- Coordinate existing *e-health* initiatives across the Commonwealth;
- Foster alignment between Commonwealth *e-health* initiatives and *e-health* initiatives supported by other international bodies or countries;
- Coordinate *e-health* policy at both a regional and global level;
- Facilitate communication on *e-health* at the regional and global level;
- Build on best practices in *e-health* used successfully in one country and extend them to other countries;

- Coordinate the private sector to realise efficiencies of scale and help to ensure sustainability;
- Build on existing initiatives and infrastructure;
- Develop regional access to required testing and diagnostic tools.

1.4 Commonwealth countries by category

7. There is a significant link between economic development and healthcare and the practicality of country wide *e-health* programmes varies by size of country. For purposes of generally sub-dividing countries into categories we have used the World Bank list of economies as per July 2007 when it was last published and added a size related grouping called “Small and Island states”.

8. The 4 categories used are:

- High income economies
- Upper middle and lower middle income economies
- Lower income economies
- Small and Island states

In this report the World Bank categories of upper middle income and lower middle income are combined into middle income.

1.5 A summary of major healthcare challenges facing Commonwealth countries

9. Healthcare faces a series of very difficult issues in all of the Commonwealth countries during the coming years which political leaders, opinion influencers, healthcare providers and populations will have little choice other than to address. The issues are many they vary by country and some of the more important include:

- In the **high income economies** the problem of how best to care for an ageing population increasingly affected by the diseases consequent on affluence, probably represents the biggest challenge. Some aspects of the care of older people will have to be moved from the hospital to the community but this is no easy task and good information communication through *e-health* is one of the pre-requisites to making this change. The result, if well managed, could be both improved care and reduced use of resources.
- In the **middle income economies** healthcare demand and costs are increasing rapidly and it is vital that the results of the thinking on the changes that *e-health* will make in communication and training is put in place before huge investments are made in infrastructure. Such an investment could become redundant far sooner than was expected when the project started if the effect of *e-health* on infrastructure needs is not properly considered in the planning phase. The hospital/community care mix in the future is a critical factor in the decision making process. *e-health* will influence those decisions.

- In the **low income economies** life expectancy is about 60 per cent of that in the developed countries and the gap is growing. The challenge in those countries is the basic provision of healthcare and health information, and tackling major diseases such as HIV/AIDS, TB and Malaria. Affordable communications to support both healthcare delivery and health education are major areas where *e-health* can help.
- **Small and Island States** share the problems of the World Bank economic category within which they fit but on a smaller scale. Development of an optimal mix between on the one hand centralised hospital type healthcare provision, with when required links to sources of scarce expertise (which may only be available outside the country) and on the other dispersed community and primary care services is critical. How *e-health* is planned and used can profoundly affect healthcare investment decisions in the smaller economies. In relative terms the impact of getting these sort of decisions wrong can be larger than in the bigger countries.

1.6 E-Health issues for Commonwealth countries by category

10. The table below summarises significant *e-health* related issues for Commonwealth countries by category. Each is discussed in more detail later in this report. The table is intended to give a sense of direction only; it is not the result of detailed research.

Commonwealth countries by economic category	Significant Issues			
	Fiscal	Legal	Infrastructure	Ethical
High Income	<ul style="list-style-type: none"> • Optimal Funding and delivery model for <i>e-health</i> Programmes. • Ineffective incentives and /or reimbursement mechanisms. • Perceived lack of value. 	<ul style="list-style-type: none"> • Intra-national organisational constraints 	<ul style="list-style-type: none"> • Poor sustainability of existing <i>e-health</i> solutions. • Enterprise wide applications needed. 	<ul style="list-style-type: none"> • Information governance and patient confidentiality. • Patient safety.
Middle income	<ul style="list-style-type: none"> • Stable funding to support the programmes and infrastructure. • Optimal 	<ul style="list-style-type: none"> • Intra-national organisational constraints. 	<ul style="list-style-type: none"> • Inter-operability. • Poor sustainability of existing <i>e-health</i> solutions. • Enterprise wide applications and clinical support. 	<ul style="list-style-type: none"> • Access to services and equity.

Commonwealth countries by economic category	Significant Issues			
	Fiscal	Legal	Infrastructure	Ethical
	Funding and delivery model for <i>e-health</i> Programmes. <ul style="list-style-type: none"> • Different health delivery systems may have different <i>e-health</i> drivers. 			
Lower income	<ul style="list-style-type: none"> • Optimal Funding and delivery model for <i>e-health</i> Programmes. • Different health delivery systems may have different <i>e-health</i> drivers. 	<ul style="list-style-type: none"> • An enabling legislative framework is needed. • Intra-national organisational constraints. 	<ul style="list-style-type: none"> • Technical and commercial infrastructure. • Poor sustainability of existing <i>e-health</i> solutions. • Enterprise wide applications and clinical support • Human resource and commercial infrastructure. 	<ul style="list-style-type: none"> • Access to services and equity.
Small and Island states	<ul style="list-style-type: none"> • Stable funding to support the programmes and infrastructure. • Different health delivery systems may have different <i>e-health</i> drivers. 	<ul style="list-style-type: none"> • An enabling legislative framework is needed. • Intra-national organisational constraints. 	<ul style="list-style-type: none"> • Poor sustainability of existing <i>e-health</i> solutions. • Enterprise wide applications and clinical support. 	<ul style="list-style-type: none"> • Access to services and equity.

Sections 2 to 6 set out the key *e-health* issues by topic and section 7 summarises them by country category.

The issues where cohesive Commonwealth action has the greatest potential are:

- | | |
|----------------|--|
| Legal | <ul style="list-style-type: none">• Enabling legislation that will facilitate <i>e-health</i>• Overcoming intra-organisational constraints• Product and service liability concerns |
| Infrastructure | <ul style="list-style-type: none">• Technical and communications infrastructure• Insistence on inter-operability• Human resource and commercial infrastructure |
| Ethical | <ul style="list-style-type: none">• Information governance and patient confidentiality issues as they relate to sharing records• Patient safety |
| Other | <ul style="list-style-type: none">• Evaluation and assessment criteria/common measures & indicators |

Commonwealth action should be a mix of:

- Advocacy to increase the adoption of *e-health* programs within Commonwealth countries;
- Fostering the exchange of knowledge of *e-health* (critical success factors, examples of successes and of failures) between Commonwealth countries
- Brokering/leveraging relationships to mobilise resources for *e-health* across the Commonwealth.

1.7 The potential role of COMSEC

11. It was recommended to ComSec (1) that it should avoid at all costs directly or inadvertently usurping the role of national governments. Ownership of *e-health* programs by the national governments is key. Key elements of the ComSec role could however include:

- Advocacy to increase the adoption of *e-health* programs within Commonwealth countries;
- Fostering the exchange of knowledge of *e-health* (critical success factors, examples of successes and of failures) between Commonwealth countries
- Brokering/leveraging relationships to mobilise resources for *e-health* across the Commonwealth.
- Providing skilled and experienced resources to help *e-health* projects get started.

2 THE COMMONWEALTH COUNTRIES

12. As explained in section 1.4, this report sets out HealthSystems view of the current *e-health* situation and the priority applications and *e-health* concerns by country category. Inevitably there are certain areas of uncertainty and overlap – Small and Island states covering all the income levels for example – it serves to identify principal differences in so far as *e-health* is concerned.

13. In general terms the position by category of Commonwealth country is summarised in the table below:

Economic category	Current <i>e-health</i> situation	Priority applications and <i>e-health</i> concerns
High income	Clinical and managerial applications in place <i>E-health</i> infrastructure in development or maturing	Applications to support emerging health priorities (long term conditions, ageing) Inter-operability across existing <i>e-health</i> services
Middle income	Initial investments but little <i>e-health</i> infrastructure Some clinical and EHR applications in major hospitals Some administrative applications in place	Is there a possibility of leap-frogging the developed countries approach to: <ul style="list-style-type: none"> • <i>E-Health</i> infrastructure • Clinical applications – a model to spread across all institutions • Applications required as part of response to emerging health priorities
Low income	Some vertical applications often aid/grant funded to support targeted health programmes Basic finance and admin. applications in some countries	How sustainable are existing <i>e-health</i> services? Public health initiatives Administrative (supplies) and financial, especially to support existing or further inward aid initiatives
Small and Island states	Dependent on economic development status	Access to and models for collaboration for delivery of external expertise from beyond the state Public health initiatives Otherwise dependent on economic development status – see above

3 FISCAL ISSUES

14. Fiscal issues are important in both senses of the dictionary definition of the word 'fiscal':

- a. 'of or relating to government revenue, especially taxes'
- b. 'of or relating to financial matters'

15. HealthSystems believe that there are four principal fiscal issues that, to a greater or lesser extent, affect and influence all Commonwealth countries. These are:

- (i) Stable funding to support the *e-health* programmes and infrastructure
- (ii) Establish optimal (best value) funding and delivery models for *e-health* programmes.
- (iii) Establish effective incentives and/or investment reimbursement mechanisms
- (iv) Recognition that different health delivery systems may have different *e-health* drivers.

Each of these fiscal issues is discussed below with comments as to its significance by the four country categories.

3.1 Stable funding to support the programmes and infrastructure

3.1.1 Appraisal

16. 'The old perspective was of *e-health* being 'just another expense' in a healthcare budget line for which there was not enough funding. The new vision should instead recognise *e-health* as part of "how to do" healthcare in the 21st Century and as a tool for 'increased productivity and quality of care' (5). However, it can take 4-5 years to realise benefits (or a positive return on investment) from significant *e-health* investments. Installation of the required infrastructure for *e-health* may not of itself deliver major benefits; it is however a pre-requisite for successful delivery of the *e-health* programmes which do deliver benefits.

17. The adoption and uptake of *e-health* initiatives is a key challenge:

- Continued political support on what can be a 'bumpy ride' is critical
- Lengthy budgetary cycles can act as a brake on implementation
- The adoption cycle in many countries is slow, with the biggest resisters often being the Health care professionals involved in the delivery of services.
- Many *e-health* initiatives are deployed without appropriate underlying technology and human resource capacity.
- Initiatives may fail to deliver the promised benefits not because of the programs themselves but because the environment is unable to support them

18. Funding models need to be informed by achievable and specified returns on investment, and clearly related to national health priorities. A balance must be struck

between capital or grant funding and an informed and realistic view of how revenue will fund ongoing *e-health* service delivery.

19. Often costs will be incurred by different organisations than those which reap the benefits. (see also section 4, legal)

3.1.2 Implication

20. Trust and proven successes have to be established before the general public will adopt new technologies related to health, and hence speedier ROI's become possible.

Realistic plans for return on investment are essential

3.1.3 Significance

21. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	Low – this is generally understood
• Middle income	High – realistic planning is essential
• Low income	Medium – this issue may be a primary concern to funding organisations (aid bodies)
• Small and Island states	High – realistic planning is essential

3.2 Establish the optimal (best and due) funding and delivery model for *e-health* programmes

3.2.1 Appraisal

22. A realistic and appropriate funding model needs to inform the approach to *e-health* service delivery. In developed countries, it is generally accepted (within EU for instance) that up to 5 per cent of all health investment should be devoted to *e-health* infrastructure/ services (4); most developed countries are currently closer to 2 per cent at the moment (5).

23. Possible delivery models span public private partnerships, grant/capital funding to existing organisations, in house control of core *e-health* levers, and/or outsourcing of services to private sector where public sector provision is unlikely to hit critical mass and/or be cost effective.

3.2.2 Implication

24. Success in achieving targeted returns on *e-health* investment and benefits is directly related to choices made about preferred and existing funding and delivery models

3.2.3 Significance

25. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	High – all Commonwealth countries in this category have major ongoing programmes where this issue is central to success
• Middle income	High – needs to be factored into plans for new <i>e-health</i> programmes
• Low income	High – sustainability of <i>e-health</i> services has proved to be a major problem
• Small and Island states	Medium – choice of delivery models in particular may be limited in practice

3.3 Establish effective incentive investment and/or reimbursement mechanisms and measure value

3.3.1 Appraisal

Reimbursement and Incentives: current systems and processes may exclude or not adequately reward clinical professionals in particular for *e-health* related tasks.

Value: End users, providers, citizens/patients may not feel that *e-health* services or investments represent good value against other potential uses for health investments.

26. The organisation making the investment, a hospital for example, may not receive the resulting benefits if they occur in primary or community care.

3.3.2 Implication

27. *E-Health* enabled transformation can seriously affect the status of health professionals and their perceived responsibilities. They as well as other participants who may not receive direct financial benefits may require convincing, and (financial) encouragement that *e-health* services will be to their benefit and will enable them to maintain and improve the quality of the care they can provide.

3.3.3 Significance

28. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	High: End-user uptake of <i>e-health</i> services and how to facilitate this is a major

Country category	Significance
	concern
<ul style="list-style-type: none"> Middle income 	Medium : More concerned with business case for initial <i>e-health</i> set up
<ul style="list-style-type: none"> Low income 	Medium: <i>E-Health</i> may be perceived to be impractical or low priority in the light of competing priorities or perceived difficulty of roll-out
<ul style="list-style-type: none"> Small and Island states 	Medium: <i>E-Health</i> may be perceived to be impractical or low priority in the light of competing priorities or perceived difficulty of roll-out

3.4 Different health delivery systems may have different *e-health* drivers

3.4.1 Appraisal

29. Across and within Commonwealth countries, a range of health service delivery and financing models exist each with a range of associated inhibitors and incentives.

Statutory Social Insurance schemes

Inhibitors:

- Admission to clinical data, who is allowed to view and use it?
- Financing (cost and benefit accrue to different groups in health care)
- Control over IT investments / healthcare delivery
- ICT not relevant to insurers

Incentives:

- Early access to drug use data
- Optimisation of statistics
- Clearer definition of benefits
- Billing and payments made faster and cheaper

Private Health insurance

Inhibitors:

- Long and unclear return of investments / healthcare delivery
- ICT not relevant to insurers

Incentives:

- Clear definition of benefits
- Billing and payments made faster and cheaper
- Speedier more accurate feed-back of results
- Cost and benefit calculations relatively straightforward

Direct out of pocket payments by citizens/patients

Inhibitors:

- Citizens' desire for anonymity/non-traceability

- Citizen groups that don't trust ICT

Incentives:

- Services delivered faster
- Payments made faster

National Health Service models

Inhibitors:

- Admission to clinical, who is allowed to view and use it?
- The NHS entity investing in *e-health* may not make any benefit itself but rather help other NHS entities
- Lack of clinical involvement in *e-health* investment decisions

Incentives:

- The overall potential benefit to healthcare delivery
- Services delivered faster
- Clinical errors, drug delivery for example, reduced

3.4.2 Implication

30. State Health provided systems may often be slower *e-health* adopters. More powerful business cases and the existence of fewer inhibitors may exist elsewhere.

3.4.3 Significance

31. The significance of this issue by country category is set out in the table below:

Country category	Significance
<ul style="list-style-type: none"> • High income 	Low – typically the early adopter phase is over
<ul style="list-style-type: none"> • Middle income 	High – private sector <i>e-health</i> adoption may be quicker than state sector and require regulation to flourish
<ul style="list-style-type: none"> • Low income 	High – private sector <i>e-health</i> adoption may be quicker than state sector and require regulation to flourish
<ul style="list-style-type: none"> • Small and Island states 	High – private sector <i>e-health</i> adoption may be quicker than state sector and require regulation to flourish

4 LEGAL ISSUES

32. Most *e-health* professionals identify three important legal issues. How these are treated can significantly enhance or inhibit the progress of *e-health*. The legal issues are:

- (i) An enabling legislative framework
- (ii) Constraints caused by split responsibilities within a country
- (iii) Product and service liability

4.1 An enabling legislative framework is needed

4.1.1 Appraisal

33. New legislation or changes to existing legislation (international agreements, national laws, regulations and administrative provisions) may be required in a number of areas including:

- enabling legislation for access to *e-health* services in general,
- payment mechanisms for *e-health* services
- specific legislation enabling e-prescription, e-referrals, e-booking, telemedicine,
- accreditation and professional qualifications of *e-health* providers,
- personal data protection
- regulations to allow sharing of clinical data between public sector organisations
- international agreements to permit *e-health* services which cross borders
- liability legislation (4)

Within EU (5), lack of legal certainty is considered a pre-requisite for businesses to invest in innovation and for buyers and users to take up new services. Further it is considered that public authorities have a 'clear responsibility in providing such certainty'

4.1.2 Implication

34. If an enabling legislative framework is not in place, health end-users cannot be expected to deliver 'risky' or possibly even illegal services. Benefits promised by *e-health* can also suffer delay or not be achieved.

4.1.3 Significance

35. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	Low – basic enabling legislative framework is in place in most countries
• Middle income	Medium – enabling legislative framework not in place in some countries
• Low income	High –enabling legislative framework not in place in many countries
• Small and Island states	High –enabling legislative framework not in place in some countries and/or between countries

4.2 Organisational constraints

4.2.1 Appraisal

36. There may be a need to address organisational constraints within a country where different ministries control different elements necessary to the success of a national *e-health* program. (The responsibility for health, financing, and ICT infrastructure often reside in three different ministries). Also within healthcare different entities have different budgets, whether public or private, but deal with the same patients. *E-Health* will often cross these organisational boundaries.

4.2.2 Implication

37. New governance structures may need to be developed to ensure *e-health* roll-out is not delayed.

4.2.3 Significance

38. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	Low – these will often have been overcome during development of national <i>e-health</i> programmes
• Middle income	High – may impede <i>e-health</i> business case

Country category	Significance
	development or implementations
<ul style="list-style-type: none"> • Low income 	High – may impede <i>e-health</i> business case development or implementations
<ul style="list-style-type: none"> • Small and Island states 	High – may impede <i>e-health</i> business case development or implementations

4.3 Product and Service Liability issues are of concern

4.3.1 Appraisal

39. Concerns or lack of clarity may exist about how *e-health* solutions could change the liability of health delivery organisations towards patients or third parties in relation to protection of information and with regard to the liability for contracted *e-health* suppliers.

40. Liability legislation (contractual and non-contractual obligations) may be required in relation to cross border access to healthcare in the context of free movement of persons and services.

4.3.2 Implication

There is a clear need for education and sharing of best practice approaches.

4.3.3 Significance

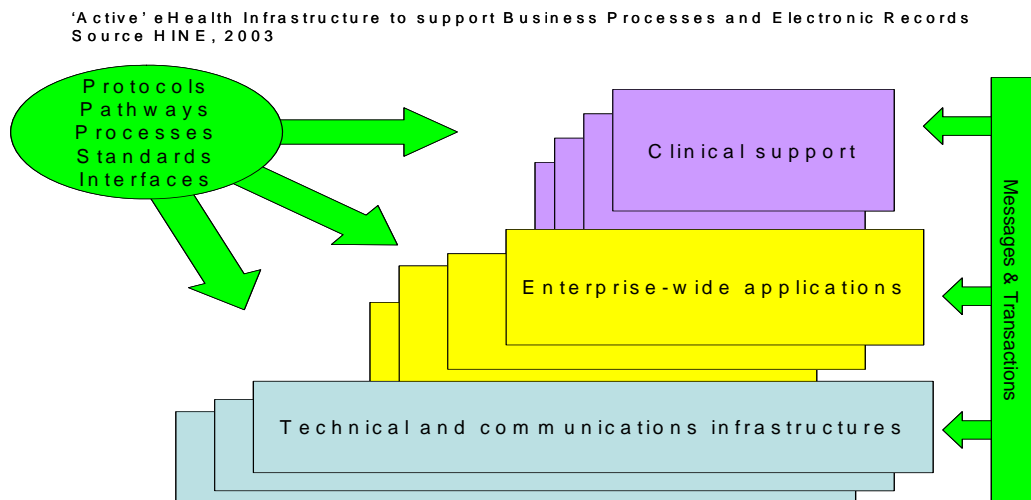
41. The significance of this issue by country category is set out in the table below:

Country category	Significance
<ul style="list-style-type: none"> • High income 	Low – probably not a major constraint
<ul style="list-style-type: none"> • Middle income 	Medium – may be cited as a reason for not moving ahead quicker
<ul style="list-style-type: none"> • Low income 	Low – probably not the most important inhibitor
<ul style="list-style-type: none"> • Small and Island states 	Medium – may be cited as a reason for not moving ahead quicker

5 INFRASTRUCTURE ISSUES

What infrastructure is required?

A conceptual diagram of the main *e-health* infrastructure components is shown below, and a discussion of the issues relating to these component parts follows:



5.1 Technical and Communications infrastructure

5.1.1 Appraisal

42. A poor infrastructure is considered to be a significant barrier to rapid and broad based deployment of *e-health* solutions in many developing countries. This may be due to the lack of affordability and/or availability of secure or appropriate broad band networks, or key elements of IT infrastructure.

43. At the same time, there are many beneficial *e-health* projects that can be undertaken with lower bandwidth technologies – mobile or satellite and if finance is not the major constraint, with higher bandwidth satellite. By way of example, 30 Red Cross volunteers in Ghana were able to conduct 2,400 health surveys in a three-day period thanks to personal digital assistants. With pen and paper, they would have only been able to complete 200 surveys in that time.

5.1.2 Implication

44. The lack of highly developed connectivity programs should not be a barrier to undertaking an *e-health* program.

5.1.3 Significance

45. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	Low – suitable infrastructure is generally available and widely used for <i>e-health</i> services
• Middle income	Medium - suitable infrastructure may exist, but is not widely used for <i>e-health</i> services
• Low income	High – may present as a major barrier
• Small and Island states	Medium - suitable infrastructure may exist, but is not widely used for <i>e-health</i> services

5.2 Inter-operability

5.2.1 Appraisal

46. The lack of interoperability of healthcare information is a huge issue throughout the world. An enormous amount of money has been and is being spent trying to resolve it. Progress is being made but the full solution will take many years. Why?

- (i) It has always been difficult to describe clinical procedures in a consistent manner even when they are **exactly** the same. The SNOMED programme adopted among others by USA and UK sets out to address this but its full implementation will take years. It involves ALL doctors describing ALL their clinical procedures with sufficient consistency to allow them to be coded and classified.
- (ii) In most countries most clinical records are still paper based and, by definition, not interoperable. A recent study in London's acute care hospitals concluded that about 60 per cent of all new clinical records were still paper based in 2007.
- (iii) By WHO agreement medical records are held for 7 years (more in certain circumstances) so "back tracking" is an enormous task.
- (iv) Training, particularly of the clinical staff, is a huge issue.
- (v) The technical aspects of interoperability, once the data is in a usable form, are not that complex.

47. Interoperability is frequently assumed to be a technical issue. It is not. The fundamental issue is how medical episodes of care are recorded and the traditional free text nature of that recording.

48. Care must be taken to ensure that *e-health* makes interoperability better and not worse.

49. The lack of or partial adoption of protocols, standards, common interfaces on the one hand and standardised approaches to transferring messages on the other and within a common *e-health* architecture may limit the ability of installed *e-health* systems to work together effectively. In order to reap the benefits of *e-health* across all health services, it is necessary to develop and adopt common standards and approaches which allow health professionals and the systems they use to work together. This has for instance been identified as a key obstacle in the development of *e-health* as a ‘lead market’ in Europe (5). Recent US studies indicate that net savings of \$75 billion or c 5 per cent of US’s 2003 healthcare spend could be achieved by installing a fully standardised and inter-operable system between the 6 major types of entity in the US health sector (5).

50. *E-Health* architectures need to provide solutions to some critical underlying problems. For instance:

- more than 20 per cent of medical records – whether electronic or paper based – current are probably duplicates. This represents an actual and potential risk to patient safety, especially in the context of roll-out of clinical applications and e-prescribing, and points to a need for an effective approach to data cleansing and identity management.
- Architectures which involve centralised (national) storage of information are increasingly being challenged, due to perceived and actual risks of information loss or corruption, through a single point of failure. A better alternative may be to use decentralised storage within an inter-operable framework, and a degree of built in redundancy

5.2.2 Implication

51. An interoperable framework is required at national, regional and local levels to overcome piece-meal *e-health* implementations which are not capable of delivering system wide *e-health* benefits.

5.2.3 Significance

52. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	Medium – in general common <i>e-health</i> architectures have been developed, the challenge is implementation
• Middle income	High – partial or piecemeal <i>e-health</i> implementations may exist, which are not able to interwork effectively
• Low income	Low – national or regional level <i>e-health</i> deployments are rare
• Small and Island states	Medium – whilst internal <i>e-health</i>

Country category	Significance
	solutions may be inter-operable, challenges may exist with external inter-operability

5.3 Poor sustainability of existing *e-health* solutions: Enterprise Wide Applications and Clinical Support

5.3.1 Appraisal

53. The benefits arising from *e-health* Programmes typically accrue or are planned to occur as a result of the use by health professionals of Enterprise Wide Applications and Clinical Support services. Choosing which value added applications to prioritise can be tricky. Too strong a focus on financial or management applications, whilst perhaps attractive from a return on investment perspective can lead to suspicion or even non co-operation from health professionals. Conversely focus on purely clinical applications may not be considered capable of delivering system wide benefit.

54. There is also the related problem of *e-health* services which have been set up for one purpose, but are not adaptable or capable of supporting other business needs. Thus an aid funded programme in a developing country with an *e-health* component to support information gathering about one clinical condition, may fall into disuse when the external programme funding comes to an end. There may also be a related problems with the human resource infrastructure required to sustain *e-health* service delivery – see 5.4 below.

5.3.2 Implication

55. *E-Health* solutions and their underpinning infrastructures have a better chance of being sustainable if they are capable of adapting to support a broad range of the managerial and clinical priorities in the country. They also need to be developed in the context of an achievable and planned approach to benefit realisation. For low countries particularly this may entail considering how externally funded *e-health* programmes can support the broader *e-health* strategy within a country and implementing plans to achieve this.

5.3.3 Significance

56. The significance of this issue by country category is set out in the table below:

Country category	Significance
<ul style="list-style-type: none"> High income 	High – clinical support and the relevance and usefulness of <i>e-health</i> services for this, remains a hot topic and is key to the realisation of target benefits
<ul style="list-style-type: none"> Middle income 	High – selection of achievable priority applications is crucial to successful <i>e-health</i> programme development and implementation

Country category	Significance
<ul style="list-style-type: none"> • Low income 	High – planning for re-use of <i>e-health</i> components as the basis for a national <i>e-health</i> infrastructure may provide a good way forward
<ul style="list-style-type: none"> • Small and Island states 	High – selection of achievable priority applications is crucial to successful <i>e-health</i> programme development and implementation

5.4 Human Resource and Commercial Infrastructure

5.4.1 Appraisal

57. Trained personnel capable of creating and sustaining *e-health* services are pre-conditions for success. In some countries patients and health care professionals able to understand and/or utilise ICT are needed and may be lacking. This can also be exacerbated by the shortage of health professionals themselves in many countries.

58. This issue whilst crucial to health service delivery organisations applies equally to commercial organisations delivering *e-health* services. An eco-system of competent suppliers is essential comprising prime contractors/systems integrators, system/application suppliers, suppliers of components or underlying communications and IT infrastructure. Should these not be present in the country implementing an *e-health* programme the cost and sustainability of *e-health* could be adversely affected. Related to this, the importance of effective (public) procurement, capable of overcoming fragmentation of demand is another important consideration(5).

59. While *e-health* may hold the ultimate promise of allowing scarce human resources to become more efficient and make best use of their skills and knowledge, in the short term it represents a transformational change and may temporarily reduce efficiency until business processes are modified to exploit the new *e-health* capabilities. What is worse, the issue goes beyond training; some countries may experience an *e-health* 'brain drain' as migration of informatics professionals to rich, Western urban centres threatens *e-health* progress in other nations.

5.4.2 Implication

60. The training and development of human resources, capable of sustaining *e-health* services needs to be taken into account prior to and as part of initial investment appraisal.

61. Attention is drawn to the importance of organising effective *e-health* procurements.

5.4.3 Significance

62. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	Low
• Middle income	Medium – may present as a constraint in some countries
• Low income	High – a major constraint on effective <i>e-health</i> programmes
• Small and Island states	Medium – may present as a major constraint in some countries

6. ETHICAL ISSUES

63. This paper discusses access to services and equity **only** as they apply to the potential use of *e-health*. Equity of access to healthcare services is a big issue and varies widely by country. For example in the UK “care is free at the point of delivery” but achieving equity is still a major issue (postcode lottery). In the USA equity can be thought of as the ability to pay. It is important to ensure that *e-health* does not introduce new equity issues but is unlikely to solve those access and equity issues that already exist.

64. By far the most important ethical issues that affect *e-health* are access to service (equity), information governance/patient confidentiality and patient safety. Each is discussed below:

6.1 Access to services and Equity

6.1.1 Appraisal

65. This issue is linked to the availability and extent of use of ICT for access to services within the general population and by health service personnel (especially in remote locations). When language or cultural diversity exists within a country, problems can occur if services are designed around one or a limited number of languages or ethnic groups. Access to *e-health* services by people with physical or psychological problems is another related consideration.

66. Where there are low levels of ICT literacy amongst the population or health service professionals and/or limited access to equipment, it can be argued that introduction of *e-health* services may limit in fact access to services (especially if they substitute for existing services), and that this adversely affects people/staff without the means to acquire the necessary equipment or without the requisite training.

67. Conversely where a high level of ICT usage exists in the general population, failure to provide *e-health* services for access or use by patients or health professionals may be considered a problem.

6.1.2 Implication

68. The impact of *e-health* services on access to services and equity in provision needs to be considered when developing *e-health* plans and addressed when problems occur. E-Health service design and architectures need to ensure that all people/citizens using the services will have adequate access to them.

6.1.3 Significance

69. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	Low – due to high levels of use of ICT services, but some residual problems / concerns
• Middle income	High – problems may arise for remote, deprived or excluded groups within the population, workforce or delivery organisations
• Low income	High – problems may arise for remote, deprived or excluded groups within the population, workforce or delivery organisations
• Small and Island states	Medium - problems may arise for remote, deprived or excluded groups within the population, workforce or delivery organisations

6.2 Information governance and Patient confidentiality

6.2.1 Appraisal

70. Doctors have a legal and ethical duty of confidentiality for all identifiable health information seen in a professional capacity.

but

Patients expect doctors to share relevant information appropriately, making it promptly accessible when necessary for their care. Patients generally have a right to expect that his or her privacy is respected and protected (by the health professional or health organisation) and that their electronic health record is handled with due regard to professional duties of confidentiality

and

If the expectation of appropriate sharing is not met patients will withhold information to the detriment of their own and other peoples' care.

In most settings, public authorities provide information governance systems to ensure that the above expectations and duties are met.

6.2.2 Implication

71. *E-Health* services need to provide information governance which may extend to cover:

- Ownership and Control of patient related information including accurate identification of named patients and healthcare professionals
- Access control and role dependent authorization, including the patient, plus audit trails of accesses
- Security and Authenticity which may include strong authentication techniques, electronic signatures, anonymisation, visible correction, single sign on etc
- Consent to record implicit consent, opt-outs for general information, opt-ins for sensitive information (visible), sealed envelopes, personalised privacy rules
- Exception handling for consent on patient vital interests or information required for care and treatment

72. *E-Health* systems should have an associated security policy that clearly describes how the confidentiality, integrity and availability of records will be preserved. This should be freely available for patients to access. Typically, system administrators should not have the right to access personal medical data.

6.2.3 Significance

73. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	High – public concern persists about the effectiveness of <i>e-health</i> information governance
• Middle income	Medium – needs to be factored into plans for <i>e-health</i> , costs and organisational issues involved may be a problem
• Low income	Low – not yet a major constraint on <i>e-health</i> adoption
• Small and Island states	Medium – needs to be factored into plans for <i>e-health</i> , costs and organisational issues involved may be a problem

6.3 Patient safety

6.3.1 Appraisal

74. Opponents of *e-health* may raise concerns about patient safety, describing the potentially negative impacts on patient safety of failures to satisfactorily address issues described elsewhere in this paper, especially in relation to lost or corrupted patient related information and/or failures to protect patient confidentiality.

75. In fact, existing paper-based processes will often have worse and usually un-quantified negative effects on patient safety. Just to pick one example, In 2003, the United States Agency for Healthcare Research and Quality found poor prescribing caused 777,000 injuries and deaths in one year (7). Properly implemented *e-health* solutions and especially clinical applications have major potential to improve patient safety, by reducing medical errors and speeding access to services. A recently published meta-analysis of 71 studies showed that 48 out of 71 (68 per cent) of decision support systems improved clinical practice (8).

6.3.2 Implication

76. The impact on patient safety of introducing *e-health* services needs to be evaluated and monitored. The beneficial effects of *e-health* systems on patient safety probably represent the most important single class of benefits.

6.3.3 6.3.3 Significance

77. The significance of this issue by country category is set out in the table below:

Country category	Significance
• High income	High – further work on quantifying impact and benefit would be helpful
• Middle income	Medium – clinical applications may not top priority
• Low income	Low – clinical applications will usually not be high priority
• Small and Island states	Medium – clinical applications may not top priority

7 SUMMARY OF ISSUES BY COUNTRY CATEGORY

78. In HealthSystems view the principal issues can be summarised as set out below.

7.1 High income countries

• Fiscal	Stable funding	A well understood issue
	Funding model	Very important
	Incentives	Very important
	<i>E-Health</i> fiscal drivers	Mostly already established
• Legal	Enabling legislation	Mostly in place
	Organisational constraints	Mostly overcome already
	Products and service liability	Not a major constraint to progress but may need to be addressed
• Infrastructure	Technical	Low, much is in place
	Interoperability	Medium, understood but hard to resolve
	Sustainability	High, very important
	Human Resource	Low, an ongoing problem but understood
• Ethical	ICT affecting access to services	Low, but some residual problems
	Information governance	High, significant concern exists
	Patient safety	High, more work needed

7.2 Middle income countries

• Fiscal	Stable funding	High, realistic planning is essential
	Funding model	High, needs to be factored into the planning
	Incentives	Medium, probably not a priority
	<i>E-Health</i> fiscal drivers	High, private sector may require fiscal regulation
• Legal	Enabling legislation	Medium, review as to whether or not it is adequate
	Organisational constraints	High, may impede progress
	Products and service	Medium, probably not a major

	liability	issue
• Infrastructure	Technical	High, avoid piecemeal building
	Interoperability	High, could make a “clean start”
	Sustainability	High, selectivity will be important
	Human Resource	Medium, normal issues
• Ethical	ICT affecting access to services	High, needs great care or could be divisive
	Information governance	Medium
	Patient safety	Medium

7.3 Low income countries

• Fiscal	Stable funding	Medium, will often be aid dependant
	Funding model	High, sustainability will be a challenge
	Incentives	Medium, other projects will compete
	<i>E-Health</i> fiscal drivers	High, private sector may require fiscal regulation
• Legal	Enabling legislation	High, often this is not in place
	Organisational constraints	High, may impede business case development
	Products and service liability	Low, probably not an inhibiting factor
• Infrastructure	Technical	High, may be a major barrier
	Interoperability	Low, not a priority yet
	Sustainability	High, keep what works working well
	Human Resource	High, may be a major constraint
• Ethical	ICT affecting access to services	High, lack of access could be a problem
	Information governance	Low, not a priority
	Patient safety	Low, ICT aspects not a major issue at this time

7.4 Small and Island states

• Fiscal	Stable funding	High, realistic planning essential
	Funding model	Medium, will vary widely by country
	Incentives	Medium, <i>e-health</i> will face competing priorities
	<i>E-Health</i> fiscal drivers	High, private v public may become an issue
• Legal	Enabling legislation	High, may need multi-state legislation in certain cases
	Organisational constraints	High, may impede progress if not resolved
	Products and service liability	Medium, but may be used as a reason for no progress
• Infrastructure	Technical	Medium, can sometimes be resolved economically.
	Interoperability	Medium to high
	Sustainability	High, important to select practical programme
	Human Resource	Medium, possibly high
• Ethical	ICT affecting access to services	Medium, particularly in remote areas
	Information governance	Medium, needs to be factored into plans
	Patient safety	Medium, clinical ICT possibly not a priority

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