Recommendations from Industry on Key Requirements for Building Scalable Managed Services involving Telehealth, Telecare & Telecoaching

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1. Introduction

Health and Social Care organisations considering commissioning a Telehealth, Telecare or Telecoaching service at scale will need to ensure the elements of service, technology, quality and commercial processes integrate to provide a safe, cost effective, and patient centric offering. This paper details the basic requirements of such a service, all of which must be included in any scalable and sustainable mainstream Telehealth service.

Although these requirements do not detail which specific technologies might be deployed, we describe the service options that might be needed to assist in a successful deployment. The actual services deployed will vary according to local requirements, affordability, clinical engagement, patient requirements and available technology. In addition, the basic elements do not stipulate the type of organisations with which to contract. There could be many different forms of contracting for Telehealth services ranging from public to private (or public/private partnerships), single organisations to consortia. These requirements could be met by a single organisation or responsibilities spread among consortium members. The various commissioning bodies will have different needs for their local population and, as such, these details will be determined as a result of each commissioning body deciding the range of services required for its local health economy and the industry capability to deliver these services.

2. Service Components

It is essential that NHS and Social Care commissioners satisfy themselves that any organisation (public or private) responding to a tender are able to give a clear description of their strategy and method to manage mainstream delivery at scale.

With this in mind, a scale managed service delivery model will, as a minimum, provide the following service components:

- **Service User Selection** – a clearly defined methodology to support the identification of patients who would benefit from a Telehealth solution, utilising best in breed data analysis/risk stratification and interpretation
- **Service and Pathway Redesign** – provide consultative design function to tailor pathways of care to ensure Telehealth becomes a mainstream option for referring clinicians, which is tailored to suit the locality
- **Referral Process** – design and delivery of a pathway for the referral of service users to the service and definition of their care plan by means of integration with electronic patient record systems, GP surgery systems and social care case management systems
- **Needs Based Assessment** - matching of individual care and support needs to appropriate technology supported services including the setting of parameters and alert thresholds
- **Monitoring of Patients for Step Up/Down** – managing patients to ensure that the level of care is appropriate to the changing needs of the patient
- **Logistics Management** – technology supply and tracking and installation
- **Training** - scalable training for patients and health and social care professionals
- **Monitoring & Triage** – receipt and management of Telecare alerts, biometric data, health alerts and verification responding within times ranging from normal working hours to 24/7 by an accredited response centre
- **Maintenance** – timely and regular remote/onsite testing and maintenance of equipment, to enable the service to be delivered in a secure manner
- **Response** – support and assistance protocols to determine the appropriate response to patients' needs, are in place with integration across the existing health and social care landscape
- **Review Process** – service user's needs regularly reviewed, outcomes assessed and reporting on cost/benefits.
- **Integration** and feedback loops with systems of choice in both health and social care

3. Service Design Considerations

Commissioners will need to satisfy themselves that providers have designed the Telehealth, Telecare and Telecoaching architecture to deliver robust, scalable services in compliance with NHS best practice and standards. The following items must be considered for initial deployment and with regard to the development of the service over the medium term.

a. **Care Programmes Definition**: This process defines the set of care programmes and services that will be offered to patients which encompass the full managed service. It may include a customised blended mixture of any or all of, Telehealth, Telecare, Telecoaching, patient education, disease management and self-management programmes, but is not restricted to these services.

b. **Managed Service Design**. This involves architecting services and designing the service delivery processes. It involves defining the interaction points between the Telehealth service and the rest of the care delivery service, how various processes will be automated to deliver the end-to-end service, how reliability and availability will be achieved and how scalability will be designed in.

c. **Governance Structures**. In addition to the standards detailed in Section 4, a Clinical Forum should be established to agree the clinical governance model with the local health care service and to ensure the service delivers the required level of quality care. This may be done within existing structures but as a minimum, the use of this service must be a mandatory standing item. The Clinical Forum will create the clinical standards, ethics and quality assurance to be adopted by the service.

d. **Service Level Agreement Planning**. This involves establishing the key service metrics and a performance monitoring system to enforce them, along with accurate and timely reporting to the commissioning body.

e. **IT Infrastructure Design**. This is a combination of the hardware and software elements that are required to deliver the integrated managed service as well as the business continuity, security, recovery and resilience elements required to deliver a managed service healthcare IT network.

4. Quality and Accreditation

Commissioners should ensure contracting parties, whether public or private, conform to basic standards. This will ensure that:

- commissioners are able to manage the risk of contracting with industry for Telehealth, Telecare and Telecoaching services in the community;
- clinicians can manage the clinical risk of patients being remotely monitored; and
- patients receive the best possible care.

These standards can be split into the following areas:

a. **Managed Service** – Prime contracting parties will offer a managed service that is compatible with or compliant to ISO/IEC 20000 – the international IT service management standard.

b. **Performance Monitoring** – Services, systems and software will be able to:

  - Monitor performance and outcomes.
  - Use available data for performance review and improvement of patient care, utilising emerging evidence from the WSD clinical study, evidence of clinical effectiveness, NICE Guidelines and other models of good practice.
  - Facilitate the efficient delivery of performance reports as required by the performance management team.
  - Collect, assess and provide data to demonstrate the economic effectiveness of the service.
  - Record patient advice in case of serious incidents or complaints.
  - Where clinical advice is provided as part of the service, providers will be registered with the CQC and commit to CQC standards of quality and safety including the use of the CQC Provider Compliance Assessment Tool.

- Monitoring systems that are required to be CE certified in compliance with the European Medical Devices Directive 93/42/EEC shall be compliant
- Services, and systems will be developed, deployed and maintained under the appropriate ISO and national certifications and directives:
  - ISO 13485: – *Quality management system for developing and testing software and medical hardware.*
  - ISO 9001: – *Quality management systems for ensuring high quality customer delivery processes.*
  - Telecare Services Association: *Services will be compliant with, or compatible to, the TSA Integrated Telecare and Telehealth Code of Practice.*

c. **Information Standards** – The following standards will apply:

- Health data will be managed in adherence with NHS recommendations and specifically Records Management and the NHS Code of Practice. This will include compliance with the current Information Governance policies and guidance.
- To achieve end-to-end interoperability, Personal Health Device providers must meet the specifications under CEN ISO/IEEE 11073 Health Informatics for medical / health device communication standards.
- Contracting parties will conform to the National Agenda for Integrated Health Records including, where practical, with the requirements for the National Programme for IT (Connecting for Health).
- Contracting parties will register as a Data Controller under the Data Protection Act 1998 and will take all reasonable measures to avoid any and all data loss and data corruption and to comply with Principle Seven (7) of the Act.
- Where appropriate contracting parties will be able to demonstrate conformity with ISO/IEC 27001:2005 – identification and mitigation of risks to protection of patient identifiable data and software used in support of clinical operations. This will include restricting access to such data to authorised users including authentication and tracking of users.
- Patient referral will be made via NHS email or NHS fax, or an approved point to point secure system.
- Where appropriate the service will be able to integrate to the local GP primary care systems, such as EMIS, Vision, SystmOne; Out Of Hours systems such as Adastra and the 111 service.
- The service will also be able to integrate with social care case management systems following recognised data transfer protocols such as the GCSX network.
- Services will implement, current and future, applicable Interoperability Tool-Kit specifications, e.g. the Personal Health Monitoring Report based on Continua Health Record Network interface.
- The service supplier will demonstrate that any implemented ITK specifications have been certified by the ITK National Integration Centre and Assurance
- Providers should ensure all data storage is hosted within a resilient data centre operating to industry standard security, to ensure patient confidentiality and protection of personal health data as defined by NHS guidelines and best practice. Connectivity to national digital services will be controlled by assessment under the Information Governance Assurance framework

d. **Technical Standards**. Providers will comply with the following standards:

- All medical equipment, including software applications, are CE marked in accordance with the Medical Devices Directive (93/42/EEC). Telecare equipment whilst being CE marked to the relevant standards should in addition be compliant with EN 50134 series standards.
- All medical devices will be registered with the appropriate medical device authority, for example the Medicines and Health Regulatory Agency (MHRA).
- All providers of technology will warrant that its equipment will not cause any disruption to the public switched telecommunications network in compliance with R&TTE Directive 99/05/EEC.

e. **General Standards –** Normal standards required of suppliers to the NHS will apply. For example:

- Providers will comply with the Corporate Manslaughter and Corporate Homicide Act 2007.
- Providers will comply with the Local Authority Social Services and National Health Service Complaints Regulations 2009 including facilitating commissioners in the execution of their duties in this regard.
- Providers of clinical services, will comply with the Health and Social Care Act 2008 (Regulated Activities) Regulation and the Care Quality Commission (Registration) Regulations 2009.
- Providers will comply with the Computer Misuse Act 1990.
- Providers will comply with the Common Law Duty of Confidence.
- Providers will comply with ISO 14001 – Environmental Management System.
- Contractors will be required to support legitimate requests made to commissioning bodies under the Freedom of Information Act, Access to Health Records Act and Data Protection Act.
- All contracting parties will certify that any staff employed with access to patients, patient records or data will have been cleared for such access through a CRB check and be appropriately trained.
- All contracting parties will operate at all times in accordance with the Caldicott Principles concerning patient identifiable data.
- All providers must commit to accept an audit on their products and services and agree to publish the findings contained therein.

5. Financial Models

Commissioners will need to consider the commercial implications of the tendering process. For efficiency and speed, existing mechanisms should be used where practical. These include the use of the Buying Solutions framework, other named frameworks or change control/extensions to existing contracts. A viable financial model which aligns the interests of patients, commissioners and industry and could include the following elements:

- **Patient Volume Commitment** - This details the minimum number of patients to be brought into the service.
- **Long Term Contract** – Ideally this should be a six year contract although for efficiency the standard 3, plus 1, plus 1 could be used. Without this commitment industry cannot commit to the revenue model providing up front capital for equipment.
- **Standing Charge for Service Availability** – A base fee that covers the costs of building but not operating the service.
- **Variable Service Usage Charge** – An incremental fee that is proportional to the number of patients on the service.

A Telehealth, Telecare and Telecoaching managed service should include the following fee rated elements:

- **Per Patient Monitored Day**
- **Per Disease Condition and Technology Package**
- **Per Service Offering (for example, Telecoaching, Telehealth, Telecare, telemonitoring)**
- **Per Service granularity (daily, weekly or monthly monitoring)**

The financial model should also allow for specified direct labour charges to be reflected in addition to the subscription fee. These might include, but are not limited to, additional staff, patient and staff training days and equipment installation or removal.