Comments on critical success factors identified by Momentum

European Momentum for Mainstreaming Telemedicine Deployment in Daily Practice
Agenda

1. Alere Inc. - Company overview
2. Featured solutions
3. Success factors
Sophisticated diagnostics & health information Solutions

World’s leading provider of near-patient diagnostics that, when combined with our novel health information solutions, enable the effective management of several chronic conditions.

- 2012 Net Sales: $2.8 billion
- 2012 Adjusted EBITDA: $606 million
- Total Employees: 17,600
- Represented In: 100+ countries
- Business Units: 6
Strong presence in Europe with a diversified portfolio

Sales by Business Unit

- Toxicology 21%
- Infectious Diseases 22%
- Chronic Care 15%
- Acute Care 13%
- Health Management 16%
- Other 12%
- Connected Health 1%

Presence in Europe

- Direct commercial subsidiaries in 12 EU member states
- Global primary manufacturing facilities in Dundee/Scotland and Oslo/Norway; additional manufacturing facilities in Germany, Spain and the UK
- 3 out of 5 global primary research centers in Europe (Jena/Germany, Cambridge and Dundee/UK)
- USD 484 million revenues in Europe in 2012
Beyond Devices – why we’re different

We manage the process that leads to health behavior change.

Biometric Devices + Patient Health Status Data Exchange + Behavioral Change-Coaching & Connectivity = Ability to Improve Health Outcomes
Agenda

- Alere - Company overview
- Featured solutions
- Success factors
## Leading in near-patient diagnostics

### Acute illnesses

Devices in cardiology, endocrinology, nephrology, infectious diseases, toxicology and intensive care

For example:

**Alere I**: rapid nucleic acid amplification test; multiple test, including **Influenza**

### Chronic conditions

<table>
<thead>
<tr>
<th>Avoid diseases</th>
<th>Handle early stages</th>
<th>Reduce impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>For example: <strong>Alere Cholestech LDX</strong> complete lipid profile and glucose in 5 minutes using finger stick blood; <strong>CAD prevention</strong>.</td>
<td>For example: <strong>Alere Afinion</strong>: immediate HbA1C, ACR, CRP; improves time and patient management for <strong>diabetes</strong> and its complications.</td>
<td>For example: <strong>Alere Heart Check</strong>: BNP using finger stick blood; connectivity via GPRS and Bluetooth. Enables continuous treatment optimization in <strong>heart failure</strong> patients from home.</td>
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</tbody>
</table>

### Underlying principle

Point of care measurement  
Connect patient and provider  
Supported by analytics  
Linked to health management
Real-time CDS drives medical evidence into clinical care practice

Alere’s Clinical Decision Support system (smartPath, HL7 web service)

**Alere Analytics Knowledge Base**
Over 30,000 evidence based care rules
Distilled from over 300 medical journals, standard text books, guidelines by leading medical authorities

**Connectivity to multiple clinical host systems**
Clinical data at EMR technology vendor, physician practice, IPA, hospital system, payer
E.g. Alere Solution Platform, Allscripts, Vitera/Greenway, Aprima, Polaris, Iowa HIE

**Real-time, focused Outputs & messaging**
Quality Alerts & Reporting
Chronic Care Management
Point of Care Alerts
Screening Alerts
Patient Safety Surveillance
Patient Focused Alert and Guideline
Probabilistic Predictive Modeling (PPM)
Population Health Management and Clinical Dashboards
Evidence Based Order Sets
Public Health Reporting
Large-scale health management globally impacted thousands of lives

Example heart failure (other health programs include COPD, asthma, diabetes, CAD, pregnancy, smoking cessation, weight loss)

EU impact since 2006

> 26,000 patients
have been cared in Germany, currently we serve 3 large German health plans

46% deaths prevented
already in the first year of care

Up to 40% admissions
have been prevented per annum, 25% of total health care costs have been saved

France hosts the service
with 2 pilot projects since 2013

US expertise since 1999

> 290,000 patients
have been managed, 88 large and mid-sized health plans are currently contracted

> 171,000 admissions
have been avoided, > $261 million could be saved per annum on average

Commercially sustainable
No public funding
Risk-sharing agreements
CORDIVA reduces hospitalizations and health care costs in German program

**Program components and workflow**

Home remote monitoring + telephone support by nurses + data pattern analysis + rule based decision making.

Customizable guideline-based rules stratify patients prognostically and regarding psychosocial stressors in order to provide individually tailored care.

Nurses telephonically follow up so patients comply with their care plan and avoid higher acuity. Patient-specific alerts undergo rule based management.

**Integration in existing pathways**

The programs are part of standard health care processes in cooperation with in- and outpatient facilities, i.e. GPs and specialists.

Physicians will be alerted whenever an intervention above the nurse care level is required, thus alleviating their workload, but keeping them in the loop.

**Program impact on hospitalization**

Since our German program (CORDIVA) is a real life program rather than a clinical trial evaluation is performed by retrospective comparison with health plan control groups using.

![Graph showing comparison of annual all cause hospitalization rate in CORDIVA and control group](image)

<table>
<thead>
<tr>
<th>Year</th>
<th>CORDIVA</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>1.04</td>
<td>1.23</td>
</tr>
<tr>
<td>Year 2</td>
<td>0.81</td>
<td>1.38</td>
</tr>
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</table>
eHealth complexity: integration of health management, health information exchange and clinical decision support

Examples for connected health care

**Southern New Jersey**

Covered Population: 1.8 million

- Care Providing Organizations
  - 8 Hospitals and EDs
  - 200+ Ambulatory Practices
  - 800+ Providers
  - 6 Ambulatory Surgical Centers
- Trading Partners
  - 5 Imaging Centers
  - 5 Laboratories
  - SureScripts
- Hospital Information Systems
  - Cerner
  - Epic
  - McKesson
  - Siemens Soarian
- Electronic Health Records
  - Alere EHR
  - Allscripts
  - eClinicalWorks
  - GE
  - NextGen

**UK NHS & City of Leeds**

Covered Population: 2.8 million

- Care Providing Organizations
  - Leeds Teaching Hospitals NHS Trust – 7 NHS Hospitals and EDs
  - Leeds Clinical Commissioning Groups – North, South and East, West – 600+ GPs
- Social, Mental, and Community Care Organizations
  - Leeds City Council
  - Leeds Community Healthcare Trust
  - Leeds & York Partnership Trust
- Hospital Information Systems
  - iSoft
- Electronic Health Records
  - EMIS
  - TPP
Success factors proposed for discussion

The Critical Success factors Momentum has already identified are adequate, relevant and not excessive. I should like to congratulate on that. In order to strengthen the overall significance one might discuss the following additional factors:

- Clarity in specifying targeted (eligible) conditions
  Inclusion and exclusion parameter

- Clear definition of services that are being offered
  Services included, when and in which period of time, and not included

- Derived from these:
  Clear success (and failure) parameters, linked to eligibility
  Size of targeted population, linked to budgeting
  Screening and inclusion procedures, decisive for inclusion rate
  Intended patient flows, linked to inclusion process
  Exclusion procedures, follow-up offers
Success factors proposed for discussion

- Tailored care by repetitive assessment
  - Clinical stratification, enables risk based intervention
  - Psychosocial stratification, allows for feasibility estimation, focuses care process
  - Modularity, ensures personalized care, linked to budget

- Clear agreement about the non-linear and iterative nature of eHealth development and implementation processes
  - Clear definition of roles and responsibilities
  - Includes determination of timeline and milestones
  - Of upmost importance if the eHealth service will be linked to other services

- From the beginning, planning, preparation and conduct of evaluation of effectiveness
  - Based on previously agreed concrete parameters
  - Applies to short-term, mid-term, long-term and continuous follow-up assessment
  - Strictly necessary for operational improvement
  - Basis for performance related compensation
Success factors proposed for discussion

- Careful planning of direct operations
  Most complicated if human workforce is involved
  Also includes ICT maintenance and modification
  Most important if time sensitive services are provided
Success factors already identified – Organization and management

– Address the needs of the primary client(s)

Almost every stakeholder will have to get moving and change their previous mode of operation. But, why should they have to do so?

It is all the more important to develop a matrix of incentives to which every stakeholder can relate. Failing that, either endangers the project by interrupting the process chain or leads to the question of whether it is absolutely essential to involve a particular stakeholder or not.

– Involve health care professionals and decision-makers

Strict attention to their existing processes and working methods is important too, sometimes innovations must even be postponed.

For example, most outpatient facilities have neither the necessary resources nor the required experiences and capabilities to host eHealth services.

Not only their patients but also professionals theirselves are at advanced age. In Germany, the average age of GPs is 53 years. eHealth was not part of their training and they often lack personal experience with novel ICT.
Success factors already identified – Organization and management

– Prepare and implement a business plan

This is also true if the service is provided by ‘non-profit or a governmental organization’. Particularly significant are, in this regard, paying customer, revenue model, customer value proposition, existing solutions, competitive differentiation, hurdles to overcome, resources required.

– Prepare and implement a change management plan

The ‘seamless implementation into the existing workflow’ places exceptionally high demands on development and implementation. ‘Each additional mouse click is too much’, a different GUI, such as a web interface, is virtually excluded. Only necessary, actionable information should be delivered and additional details can be given at request.

– Put the patient at the centre of the service

Person-centred care is a highly promising approach to solve central eHealth problems, such as engagement of elderly and women. However, it is much more than ‘developing the service with the patients’ perspective in mind’. It changes the starting point for health care in general and application of person-centred care in eHealth is currently subject of intensive research.
Success factors already identified – Technique and infrastructure

– Ensure that the IT and eHealth infrastructures needed are in place

Without the exception of eHealth ecosystems, normally neither IT nor eHealth infrastructure are in place. Often PMR, EMR, HIS, LIS, HER or PHR are partially established, but interfacing (including HL7 and its different phenotypes) and/or normalization appear to be most complicated. Establishing connectivity is a notorious resource hog.

The smaller the intended eHealth programme is the greater is the resulting budget burden, for example in regionally or locally organized health care systems.

– Ensure that the technology is user-friendly

Beside handling of technology, appropriateness and economic viability are most important. I.e. integrate only technology, which directly intervene in favour of the success parameters and remove everything not needed, for example, sensors which are no sufficiently predictive to detect emerging deterioration of disease.
Success factors already identified – Technique and infrastructure

– Monitor the service

Operational monitoring is indeed crucial must go hand in hand with operational management and dedicated resources. Please recognize the non-linear and iterative nature of eHealth development and implementation processes.

An eHealth intervention is almost never entirely and finally developed and implemented since the underlying working conditions change constantly.

– Guarantee that the technology has the potential for scale-up (i.e., “think big”)

‘Consider that it may be important to grow and extend the telemedicine service to a larger scale […] The potential for scale-up can be achieved by using either standard technologies or technologies that are similar and yet are produced/offered by a range of suppliers […]’

The dimensions of scalability go far beyond technology. It is highly recommended to think of scalability right from the beginning, for both customer and companies involved, since eHealth have the capability to shape the ways health care is delivered entirely.
Success factors already identified – Strategy

- Check that there is cultural readiness towards telemedicine
- Ensure leadership through a champion
- Identify a compelling need
- Put together the resources needed for deployment and sustainability
Success factors already identified – Regulation and safety

- Establish that the service is legal
- Ask advice from legal, ethical, privacy and security experts
- Apply relevant legal and security guidelines
- Ensure that telemedicine doers and users have “privacy awareness”
eHealth complexity: various medical interventions with different scopes of application

<table>
<thead>
<tr>
<th>Patient self-management support</th>
<th>Patient behaviour change programme</th>
<th>Patient education</th>
<th>Information technology</th>
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<tr>
<td>Home care support</td>
<td>Internet support</td>
<td>Nurse-led support</td>
<td>Clinical engagement and coordination</td>
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<tr>
<td>Predictive modelling</td>
<td>Risk assessment and stratification</td>
<td>Clinical data aggregation and reporting</td>
<td>Remote patient monitoring</td>
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<tr>
<td>Pharmacy management</td>
<td>Health coaching</td>
<td>Wellness coaching</td>
<td>Secure data exchange</td>
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It is easy to get overwhelmed at the sheer number of possible interventions, which significantly complicates both implementation and evaluation. In this context, the identification of eligible pts is crucial, but related standards are still missing.

The decision as to whether or not comparability exists between different eHealth programmes has to be taken carefully.
eHealth complexity: individual health care context involving different stakeholders

A seamless integration of eHealth in existing care pathways is recommended, but these pathways are often highly fragmented or even absent.

Different regulations and practices led to the establishment of specific stakeholders, for example specialists employed exclusively in hospitals (SWEDEN) or physician emergency services after hours (UK).

Remote treatment is not basically permitted in different countries (GERMANY).
There are highly integrated health care and social security systems (UK) or almost disintegrated systems established (GERMANY)

Repetitive pts education and training is sometimes highly standardized and directly reimbursed (UK, FRANCE) or it depends on the continuing engagement of individual stakeholders only (GERMANY)

Highly variable pervasiveness and efficacy of pts self-help organizations and expert pts systems

Depending on the regulations local, regional or nation-wide implementation is require under local, regional or central administration
eHealth complexity: different pre-existing information and communication infrastructures

Highly fragmented (GERMANY) or uniform systems (CATALONIA) are already established

Data privacy and security requirements

Medical data exchanges standards, e.g. HL7 and IHE

Fixed or mobile ICT networks

Local PMR and EMR

HIS and LIS

Shared EHR and PHR

Lack of a common European standard

Highly different manifestation of a single standard aggravate implementation

Varying availability of ICT networks, sometimes only pragmatic solutions possible (eHealth via digital TV in SCOTLAND)

There are highly different stages of integration, only in exceptional cases an EHR is already established (CATALONIA, NORTHERN IRELAND)

PMR Practice management software
EMR Electronic medical record
HIS Hospital information system
LIS Laboratory information system
EHR Electronic health record
PHR Personal health record

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eHealth complexity: diverse business environments based on different reimbursement systems

- Paying customer
  - Revenue model
  - Customer value proposition
  - Existing solutions
  - Competetive differentiation
  - Resources required

In almost all European countries the way of reimbursement is not clarified.

For inexperienced customers, it is very difficult to define exactly, what is the expected effect or value of an eHealth solution (First choice in FRANCE acceptance, in GERMANY cost savings).

EU and national funding regarding practical implementation and procurement was initiated much too late.

Inter alia through excessive ‘pilotitis’ a clear understanding of existing solutions and their differentiation in missing.