DIABETES: Applying Evidence-Based Medicine in Telehealth

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• Overview of current status and need for Evidence Based Medicine in telehealth for Diabetes Mellitus (DM).

• RENEWING HEALTH selection of outcomes for the evaluation of large scale telehealth service development.

• UNITED4HEALTH: Transforming Renewing Health outcomes in everyday clinical practice of DM with telehealth.
• Chronic illnesses, such as asthma, COPD, diabetes, heart failure and hypertension represent a significant burden of disease.

• Telehealth has attracted interest as a potential solution to the global challenge of providing care for populations living with chronic diseases.

• Current findings lend some support to the assertion that a service redesign that included telehealth can improve care, reduce admissions and mortality in people with long term conditions.
• **Action 75: Give Europeans secure online access to their medical health data and achieve widespread telemedicine deployment**
  
  Undertake pilot actions to equip Europeans with secure online access to their medical health data by 2015 and to achieve by 2020 widespread deployment of telemedicine services.

• **What is the problem?**
  
  Sustainability of healthcare systems is at stake

• **Why is EU action needed?**
  
  "Patients' empowerment and deployment of telemedicine services are key to ensuring the sustainability of healthcare systems. Telemedicine is also an promising tool to improve mental health, increase the social impact of public health intervention, provide efficient health support in remote areas, and to respond to the shortage of healthcare professionals and the lack of financial resources."
Telehealth services face important challenges regarding:

- legal framework and liability issues
- harmonization of diagnosis related groups that can be treated by telemedicine
- accreditation of health professionals who provide telemedicine applications
- interoperability issues
- cost effectiveness
- reimbursement for telemedicine services

Evidence-based clinical practice is an approach to decision-making in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the option which suits that patient best.

Where “clinical evidence” comes from?

Ref.: Health Information Technology Knowledge Base, (2010) The USA Office of the National Coordinator for Health Information Technology (ONC)
Medline publications on telemedicine and five chronic diseases. There were 1324 publications between 1990 and 2011.
Despite calls for robust effectiveness trials of telemonitoring in chronic diseases, systematic reviews have reported inconclusive results.

Despite patients’ attitudes and receptiveness towards this approach being “promising,”

But the evidence is insufficient to draw firm conclusions about clinical effectiveness.
Remote monitoring (no implanted device)
The optimum approach to non-invasive remote monitoring is uncertain, and RCTs performed to date have given inconsistent results and do not yet support a guideline recommendation.

Structured telephone support
Although a meta-analysis of RCTs suggests that structured telephone support in addition to conventional care may reduce the risk of hospitalization in patients with HF, few individual RCTs showed this benefit, and the evidence is not robust enough to support a guideline recommendation.
Telemedicine Standards and Clinical Guidelines are required

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Telemedicine Standards & Guidelines

Standards, guidelines and quality assurance mechanisms are important priority areas for the Association. The Standards and Guidelines Committee is charged with providing overall guidance in the following: identifying, overseeing, and assisting work groups that would be charged with developing individual standards and guidelines and recommending the relative priority for each specific area to the Board of Directors, reviewing existing telemedicine/telehealth standards documents that have been developed by other groups and acting on this information as appropriate, maintaining documents of telemedicine/telehealth terminology, guidance and policies that provide instructions and a framework for incorporation into specific standards that will be developed by work groups. (See documents below for completed guidelines and policy and guidance for the Committee.)

Completed ATA Standards and Guidelines

The following Standards and Guidelines have been released by ATA.

- **Quick Guide to Store-Forward Teledermatology for Referring Providers** (April 2012)
- **Quick Guide to Live-Interactive Teledermatology for Referring Providers** (April 2012)
- **Expert Consensus Recommendations for Videoconferencing-Based Telementoring** (October 2011) - This expert opinion consensus document focuses on interactive videoconferencing-based telementoring for health care professionals who are competent in skills and knowledge required to provide the service.
CURRENT EVIDENCE: “Telemedicine use for diabetes care is feasible and acceptable. Its effectiveness though on improving HbA$_{1c}$, reducing costs while maintaining HbA$_{1c}$ levels and improving other aspects of diabetes management still needs to be proved.”

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment n</th>
<th>Mean (SD)</th>
<th>Control n</th>
<th>Mean (SD)</th>
<th>WMD (95% CI fixed)</th>
<th>Weight %</th>
<th>WMD (95% CI fixed)</th>
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<td>33</td>
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<td>20</td>
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<td>Wojcicki (2001)</td>
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<td>Fallucca (1996)</td>
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<td>-</td>
<td>2.6</td>
<td>0.19 (−0.78, 1.16)</td>
</tr>
</tbody>
</table>

Total (95% CI) 322
Test for heterogeneity $\chi^2 = 6.66$, d.f. = 8, $P = 0.57$
Test for overall effect $z = 1.42$, $P = 0.16$

Comparison of changes in HbA$_{1c}$ control vs. intervention

Clusters 2, 4, 7: Diabetes, COPD, CVD - Thessaly (GR)
Renewing health multicenter trial cluster 2:

Long-term telemonitoring of patients with type 2 diabetes mellitus

Primary Outcome Measures:

- Health related *quality of life* of the patients measured by the SF-36 version 2 questionnaire [ Time Frame: 12 months minimum- at the entry point of the intervention and the end. ]

- *Glycated hemoglobin* (HbA1c) levels at the entry point and after a period of 12 months.

Secondary Outcomes: among others Cost Effective/Utility Analysis
Renewing Health (RH) multicenter trial cluster 2: LONG-TERM TELEMONITORING OF PATIENTS WITH TYPE 2 DIABETES MELLITUS

823 patients with DMT2, HbA1c > 53 mmol/mol (7.0 % according to NGSP) and capability to use the telemonitoring device, were randomly assigned per region in the telemonitoring group (N=555) and the control (N=268) group.

A different age group was the focus in each region/setting: Mean Age (M) / Standard Deviation (SD) 81.05 years (11.03) in Berlin, Germany. 58.28 years (0.93) in Thessaly, Greece. and 73.05 years (5.79) in Veneto, Italy.
RH telehealth trial outcomes on glycemic control (HBA1C) and generic quality of life (QoL)

Outcomes submitted for presentation at:

American Diabetes Association

75th Anniversary Scientific Sessions
June 5-9, 2015 • Boston, MA
Estimated economic outcomes at pilot level in Thessaly (Central Greece)

In Central Greece pilot, cost of telemedicine devices was based on market prices reimbursed by the healthcare system; cost of staff was according to the salary of public sector employees; readmission cost was calculated using DRG rates; and the costs of outpatient visits, GP visits and emergency department visits were calculated using the national tariff rates.
Cost Utility Analysis of the telehealth service for T2DM patients in Thessaly, Greece RH Cluster 2 pragmatic RCT

Outcomes submitted for presentation at:

ATTD
Advanced Technologies & Treatments for Diabetes
Paris, France
February 18-21 2015
Renewing Health Diabetes type 2 pragmatic RCT conclusions:

• The conclusion of this study is that the impact of telemedicine services varies among different DMT2 patients populations and settings, and seems to provide an effective tool for tighter glycemic control in patients under 60 years old.

• The study revealed that the economic impact of telemedicine implementation varies among health systems due to differences in wages and prices for the telemedicine equipment.
Optimal care will require new models of service provision with the use of ICT

• Information and Communication Technologies (ICTs) have an ever-growing impact on our working and private lives and the healthcare sector is no exception.

• Used appropriately, telehealth can provide better, more efficient healthcare services for all.

• ICT in HEALTH/CARE SECTOR could become the catalyst for the re-formation of the traditional health care models.

• “old organisation with new equipment means more costly organisation”.

From RCT to everyday clinical practice:
From Renewing Health to UnitedforHealth

- **Randomized controlled trials** have specific inclusion and exclusion criteria that are often quite restrictive, whereas **Observational Studies** usually apply to a much broader population and are frequently even population-based. Thus, extrapolation to the entire population may be unwise.

- **On the other hand, the results for all patients in the observational studies** are of great interest because they reflect actual practice patterns and because they allow subset analyses that will speak to precisely which patients benefit from each treatment/intervention.
• **United4Health objectives:**

• Collect and assess data at large scale from across many regions and institutions in Europe that can be aggregated at European level; thus providing data.

• Adapt clinically validated services from some regions and institutions in Europe (Renewing Health partners) in the local setting of a large number of other regions and institutions (United4Health partners).

• Maximize the transferability of services and knowledge among European healthcare providers at such large scale and in close collaboration.
Diabetes Pilot ©

Ongoing Health Coaching

Patient’s home

- PATIENT
- TELEMONITORING DEVICE

GATEWAY

- DATA TRANSMISSION

SERVER

- DATA ACCESS
- OPTIONAL CONTACT (DIRECT/INDIRECT)

eHealth Centre

- REGIONAL CENTRE’S OPERATOR

OTHER INVOLVED HEALTHCARE PROFESSIONALS
- DIABETOLOGISTS AT HOSPITAL OR LOCAL HEALTH DISTRICT
- FAMILY

GENERAL PRACTITIONER

www.united4health.eu
Diabetes pilot

- The intervention aims to promote self-care and self-management by encouraging use of self-monitoring glucose and lifestyle risk factors and by providing ongoing health coaching.
- The patient at home uses the provided device for the measurement of blood glucose level. The device, used by the patient, collects the data and sends them to the gateway automatically.
- The gateway device transmits data collected by the patient to the server of a Regional eHealth Centre and processed according to local policy, i.e. the data can be made available or forwarded to the appropriate person.
- The telemonitoring software will allow healthcare professionals to monitor and manage the data as locally agreed, including the provision of a summary and an access to the web based portal to monitor the patients’ health conditions at any time.
Thank you for your attention!
Ευχαριστώ για την προσοχή σας!
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