5. Agreement with TIA clinic service provider including rapid review of referred patients

**CONCLUSIONS:**

We followed MRC guidance to develop a clinical intervention for assessment and referral of low risk TIA patients attended by emergency ambulance paramedic. We are testing feasibility of implementing and evaluating this intervention in the TIER feasibility trial which may lead to fully powered multicentre randomized controlled trial (RCT) if predefined progression criteria are met.

## VP89 Assessing mHealth: Proposal Of A New Framework

**AUTHORS:**

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**INTRODUCTION:**

The use of health apps is rapidly increasing. They intend to promote health or to treat diseases; in some cases, substituting medical duties. No specific frameworks to assess mHealth solutions in a broad scope and in a comprehensive way have been identified. We aim to propose a framework for mHealth assessment.

**METHODS:**

The framework development was based on:

- Literature review to identify existing assessment models including the evaluation of health effects
- Exploratory analysis with experts and user group discussions
- Definition of the assessment model, following the domains of health technology assessment.

**RESULTS:**

Existing frameworks are mainly focused on certification criteria. Professionals and users agreed on the need to undertake mHealth assessments as to better inform user decisions. Assessments should be sensible to continuous changes of these technologies and be undertaken by independent organizations.

The proposed framework offers a step-by-step process by which any mHealth solution can be categorized and analyzed, according to: (i) Risk classification matrix: combining intervention type and patient type, (ii) Users: patients, professionals, informal caregivers individually or all of these together and (iii) Integration: stand-alone, fully integrated.

The model has four evaluation domains: technical maturity, risks, benefits and resources needed, including the commonly accepted evaluation perspectives: technical, contents, clinical/health, user perspective, organizational and socio-economic. Sub-domains are defined as: end-user, organization, healthcare system and community (society as a whole). Aspects to be assessed are selected according to the purpose of the evaluation (intended use / intended impact) and vary depending on the type of the mHealth solution: product or service.

**CONCLUSIONS:**

The mHealth assessment process is needed and should be: (i) continuous/iterative, providing timely conclusions and recommendations for improvement, (ii) inclusive/collaborative, involving all stakeholders,and (iii) constantly adapting to standards. The proposed framework is intended to support informed decisions when developing, integrating, selecting, recommending, or adopting mHealth solutions.

## VP90 Uniform Assessment Methods To Assess New Genomic Tests

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## INTRODUCTION:

With the possibility to analyze gene expression a plethora of new genomic tests are surging into the medical market. The assessment of these new technologies in Health Technology Assessment (HTA) reports is challenging and we need international consensus on uniform criteria to support HTA, but also to establish clear and standardized requirements for clinical studies.

## METHODS:

The German Institute for Quality and Efficiency in Health Care (IQWiG) has been commissioned to assess the benefits and harms of biomarkers to predict which women would benefit from chemotherapy treatment after surgery of primary breast cancer. The final report was published in October, 2016 (1).

## RESULTS:

Only eight studies complied with the inclusion criteria of the systematic review. No prognostic study fulfilled the inclusion criteria. Only two randomized controlled trials (RCTs) delivered information utilizable for benefit assessment. Based mainly on 5-year results from the MINDACT trial, the report concluded that there currently is not enough information to support a positive decision on biomarkers in this specific indication. Ongoing randomized controlled trials like TailorX, PlanB, RxPONDER, ADAPT or OPTIMA are expected to provide some additional evidence in the near future. After publication of the IQWiG report an extensive debate on several methodological characteristics of this report was fuelled. In addition, some other HTA agencies, such as the National Institute for Health and Care Excellence (NICE) made slightly different conclusions.

## CONCLUSIONS:

The presentation will give a résumé of the main arguments and focus on differences between the IQWiG report and other HTA reports. Questions, like the required study type, study characteristics (for example, attrition rate, follow up, outcomes), data quality, cut-offs or patient preferences in diagnostic information will be provided. The aim of the presentation and discussion is to get a step forward in defining key characteristics and elements of benefit assessment and primary studies for these new technologies. A consensus among HTA reviewers in these approaches seems to be essential in the near future.

## REFERENCES:

1. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Biomarkerbasierte Tests zur Entscheidung für oder gegen eine adjuvante systemische Chemotherapie beim primären Mammakarzinom; Abschlussbericht; Auftrag D14-01 [online]. 15.12.2016 [Zugriff: 05.12.2016]. (IQWiG-Berichte; Band 457). URL: https://www.iqwig.de/download/D14-01_Abschlussbericht_Biomarker-bei-Mammakarzinom.pdf.

# VP94 Framework Of High-Quality Value Assessment Criteria In Health Care

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## INTRODUCTION:

No single assessment can evaluate the wide spectrum of health technologies pending access to healthcare systems. It is important to envision a complex systematic framework, in which different instruments are used for different purposes - all criteria should be used to ensure the transparency of the process, and should model good assessment and implementation practices (1,2).

## METHODS:

A cross-sectional web-based survey was conducted from September 2013 to May 2015 which was designed to gain information about the present status of Health Technology Assessment (HTA) activities; to examine its institutional contexts and the kind of application of its principles, logic, assessment methods, tools and best practices.



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