

reimbursement bodies, and we explore academic research into the methodology of surrogacy and the need for better reporting of surrogacy papers.

RESULTS:

A number of factors affect the relationship between PFS and OS. Therefore, there is no unique correct answer for the question of whether PFS is an appropriate surrogate for OS in oncology. Many of these factors are related to the length and characteristics of post-progression survival (PPS).

CONCLUSIONS:

Any consideration of evidence relating to PFS should consider both tumour type and other factors, particularly those related to PPS. Protocols of future follow-up of clinical trial patients should specify procedures for gathering information about the effect of post-progression management of the disease. This should allow stronger conclusions to be extracted from statistical analyses. Improved reporting standards will aid in achieving this goal. In addition, it is very likely that increasing the use of IPD will result in greater precision in estimating the benefits of worthwhile drugs.

REFERENCES:

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VP88 Transient Ischaemic Attack Referral (TIER) Intervention Development

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INTRODUCTION:

Transient Ischaemic Attack (TIA) is a neurologic event with symptom resolution within 24 hours. Early specialist assessment of TIA reduces risk of stroke and death. National United Kingdom (UK) guidelines recommend patients with TIA are seen in specialist clinics within 24 hours (high risk) or seven days (low risk).

We aimed to develop a complex intervention for patients with low risk TIA presenting to the emergency ambulance service. The intervention is being tested in the TIER feasibility trial, in line with Medical Research Council (MRC) guidance on staged development and evaluation of complex interventions.

METHODS:

We conducted three interrelated activities to produce the TIER intervention:

- Survey of UK Ambulance Services (n = 13) to gather information about TIA pathways already in use
- Scoping review of literature describing prehospital care of patients with TIA
- Synthesis of data and definition of intervention by specialist panel of: paramedics; Emergency Department (ED) and stroke consultants; service users; ambulance service managers.

RESULTS:

The panel used results to define the TIER intervention, to include:

1. Protocol for paramedics to assess patients presenting with TIA and identify and refer low risk patients for prompt (< 7day) specialist review at TIA clinic
2. Patient Group Directive and information pack to allow paramedic administration of aspirin to patients left at home with referral to TIA clinic
3. Referral process via ambulance control room
4. Training package for paramedics

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

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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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