in small populations but were not yet ready to make formal coverage decisions or support widespread adoption of specific techniques. Most patients were optimistic about the promise of digital health solutions, with the greatest expectations for chronic disease management. Skepticism about incremental value and costs led most respondents to desire stringent evaluation criteria and evidence standards that are transparent, preferably for 7 years and beyond. Computer-assisted examination of digital health solutions would need to demonstrate decreased costs and improved clinical outcomes. The most commonly desired attributes of digital health technologies are narrating devices, clinical decision support, and proven patient benefit. Digital health technologies will drive more consistent coverage outcomes and facilitate faster patient access to novel digital health technologies.

PMID 64
COMPANION DEVICES: TRANSFORMATIVE MOBILE HEALTH TECHNOLOGY TOWARDS IMPROVING PATIENT CARE DEFICITS
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OBJECTIVES: Companion devices enable Mobile Health (mHealth) via remote monitoring of patients’ biometrics. By 2020, the global mHealth market is estimated to reach $62.28 billion. While mHealth is expected to revolutionize delivery of patient care, especially for chronic diseases such as diabetes or asthma, it has not realized its full potential. To that end, the objectives of this study were to: 1) Characterize benefits that companion devices may deliver to key stakeholders, including patients, HealthCare Providers (HCPs), payers, and biomedical device manufacturers; 2) Determine how HCPs currently utilize companion devices and key unmet needs; 3) Identify perceived roadblocks by payers in coverage & reimbursement of companion devices. METHODS: HealthCare Providers (HCPs) and patients were interviewed via clinical trial, and publications archived in MEDLINE and PubMed were analyzed to assess potential benefits, challenges, and historical valuation of companion devices. Additionally, a 509-page companion device portfolio was developed to evaluate coverage and reimbursement and associated evidence requirements in the US and 5 major EU markets. RESULTS: Companion devices can potentially deliver benefits across the continuum of care that may be categorized into three areas: patient management (remote monitoring or observatory compliance), disease management (dose and clinical events). Current barriers to adoption appear to be primarily cost of technology, potentially increased liability exposure, compliance with patient confidentiality challenge in demonstrating positive budget impact, and importantly, lack of optimal reimbursement (separate vs bundled payment). CONCLUSIONS: While relatively nascent, companion devices are expected to play a role along the full continuum of patient care: from prevention, diagnosis, treatment, and management to end of life. This study indicates that companion devices with care plans is potentially hinging around three key issues: a) patient education and awareness, b) physician engagement via streamlined clinical workflow, and c) demonstration of long-term economic benefits to payers.

PMID 65
UNIVERSAL SCREENING IDENTIFIES HIGHER THYROID DYSFUNCTION IN PREGNANCY: EVIDENCE BASED META-ANALYSIS
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OBJECTIVES: Pregnancy poses a high risk of thyroid dysfunction (TD) causing adverse outcomes in mother, fetus and neonate. This makes screening pregnant women a pivotal step. The objective of this study is to assess whether universal screening with TD (serum TSH and FT4) during pregnancy is better than targeted screening (TS) where only women at high-risk get tested for TD during pregnancy. Existing guidelines do not recommend US. Thus we performed a multi-country prospective analysis to specifically evaluate the role of universal screening in pregnant women for TD essential. Universal screening (US) aims to screen all women in pregnancy, to monitoring. As such, this study indicated that the integration of companion devices play a role along the full continuum of patient care: from prevention, diagnosis, treatment, and management to end of life. This study indicates that companion devices with care plans is potentially hinging around three key issues: a) patient education and awareness, b) physician engagement via streamlined clinical workflow, and c) demonstration of long-term economic benefits to payers.

PMID 66
THE RISE OF THE VALUE ANALYSIS COMMITTEE AT US HOSPITALS, BETTER OR WORSE FOR MEDICAL DEVICE COMPANIES?
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OBJECTIVES: In response to increased pressure to contain costs and optimize patient outcomes, hospitals have implemented standardized decision-making processes utilizing value analysis committees (VACs). In 2012, 64% of hospitals reported using some form of VAC. The objective of this analysis was to quantify the adoption of VAC, the product features considered impactful by VAC, timing of review and evidence requirements. METHODS: Qualitative interviews (n =40) and quantitative online survey (n =76) were conducted with C-suite executives, purchasers, and clinician leads in the second half of 2014. Research participants were drawn from across the US, from a diverse selection of hospitals, including large/small, rural/urban and profit/non-profit. Outcomes of the research included adoption of VAC, triggers for VAC review, timing of review process and evidence requirements and implications for medical device companies. RESULTS: 100% of hospitals surveyed report use of VAC for all new products being considered. Existing products may undergo a review when price or features change. Most products were imported to the VAC by the service line head, although one third of hospitals report use of VAC for all new products being considered. Most hospitals consider VAC a multi-strategy process as US hospitals, medical device companies must have a thorough understanding of the process and evidence requirements. Opportunities exist for increased communication between innovators and hospital decision-makers to align solutions with needs. Facility specific value propositions and data are frequently required to secure product approval.