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Navigating the new health

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Direct-to-Patient Studies

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What are Direct-to-Patient Studies?

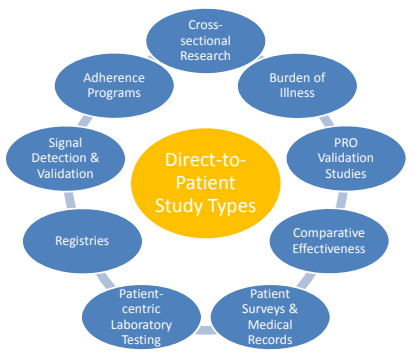
- Rapid adoption of the internet has created research opportunities
 - Patients empowered to influence care and participate in research without their personal physician
 - Internet allows for rapid access to large numbers of patients
 - Email allows for cost-effective, bi-directional communication
- Direct-to-patient studies include the direct recruitment of study subjects, without physician sites
- Studies can include self-reported data as well as consents for medical record access and lab collection

Data Sources Driven by Patient Consent

Patient Survey	<ul style="list-style-type: none"> • Disease status • Quality of life • Treatment satisfaction • Work productivity
Medical Record	<ul style="list-style-type: none"> • Diagnosis confirmation • Comorbid conditions • Treatments
Lab Testing	<ul style="list-style-type: none"> • Blood & urine based labs • Genomic testing (blood or saliva) • Sample banking

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Examples of Direct-to-Patient Study Types



Works best when validated PRO instruments exist for physician gold-standard

- Depression: QIDS-SR ⇔ HAM-D
- Rheumatoid arthritis: RADAI ⇔ DAS28

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Benefits and Limitations of the Direct-to-Patient Method

<p>Benefits</p> <ul style="list-style-type: none"> – Time and cost efficiencies – Strong patient interest in method <ul style="list-style-type: none"> • Helping others • Alignment of patient incentives • Comprehensive condition monitoring and tracking 	<p>Limitations</p> <ul style="list-style-type: none"> – Data quality? <ul style="list-style-type: none"> • Verification of patient diagnosis • Varying ability to report complex medical information (Dx, Tx) • Lack of randomization • Length of recall – Representativeness? – Ethics undefined in some countries
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Longitudinal PRO Case Example: Diary Study in Menstrual Bleeding

- Objective:
 - Examine burden of illness associated with menstrual bleeding
- Approach:
 - 250 women recruited directly to complete a survey on menstruation including questions on resource use
 - A subset (n=74) were asked to complete an online daily diary to obtain actual information on bleeding management
 - Women were contacted daily to determine the start of their menstrual cycle
 - Once started, women completed a daily diary to record pain and resource use
- Outcomes:
 - 65 of 74 women successfully completed (i.e., missed no more than 1 diary day)



PRO+EMR Case Examples: US & UK

- US MediGuard members invited to study with questionnaire and medical record access
 - 10% response rate
 - 93% willing to have records accessed
- 50 patients completed the online questionnaire and provided electronic signature for medical record access
 - 84% compliance rate in returning the paper form
- 39 of 50 (78%) medical records were extracted:
 - 29 with electronic signature
 - 10 with paper signature
- UK study now underway in Wales
 - The objective is two-fold:
 - To validate the EMR+PRO methodology between MediGuard and SAIL
 - To collect data on patient's ability to report cholesterol levels/control and the correlation between accurate self-reporting and treatment satisfaction, adherence, demographics, etc.
 - The study was approved by the external Information Governance Review Panel for the Center for Health Information Research and Evaluation (CHIRAL)
 - No further ethics was required
 - 70 of 250 participants recruited in the first 2 weeks

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Panel / Audience Discussion on
 Benefits and Limitations of Real-
 world Research Methods



Framework for Comparison of Observational Research Methods

	Physician Registries	Electronic Medical Data	Direct-to-Patient
When this works well?			
When this doesn't work well?			

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