

Appendix Table 1: Results of Randomized Controlled Trials

Study	Study Design	Intervention and patient population	Primary outcomes and IOM Dimension(s)	Main findings	Limitations	Score (total 95)
Grant et al. ³⁴	RCT (N= 244)	Intervention: Access to integrated web portal-based personal health record and disease-specific health information Patient population: Patients diagnosed with diabetes.	<u>Effectiveness</u> 1. Hb A1c 2. Blood pressure 3. LDL-C	1. Modest improvement in HBA1c for both intervention and control patients, no significant difference at post-intervention (0.16% vs 0.26%, P=0.62); similar HbA1c levels and 1 year follow-up (7.1% vs 7.2%; P=0.45). 2. A statistically similar improvement over time in both study arms was also seen for blood pressure. 3. A statistically similar improvement over time in both study arms was also seen for LDL-C control.	<ul style="list-style-type: none"> • Low participation rates (7-14%) • Good control of health parameters at baseline • No indication of when the study took place • Non-random group assignment 	73
Shaw et al. ⁵¹	RCT (N=193)	Intervention: Intervention group given access to electronic antenatal record and personalized information through a condensed version of the clinical antenatal care planner and access to general pregnancy resource links Patient population: Pregnant women.	<u>Effectiveness</u> 1. Frequency of use 2. Perceived usefulness of the web-based information <u>Patient-centeredness</u> 3. Satisfaction with the web-based information	1. The mean number of log-ins was significantly different (P<0.001) for the personalized information group was 10.4 (SD 17.8) and the general information group was 1.8 (SD 1.4). 2. No significant difference. 3. No significant difference.	<ul style="list-style-type: none"> • High attrition rate • Single site study • Subjects not randomly selected for inclusion 	66
Spodik et al. ⁴²	RCT (N=115)	Intervention: Intervention group provided with post procedure report after an outpatient endoscopy. Patient population: Patients undergoing an elective endoscopy.	<u>Effectiveness</u> 1. Post procedure anxiety <u>Patient-centeredness</u> 2. Satisfaction with endoscopy procedure	1. The intervention group had lower post procedure anxiety scores than the control group (P=0.001). 2. No significant differences.	<ul style="list-style-type: none"> • Single site study • Small sample size • 27.8% attrition rate • Subjects were not randomly selected for inclusion 	76
Tuil et al. ⁵⁷	RCT (N=180)	Intervention: Intervention group given access to a personal health record with secure email. Patient population: IVF patients.	<u>Patient-centeredness</u> 1. Patient empowerment	1. No significant differences.	<ul style="list-style-type: none"> • Small sample • Limited power • Lack of a validated empowerment scale for this population • Subjects were not randomly selected for inclusion 	80

Ross et al. ⁵⁰	RCT (N=328)	Intervention: Intervention group given access to a PHR. Patient population: Patients with type 2 diabetes.	<u>Effectiveness</u> 1. Usage	1. Usage was higher in the intervention group over the course of the study (772 vs. 319 days logged in, p=.001). Same proportion logged in at least once 83% intervention, 84% controls.	<ul style="list-style-type: none"> Sample representativeness Subjects were not randomly selected for inclusion 	66
Ross et al. ¹⁸	RCT (N=107)	Intervention: Intervention group given access to a PHR. Patient population: Patients diagnosed with heart failure.	<u>Patient-centeredness</u> 1. Self-efficacy 2. Patient satisfaction with doctor patient-communication	<ol style="list-style-type: none"> No significant differences. No significant differences. 	<ul style="list-style-type: none"> Small sample size 30% attrition rate in intervention group. Subjects were not randomly selected for inclusion 	66
Saunders et al. ⁵⁵	RCT (N=107)	Intervention: Intervention group given a copy of the letter sent from the specialist to general practitioner. Patient population: All patients under the care of the consultants.	<u>Patient-centeredness</u> 1. Overall satisfaction with consultation	1. Significant difference between the two groups (P=0.014).	<ul style="list-style-type: none"> Small sample Low response rate (58.8%) Subjects were not randomly selected for inclusion 	53
Maly et al. ⁴⁷	RCT (N=276)	Intervention: The experimental group received copies of their medical record progress note and completed question lists for physician review. The control group received health education sheets and completed suggestion lists for improving the clinic. Patient population: Patients seen in the study site clinic with a chronic medical condition.	<u>Effectiveness</u> 1. General health 2. Physical functional status 3. Patient adherence <u>Patient-centeredness</u> 4. Patient satisfaction with care	<ol style="list-style-type: none"> Significant improvement in the experimental group (P=0.001) but not controls (p=0.39). Significant improvement in the experimental group means (p=0.001). No significant differences. Experimental group reported more satisfaction than the control group patients (P=0.045). 	<ul style="list-style-type: none"> Single site study Small effect size Subjects were not randomly selected for inclusion 	77
Homer et al. ⁵⁶	RCT (N=150)	Intervention: Intervention group held their entire antenatal record through pregnancy versus standard practice (small, abbreviated card). Patient population: Women attending the hospital clinic for their first antenatal visit.	<u>Patient-centeredness</u> 1. Sense of control 2. Involvement in care	<ol style="list-style-type: none"> Intervention group patients were more likely to indicate they felt in control (P=0.013). <ol style="list-style-type: none"> Patients in the control group were more likely to indicate they felt anxious (P=0.025). Intervention group more likely to indicate that the doctor/midwife explained everything in the record (p=0.006). 	<ul style="list-style-type: none"> Subjects were not randomly selected for inclusion 	71
Banet and Felchli ⁴⁵	RCT (N=58)	Intervention: Intervention patients received a copy of their medical history, clinical resumes, notes on outpatient visits, x-ray and scan reports, pertinent laboratory results and education packet on strokes. Patient population: First time stroke patients referred to the Stroke Team.	<u>Effectiveness</u> 1. Intention to modify health behaviors 2. Compliance with treatment	<ol style="list-style-type: none"> No significant differences. No significant differences. 	<ul style="list-style-type: none"> Small sample Limited measurement Subjects were not randomly selected for inclusion 	71

Liaw et al. ⁴⁶	RCT (N=364)	<p>Intervention: Three intervention groups: 1) Patient given the Health Education Authority's written PHR, 2) Patient given a print out of the patient's computerized medical summary (CHR), 3) Patient given both the PHR and CHR.</p> <p>Patient population: Patients at five practices in Oxfordshire.</p>	<p><u>Effectiveness</u></p> <ol style="list-style-type: none"> 1. Patient responses to receiving a personal health record <ol style="list-style-type: none"> a. Attend health check b. Kept and looked at record c. More aware of ways of staying healthy d. Reduced alcohol intake e. Felt no need to change 	<ol style="list-style-type: none"> 1. <ol style="list-style-type: none"> a. Patients receiving a CHR were more likely to attend a health check ($p=.016$). b. Having both records was associated with keeping and looking at the records ($p=.014$, $p=.029$, respectively). c. No significant differences. d. Patients receiving a PHR were more likely to report drinking less alcohol ($P=0.026$). e. Patients receiving a CHR were more likely to say that they felt not need to change ($P=0.022$). 	<ul style="list-style-type: none"> • Low response rate for follow-up questionnaire (52%) • Used two recruitment methods – one sample was not randomly selected for inclusion 	61
Elbourne et al. ⁴⁰	RCT (N=290)	<p>Intervention: Intervention group was given full case notes to hold. Usual care group was given a co-operation card.</p> <p>Patient population: Women less than 34 weeks gestation who booked for antenatal care with one of the authors at the peripheral clinic at the Sandford Hospital, Newbury.</p>	<p><u>Effectiveness</u></p> <ol style="list-style-type: none"> 1. Anxiety 2. Depression <p><u>Patient-centeredness</u></p> <ol style="list-style-type: none"> 3. Satisfaction with maternity care 4. Feel better informed 5. Confidence 6. Control 7. Involvement of fathers 8. Communication 	<ol style="list-style-type: none"> 1. No significant differences. 2. No significant differences. 3. No significant differences. 4. No significant differences. 5. No significant differences. 6. Women carrying their own notes were nearly one and a half times more likely to say they felt more in control of their pregnancies (95% CI 1.08-1.95). 7. No significant differences. 8. Women carrying their own notes were more than one and a half times more likely to say they found it easier to talk to doctors and midwives antenatally (95% CI 1.16-2.59). 	<ul style="list-style-type: none"> • Single site study • Subjects were not randomly selected for inclusion 	66
Jones et al. ⁴⁹	RCT, three groups (N=525)	<p>Intervention: Three intervention groups 1) General PHR giving patients general information about cancer. 2) Personal PHR giving patients a summary of their medical record and information about all the concepts and terms. 3) Booklet information - patients given printed booklets.</p> <p>Patient population: Patients diagnosed with breast, cervical, prostate, or laryngeal cancer.</p>	<p><u>Effectiveness</u></p> <ol style="list-style-type: none"> 1. Compare patient use <p><u>Patient-centeredness</u></p> <ol style="list-style-type: none"> 2. Satisfaction 	<ol style="list-style-type: none"> 1. Usage: <ol style="list-style-type: none"> a. Personal versus general computer information: The personal computer information group were more likely to use the computer between the three week and three month follow-ups ($P=.002$). 3. Satisfaction: <ol style="list-style-type: none"> a. Personal versus general computer information: The personal computer information group had higher satisfaction score ($p=.04$). b. Computer versus booklet group: No significant difference. 	<ul style="list-style-type: none"> • Single site study • Subjects were not randomly selected for inclusion 	71

Lovell et al. ⁵⁴	RCT (N=235)	Intervention: Intervention group was given their maternity case notes to retain during the course of pregnancy. Patient population: All women seeking antenatal care at site.	<u>Patient-centeredness</u> 1. Satisfaction with the care given 2. Informed 3. Shared decision making	1. No significant differences. 2. Only 1.1% of mother's did not feel well informed during labor and delivery compared to 12.1% in the card group p<.01. 3. No significant differences.	<ul style="list-style-type: none"> • Single site study • Subjects were not randomly selected for inclusion 	71
Rubin et al. ⁴⁸	RCT (N=78)	Intervention: Intervention group received the same verbal report and the standard computer-generated endoscopy report compared and the control group received usual care (verbal report alone). Patient population: Patients who presented to three endoscopists at the study site.	<u>Effectiveness</u> 1. Recall of endoscopic indications 2. Recall of endoscopic results 3. Recall of recommendations	1. Overall survey score for the intervention group were significantly higher (P=0.002). 2. No significant differences. 3. The intervention group were better able to recall the recommendations were made (P=0.003).	<ul style="list-style-type: none"> • Single site study • The intervention group could be reading their reports at the time of the survey • Subjects were not randomly selected for inclusion 	86
Gravis et al. ⁴¹	RCT (N=336)	Intervention: Patients provided with comprehensive cancer information through an organized medical record briefcase (OMR) and usual care (information and medical record delivered at the physician's initiative or upon the patient's request). Patient population: Patients newly diagnosed with breast cancer, colon cancer, Hodgkin lymphoma, and non-Hodgkin lymphoma that were to receive adjuvant chemotherapy in an outpatient setting.	<u>Effectiveness</u> 1. Anxiety levels, 2. Quality of life <u>Patient-centeredness</u> 3. Satisfaction with the care process	1. No significant differences 2. No significant differences 3. No significant differences	<ul style="list-style-type: none"> • Young women in early stages of cancer with a good prognosis • Single site study • Site already makes effort to help patients access information • Subjects were not randomly selected for inclusion. 	71
Ralston et al. ³⁶	RCT (N=83)	Intervention: Intervention group met with care manager for 1 hour using a collaborative care approach to review online record together. This included an introduction to the web-based program and encouragement to review the online medical records, send weekly glucose readings, and secure emails as necessary. Control group received usual care alone. Patient population: Patients with type 2 diabetes.	<u>Effectiveness</u> 1. Change in GHb between baseline and end of the 12-month study period (adjusted for age, sex, and baseline GHb)	1. GHb declined significantly in the intervention group compared to the usual care (change - 0.7%; P=0.01) at 12 months	<ul style="list-style-type: none"> • Cannot determine the impact of the care manager • Patients and providers were not blinded • Small sample • Subjects were not randomly selected for inclusion. 	76

Wagner et al. ³⁹	RCT (N=443)	Intervention: Intervention patients were given access to a PHR. Control group did not have access to a PHR. Patient population: Patients with hypertension.	<u>Effectiveness</u> 1. Blood pressure <u>Patient-centeredness</u> 2. Patient empowerment 3. Patient perception of quality of care	1. No significant differences 2. Clinically insignificant difference in empowerment score 3. Clinically insignificant difference in patient perception of quality of care	<ul style="list-style-type: none"> • Sample representativeness • Subjects were not randomly selected for inclusion. • Relied on self-report of PHR use 	71
McCarrier et al. ³⁵	RCT (N=77)	Intervention: Intervention Patients in the intervention group received usual care and were provided access to a nurse case manager and access to five websites: a PHR, diabetes diary, a planner, patient education, and a site to upload blood glucose readings. The control group received usual care. Patient population: Patients diagnosed with type 1 diabetes.	<u>Effectiveness</u> 1. HbA1c <u>Patient-centeredness</u> 2. Self-efficacy (Diabetes Empowerment Scale)	1. No significant differences 2. Significant difference between the control and intervention groups (p=0.044). The intervention group's mean score increased while the control group decreased.	<ul style="list-style-type: none"> • Cannot determine the impact of the care manager • Small sample size • Subjects were not randomly selected for inclusion. 	71
Liaw et al. ⁴⁶	RCT (N=72)	Intervention: Intervention group was given access to computer generated, patient held record. Patient population: Patients with one or more chronic health problems.	<u>Effectiveness</u> 1. Functional status 2. Use of Medications 3. Health problems a. Systolic blood pressure b. Use of Alcohol c. Use of Tobacco	1. No significant differences. 2. No significant differences. 3. a. No significant differences. b. No significant differences. c. No significant differences.	<ul style="list-style-type: none"> • Small sample size. • Does not report p values for a number of the comparisons, these variables were not included. • The variable functional status is not defined. 	67

RCT randomized control trial, HbA1c glycated hemoglobin A1C, LDL-C Low-density lipoprotein cholesterol, PHR personal health record, CHR computerized medical summary, BMI body mass index, ACEi Angiotensin converting enzyme inhibitor, IVF In vitro fertilization

Appendix Table 2: Uncontrolled Observational Studies with a comparison group

Study	Study Design	Intervention and patient population	Primary outcomes (with comparisons)	Main findings	Limitations
Zhou et al. ⁵⁸	Cohort with matched-controls (administrative data) (N=6402)	<p>Intervention: Comparison of registered to PHR users and match-control group non-users.</p> <p>Patient population: Adult members of Kaiser Permanente Northwest</p>	<p><u>Efficiency</u></p> <ol style="list-style-type: none"> 1. Annual adult primary care office visit rates, 2. Documented telephone contact rates 	<ol style="list-style-type: none"> 1. The intervention group office visit rates decreased by 10.3% (P<0.001) and controls decreased by 3.7 % (P<0.003). The difference between the change was significant (P<0.003). 2. The intervention group telephone rates significantly increased 16.2% (P<0.001) and the control significantly increased 29.9% (P<0.001). The difference between the increase was statistically significant at 13.7% (P<0.01). 	<ul style="list-style-type: none"> • Subjects and controls were not matched by baseline office visit or telephone contact rates.
Staroselsky et al. ⁵²	cross-sectional survey (N=163)	<p>Intervention: Comparison of the medication list accuracy PHR users and non-users</p> <p>Patient population: Primary care patients at the study site.</p>	<p><u>Effectiveness</u></p> <ol style="list-style-type: none"> 1. Medication lists accuracy 2. If the patient had stopped taking it 3. If they had changed the regimen 4. Any new prescriptions and/or over the encounter drugs patients were currently taking 	<ol style="list-style-type: none"> 1. No significant differences. 2. No significant differences. 3. No significant differences. 4. No significant differences. 	<ul style="list-style-type: none"> • Single site study. • Low response rate.

Wijler et al. ⁴⁴	Quasi-experimental pre/post (N=250)	Intervention: The intervention group was given access to a PHR. Patient population: Patients diagnosed with breast cancer.	<u>Effectiveness</u> 1. Anxiety levels <u>Patient-centeredness</u> 2. Self-perceptions of self-efficacy	1. Patients were less anxious at the post-test (p=.03). 2. No significant differences.	<ul style="list-style-type: none"> 64% were active treatment, remainder were post treatment. Almost half of the participants did not finish all the instruments.
Palen et al. ⁵⁹	Retrospective cohort with matched controls (n=158869)	Intervention: PHR users that had active access for at least 12 months and used at least 1 feature versus non-users enrolled in the health plan Patient population: Kaiser Permanente Colorado members.	<u>Efficiency</u> 1. Healthcare utilization a. Office visits b. Telephone c. After-hour clinic visits d. ER visits e. Hospitalizations	1. a. Significant increase in office visits (0.7 per member per year, 95%CI, 0.6-0.7, p<.001). b. Significant increase in telephone encounters (0.3 per member per year; 95%CI, 0.2-0.3, p<.001). c. Significant increase in after- hour clinic visits (18.7 per 1000 members per year, 95% CI, 12.8-24.3, p<.001). d. Significant increase in member rates of ER visits (11.2 per 1000 members per year, 95% CI, 2.6-19.7, p<.001). e. Significant increase in member rates of hospitalizations (19.9 per 1000 members per year, 95% CI, 14.6-25.3, p<.001)	<ul style="list-style-type: none"> Single site study. Were not able to access to the reasons why patients made contact with the health care system Large sample size.
Tenforde et al. ³⁷	Retrospective cohort study (n=10,746)	Intervention: Patients using the PHR versus non-users. Patient population: Primary care patients diagnosed with diabetes.	<u>Effectiveness</u> 1. Diabetes quality measures a. HbA1c b. LDL-C c. Blood pressure d. BMI e. HbA1c testing f. ACEi/ARB use and/or micro albumin testing g. Pneumococcal vaccination h. Foot and dilated eye exam i. Smoking status	1. a. Users had lower HbA1c test values (p<.01). b. Users had lower mean LDL cholesterol (p<.01) c. Users had lower SBP and DBP values (p<.01) d. Users had higher BMI (p<.01) e. Users were more likely to have a HbA1c test completed during the study period (p<.01). f. No significant differences. g. No significant differences. h. No significant differences. i. Users were more likely to be non-smokers (p<.01).	<ul style="list-style-type: none"> Representativeness of the sample

Wackerle et al. ⁵³	Cohort study (n=400)	<p>Intervention: Intervention group received a USB stick containing their complete antenatal medical records to hold. The control group received usual care.</p> <p>Patient population: Intervention group-received care antenatal-to-postnatal at site. Controls received care elsewhere and only delivered at the site.</p>	<p><u>Patient-centeredness</u></p> <ol style="list-style-type: none"> 1. Overall satisfaction with pregnancy 2. Overall satisfaction with delivery 	<ol style="list-style-type: none"> 1. No significant differences 2. No significant differences 	<ul style="list-style-type: none"> • Single site study. • The control group did not receive care at the same institution as the intervention group.
Stevens et al. ⁴³	Cohort study (N=50)	<p>Intervention: The intervention group was given free access to their hospital record. In the control group, the record was kept from the patient's view.</p> <p>Patient population: Patients admitted to the study site.</p>	<p><u>Effectiveness</u></p> <ol style="list-style-type: none"> 1. Subjects' ability to list their diagnoses 2. Subjects' ability to list their medication, 3. Depression 4. Anxiety <p><u>Patient-centeredness</u></p> <ol style="list-style-type: none"> 5. Contentment 	<ol style="list-style-type: none"> 1. No significant differences 2. No significant differences 3. No significant differences 4. No significant differences 5. No significant differences 	<ul style="list-style-type: none"> • Single site study • Small sample size

HbA1c glycated hemoglobin A1C, LDL-C Low-density lipoprotein cholesterol, PHR personal health record, CHR computerized medical summary, BMI body mass index, ACEi Angiotensin converting enzyme inhibitor, ARB angiotensin receptor blockers