Use of patient-held paper-based &
electronic-based portable health files (PHFs)
to facilitate reliable health knowledge
transfer among direct health-care providers
and their consumer- patients:
a clinical trial.

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Real Case Study

• 18 August 2004: Dr Lassere’s private rooms
• New patient Mrs RI, 68 yrs,
• GP referral letter: date 25 May 2004
• Problem: pain in hands, knees, neck
• Medical conditions: diabetes, arthritis, hypertension, osteoporosis, thyroid disease
• Meds: Diabex, Pravachol, Lipitor, Atacand, Karvezide, Lasix, Zantac, Oroxine, Diamicron, Ostelin, Caltrate, Brufen, Voltaren,
Dr Lassere: “so you are on Atacand, ... for .....”
Mrs RI: “no, the heart doctor or was it my GP ... changed my tablets ... I’m not taking Brufen. And I’m now on a little white tablet for my heart”
Dr L: when did this happen?
Mrs RI: 6 weeks ago.
Dr L. “Why did you see a heart doctor?”
Mrs RI: “Because I had pain in the chest”
Dr L. “who is your heart doctor?”
Mrs RI: “I think I have his card here .... No I don’t. My daughter can tell you .. She’s at work now .. You can give her a call”
Dr L Why were the tablets changed?
Mrs RI: I don’t know
Dr L: Did he think the pain in the chest was your heart? Or did he think it was from your stomach?
Mrs RI: I don’t know.
And so on ....
Exam: Synovitis wrists, MCPJs, knees

PDx: Inflammatory arthritis ? RA
DDx: pseudogout, seronegative RA, CTD, malignancy, viral

Investigations:
Dr L: “ …I would like you to get these blood tests done”
Mrs RI: “More blood tests! But I just had blood tests last week.”
Dr L: “what were they for ..? Where were they done ..?
Mrs RI: “kidney I think … down in the shopping centre …”
Dr L: (rings GP practice, phone engaged) “I will have to ask you to get these blood tests again … they probably are different to the one’s you had last week anyhow. You also need to have xrays of your hands and knees.
Mrs RI: “but I had xrays last year …”
Lyle Berkowitz – keynote address

• “what is good for the physician will roll down and benefit the patient”
• Methodology: Plan-Do-Study-Act
• Tools: Process>people>technology
• Model: create, validate and spread
Information
Communication

Patient ↔ Doctor

Doctor ↔ Doctor

Patient ↔ Family

Providers ↔ Providers
Health-care in Urban Australia

• The bulk of health care services (and costs) are for older patients with multiple chronic medical conditions.

• Patients with chronic medical conditions have multiple health care providers: in the community, in hospitals, some public, some private. These include GPs, specialists (medical, surgical).

  – Average age of my in-patients....
  – Average age of my outpatients....
  – Average no. of medical conditions....
  – Average no. of specialist visits...
  – Average number of medications.....

• Information communication among health-care providers is not part of medical culture and is uncommon
Information Communication

- The patient-consumer is the link among these providers - the patient is the physical person in the centre.
- The patient provides a history, but their medical knowledge and understanding is limited and they can’t provide details of previous examinations, findings, investigations etc

- Poor medical information flow
- Compromised medical decisions
- Adverse events, hospitalizations and death
- Duplication of services
- Frustrated and helpless providers and patients
Patient is in the Centre

- Specialists
- GP(s)
- Pharmacist
- Diagnostic Services
- Payers (Medicare, Health Insurance)
- Hospital Inpatient
- Hospital Outpatient
- Allied Health Services
- Family &/or Friends
- Home, Hostel or Nursing Home

Patient
Bottom-Up Approach: Patient is the ‘Glue’

Information Communication Follows the Patient

- Specialists
- GP(s)
- Pharmacist
- Family &/or Friends
- Home, Hostel or Nursing Home
- Hospital Inpatient
- Hospital Outpatient
- Allied Health Services
- Diagnostic Services
- Payers (Medicare, Health Insurance)
- Patient
Literature on patient held portable health files (PHF) (1)

• Improved continuity of care
• Improved patient understanding of instructions
• Patients can take active or passive role in maintaining their health

• Determinants of patient acceptance and use are:
  – physicians' support of the process
  – actual size of the record – the smaller the better

• Patients mostly perceive the PHR as a personal document for reference
• GPs perceive it as a management and communication tool
Literature on patient held portable health files (PHF) (2)

- Different types of patient-held records have been considered: full copies of patient files, extracted summaries and censored summaries.
- Stand alone systems or systems integrated with health provider electronic medical records
- PHF carried on **smart cards, CDs, USB** memory drives,
- Promoted as a means of providing patients and providers with universal access to updated medical information
- Some systems are free or open source and claim to meet requirements of **data encryption, secure access, authentication and authorization**
- None rigorously evaluated to quantify real risk/benefits using scientific methods
E-Health Top-Down Approach

Providing a roadmap to achieve system interoperability

Interoperability Framework

Shared EHR Specifications
Clinical Information
Clinical Terminologies
Personal Healthcare Identifier
Healthcare Provider Identifier

Health IT Vendors → Hospitals And Other Providers

Request lab tests → Results of lab tests

Clinicians → Health record
Event summary

Consumers
Longitudinal Health Record

Administrators & Funders
Researchers

Medical Product Directory
Secure Messaging
User Authentication
E-Health Consent Frameworks
Standards Implementation
Project: alternative solution while we wait for Top-Down to be rolled out
Objectives

1. **Develop** a paper-based and an electronic-based patient-held portable health file (p-PHF & e-PHF).

2. **Evaluate** a paper-based and an electronic-based patient-held portable health file (PHF).
Methods

• Project Team: Specialists, GPs, allied health professional, research nurses, patients, clinical informatics experts, software programmers, social scientists, health policy experts, consumer organisations

• Project funding was 9 months

• Funded by Commonwealth Department of Health and Ageing

• UNSW and Area Health Service Human Research Ethics Committee Approval
Methods (1)

Using **rapid prototyping, quality improvement methods** & the expertise of the team, two patient-held portable health files, i.e. shared-records, were developed:

- portable, USB-drive synchronized Java electronic PHF
- passport-sized booklet, paper-PHF
Methods (2)

Pilot Trial to evaluate the PHFs

- Study population: patients with rheumatoid arthritis requiring specialist care
- Recruitment order: 1. rheumatologists, 2. their patients, 3. the patient’s GP
- PHF ‘Interventions’ for evaluation
  - My Health Record\textsuperscript{v2}
  - paper PHF
  - electronic PHF
Methods (2)

• Method of allocation to interventions
  – 1\textsuperscript{st} 25% allocated to no PHF (control)
  – 2\textsuperscript{nd} 25% allocated to NSW Health My Health Record
  – 3\textsuperscript{rd} 25% allocated paper-PHF
  – 4\textsuperscript{th} 25% allocated electronic-PHF

• Quota allocation because the PHFs required development and project timelines tight

• Patients of GPs without computers were not allocated e-PHF

• Halfway through project patients in the No PHF arm were crossed to either paper-PHF or electronic-PHF arm
Methods (3)

- Limited information regarding the degree of computerisation of GPs who agreed to take part in the trial.
- Patients could only receive the electronic portable health file if their GP was able to use it.
- At trial onset, **GPs completed a questionnaire on the electronic health informatics technologies** they used for patient-care.
Methods (4)

Qualitative methods to probe issues

• Patients: Two semi-structured focus-groups were conducted midway through project.
• Allied health and consumers representatives focus group
• General practitioner: feedback meeting
• Ongoing informal feedback from all project participants
Methods (5)

Quantitative methods with questionnaires

- General practitioners and patients at project end were asked to complete a questionnaire on the project and its tools.

- Data entry in the p-PHF and e-PHF was analysed.
Methods (6)

Quality Indicator implementation and patient outcomes:

• Data abstracted from patient medical records of GPs and rheumatologists to evaluate QI implementation during the 2 year period before the trial and during the 6 month trial period

• Patients also completed questionnaires on quality of life, functional status and co-morbidity at beginning and end of trial.
Results for Methods 1,3,4,6

1. Development of ePHF: Doctors programmers and patient-consumers think (and work) in different modes (13.30 System Design: Andrew Parle)

3. GP Health IT uptake: (e-Poster: Lassere)

4a. Privacy, health information security and confidentiality (Tues 11.00 Privacy: Lassere)

4b. Who should be responsible for holding medical information: GP, specialists, patients ....? (Tues 11.00 Privacy: Rowena Forsyth).

6. No presentation
Results (1)

- Paper and electronic-files contained a core-data set of information
- Included a **directory of health care providers, medical conditions, medications (current and past), investigations, visit summaries, RA specific measures and quality indicators**
- Core-data functioned as a subset of a more comprehensive electronic or paper medical record held by the doctor
- Structured to be **patient and doctor friendly**
- Portable health file was updated by the doctor at each visit and could also be updated by patient between visits
Results (1) p-PHF

- Three prototypes, all passport size
- 40 pages, uncluttered style, black and white
Results (1) e-PHF v1/v2

• Advantages:
  – Java chosen for rapid development & supportable on most platforms
  – functions such as doctor authentication, audit trail, non-repudiation and saving of changes built-in and automated
  – file was read-only without USB drive
  – USB drive robust, fast, and stored large data files as well as all required software
  – many more interface and functionality features

• Disadvantage:
  – data migration programmable for use with other computer systems, but not fully interoperable
Results (2) clinical trial

- We recruited 4 specialist rheumatologists.
- Over a period of about 3-4 months (late September 2005 to early February 2006), a consecutive sample of 105 patients with rheumatoid arthritis from 3 rheumatologists were asked to participate and 79% agreed after discussion with family and their general practitioners.
- Some patients were keen to participate but were dissuaded by their general practitioners.
- Main general practice reasons for non-participation were privacy and confidentiality. Almost all of these GPs had practices outside the area health service that was conducting the project.
Results (2) clinical trial

- final sample was 76 patients.
- Average age was 63 years (33-85 years), 78% were female and 74% were Australian born.
- final general practitioner sample was 62.
- Planned that the patient to general practitioner ratio would be 4:1 however the ratio was almost 1:1. Unanticipated and caused project timeline difficulties as well as other logistic problems to do with electronic PHF software installation and deployment.
Results (2) clinical trial

• Patients who transferred from My Health Record (red plastic cover, 23cm x 15cm in size) to the compact passport-sized PHF preferred the latter.

• **Men said they would not carry** something that would not fit in their hip or shirt pocket.

• **10% of patients forgot** to bring the PHF to either their rheumatologist or general practitioner.

• Many **practitioners requested the patients PHF** at the start of the consultation.

• Some GPs with older computers obtained a USB drive extension cord to facilitate ease of use.
Results (5) Patients

• 80% would recommend a PHF to others

• 95% liked the idea of carrying their own health data using a PHF

• 13% were often or sometimes concerned about privacy

• 55% added information to the PHF
Results (5) Patients

- 70% said was easy to ask their GP to fill in their PHF
- 90% said was easy to ask their specialist to fill in their PHF
- 75% patients mostly perceived PHF as a means of carrying information between health care providers
Results (5) GPs

- 80% happy to use a PHF in the future
- 15% were concerned about confidentiality and accuracy
- Most common GP entry was BP, blood tests and medications
- (Rheumatologists completed visit summary, medications, investigations, QIs)
Results (5) GPs

- Twelve general practitioners attended a face-to-face feedback session.
- Although many did not see the need for their own personal PHF there was no hesitation recommending a PHF for their parents.
- GPs wanted a means to download medication lists from their existing electronic medical software, that included electronic prescriptions, to the PHF.
- None wanted a system that required duplicate electronic data entry.
- All agreed that the interface for both the electronic and paper PHF required refinements.
Conclusions 1

• Successful “proof-of-concept” study but very limited by its size, duration and early prototype PHFs
Conclusions 2

• Older patients with chronic medical conditions that need care of multiple health care providers believe that improving quality of their health care outweighs the risk of losing privacy.
Conclusions 3

• Where technology provides functionality that speeds the doctors’ workflow,
• e.g. rapid generation of prescriptions, the adoption rate is high.
Next: 4 year Randomized Controlled Trial

ARM 1
ELECTRONIC PORTABLE HEALTH FILE ON USB FLASH DRIVE (openEHR?)

ARM 2
PAPER PORTABLE HEALTH FILE

ARM 3
CONTROL

ROUTINE CARE
Phase 3 RCT Design

• Randomised Controlled Trial
• Enriched population
  – ≥ 60 years
  – ≥ 2 specialist visits in previous 12 months
  – ≥ 6 doctor visits in previous 12 months
• 999 patients
• Duration: 4 years
• 50-100 GPs, 10-20 patients per GP, plus specialists and other health care providers.
Trial Goals

• Test whether an electronic or paper patient-held portable health file reduces significant clinical outcomes - hospitalisations and death - compared to control

• Other outcomes
  – GP and specialist workflow, acceptability etc
  – Uptake of guidelines/quality indicators
  – Health service utilisation
  – Patient quality of life, co-morbidity
  – Impact on privacy and confidentiality
  – Others....
Anticipated Trial Issues

• Smooth integration with clinician workflow
• Security
• Synchronicity and backup of data
• Support over 5 years
• Computer viruses
• Compatibility with future EMR directions
Acknowledgements

- AMQuIP Funding
  - Johnson K
  - Iedema R
  - Rubin G
  - Stelter K
  - Sara A
  - Boyages S
  - Rees D
  - Parle A
  - Gellatley W
  - Rappo J
  - Carlton K
  - Michael R
  - Thiele M
  - GPs, Rheumatologists,
  - PATIENTS

- NHMRC Funding
  - Johnson K
  - Iedema R
  - Rubin G
  - Westbrook J
  - McCauley V
  - Broadbent M
  - Forsyth R
  - Maddock C
  - Rappo J