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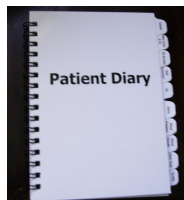 Use of patient-held paper-based & electronic-based portable health files (PHFs) to facilitate reliable health knowledge transfer among direct health-care providers and their consumer- patients: a clinical trial.

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Patient Diary

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, maligancy, 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**
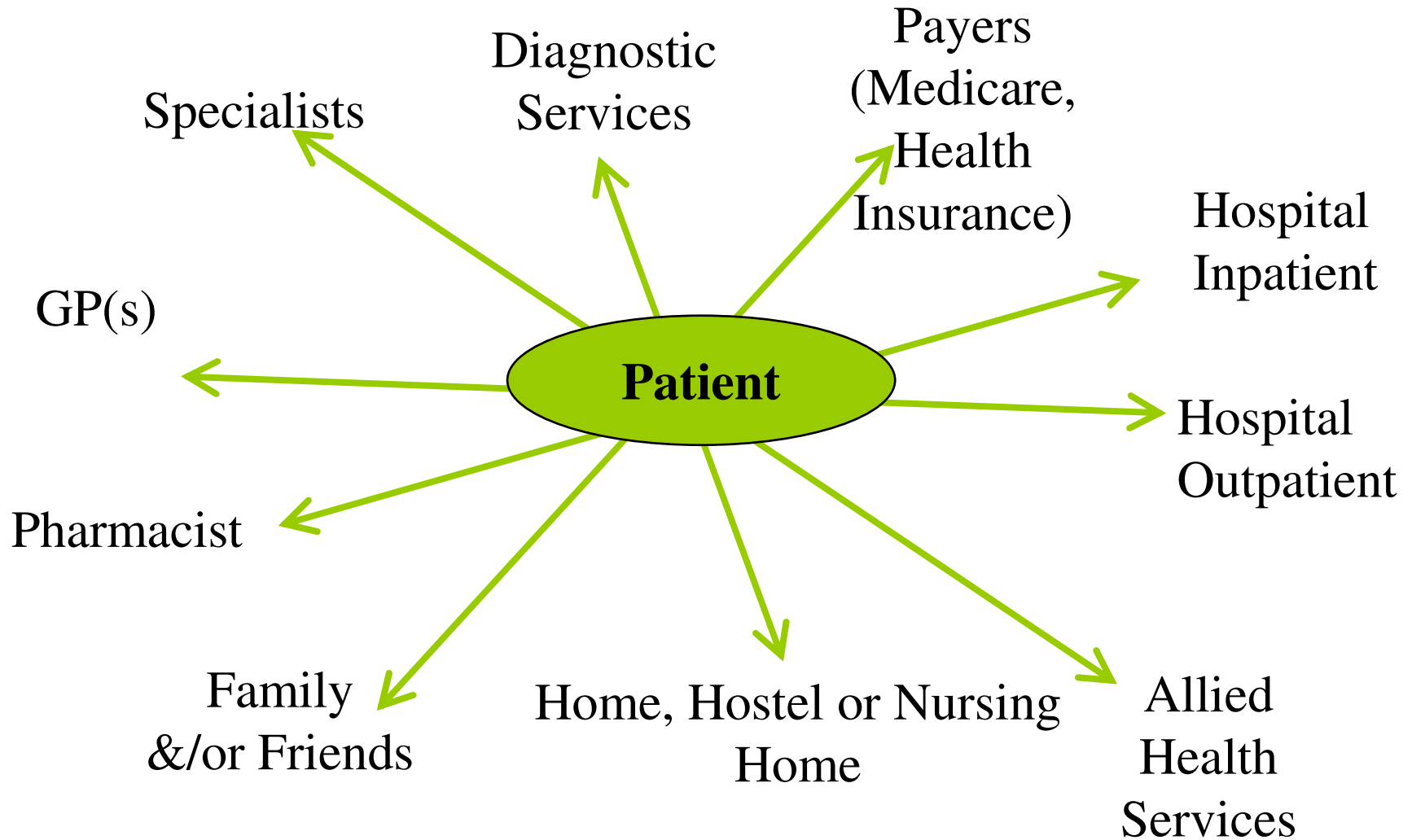
Information Communication

- 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
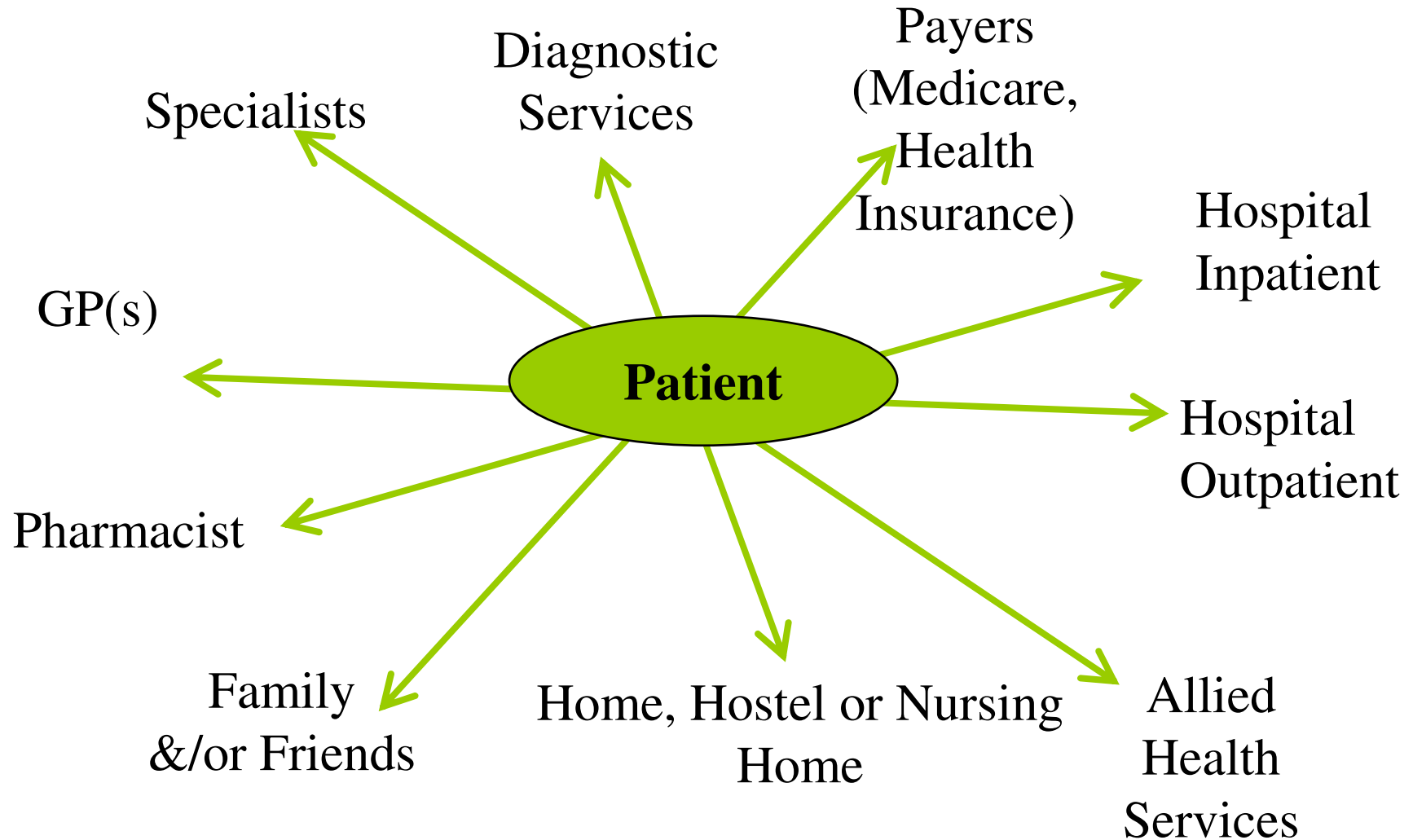- Frustrated and helpless providers and patients

Patient is in the Centre

Bottom-Up Approach : Patient is the 'Glue'
Information Communication
Follows the 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**
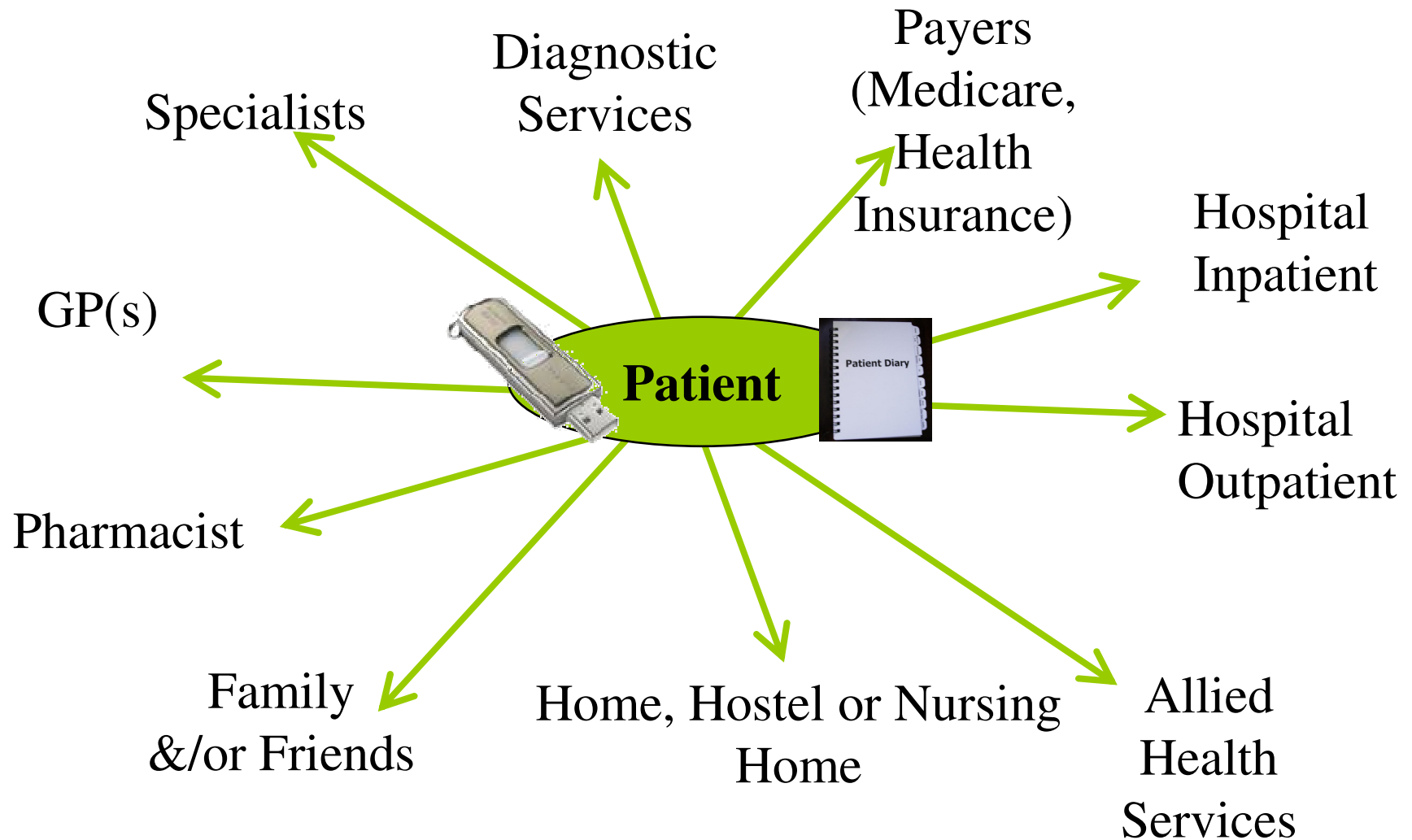
E-HealthTop-Down Approach

Providing a roadmap to achieve system interoperability

nehta
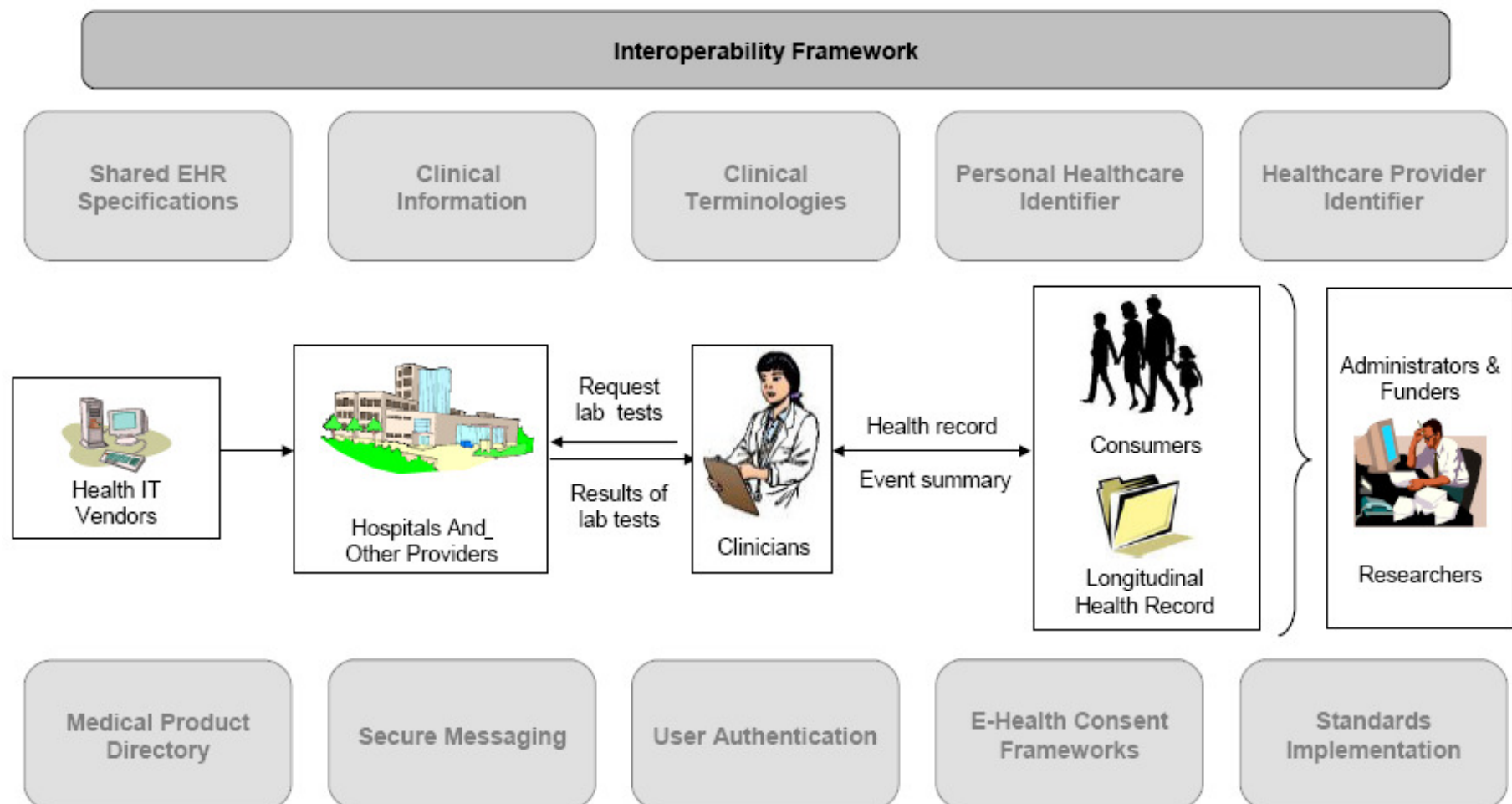
Project: alternative solution while we wait for Top-Down to be rolled out

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).
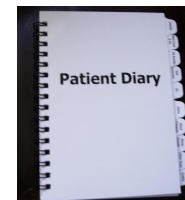
Methods

- 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
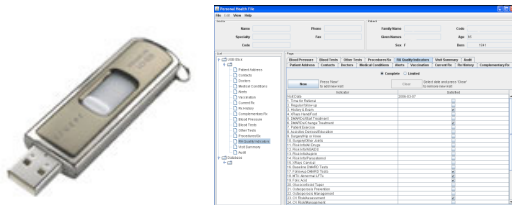
Methods (2)

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$_{v2}$

  - paper PHF

  - electronic PHF
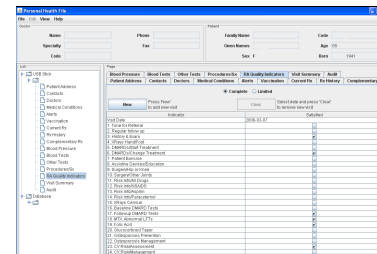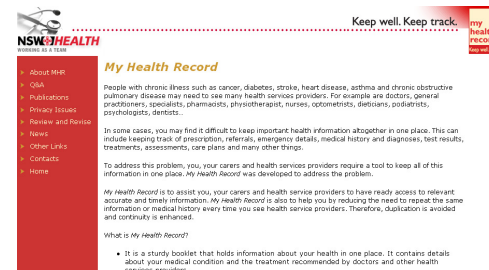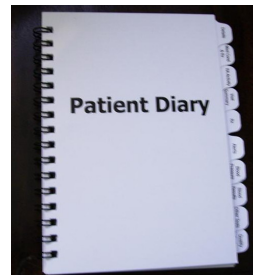
Methods (2)

- **Method of allocation to interventions**
  - 1st 25% allocated to no PHF (control)
  - 2nd 25% allocated to NSW Health My Health Record
  - 3rd 25% allocated paper-PHF
  - 4th 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
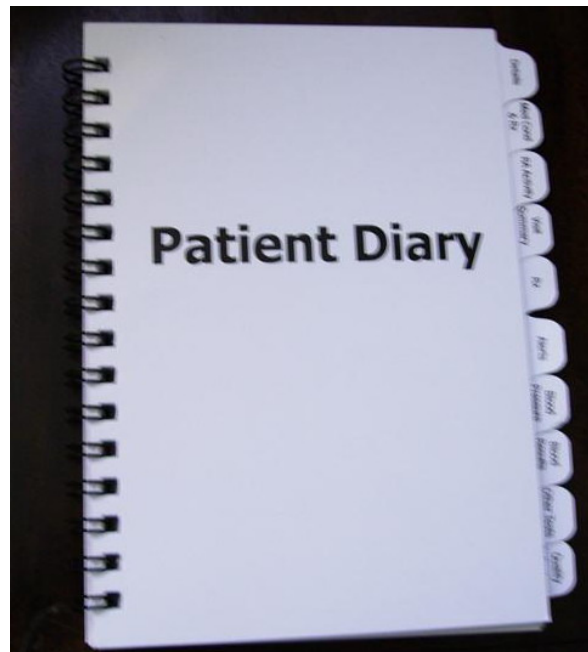
Results (1) e-PHF v1/v2

- **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

Personal Health File

File Edit **View** **Help**

Doctor

Name		**Phone**	
Specialty		**Fax**	
Code			

Patient

Family Name		**Code**	
Given Names		**Age**	65
Sex	F	**Born**	1941

List

- USB Stick
  - Patient Address
  - Contacts
  - Doctors
  - Medical Conditions
  - Alerts
  - Vaccination
  - Current Rx
  - Rx History
  - Complementary Rx
  - Blood Pressure
  - Blood Tests
  - Other Tests
  - Procedures/Sx
  - RA Quality Indicators
  - Visit Summary
  - Audit
- Database

Page

Tabs: Blood Pressure | Blood Tests | Other Tests | Procedures/Sx | **RA Quality Indicators** | Visit Summary | Audit

Patient Address | Contacts | Doctors | Medical Conditions | Alerts | Vaccination | Current Rx | Rx History | Complementary Rx

● Complete   ○ Limited

New	Press 'New' to add new visit	**Clear**	Select date and press 'Clear' to remove new visit

Indicator	Satisfied
Visit Date	2006-03-07
1. Time for Referral	☐
2. Regular follow up	☐
3. History & Exam	✔
4. XRays Hand/Foot	☐
5. DMARDs/Start Treatment	☐
6. DMARDs/Change Treatment	✔
7. Patient Exercise	☐
8. Assistive Devices/Education	☐
9. Surgery/Hip or Knee	☐
10. Surgery/Other Joints	☐
11. Risk Info/All Drugs	☐
12. Risk Info/NSAIDS	☐
13. Risk Info/Aspirin	☐
14. Risk Info/Paracetemol	☐
15. XRays Cervical	☐
16. Baseline DMARD Tests	☐
17. Followup DMARD Tests	✔
18. MTX: Abnormal LFTs	✔
19. Folic Acid	✔
20. Glucocorticoid Taper	☐
21. Osteoporosis Prevention	☐
22. Osteoporosis Management	☐
23. CV Risk/Assessment	✔
24. CV Risk/Management	☐

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 **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 <u>limited by its size, duration and early prototype PHFs</u>**

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

Patient Diary
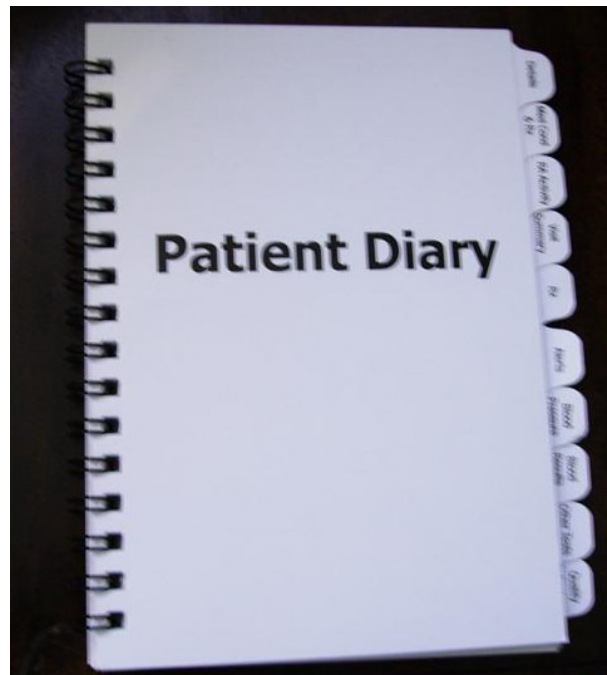
ARM 3

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 a 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