FACULTY OF HEALTH SCIENCES

UNIVERSITY OF CAPE TOWN

Cancer Research Initiative Hospital Database Seminar December 2018

Cancer Research Initiative

UNIVERSITY OF CAPE TOWN
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Hospital-based cancer databases – Sep 2017 meeting

- CRI raised funds for 3 years of database support
  - CRI will appoint a research person with database experience to support groups wanting to set-up a hospital database
  - CRI will fund Clinical Research Centre support required for development and maintenance of a secure database, using Redcap
  - Ideally set up and support 3 new databases by 2020

CRI areas of support

Development/Migration	✓ **Create variables/forms in REDCap from scratch or adapt from existing instruments/sheets/database forms**
Training	✓ **We offer 2 hours training course per week over 6 weeks in Clinical Data Management (Using REDCap)**
Implementation	✓ **Fixed number of hours per week to assist with implementation or orientation of the database in the clinic** ✓ **Assist with figuring out database workflows and document them** ✓ **Assist with figuring out quality control measures to be put in place and documenting them** ✓ **Not capturing data for databases; but assist those capturing data when they run into technical problems relating to data management systems in their first few weeks of capturing**
Trouble-shooting	✓ **Support for a number of hours per month to assist with any database problems that crop up, or new team members that need database orientation**
Further development and Training	✓ **Creating new variables/forms either from scratch or by adapting existing instruments/sheets/databases forms to integrate into existing database, or refine existing database**

CRI current support status

	Development	Migration	Training	Implementation	Troubleshooting	Further development
1						
2						
3						
4						
5						
6						
7						
8						

Challenges

- Lack of Standard operating Procedures
- Overly complex/Long case report forms (CRFs)
- Lack of planning for implementation
- Validation

Lack of Standard Operating Procedures (SOPs)

DB either totally lack SOPs or completely ignore existing ones because they're outdated

Imagine having to find directions in a puzzling situation

Overly complex/long case report forms

- A database with a large number of variables may allow for good analyses, but may be very burdensome as to discourage investigator and patient enrolments.

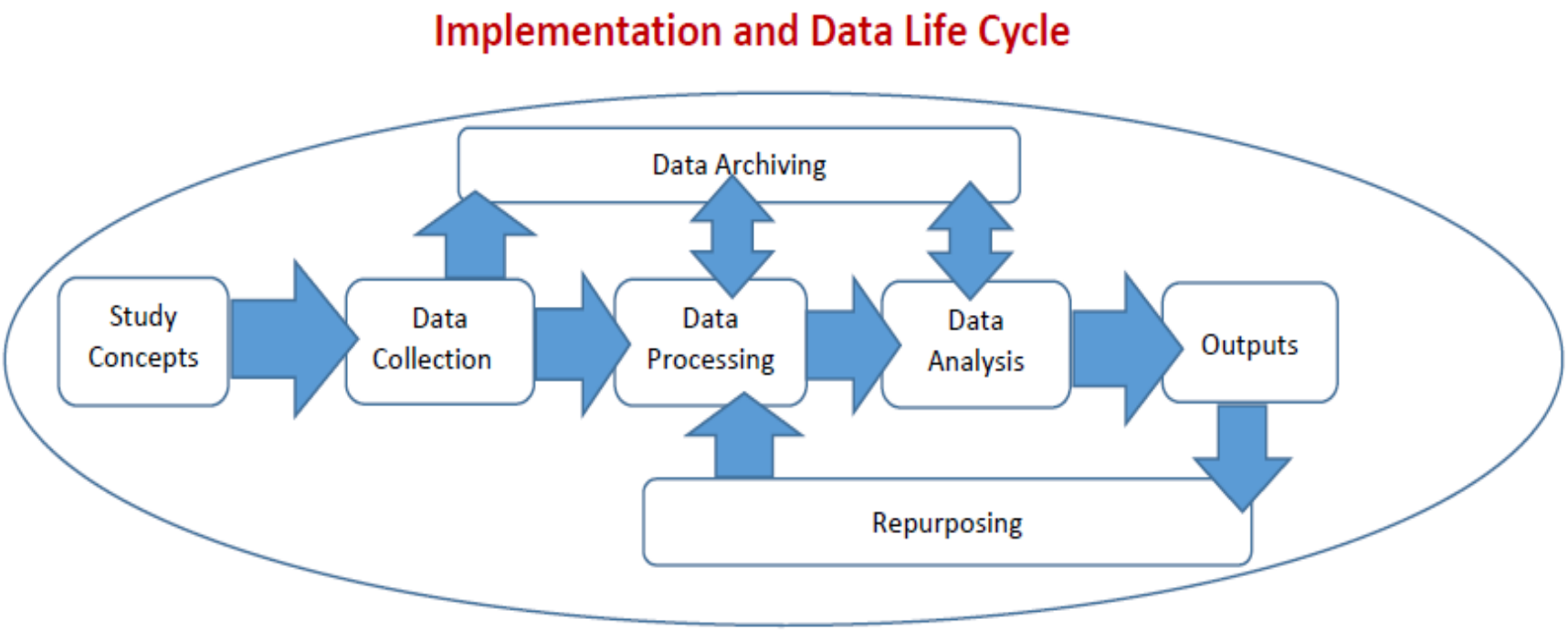
- Variables

  Min 45

  Max 390

Lack of planning for implementation

- It is Important to plan from the beginning **(who is responsible for what in the process)**
- Ensure adherence to routine practises **(cleaning, storage, validation and sharing)**



Data Validation

Ensuring data undergoes cleaning to ensure that it meets quality standards

- Checking and consolidating duplicating data
- Checking CRF against hospital records
- Computerised checks- REDCap has inbuilt quality checks
- Generating performance or operational reports

Support for Cancer Databases

Linda.Mbuthini@uct.ac.za

REDCap support

RedCap@uct.ac.za

CRI Resource Page

http://www.health.uct.ac.za/resources-32

Thank You!

Registry Development

Insights into Privacy, Confidentiality and informed Consent

Prof Marc Blockman

December 2018

Registries

Registries or data banks are collections of information or databases whose organisers:

- Receive information from multiple sources.
- Maintain the information over time.
- Control access to and use of the information by multiple users or for multiple purposes which may change over time.

Registries often contain codes that link information and specimens to their donors' identity.

Examples of South African registries include the National Cancer Registry, the Hereditary Colorectal Cancer Registry, The South African Renal Registry; and the South African Bone Marrow Registry.

What is the difference between Privacy and Confidentiality?

Privacy is about people.

Confidentiality is about data.

Definitions

- **Privacy** – about people and our sense of being in control of others access to ourselves or to information about ourselves with others.

- **Confidentiality** – treatment of identifiable, private information that has been **disclosed** to others; usually in a relationship of trust and with the expectation that it will not be divulged except in ways that have been previously agreed upon.

Privacy and Confidentiality are supported by two principles of the Belmont Report

- Respect for Persons
  - Individuals should be treated as autonomous agents
  - Allows individuals to exercise their autonomy, including the right to privacy and the right to have private information remain confidential.

- Beneficence
  - Do no harm
  - Minimize risk and maximize possible benefits

- Maintaining privacy and confidentiality reduces potential harms including psychological harm such as embarrassment or distress; social harms such as loss of employment or damage to one‘s financial standing; and criminal or civil liability.

HREC Regulations

In order to approve human subjects research, the HREC shall determine that where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data.

Privacy Issues

- Sensitivity of the information being collected – greater sensitivity = greater need for privacy
- Method of data collection
  - Will subjects feel comfortable providing the information in this manner?
- NOTE: Privacy is in the eye of the participant, not the researcher or the REC.

Methods to Maintain Confidentiality

- Restrict access to data (password protect, lock)
- If data stored on a computer; maintain on a standalone computer; no network connection
- Use encryption software, if data is accessed it is unable to be deciphered
- Minimize storage of subject identifiable data on a laptop computer, phones or flash drives which can be lost or stolen.

Informed Consent

Since a repository with linked or identifiable information may be used by many researchers and for many studies over time, informed consent is essential

Dr Joseph Mengele

POSNER'S TESTIMONY

- "In the workroom next to the dissecting room, fourteen Gypsy twins were waiting and crying bitterly. Dr Mengele didn't say a word to us, and prepared a 10cc and a 5cc syringe. From a box he took Evipal and from another box he took chloroform, and put these on the operating table. After that the first twin was brought in … a 14 year old girl. Dr Mengele ordered me to undress the child and put her head on the dissecting table. Then he injected the Evipal into her right arm intravenously. After the child had fallen asleep, he felt for the left ventricle of the heart and injected 10cc of chloroform … . After 1 little twitch the child was dead … in this manner all 14 were killed."

POSNER'S TESTIMONY

Mengele then removed the eyes from the dead twins and shipped them off to Berlin for further study.

Nuremburg Code 1948

- Emphasised the importance of **voluntary consent,** avoidance of unnecessary suffering and the observance of high scientific standards

- Adopted by the United Nations in 1948 as a guideline to research, but did not carry much legal weight

Not only in Germany

- Also Britain and the USA
- Dysentery vaccines given to orphans and institutionalised mentally disabled people
- Psychotic patients given malaria
- Penicillin given to prisoners in order to test the most effective dose
- **"It was felt that some sacrifices were necessary for the good of society"**

Tuskegee Syphilis Study 1932 – 1972

- US Public Health Service
- Labourers with syphilis
- Monitored for 40 years
- Even though a **proven cure (penicillin) available in the 1950s,** the participants weren't treated, but merely observed
- 1972: details were made public = political embarrassment

Consequences in the USA

- National Research Act of 1974
- **Belmont Report of 1979:**
  - 3 fundamental ethical principles
    - **Respect for persons**
    - Beneficence
    - Justice

The need to protect research subjects from abuse

- 1997: President Clinton apologised to the nation

Declaration of Helsinki 1964

- World Medical Association
- Statement of ethical principles to provide guidance to physicians and other participants in medical research involving human beings
- Updated 7 times: last amended 2013

Autonomy

- We are obliged to observe the right of a participant to determine what should or shouldn't be done to them
- **Respect for autonomy has priority over justice, beneficence & non-maleficence**
- Can't coerce anyone to participate in any study on the basis that:
  - There would be enormous benefit for either the subject or society in general
  - That great harm would ensue if the **experiment** weren't done

Informed consent

- Respect for autonomy is vital

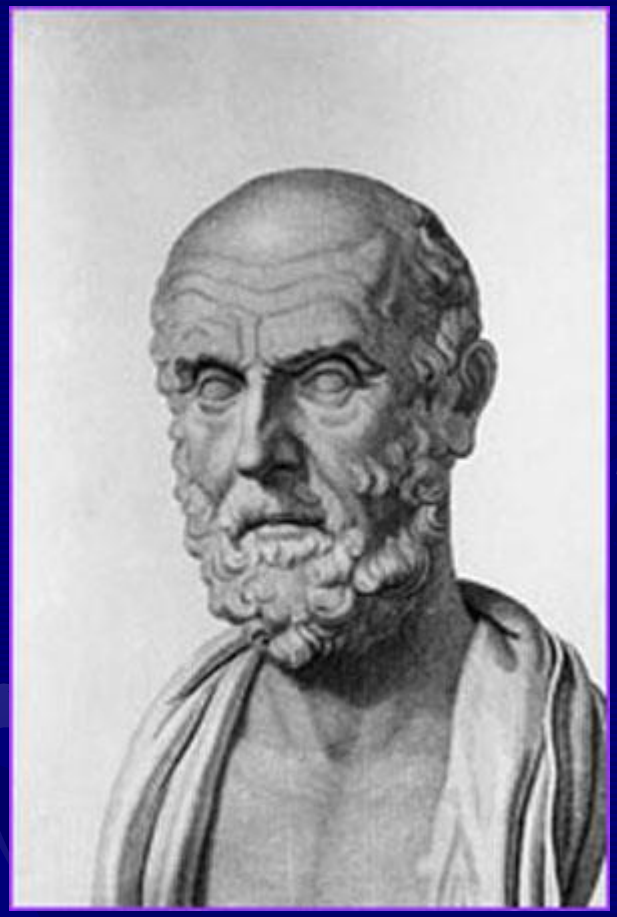
- Autonomy is abused if the participant is pressed into agreement to participate, or consent is based on inadequate information

Informed consent

- Comprehension is as important as the information provided – discussion should be carried out in layperson's terms & participants' understanding/comprehension assessed along the way

- NB: Legal rights are not eroded!

Hippocrates 5 BC



Hippocratic oath

- Medicine's earliest ethical precept:
- *"As to diseases, make a habit of two things – to help or at least to do no harm."*

- Confidentiality/data protection issues:
- *"Whatever I see or hear which ought not to be spoken of abroad, I will not divulge."*


Questions

How can the Provincial Health Data Centre help you with your RedCAP Cancer Registry?

Nicki Tiffin

nicki.tiffin@uct.ac.za

Andrew Boulle, Alexa Heekes

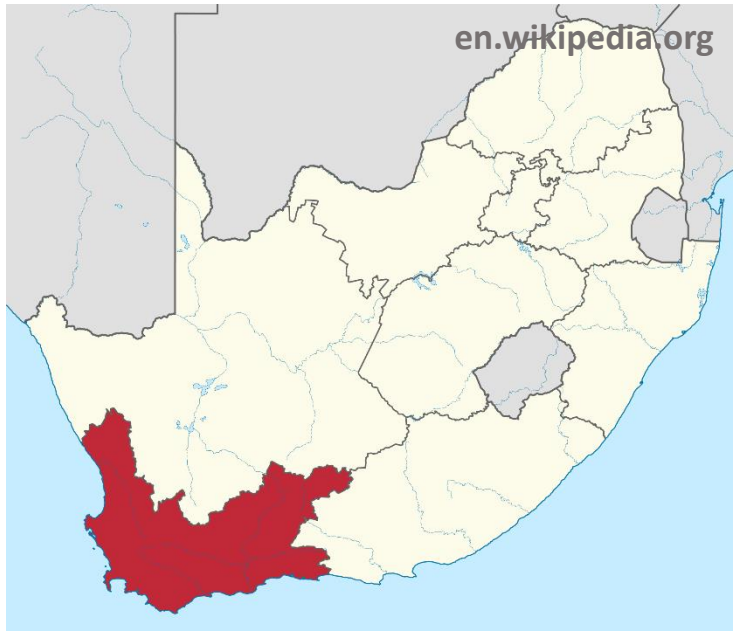
Department of Health, Western Cape Government

University of Cape Town

The Provincial Health Data Centre (PHDC)

- An African **Health Information Exchange**
- Developed and hosted at the Western Cape Department of Health

~ 6 million individuals



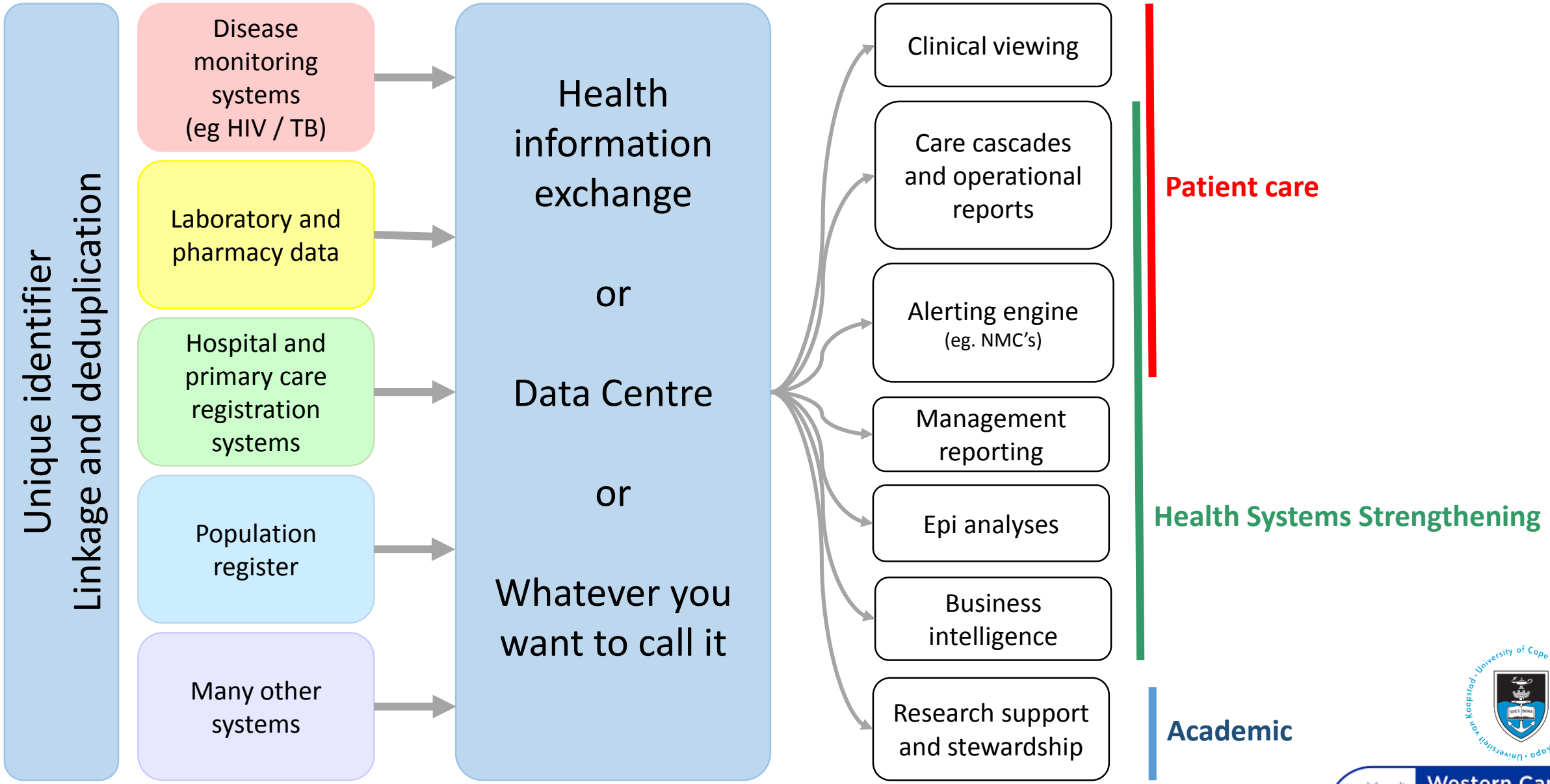
Routine electronic administrative records

- Individual patients
- Multiple data sources

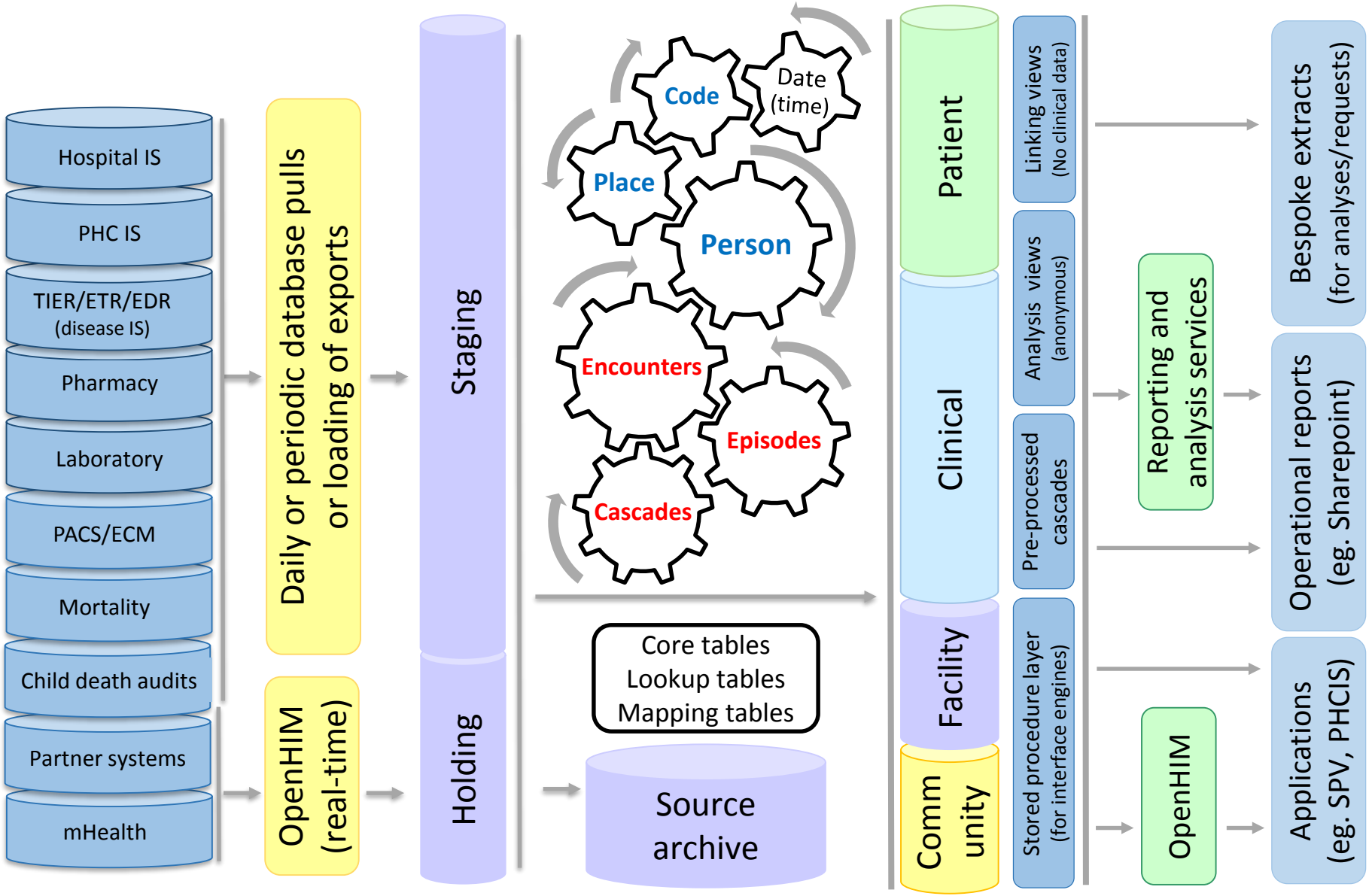
Linking of data to a Patient Master Index

- Facilitated by Province unique health ID

Western Cape Government
Health



High level architecture



What do PHDC data look like?

- Longitudinal administrative health data for all health care clients in Western Cape
- Laboratory, pharmacy, healthcare encounters
- Updated daily – valid up to midnight last night.

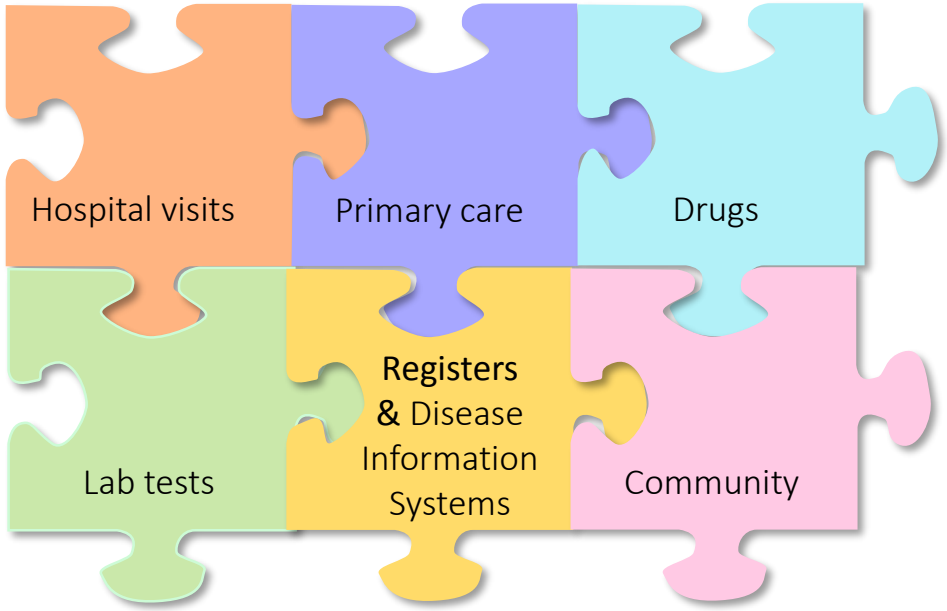
- Derived information: episodes, cascades

– identify burden of disease

– identify outcomes

– identify gaps in care

How are episodes defined?



Outcome	•Evidence of an outcome for the episode •High confidence score
High confidence	•Strong enough evidence to start an episode •High confidence score
Weak-Moderate evidence	•Able to start an episode, however more evidence is required to improve confidence in the episode
Supporting only	•Can only be appended to existing episode - not strong enough to start an episode •Improves confidence in existing episodes

Pregnancy example

Evidence	Source	Category	Date
Rhesus test performed	Labs	High confidence	2015-01-23
Iron & Folate dispensed	Drugs	Supporting	2015-04-03
Has live birth record	Birth register	Outcome	2015-06-16
Has diagnosis code indicating live birth	Diagnosis codes	Weak-Moderate	2015-06-16

Rolled up into a single record per pregnancy

Patient	Pregnancy number	Start Date	End Date	Last Contact date	Evidence list	End date evidence list	Facility	Confidence
xxx	1	2015-01-23	2015-06-16	2015-06-16	Birth Record, Diagnosis code, Rhesus Test, Iron & Folate	Birth Record, Diagnosis code	MMH	0.95 ➔ High confidence

Western Cape Government
Health

Cancer episodes defined to date

Type	Total alive (2017)	New (2017)
Breast cancer	19809	2546
Cervical cancer	14183	1611
Lung cancer	5926	1647

Using PHDC data for registries

Considerations:

- Implicit provider-client agreement that data are for providing health care
- No consent for research or secondary data use
- Incomplete data coverage, data limitations

A model for RedCAP within the PHDC infrastructure

Routine health data

Health Provider

Clinical Ethics

Researcher

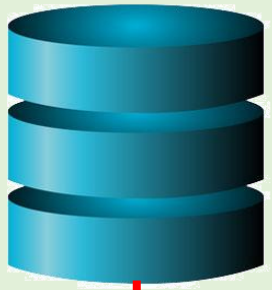
Informed consent

Additional research data

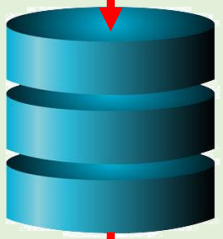
Clinicom, PHCIS, NHLS, JAC, Tier, EDR, …

Data for consenting individuals

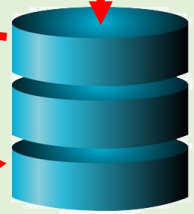
WCGH Server **FIREWALL**



Platform routine data



Data Centre



RedCAP Database

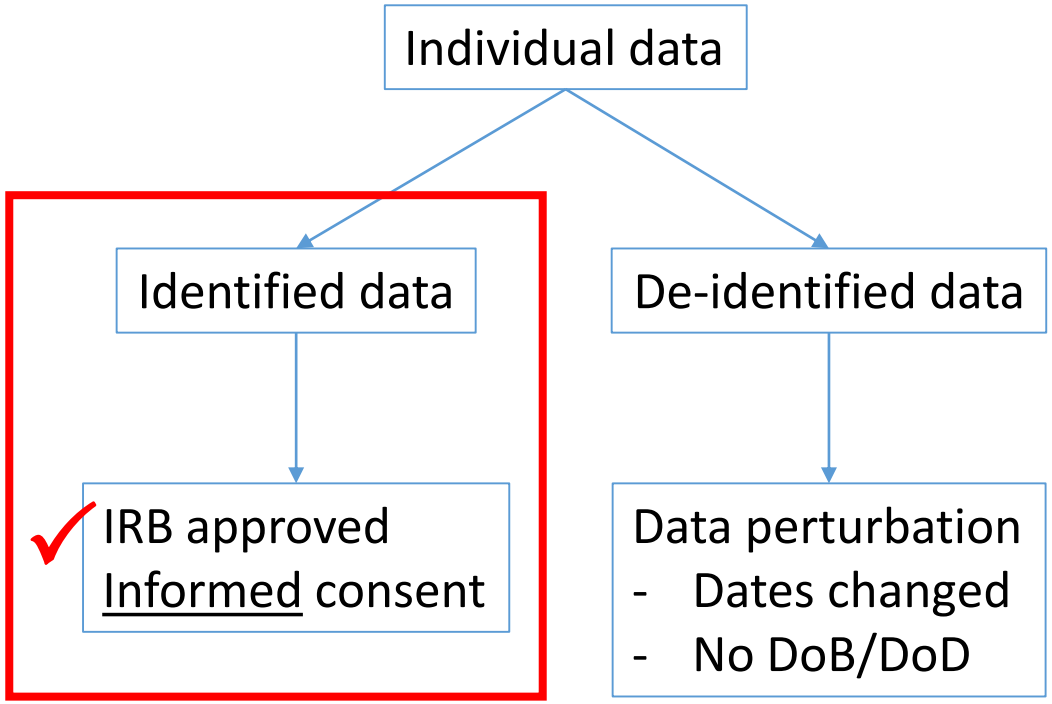
Western Cape Government

Health

Access model

Data privacy ↔ Data use to improve health

Research requests: Research use from outside the DoH



Thank you

PHDC:

Andrew Boulle

Alexa Heekes

Mariette Smith

Themba Mutemaringa

Nesbert Zinyakatira

Florence Phelanyane

Njabulo Dube

Cara Peinaar

HIA Directorate

FUNDING:

Wellcome CIDRI-AFRICA grant (203135/Z/16/Z)

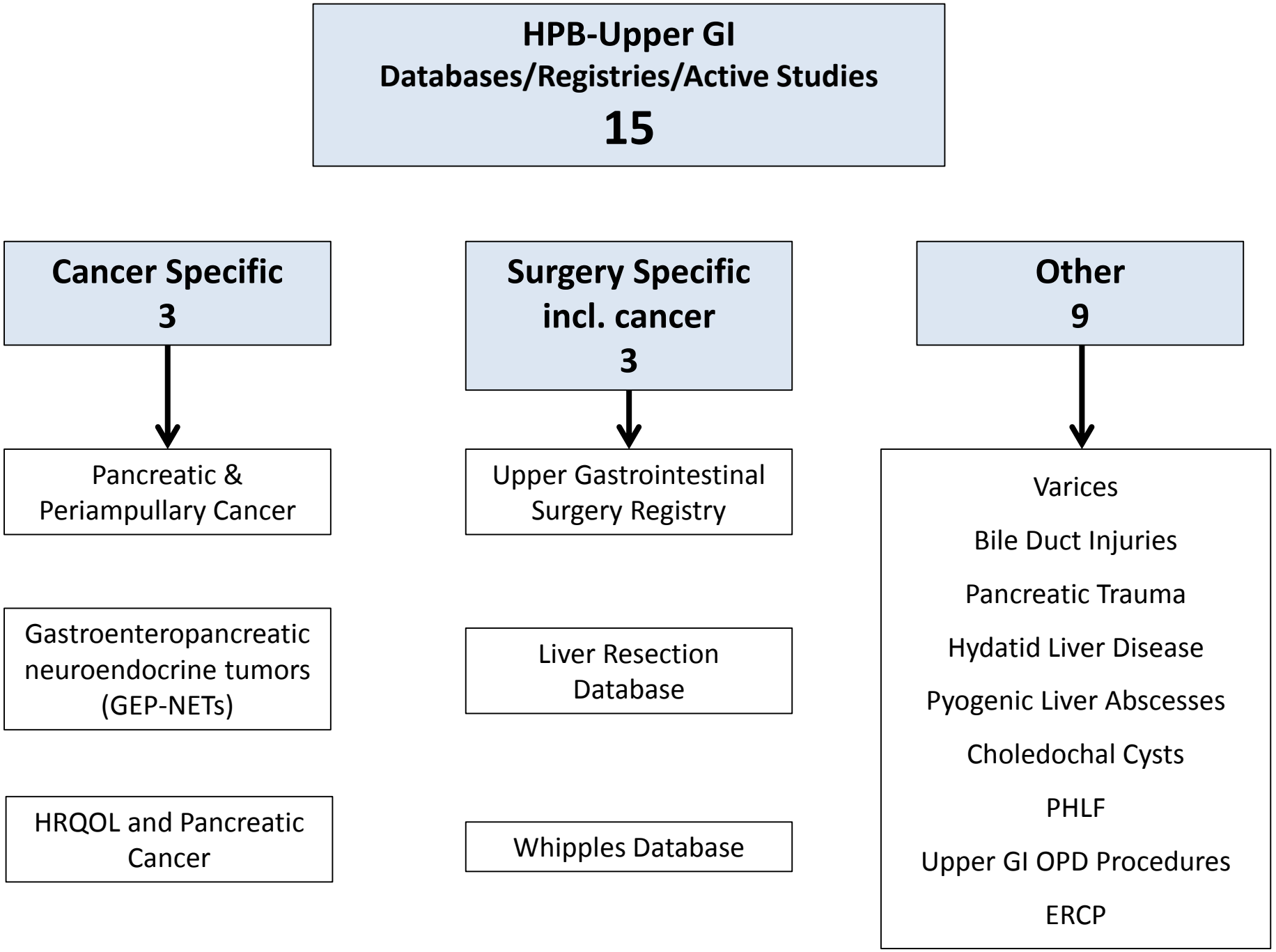
The National Institute of Child Health and Development (NIH, USA): B-Positive R01HD080465

The Bill and Melinda Gates foundation: The African Health Information Exchange: OPP1164272

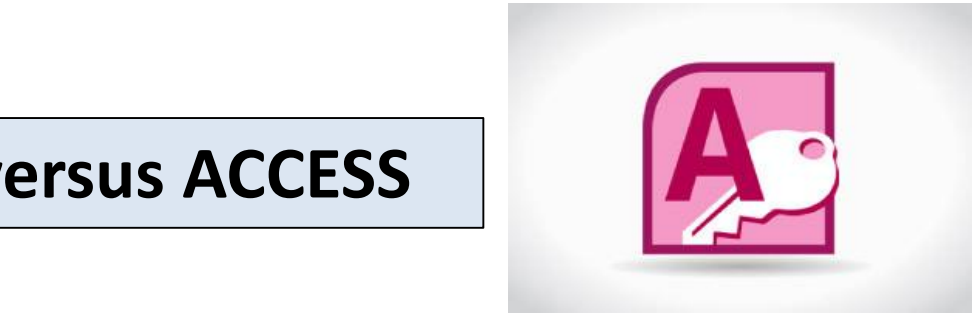
National Human Genome Research Institute (NHGRI), National Institutes Of Health (OD) H3ABioNet award, number U24HG00694

HPB and Upper GI Surgery Unit

CRI Database Seminar 06 December 2018


HPB-Upper GI
Databases/Registries/Active Studies
15
Cancer Specific
3
Surgery Specific
incl. cancer
3
Other
9
Pancreatic &
Periampullary Cancer
Gastroenteropancreatic
neuroendocrine tumors
(GEP-NETs)
HRQOL and Pancreatic
Cancer
Upper Gastrointestinal
Surgery Registry
Liver Resection
Database
Whipples Database
Varices
Bile Duct Injuries
Pancreatic Trauma
Hydatid Liver Disease
Pyogenic Liver Abscesses
Choledochal Cysts
PHLF
Upper GI OPD Procedures
ERCP

REDCap versus ACCESS



Cancer Specific 3	Surgery Specific incl. cancer 3	Other 9
		PHLF
Pancreatic & Periampullary Cancer	Upper Gastrointestinal Surgery Registry	ERCP
		Varices
Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	Liver Resection Database	Bile Duct Injuries
		Pancreatic Trauma
		Hydatid Liver Disease
HRQOL and Pancreatic Cancer	Whipples Database	Pyogenic Liver Abscess
		Choledochal Cysts
		Upper GI OPD Procedures

Surgery Specific Databases

Upper Gastrointestinal Surgery Registry	Est Nov 2016 Retrospective up to 2013 Prospective data collection **n=578** Oesophageal Cancer n=40 OGJ Cancer n=35 Gastric Cancer n=205
Liver Resection Database	Est 1990 (ongoing) Prospective data collection **n=535** CRCLM n=268 HCC n=44 Cholangiocarcinoma n=34
Whipples Database	Est 1990 (discontinued 2016, now data collected in Pancreatic Cancer database on REDCap) Prospective data collection **n=245** Pancreatic Adenocarcinoma n=69 Ampullary carcinoma n=67 Cholangiocarcinoma n=30

Cancer Specific Database

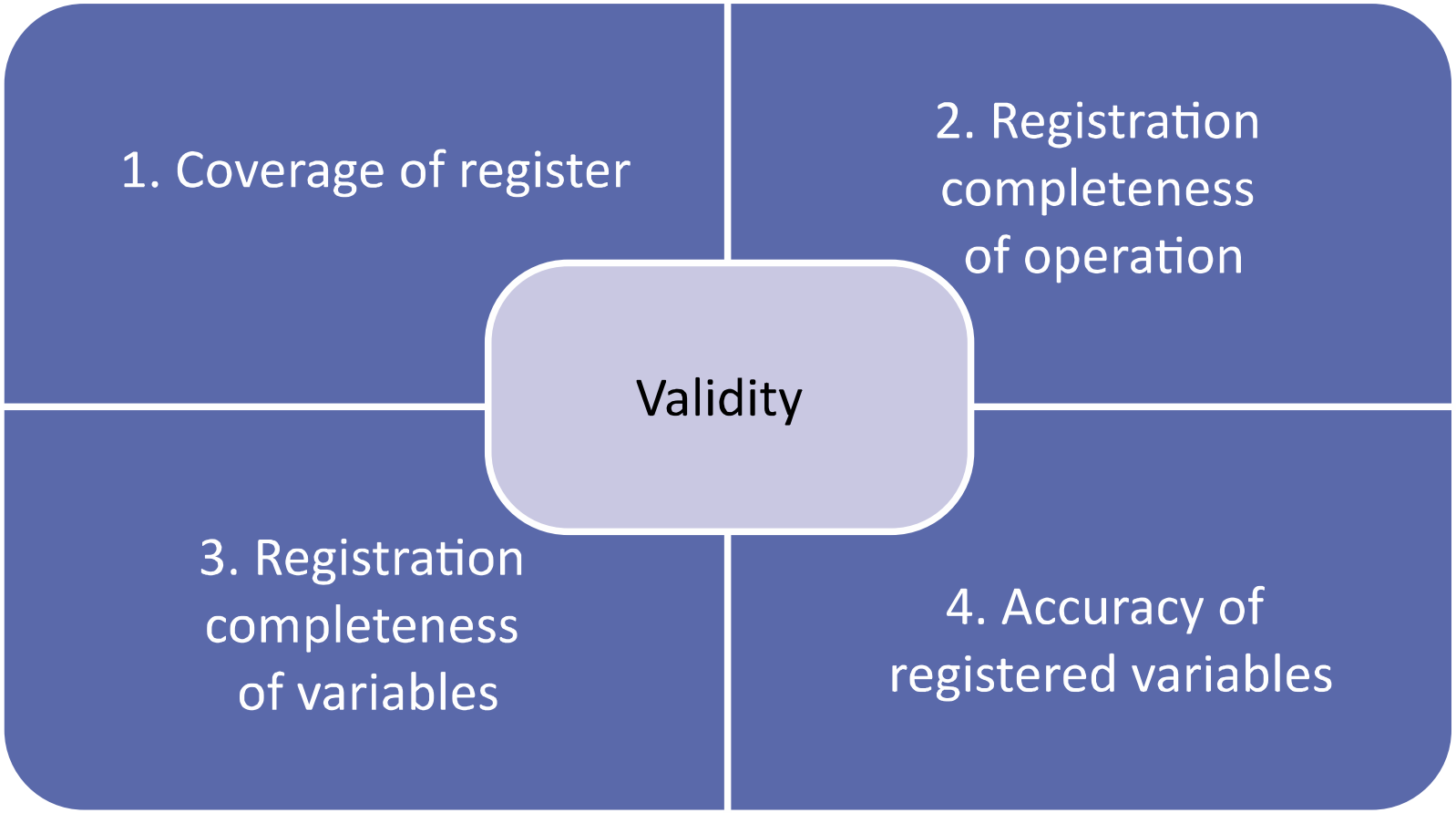
Pancreatic & Periampullary Cancer	Est Oct 2016 Prospective data collection **n=243**
Gastroenteropancreatic neuroendocrine tumours (GEP-NETs)	Est Sept 2017 Retrospective up to 2013 Prospective data collection **n=104**

Database Instruments

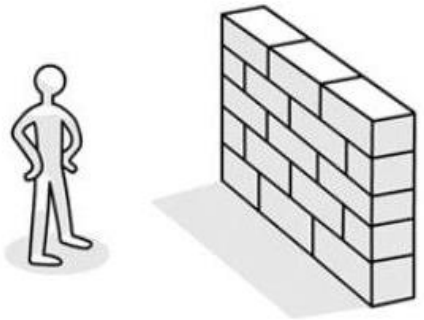
NEW 123456

Data Collection Instrument	Status
Basic Demography	
Baseline Visit	
Blood Results	
Staging Investigations	
Interventions	
Baseline Histology / Cytology	
MDT	
Codman Score	
Definitive Surgery (Curative Sx)	
Bypass Surgery	
Pathology TNM	
Pathology intra-operative biopsy	
Post-operative Course	
Oncology	
Follow-up	
Patient Contact	
Outcome	

Quality Assurance = Validation



Challenges

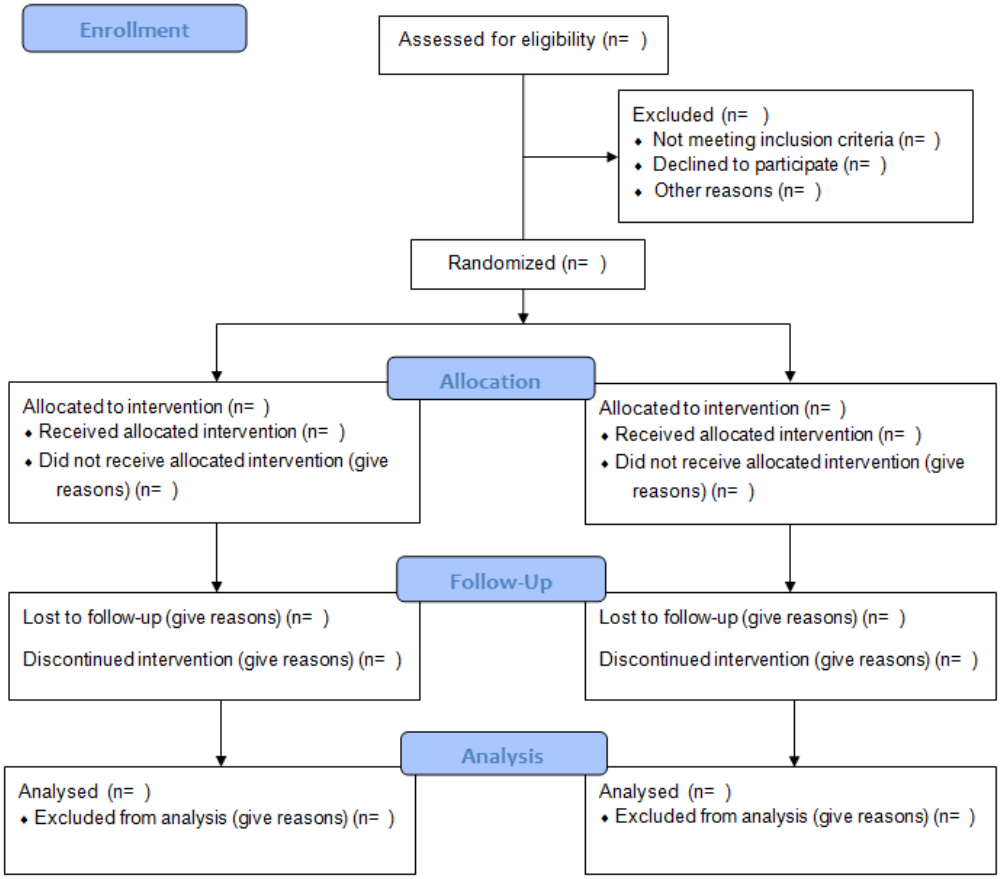


- No reliable hospital database
- No access to the death registry
- On-line access
- Paper patient documentation
- Difficult follow-up
- Non-compliance of clinicians
- No dedicated resources

Challenges with Research Requirements

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram



What are we doing with the cancer related data?

Academic related activities

Registry (2016-2018)	PhD MPhil MMed	Local Presentations	International Presentations	Peer-reviewed Publications
Upper GI Surgery Registry	3	6	4	1
Pancreatic & Periampullary Cancer	3	2	3	-
Liver Resection	1	4	-	2
GP-NET	1	-	-	-

Translational research activities

Clinical auditing tool

- **Clinical Data Management Course at CRC and sponsored by CRI**
- **Site Visit by Linda (CRI)**

  troubleshooting with databases

  guidance in drawing up SOP
- **Help is just an email /telephone call away**

  Linda, Annemie, Amanda, Chedwin

Cancer Research Initiative

UNIVERSITY OF CAPE TOWN

UCT CLINICAL RESEARCH CENTRE

every step of the study

Purposeful, Planned, Positive

PALLIATIVE CARE

Palliative Care Database

Palliative Care Team GSH

Number of databases

- One version 2 (removed data)
- Keeping it as simple as possible

Why and how long:

Purposeful, Planned, Positive
PALLIATIVE CARE

- New program not disease specific.
- Program evaluation
- Where, where not, what services, by whom, readmissions.

- Started in 2016
  - Developed with a small grant from Internal Medicine
  - 1 800 patients on database

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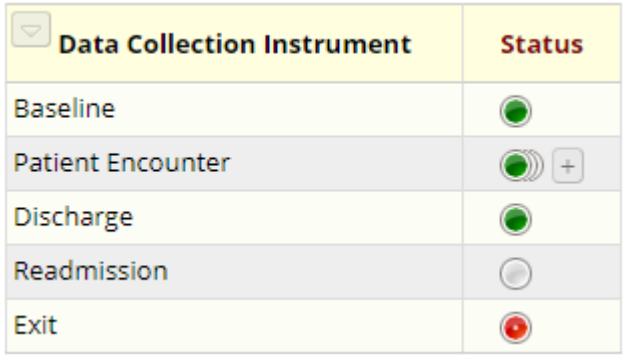
Domains

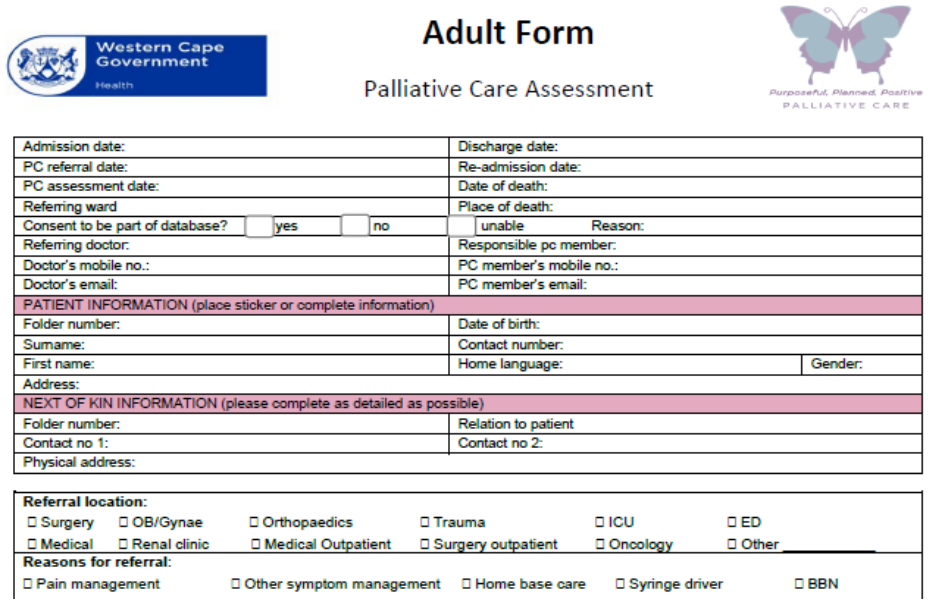
- Demographics
- Reasons for referral and diagnoses (as given to us)
- PC needs assessment at referral
- Follow up encounters
- Discharge history (where to and when)
- Readmission: why and when
- Exit: date of discharge; date of death; bereavement phone call



Data Collection Instrument	Status
Baseline	
Patient Encounter	
Discharge	
Readmission	
Exit	

Data collection

- PC assessment aligned with database
- PC has clerk that enters the data.
  - UCT internet point
- Checked by myself and project manager.



Adult Form

Palliative Care Assessment

Admission date:	Discharge date:	
PC referral date:	Re-admission date:	
PC assessment date:	Date of death:	
Referring ward	Place of death:	
Consent to be part of database? ☐ yes ☐ no ☐ unable Reason:		
Referring doctor:	Responsible pc member:	
Doctor's mobile no.:	PC member's mobile no.:	
Doctor's email:	PC member's email:	
PATIENT INFORMATION (place sticker or complete information)		
Folder number:	Date of birth:	
Surname:	Contact number:	
First name:	Home language:	Gender:
Address:		
NEXT OF KIN INFORMATION (please complete as detailed as possible)		
Folder number:	Relation to patient	
Contact no 1:	Contact no 2:	
Physical address:		

Referral location:

☐ Surgery ☐ OB/Gynae ☐ Orthopaedics ☐ Trauma ☐ ICU ☐ ED

☐ Medical ☐ Renal clinic ☐ Medical Outpatient ☐ Surgery outpatient ☐ Oncology ☐ Other _____

Reasons for referral:

☐ Pain management ☐ Other symptom management ☐ Home base care ☐ Syringe driver ☐ BBN

Quality assurance

- Running of reports.
- We have checked using the files vs. database.
- Not done regularly enough.

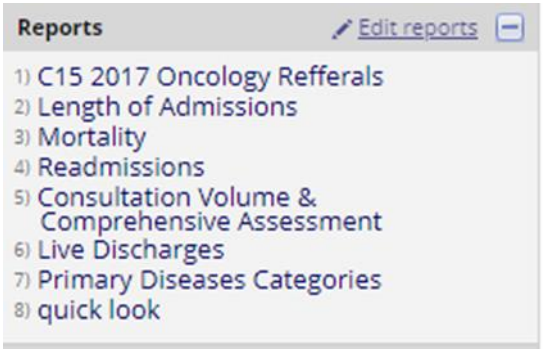
CRI support

- Training of staff
- Development of specific reports
- Constant “pop in support”

What are we doing with the data

Purposeful, Planned, Positive
PALLIATIVE CARE

- Specific reports
- Audits of program
- Targeted PC input



- Assist with developing monitoring and evaluation tools for provincial palliative care implementation.
- Research

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Challenges

- Data quality
- Time
- Consent in the very frail

Thank you

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CRI Database Seminar

Breast cancer database
REDCAP

Dr David Anderson
Consultant, Radiation Oncology
LE33
GSH

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1. Number of databases

- One
- Version 3
  - More concise
  - Fewer instruments

Hospital folder number **10315240** (,)

Data Collection Instrument	Cancer 1	Cancer2 (New or Recurrence)	Cancer3 (New or Recurrence)	Cancer4 (New or Recurrence)
Surgery / Oncology - Demographics				
Surgery - SOPD				
Oncology - Oncology Consult				
Surgery / Oncology - CBC				
Surgery - Operative Data				
Surgery - Perioperative Morbidity				
Surgery / Oncology - Post Op Data And Stage				
Oncology - Final oncology treatment plan				
Oncology - Recurrence / Metastasis				
Follow Up Palliative				

Repeating Instruments

Oncology - Oncology Consult
Cancer 1

2. Background

- Timeline
  - March 2017: Decision made to develop an EPR / database
  - June 2017: Roll out Version 1
    Instruments: 18
    Started in SOPD and CBC
  - July 17- Feb 18: Editing of instruments
  - March 2018: Version 2 “finalised”
  - Sept 2018: Reviewed the database
    25% of instruments being completed
  - Nov 2018: Version 3 roll out
    Abbreviated 10 instruments

3. Database domains

- Version 1 & 2
  - Demographics
  - Surgical consult
  - Oncology NEW consult
  - Results prep downstairs
  - CBC
  - Plan
  - Operative data
  - Peri-op morbidity
  - Oncology post op
  - Chemotherapy
    - Radical
    - Palliative
  - Radiation
    - Radical
    - Palliative
  - Follow up
  - Treatment completion
  - Palliative

- Version 3

Data Collection Instrument
Surgery / Oncology - Demographics
Surgery - SOPD
Oncology - Oncology Consult
Surgery / Oncology - CBC
Surgery - Operative Data
Surgery - Perioperative Morbidity
Surgery / Oncology - Post Op Data And Stage
Oncology - Final oncology treatment plan
Oncology - Recurrence / Metastasis
Follow Up Palliative

Breast EPR

Save & Exit Form | Save & Go To Next Form | -- Cancel --

Actions: Download PDF of instrument(s) | Share instrument in the Library | VIDEO: Basic dat

Surgery / Oncology - Demographics

Editing existing Hospital folder number **10394104** (Adams, Mary-Anne)

Event Name: **Cancer 1**

Hospital folder number	10394104
Today's date	10-11-2017 Today D-M-Y
SA ID number / Passport number	
Patient referred from	Private GP
Patient	
First Name	Mary-Anne
Middle name	
Surname	Adams
Contact Information - Participant	
Phone number (own, 1)	
Phone number (own, 2)	
E-mail	
Contact Information - Alternative contact person	
Contact person	
Contact telephone	
Relationship to participant	
Demographic characteristics	
Date of birth	21-04-1976 Today D-M-Y
Age today (years)	42 View equation
Sex	Female Male Other

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Breast EPR

Save & Exit Form | Save & Go To Next | -- Cancel --

Actions: Download PDF of instrument(s) | Share instrument in the Library | VIDEO: Basic dat

Surgery - SOPD

Editing existing Hospital folder number **10394104** (Adams, Mary-Anne)

Event Name: **Cancer 1**

Hospital folder number	10394104
Date of consultation in SOPD	10-11-2017 Today D-M-Y
BREAST Symptoms	
Breast Complaint	○ Asymptomatic ◉ Symptomatic reset
Duration of symptoms (number of months - use decimal to indicate weeks)	12.0 0.1 = 1 week / 1.0 = 1 month
Symptoms	

	Right	Left	None
Screen detected lesions * must provide value	☐	☐	☑
Any symptoms * must provide value	☑	☐	☐
Lump * must provide value	☑	☐	☐
Nipple discharge * must provide value	☐	☐	☐
Mastalgia * must provide value	☐	☐	☐
Other (additional) breast symptom(s) * must provide value	☐	☐	☐

Currently breastfeeding	○ Yes ◉ No reset
Pregnant	○ Yes ◉ No reset
PREVIOUS BREAST HISTORY	
Previous Mammogram	○ Yes ◉ No reset

-- Cancel --

ENDOCRINE HISTORY	
Number of pregnancies	3 (0 - 20)
Age when her 1st child was born	21 (14 - 40)
History of Breastfeeding	(•) Yes ( ) No reset
Current contraception use	( ) Yes (•) No reset
Menopause status	Pre
PAST MEDICAL AND SURGICAL HISTORY	
Any other medical history	( ) Yes (•) No reset
SOCIAL HISTORY	
Smoker	(•) Yes ( ) No reset
Alcohol use	( ) Yes (•) No reset
OCCUPATIONAL HISTORY	
Were you ever employed	(•) Yes ( ) No reset
Did you ever work night shift?	(•) Yes ( ) No reset
CLINICAL EXAMINATION	
Laterality	[x] Right [ ] Left
RIGHT	
cT	T3
cN	N0
Form Status	
Complete?	Incomplete

4. Who collects it

- By far the biggest problem!
- Split surgery and oncology responsibilities
  - Instruments are named according to responsibility
- Registrars and consultants
- Dedicated MO time
- Nurse specialist and intern
- How:
  - “real time” and retrospective
  - Paper and electronic

5. QA

- Very little
- Consent
  - CBC
- MO: Ongoing
- Consultants: Review x 1 (year after roll out)

6. Challenges

- GSH is a paper based system
  - Duplication
- Clinical burden
  - Patient numbers restrict real-time input
  - No dedicated “research” time (retrospective input)
- No integration of PACS / NHLS / Clinicom
- Lack internet access
- Lack of IT terminals
- Lack of printing access

7. Data usage

- Research
  - MMEDs
  - Retrospective audits
  - Pharma

- Planning
  - Patient numbers
    - Different breast cancer subgroups
  - Chemo / RT usage
  - Dept Health role outs

8. CRI Support

- Excellent
- Annemie Stewart
  - Planning
  - Teaching
  - Development
  - Improvements
- Future
  - Logistical issues are our focus


SPES
BONA

Gynaecological Cancer
Research Centre

Gynae oncology Databases

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

WSU
Walter Sisulu University

CRI Seminar: Hospital Cancer Databases

06 Dec 2018

Overview

GCRC Data management section

- The Data Section is responsible for the overall data management & maintenance of the all the gynae databases – collection to curation
- Provide intuitive interfaces with inherent data quality controls

Overview

GCRC Main databases:

- GSH Gynae Oncology
  - **9152 patients (pats)**
- East London Registry
  - **4052 pats**
- Colposcopy database
  - First Visit – **8741 pats**
  - Follow-up – **5649 pats**

Gynae Oncology Database

- Started in 1990
- Used a **dBase IV** database management system
- Entries of records
  - Retrospective records from1984 – 1989
  - Prospective records are from 1990 to date
- Database converted to C# & SQL in 2016
- The database runs on UCT network
  - we liaise with UCT ICTS for any changes on the database

East London Database

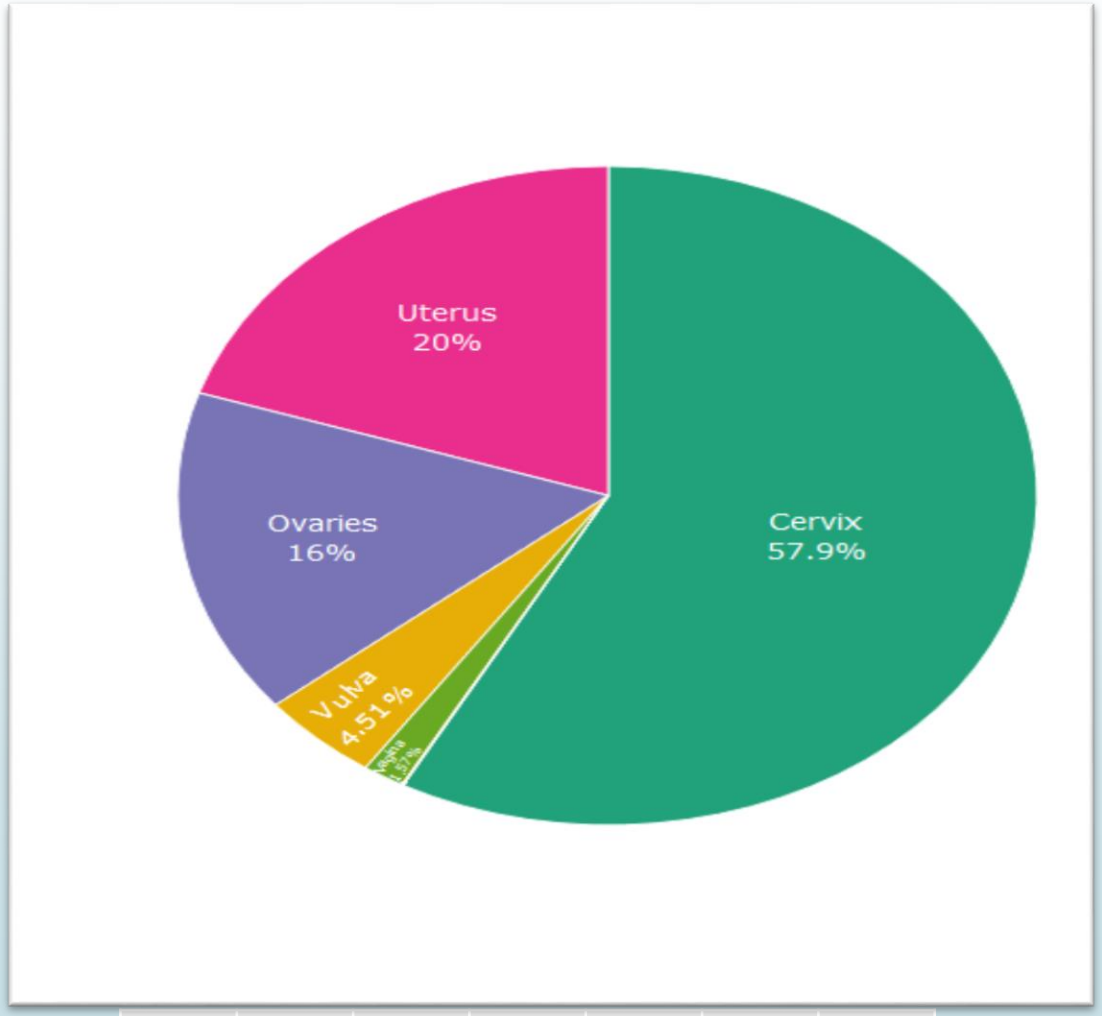
- Started in 2015
- Used a C# & SQL database management system
- Entries of records
  - Retrospective records 2008 – 2016
  - Prospective records from 2017 to date
- Moved to REDCap in 2017

Colposcopy Database

- Started 2010
- Initially on Access database
- Upgrade to C# & SQL database management system in 2016
- Currently moving to REDCap system

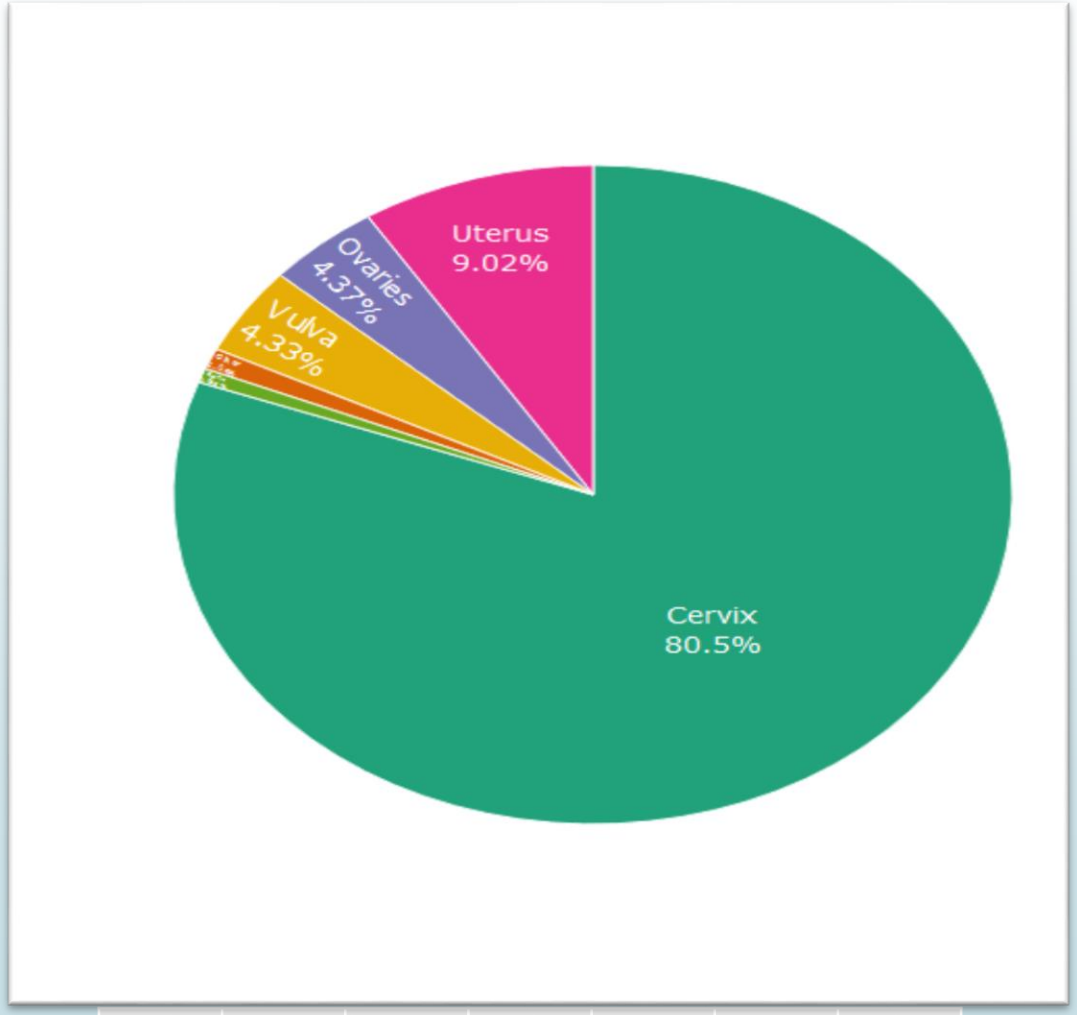
GCRC Cancer Summary

GSH Gynae Oncology - **9152**



Cancer	Cervix	GTN	Ovary	Uterus	Vagina	Vulva
Freq	5299	5	1465	1826	144	413

East London - **4052**



Cancer	Cervix	Other	Ovaries	Uterus	Vagina	Vulva
Freq	3259	42	177	365	28	175

Data Fields Collected

- Basic demographic
  - Age, DOB, Race etc
- HIV Status
- Cancer diagnosis
  - Type of cancer
  - Previous, synchronous or subsequent cancers.
- Diseases details
  - Stage
  - Histology
  - Treatment
  - Complications
- Cancer status
  - Relapse information
  - Response to treatment
  - Current living status (dead/alive)

Data Collection & Validation Process

- Use Case report form (CRF) to collect data
- Manual quality checking performed before data capturing
- REDCap setup with restrictions and quality control measures (*EL registry*)
- Data Capturer receives CRFs (*gynae oncology registry*)
  - Performs quality checks
  - Enter data on the electronic system
  - Communicates with Leon on issues arising on forms
- C# functions in-place to enforce data quality
    - Date fields verification
- Developed SQL scripts
  - Data verification & cleaning
  - Extract reports

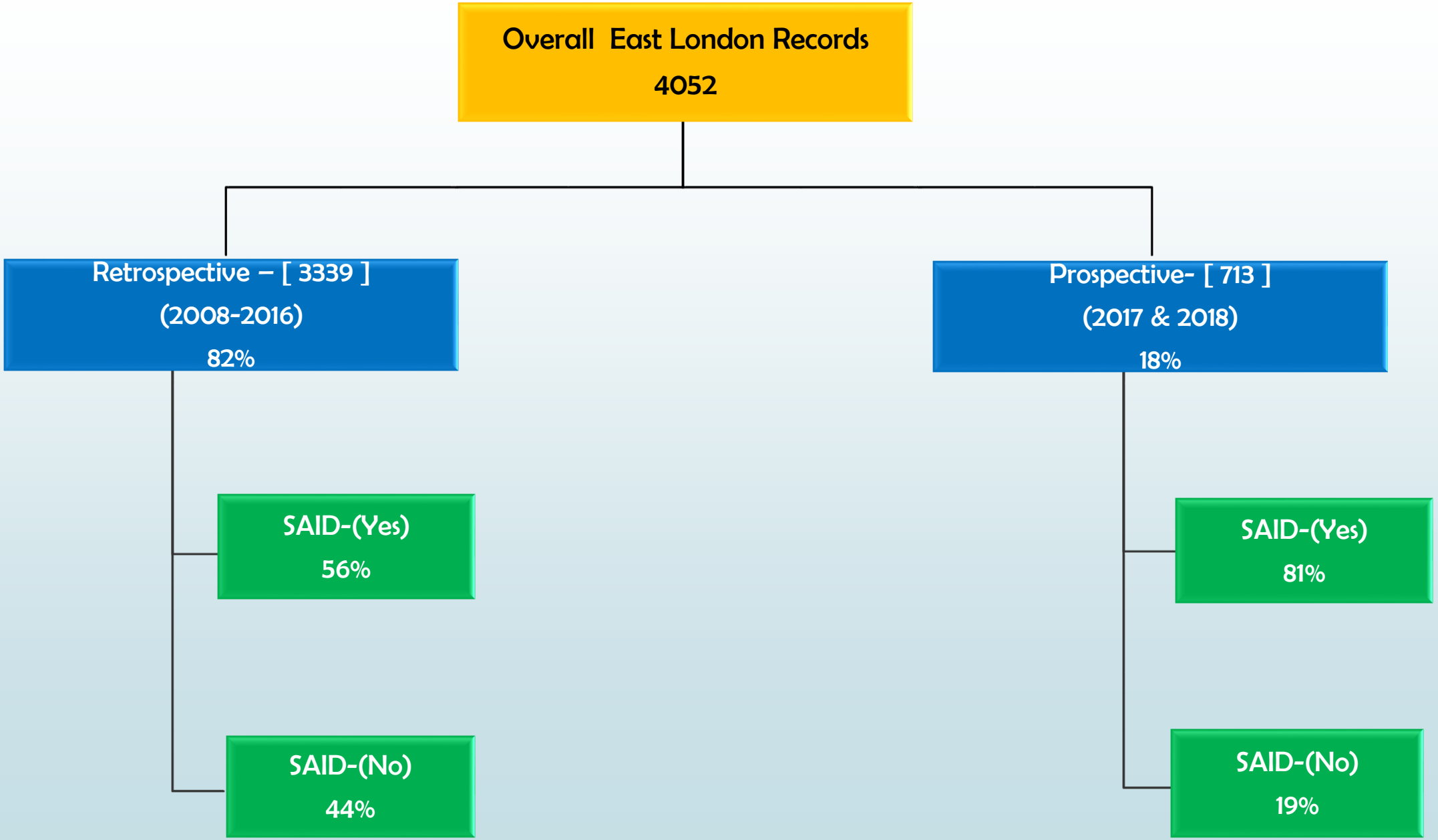
Database Uses

- Clinical Audits
  - Patient outcomes
  - Annual reports
- Research
  - Publications from MMed students and specialist projects
  - Radiation oncology division and O&G department

Challenges

Database maintenance issues	Incomplete forms	Missing data	Data linkage with the National Population Register (NPR)
Problems in programming of the system C# programmer expert required	Missing fields on Case report forms (CRFs)	Gaps in the database * incomplete CRFs * further additions of fields on CRFs	Difficulties in getting SAID numbers from rural based patients & foreigners These cases can not be linked for update of living status

East London Registry Overall South African IDs Summary



Achievements

- Publications
  - MMed thesis
  - Radiation oncology division and O&G department
- Updating patient records through linkage with NPR (*thanks to Prof. Boulle*)
  - Dead/Alive status
- East London database successfully moved to REDCap
- Effective & Efficient data management of the EL database
  - Quality control measures
    - Restrictions on specific fields
- Gynae database system stability
- Availability of a data capturer
  - Data entering
  - Quality checking

Future Plans

- Moving all databases to REDCap data management system
- Utilise assistance & guidance from CRI

Thank you ALL…

Division Haematology: Cancer databases

Estelle Verburgh MD PhD

Department of Medicine, Division Clinical Haematology,

in cooperation with Department of Pathology, Divisions Haematopathology, Anatomic Pathology & Genetics

and Department of Radiotherapy Oncology

* *Excel databases in a number of malignant haematologic disorders:*
  * Different lymphoma databases
  * Stem cell transplantation database
  * EBMT reporting data
  * BM reporting data
  * MPN database
  * ALL database
  * APL database

* All of these put together by clinicians

* REDCap databases developed in 2016/7:
  * Lymphoma aggressive (NRF funding) – not functional
  * Lymphoma rapid access biopsy clinic study
  * Haemophilia (NovoNordisk funding) – not functional
* REDCap databases developed in 2018:
  * AML database (truly interdepartmental)
  * Haploidentical BMT database for a national project
  * Planned REDCap Blitz to complete each malignant disease entity instrument by end 2018

* **Type of data:** depending on disease subset, but generally includes demographics, disease specifics and staging, therapy, and certain measures of outcome

* Enter the Atomium:

  * Putting together retrospective databases intensely time-consuming and specialistic
  * Heavy clinical load and no research nurses
  * Create opportunity to gather data in real-time

    → Develop instrument:

    PRESENTATION TO HAEMATOLOGY

* Structure of E5 clinic databases
  * **Local: Atomium**

  * **National: Multilayered cake**

* Quality assurance
  * Physician driven
  * Implement as part of **routine care** PLUS **disease champions**
  * Continual refinement of workflow ensures continuity of data

* **Challenges and aims**
  * Moving from a physician driven, spottily executed, enterprise to a continuum of data management thereby:

    → ensuring accredited and protocolised activity on all levels for best patient care and continual improvement

    → Maximising interdisciplinary, interdepartmental and intra-national cooperative projects to answer scientific questions

* **CRI support:**
* *Indescribable…!*
* Obvious: "**DITT**" goals being realised
* But also:
  * Motivation and focus, common goal, momentum
  * Learning to think algorithmically and manage projects