Integrating practice and research in non academic environment

Alessandro Brunelli

St. James’s University Hospital
Leeds, United Kingdom
- Tertiary referral center
- Major trauma center
- 1,500 operations/year
- 300 lung resections/year
- 6 consultant surgeons
- 8 residents/trainees

- No budget for research
- No data manager
- No research personnel
- No departmental research facility/resources

- From 2004 to 2014: only 20 papers published
MOST OF THE PROJECTS PUBLISHED IN THORACIC SURGERY CONCERN SERVICE EVALUATION

“Research is concerned with discovering the right thing to do; audit with ensuring that it is done right”

KEEP THINGS SIMPLE: AUDIT

The Audit Cycle

1) Identify the issues
2) Obtain or define standards
3) Collect data
4) Compare performance with standards
5) Implement change
6) Re-audit
EXAMPLES OF CLINICAL AUDIT

• Impact of co-morbidities on outcome after surgery
• Influence of timing of surgery on outcome
• Evaluation of postoperative costs
• Quality of life evolution after radical treatment for lung cancer
• Incidence and risk factors for hospital readmissions
DATA COLLECTION IS THE MAINSTAY OF RESEARCH

• Clinical and specialty-specific variables
• Representative but parsimonious
• Prospectively maintained
• High quality
• Data protection and confidentiality
• Safe
• Compatible with National and International databases
• Data exportable to statistical software for analysis
Challenges I found in Leeds

- No database
- No data manager
- No research nurse
- High volume
- Poor quality retrospective data source
- Hospital/Regional patient electronic information system: data are not organized in a database. Clinical documents scanned and uploaded
START FROM THE SCRATCH

• Educate the team about importance of data collection
• Involve the team: explore for possible solutions to overcome resource and time constraints. Listen
• Create a core group with a specific interest in research
• Create a database
• Focus on a topic (Lung resection)
• USE ROUTINE DATA
### Definition of variables

The Society of Thoracic Surgeons and The European Society of Thoracic Surgeons General Thoracic Surgery Databases: Joint Standardization of Variable Definitions and Terminology

Felix G. Fernandez, MD, Pierre E. Falcoz, MD, PhD, Benjamin D. Kozower, MD, MPH, Michele Salati, MD, Cameron D. Wright, MD, and Alessandro Brunelli, MD

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Date of birth</td>
<td>Patient's date of birth using 4-digit format for year (dd/mm/yyyy)</td>
</tr>
<tr>
<td>2 Age</td>
<td>Patient's age in years, at time of operation; this should be calculated from the date of birth and the date of operation</td>
</tr>
<tr>
<td>3 Gender</td>
<td>Patient's gender at birth as either male or female</td>
</tr>
<tr>
<td>4 Height, m</td>
<td>Height of the patient in meters at the time of operation</td>
</tr>
<tr>
<td>5 Weight, kg</td>
<td>Weight of the patient in kilograms at the time of operation</td>
</tr>
<tr>
<td>6 Current treatment for hypertension</td>
<td>Patient has a diagnosis of hypertension, documented by current pharmacologic therapy, diet, and/or exercise to control hypertension</td>
</tr>
<tr>
<td>7 Current treatment for cardiac failure</td>
<td>Patient is currently using pharmacologic therapy to treat congestive heart failure; heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention; or the description of rales, jugular venous distention, pulmonary edema on physical examination, or pulmonary edema on chest roentgenogram; a low ejection fraction without clinical evidence of heart failure does not qualify as heart failure</td>
</tr>
<tr>
<td>8 Coronary artery disease</td>
<td>Patient has a history of coronary artery disease (CAD) as evidenced by one of the following: 1. Currently receiving medical treatment for CAD 2. History of myocardial infarction 3. Prior CV intervention including, but not limited to, CABG, PCI, or both</td>
</tr>
<tr>
<td>9 Any previous cardiac surgical procedures</td>
<td>Patient has undergone any prior cardiac surgical procedure that required a general anesthetic and an incision into the mediastinum or chest</td>
</tr>
<tr>
<td>10 Neoadjuvant chemotherapy</td>
<td>Patient received preoperative chemotherapy (or chemoradiotherapy) for the current thoracic malignancy; do not report treatment for prior cancers</td>
</tr>
<tr>
<td>11 Neoadjuvant radiotherapy</td>
<td>Patient received preoperative radiotherapy (or chemoradiotherapy) for the current thoracic malignancy; do not report treatment for prior cancers</td>
</tr>
</tbody>
</table>
Coding of variables:
avoid free text, use drop down menu

<table>
<thead>
<tr>
<th>Variable</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiaccomorbidity1</td>
<td>0 - None, 1 - Coronary Artery Disease, 2 - Any Previous Cardiac Surgery, 3 - Current Treatment for Hypertension, 4 - Current Treatment for Arrhythmia, 5 - Current Treatment for Cardiac Failure, 6 - Liver disease, 7 - Connective tissue disease, 8 - Myasthenia Gravis, 9 - Previous malignancy, 10 - Other</td>
</tr>
<tr>
<td>Othercomorbidities1</td>
<td>0 - None, 1 - Insulin-dependent Diabetes, 2 - Serum Creatinine &gt; 2mg/dl, 3 - CVA, 4 - Chronic kidney failure, 5 - COPD, 6 - Gastric ulcer</td>
</tr>
<tr>
<td>Pt</td>
<td>0 - X, 1 - 0, 2 - is, 3 - 1, 4 - 1a, 5 - 1b, 6 - 2, 7 - 2a, 8 - 2b, 9 - 3, 10 - 4</td>
</tr>
<tr>
<td>Pn</td>
<td>0 - X, 1 - 0, 2 - 1, 3 - 2, 4 - 3</td>
</tr>
<tr>
<td>Pm</td>
<td>0 - X, 1 - 0, 2 - 1, 3 - 1a, 4 - 1b</td>
</tr>
</tbody>
</table>
Thoracic Surgery Lung Resection
Database Leeds

112 variables

11 Patient Basic Demographics variables
43 Pre Surgery Data variables
22 Surgery Data variables
36 Post Surgery Data variables
### Thoracics Data - Patient Basic Demographics Data Form

**Date of surgery (dd/mm/yyyy):** 01/01/2008

**NHS No:** 12585900

**DOB (dd/mm/yyyy):** 01/01/1960

**Gender (M, F):** Female

**Surname:** TEST

**First Name:** SAMPLE

**Height (cm):** 165

**Weight (Kg):** 85

---

### Thoracics Data - PRE-OPERATION DATA Form

**Date of surgery (dd/mm/yyyy):** 01/01/2008

**NHS No:** 12585900

**DOB (dd/mm/yyyy):** 01/01/1960

**Surname:** TEST

**First Name:** SAMPLE

**Gender (M, F):** Z

<table>
<thead>
<tr>
<th>FEV1% Pred</th>
<th>DLCO% Pred</th>
<th>FEV1/FVC%</th>
<th>N obstructed segments</th>
<th>TLC%</th>
<th>RV%</th>
<th>RV/TLC</th>
<th>CPX requested</th>
<th>VE (L/min)</th>
<th>WORK (watts)</th>
<th>WORK%</th>
<th>AT(ml/kg/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VO2max (ml/kg/min)</th>
<th>VO2max%</th>
<th>Heart Rate max</th>
<th>pre-op Hb</th>
<th>CKD</th>
<th>Diabetes</th>
<th>Angina</th>
<th>CVD</th>
<th>CAD</th>
<th>MI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---
The process of data collection in Leeds

- Residents input **baseline and surgical variables** at the end of each case
- **Complications** are recorded prospectively in the patient records and input monthly after review in the monthly M&M and Audit meeting
- **Histopathology and staging** are input monthly as they become available
- **Survival (date of death)** is retrieved from the patient electronic information system and linked to the database through NHS number
- Monthly **data management**: complete missing data, complete missing patients
INTERCONNECTED STREAMS OF RESEARCH: CREATE SCIENTIFIC CONTINUITY

- Quality of care
- Enhanced Recovery
- MITS
- Risk models
- Outcome analyses
- Health economics

Patient reported outcomes
• PLICS categorises Trust’s costs as direct, indirect or as overhead to patient care in accordance with NHS Clinical Costing Standards.

• Using pt activity PLICS allocates these costs to each patient in the most appropriate and granular method.

• PLICS DATA LINKED TO CLINICAL DATABASE
In a patient with COPD and DLCO<60% the expected cost of VATS lobectomy is **4270€ higher** than in a patient without COPD and with higher DLCO
503 consecutive patients submitted to lung resection for lung cancer (April 2014-March 2016)

<table>
<thead>
<tr>
<th>TMM Grade</th>
<th>Patients, n</th>
<th>Postoperative Cost, $, mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>272</td>
<td>3,560 ± 1,012</td>
</tr>
<tr>
<td>I</td>
<td>57</td>
<td>4,548 ± 1,562</td>
</tr>
<tr>
<td>II</td>
<td>108</td>
<td>4,909 ± 1,947</td>
</tr>
<tr>
<td>IIIa + IIIb</td>
<td>29</td>
<td>6,392 ± 2,866</td>
</tr>
<tr>
<td>IVa + IVb</td>
<td>17</td>
<td>14,547 ± 15,975</td>
</tr>
<tr>
<td>V</td>
<td>20</td>
<td>17,695 ± 13,779</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Complications</th>
<th>Patients, n</th>
<th>Postoperative Costs, $, mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>272</td>
<td>3,560 ± 1,012</td>
</tr>
<tr>
<td>1</td>
<td>155</td>
<td>5,045 ± 1,912</td>
</tr>
<tr>
<td>2</td>
<td>40</td>
<td>6,144 ± 2,651</td>
</tr>
<tr>
<td>3</td>
<td>13</td>
<td>8,562 ± 6,658</td>
</tr>
<tr>
<td>&gt;3</td>
<td>23</td>
<td>20,005 ± 17,063</td>
</tr>
</tbody>
</table>
Quality is more important than number of patients

- Network with other centers (ESTS may serve as a scientific platform)
- Keep collecting high quality data and be patient
- Participate to the ESTS database
Statistics for the rest of us

• Be independent
• Improve your statistical knowledge to unlock your research potentials
• Become familiar with common statistical software (SPSS, Stata etc.)
• Professional statistical input for complex statistics
• Read and learn from Statistical Editorial published in our specialty journals
FINAL OUTPUT: LEEDS 2014-2018

95 PAPERS PUBLISHED IN PEER REVIEWED IMPACT FACTORED JOURNALS

37 local co-AUTHORS (surgeons, oncologists, pulmonologists, trainees, students, nurses)

40+ external co-authors in multicenter studies