

# Measuring Outcomes with Devices

HRC 2010

Dr Jay Wright

Liverpool Heart and Chest Hospital

# Historical Data Collection on Device Complications

**Br Heart J. 1995 Jun;73(96):571-5**

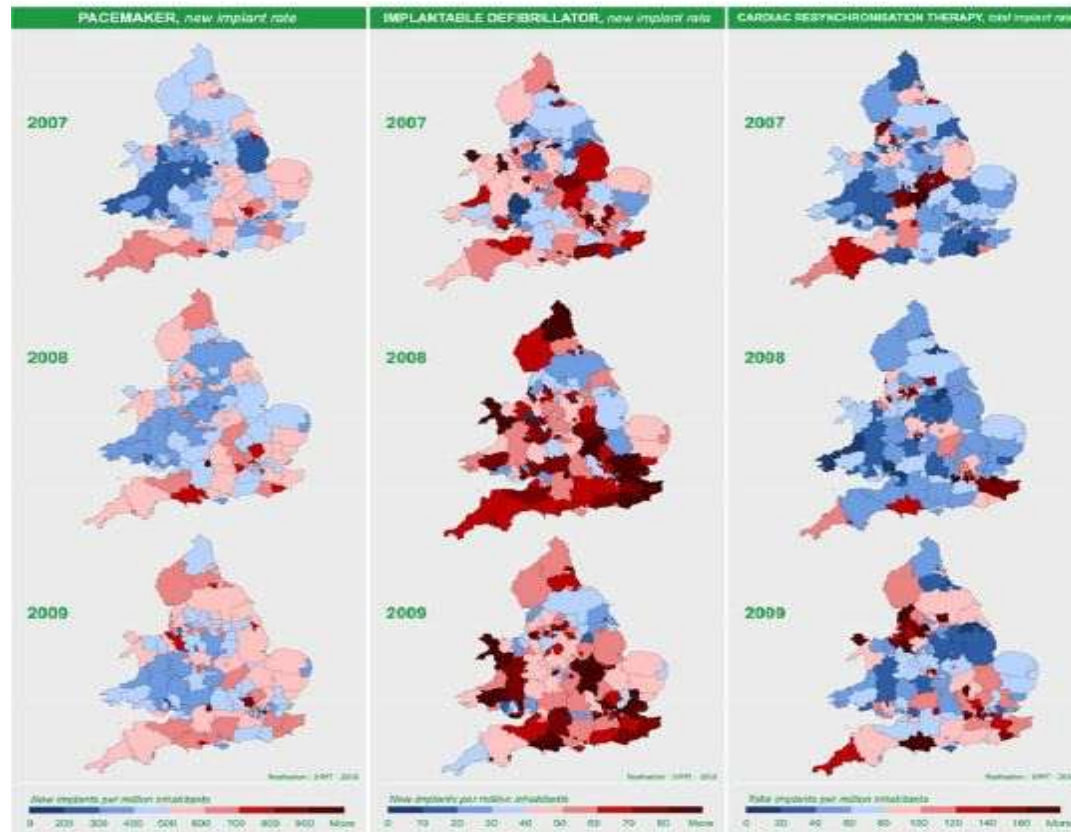
Early complications DDD vs VVI

- Apr 1992 – Jan 1994
- 1088 implants (DDD 54%)
- Complications
  - Pneumothorax 1.8%
  - Arterial puncture 2.7%
  - Lead displacement 1.4%
  - Haematoma 0.5%
  - Explant (1yr) 1.5%

# Current Data Collection on Device Complications

?

# Heart Rhythm Devices: UK National Survey 2009



**David Cunningham**  
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**Richard Charles**  
*Chairman, Network Device Survey Group*

**Morag Cunningham**  
*CRM Database Coordinator, Central Cardiac Audit Database*

**Adél de Lange**  
*Data analyst, Central Cardiac Audit Database*

**Patient Details**

Hospital  
 Hospital Number  
 NHS Number  
 Surname  
 Forename  
 Date of Birth  
 Patient's Admin Sta  
 Consultant Respon

**Select Keywords**

Keywords

- 0. None
- 1. Pneumothorax
- 2. Pneumothorax aspiration
- 3. Chest drain inserted
- 4. Haematoma
- 5. Haematoma exploration
- 6. Tamponade
- 99. Unlisted

**Procedure Details**

Procedure Date: 04/01/2010 00:00

Implanted at: BHL, Liverpool Heart and Chest Hospital

Intervention (Procedure Type): GN+LD, Generator + Lead

Pacing Mode at Discharge: VVIR

Operator 1: DJ.Wright

Operator 2:

High energy (ICD) device?  0. No  1. Yes

Biventricular (CRT) device?  0. No  1. Yes

Date of First Implant: 04/01/2010 16

**Implant Procedure** | **Indications for Implant** | **In Hospital** | **User Fields**

Procedure complications: 0. None

Additional comments:

**Document History**

Original author: Colette McGee on 02/02/2010 at 14:26

Subsequently edited by: Colette McGee, CCAD Template Development

Date/Time last modified: 12/02/2010 21:26

See pick list, cycle with space bar or enter first characters. Indicate maximum generator capability

- Clinical
- Details
- DMC
- Procedure Log
- Generator
- Leads
- Staff
- Letters

### Pacemaker Insertion - Diagnosis, Medication & Complications

Test Date	19/04/2010	Reported by	MHALL	Mark Hall
Interesting Case	<input type="checkbox"/>	Authorised by	CMCGE	Colette McGee

#### Post Clinical Diagnosis

Select	
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#### Pre Clinical Medication

Select	
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#### Clinical Complications

Select	LV Lead displaced
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# Data collection following inaugural device leads meeting

Liverpool Heart and Chest Hospital

The Heart Hospital, London

Poole Hospital

Sandwell and West Birmingham Hospitals

Barnet and Chase Hospital

# Procedural numbers

Center	Dates	Duration	Total number
Liverpool	Apr 2008 to Mar 2009	12 months	1587 *
London	Jan 2004 to Dec 2006	36 months	840 **
Poole	Apr 2008 to Dec 2009	21 months	386
Birmingham	Sept 2008 to Jan 2010	18 months	177
Barnet/Chase	Apr 2009 to Mar 2010	12 months	338
<ul style="list-style-type: none"> <li>• New system implants, system revisions and box changes</li> </ul>			
<b>TOTAL</b>	<ul style="list-style-type: none"> <li>• Liverpool data includes 66 explants (*)</li> <li>• London data for ICD and CRT work alone (**)</li> </ul>	99 months	3334

# Type of Device

Centre	Reveal	PPM	ICD	CRT-P and -D
Liverpool	145	813	270	356
London	0	0	580 <ul style="list-style-type: none"> <li>■ 467 new implants</li> <li>■ 113 revision/box change</li> </ul>	260 <ul style="list-style-type: none"> <li>■ 222 new implants</li> <li>■ 38 revision/box changes</li> </ul>
Poole	19	367 <ul style="list-style-type: none"> <li>■ 281 new implants</li> <li>■ 86 box changes</li> </ul>	0	0
Birmingham	9	154 <ul style="list-style-type: none"> <li>■ 149 new implants</li> <li>■ 5 box changes</li> </ul>	8	6
Barnet/Chase	30	307 <ul style="list-style-type: none"> <li>■ 257 new implants</li> <li>■ 50 box changes</li> </ul>	1	0
<b>TOTAL</b>	<b>203</b>	<b>1642</b>	<b>859</b>	<b>622</b>

# Crude Complication Rates

Centre	No of complications	Number of procedures	Frequency
Liverpool	30	1587	1.84%
London	77 <ul style="list-style-type: none"> <li>■ 54 new implants</li> <li>■ 23 revision/box change</li> </ul>	840 <ul style="list-style-type: none"> <li>■ 689 new implants</li> <li>■ 151 revision/box change</li> </ul>	9.2% <ul style="list-style-type: none"> <li>■ 7.8% new implants</li> <li>■ 15.2% revision/box change</li> </ul>
Poole	34	386	8.8%
Birmingham	13	177	7.3%
Barnet/Chase	12	338	3.6%
TOTAL	166	3334	5.0%

<b>Complication</b>	<b>Liverpool</b>	<b>London</b>	<b>Poole</b>	<b>Birmingham</b>	<b>Barnet/Chase</b>
TOTAL	1587	840	386	177	338
Lead displacement	18 (1.12%)	43 (5.1%)	19 (4.92%)	6 (3.39%)	7 (2.01%)
Haematoma	2 (0.13%)	2 (0.24%)	4 (1.04%)	0	0
Infection	0	19 (2.26%)	1 (0.26%)	1 (0.56%)	0
Pneumothorax	5 (0.31%)	4 (0.48%)	3 (0.78%)	0	0
Haemothorax	1 (0.06%)		1 (0.26%)	0	0
Cardiac perforation	1 (0.06%)		0	0	0
Cardiac tamponade	1 (0.06%)		0	0	0
Haemorrhage	1 (0.06%)	0	1 (0.26%)	0	0
Wound revision	0	6 (0.71%)	1 (0.26%)	0	3 (0.89%)
Death	0	3 (0.36%)	0	0	0
Erosion or Migration	0	0	1 (0.26%)	1 (0.56%)	0

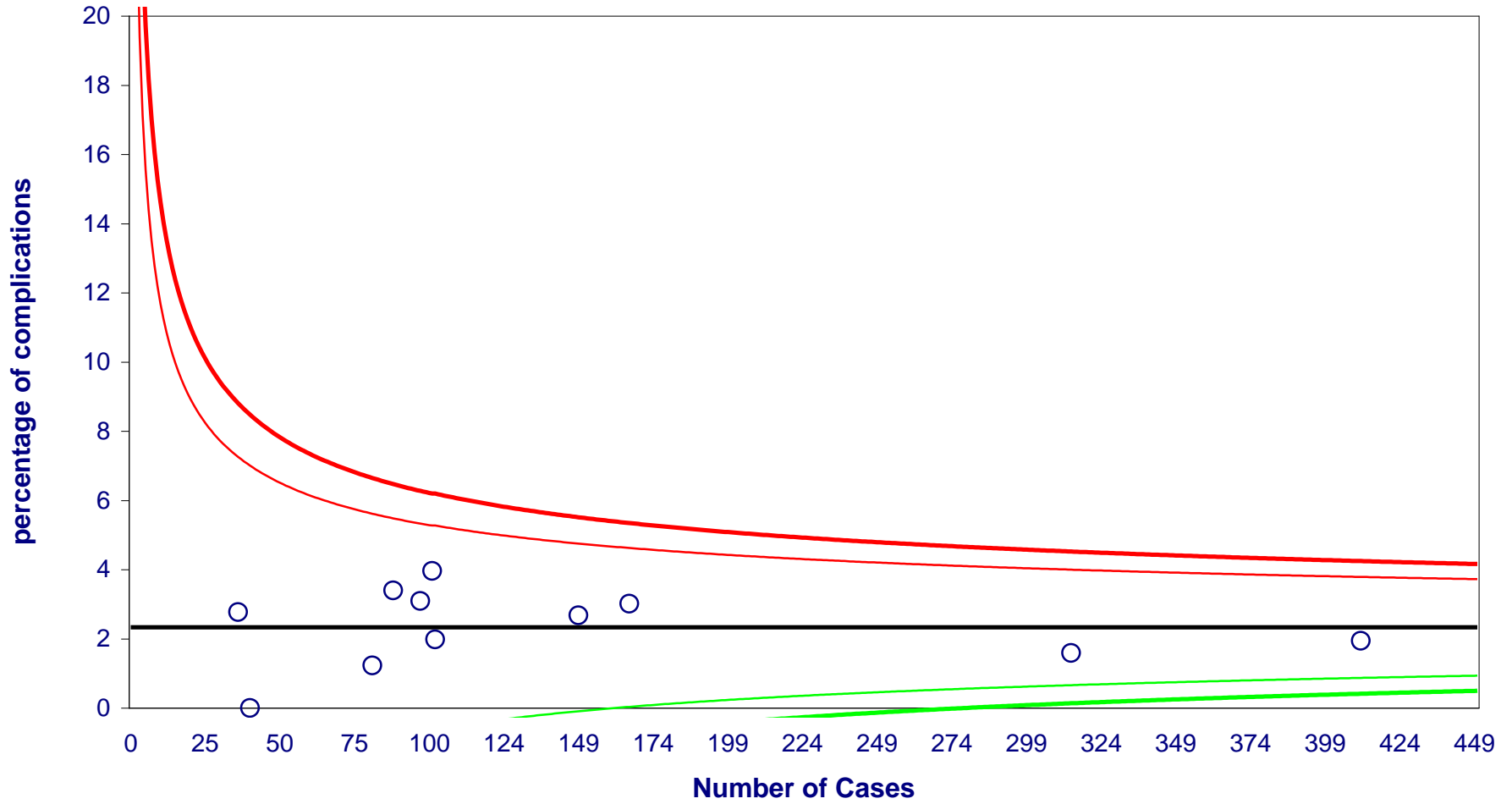
## Complications as a percentage (2009-10)

- Lead displacement 1.61% (1.66) (21/1298 all new implants/revisions/explants)
- Pneumothorax 0.92% (0.44) (12/1298 all new implants/revisions/explants)
- Haematoma 0.13% (0.13) (2/1587 all procedures)
- Pericardial Effusion 0.07% (0.09) (1/1298 all new implants/revisions/explants)

# Complication percentage against procedures

	Total							
Consultant	Procedures	Reveals	Pacemakers	ICD's	BiV'S	Complications	%	
DG	101	5	66	20	10	4	3.96	
MH	166	28	91	20	27	5	3.01	
JH	81	3	33	22	23	1	1.23	
WLM	36	6	29	1	0	1	2.77	
JP	149	3	68	21	57	4	2.68	
DRR	40	9	30	1	0	0	0	
AR	411	35	191	54	131	8	1.94	
RS	101	14	59	17	11	2	1.98	
DT	88	15	38	12	23	3	3.4	
JEW	97	11	53	19	14	3	3.09	
DJW	314	16	155	83	60	5	1.59	

# Complication following Pacing & ICD Procedures April 2009- March 2010



— Upper 95% CI — Lower 95% CI — Upper 99% CI — Lower 99% CI — Unit Average % ○ Operator

# Problems

Few centres submitting

Variable timescale of data collection

Non comparative implant populations

No standard of complication inclusion

No standard complication definition

Huge variation in complication rates

Lead displacement appears commonest

# Issues

Essential part of governance/appraisal

No culture of complication data collection – devices/EP

Variation in data base usage (? Facility)

No time allocated

Financial cost during fiscal times

No standard definition of complications

Complications can occur late (infection)

No risk adjustment

# Potential Solutions

Prioritise here and through HRUK

Formulate list of complications (basic)

Formulate clear definitions

Make submission to CCAD compulsory

Begin with select centres with robust data

Consider risk adjustment

Accountability at local level

# Potential Complications / Definitions

Pneumothorax

Haemothorax

Lead displacement (A, RV, LV) requiring reposition

Haematoma (requiring evacuation)

Pericardial effusion

Tamponade

# More difficult but important issues

Infection requiring explant within 1 year

Revision for pain/pre-erosion

# Acknowledgements

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Colette McGee