All Patients should be on remote follow up only:

For

Stuart Allen
The Manchester Heart Centre
Winning a debate?

• A philosophical quote from a highly respected academic
• Research that can’t be argued with
• Lots of graphs/ pictures (some may bare no relevance at all to the debate)
• Interrupt a lot
The philosophical quote by a highly respected academic

“I don’t understand why, just because the earth has gone round the sun once a device patient needs to be followed up?”

Dr Adrian Morely-Davies – BHRS council meeting April 2011
A title for a really great piece of research, just the best, really

Donald J. Trump
Trump University

Introduction

The current research, and it is really great research, it really is. It relies on the theory – and I have the best theories, you know, I use the best theories in my research. It really is quite amazing just how great the theory is, but I’m not really, in fact – it is a theory. A really good one and I’ve talked to people and, lots of people actually, and they all think what I said. It has a lot of appeal. It’s really just all there and what it is. If people, you know, losers and whatever, if they don’t get it, then what are you going to do? It’s not like the idea isn’t there and that, you know, it’s what it is. I have to shake my head. Everyone is just shaking their heads. It really is.

Along with the theory, there’s other work. Existing data – and again, I have the best data. You would really, if you had the same great data, be completely happy and the data are there. And they are really, you know, data and we have all kinds. The best kinds. And that is what we base the current work, which is great work, that I did and it’s great. If other people want to be walked through like babies or something, then I don’t know what their problem is. The data just are there so get off your lazy butts and stop looking for handouts. I’m not here to give handouts, you shouldn’t expect that.

There are other people who have data that, at least on first glance, and if you believe the haters and losers who want to stop what I am doing. Sure, I could terminate these everything and it was better, and still cost less – because I am the one paying for this. It is money out of my pocket. And my pockets are deep because I am, and have been, a huge success in everything that I have done. I don’t owe, even a cent, to funding agencies at all, this is all mine so I’m not beholden to anyone. The research, and I know research, and this is top-shelf research was the best. One of the best research papers in the world, by the way. Make no mistake. Make no mistake at all – this is what those other people wish they had done or what they wish they were doing, but they aren’t because I am. So, you know, they are whatever, not worth the time.

Results

We ran analyses. The best analyses, make no mistake, these analyses were absolutely top notch. And there were, of course, numbers and the best numbers. They really were. The numbers that is. The findings, what the numbers said, they are great. If you look at them, and I have, other people have and it is clear – and you cannot really argue about it – the analyses are, in fact, tremendous. And it is really something. It is. I’ve seen findings over the years, and I’ve had a lot of dealings with numbers – big numbers – and, no mistake, these numbers are, even by the standards of bozos who don’t believe what they see, these numbers are really great. These are numbers, no doubt. And those are the best numbers. You can rely on those numbers because they are great numbers. It is impressive.
Central Manchester University Hospitals
The Royal Brompton Hospital
What's our ‘normal’ FU policy

Current
• PPM/ ICD – 3 x RFU, 1F2F
• CRT-P/ CRT-D – Alternate RFU and F2F
• Battery/ lead monitoring/ AF – monthly RFU
• Increasing number of PPM/ ICD on RFU only

Work in progress
• Moving all PPM and ICD onto RFU only
• CRT 1 year post implant – 3x RFU, 1 x FU
• Next – CRT RFU download to coincide with HF clinic – no need for device in-clinic check?
Historical in clinic - device checks

- 5 to 15 mins per patient
- Magnet rate
- Manual threshold/impedance/sensing check
- Battery evaluation
- Evaluation of rate histogram (and counters)
- Evaluation of stored episodes
- Site check
Current device in-clinic follow up

- 5 to 30 mins per patient – reality less than 30 mins to evaluate CRT - vast differences across UK
- No magnet rate
- Trend data for Threshold/ impedance/ sensing checks – manual tests rarely needed
- Battery evaluation
- Evaluation of histograms – Rate, Sensor, AF burden, Rates during AF etc
- Evaluation of clinical stored episodes
- Evaluation of HF diagnostics
- Site check
- The vast majority of device in clinics checks/ evaluations do not require a F2F
Analysis of CMFT in-clinic follow up

- 60% of PPM patients have no cardiac co-morbidity – the only reason they ever attend the heart centre is for a device check
- 91% of ALL device patients have no further programming changes after 2/4/6 week in-clinic FU
- To facilitate a 2 week appt/ urgent checks clinics have to overbooked
In-clinc device check: Poor value for the patient??
Would patients prefer RFU only?

Average time spent by a **patient in the hospital** from check in to check out. 62% of that time is waiting time. AND in average 37% of the consultation time adds value to the patient.
## Cost of F2F follow up

<table>
<thead>
<tr>
<th>Description</th>
<th>Time</th>
<th>Cost per minute</th>
<th>Source/Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician time consumption for an in-clinic FU</td>
<td>34.30</td>
<td>£1.4</td>
<td>Boriani et al 2011, Picturenomics UK PwC Report</td>
</tr>
<tr>
<td>Physician time consumption for a remote follow up</td>
<td>8.40</td>
<td>£1.4</td>
<td>Raatikainen et al. 2008, Picturenomics UK PwC Report</td>
</tr>
<tr>
<td>Patient mean travel for round trip to clinic</td>
<td>60.80</td>
<td></td>
<td>MDT UK info available per clinic (based on over 1000 patients)</td>
</tr>
<tr>
<td>Cost per km of travel (car)</td>
<td>£0.25</td>
<td></td>
<td>UK HMRC Fuel allowance</td>
</tr>
<tr>
<td>CO2 emissions per km of travel (car) in grams</td>
<td>149.5</td>
<td></td>
<td>Average new car sold in the UK in 2009</td>
</tr>
<tr>
<td>Annual scheduled ambulatory visit</td>
<td>4.00</td>
<td>Routine device checks performed</td>
<td>User entry</td>
</tr>
<tr>
<td>Scheduled ambulatory visits replaced with remote follow-up</td>
<td>3.00</td>
<td>Routine device checks done remotely</td>
<td>User entry</td>
</tr>
<tr>
<td>CO2 emissions savings (grams)</td>
<td>27269</td>
<td></td>
<td>CALCULATED</td>
</tr>
<tr>
<td>Hospital staff time saving from remote follow-up</td>
<td>£107</td>
<td></td>
<td>CALCULATED</td>
</tr>
</tbody>
</table>
Parking

Hospital Car Parking: The Impact of Access Costs

Anne Mason

Centre for Health Economics, University of York, UK
Current patient flow...

High variation in time spent

Patient regular in-office follow-up

Reception check-in (1 min)

Device evaluation (12.7 min)

Waiting

Reception check-out

Patient goes home

Depending on clinical need

Waiting

Unpredictable process, mean of 35.5 minutes but highly variable

• P95= 80.6 minutes
• P50= 29.2 minutes
What contributes to the variation?

Waiting...?

- Average device follow up consultation - 12.7 minutes
- P95 = 26.2; P50 = 11.6
- Average total time spent waiting = 21.3 minutes

- 90% of patients arrive early or on time: on average 20 minutes early

Patient arrival time

% Waiting time

- 37%
- 63%
On time starts...

Late starts due to unscheduled activity, urgent checks, problem patients...

- 71% of appointments start early or on time
- Early average of 16.7 minutes
- 29% start late: 16.2 minutes on average

- 10% DNA rate approx
- 10% daily activity is unscheduled device check: ward checks, urgent visits
Time spent analysis

Large proportion of VA activity: 55%
SNVA consist mostly of admin/database entry and scheduling on remote systems for next appointments
Increased use of devices creates a significant growth in demand for device follow-up resources.

Growth:
- **140%** (year 2000-2005) - actual
- **160%** (year 2005-2010) - estimated

Economic modelling based on CCAD data

NICE recommendations are 5 FU per year - model based on 1.3 pacemaker FU and 3 ICD / CRT FU.
Number of implanted devices is high and still increasing...

UNITS PER MILLION INHABITANTS

ICDs

+61%

2007 2012
169 273

Pacemakers

+19%

2007 2012
634 756

Cardiac device follow-up burden keeps increasing

SPENDING PRIORITIES OVER THE NEXT 5 Y.

Definitely will reduce spending
Mean

Information Technology

Drugs/Pharmaceuticals

Facilities

Large Med Devices

Small Med Devices

Disposables

Human Resources

Human resource spending not a priority

Strategic Review of Cardiac Physiology Services

STRATEGIC REVIEW OF CARDIAC PHYSIOLOGY SERVICES IN ENGLAND: FINAL REPORT
Physiologist workforce

Figure 1: Summary workforce modelling

- **Demand base case**: The current workforce profile and service commissions at 13/14 and intentions rolled forward for five years 14/15, 15/16, 16/17, 17/18, 18/19, including the savings plans.

- **Modelled future demand**: The base case plus quality improvement, plus an uplift for 7-day services, plus the impact of developing primary and secondary prevention and cardiology provision in primary care.

- **Supply base case**: The combined effect of inflows and outflows, including locum back-fills, but excluding new entrants from the labour market (recruitment). The resultant gap between supply and demand is therefore the recruitment requirement over time.
## Remote monitoring: EVIDENCE LANDSCAPE

<table>
<thead>
<tr>
<th>Year</th>
<th>Study</th>
<th>Authors</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008-2009</td>
<td>Swerdlow, et al.</td>
<td>n = 15,470, ICD</td>
<td>LIA provides early warning of inappropriate shocks due to lead failure</td>
</tr>
<tr>
<td>2010-2011</td>
<td>Velu, et al.</td>
<td>n = 92, ILR</td>
<td>40% reduction in mean time from ILR implant to diagnosis</td>
</tr>
<tr>
<td>2012</td>
<td>COMPAS®</td>
<td>n = 535, 15m, ICD/CRTD</td>
<td>66% fewer hospitalizations from atrial arrhythmias; 55% fewer hospital visits</td>
</tr>
<tr>
<td>2013</td>
<td>Drak-Hernandez, et al.</td>
<td>n = 305, ICD</td>
<td>75% reduction in time from implant to diagnosis; decrease in unplanned visits and ER care</td>
</tr>
<tr>
<td>2014</td>
<td>Mittal, et al.</td>
<td>n = 345,742, PM/ICD/CRTD</td>
<td>Patients with high RM adherence had 53% greater survival than low RM and 140% greater survival than no RM</td>
</tr>
<tr>
<td>2015</td>
<td>Parthiban, et al.</td>
<td>n = 6,469</td>
<td>RM and IO follow-up showed comparable overall outcomes related to patient safety and survival, with a potential survival benefit in PRTs using daily transmission verification.</td>
</tr>
</tbody>
</table>

### Evidence Landscape

- **OEDIPE** (n = 379, ICD) 4.1% risk reduction in major adverse events
- **Raatikainen, et al.** (n = 47, ICD) 41% cost savings per patient
- **OFISSE®** (n = 190, CRTD) 55% fewer hospitalizations; 44.4% fewer hospital days
- **PREFER** (n = 587, ICD) 26% faster diagnosis of clinical actionable events |

### Devices

- Medtronic
- Boston Scientific
- St. Jude Medical
- Biotronik
- Non-Industry or Collaborative
The CONNECT trial

Results
The median time from clinical event to clinical decision per patient was reduced from 22 days in the in-office arm to 4.6 days in the remote arm (p < 0.001). The health care utilization data revealed a decrease in mean length of stay per CV hospitalization visit from 4.0 days in the in-office arm to 3.3 days in the remote arm (p = 0.002).

Conclusions
Wireless remote monitoring with automatic clinician alerts as compared with standard in-office follow-up significantly reduced the time to a clinical decision in response to clinical events and was associated with a significant reduction in mean length of CV hospital stay. (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision [CONNECT]; NCT00402246) (J Am Coll Cardiol 2011;57:1181–9) © 2011 by the American College of Cardiology Foundation

Nashville, Tennessee; Milwaukee, Wisconsin; Minneapolis, Minnesota; and Redwood City, California
Reduced healthcare utilisation
REMOTE MONITORING OF IMPLANTABLE CARDIOVERTER DEFIBRILLATOR PATIENTS:

Aims
Prospective investigation to determine if Internet-based remote monitoring offers a safe, practical, and cost-effective alternative to the in-office follow-up visits of patients with an implantable cardioverter defibrillator (ICD).

Methods
Forty-one patients with previously implanted Medtronic ICDs were followed for 9 months.

Results
- 119 scheduled and 18 unscheduled data transmissions were performed
- There were no device related adverse events
- > 90% of patients found the system easy to use
- Physicians reported the system as being “very easy” or “easy” to use
- All unscheduled data transmissions were addressed remotely
- Compared with in-office visits, remote monitoring required less time from patients (6.9 ± 5.0 vs. 182 ± 148 min, P < 0.001) and physicians (8.4 ± 4.5 vs. 25.8 ± 17.0 min, P < 0.001) to complete follow-up
- Substitution of two routine in-office visits during the study by remote monitoring reduced the overall cost of routine ICD follow-up by 524€ per patient (41%) over traditional device interrogation in 99% of the cases.

Study Conclusion
Remote monitoring offers a safe, feasible, time-saving and cost-effective solution to ICD follow-up.

Reduced healthcare optimisation & enhanced patient care

EFFICACY AND SAFETY OF AUTOMATIC REMOTE MONITORING FOR IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR FOLLOW-UP

**Aims**
Test the hypothesis that remote home monitoring with automatic daily surveillance (HM) is safe and effective for ICD follow-up for 1 year and enables rapid physician evaluation of significant events.

**Methods**
- 1,339 Lumos-T ICD patients (BIO) were randomized 2:1 to HM or conventional follow-up
- Follow-up checks occurred at 3, 6, 9, 12 and 15 months after implantation

**Results**
- HM reduced total in-office visits by 45% without affecting morbidity ($p < 0.001$)
- Median time from onset to physician evaluation was < 2 days in the HM group compared with 36 days in the conventional group ($p < 0.001$)
- Improved compliance to follow-up in RM group (93.5% vs. 88.7%, $p < 0.001$)

**Study Conclusion**
HM is safe and allows more rapid detection of actionable events compared with conventional monitoring in patients with implantable electronic cardiac devices.
Reduced healthcare utilisation

COMBINED HEART FAILURE DEVICE DIAGNOSTICS IDENTIFY PATIENTS AT HIGHER RISK OF SUBSEQUENT HEART FAILURE HOSPITALIZATIONS

**Aims**
Determine if the retrospective evaluation of combined diagnostics recorded by CRT-D devices can identify HF patients at risk for subsequent heart failure hospitalizations.

**Methods**
- Prospective, observational study with retrospective review of RM data collected over 12 months (n = 694)
- A combined diagnostic algorithm using 5 Cardiac Compass™ trends was used to assess risk

**Results**
- Patients with a positive combined diagnostic were 5.5 times more likely to have an HF hospitalization in the next 30 days
- More frequent evaluations enhance risk stratification (15-day evaluation vs. 30-day)

**Study Conclusion**
Monthly review of HF device diagnostic data identifies patients at a higher risk of HF hospitalizations within the subsequent month.

Reduced healthcare hospitalisation

REMOTE MONITORING OF CARDIOVASCULAR DEVICES: A TIME AND ACTIVITY ANALYSIS

Aims
To determine the impact of remote monitoring on device clinic workflow.

Methods
Detailed workflow data were prospectively collected from 434 patients over a 2-week period in a busy device clinic.

Results
- The mean time spent per transmission was 11.5 ± 7.7 minutes, which was less than in-person interrogations (27.7 ± 9.9 minutes; P < .01)
- 27% of transmissions demonstrated clinically important findings
- 5.8% of transmissions were duplicates
- Transmissions that revealed clinically important findings took longer to process than those that did not (21.0 ± 7.4 minutes vs. 10.1 ± 2.1 minutes; P < .05)

Study Conclusion
- Analysis of remote transmissions has significant implications for the device clinic workflow
- Remote transmissions are rapidly processed, allowing clinicians to focus on clinically important findings
- Poor patient compliance complicates the workflow efficiency

Figure 1: Time to process remote transmissions and in-person follow-ups. Processing of remote transmissions was faster than in-person follow-ups, taking 11.5 ± 7.7 minutes vs 27.7 ± 9.9 minutes.

Clinical evidence: enhanced patient care

- Carelink remote patient management along with carealerts: evidence based care for cardiac device patients

<table>
<thead>
<tr>
<th>Reduce time to clinical decision</th>
<th>Reduce Hospital length of stay</th>
<th>Reduce A&amp;E visits in HF patients</th>
<th>Reduced time to diagnosis for ILR patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced time to clinical decision</td>
<td>Reduced hospital length of stay</td>
<td>Reduced ED visits</td>
<td>Reduced time to diagnosis</td>
</tr>
<tr>
<td>79%</td>
<td>18%</td>
<td>35%</td>
<td>47%</td>
</tr>
</tbody>
</table>

2. Landolina et al. Circulation. 2012. 125; 2985-2992
In Europe, with nearly 2 million existing cardiac device patients, 2.6 million in-office follow-up visits will be potentially needed.¹

Remote Interrogation reduces device check time by more than 60%.²

Compared to standard follow-up through in-office visits and audible ICD alerts, remote monitoring results in increased efficiency for healthcare providers and improved quality of care for patients (Evolvo Clinical Trial).³

1. Medtronic Data on file
Clinical value of remote monitoring

According to the recent ESC Guidelines, Device-based remote monitoring is a IIa, Level of Evidence A, recommendation.²

Device-based remote monitoring should be considered in order to provide earlier detection of clinical problems (e.g. ventricular tachyarrhythmias, atrial fibrillation) and technical issues (e.g. lead fracture, insulation defect).

In CRT Patients, Remote monitoring and follow-up in addition to in-clinic follow-up is recommended. Patients should be encouraged to initiate a remote transmission if new symptoms or concerns arise.⁷
## Transmissions: Active Transmissions (5)

### Active Transmissions with Events (3)

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Date/Time</th>
<th>Event Description</th>
<th>Status</th>
<th>Battery</th>
<th>Device</th>
<th>Next Send</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taylor, Andy</td>
<td>23-Aug-2007 02:36 PM</td>
<td>No Events</td>
<td>New</td>
<td>3.20 V</td>
<td>Adapta</td>
<td></td>
</tr>
</tbody>
</table>
Spot the difference!

### Device Status (Implanted: 11-Jan-2012)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Voltage (RRI=2.77V)</td>
<td>2.93 V</td>
<td>2.93 V</td>
<td>2.93 V</td>
</tr>
<tr>
<td>Remaining Longevity (based on initial interrogation)</td>
<td>2 years (1.5 - 2.5 years)</td>
<td>2 years (1.5 - 2.5 years)</td>
<td>2 years (1.5 - 2.5 years)</td>
</tr>
<tr>
<td>Lead Impedance</td>
<td>399 ohms</td>
<td>418 ohms</td>
<td>722 ohms</td>
</tr>
<tr>
<td>Capture Threshold</td>
<td>1.000 V @ 0.40 ms</td>
<td>1.375 V @ 1.60 ms</td>
<td>1.375 V @ 1.60 ms</td>
</tr>
<tr>
<td>Measured On</td>
<td>07-Jul-2016</td>
<td>07-Jul-2016</td>
<td>07-Jul-2016</td>
</tr>
<tr>
<td>Programmed Amplitude/Pulse Width</td>
<td>2.00 V / 0.40 ms</td>
<td>2.00 V / 1.50 ms</td>
<td>2.00 V / 1.50 ms</td>
</tr>
<tr>
<td>Measured P/R Wave</td>
<td>0.3 mV</td>
<td>3.3 mV</td>
<td>0.3 mV</td>
</tr>
<tr>
<td>Programmed Sensitivity</td>
<td>0.15 mV</td>
<td>0.15 mV</td>
<td>0.00 mV</td>
</tr>
</tbody>
</table>

### Parameter Summary

<table>
<thead>
<tr>
<th>Mode</th>
<th>VVIR</th>
<th>LV &gt; RV</th>
<th>Upper Sensor</th>
<th>130 bpm</th>
</tr>
</thead>
<tbody>
<tr>
<td>V. Facing</td>
<td>Lower Rate</td>
<td>&gt;171 bpm</td>
<td>All Rx Off</td>
<td></td>
</tr>
<tr>
<td>AT/AF</td>
<td>Monitor</td>
<td>VT Monitor</td>
<td>&gt;171 bpm</td>
<td>&gt;150 bpm</td>
</tr>
</tbody>
</table>

### Cardiac Compass Trends (May-2015 to Jul-2016)

- **Treated AT/AF (Monitor):**
  - Monitored: 0
  - VT (>4 beats): 0
  - Fast A&V: 1
  - AT/AF: 1
  - Time in AT/AF: 24.0 hr/day (100.0%) Last Week: 0.1 hr/day

### Therapy Summary

- **Pace-Terminated Episodes:**
  - AT/AF: 0
  - AS-VP: 99.9%
  - AP-VP: 0.0%
  - AP-VF: 0.0%

### Observations (4)

- 23 days with more than 6 hr AT/AF.
- Possible fluid accumulation exceeded OptVol Threshold, 17-May-2016 — ongoing.
- LV Capture Management determined that threshold increased by 0.025 V from 25-Jun-2016 to 29-Jun-2016. This increase was greater than Amplitude Safety Margin (+0.5 V) and may have compromised capture.
- Patient Activity less than 1 hr/day for 3 weeks.
HF Management

Date of Birth: 19-Aug-1934
Implant: 11-Jan-2012
EF, on: ---
Hospital: ---

Clinical Status (15-Jun-2016 to 07-Jul-2016)

<table>
<thead>
<tr>
<th>AT/AF</th>
<th>V. Pacing</th>
<th>100.0%</th>
<th>Lower Rate</th>
<th>60 bpm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time in AT/AF</td>
<td>Atrial Pacing</td>
<td>0.0%</td>
<td>Upper Rate</td>
<td>130 bpm</td>
</tr>
<tr>
<td></td>
<td>Battery</td>
<td>OK</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Observations (3) (15-Jun-2016 to 07-Jul-2016)
- 23 days with more than 6 hr AT/AF.
- Possible fluid accumulation: exceeded OptiVol Threshold, 17-May-2016 -- ongoing.
- Patient Activity less than 1 hr/day for 3 weeks.

Heart Failure Risk Status on 07-Jul-2016 is High*

Risk of Heart Failure Event in Next 30 Days
(based on maximum daily risk status in prior 30 days)

Risk Factors
- OptiVol
- Patient activity
- AT/AF
- Ventricular rate during AT/AF
- % Ventricular pacing
- Night ventricular rate
- Heart rate variability
What could the future device FU clinic look like?

• All patients on RFU
• Device clinics replaced with arrhythmia management clinics and urgent device/site evaluation
• ?need for CRT clinics if device downloads are available for HF doctor/nurse
• Evaluation/interpretation of downloads by physiologist with HF team in clinic could provide better management and FU strategies
Conclusions

• I do like seeing patients – but only the ones that need to be seen
• The traditional role of the device physiologist routinely seeing patients in clinic will change
• Workflow has to evolve with technology
• Significant patient benefit and value of RFU rather than F2F
Thank you