

Optimising the identification of acute deterioration and sepsis through digital technology

A thesis by

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Contents

Abstract.....	1
Acknowledgements	3
Declaration of Originality	6
Copyright Declaration	6
Peer-reviewed publications	7
Impact from this thesis	10
Presentations to learned societies from this thesis	12
International Oral Presentations:.....	12
International Poster Presentation.....	12
National Oral Presentation:	12
National Poster Presentation:	13
List of Figures.....	16
List of Tables	18
Table of abbreviations	20
Chapter 1 Introduction	21
1.1 Sepsis	22
1.1.1 Definition.....	22
1.1.2 Incidence.....	22
1.1.3 Morbidity and mortality.....	23
1.1.4 Financial Burden.....	23
1.1.5 Signs and symptoms	24
1.1.6 Diagnosis	24
1.1.7 Classifications.....	25
1.1.8 Treat sepsis early	28
1.2 Patient Deterioration & Early Warning Scores	28
1.2.1 Morbidity & mortality for ward-based patients.....	28
1.2.2 Origin of the Early Warning Score (EWS).....	29
1.2.3 NEWS (National Early Warning Score).....	30
1.2.4 Frequency of NEWS assessments and setting trigger points for scoring.....	32
1.2.5 Evidence that Early Warning Scores improves patient care and outcomes	33
1.2.6 Measuring Vital Sign Observations.....	33
1.2.7 Errors in reporting of vital signs with current paper-based systems	37
1.3 The need for new technology developments	38
1.3.1 Continuous monitoring of vital signs	38
1.3.1.1 Paradigm change in monitoring.....	38
1.3.1.2 Continuous monitoring and early research in patient outcome measures	39
1.3.1.3 Continuous monitoring and enhanced recovery	39
1.3.1.4 Additional advantages of wearable sensors.....	40

1.3.2 The current challenge	43
1.3.3 A review of the latest wearable sensors measuring several vital signs continuously	43
1.3.3.1 Early Sense Monitoring System	45
1.3.3.2 Vital Connect HealthPatch™	46
1.3.3.3 Sotera Wireless VisiMobile System	47
1.3.3.4 Philips Bio Sensor	48
1.3.3.5 Isansys Lifetouch Sensors	49
1.3.3.6 Zephyr Bio-Harness™	49
1.3.3.7 Advanced Medical mONitoring (AMON) Wearable Sensor	50
1.3.3.8 Sensium Vitals Monitoring Technology	51
1.3.3.9 Comparison of the sensors described	53
1.4 Thesis Aims	57
1.4.1 Hypothesis	57
1.4.2 Research Aims	58
Overall Thesis Plan	59
Chapter 2 A Systematic Review and Meta-Analysis Can Digital Alerting Improve Sepsis Outcomes and Hospital Length of Stay?	60
2.1 Introduction	60
2.2 Aims:.....	62
2.3 Methods	63
2.3.1 Data sources and searches	63
2.3.2 Outcome measures.....	63
2.3.3 Study selection.....	63
2.3.4 Data extraction and quality assessment	64
2.3.5 Data synthesis and analysis	66
2.3.6 Risk of bias assessment	66
2.4 Results	68
2.4.1 Characteristics of studies & digital alerting used	73
2.4.2 Hospital Length of Stay	76
2.4.3 ICU Length of Stay.....	77
2.4.4 Mortality	78
2.4.5 Time to Antibiotics	79
2.4.6 Diagnostic Accuracy.....	80
2.4.7 Risk of bias assessment	82
2.5 Discussion	84
2.5.1 Summary of main findings	84
2.5.2 Strengths	85
2.5.3 Limitations.....	86
2.5.4 Future work.....	87
2.5.5 Conclusion	88
Chapter 3 Testing of the wearable patch to assess reliability.....	90
3.1 Introduction	90

3.1.1 Evidence for benefits of early detection of deteriorating patients	90
3.1.2 How deterioration is detected early	90
3.1.3 Potential of wearable sensors in detecting deterioration	91
3.1.4 Sensor Reliability	91
3.2 Aims:.....	93
3.2.1 Null Hypothesis	93
3.3 Methods	94
3.3.1 Sensium Sensor	94
3.3.2 How the patch works and institutional set up.....	95
3.3.2.1 Heart rate	102
3.3.2.2 Respiratory Rate	103
3.3.2.3 Temperature.....	104
3.3.2.4 Challenges of ambulatory monitoring	104
3.3.2.5 Sensium inbuilt algorithms for signal quality.....	104
3.3.3 Current ward monitoring	106
3.3.4 Study design	107
3.3.5 Study location.....	108
3.3.6 Participants	108
3.3.7 Recruitment	109
3.3.8 Study Procedure.....	110
3.3.9 Signal Analysis & Statistical Analysis	112
3.4 Results	118
3.4.1 Patient Demographics.....	118
3.4.2 Reliability of ward data	121
3.4.3 Review of different averaging time windows for the sensor.....	123
3.4.4 Heart rate	125
3.4.5 Respiratory Rate	128
3.4.6 Temperature.....	131
3.5 Discussion	134
3.5.1 Heart Rate	134
3.5.2 Respiratory Rate	134
3.5.3 Temperature.....	136
3.5.4 Alerting time windows	136
3.5.5 Strengths	139
3.5.6 Limitations.....	140
3.5.7 Conclusions	141
Chapter 4 Assessing speed of wearable sensors to detect patient deterioration and sepsis as compared to current monitoring.....	143
4.1 Introduction	143
4.1 Aims.....	147
4.3 Methods.....	148
4.3.1 Study design	148
4.3.2 Study location.....	148

4.3.3 Participants	148
4.3.4 Study Procedure.....	149
4.3.4.1 Identifying unwell patients	150
4.3.4.2 Identifying patients with sepsis	152
4.3.4.3 Reviewing alerting based on ward observations	155
4.3.4.4 Analysis	160
4.5 Results	161
4.5.1 Risk stratification and coding of all patients based on NEWS.....	161
4.5.2 Patients with Infection	164
4.5.3 Patients with Sepsis	164
4.5.4 Alerting from ward observations stratification in unwell patients using a 10 minute alert.....	167
4.5.4.1 Heart rate alert comparison for all patients	169
4.5.4.2 Heart rate alert comparison for patients with infection or sepsis	171
4.5.4.3 Heart rate alert comparison for patients with a red NEWS alert.....	173
4.5.4.4 Heart rate alert comparison for patients with an amber NEWS alert	175
4.5.4.5 Respiratory Rate alert comparison for patients for all patients	177
4.5.4.6 Respiratory Rate alert comparison for patients with infection or sepsis	180
4.5.4.7 Respiratory Rate alert comparison for patients with a red NEWS alert.....	182
4.5.4.8 Respiratory Rate alert comparison for patients with an amber NEWS alert.....	184
4.5.4.9 Temperature alert comparison for patients for all patients.....	186
4.5.4.10 Temperature alert comparison for patients with infection or sepsis.....	188
4.5.4.11 Temperature alert comparison for patients with a red NEWS alert	190
4.5.4.12 Temperature alert comparison for patients with an amber NEWS alert.....	192
4.5.5 Alerting from the sensor using a 10 minute alert	194
4.5.5.1 Alerting from the sensor for HR in all patients using a 10 minute window.....	197
4.5.5.2 Alerting from the sensor for HR in patients with infection or sepsis using a 10 minute window	198
4.5.5.3 Alerting from the sensor for RR in all patients using a 10 minute window	199
4.5.5.4 Alerting from the sensor for RR in patients with infection or sepsis using a 10 minute window	200
4.5.5.5 Alerting from the sensor for temperature in all patients using a 10 minute window	201
4.5.5.6 Alerting from the sensor for temperature in patients with infection or sepsis using a 10 minute window	202
4.6 Discussion	203
4.6.1 Summary of main findings	203
4.6.2 Wider Literature	205
4.6.3 Strengths	210
4.6.4 Limitations.....	211
4.6.5 Future.....	213
4.6.6 Conclusion.....	215
Chapter 5 Patient experience of wearable sensors: a mixed methods evaluation.....	216

5.1 Introduction	216
5.1.1 Importance of patient experience	217
5.2 Aims:.....	220
5.3 Methods	221
5.3.1 Study design	221
5.3.2 Ethics	221
5.3.3 Patient recruitment.....	221
5.3.4 Quantitative Research Methodology	222
5.3.5 Qualitative Research Methodology	223
5.3.6 Analysis	224
5.4 Results	226
5.4.1 Questionnaire Patient demographics	226
5.4.2 Interview Patient demographics	226
5.4.3 Questionnaire results	228
5.4.3.1 The wearable patch was comfortable to wear	230
5.4.3.2 I found this system unnecessarily complex	230
5.4.3.3 I understood what the patch was for	230
5.4.3.4 I felt safer being monitored whilst wearing the wearable patch.....	230
5.4.3.5 I knew who to contact if I had any problems with the wearable patch	231
5.4.3.6 I would wear the patch again when in hospital	231
5.4.3.7 I found this system very cumbersome to wear	231
5.4.3.8 I would wear the wearable patch in my home	232
5.4.3.9 I needed to learn a lot of things before I could get going with this system.....	232
5.4.3.10 Questionnaire comments	233
5.4.4 Main results: semi-structured interviews.....	234
5.4.4.1 Centralised monitoring	235
5.4.4.2 Safety	235
5.4.4.3 Nursing Staff.....	237
5.4.4.4 Comfort & Usability	238
5.4.4.5 The future	240
5.4.4.6 Further Concerns	241
5.5 Discussion	242
5.5.1 Summary of findings and Existing Literature	242
5.5.2 Strengths	245
5.5.3 Limitations.....	246
5.5.4 Future work.....	247
5.5.5 Conclusion	247
Chapter 6 Staff perspective of the wearable sensor and continuous monitoring	248
6.1 Introduction	248
6.2 Aims:.....	250
6.3 Methods	251
6.3.1 Participants and setting.....	251
6.3.2 Qualitative Research Methodology	252

6.3.3 Analysis	254
6.3.4 Assurance of qualitative rigour.....	254
6.4 Results	255
6.4.1 Problems with current management	257
6.4.2 Problems with current management and patients with sepsis	260
6.4.3 Patient Safety	263
6.4.4 Patient Safety in patients with Sepsis	269
6.4.5 Impact on staff.....	271
6.4.6 Impact on patients.....	277
6.4.7 Changes	280
6.4.8 The future	282
6.4.9 Staff training	285
6.5 Discussion	287
6.5.1 The necessity for change	287
6.5.2 Patient Safety.....	288
6.5.3 Impact on staff and Nursing workload	289
6.5.4 Impact on patients.....	290
6.5.5 Suggested sensor improvements.....	290
6.5.6 Future.....	291
6.5.7 Wider Literature	292
6.5.8 Strengths	293
6.5.9 Limitations.....	293
6.5.10 Conclusion	294
Chapter 7 A pilot study to investigate real digital alerting on the time taken to identify unwell patients and those with sepsis.	295
7.1 Introduction	295
7.2 Aims.....	296
7.3 Methods.....	297
7.3.1 Study Design	297
7.3.2 Study Location.....	297
7.3.3 Participants	297
7.3.4 Recruitment	298
7.3.5 Staff Training.....	298
7.3.6 Updating Software.....	299
7.3.7 The alerting device	299
7.3.8 Study Procedure.....	307
7.4 Results	309
7.4.1 Total number of vital sign alert notifications	309
7.4.2 Alert actions taken	312
7.5 Discussion	315
7.5.1 Summary of findings and context within the literature	315
7.5.2 Strengths	317
7.5.3 Alerting challenges	318

7.5.4 Limitations.....	319
7.5.5 Further research	320
7.5.6 Conclusion.....	321
Chapter 8 Discussion and conclusion.....	322
8.1 Findings of this research – Summary of key findings by aim	324
8.1.1 To review the latest wearable sensors measuring multiple vital signs.....	324
8.1.2 To explore the link between digital alerting and sepsis outcomes.	324
8.1.3 To investigate the reliability of wearable sensors as compared to standard ward monitoring in acutely unwell patients.	325
8.1.4 To assess the speed in which wearable sensors detect unwell patients and sepsis as compared to standard ward monitoring.	327
8.1.5 To assess the opinions of patients who had worn the wearable sensor.	327
8.1.6 To assess the opinions of staff members who had either used the wearable sensor or treated patients wearing the sensor.	328
8.1.7 To assess the use of wearable sensors and real-time digital alerting in identifying unwell patients and those with sepsis in an acute hospital setting	329
8.2 Wider Literature	331
8.2.1 Wearable sensors in surgical patients.....	331
8.2.2 Elderly people and wearable technology.....	332
8.2.3 Patients with cancer	333
8.2.4 Patients with Peripheral Vascular Disease	333
8.2.5 Patients with Chronic Obstructive Pulmonary Disease (COPD).....	334
8.2.6 Future sensor use in disaster setting and in places of remote monitoring	334
8.3 Thesis Strengths	336
8.4 Thesis Limitations	339
8.4.1 Single Centre Design	339
8.4.2 Scalability	339
8.4.3 Single sensor design	340
8.4.4 Number of patients with deterioration and or sepsis	341
8.4.5 Data Processing	343
8.4.6 Staff Education, Research nurses and the wider hospital team	344
8.5 Future research	346
8.5.1 Future Digital Dashboards.....	348
8.5.2 Managing digital data growth.....	351
8.5.3 Future wearable sensors.....	353
8.6 Future Challenges & Implications.....	358
8.7 Personal Reflections	361
8.7.1 Deep Mind	362
8.7.2 Sensium	362
8.7.3 Royal College of Surgeons Research Fellowship.....	364
8.7.4 NHS England Sepsis Board.....	365
8.7.5 Achievements	365
8.8 Conclusions	366

References.....	367
Appendix 1.1	393
The standardised observational chart for the National Early Warning Score	393
Appendix 2.1	394
Literature Review	394
2.1.1 Medline Search.....	394
2.1.2 Embase search	395
2.1.3 Health Management Information Consortium (HMIC) Search.....	396
2.1.4 Psych Info Search	397
2.1.5 Cochrane	398
Appendix 3.1	399
Participant information sheet.....	399
Appendix 3.2	404
Participant consent form.....	404
Appendix 3.3	405
Bland Altman Plots and histograms for the 6-minute time window for HR using both the means and medians.....	405
Appendix 3.3	406
Bland Altman Plots and histograms for the 6-minute time window for RR using both the means and medians.....	406
Appendix 3.3	407
Bland Altman Plots and histograms for the 6-minute time window for temperature using both the means and medians.....	407
Appendix 3.4	408
Bland Altman Plots and histograms for the 12-minute time window for HR using both the means and medians.....	408
Appendix 3.4	409
Bland Altman Plots and histograms for the 12-minute time window for RR using both the means and medians.....	409
Appendix 3.4	410
Bland Altman Plots and histograms for the 12-minute time window for temperature using both the means and medians	410
Appendix 3.5	411
Bland Altman Plots and histograms for the 16-minute time window for HR using both the means and medians	411
Appendix 3.5	412
Bland Altman Plots and histograms for the 16-minute time window for RR using both the means and medians	412
Appendix 3.5	413
Bland Altman Plots and histograms for the 16-minute time window for temperature using both the means and medians	413
Appendix 3.6	414
Bland Altman Plots and histograms for the 18-minute time window for Heart Rate using both the means and medians.....	414

Appendix 3.6	415
Bland Altman Plots and histograms for the 18-minute time window for Respiratory Rate using both the means and medians	415
Appendix 3.6	416
Bland Altman Plots and histograms for the 18-minute time window for Temperature using both the means and medians	416
Appendix 4.1	417
Patient demographic data collection sheet.....	417
Appendix 4.2	418
Trust sepsis risk assessment proforma.....	418
Appendix 5.1	420
Patient Questionnaire.....	420
Appendix 5.2	421
Semi structured interview guides for patients	421
Appendix 5.3	422
Participant information sheet for semi structured interviews	422
Appendix 5.4	425
Consent form for patient interviews	425
Appendix 5.5	426
The wearable patch was comfortable to wear	426
Appendix 5.6	427
I found this system unnecessarily complex	427
Appendix 5.7	428
I understood what the patch was for	428
Appendix 5.8	429
I felt safer being monitored whilst wearing the wearable patch.....	429
Appendix 5.9	430
I knew who to contact if I had any problems with the wearable patch	430
Appendix 5.10	431
I would wear the patch again when in hospital	431
Appendix 5.11	432
I found this system very cumbersome to wear	432
Appendix 5.12	433
I would wear the wearable patch in my home	433
Appendix 5.13	434
I needed to learn a lot of things before I could get going with this system.....	434
Appendix 5.14	435
Questionnaire free text positive comments	435
Appendix 5.15	443
Questionnaire free text negative comments.....	443
Appendix 5.16	446
Questionnaire free text neutral comments	446
Appendix 6.1	448
Staff Information Sheet	448

Staff Consent Sheet	450
Appendix 6.3	451
Semi structured interview guide	451

Abstract

Sepsis is a global health concern with a high mortality. For every hour's delay in sepsis treatment, mortality increases by 7.6%. Vital sign changes are used to detect alterations in a patient's physiology and detect deterioration. Novel wearable sensors, which measure vital signs continuously, may identify unwell patients and sepsis sooner. We aimed to determine if such sensors could reliably identify unwell patients and those with sepsis sooner.

A sensor was selected which measures multiple vital signs simultaneously. The sensor measures heart rate, respiratory rate and temperature every 2 minutes. Sensor and nursing ward data were compared, patient data and staff feedback was collected.

A 500-patient study is complete with admitted patients wearing the sensor in addition to standard clinical monitoring. Comparisons between sensor readings and ward observations taken by nurses were made. A comparison of sensor time windows for alert generation was made and the 10 minute window selected. The correlation coefficient between Sensium data and ward observation data for Heart Rate (HR) was 0.79 ($p=0.0001$) and a mean difference of less than 3 beats per minute. The correlation coefficient between Sensium data and ward observation data for Respiratory Rate (RR) was 0.3 ($p=0.0001$) and a mean difference of less than 2 breaths per minute. The correlation coefficient between Sensium data and ward observation data for temperature was 0.43 ($p=0.0001$) and a mean difference of less than 0.5° C. In 82% of cases of HR and 81% of RR the sensor was faster than ward observations in time to detection.

Patient feedback was positive (453 questionnaires analysed) with 86% agreeing to wear the sensor again and 85% agreeing it was comfortable. Staff groups were interviewed; feedback was positive with problems in current monitoring highlighted.

Wearable sensors may cause a paradigm shift in future patient monitoring with safer, smarter wards.

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In the clinical world where we see the devastating effects of missed patient deterioration and sepsis, I can see the need and relevance of exploring new digital tools to aid patient care. This is where the journey really began and comes back to.

Finally, Dad, I did this for you, I hope to make you proud.

Declaration of Originality

The work presented in this thesis is my own and all else is appropriately referenced.

Copyright Declaration

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Peer-reviewed publications

Is it time for hospitals with smart wards?

Joshi M, Ashrafian H, Darzi A

J R Soc Med. 2018 Oct;111(10):345-346. PMID: 30318998

Wearable sensors to improve detection of patient deterioration.

Joshi M, Ashrafian H, Aufegger L, Khan S, Arora S, Cooke G, Darzi A.

Expert Rev Med Devices. 2018 Dec 22. PMID:30580650

Digital Alerting and Outcomes in Patients With Sepsis: Systematic Review and Meta-Analysis.

Joshi M, Ashrafian H, Arora S, Khan S, Cooke G, Darzi A

Journal of Medical Internet Research. 2019 Dec 20;21(12). PMID: 31859672

Performance of continuous digital monitoring of vital signs with a wearable sensor in acute hospital settings

Meera Joshi, Mr Mansour Sharabiani, Mr Hutan Ashrafian, Miss Sonal Arora, Mr Kenny McAndrew, Dr Sadia N Khan, Professor Graham S Cooke & Professor Ara Darzi

Submitted to Anaesthesiology in September 2020

Assessing the speed of wearable sensors to detect patient deterioration and sepsis

Miss Meera Joshi, Miss Antonia Koutsoukou, Mr Kenny McAndrew, Mr Mansour

Sharabiani, Mr Hutan Ashrafian, Miss Sonal Arora, Dr Sadia N Khan, Professor Graham S

Cooke & Professor Ara Darzi

Submitted to Lancet Infectious Disease in September 2020

Patient perspectives of wearable sensors: a mixed methods evaluation

Meera Joshi, Stephanie Archer, Abi Morbi, Sonal Arora, Hutan Ashrafian, Sadia Khan,

Graham S Cooke & Ara Darzi

Submitted to the Journal of Medical Internet Research in April 2020

Surgical staff perceptions on the use of wearable sensors and continuous monitoring in surgical patients

Meera Joshi, Stephanie Archer, Abi Morbi MBBS, Hutan Ashrafian, Miss Sonal Arora, Dr

Sadia N Khan, Professor Graham S Cooke & Professor Ara Darzi

Submission to the Journal Sensors in April 2020

A pilot feasibility study to investigate real digital alerting on the time taken to identify unwell patients and those with sepsis.

Meera Joshi, Mr Mansour Sharabiani, Mr Hutan Ashrafian, Miss Sonal Arora, Mr Kenny McAndrew,, Dr Sadia N Khan, Professor Graham S Cooke & Professor Ara Darzi

Submitted to the Royal Society of Medicine in August 2020

Impact from this thesis

2020	<i>Awarded the Isambard Kingdom Brunel Lecture – British Science Festival, ‘Wearable sensors - the future of healthcare?’ (pending)</i>
2020	<i>Royal Society of Medicine – Expert Panel ‘Patient Generated Data’ (pending)</i>
2020	<i>Invited to speak at Whitehall Department of International Trade ‘Future of therapeutics’ (pending)</i>
2019	Rosetrees Essay Prize Runner Up Royal College of Surgeons
2019	Winner of the London Surgical Symposium, Oral Presentation
2019	Invited to the House of Lords Embracing Technology in The Fight Against Sepsis
2019	Second Place overall PhD winner at Imperial Summer Showcase

2019	Invited judge for the Imperial Industry xChange
2019	Winner of Imperial Industry xChange: Transformative Innovation
2018	Invited Speaker by the Royal College of Surgeons to present at Freemasons Supreme Grand Chapter Convocation
2018	Winner of Medopad's Greatest NHS Minds competition
2018	Simson Smith Travel Award – The London Surgical Symposium
2018	The London Surgical Symposium – Prize Poster Session 2 nd Place
2017	Rasi Day prize winner – Chelsea and Westminster Hospital
2017	Freemasons' Royal Arch Research Fellow
2017	RCS Research Fellowship – Royal College of Surgeons
2017	Invited to be on the NHS England Sepsis Board (only trainee member) – NHS England

Presentations to learned societies from this thesis

International Oral Presentations:

Invited Speaker:

Sept 2018 Digital systems for monitoring vital signs
European Resuscitation Council Bologna 2018
M Joshi, H Ashrafian, S Arora, S Khan, G Cooke & A Darzi

International Poster Presentation

Jun 2019 Reliability of continuous digital vital sign monitoring through wearable
sensors in acute patients.
Miss Meera Joshi, Mr Mansour Sharabiani, Mr Hutan Ashrafian, Ms Sonal
Arora, Dr Sadia Khan, Professor Cooke & Professor Ara Darzi
Hamlyn Symposium

National Oral Presentation:

Oct 2019 Optimising the identification of patient deterioration and sepsis through
wearable sensors and digital alerting.
The London Surgical Symposium (**1st Place Prize Winner**)
National Geographic Society

Apr 2019 Identification of unwell patients using wearable sensors
Selected speaker

Imperial College London Industry xChange: Transformative Innovation
event

- Nov 2018 Early identification of sepsis through wearable sensors
Invited Guest Speaker
Meeting of the Freemasons Supreme Grand Chapter Convocation
Freemasons' Hall, Great Queen Street, London
- Oct 2017 Optimising the identification of patient deterioration and sepsis through
wearable sensors and digital alerting.
Meera Joshi, Richard Kwasnicki, Sonal Arora, Stephanie Archer, Sadia
Khan, Ara Darzi
Rasi Event Chelsea & Westminster Hospital (**Prize Winner**)
- May 2017 Exploring the earlier identification of sepsis through new technologies.
Invited Guest Speaker for Sepsis Awareness Day,
Royal Sussex County Hospital

National Poster Presentation:

- Dec 2018 A review of wearable sensor technology in improving detection of patient
deterioration.
M Joshi, H Ashrafian, L Aufegger, S Arora, S Khan, G Cooke & A Darzi
Division of Surgery Research Afternoon Imperial College London
- Dec 2018 A general surgery ward based study of patient attitudes towards continuous

monitoring through wearable sensor technology

M Joshi, H Ashrafian, S Arora, S Khan, G Cooke & A Darzi

Division of Surgery Research Afternoon Imperial College London

- Nov 2018 Patient feedback on the use of light weight wearable sensors and digital alerting
- M Joshi**, H Ashrafian, S Archer, S Arora, R Kwasnicki, S Khan, G Cooke & A Darzi
- NIHR Imperial Patient Safety Translational Research Centre Annual Symposium, Royal Academy of Engineering
-
- Sep 2018 Patient feedback on the use of light weight wearable sensors and digital alerting
- M Joshi**, H Ashrafian, S Arora, S Khan, G Cooke & A Darzi
- The London Surgical Symposium
-
- Sep 2018 A systematic review and meta-analysis. Can digital alerting improve sepsis outcome measures and hospital length of stay (**2nd place prize poster session**)
- M Joshi**, H Ashrafian, S Arora, S Khan, G Cooke & A Darzi
- The London Surgical Symposium
-
- Sep 2017 Optimising the identification of patient deterioration and sepsis through wearable sensors and digital alerting.
- Meera Joshi**, Richard Kwasnicki, Sonal Arora, Stephanie Archer, Sadia Khan, Ara Darzi
- Rasi Event Chelsea & Westminster Hospital (**Poster prize winner**)

- Jun 2017 Optimising the identification of patient deterioration and sepsis through wearable sensors and digital alerting.
- Meera Joshi**, Richard Kwasnicki, Sonal Arora, Stephanie Archer, Sadia Khan, Ara Darzi
- Royal College of Surgeons Fellowship Poster Session (**Awarded fellowship**)
-
- Apr 2017 An Overview of Usability Testing in Health Care.
- Miss Meera Joshi**, Dr Stephanie Archer, Mr Maximilian Johnston, Mr Dominic King & Professor Ara Darzi
- Association of Surgeons of Great Britain and Ireland (ASGBI), Glasgow

List of Figures

Figure 1.1 - Adopted from The Chain of Prevention by Professor Gary Smith - Identifying patient deterioration through bedside observations(60).....	37
Figure 1.2. Sensium patch placed on a patient’s chest. Image reproduced with permission from Sensium, Abingdon, UK.	52
Figure 1.3. I Pod with the Sensium application.....	53
Figure 2.1 PRISMA Flow Diagram.....	65
Figure 2.2 Forrest Plot for Hospital Length of Stay	76
Figure 2.3 Forrest Plot for Intensive Care Unit Length of Stay.....	77
Figure 2.4 Forrest Plot for Mortality.....	78
Figure 2.5 Forrest Plot for Time to Antibiotics	79
Figure 3.1 A schematic floor plan of the clinical areas with the bridge locations.....	96
Figure 3.1a Bridge locations on the Acute medical unit.....	96
Figure 3.1b Bridge locations on Syon 1 and Syon 2 wards	97
Figure 3.1c Bridge locations on the Surgical Admissions Unit and Richmond ward	98
Figure 3.2 The monitoring system used for the Sensium wearable sensor.....	99
Figure 3.3 The recording of sensor vital sign data in 2 minutes cycles.....	101
Figure 3.4 Modified Sensium electrode position as compared to standard ECG electrodes.	102
Figure 3.5 Impedance Pneumography in a diagrammatic form.....	103
Figure 3.6 Signal quality checks of vital sign data by the Sensium algorithms.	106
Figure 3.7 The potential readings for HR, RR and temperature over a 10-minute time window which gives 5 actual data readings are shown.	115
Figure 3.8 Sensium averaging time windows around the ward data time	116
Figure 3.9 Screening and enrolment log for the study.....	118
Figure 3.10 A pie chart of patient recruitment by location.....	120
Figure 3.11 Bland Altman plots for the mean and median matched pairs of Sensium HR and ward observations in a 10-minute averaging time window	127
Figure 3.12 Histograms for the mean and median matched pairs of Sensium HR and Ward observations in a 10-minute averaging time window	127
Figure 3.13 Bland Altman plots for the mean and median matched pairs of Sensium RR and ward observations in a 10-minute averaging time window	130
Figure 3.14 Histograms for the mean and median matched pairs of Sensium RR and Ward observations in a 10-minute averaging time window	130

Figure 3.15 Bland Altman plots for the mean and median matched pairs of Sensium temperature and ward observations in a 10-minute averaging time window	133
Figure 3.16 Histograms for the mean and median matched pairs of Sensium RR and Ward observations in a 10-minute averaging time window	133
Figure 4.1 A flow diagram depicting the afferent and efferent limbs in detecting unwell patients.	145
Figure 4.2 showing the thresholds used for alerting of the National Early Warning Score 2 and the Sensium device (169).	152
Figure 4.3 A Flow diagram identifying which patients to include in time to deterioration analysis.....	158
Figure 4.4 – Alerting model on Excel to alerts for HR, RR and temperature	159
Figure 4.5 The proportions of highest recorded NEWS categories on ward observation charts in all recruited participants.....	162
Figure 4.6 The proportions of highest recorded NEWS categories on ward observation charts in all recruited participants from the time of sensor placement.....	163
Figure 4.7 Venn diagram of overlapping sepsis definitions	167
Figure 4.8 A pie chart showing the NEWS score on sensor observations for all participants recruited in the study.....	195
Figure 5.1 Themes and subthemes from thematic analysis	234
Figure 6.1 Themes and subthemes from thematic analysis	256
Figure 7.1 The Ascom Myco 2 alerting device.....	301
Figure 7.2 Online help section for end-users. The Sensium® App. Image used with permission from SENSIMUM (Abingdon, United Kingdom)) (not real patient data)	304
Figure 7.3 An image of the home screen with patients highlighted. The Sensium® App. Image used with permission from SENSIMUM (Abingdon, United Kingdom) (not real patient data).....	305
Figure 7.4 An image showing all vital sign icons and their relevant meanings. The Sensium® App. Image used with permission from SENSIMUM (Abingdon, United Kingdom).	306
Figure 7.5 Real time detection of acute deterioration.....	309
Figure 7.6 – Respiratory rate alerts sent to the mobile Sensium application for the clinical team. Image used with permission from SENSIMUM (Abingdon, United Kingdom).....	310
Figure 8.1 An example of the interface of a digital dashboard.....	350

List of Tables

Table 1.1 The SOFA Score adapted from Vincent et al (24).....	26
Table 1.2 The NEWS 2 Scoring System.....	31
Table 1.3 A summary of each wearable sensor and the vital signs measured (99).	54
Table 1.4 A description of each wearable sensor (99).....	55
Table 2.1 Characterisation of Studies & Digital Alerts Used.....	69
Table 2.2 All studies reviewing outcome measures.....	71
Table 2.3 Diagnostic Accuracy.....	81
Table 2.4 Risk of bias of non-randomised prospective comparative cohort comparing pre- and post-alerting based on the Newcastle –Ottawa Scale	83
Table 3.1 – The ethnicity of all patients recruited in the study.....	121
Table 3.2 –Documentation of Ward Observations for each vital sign in all patients	122
Table 3.3 - A comparison of the different averaging time windows for sensor readings with both means and medians given	124
Table 4.1 A table to show how patients with sepsis in the study were identified	166
Table 4.2 Using a 10 minute HR alert the number of all patients with a Red or Amber alert on ward observations and comparison of Sensium alerting times.....	170
Table 4.3 Using a 10 minute HR alert the number of patients with infection and or sepsis generating an amber or red alert on ward observations	172
Table 4.4 Using a 10 minute HR alert the number of all patients with a red alert on ward observations and comparison of Sensium alerting times	174
Table 4.5 Using a 10 minute HR alert the number of all patients with an amber alert on ward observations and comparison of Sensium alerting.....	176
Table 4.6 Using a 10 minute RR alert the number of all patients with a Red or Amber alert on ward observations and comparison of Sensium alerting times.....	178
Table 4.7 Using a 10 minute RR alert the number of patients with infection and or sepsis generating an amber or red alert on ward observations	181
Table 4.8 Using a 10 minute RR alert the number of all patients with a red alert on ward observations and comparison of Sensium alerting times	183
Table 4.9 Using a 10 minute RR alert the number of all patients with an amber alert on ward observations and comparison of Sensium alerting times.....	185

Table 4.10 Using a 10 minute temperature alert the number of all patients with a Red or Amber alert on ward observations and comparison of Sensium alerting times.....	187
Table 4.11 Using a 10 minute temperature alert the number of patients with infection and or sepsis generating an amber or red alert on ward observations.....	189
Table 4.12 Using a 10 minute temperature alert the number of all patients with a red alert on ward observations and comparison of Sensium alerting times.....	191
Table 4.13 Using a 10 minute temperature alert the number of all patients with an amber alert on ward observations and comparison of Sensium alerting times.....	193
Table 5.1 Patient Demographics for patient interviews.....	227
Table 5.2 Descriptive statistics for each questionnaire item.....	229
Table 7.1 List of actions on the application to be acknowledged by nurses when there are changes in vital signs.	303
Table 7.2 Sensor vital sign notifications, acknowledgements and actions taken by the clinical team.....	313

Table of abbreviations

Abbreviation	Definition
NHS	National Health Service
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation
NIHR	National Institute for Health Research
NICE	National Institute for Health and Care Excellent (NICE)
PSTRC	Patient Safety Translational Research Centre
Obs	Observations
NEWS	National Early Warning Score
EWS	Early Warning Score
SIRS	Systemic Inflammatory Response Syndrome
QSOFA	Quick Sequential Organ Failure Assessment
HR	Heart Rate
RR	Respiratory Rate
Temp	Temperature
GCS	Glasgow Coma Scale
AVPU	Alert to Voice, Pain, Unresponsive
ITU	Intensive Treatment Unit
ICU	Intensive Care Unit
LOS	Length of Stay
ED	Emergency Department
RCP	Royal College of Physicians
RCS	Royal College of Surgeons
ERAS	Enhanced Recover After Surgery
FDA	Food and Drug Administration
CE	European Conformity
ECG	Electrocardiography
NOS	Newcastle-Ottawa scale
PDSA	Plan-Do-Study-Act
CI	Confidence Interval
RCT	Randomised Controlled Trial
NCEPOD	National Confidential Enquiry into Patient Outcome and Death
WMUH	West Middlesex University Hospital
AMU	Acute Medical Unit
ASU	Acute Surgical Unit
SAU	Surgical Admission Unit
ICD	International Classification of Disease
COPD	Chronic Obstructive Pulmonary Disease
HCA	Health Care Assistant
JN	Junior Nurse
SN	Senior Nurse
J	Junior Doctor
S	Senior Doctor

Chapter 1 Introduction

The ancient Greeks first described rotten flesh and putrefaction(1). In the 1680s some of the early descriptions of bacteria were described(2). However it was not until 200 years later that the link between bacteria and infection was formed (2). In the nineteenth century there was a growth in surgical procedures as well as developments in anaesthetics(3). However at the same time there was a rise in infection and death from post-operative sepsis(3).

The nineteenth century was a revolutionary era in the knowledge of infectious disease. One of the founders of modern medicine was Joseph Lister. Previous beliefs on sepsis was that it developed due to contagions in the air(3). Lister believed that the infectious agents gained entry to the body through a break in the skin(3). Lister went on to use carbonic acid in wound dressings and significantly reduced wound sepsis and death(3). This landmark work went on to transform surgery, improving safety and reducing mortality. This work became the antiseptic principle in the practice of surgery and Professor Lister went on to become one of the founding fathers of modern surgery.

The treatment of infection was attempted as early as Hippocrates through substances such as wine and salts to treat wounds(3). However, it was not until 1929 when Alexander Fleming noticed an area of a petri dish left out of an incubator where bacteria did not grow. The substance preventing bacteria from growing was called 'penicillin' and the era of modern antibiotics was born.

The early pioneering work of Lister, Fleming and others have revolutionised our understanding and treatment of sepsis in modern day medicine. Sepsis however is still a major health problem and causes significant morbidity and mortality for all patients. The most common cause of patient deterioration is still sepsis. Although treatments now exist for sepsis and understanding has improved, patients with sepsis are identified late and have poorer outcomes as a result. The current care for sepsis patients is still inadequate. The earlier detection of sepsis may occur through novel digital solutions such as wearable sensors and digital alerting systems. These will be explored in this PhD thesis.

1.1 Sepsis

1.1.1 Definition

The term sepsis is used to describe a variety of clinical conditions; the most recent recommendations suggest sepsis should be defined as a ‘life threatening organ dysfunction caused by a dysregulated host response to infection’(4). Septic shock refers to sepsis accompanied by hypotension or the need for vasopressors despite appropriate fluid resuscitation being given.

1.1.2 Incidence

In the United States, the average annual age adjusted incidence is 300 to 1000 cases per 100,000 people(5). The average incidence of sepsis in the UK population is 147,000 cases per year(6). This is thought to be significantly underreported due to sepsis being attributable to other causes of disease such as pneumonia (6). The actual incidence may be as high as 260,000 cases per year(6).

1.1.3 Morbidity and mortality

Both severe sepsis and septic shock are major health concerns causing significant mortality worldwide. The mortality for severe sepsis and septic shock is as high as one in four with a rising incidence(7)(8)(9)(10). Sepsis is the leading cause of morbidity and mortality for patients admitted to the Intensive Care Unit (ICU)(11)(7). A retrospective multicentre study found for every hour's delay in the treatment of sepsis, the risk of death increases by 7.6%(12). In a large observational cohort study of 847 hospitals, sepsis was the most common cause of death in non-coronary intensive care units(7).

A large cohort study found sepsis not only caused deaths in the acute period but also increased the risk of death for up to 5 years after the septic episode(13). This was even when co-morbidities were accounted for(13). After the initial episode of sepsis resolves patients may have significant morbidity and undergo a prolonged hospital stay. Many patients that survive sepsis are left with devastating lifelong mental and physical morbidity such post-traumatic stress disorder, chronic pain, fatigue, organ dysfunction and amputation(14). The sequelae of sepsis may result in significant physical, emotional and financial health burdens.

1.1.4 Financial Burden

The costs of treating patients with sepsis is very high. The annual total costs of sepsis in the US was \$20 billion in 2011(15). The estimated costs each year in the UK are £7.76 billion, including approximately £830 million of direct costs. Direct costs are those that have arisen during the acute hospital admission whilst indirect costs are the cost to society and loss of productivity in adults of working age. Massive resources are required to manage patients with sepsis, particularly if they are in an ICU. The net effect is that the treatment can be very costly. The average adult costs of care for patients with sepsis in the US varied from \$21,000-

25,000(7). The costs of managing infants is significantly higher at \$54,300(7). These high costs may be explained by infants with sepsis most commonly being managed in ICU. The older population may be left with several long term health problems after severe sepsis which include cognitive dysfunction and functional disability(16). Sepsis may also have a significant impact on a patient's quality of life meaning they need further social care, which can be very costly.

1.1.5 Signs and symptoms

The signs and symptoms of sepsis vary due to the infecting organism, port of entry, inflammatory response of the host and the natural evolution of the condition(17)(18). It is hard to recognise patients with sepsis as the signs and symptoms overlap with other conditions that cause non-infective inflammation(18). The signs and symptoms of sepsis are variable and subtle signs of hypoperfusion can easily be overlooked in otherwise well adults (17). The physical examination should be used to try and identify a focus of infection and guide possible source control. Small trivial looking wounds may lead to eventual fatal sepsis (17). In hospitalised patients indwelling devices (urinary tract or intravascular catheters) can act as a source of infection and should be the first to be suspected as a source. People may also present with non-localised presentations and an absence of a high temperature may be found(19). The importance of paying attention to concerns expressed by the patient or family member have been stressed (19). Symptoms in sepsis may be nonspecific and clinicians should maintain a high degree of suspicion for the condition (17).

1.1.6 Diagnosis

There is no single parameter that has accurate sensitivity and specificity to diagnosis sepsis. A combination of laboratory markers, physiological assessments and clinical suspicion are used. Procalcitonin, a precursor in calcium homeostasis, has been extensively studied in sepsis.

However a systematic review and meta-analysis has found that procalcitonin cannot differentiate sepsis from other causes of a systemic inflammatory response (20). In the absence of a single parameter or laboratory test there are several recommendations and classifications of use to help diagnose sepsis which can be described below.

1.1.7 Classifications

Several ways to classify sepsis have been described. The Systemic Inflammatory Response Syndrome (SIRS) was first proposed at a conference of the American College of Chest Physicians and the Society of Critical Care medicine in 1991(21). SIRS measures the vital signs of heart rate, temperature and respiratory rate as well as the white blood cell count. SIRS is defined when any of the 2 criteria out of the 4 criteria are met(21);

- Temperature > 38°C or <36°C
- Heart rate > 90/min
- Respiratory Rate > 20/MIN or arterial CO₂ lower than 32 mmHg
- White blood cell count > 12000 cells /μL or lower than 4000 cells/μL

They defined septic shock as ‘sepsis induced hypotension persisting despite adequate fluid resuscitation’(21). The SIRS criteria is commonly used in clinical practice as part of clinical bundles of care and for research(22)(23). However, there have been questions raised over the specificity for SIRS in ward patients and whether it is time-consuming and impractical(24).

In a large prospective multicentre study from 16 different countries the Sequential Organ Failure Assessment Score (SOFA) was assessed(25). SOFA has been successfully used to assess both incidence and severity of organ failure in critically unwell patients(25). A summary

of the score can be found in Table 1.1. Those patients with no organ dysfunction have a SOFA score of 0. Organ dysfunction is identified by a score of 2 or more. The authors suggest that regular and repeated scoring of patients may help monitor patient condition(25). The use of the score outside the critical care setting is largely unknown and is impractical in a ward setting.

Table 1.1 The SOFA Score adapted from Vincent et al (24)

SOFA Score	1	2	3	4
Respiration <i>PaO₂/FIO₂,mmHg (kPa)</i>	<400	<300	<200 With respiratory support	<100 With respiratory support
Coagulation <i>Platelets, ×10³/μL</i>	<150	<100	<50	<20
Liver <i>Bilirubin, mg/dL (μmol/L)</i>	1.2-1.9 (20-32)	2.0-5.9 (33-101)	6.0-11.9 (102-204)	>12.0 (204)
Cardiovascular <i>Mean Arterial Pressure</i>	MAP <70mmHg	Dopamine <5 or dobutamine (any dose) (a)	Dopamine 5.1-15 or epinephrine ≤0.1 or norepinephrine ≤0.1b Dopamine (a)	Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1(a)
Central nervous system <i>Glasgow Coma Score</i>	13-14	10-12	6-9	<6
Renal <i>Creatinine, mg/dL (μmol/L) or Urine output,mL/d</i>	1.2-1.9 (110-170)	2.0-3.4 (171-299)	3.5-4.9 (300-440) <500	>5.0 (440) <200

Key (a) Catecholamine doses are given as μg/kg/min for at least 1 hour.

Whilst SOFA is used for ICU patients, a quick SOFA (qSOFA) score has been developed and can be used as a fast assessment of patients outside the ICU setting. The qSOFA scores 1 point for each of (i) respiratory rate greater than or equal to 22 breaths per minute (ii) altered mentation of a GCS less than 15 (iii) a systolic blood pressure equal to or less than 100mmHg. A total score of greater than or equal to 2 suggests a high risk of poor outcome in patients with a suspected infection. The qSOFA score is intended to act as a prompt for clinicians to perform a more thorough assessment.

A challenge both clinically and academically in sepsis is the way sepsis is classified. With large multi-centre trials using different definitions of sepsis comparability is poor. The multiple definitions of sepsis and classifications of sepsis may lead to significant discrepancies in incidence and observed mortality. A taskforce of international sepsis experts was set up to evaluate and update sepsis definitions. The incidence and long-term outcomes of patients diagnosed with SIRS, SOFA and qSOFA classifications were reviewed(4). This was a large retrospective analysis of population records(4). The definition of a serious infection used in the study was ‘one that required admission to the accident & emergency department or hospital for infection’(7). The taskforce found SIRS, SOFA and qSOFA have varying incidences and mortality(7). The SIRS definition of sepsis was criticised for a lack of sensitivity and specificity(7). The authors recommended that in patients with infection who are at elevated risk of poor outcomes the SOFA and qSOFA classifications be used(4). They suggested that these definitions be used in epidemiological studies and further research reviewing sepsis to ensure consistency (4). There are a few recent studies that have attempted to compare qSOFA, SIRS and NEWS in prognostic accuracy for sepsis. In a comparison of qSOFA and SIRS in patients eventually admitted to ICU, a qSOFA calculation prior to ICU admission had a greater accuracy for predicting mortality and ICU free days(26). In a UK based retrospective cohort

study NEWS had similar or superior prognostic accuracy as compared to qSOFA and SIRS(27). Large multicentre studies are required to review this further.

1.1.8 Treat sepsis early

The principles of treatment for sepsis are eradication of the cause of infection with antibiotics, surgical source control and supportive treatment(28). Identifying sepsis early and initiating treatment results in an improved patient outcome as well as reduced patient morbidity and costs(29)(30)(31). An international committee of experts have reviewed the current evidence and created the surviving sepsis guidelines. They recommend urgency in identifying patients with sepsis and that antibiotics be started within 1 hour in patients with septic shock(32). Identifying unwell patients early in sepsis is key to survival. Slow transfers to ICU in patients with changes in physiology in high risk patients is associated with an increased mortality(33). The use of novel technology and digital tools may be used to identify patients with sepsis earlier to hopefully improve outcomes.

1.2 Patient Deterioration & Early Warning Scores

1.2.1 Morbidity & mortality for ward-based patients.

It is well-known that in general a failure to recognise and respond to patients deteriorating in hospitals is a major cause of morbidity and mortality (34)(35)(36)(37)(38). The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) data shows that clinical deterioration may present several hours prior to an adverse event(34). Unfortunately, unwell patients are still currently falling through the ‘safety net’(37). A staggering 39% of acute

emergency patients admitted to the ICU are referred late(39). It is known that respiratory function deteriorates in a significant number of patients prior to an ICU admission(40). The resources of both HDU (High Dependence Unit) and ICU are limited across all NHS (National Health Service) trusts and it is vital that the correct patients are identified early to be suitable for critical care. A measurement of a patient's vital signs is often the first step in assessing for any acute deterioration in their clinical condition(41) (42). An acute deterioration in patient's condition is accompanied by changes in their physiological parameters first(43)(44). A patient's vital signs are crucial to ensure an earlier detection of sepsis(45)(46). If these changes are not detected and treated there is a risk of cardio-respiratory arrest(47) (48). The need for earlier identification of acutely deteriorating patients is clearly apparent and newer ways to successfully achieve this must be explored.

1.2.2 Origin of the Early Warning Score (EWS)

An Audit Commission report in 1999 suggested the effectiveness of critical care varied between hospitals and advised that early warning systems may help identify deteriorating patients(49). They can aid a faster communication between nursing staff and the clinical team to help identify when a patient is deteriorating. The Early Warning Score (EWS) first devised by Morgan et al was based on bedside tests such as pulse rate, systolic blood pressure, respiratory rate, temperature and AVPU score(50). AVPU is an acronym whereby the patient is Alert or responds to Voice or responds to Pain or is Unresponsive. The Modified Early Warning Score (MEWS) uses five physiological parameters: systolic blood pressure, pulse rate, respiratory rate, body temperature and neurological status(51). The score has been further modified for the use in surgical patients and was shown to aid earlier detection of those developing a critical illness in this population(52). The National Institute for Health and Clinical Excellence (NICE) suggested a multi-physiological parameter or aggregate weighted

scoring system be used to assess all acutely unwell patients and monitor them to detect any signs of deterioration(37). There were several scoring systems previously used to identify acutely ill patients. However, the identification and response to acutely ill patients varied with no standardisation. It was realised that there should be one evidence-based universal system across the NHS. This would help to ensure standardisation across the NHS and aid members of staff constantly changing hospitals such as nurses and doctors in training.

1.2.3 NEWS (National Early Warning Score)

The National Early Warning Score (NEWS) is based on the Royal College of Physicians (RCP) recommendations published in 2012(53). The RCP suggested that NEWS scores be used both in the first assessment and further monitoring of all adult inpatients excluding pregnant women. It is suggested that the NEWS is better at predicting mortality than other scores available. When comparing NEWS and EWS score, NEWS is better at predicting outcomes in acute medical admissions(54). Wales was the first country in the world to implement the use of NEWS in all hospitals(55).

NEWS uses 6 physiological parameters: respiratory rate, oxygen saturations, temperature, systolic blood pressure, pulse rate and level of consciousness. Patients may also score an additional 2 if they require oxygen either in the form of a face mask or nasal cannula. All the parameters are combined to assess a patient's NEWS score. It is suggested that alerts be sent out to the clinical team for certain scores. An aggregated score of 0-4 is low and the response is ward based care. A medium score is 5-6 and this suggests a marked variation in physiological parameters and is a key threshold for urgent response. A high score of 7 or more suggests this patient is in imminent danger and requires immediate attention and possible escalation of care to either the High Dependency Unit (HDU) or ICU setting. In addition, a red score can be

triggered if there is a significant change in a single physiological parameter, so it individually has a score of 3. This requires immediate clinical attention and places the patient up into the medium score category. The NEWS alerts and thresholds can be seen in Table 1.2.

Table 1.2 The NEWS 2 Scoring System

Physiological parameter	3	2	1	Score 0	1	2	3
Respiration rate (per minute)	≤8		9–11	12–20		21–24	≥25
SpO ₂ Scale 1 (%)	≤91	92–93	94–95	≥96			
SpO ₂ Scale 2 (%)	≤83	84–85	86–87	88–92 ≥93 on air	93–94 on oxygen	95–96 on oxygen	≥97 on oxygen
Air or oxygen?		Oxygen		Air			
Systolic blood pressure (mmHg)	≤90	91–100	101–110	111–219			≥220
Pulse (per minute)	≤40		41–50	51–90	91–110	111–130	≥131
Consciousness				Alert			CVPU
Temperature (°C)	≤35.0		35.1–36.0	36.1–38.0	38.1–39.0	≥39.1	

The standardised NEWS chart as recommended by the task force comes with a simple white, pale yellow, amber and red coding that is easy to use to aid the identification of deteriorating patients for all healthcare professionals. An example of the NEWS chart can be found in Appendix 1. The task force recommend that the chart should be in colour and in the actual size shown below without any amendments or modifications. Any potential changes in the size of the scale, for example, may lead to confusion and an error in the documentation of vital signs. The NEWS chart also can chart urine output and pain score which are useful in the overall clinical evaluation of the patient although these are not part of the NEWS score itself.

It is worth noting that the NEWS can only be used for adults above 16 years. It is also not appropriate to be used in pregnant women or those with Chronic Obstructive Pulmonary Disease (COPD) where physiological ranges will vary from that of the normal ranges. A NEWS score may be used not only in the first assessment of a patient but also throughout their inpatient stay. The ethos is that if one tracks the score at regularly time intervals, any possible clinical deterioration can easily be identified, and care escalated to the appropriate clinical team. It may also aid physicians tracking the progress of those patients recovering from an illness and assist in decision making for patient discharges. This can be applied most noticeably in the surgical patients that are ready for discharge for example post operatively. The RCP working group advised that NEWS should be used in all acute hospital settings throughout the UK.

1.2.4 Frequency of NEWS assessments and setting trigger points for scoring

It is suggested that those scoring 0 have monitoring of 12 hourly and those with a score of 1-4 have 4-6 hourly observations. Patients with a score of 5-7 may require hourly monitoring and those with a score greater than 7 need continuous monitoring and escalation of care. The frequency of observations, however, does not appear to be standardised and can vary across NHS trusts. There is variation across NHS trusts for the exact triggers used for the patient to score. For example, in Wales the trigger points for low, medium and high risk were set at a NEWS score of 3, 6 and 9 respectively. Additional guidance with the prompts is also available. A score of 3-5 suggests the patient may have an acute illness or an unstable chronic disease. A NEWS 6-8 implies that the patient may deteriorate rapidly. A NEWS of 9 or more implies the patient is at risk of an immediately life-threatening critical illness(55). Much of the documented literature in NEWS has been for medical patients. Although poorly researched thus far, it has been shown that NEWS score has a comparable performance for both surgical and medical

acute admissions(56). An early warning system is an important risk management tool for all surgical inpatients(57).

1.2.5 Evidence that Early Warning Scores improves patient care and outcomes

Several studies have reviewed the impact of early warning scores on patient outcomes. A variety of outcome measures to assess impact have been used. The common outcome measures reviewed are mortality, length of hospital stay, cardiac arrest, ICU transfers and serious adverse events experienced by the patient. A systematic review assessed the impact of early warning scores on patient outcomes(58). In this review, seven studies met the inclusion criteria and a positive trend towards a better outcome was found when EWS was adopted (58). The authors suggested that the introduction of a critical care outreach service coupled with EWS leads to a timelier patient treatment response(58).

Another systematic review of early warning scores and medical response teams highlights the need for both an aggregated warning system to detect patient deterioration coupled with a response team lead by a clinician with critical care experience (59). In a study where several different warning systems were compared those using a single parameter system appeared to have the lowest predictive accuracy for adverse events. In contrast the systems using weighted scoring had the highest predictive accuracy. The optimal number for weighted scoring is unknown.

1.2.6 Measuring Vital Sign Observations

All patients have their observations measured when they enter hospital. The observations taken include temperature, pulse, respiratory rate, blood pressure and oxygen saturation

levels. Vital signs inform and guide clinicians on how the patients are progressing during hospital admissions, and alert in cases of patient deterioration. A measurement of a patient's vital signs is often the first step in assessing for any acute deterioration in their clinical condition (60)(42). An acute deterioration in patient's condition is accompanied by changes first in their physiological parameters (43)(44). The vital signs can help detect several problems such as cardiac, respiratory, shock and sepsis. A patient's vital signs are crucial to ensure an earlier detection of sepsis(45)(46). If these changes are not detected and treated, there is a risk of cardio-respiratory arrest(47)(48). With stretched resources and a busy ward, the opportunity to identify deteriorating patients early can be easily missed. Consequently, acute wards with a high turnover of patients are most at risk and admit sicker patients.

For ward patients, most hospitals offer intermittent monitoring. A range of observation machines are available and vary depending on the NHS trust. The most commonly used observation machines in the NHS are the Dinamap Vital Signs Monitor(61) and the Welch Allyn Spot Vital Signs® Device (62). Most observation machines provide a local display for the healthcare professional reviewing the observations. During the time of monitoring a physical check on the patient is performed by a healthcare assistant or junior nurse. This normally takes around 5-10 minutes and a portable observation machine is used. The observation machines are connected to the patient through several ways.

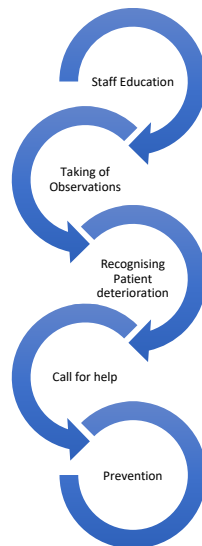
Blood pressure is measured by using an appropriately sized blood pressure cuff which is attached to the patient during the monitoring process; this often takes a few minutes to calculate and gives both a systolic and diastolic reading. A finger-based probe measures the oxygen saturations and heart rate. The temperature is often recorded using a portable tympanic probe.

There are other routes of recording temperature that are less common such as axillary, oral and rectal. In most hospitals, the observation machines have a local display, and this is copied onto the paper-based observation chart by the healthcare staff member that is taking the observation. The way that vital signs are obtained in healthcare has not changed for several decades with often a single ward nurse managing many patients. Currently in most hospitals the monitoring of respiratory rate is not automated and cannot be calculated by the observation machine itself. Instead, the respiratory rate is measured by the healthcare professional counting the breaths over a time period either for a full minute or for 30 seconds and multiplying it by two. The current way of measuring respiratory rate has been shown to highly inaccurate and poorly reported(63). Level of cognition is assessed by healthcare staff at the bedside and it is unlikely this can be automated. It is normally measured through simple scales such as AVPU whereby the patient is Alert or responds to Voice or responds to Pain or is Unresponsive.

In the accident and emergency setting, vital sign monitoring takes place when the patient is being triaged. The observations are normally performed by the triage nurse on duty. This observational data, the clinical history and examination, can act as a guide to the level of care the patient receives. The common practice for measuring a patients vital signs as recommended by The National Institute for Health and Care Excellent (NICE) is all patients have their vital signs recorded every 12 hours as a minimum(37). Although ward observations should be taken every 4-6 hours, overnight they are often infrequent. The frequency of monitoring is depended on each individual trust policy and may be increased in certain clinical circumstances such as very unwell patients or those with a head injury, for example, that require more frequent monitoring. The limitations to current monitoring practice is that deterioration between these time periods of monitoring may easily be missed.

However, patient deterioration can be very serious before it is identified. Bedside observations also occur at other times such as before and after any treatment, procedure, surgery or certain medications. For most patients on a general ward in hospital a healthcare professional measures their vital signs and documents them. These observations are often not added to a patient's bedside chart at the time but written on paper and transcribed later. The healthcare professional is normally assigned to one or two bays on a ward and performs the observations on each consecutive patient. Whilst registered and non-registered nursing staff can take observations, it is often a healthcare assistant that takes these observations. Healthcare assistants are nursing assistants that work under the direction of a qualified professional and provide a wide range of tasks to support patients in hospital. It is important that staff appreciate the importance of accurate reporting and have the knowledge to interpret this data to ensure patient safety. Although some may perceive the taking of observations as a basic skill/activity, it must be emphasised it plays a pivotal role in recognising early deterioration of unwell patients. The education of staff taking observations is the first step in observation recording (Figure 1.1).

Figure 1.1 - Adopted from The Chain of Prevention by Professor Gary Smith - Identifying patient deterioration through bedside observations(60).



1.2.7 Errors in reporting of vital signs with current paper-based systems

The reporting of vital signs has been prone to errors for several reasons. Firstly there may be an inadequate monitoring frequency for some patients(64)(65)(66). The calculation of the early warning score itself may be inaccurate(67)(68)(69)(70)(71). Paper-based observation charts have been used over the last 50 years. Most causes of error arise from the use of paper-based observation charts. Often a nurse may write patients observations on a scrap of paper or the back of a glove. These may be easily misplaced, and observations distorted, leading to inaccurate or incomplete vital signs. The paper charts that have been traditionally used are placed at the patient's bedside. Any damage to the paper chart due to spillage, for example, or poor documentation may render them illegible and lead to false interpretation(72) (73). As described above, if these physiological parameters are recognised early then adverse events such as cardiac arrest and mortality may be prevented. There should be an improvement in data

collection methods and interpretation of vital signs. Newer information technology systems may be able to help.

1.3 The need for new technology developments

1.3.1 Continuous monitoring of vital signs

1.3.1.1 Paradigm change in monitoring

For decades, the way vital sign observations are measured has not changed. They are taken at static moments in time. Wearable sensors may cause a paradigm change. There may be a dramatic change in the landscape of assessment of vital signs as these new technologies develop further. Patients will be continuously monitored, which in turn will be combined with real-time analytics hoping to identify unwell or deteriorating patients sooner than current technologies. The use of these sensors in high-risk patients and acutely unwell patients will be an early source of interest.

Continuous monitoring of vital signs through the latest wearable sensors may help in the early identification of patient deterioration. Fortunately, to tackle the above challenges, there have been significant developments of wearable sensors in recent years (74)(75)(76)(77)(78)(79)(80)(81). It has been possible to develop smaller, lightweight sensors, with greater sampling frequency that can relay information wirelessly ensuring that patient mobility is not compromised, and the sensors will be well tolerated.

1.3.1.2 Continuous monitoring and early research in patient outcome measures

The continuous monitoring of heart rate and respiratory rate can predict and reduce the occurrence of potentially adverse events such as cardiac arrest and respiratory failure. It has been shown that respiratory function deteriorates in a significant number of patients prior to an ICU admission(40). As well as the standard vital signs mentioned above newer wearable sensors may be able to measure the ‘physiological signal’ which may represent the complexity of the integrated compensatory responses that change early in the clinical process rather than outcome variables such as vital signs(82). Newer markers such as age combined with traditional vital signs may help better triaging of patients than traditional vital signs (83).

With faster and better prediction of patient deterioration through proactive monitoring of a patient’s vital signs, it is likely patient outcome measures will improve and make substantial improvements to patient safety. Whilst it is likely that wearable sensors will improve patient safety and patient outcomes the use of wearable sensors in clinical practice is currently very novel. Consequently, there are very few high-quality studies or randomised controlled trials thus far reviewing patient outcomes.

1.3.1.3 Continuous monitoring and enhanced recovery

The current forms of monitoring used on the wards are often bulky and have multiple wires restricting the movement of patients. Whilst they are useful for patients confined to bed, most patients are ambulating on the ward and would be severely restricted if such monitoring was continuous. In addition, there is the potential that current monitoring used continuously may inadvertently slow recovery by reducing mobility.

Patients on high dependency units and intensive care often require continuous monitoring as small changes in physiology may have a profound effect on patient outcome measures. This monitoring is impractical for ambulating ward patients as existing systems are often heavy, expensive and require indwelling lines and/or additional wires. One of the key strengths in the use of wearable sensors is to encourage patients to ambulate early in hospital. There are significant data that shows the benefits of early ambulation in hospitalised patients and an improvement in recovery. Much of this work started in the 1990s when the concept of enhanced recovery after surgery was first proposed(84). Early mobilisation of surgical patients is one of the pillars in the Enhanced Recover After Surgery (ERAS) programme adopted worldwide. Improved adherence to ERAS is associated with improved clinical outcome measures after patients undergo major colorectal surgery(85). Early physical rehabilitation has been shown to reduce hospital length of stay in medical patients such as those with acute respiratory failure(86). Early mobilisation after an intensive care unit admission have been shown to improve neuromuscular weakness and physical function(87).

1.3.1.4 Additional advantages of wearable sensors

The newer wearable sensors that have been developed offer several advantages to current monitoring. The sensors are lighter and smaller in size and so can be worn more discretely by patients. They offer more comfort than current forms of bedside monitoring. Performing manual observations on patients can take between 5-10 minutes per patient and can be time consuming for staff. The use of automatic monitoring systems such as wearable sensors can free up staff to perform other tasks.

The way that observations are taken currently is open to user interpretation, whereas wearable sensors will help to reduce any bias in recording observations assuming they are accurate. Respiratory rate is manually counted by a nurse at the bedside and is not currently automated. Data shows that respiratory rate is repeatedly the vital sign where documentation is poor(88) and often inaccurately calculated and recorded(89). Automated ways of calculating respiratory rate through wearable sensors aim to provide greater accuracy and greater documentation. Additionally vital sign data from wearable technology can be used in the development of ‘automated health event prediction, prevention and intervention’(90).

Continuous monitoring has the potential to be a great benefit in identifying patients with sepsis where deterioration can be very rapid (12). Additionally, identifying the ‘normalisation’ of patients earlier may result in earlier discharges, reducing both length of stay and costs. With the growing elderly population and more patients with chronic disease being managed in the community there is an increasing role for continuous monitoring at home too.

The NHS is undergoing a series of significant changes. Healthcare trusts are merging or being taken over and this is particularly marked in London. Consequently, senior clinicians may be working geographically across several sites. It may be difficult to receive updates on a patient’s status if the clinician is in a different hospital and the junior team is unavailable for contact (such as being scrubbed in theatre for example). However, with the development of new technology and electronic alerts being sent via a clinician’s smartphone, for example, any deterioration in a patient’s condition might be recognised faster resulting in timelier intervention.

Newer wireless technology raises the potential of sensors to continuously take a patient's vital signs and update them accordingly. In a recent study, wireless sensors were used to provide continuously ambulatory monitoring of vital signs and compared to a clinical vital signs monitor(91). The disposable wireless sensor is uploaded to a virtual server via a bridging device and seen via a notification device (smartphone) or a nursing computer. This is one of the first studies of its kind, and the role of continuous observational monitoring of vital signs on ward patients needs to be explored further. A range of options are used to transmit the data from the sensor wirelessly including Bluetooth, radiofrequency and Wi-Fi signal. The wearable sensor technology can transmit data back to the clinicians via alerting through a centralised monitoring system, integrating into electronic health records and alerting to mobile applications for portable handheld devices such as smart phones and Personal Digital Assistant (PDA). Most clinicians appear to have smartphones which often have several applications. The current generation of smartphones are not only faster but also portable and far more appealing than the slow cumbersome desktop computers with outdated software currently still being used. If alerts in early warning scores were able to be viewed via smartphones and continuous sensors it is likely that patient deterioration will be picked up significantly faster than current practice.

All new technologies being used within the NHS should be compliant with General Data Protection Regulation (GDPR). This is new regulation that came into law on 25th May 2018 and replaced the UK data protection act in 1998(92). With similar principles to the data protection act GDPR regulations also ensure more accountability with requirements for transparency in data use and penalties for non-compliance.

1.3.2 The current challenge

The patient safety challenge is twofold;

- 1) Earlier detection of unwell patients with sepsis.
- 2) A better escalation response.

Delayed antibiotics after sepsis has been identified to increase the in hospital mortality(93)(94). Early use of vasopressors in patients with septic shock increases survival(95). The sooner patients with sepsis are identified, the better the outcome. Earlier detection of patient deterioration may occur through new technologies and wearable sensors. Ideally the wearable sensors should populate electronic health records (EHR) so that sepsis alerts can be automatically generated. Improvements in the identification and escalation of unwell patients and those with sepsis may occur through digital technologies. This will be explored in this thesis.

1.3.3 A review of the latest wearable sensors measuring several vital signs continuously

Wearable sensors that continuously monitor patient observations offer much promise; they have the potential to identify sepsis sooner and alert clinicians of patient deterioration. The wearable sensor market is rising rapidly and driven by major technology companies (Google and Apple) as well as those specialising in sports clothing (Nike and Adidas). This is a huge industry with an expected market worth of \$2.86 billion dollars by 2025(96). There is currently no outright leader in the field. The key factors in wearable sensor growth are a combination of higher user demand, advancement in sensor technologies resulting in miniaturisation, reduced production costs, coupled with both wireless communication streams and a longer battery life.

There are three different strategies for wireless body sensor communications(97);

- 1) Off body – devices worn on the body communicates with a device off the body
- 2) On- Body – several devices worn on the body communicate together
- 3) In-Body – devices may be implanted such as a pacemaker or ingestible sensor

The key issues in sensor technology are: the need for a reliable sensor, the data to be reliably transmitted and security of all patient datasets(97).

Wearable bio sensors are non-invasive devices that capture, transmit and process health related data(98). Ideal sensors should be low cost, reliable, lightweight, easy to wear, easy to use, have a long battery life and allow the wearer to ambulate normally. Thus, far there is little in the literature for wearable sensor use in routine ward-based patient care. A review of the latest wearable sensors that can measure multiple vital signs continuously was performed(99). A formal systematic review of the literature was unable to be performed as many of the latest technologies are yet to be on medical search engines. Whilst most available sensors are consumer graded there are a few manufacturers that have obtained European Conformity (CE) and or Food and Drug Administration (FDA) approvals for use in hospital settings. Only those wearables that had both FDA and CE marking approvals were described, as these are the sensors that will be used on patients in this thesis. Unless expressed below many of the sensors have not been validated in a hospital setting.

1.3.3.1 Early Sense Monitoring System

The Early Sense Monitoring System is a non-disposable sensor placed under the patient's mattress(74). It is attached to the bedside monitor and display centre for healthcare professionals via a wire (74). It measures heart rate, respiratory rate and bed motion. In addition to the sensor there is a central display station and software. All equipment is attached to a mains power supply, so battery life is not a problem. Any alerts from the sensor are transmitted to the bedside unit, central display station and a mobile device. Sensor weight is not a concern as the sensor is not directly attached to the patient. The main feature of the sensor is that it can only be used when the patient is in bed (100). The Early Sense system is both FDA approved and CE marked with more research than any other system thus far(99). In one study the costs of the Early Sense system were reviewed using 2 different care models (101). Model A was a care-based model that estimated total cost savings of intervention effects. Whilst model B was more conservative model and only the direct variable cost component for the final day of length of stay and treatment of pressure ulcers was included (101). The study found both cost models had a positive return on investment when used in both surgical and medical wards(101).

Another study found significant reductions in both the length of stay and Intensive Care Unit days for transferred patients(102). The authors believed that the reduction in length of stay was likely to be attributable to the continuous monitoring of vital signs, which helped in earlier detection of deterioration and more effective intervention for clinical problems which are known to prolong both ICU and hospital stay(102). Currently the Early Sense System has mainly been used for research purposes as opposed to routine clinical care. The main

limitations of the system are the inability of the sensor to be used in an ambulating patient and it is currently unable to interface with the electronic medical record.

1.3.3.2 Vital Connect HealthPatch™

The Vital Connect HealthPatch™ monitors eight vital signs: single lead Electrocardiography (ECG), HR, HR variability, RR, skin temperature, body posture, fall detection and activity (103). A wireless adhesive sensor is placed on the patient's chest. The sensor has a battery life of 4 days and is disposable with CE markings and FDA approval (103). The sensor is light weight with specifications of a weight of 11 grams and size of 11.5 x 3.6 x 0.8 cm. The vital connect sensor transmits signals via Bluetooth to a centralised monitoring device and via text to a mobile device. Real-time continuous observation data transmission is at a sampling frequency of 125Hz(75). Patch validation was in health individuals undergoing various physiological assessments such as exercising. A comparison was made between the patch and standard reference monitoring and 3 patches were placed on each patient (75)(99). The patches were placed in three possible locations: (1) in a modified lead-II configuration on the left midclavicular line over intercostal space (ICS) 2, (2) vertically over the upper sternum, or (3) horizontally on the left midclavicular line over ICS 6(75)(99). The reference monitoring used was a Actiheart device for heart rate, oxygen cannula attached to an Oridion Capnostream capnography monitor for respiratory rate and two pedometers (Omron and FitBit) for measuring steps(75)(99). The patch accuracy was confirmed (75). When compared to the reference monitoring the heart rate measurement had a mean absolute error (MAE) of less than 2 bpm(75). Respiratory rate had an MAE of 1.1 breaths per minute during metronome breathing(75)(99). The posture detection had an accuracy of over 95% in two of

the three patch locations, steps were counted with an absolute error of less than 5%, and falls were detected with a sensitivity of 95.2% and specificity of 100%(75)(99). However, the sample size was small with only 25 healthy participants. In another study, the patch was tested in well elderly subjects with various medical co-morbidities over 50 consecutive days in their homes(104). The patch sensor was paired to a smart phone in which data streams could be reviewed in real-time. The patch sensor was compared to comparative reference devices; Actiheart (CamNtech Inc) for HR, DataTherm temperature probe (GeraTherm) for temperature and Capnostream 20 monitor (Oridion) for respiratory rate (104). HR, RR and skin temperature estimated the mean absolute errors to be <3 beats/min, <3 breaths/min and <1.2 °C, compared to reference monitoring(104)(99). This study supported the use of wearable sensors to provide monitoring at home in both elderly and vulnerable patients.

1.3.3.3 Sotera Wireless ViSiMobile System

The ViSiMobile System is a wrist based sensor with oxygen saturations measured by the thumb. The ViSiMobile System allows continuous measures of HR, ECG, RR, oxygen saturation level, skin temperature and non-invasive blood pressure(76). The validation of the sensor has not been released by the company. The sensor weights 110 grams with size dimensions of; 2.6 cm in height x 4.9 cm in width x 9.4 cm in length. It is a non-disposable sensor with a battery life of between 12-14 hours before it needs to be recharged. Through Wi-Fi technology, it can integrate into the electronic health systems and allows alerts to be sent to tablets or smartphone devices if significant changes in vital signs are found. The ViSiMobile System has been FDA approved and CE marked. A quality improvement study at John Hopkins Hospital has used the ViSiMobile System for patients on a surgical ward (105).

Although the results are currently being analysed, early results are encouraging. The 3-month surveillance has identified patients with pulmonary emboli, the early stage sepsis, myocardial infarction and atrial fibrillation(105). On discharge 98% of patients showed satisfaction with the system(105). The satisfaction from nursing staff was recorded at 70-75%(105). A concern for multi parameter continual vital sign monitoring is the risk of alarm fatigue by nurses. If nursing staff are exposed to frequent alarms, they may become desensitised(99). This system in particular has been shown to have low rates of alarm fatigue(106).

1.3.3.4 Philips Bio Sensor

The Philips Bio Sensor is a wireless self-adhesive sensor worn on the chest. It measures HR, RR, skin temperature, body posture, fall detection, single lead ECG, RR-interval and step count(78). It weighs 12 grams and the size dimensions are 1cm x 3.6cm x 0.8 cm. During a normal ECG waveform, the R interval equates to a point corresponding to the peak of the QRS complex(99). The RR-interval in this context is the interval between successive R peaks on an ECG(99). The Philips Bio Sensor is disposable and has a battery life of 4 days(99). The sensor technology is ECG electrodes that detect heart rate, a thermistor to detect skin temperature and 3 axis accelerometer to detect motion(78)(99). The patient data is transmitted via Bluetooth to an IntelliVue Guardian Software tool which can integrate into electronic medical records and alert to smartphone devices(99). The sensor has both FDA approvals and CE markings. There are currently no research papers about the use of the sensor on the wards for continuous monitoring and the validation data of the sensor has not been released by the company (99).

1.3.3.5 Isansys Lifetouch Sensors

The Isansys Lifetouch measures HR, RR and heart rate variability. It is attached to the patient's chest via ECG electrodes(79). It is a light weight sensor with a weight of 7 grams and sensor dimensions for a small sensor are 14cm x 4.7cm x 0.95cm(79). It is attached to the patient's chest via ECG electrodes(79). Data is extracted from the ECG trace and then relayed to a central server (79). This sensor is disposable with a battery life is between 4- 6 days as a maximum(79). Data transmission is via Bluetooth and it can be transferred into electronic health systems. This is FDA and CE marked. In addition there is another sensor they have called Lifetemp which sticks to the body by using silicone gel adhesive and is normally placed in the axilla(79). It can continuously measure relative skin temperature from patients and transmit readings wirelessly to a blue tooth enabled receiver. There are currently no research papers about the use of the sensor on the wards for continuous monitoring and the validation data of the sensor has not been released by the company (99).

1.3.3.6 Zephyr Bio-HarnessTM

The Bio-HarnessTM is predominantly used for commercial purpose and has been tested in fields such as sport and the military(80)(99). This is a wearable sensor with an elasticated belt that is typically worn around the chest(80). It is non-disposable with a battery life of 24 hours(99). The data is transmitted via ECHO or Bluetooth to a centralised display. The sensor is both FA approved, and CE marked. The sensor can measure HR, HR Variability, RR, temperature, posture and accelerometry data(99). HR is captured through electrode sensors within the chest strap and reported as beats per minute(99)(107). RR is measured

using a capacitive pressure sensor that detects expansion and contraction of the torso and gives an output of breaths per minute(99)(107). Triaxial accelerometry uses piezoelectric technology and reports 1Hz per second(99)(107). There is also a micro electro-mechanical sensor accelerometer with a capacitive measurement scheme and is sensitive along 3 orthogonal axes (vertical, sagittal and lateral) (99)(107). The skin temperature is measured using an infrared sensor through a clear window at the apex of the device(99)(107). These sensor parameters were tested using a repeated, discontinuous incremental treadmill protocol(99)(107). The coefficient of variation was low for HR, accelerometry, posture and skin temperature, the RR was less reliable (99)(107). There are currently no additional research papers about the use of the sensor on the wards for continuous monitoring and the validation data of the sensor has not been released by the company (99).

1.3.3.7 Advanced Medical mONitoring (AMON) Wearable Sensor

The Advanced Medical mONitoring (AMON) is a wrist worn sensor that weights 286 grams (99). It continuously measures HR, oxygen saturations and temperature of a patient (81). In addition, it can measure the level of physical activity, blood pressure and one lead ECG when necessary (99). The sensor is a non-disposable sensor with a variable battery life depending on power consumption(99). The data is uploaded via Wi-Fi to centralised monitoring and can incorporate into electronic health records(99). This sensor has both FDA approval and CE marking. Automatic alerts can be sent to the healthcare team if any deviations are found in measurements(99). In a study of 33 healthy volunteers the accuracy of the device when compared to manual observations was questioned(81). There was initially a design flaw in the pulse algorithm; once corrected 85% had a difference of less than 5 beats per minute(81)

(99). There was unfortunately great deviation in the oxygen saturations measured and there was no ECG concordance apart from HR(81)(99). There are currently no additional research papers with the use of the sensor on the wards for continuous monitoring and the validation data of the sensor has not been released by the company (99).

1.3.3.8 Sensium Vitals Monitoring Technology

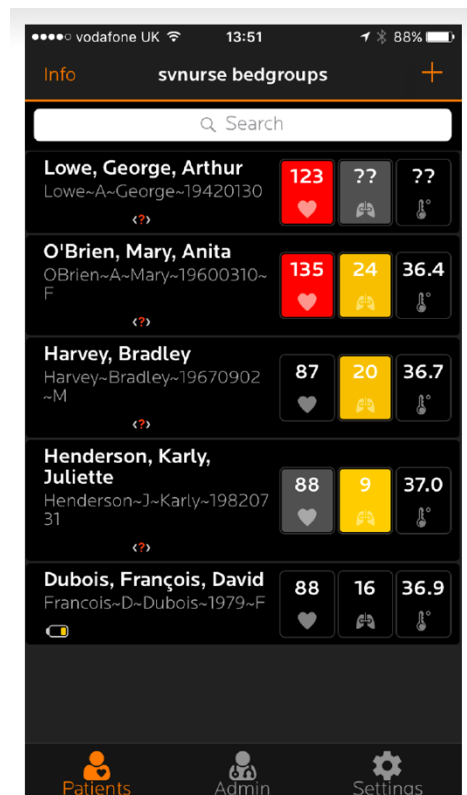
The Sensium device is a wearable, wireless device which allows monitoring of HR, RR and axillary temperature every 2 minutes(77). The sensor is both FDA approved, and CE marked. It is a low cost, single use, low powered device with a battery life of 5 days. The patch is attached to the patient's chest via ECG electrodes and a wire is attached around the patient's back with a sensor measuring axillary temperature. Figure 1.2 shows the patch placed on a patient's chest. The battery life for this sensor is up to 5 days. The lower power consumption is a real strength of this product over its competitors(99). Patients can wear the patches for all their daily activities including whilst sleeping and when washing as the patch is waterproof(99).

Figure 1.2. Sensium patch placed on a patient's chest. Image reproduced with permission from Sensium, Abingdon, UK.



Data from the sensor is transmitted via a proprietary low power radio frequency link to a Sensium Vitals bridge that is connected into the hospital secure network. The patient's physiological data trends can be viewed by clinical staff on terminals or handheld/mobile devices. The handheld notification device will be an I-Pod (version 6) with the Sensium application downloaded as seen in Figure 1.3 (all names and details are made up; no real patient details are provided). If a patient's vital sign measurements cross pre-set and configurable thresholds for a defined period of time, a notification will be generated and targeted to the clinical staff member responsible for that patient's care. The Sensium Vitals system contains only 3 of the 7 National Early Warning Score (NEWS) parameters. NEWS is the current national track and trigger system and standard of care for monitoring acutely unwell adult patients. It is proposed that this wearable sensor system is an addition to the current standard of care, which is the observation round, rather than to replace it.

Figure 1.3. I Pod with the Sensium application



The patch has been tested in 60 patients and has been shown to have reliable heart rate values(108). The study was performed in recovery after patients underwent routine surgery and on a general ward. The wearable patch has ambulatory algorithms which ensure that noisy or irregular signals are not reported to ensure a reduction in false alerts and alert fatigue(77)(109).

1.3.3.9 Comparison of the sensors described

A range of sensors measuring a variety of vital signs have been described above and the results are encouraging.

A summary of each wearable sensor and the vital signs measured can be found in Table 1.3.

A further description of each wearable sensor can be found in Table 1.4

Table 1.3 A summary of each wearable sensor and the vital signs measured (99).

<u>Device</u>	Heart Rate	Heart Rate Variability/ RR Interval	Single Lead Electrocardiography	Respiratory Rate	Skin Temperature	Bed Motion	Body Posture	Fall Detection	Activity	Oxygen Saturations	Non-invasive Blood Pressure
<u>Current Monitoring Devices</u>	Yes				Yes					Yes	Yes
<u>Early Sense monitoring</u> (74)	Yes	Yes		Yes		Yes					
<u>Vital Connect</u> (75)	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes		
<u>VisiMobile System</u> (76)	Yes		Yes	Yes	Yes					Yes	Yes
<u>Philips Bio Sensor</u> (78)	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes		
<u>Isansys Life Touch Sensor</u> (79)	Yes	Yes		Yes							
<u>Zephyr Wearable Sensor</u> (80)	Yes	Yes		Yes	Yes		Yes		Yes		
<u>Amon wearable Sensor</u> (81)	Yes		Yes, measured 3 times a day or on request		Yes				Yes	Yes	Yes, measured 3 times a day or on request
<u>Sensium Vitals</u> (77)	Yes			Yes	Yes						

Table 1.4 A description of each wearable sensor (99).

<u>Device</u>	Description of sensor	Duration / sensor use	Disposable	Tested on Patients	Approval	EHR Integration	Mechanisms of alerting
<u>Early Sense monitoring</u> (74)	Sensor placed under patient's mattress	N/A	No	Yes	FDA Approved + CE marked	No	Centralised
<u>Vital Connect</u> (75)	Wireless adhesive sensor placed on the chest	4 days	Patch disposable, Sensor not disposable	Yes	FDA Approved + CE marked	Yes	Centralised & Mobile Device
<u>VisiMobile System</u> (76)	Sensor worn around the wrist to measure BP, a chest sensor to measure HR, RR and skin temperature, a thumb sensor for oxygen saturation	Battery Life 12- 14 hours	No	Yes	FDA Approved + CE marked	Yes	Centralised & Mobile Device
<u>Philips Bio Sensor</u> (78)	Self-adhesive sensor worn on the chest	4 days	Yes	Yes	FDA Approved + CE marked	Yes	Centralised & Mobile Device
<u>Isansys Life Touch Sensor</u> (79)	Adhesive sensor on the chest attached via ECG electrodes	4-6 days	Yes	Yes	FDA Approved + CE marked	Yes	Centralised & Mobile Device
<u>Zephyr Wearable Sensor</u> (80)	Sensor worn in a belt, typically around the chest	24 hours	No	Yes	FDA Approved + CE marked	Unknown	Centralised
<u>Amon wearable Sensor</u> (81)	Wrist worn sensor	Variable depending on power consumption	No	Yes	FDA Approved + CE marked	Yes	Centralised
<u>Sensium Vitals</u> (77)	Adhesive sensor on the chest attached via ECG electrodes	5 days	Yes	Yes	FDA Approved + CE marked	Yes	Centralised & Mobile Device

BP = Blood pressure, HR = Heart Rate, RR = Respiratory Rate, ECG = Electrocardiography, CE = Conformity European (CE), FDA = Food and Drug Administration

Wearable sensors and digital technology have the potential to improve patient safety for both hospital patients and those at home. Several sensor designs are available. The Early Sense monitoring system sensor is placed under the mattress. Although useful for some patients, those that are ambulating on the wards or in a chair next to the bed, for example, would not receive monitoring. Several sensors were placed on the chest either through adhesives or ECG electrodes (Vital Connect, Sensium, Philips and Isansys). These can easily be worn under the patient's clothes and are unobtrusive. The wrist worn sensors were the Amon and VisiMobile ones whilst the Zephyr sensor is worn around the chest. All the sensors described above measure HR which is the most commonly measured vital sign. Respiratory rate and temperature were the second most commonly measured vitals. No system yet exists that can perform all routine observations. For example, assessing cognitive levels are difficult to assess using wearable sensors. In addition, there is yet insufficient data to allow wearable sensors to replace routine ward observations. The power consumption of the sensors is quite variable: the VisiMobile system battery life was 12-14 hours whilst the Sensium vitals patch could be worn for up to 5 days. All sensors reviewed in this study had a combination of FDA and or CE marking approvals.

Due to the low cost, long battery life, ability to measure HR, RR and temperature (parameters that change in sepsis), built in algorithms and some early research studies the Sensium wearable sensor was the one chosen to be assessed in this thesis. The validation data on the sensor algorithms is held under patent by the company and is unable to be shared. Many of the wearable sensor companies did not respond when contacted or were unwilling to use their sensor as part of a trial. Just one sensor was selected to allow a thorough assessment.

1.4 Thesis Aims

To determine the impact of wearable sensors and digital alerting systems on the detection of sepsis.

1.4.1 Hypothesis

The null hypothesis states that novel wearable sensors that provide continuous monitoring of patients and digital alerting systems are unable to detect patient deterioration and sepsis quicker than current methods.

1.4.2 Research Aims

1. To offer an up-to-date systematic review and meta-analysis of digital alerting systems on patient sepsis outcomes (Chapter 2).
2. To test the reliability of a wearable sensor monitoring heart rate, respiratory rate and temperature when compared to standard ward monitoring (Chapter 3).
3. To identify the ideal time windows for alert generation from the sensor (Chapter 3).
4. To investigate the speed at which the wearable sensor detects patient deterioration and the subset of patients with sepsis when compared to standard monitoring (Chapter 4).
5. To explore patient experience of wearable sensor technology and continuous monitoring through questionnaire and interview studies (Chapter 5).
6. To explore staff experience of wearable sensor technology and continuous monitoring through interview studies (Chapter 6).
7. To perform a pilot feasibility study to investigate how digital alerting can affect the time taken to identify unwell patients and those with sepsis (Chapter 7).
8. Discussions and conclusions (Chapter 8).

Overall Thesis Plan

Section 1: Introduction	
Chapter 1	Chapter 2
Background to Sepsis, Wearable Sensors and patient deterioration.	A Systematic Review and Meta-Analysis Can Digital Alerting Improve Sepsis Outcomes and Hospital Length of Stay?
Section 2: Testing the wearable Sensor for Sepsis	
Chapter 3	Chapter 4
Assess the reliability of a wearable sensor.	Assess the speed the wearable detects sepsis and patient deterioration.
Section 3: Human Factors	
Chapter 5	Chapter 6
Quantitative and qualitative review of wearable sensors through questionnaire and interview studies with patients.	Qualitative review of wearable sensors through interview studies with staff.
Section 4: Real time digital alerting	
Chapter 7	
Pilot study on the use of real time digital alerts to detect unwell patients and those with sepsis.	
Section 5: Discussions and Conclusions	
Chapter 8	
Discussions, Summary of Research Findings, Wider Literature, Thesis Strengths, Thesis Limitations, Future Research, Personal Reflections and Conclusions.	

Chapter 2 A Systematic Review and Meta-Analysis Can Digital Alerting Improve Sepsis Outcomes and Hospital Length of Stay?

2.1 Introduction

Sepsis is a major health concern causing significant mortality worldwide(7)(8). Although used to describe a variety of clinical conditions, the most recent recommendations suggest sepsis should be defined as a ‘life threatening organ dysfunction caused by a dysregulated host response to infection’(4). In the United States, the average annual age adjusted incidence is 300 to 1000 cases per 100,000 people(5). The mortality from this condition is as high as one in four patients with a rising incidence - despite numerous interventions (7)(8)(9)(10). In addition, it poses a significant financial burden on healthcare systems. The annual total US costs of sepsis was \$20 billion in 2011(15). Additionally, there are numerous indirect costs which may significantly impact on patients’ quality of life. For example, the older population may suffer with severe long-term health problems after sepsis including both cognitive dysfunction and functional disability(16).

Recognising sepsis early and initiating timely treatment results in improved patient outcome measures as well as significant cost reduction(30)(31). The International Surviving Sepsis Campaign recommends early identification of patients with sepsis and prompt treatment such as antibiotics within one hour in the suspicion of sepsis (110). A retrospective multicentre study found for every hour’s delay in the treatment of sepsis, the risk of death increases by 7.6%(12). It is well known that in general a failure to recognise and respond to patient deteriorating in hospitals is a major cause of morbidity and mortality (34)(35)(36)(37)(38). Delays in identification of sepsis are often attributable to a lack of diagnostic tools, a gradual disease progression and no gold standard for diagnosis(111). Interventions such as regular monitoring

of vital signs and elevated lactate aid earlier recognition(112). However, despite these, patients are still being identified late. Although track and trigger scoring systems such as the National Early Warning Score (NEWS) have standardised the documentation of vital signs and enabled earlier recognition to a degree, they are still subject to inaccuracies in recordings due to their subjective nature and intermittent monitoring(113). Alternative strategies in sepsis detection are therefore urgently required to improve outcomes.

Digital technology holds significant promise in enabling earlier sepsis recognition. Coupled with the rapid expansion of electronic health records worldwide, it is now possible to provide healthcare staff with real-time information on laboratory tests, imaging and physiological vital signs at the bedside. This is particularly relevant in sepsis due to the traditional reliance on risk scoring systems used to define sepsis. These include Systemic Inflammatory Response Syndrome (SIRS) and Sequential Organ Failure Assessment (SOFA) score(114)(25). Although usually calculated through paper based observational charts alongside separate interfaces to retrieve blood test results, both have the potential to be automated using Electronic Health Records (EHR) to reduce error and enhance digital alerting. There is now an increased literature in this field that can support new clinical decisions in sepsis management.

2.2 Aims:

The aim of this chapter is to offer an up-to-date systematic review of digital alerting systems on patient sepsis outcomes.

2.3 Methods

2.3.1 Data sources and searches

I applied the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement for this review(115). The search performed on the 12th February 2019 included Embase, Medline, HMIC, Psych Info and Cochrane (April 1964 -12th February 2019) without language restriction. The search was limited to adult hospitalised patients that were not initially in intensive care. There were supplemental references that were manually gathered through reference lists. The main concepts in the search were digital technology and sepsis. The search terms included digital technology and sepsis (for complete search strategy please see Appendix 2.1).

2.3.2 Outcome measures

Our primary outcome measure was hospital Length of Stay (LOS). Secondary outcome measures included Intensive Care Unit (ICU) LOS, sepsis-associated mortality and the time to antibiotics.

2.3.3 Study selection

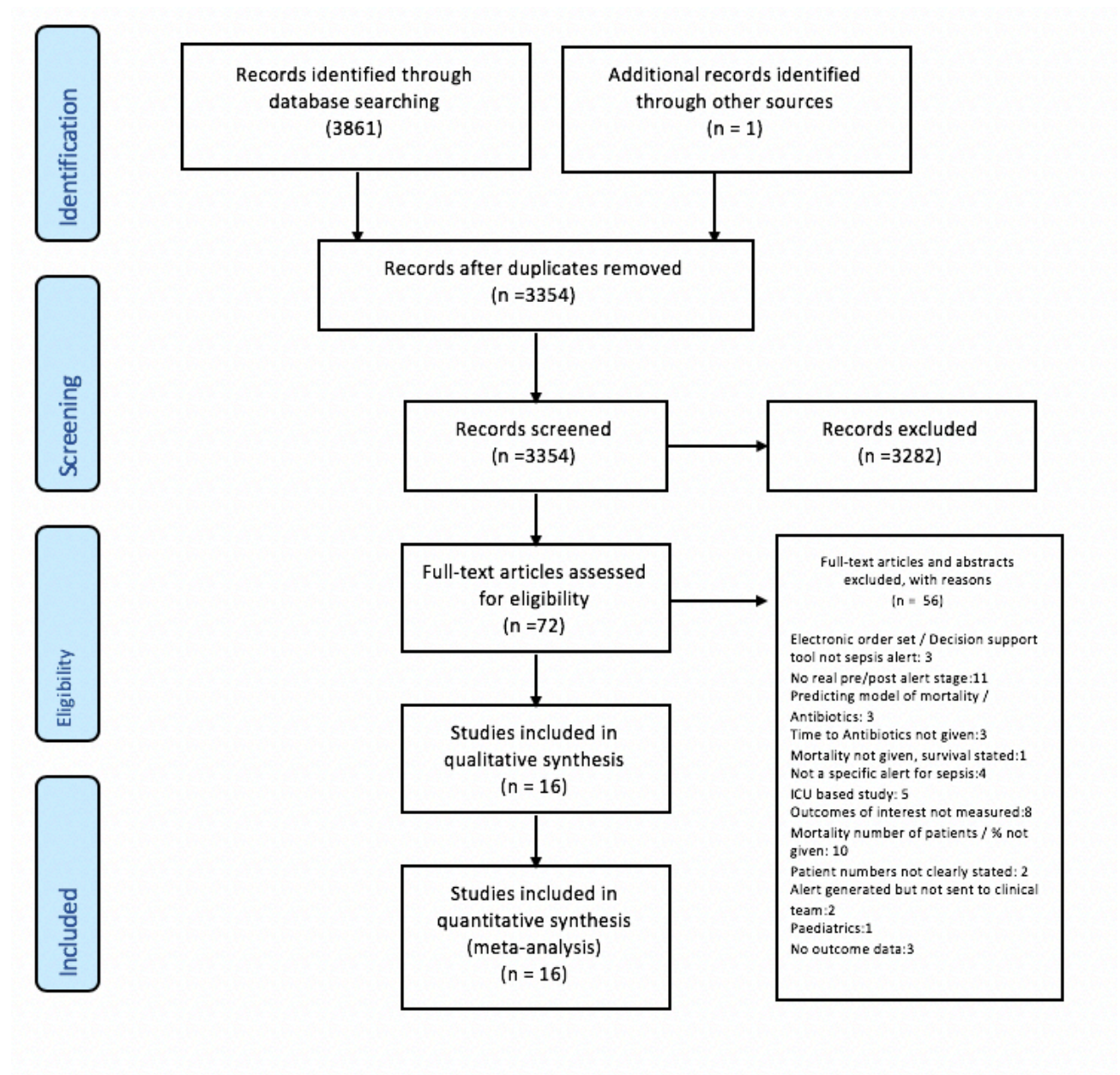
Studies were eligible for inclusion if patients had sepsis with a clear reporting of the diagnostic criteria. In addition, studies were only eligible for inclusion if the outcome measures could be compared pre and post introduction of digital alerts for sepsis. Studies where the clear outcome measures of interest were not stated were not included. The outcome measures of interest were; mortality, time to antibiotics and ICU / hospital LOS. Studies only

required one outcome measure of interest to be eligible for inclusion. There was no fixed number of patients required in each treatment group nor a fixed duration of follow up.

2.3.4 Data extraction and quality assessment

All included study characteristics and outcome measures were extracted by one investigator (Ms Meera Joshi) and verified by a second (Mr Hutan Ashrafian who is Chief Scientific Adviser in the Department of Surgery and Cancer, Imperial College London). All full text reports of studies identified as potentially eligible after title and abstract review were obtained for further review. All empirical research into digital sepsis alerting in adults and outcome measures were included. Information on the study location, type of hospital, type of alert and whom the alert was directed at were all extracted using a set standardized form. Studies were only included if a comparative study of pre-and post-alerting groups were given and the number of patients in each group clearly stated. Studies reference lists were also checked to see if any additional eligible papers were found. Studies solely based in intensive care were excluded as extra levels of care and treatments offered to these patients would affect sepsis outcome measures. Additionally, case reports, narrative reviews, editorials and commentaries were excluded. After full text review if a study was excluded the reasons were noted and disagreements were resolved by a third reviewer. A Prisma flow diagram was used to map studies included, excluded and the reasons why (Figure 2.1).

Figure 2.1 PRISMA Flow Diagram



2.3.5 Data synthesis and analysis

A qualitative assessment of all studies was performed. For the primary outcome measure of hospital length of stay a weighted mean difference was calculated. A weighted mean difference is used to calculate the difference between the two means. A weighted mean difference was also used in ICU LOS. For the secondary outcome measure of mortality, we used percentage change between the pre-and post-alerting groups. To ensure a standard way to compare the studies all times to antibiotics were converted into minutes and number of days used for ICU / hospital LOS. For meta-analysis, outcome measures were analysed by calculating through studies with difference in means or the ratio of means within each study. We substituted median for mean in studies where only the median was reported to allow comparisons to be made. We utilised an inverse-variance approach with a random-effects model of DerSimonian and Laird methodology for both continuous and categorical variables. This was accomplished using Stata 13 [StataCorp., College Station, Texas, US]. The I^2 statistic was used to estimate the degree of heterogeneity between studies. Mr Hutan Ashrafiyan (Chief Scientific Adviser in the Department of Surgery and Cancer, Imperial College London) assisted with the analysis performed for the systematic review and meta-analysis.

2.3.6 Risk of bias assessment

The Newcastle-Ottawa scale (NOS) was used to quality score the included papers(116). Two independent judges reviewed the papers. Studies were scored based on: selection of study groups (this has 4 numbered items from groups truly representative of cohort group, selection of non-exposed group, ascertainment of exposure, and outcome of interest not present at the start of the study), the comparability (based on comparability of cohorts on study design or

analysis) and outcome measures (with three items based on assessment of outcome, appropriateness of length of follow-up, adequacy of follow-up cohorts). A maximum score of one star was given for each listed item except for comparability where a maximum of two stars could be given. The range of score was from 0 to 9. Studies with a score of 7 or greater stars were rated as 'higher' studies whilst those with a score less than 7 were rated as 'lower' studies as demonstrated previously in the literature(117). Mr Hutan Ashrafian assisted with the risk of bias assessment.

2.4 Results

The literature search identified 3861 references (Appendix 2.1). One article was found through hand searching. After screening 72 full text reviews were reviewed. Some 16 studies met the inclusion criteria and were included in the final analysis. A description of the studies including the sepsis intervention, alert type and criteria used to define sepsis can be found in Table 2.1. All studies defined sepsis alerts and pre-and post-alerting stage (Table 2.2).

Table 2.1 Characterisation of Studies & Digital Alerts Used

Study	Intervention	Alert Type	Digital Sepsis Alert Criteria
Arabi et al, 2017 A (118)	Group 1 is Sepsis Alert alone	sepsis e-alert + computerized physician order entry (CPOE) sepsis management order-set	A combination of SIRS and 1 organ dysfunction. ≥ 2 SIRS criteria AND at least one of the following organ dysfunctions (systolic blood pressure 86–90 mmHg with intravenous fluids or < 86 mmHg regardless of fluids; blood oxygen saturation of 85–90% with supplemental oxygen or $< 85\%$ without oxygen; lactate > 2 mmol/L) OR two of the above organ dysfunctions
Arabi et al, 2017 B (118)	Group 2 is Sepsis Alert and the Rapid Response Team (ICU Registrar + Trained sepsis nurse)	sepsis e-alert + computerized physician order entry (CPOE) sepsis management order-set	A combination of SIRS and 1 organ dysfunction. ≥ 2 SIRS criteria AND at least one of the following organ dysfunctions (systolic blood pressure 86–90 mmHg with intravenous fluids or < 86 mmHg regardless of fluids; blood oxygen saturation of 85–90% with supplemental oxygen or $< 85\%$ without oxygen; lactate > 2 mmol/L) OR two of the above organ dysfunctions
Austrian et al, 2018 (119)	Sepsis Alert	Alert on Electronic Medical record	SIRS advisory alert = ≥ 2 SIRS criteria or sepsis advisory alert = systolic blood pressure < 90 mmHg or Lactate ≥ 4 mg/dl
Benson et al, 2014 (120)	Sepsis Alert + Nurse Practitioner Rapid Response Team	Alert to Nurse Practitioner Rapid Response Team	≥ 2 SIRS criteria + anion gap acidosis
Berger et al, 2010 (121)	Sepsis Alert	Clinical decision support (Electronic alert)	≥ 2 SIRS criteria + physician suspicion of infection
Crum et al, 2013 (122)	Sepsis Alert	Computerised decision support system (CDSS) alert	≥ 2 SIRS criteria; infectious ED diagnosis OR symptom diagnosis and antibiotic administration in the ED; AND acute organ dysfunction (lactate ≥ 4.0 mmol/L, persistent hypotension within 6 hours of triage or vasopressor use)
Ferreras et al, 2015 (123)	Sepsis Alert	Alert on Electronic Medical record	Abnormal vital signs (SBP < 90 mmHg, HR > 90 , Temperature > 38 °C or < 36 °C, RR > 30 /min, oxygen saturation $< 90\%$, hyperglycemia (140 mg/dl in the absence of diabetes). 2 Types of alert. 1 sepsis alert if any 2 parameters an alert sent. Serious alert if any 2 parameters but one is hypotension OR any 3 parameters abnormal.
Guirgis et al, 2017 (124)	Sepsis Alert + Rapid Response Team + educational programme + electronic order set	Alert on Electronic Medical record	≥ 2 SIRS criteria + documented source of infection.
Hayden et al, 2016 A (125)	Sepsis alert, direct communication, mobilization of resources + order sets	Alert on Electronic Medical record + Paging at the discretion of ED attending	SWAT A – SBP < 90 mmHg + any other SIRS criteria or suspected or known infection
Hayden et al, 2016 B (125)	Sepsis alert, direct communication, mobilization of resources + order sets	Alert on Electronic Medical record + Paging at the discretion of ED attending	SWAT B – SBP > 90 mmHg + ≥ 2 SIRS criteria + concern for an infection source
Manaktala et al, 2017 (126)	Sepsis alert, staff education on sepsis screening programme, creating sepsis order sets	Alert sent to mobile device	SIRS Criteria + Infection (Comorbidities or Medications that alter parameters, <u>such creatinine assessed differently in renal failure patients</u>). If no then alert, if co morbidities or medications alter parameters, adjust parameter cut-offs based on comorbid conditions
Mathews et al, 2014 (127)	EHR-based clinical decision tool	Alert on Electronic Medical record, automated clinical decision tool	<i>Automated clinical decision tool (only abstract, no further details)</i>
McRee et al, 2017 (128)	Sepsis Alert	Alert on Electronic Medical record	≥ 2 SIRS criteria
Narayanan et al, 2016 (129)	Sepsis Alert	Alert on Electronic Medical record	2 EMR alerts: 1 alert if ≥ 2 SIRS criteria and another if severe sepsis / septic shock criteria (i.e., ≥ 2 SIRS criteria + end-organ dysfunction OR fluid nonresponsive hypotension)
Pulia et al, 2016 (130)	Sepsis Alert	Alert on Electronic Medical record	Fever + an additional abnormal vital sign

Study	Intervention	Alert Type	Digital Sepsis Alert Criteria
Sawyer et al, 2011 (131)	Sepsis Alert	Text page to nurse in charge of the ward	Algorithm consisting of laboratory values + hemodynamic parameters including the shock index (HR / SBP), mean arterial pressure, international normalized ratio, white blood cell count, haemoglobin, absolute neutrophil count, serum albumin, total bilirubin, and sodium.
Umscheid et al, 2015 (132)	Sepsis Alert	Alert to the covering provider and rapid response coordinator by text page. The bedside nurses had an alert on Electronic Medical record	SIRS + organ dysfunction (SBP < 100 mm Hg + serum lactate measure >2.2 mmol/L)
Westra et al, (2017) (133)	Sepsis alert	Alert sent to mobile device, order sets, staff education and setting up an interdisciplinary governance committee	Alerting based on 2012 Surviving sepsis campaign and critical care surviving sepsis campaign guidelines. Alerts were disease and medication specific to account for abnormal laboratory tests and vital sign abnormalities.

There were 16 eligible studies, and 2 studies had separate subgroups for alerting. For completeness the subgroups have been listed separately.

Table 2.2 All studies reviewing outcome measures

Study, Year (Reference)	Study Center	Study Design	Setting	Patients, n Pre-Alerting	Patients, n Post Alerting
Hospital Length of Stay					
Arabi et al, 2017 A (118)	Single center 900-bed tertiary care academic hospital	Pre –Post implementation study (full text)	ED	436	195
Arabi et al, 2017 B (118)	Single center 900-bed tertiary care academic hospital	Pre –Post implementation study (full text)	ED	436	699
Austrian et al, 2017 (119)	Single center	Pre –Post implementation study (full text)	ED	838	1306
Guirgis et al, 2017 (124)	Single center 696 – bed level I trauma, 142 Intensive Care Beds	Retrospective Pre –Post implementation study (full text)	Hospital-wide sepsis alert program	1637	1568
Hayden et al, 2016 A (125)	Single center, academic, annual volume 48,000	Retrospective quasi experimental study (full text)	ED	108	130
Hayden et al, 2016 B (125)	Single center, academic, annual volume 48,000	Retrospective quasi experimental study (full text)	ED	13	32
McRee et al, 2017 (128)	Single center	Retrospective Pre –Post implementation study (full text)	medicine patients (intervention vs. control units)	75	96
Sawyer et al, 2011 (131)	Single center, 1250 bed, academic	Prospective observational Pre –Post implementation study (full text)	6 medicine wards (2 intervention wards, 4 controls)	181	89
Umscheid et al, 2015 (132)	Multicenter, 3 hospitals, total 1500 bed, annual volume 70,000	Pre –Post implementation study (full text)	Adult acute inpatient units	594	545
Westra et al, 2017 (133)	Single center, 941 beds, annual volume 42,000	Pre –Post implementation study (full text)	2 respiratory care units and 1 medical surgical unit	566	212
Total				3948	4872
ICU Length of Stay					
Arabi et al, 2017 A (118)	Single center 900-bed tertiary care academic hospital	Pre –Post implementation study (full text)	ED	436	195
Arabi et al, 2017 B (118)	Single center 900-bed tertiary care academic hospital	Pre –Post implementation study (full text)	ED	436	699
Austrian et al, 2017 (119)	Single center	Pre –Post implementation study (full text)	ED	838	1306
Guirgis et al, 2017 (124)	Single center 696 – bed level I trauma, 142 Intensive Care Beds	Retrospective Pre –Post implementation study (full text)	Hospital-wide sepsis alert program	1637	1568
Hayden et al, 2016 A (125)	Single center, academic, annual volume 48,000	Retrospective quasi experimental study (full text)	ED	108	130
Hayden et al, 2016 B (125)	Single center, academic, annual volume 48,000	Retrospective quasi experimental study (full text)	ED	13	32
Umscheid et al, 2015 (132)	Multicenter, 3 hospitals, total 1500 bed, annual volume 70,000	Pre –Post implementation study (full text)	Adult acute inpatient units	595	545
Total				3627	4475
Time to Antibiotics					
Arabi et al, 2017 A (118)	Single center 900-bed tertiary care academic hospital	Pre –Post implementation study (full text)	ED	436	195
Arabi et al, 2017 B (118)	Single center 900-bed tertiary care academic hospital	Pre –Post implementation study (full text)	ED	436	699
Crum et al, 2013 (122)	Single center academic level I trauma center	Pre –Post implementation study (abstract only)	ED	98	103
Hayden et al, 2016 A (125)	Single center, academic, annual volume 48,000	Retrospective quasi experimental study (full text)	ED	108	130
Hayden et al, 2016 B (125)	Single center, academic, annual volume 48,000	Retrospective quasi experimental study (full text)	ED	13	32
Narayanan et al, 2016 (129)	Single center, academic	Pre-post implementation observational study (full text)	ED	111	103
Pulia et al, 2016 (130)	Single center	Pre –Post implementation study (abstract only)	ED	225	211

Study, Year (Reference)	Study Center	Study Design	Setting	Patients, n Pre- Alerting	Patients, n Post Alerting
Total				991	1473
Mortality					
Arabi et al, 2017 A (118)	Single center 900-bed tertiary care academic hospital	Pre –Post implementation study (full text)	ED	436	195
Arabi et al, 2017 B (118)	Single center 900-bed tertiary care academic hospital	Pre –Post implementation study (full text)	ED	436	699
Austrian et al, 2017 (119)	Single center	Pre –Post implementation study (full text)	ED	838	1306
Benson et al, 2014 (120)	Single center 350-bed teaching hospital	Retrospective Pre –Post implementation study (full text)	All Medical / Surgical wards	123	116
Berger et al, 2010 (121)	Single center tertiary care level 1 trauma center, annual volume 70,000	Pre –Post implementation study (full text)	ED	908	890
Ferreras et al, 2015 (123)	Single center	Retrospective Pre –Post implementation study (full text)	ED	117	116
Guirgis et al, 2017 (124)	Single center 696 – bed level I trauma, 142 Intensive Care Beds	Retrospective Pre –Post implementation study (full text)	Hospital-wide sepsis alert program	1637	1568
Hayden et al, 2016 A (125)	Single center, academic, annual volume 48,000	Retrospective quasi experimental study (full text)	ED	108	130
Manaktala et al, 2017 (126)	Single center, 941 beds, annual volume 42,000	Pre –Post implementation study (full text)	2 respiratory units and one general medicine unit.	566	212
Mathews et al, 2014 (127)	Single center	Pre –Post implementation study (abstract only)	medicine patients (intervention vs. control units)	879	1212
McRee et al, 2017 (128)	Single center	Retrospective Pre –Post implementation study (full text)	medicine patients (intervention vs. control units)	75	96
Sawyer et al, 2011 (131)	Single center, 1250 bed, academic	Prospective observational Pre –Post implementation study (full text)	6 medicine wards (2 intervention wards, 4 controls)	181	89
Total				5868	6629

The studies by Arabi et al (118) and Hayden et al (125) had 2 separate cohorts of patients.

2.4.1 Characteristics of studies & digital alerting used

All studies investigated digital sepsis alerts table 2.1. Several studies additionally used a rapid response team in combination with the digital sepsis alert in the alerting group (118)(124)(120). An electronic order set was used by 4 studies in the alerting group(125)(124)(126)(133).

The studies were predominantly single center studies however there was one study that was multi center across three hospital sites(132). Most studies were based in the USA however there was one study from the Kingdom of Saudi Arabia(118) and one from Spain (123). A majority of the studies were based in large hospital settings with 6 studies that were based in academic centers (118)(125)(131)(122)(129)(120) and 3 centers that were level 1 trauma centers (124)(122)(121). Within the hospital setting only one study was a hospital wide sepsis alert (124). There were 8 studies solely in the emergency department (118)(119)(125)(122)(129)(130)(121)(123). There were 5 studies only on medical wards (128)(131)(132)(126)(127) and 2 studies both on medical and surgical wards (120)(133). All of the studies were pre-and post-implementation studies.

The type of electronic alerts used in the studies varied. The majority of studies used digital alerts generated through electronic health records on desktop based computers (118)(120)(121)(122)(124)(125)(128)(129) (119)(130)(123)(127). There were 2 studies in which alerting was via a mobile device (126)(133) and there were two studies which used text paging (131)(132). One study was predominantly alerting through electronic health

records but used additional text paging at the discretion of the Emergency Department [ED] attending(125). This is all shown in Table 2.1. Most of the digital alerts in the study were aimed at nursing staff (118)(120) (125)(119)(126)(131)(133). Whilst one study was aimed solely at clinicians (121) two studies had alerts beings sent to both clinicians and the rapid response team (124)(132). There were 4 studies in which it was unknown as to whom the digital alerts were sent to (122)(130)(123)(127).

The sepsis alerting criteria varied; many of the studies used a variation of the Systemic Inflammatory Response Syndrome (SIRS) criteria

(118)(120)(121)(122)(124)(125)(126)(128)(129)(132) (119). SIRS is defined as a; temperature $>38^{\circ}\text{C}$ or $<36^{\circ}\text{C}$; heart rate >90 beats/min; respiratory rate >20 breaths/min OR arterial CO_2 lower than 32mmHg ; WBC count $>12,000/\text{mm}^3$ or $<4000/\text{mm}^3$ (114). There was only one study that used ≥ 2 SIRS criteria alone(128). Some used ≥ 2 SIRS criteria with a suspicion of infection(121)(124)(126)(125). Hayden et al used ≥ 2 SIRS criteria with a suspicion of infection but had 2 subgroups of patients; one with a systolic blood pressure (SBP) of <90 mmHg and one >90 mmHg. A combination of ≥ 2 SIRS criteria with evidence of end organ dysfunction was also used as a criteria to alert (118)(132)(129). Narayanan et al had 2 types of sepsis alert; 1 alert if ≥ 2 SIRS criteria and another if severe sepsis / septic shock criteria (i.e., ≥ 2 SIRS criteria and end-organ dysfunction OR fluid nonresponsive hypotension)(129). One study used the combination of if ≥ 2 SIRS criteria and an anion gap acidosis calculated from an arterial blood gas(120). Crum et al used a combination of ≥ 2 SIRS criteria; infectious ED diagnosis or symptom diagnosis and antibiotic administration in the ED; and acute organ dysfunction (lactate ≥ 4.0 mmol/L, persistent hypotension within 6 hours of triage or vasopressor use) (122). Austrian et al had 2 types of alert; one with ≥ 2 SIRS criteria and another with a systolic blood pressure $<90\text{mmHg}$ or Lactate of $\geq 4\text{mg/dl}$. Not

all studies used SIRS; Pulia et al used a fever plus any abnormal vital sign (130) whilst Sawyer et al (131) and Ferreras et al (123) used an algorithm consisting of laboratory values and hemodynamic parameters. Mathews et al was an abstract only and no details were found on the alerting criteria used(127).

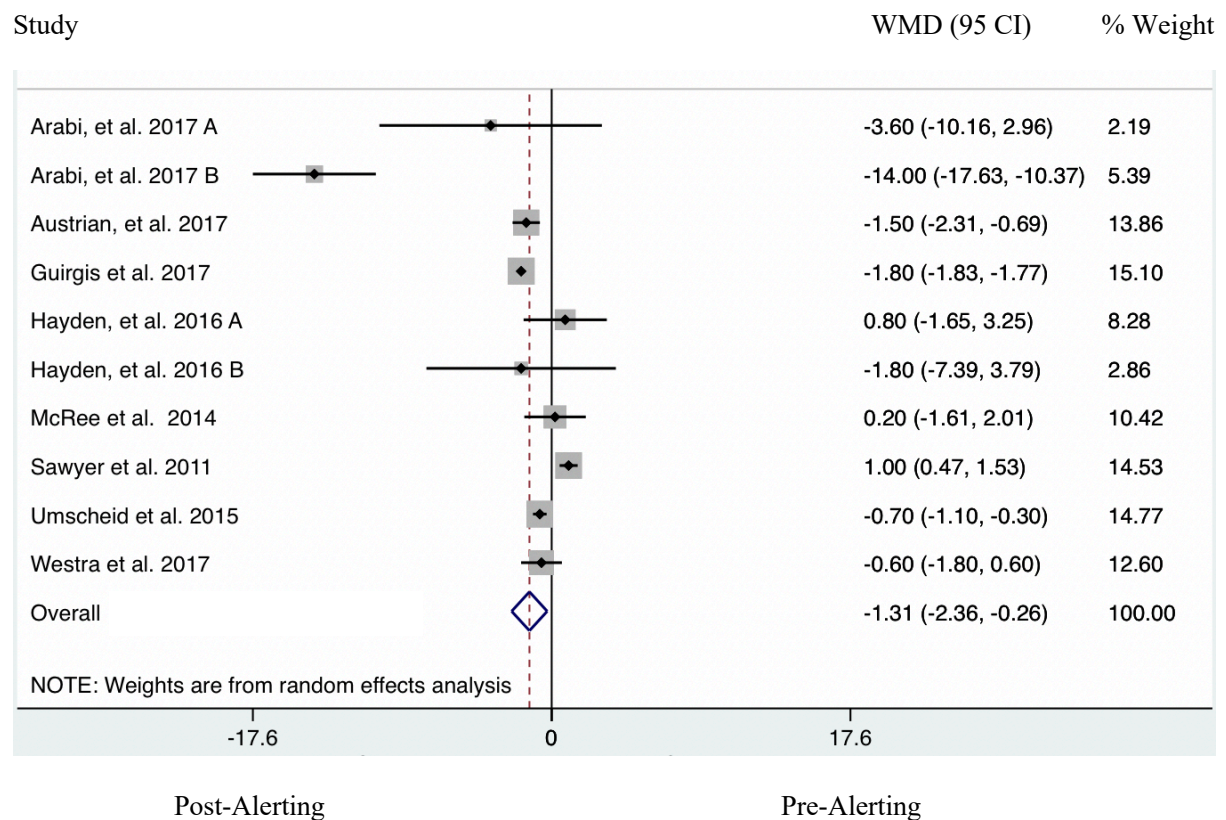
All studies included had clear outcome measures with a defined sepsis alert and pre-and post-alerting stage; these can be found in Table 2.2. Some studies reviewed several outcome measures of interest. All studies were non-ICU based and either alerted in the ED or on the hospital wards. In total 8 studies with hospital LOS, 5 studies with ICU LOS, 11 with mortality outcomes and 5 studies reviewed the time to antibiotics. Several of the studies have tried to adjust for potential confounders. Guirgis et al performed multivariate adjusted comparisons (124) whilst Westra used techniques such as propensity scoring and bootstrapping to adjust for confounders (133).

Each outcome measure will now be reviewed in further detail.

2.4.2 Hospital Length of Stay

Hospital LOS was included in 8 studies (118)(124)(125)(128)(131)(132)(133)(119) In total, there were 3948 patients in the pre-alerting group and 4872 in the post-alerting group across these 8 studies. Results highlight there was a significant reduction in hospital LOS by 1.311 days in the post-alerting group (95% CI -2.362 - -0.261, $p=0.014$, Figure 2.2). The study with the biggest impact on length of stay was that of Arabi et al B(118). The strong treatment effect seen may be partly explained by the addition of a rapid response team however the rapid response team was also used in the study by Guirgis et al and the effect on length of stay was not as great (124).

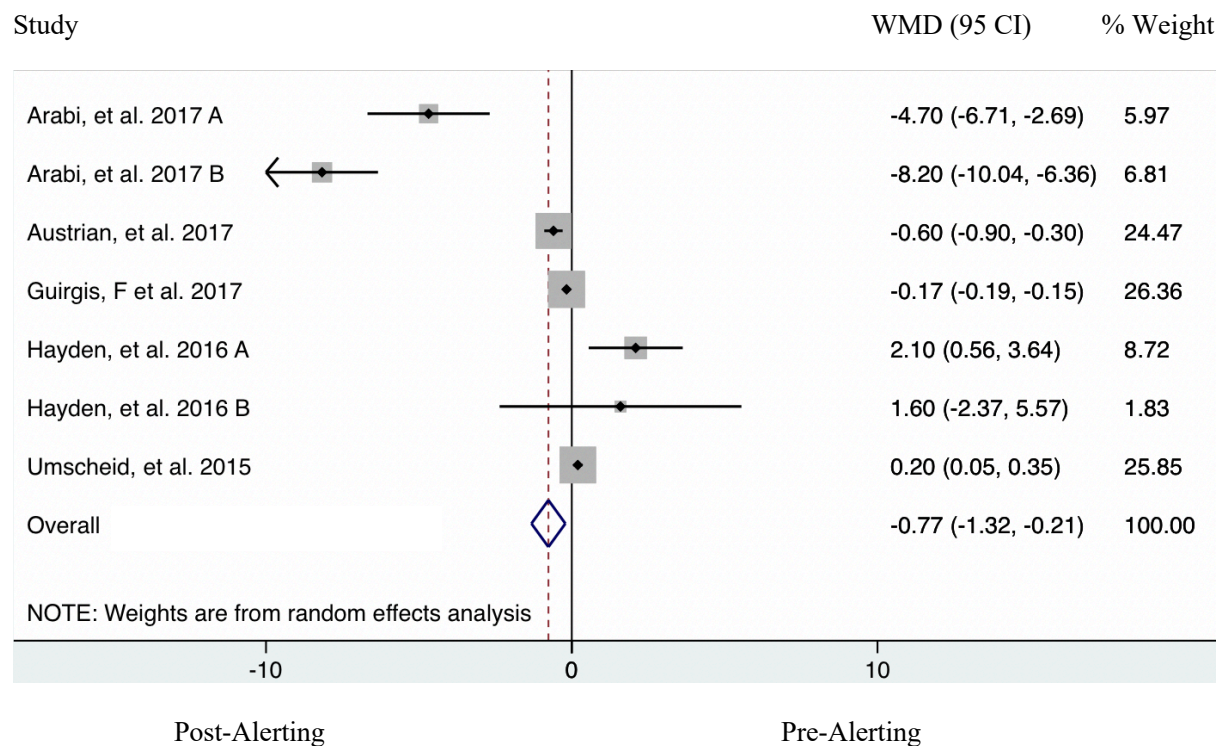
Figure 2.2 Forrest Plot for Hospital Length of Stay



2.4.3 ICU Length of Stay

For ICU LOS (when patients were escalated from the ward setting) there were 5 studies included (118)(124)(125)(132)(119). These are shown in table 2.2. In total, there were 3627 patients in the pre-alerting group and 4475 in the post-alerting group. The weighted mean difference for all studies shows a significant reduction in ICU LOS by 0.766 days for the alerting group vs the pre-alerting group (95% CI -1.324– 0.209, $p=0.007$, Figure 2.3). The biggest impacting study again was by Arabi et al B. This may have been explained by the addition of a rapid response team however the rapid response team was also used in the study by Guirgis et al and the effect on length of stay was not as great (124).

Figure 2.3 Forrest Plot for Intensive Care Unit Length of Stay



2.4.4 Mortality

For mortality, there were 11 studies included

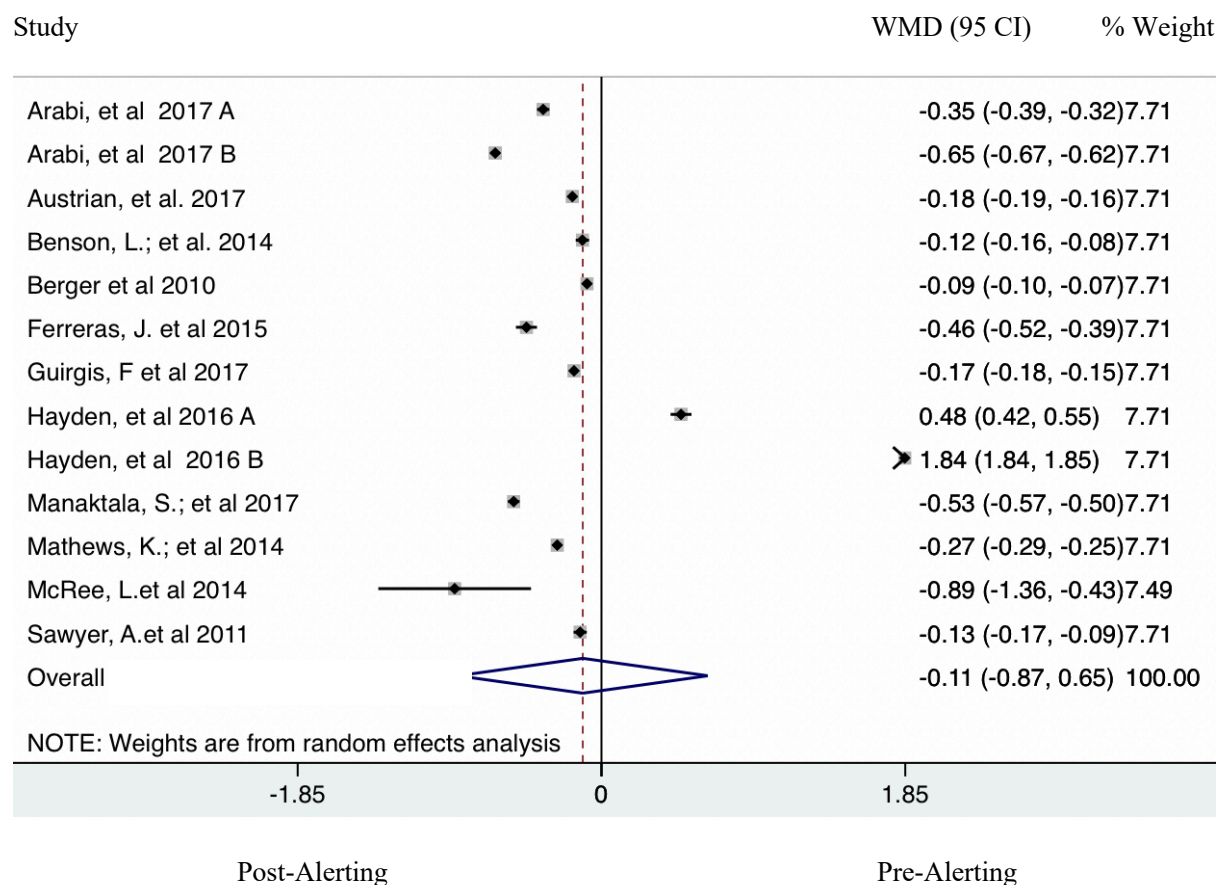
(118)(120)(121)(123)(124)(125)(126)(127)(128)(131)(119). In total, there were 5868

patients in the pre-alerting group and 6629 in the post-alerting group. Across all studies the

mortality in the post-alerting vs pre-alerting group was significantly reduced by 11.4% (95 CI

-0.873–0.646 P=0.769, Figure 2.4).

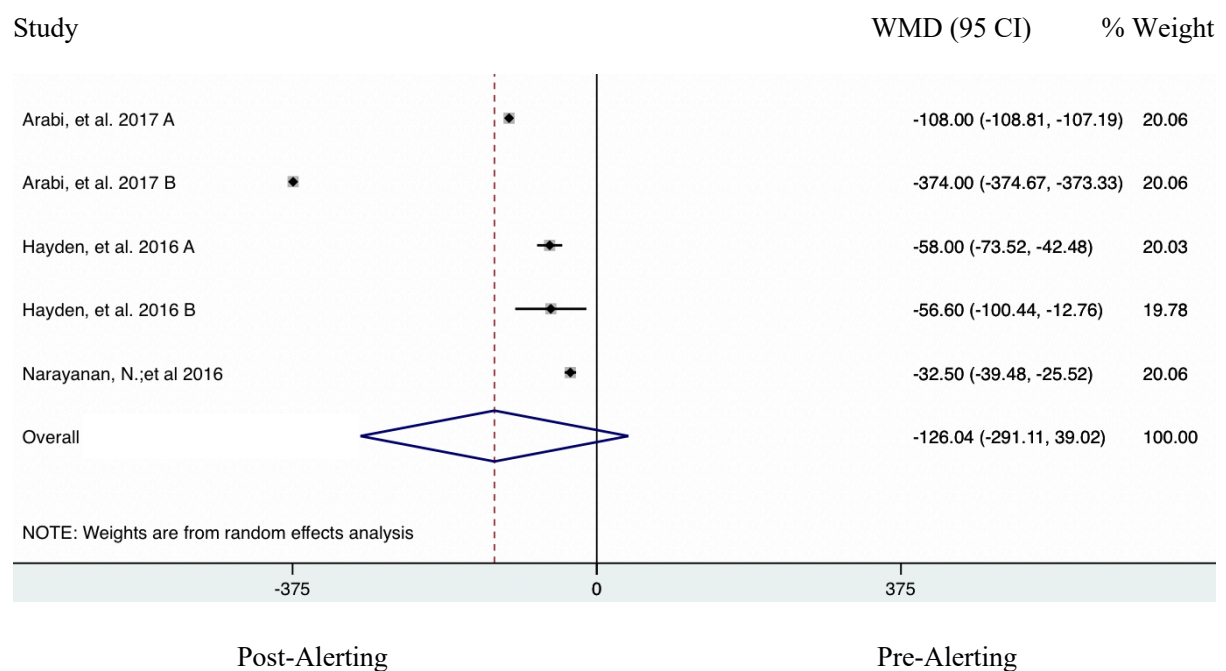
Figure 2.4 Forrest Plot for Mortality



2.4.5 Time to Antibiotics

For time to antibiotics there were 5 studies included (118)(122)(125)(129)(130), these are shown in Table 2.2. In total, there were 991 patients in the pre-alerting group and 1473 in the post-alerting group. Based on three studies with available data the weighted mean difference in time to antibiotics from the pre-alerting to the alerting group was a reduction in time to antibiotics by 126 minutes (95% CI -291.113 – 39.015, P=0.134, Figure 2.5).

Figure 2.5 Forrest Plot for Time to Antibiotics



2.4.6 Diagnostic Accuracy

The diagnostic accuracy of the digital sepsis alerts is shown in Table 2.3. Out of all the above studies included in the review only 5 studies attempted to address diagnostic accuracy (126)(132)(133)(123)(119). There was high heterogeneity in the accuracy of the alerting in these studies. The specificity of digital alerting in sepsis remained high with four studies reporting specificities of 81.92% (78.73-84.8) (126), 97%(132), 82.0%(133) and 94.56% (93.64-95.32)(123). Whilst the specificity remained high the sensitivity showed high heterogeneity; 95.16 % (89.77-98.20) in one study (126), 95.2%(133), 87% (81.93-91.66) (123), 80.4% (119) and 16% in another (132). The sensitivities and specificities were not given in any other studies. Three studies had high negative predictive values of digital alerting and sepsis ranging from 94% (132) to 98.88% (97.58, 99.59) (126) and 99.11% (98.69-99.4) (123). The positive predictive value was much lower at; 14.6% (119), 26% (132), 50.21% (43.64, 56.78) (126) and 51.64% (46.15-57.11) (123).

Table 2.3 Diagnostic Accuracy

<u>Study</u>	<u>Sensitivity (95% Cis)</u>	<u>Specificity (95% Cis)</u>	<u>Positive Predictive Value (95% Cis)</u>	<u>Negative Predictive Value (95% Cis)</u>	<u>Likelihood Ratio (95% Cis)</u>	<u>Positive Likelihood Ratio (95% Cis)</u>	<u>Negative Likelihood Ratio (95% Cis)</u>
Arabi et al, 2017 A & B (118)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Austrian et al, 2017 (119)	80.4%	Not given	14.6%	Not given	Not given	Not given	Not given
Benson et al, 2014 (120)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Berger et al, 2010 (121)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Crum et al, 2013 (122)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Ferreras et al, 2015 (123)	87% (81.93-91.66)	94.56% (93.64-95.32)	51.64% (46.15-57.11)	99.11% (98.69-99.4)	Not given	Not given	Not given
Guirgis et al, 2017 (124)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Hayden et al, 2016 A (125)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Hayden et al, 2016 B (125)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Manaktala et al, 2017 (126)	95.16 % (89.77-98.20)	81.92% (78.73-84.8)	50.21% (43.64, 56.78)	98.88% (97.58, 99.59)	Not given	5.26 (4.45-6.23)	0.06 (0.03-0.13)
Mathews et al, 2014 (127)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
McRee et al, 2017 (128)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Narayanan et al, 2016 (129)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Pulia et al, 2016 (130)	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Sawyer et al, 2011 (131)	Not given	Not given	19.5% (quoted from another reference and not found in this paper)	95.8% (quoted from another reference and not found in this paper)	Not given	Not given	Not given
Umscheid et al, 2015 (132)	16% (alert group) 17% (validation group)	97% (alert group) 97% (validation group)	26% (alert group) 28% (validation group)	94% (alert group) 95% (validation group)	5.3 (alert group) 5.7 (validation group)	Not given	Not given
Westra et al, 2017 (133)	95.2%	82.0%	50.6%	Not given	Not given	Not given	Not given

2.4.7 Risk of bias assessment

All included studies were assessed for the quality of their methodology. All studies had a non-randomized design methodology and the Newcastle Ottawa Scale (NOS) was used; the results are shown in Table 2.4. Of all studies included only six were of ‘higher’ quality. Many suffered from poor comparability due to a lack of randomization and selection bias being a caveat.

Table 2.4 Risk of bias of non-randomised prospective comparative cohort comparing pre- and post-alerting based on the Newcastle –Ottawa

Scale

Study	1.Selection: Representative of exposed cohort	2.Selection: Representative of control cohort	3.Ascertainment of exposure	4.Absence of outcome at start of study	5.Comparability: study controls for study design	6.Comparability: study controls for analysis	7.Assessment of outcome	8.Duration of Follow- up	9.Adequacy of follow- up	Total score
Arabi et al, 2017 (118)	1	1	1	1	1	1	1			7 Higher
Austrian et al, 2017 (119)	1	1	1	1	1	1	1			7 Higher
Benson et al, 2014 (120)	1	1	1	1			1			5 Lower
Berger et al, 2010 (121)	1	1	1	1		1				5 Lower
Crum et al, 2013 (122)		1	1	1			1			4 Lower
Ferreras et al, 2015 (123)	1	1	1				1			4 Lower
Guirgis et al, 2017 (124)	1	1	1	1	1	1	1			7 Higher
Hayden et al, 2016 (125)	1	1	1	1	1	1	1			7 Higher
Manaktala et al, 2017 (126)	1	1	1	1	1	1	1			7 Higher
Mathews et al, 2014 (127)	1	1	1	1			1			5 Lower
McRee et al, 2017 (128)		1	1	1	1	1	1			6 Lower
Narayanan et al, 2016 (129)		1	1	1	1	1	1			6 Lower
Pulia et al, 2016 (130)		1	1	1		1	1			5 Lower
Sawyer et al, 2011 (131)		1	1	1		1	1			5 Lower
Umscheid et al, 2015 (132)		1	1	1		1	1			5 Lower
Westra et al, 2017 (133)	1	1	1	1	1	1	1			7 Higher

2.5 Discussion

2.5.1 Summary of main findings

This review found that digital alerting in sepsis is associated with significant reductions in hospital LOS by 1.311 days ($p=0.014$) and ICU LOS by 0.766 days ($p=0.007$). Both mortality and time to antibiotics showed no significant difference between the pre-alerting and post-alerting groups.

A previous systematic review on the diagnostic accuracy and effectiveness of digital alerts found no improvements in clinical outcome measures when digital alerts in sepsis were employed (134). However, since its publication there has been a growth in the number of empirical studies on digital alerting and sepsis outcomes, as more hospitals worldwide are transferring to electronic health records and digital solutions. All studies identified in this review are recent and after 2010, reflecting the entry of new technology in this field.

This review also identified a wide variation in the diagnosis of sepsis and multiple measures used for this purpose. Many of the studies included in the review have used the SIRS definition of sepsis or a modification of it. This is perhaps as it is the most practical in a clinical setting with readily available vital sign data and laboratory tests. Although SIRS was routinely used as a definition of sepsis the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis 3) declared that the use of ≥ 2 SIRS criteria in identifying sepsis was not specific enough(4). The SIRS criteria may be met without infective disease processes, such as trauma(18). The variation in diagnostic criteria may explain the lack of literature meta-analysis in digital sepsis alerts to date. The ideal alerting criteria required for sepsis in combination with guidance on the latest definitions must be reviewed in further

large-scale randomised studies. The ideal sepsis alerts must correctly identify those patients with sepsis and exclude those without. Alerting with low positive predictive value is likely to contribute to alert fatigue and it is suggested that more sophisticated algorithms may be required to correctly identify patients with sepsis(119). A recent retrospective comparison of scoring systems found the National Early Warning Score [NEWS] to be more accurate in detecting sepsis when compared to other scoring systems including SIRS(135). Further multicentre studies are required to review these findings. In addition to the alert itself the way the alert is delivered must be reviewed. There is no one best method in the literature to the type of alert to be used and who it needs to be sent to. A combination of EHR, text paging and mobile alerts have been used in the studies included in this review.

Out of all the above studies included in the review only 5 studies attempted to address diagnostic accuracy (126)(132)(133)(123)(119). There was high heterogeneity in the accuracy of the alerting in these studies. Far more research is required in large studies to elucidate diagnostic accuracy in digital alerting. Whilst digital alerting in sepsis is beneficial, it is likely that the alerts be used in combination with an application of other resources such as staff education, direct communication for patients with sepsis and rapid response teams. In one study 5 months of training in addition to the sepsis alert helped contribute to a reduction in sepsis mortality(126).

2.5.2 Strengths

This is the first review to perform a meta-analysis of the evidence and measure the clinical outcomes of digital alerting systems in sepsis. It is the most up to date study with no language restrictions set. All study settings, diagnostic sepsis criteria , interventions and types of alerts were reviewed. The diagnostic accuracy of the alerting was attempted. Quality assessment of

all the studies was performed. There is the potential for digital alerts to be utilised in the future to reduce sepsis outcomes.

2.5.3 Limitations

Despite the significance on some of the clinical outcome measures assessed, our study has limitations due to the variability of methodologies and study types and most studies scored low on quality. Most of the studies are observational in design thus creating a high risk of bias. There was a high heterogeneity between the studies and there was very limited data on the diagnostic accuracy of many of the included results. Furthermore, the pre-and post-alerting study design may be prone to selection bias due to variations in the patient population and changes in ways of providing care at hospitals over time. A further limitation of the studies is the size of the post-alerting cohort is larger than the pre-alerting cohort. Whilst all studies used electronic digital alerting, some studies additionally used a rapid response team and electronic order sets. This may have led to a confounding bias in outcomes.

There are several studies published recently with different study designs to help address some of these concerns. The first is a retrospective cohort study with patients exposed or not exposed to the electronic intensive care unit (eICU) telemedicine sepsis management in the emergency department(136). This is a novel form of alerting using telemedicine. In this study the exposed cohort had a quicker time to antibiotics 122.3 minutes (122.3 minutes $\pm$ 83.3 versus 163.4 minutes $\pm$ 204.4, $P=0.043$) (136). However, the hospital LOS and mortality were similar between both cohorts.

Another study design is the use of a prospective quality improvement study(137). The alerting system was customised to local practice with regularly incorporated feedback through the Plan-Do-Study-Act [PDSA] cycles(137). In this study a machine learning algorithm was implemented with continuous incorporations of feedback creating a system tailor made to the hospital workflow(137). After several PDSA cycles the machine learning algorithm sepsis mortality reduced by 60.24% with a hospital length of stay reduction of 9.55%(137). The alerting in this study was very different to other studies due to the machine learning approach(137). Although it was not included in the original meta-analysis the analysis was re-done to include this study and there was no difference in either the hospital length of stay [proportional decrease 11.3%, CI -0.189 – 0.038, p=0.003] or mortality [mean decrease 11.4%, CI -0.844 – 0.616, p=0.760].

2.5.4 Future work

Further research should also seek to answer several other important questions such as the optimal type of sepsis alert and which team members should be alerted and at what frequency. A recent observational cohort study reviewing successive improvements over a 10 year period found reviewed sepsis alerts sent to a telephonist and alerts sent to a nurse's mobile phone(138). They found that time to antibiotics was reduced to 1:00 (0:55 – 1:30) hours when the alert was sent to the telephonist and to 0:45 (0:30 – 1:00) minutes when the alert was sent directly to the nurse's mobile phone (p = 0.02) (138).

Further large scale multicentre prospective RCT [randomised controlled trials] with a single standardised sepsis alert are required. An RCT would help exclude confounding biases although implementation maybe challenging. Two recent RCTs have been published however

both studies had small sample sizes with insufficient power to detect differences between the pre-alerting and post-alerting groups(139)(140). The results of both RCTs were also contradictory. One RCT performed of sepsis alerting through electronic health records found no significant difference in outcome measures after alerting(139). However at least 66% of patients were on antibiotics at the time of the alert, this high baseline compliance may have led to a lower marginal return on improved detection through alerting and partly explain these findings(139). The other RCT on the use of machine learning based sepsis prediction systems supported similar findings to this review with a reduction in hospital length of stay by 2.7 days and a mortality reduction of 58% (140).

The cumulative effect of an additional rapid response team, staff education and electronic order sets alongside digital alerting must also be evaluated. Further studies should also be performed in different clinical health systems as the value of alerting is likely to depend on baseline performance of health systems. This would aid generalisability and widespread implementation. Importantly the diagnostic accuracy for the digital alerting in most studies included is unknown and needs to be clearly defined in future work to ascertain validity of findings. Finally, the cost effectiveness of digital sepsis alerts also needs further evaluation if we are to justify its use in the current fiscal climate.

2.5.5 Conclusion

This chapter has shown that intermittent vital sign monitoring and automated digital alerts can improve the sepsis outcome measures of both hospital length of stay and intensive care length of stay. This chapter highlights a significant reduction in hospital LOS by 1.311 days

and ICU LOS by 0.766 days. The emergence of digital technologies has the capacity to transform the rapid identification of patient physiological deterioration and in turn may revolutionise patient care through alerts and novel treatment innovations (such as ‘smart wards’). Higher quality evidence through larger, better-designed randomised studies is needed to guide the application of digital alerting in patients at risk of sepsis.

The use of more continuous vital sign monitoring in ward patients is unknown. Novel wearable sensors can measure multiple vital signs in real-time. The next chapter will explore the reliability of wearable sensors.

Chapter 3 Testing of the wearable patch to assess reliability.

3.1 Introduction

Chapter 2 highlighted that digital alerting can improve sepsis outcome measures using intermittent vital signs monitoring. The latest wearable sensors offering continuous monitoring of multiple vital signs have been described in the introductory chapter. The reliability of many of these sensors in a real hospital setting is unknown. This chapter reviews the reliability of the Sensium wearable sensor for acutely unwell patients in hospital and compares the sensor to standard ward monitoring.

3.1.1 Evidence for benefits of early detection of deteriorating patients

As discussed in previous chapters it is well known that a failure to recognise and respond to patient deteriorating in hospitals is a major cause of morbidity and mortality (34)(35)(36)(37)(38). NCEPOD data shows that clinical deterioration may present several hours prior to an adverse event(34). Unfortunately, unwell patients are still falling through the ‘safety net’(37). Up to 39% of acute emergency patients admitted to the ICU are referred late(39). It has been shown that respiratory function deteriorates in a significant number of patients prior to an ICU admission(40). The resources of both High Dependency Unit (HDU) and ICU are limited across all NHS (National Health Service) trusts and it is vital that the correct patients are identified early to be suitable for critical care.

3.1.2 How deterioration is detected early

As described in the introductory chapter section 1.2.6, a measurement of a patient's vital signs is often the first step in assessing for acute deterioration in their clinical condition(41) (42). Unfortunately, patients with sepsis are often identified very late in hospitals both in the UK and worldwide. We are hoping to identify patients with sepsis sooner through new technologies and wearable sensors.

Intermittent vital signs observations which are typically between 6-8 hours apart are the current way vitals are measured for patients on general wards(141). The ideal sampling frequency for vital sign measurements is still largely unknown(142). It is known that interval observations can miss early signs of patient deterioration.

3.1.3 Potential of wearable sensors in detecting deterioration

Continuous monitoring in the form of wearable sensor technology has the potential to identify unwell patients and those with sepsis sooner. There are new devices which can measure vital signs at an increased monitoring frequency than standard current nursing monitoring. Whilst there are many sensors now on the market the reliability of the sensors in an acute or hospital setting is still largely unknown.

3.1.4 Sensor Reliability

The first criteria in assessing any new device is that it is safe, reliability and the data is valid. It needs to be proved that the data from the sensor is reliable and equivalent to the monitoring currently being used in the hospital in the form of nursing observations. The safety of any new device is paramount. Before a hospital or trust pays for a new device it must be ensured

to be both safe and reliable. Although wearable sensors are currently available, little is known about the diagnostic accuracy of these sensors. Whilst most available sensors are consumer grader there are a few manufacturers that have obtained European Conformity (CE) and or Food and Drug Administration (FDA) approvals for use in hospital settings. Validity and accuracy of these devices has not been widely researched in real hospital settings.

3.2 Aims:

To investigate the reliability of a wearable sensor platform in continuous monitoring of vital signs in acutely unwell patients.

In addition, the ideal time windows for alert generation from the sensor were reviewed.

3.2.1 Null Hypothesis

The null hypothesis states that wearable sensors are not able to provide reliable monitoring of heart rate, respiratory rate and temperature when compared to observations taken by the nurses.

3.3 Methods

3.3.1 Sensium Sensor

The Sensium wearable sensor was selected in this thesis for several reasons. As described in the introductory chapter it is a lightweight, low cost device with a longer battery life than most of its competitors(99). This means that during an average patient admission, most patients will only require one sensor before they are discharged and thus reduce costs. The Sensium wearable sensor is different to several other sensors in that it measures three vital sign parameters that change early in both patient deterioration and sepsis (HR, RR and temperature). The Sensium sensor has inbuilt algorithms which many others sensors do not, which assess the quality of the signal being sent. If the quality thresholds are not met the signal is not sent potentially minimising alert fatigue. The Sensium wearable sensor has been Food and Drug Administration (FDA) approved and has a 'Conformite Europeene' (CE) Mark. Currently there is very little known about the diagnostic accuracy of this device in a hospital setting.

A very early study performed compared the Sensium wearable sensor to the conventional bedside clinical monitor (Intellivue MP30, Philips, Amsterdam)(91). In this study there were 2 patient groups; 1 group of 20 patients undergoing elective surgery and another group of 41 patients recruited from the ward or clinic(91). This study confirmed that the sensor provided reliable information on HR from patients with normal sinus rhythm(91). The mean difference between the 2 groups was ± 1 beats per minute in all patient groups studied(91). RR was only valid around 50% of the time(91). When valid RR data was recorded accuracy was good with a mean difference of less than 1 breath rate per minute (brpm) compared with the bedside monitor(91). Temperature was not assessed in this study and patient monitoring for all

patients was only around 2 hours(91). It is still unknown what the outcomes would be in a real-time setting with acutely unwell patients over longer time periods. This currently is the same for other ‘medical-grade’ wearable sensors.

3.3.2 How the patch works and institutional set up

The Sensium wearable patch is a lightweight single use device which monitors the HR, RR and temperature. It is designed to be used in a hospital setting as an ambulatory wireless monitoring for patients as an alternative to intermittent observations. The device is easily attached to a patient’s chest by two adhesive ECG electrodes. Each patch wirelessly links and transmits the signal via a dedicated secure intranet hot spot (bridges). All research was performed at West Middlesex University Hospital. Much of the preliminary work at the hospital prior to the trial commencing has been the installation of these bridges across the medical and surgical wards. The installation was performed via engineers at West Middlesex University Hospital and by Sensium. A floor plan of all bridges in the clinical wards can be found in Figure 3.1 This was performed after all regulatory approvals at the hospital were met. All bridges were successfully tested prior to the trial commencing. All bed areas needed to be within a defined proximity to the bridge and the entire ward was covered to avoid any dark spots.

Figure 3.1 A schematic floor plan of the clinical areas with the bridge locations.

Figure 3.1a Bridge locations on the Acute medical unit



Figure 3.1b Bridge locations on Syon 1 and Syon 2 wards



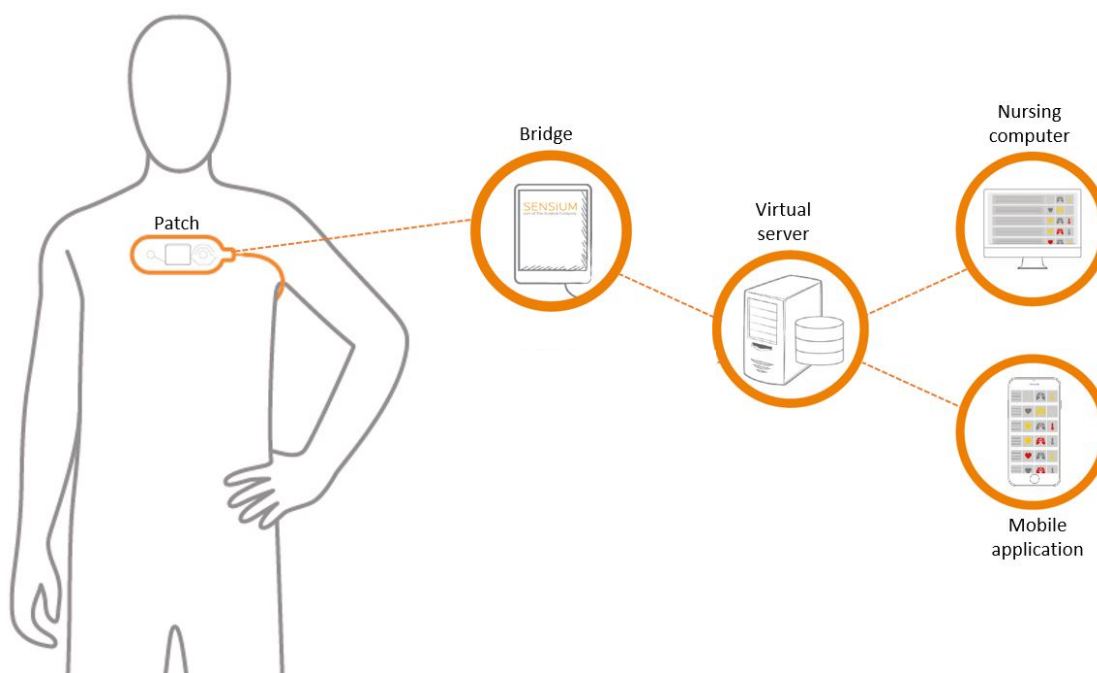
The floor plan shows the following rooms and dimensions:

- ROOM 10: 10.00 x 10.00
- ROOM 11: 10.00 x 10.00
- ROOM 12: 10.00 x 10.00
- ROOM 13: 10.00 x 10.00
- ROOM 14: 10.00 x 10.00
- ROOM 15: 10.00 x 10.00
- ROOM 16: 10.00 x 10.00
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- ROOM 94: 10.00 x 10.00
- ROOM 95: 10.00 x 10.00
- ROOM 96: 10.00 x 10.00
- ROOM 97: 10.00 x 10.00
- ROOM 98: 10.00 x 10.00
- ROOM 99: 10.00 x 10.00
- ROOM 100: 10.00 x 10.00

The information from the bridges is sent to a central monitoring station or server. To avoid any confounding bias in the study, the data was not checked in real-time but only when the patients had left the hospital. A retrospective review of all sensor data and ward observation data was performed. All sensor data was downloaded from the hospital server. In the real system when the sensor runs live, sensor data may also be incorporated into electronic health records or sent to an alerting device such as a mobile phone. This alerting will be assessed in future chapters. A schema of this monitoring system can be shown in Figure 3.2 below.

Figure 3.2 The monitoring system used for the Sensium wearable sensor.

Image reproduced with permission from Sensium, Abingdon, UK.



The Sensium device is a low-cost device and costs approximately £100 per sensor. If patients require more than one sensor per admission only one sensor is charged for by the company.

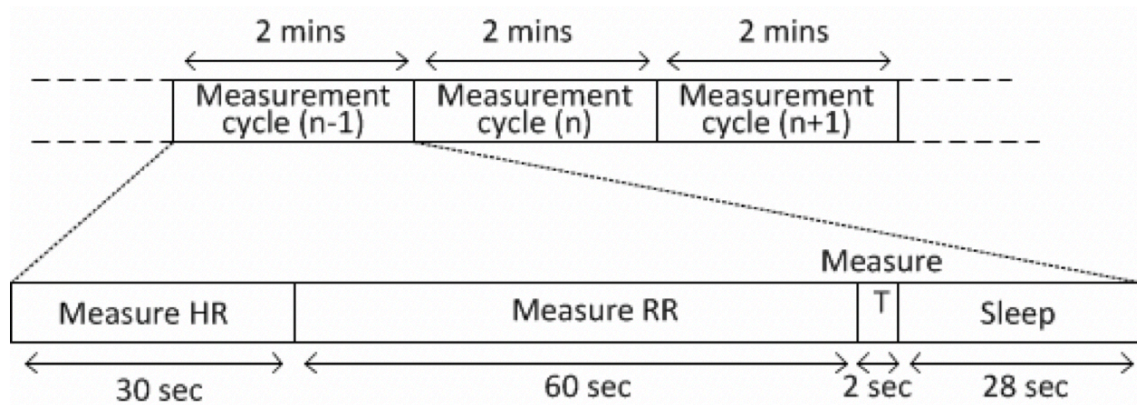
The sensor price is significantly lower than competitor companies which can go up to \$520(143). Funding for the study set up and device was secured by the charity CW Plus. The

device can be worn by patients for up to 5 days. The Sensium wearable sensor records vital sign observations wirelessly every 2 minutes. The patch is removed and discarded when the patient is discharged removing any obstacles with cleaning or the potential risk of cross contamination. Unlike several other sensor designs the Sensium device is able to measure three important vital signs: heart rate, respiratory rate and body temperature, in one device(99). These give us important early indicators if a patient becomes unwell and may have sepsis.

The wearable sensor is attached to the skin via 2 adhesive electrode patches on the patient's skin and worn under the patient's clothes. A wire is placed from the sensor into the axilla to measure temperature. The axilla of the patient's non-dominant hand is used so not to restrict any patient movement and limit any potential interference. A plastic strip attached to the sensor is pulled to activate the device. The sensor records in a sequential cyclical 2-minute fashion. The sensor records HR in the first 30 seconds, and then measures RR in the next 60 seconds. The calculation and processing takes 2 seconds which is followed by a sleep cycle for 28 seconds. This sleep period helps to lower battery consumption, so the sensor lasts for a greater number of days. The 2-minute cycles of sensor recordings can be shown in Figure 3.3 Individual vital sign readings are measured and processed in time order.

Figure 3.3 The recording of sensor vital sign data in 2 minutes cycles.

Image reproduced with permission from Sensium, Abingdon, UK.



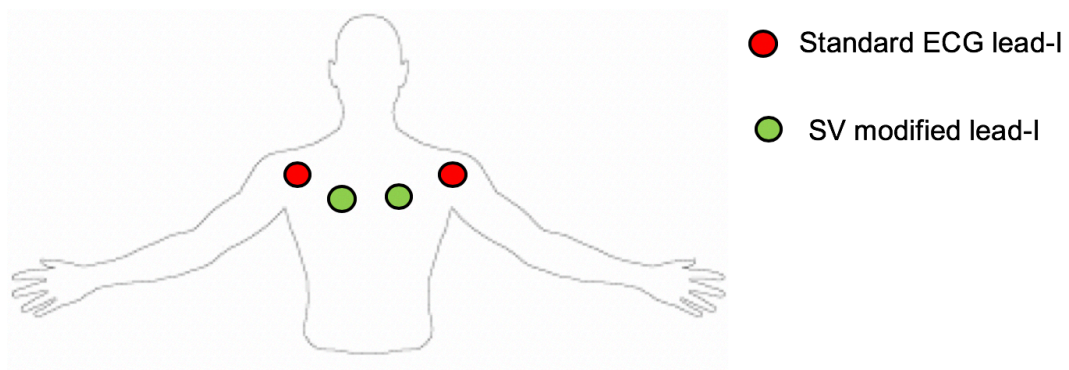
Once the physiological trace has been captured there is an algorithm within the microchip found on sensor. This has an inbuilt processing unit which transmits the average values of HR as beats per minute and RR as breaths per minute, to the nearest bridge. It is then transmitted to the central server(91). Each sensor has a unique bar code identifier to identify an individual's sensor readings.

3.3.2.1 Heart rate

Heart rate is calculated from a 30 second ECG strip using the modified lead positions. Figure 3.4 shows the modified Sensium electrode position in green as compared to the standard electrode position in red.

Figure 3.4 Modified Sensium electrode position as compared to standard ECG electrodes.

Image reproduced with permission from Sensium, Abingdon, UK.



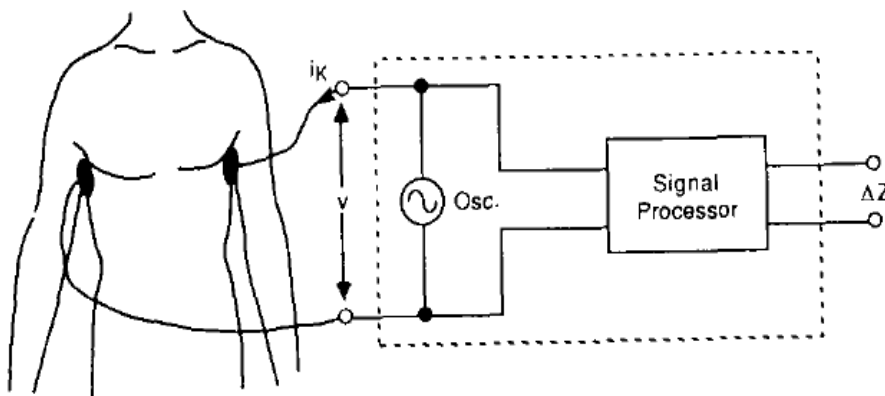
A predictive strategy is used calculate HR based on the RR interval(91). This approach has been described previously(144)(145). The individual R-R intervals from the ECG strip are rank ordered and the median value is taken as the average HR.

3.3.2.2 Respiratory Rate

Impedance Pneumography (IP) is the technique used to measure RR by the Sensium sensor. This is a common technique used to measure a person's breathing rate(146). Whilst the gold standard to measure RR is capnography this is impractical for long term ambulating patient monitoring. IP is measured through superficial electrodes the impedance will measure both the respiratory volume and rate via the relationship between depth and thoracic impedance change(147). The RR is derived from changes in the impedance of the thorax due to inhalation and exhalation. A very small current (i_K) is injected through the ECG electrodes. The thoracic impedance changes are detected as variations in the voltage (V) measured at the ECG electrodes. Inhalation (peak resistance) and exhalation (trough resistance) are detected from a 60 second segment of IP waveform to calculate a median RR. Figure 3.5 helps explain this in a diagrammatic form where i_K is current, V is voltage and Z is donated as the resistance. The principle theory being this relationship is that of Ohm's Law.

Figure 3.5 Impedance Pneumography in a diagrammatic form.

Image reproduced with permission from Sensium, Abingdon, UK.



3.3.2.3 Temperature

Temperature is measured using a calibrated thermistor which is placed in the patient's axilla and is a temperature sensitive resistor. The axilla temperature offers a practical way of continuous monitoring. The temperature algorithm uses a prior knowledge about how the core body temperature typically changes over time to 'filter' the temperature readings. Any abrupt or sudden drastic temperature changes associated with noisy readings (e.g. lifting the arm) are discriminated to minimise the occurrence of false alerts.

3.3.2.4 Challenges of ambulatory monitoring

The average values of HR, RR and temperature are calculated from the raw ECG, IP and thermistor measurements. For 'clean' signals e.g. the patient is sitting or resting, and the algorithmic processing required is quite straightforward. Real life situations can result in corrupted or irregular signals which need to be recognised by the algorithms so as not to give spurious or clinically invalid results. Signal corruptions can result from various means including mains interference, motion artefact (ambulatory patients), or poor skin preparation. Following the calculation of a median HR and RR value, a further statistical check is performed to validate signal quality. If the statistical check fails, the median vital value is rejected.

3.3.2.5 Sensium inbuilt algorithms for signal quality

The chip built into the device has 2 algorithms for determination of HR and RR. There are two stages to signal processing, in the first stage unwanted artefacts are removed(91). This is

an important step in processing. Unwanted artefacts may be caused by external sources; muscular electrical activity, electrode-electrolyte changes and disturbances due to a patient's movement. These offer barriers to ambulatory monitoring and ways to minimise any artefactual disturbance are needed.

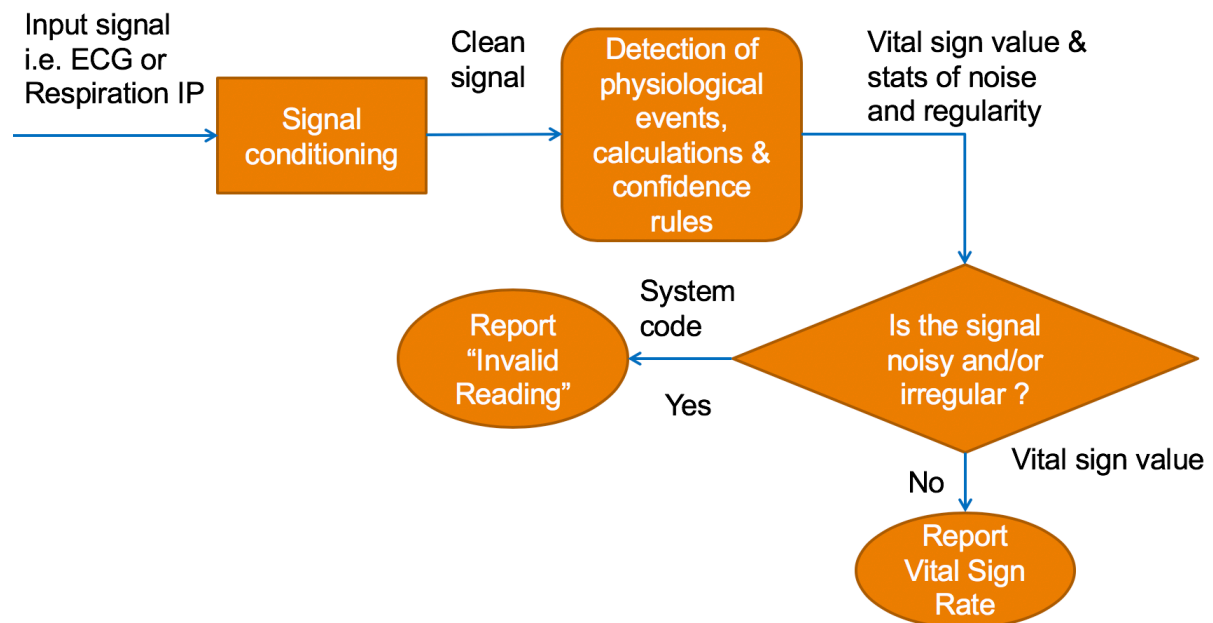
The signal is then passed to the second stage which is decision making(91). Here the HR is calculated from intermittent ECG periods with the 30s duration. There are a set of rules and empirically derived thresholds which ensure that quality assurance checks are passed(91). These built-in algorithms are under patent by the company. The ECG segment may be severely corrupted if, for example, the ECG electrodes move affecting contact with the patient's skin, this in turn may generate a transient voltage much higher than those normally recorded(91). Voltage changes can also occur from static electricity coupling to the patients skin(91). All of these changes are picked up by the inbuilt algorithm and additional rules and statistical estimators applied to verify the signals integrity(91). If any ECG waveform is corrupted and the amplitude or periodicity of the ECG segment does not meet pre-set experimental thresholds, these are automatically deleted from any calculations of HR(91). If the majority of the signal i.e. 85% of the data segment is corrupted, then this entire segment is excluded.

The respiratory rate algorithm also has 2 stages. The first is a pre-processing stage that picks up and filters any interference. Here a novel filter has the ability to tune its rejection frequency to the HR already obtained during that current monitoring cycle(91). This attenuates any heart artefacts produced by dynamic changes in impedance due to the inflow and outflow of blood to both the heart and great vessels(91). The post-processing stage detects valid breathing cycles to give an accurate RR. Any erroneous data that has been

detected is automatically discarded and is sent as a minus 1 reading to the server. The proportion of no vital sign reporting is unknown in a real hospital setting. A summary diagram to show the signal quality checks can be found in Figure 3.6.

Figure 3.6 Signal quality checks of vital sign data by the Sensium algorithms.

Image reproduced with permission from Sensium, Abingdon, UK.



3.3.3 Current ward monitoring

To test the reliability and validity of the sensor data it will be compared to manual nursing observations that are routinely taken by nurses on average every 4-6 hours for ward-based patients. In this part of the study both the clinical team and the health care team will be blind to the sensor data in real-time. It has been stored on the central server with no alerting mechanism. At this stage it is not known whether the continuous monitoring methodology is superior to current practice. If researchers or the clinical team were not blind any alert sent

may prompt the need for additional observations to be taken. If this occurred the baseline speed of sepsis detection explored in the next chapter would be confounded.

In the absence of specific clinical directions otherwise, bedside observations were taken at 4-6-hour intervals by nurses and healthcare assistants. The reference clinical device was a conventional bedside clinical monitor (IntelliVue MP30, Philips, Amsterdam, The Netherlands). This device measures HR, blood pressure, and oxygen saturations. A tympanic temperature was used (Braun ThermoScan PRO 6000) (148). More frequent observations were taken for ward patients depending on clinical judgement. The observations were recorded on paper observation charts by the relevant healthcare professional and these were held in a folder at the patient's bedside. The real-time observational data taken by the nurses acted as a comparison for the vital signs taken by the sensor. A member of the research team collects the observation charts 24 hours after the sensor has been placed. The research team included Dr Arti Sharma and Miss Antonia Koutsoukou, both research nurses from the National Institute for Health Research (NIHR) clinical research network that were assigned to the study. They both assisted with patient recruitment, collection of ward observations and data entry. The observations for these times were recorded on an Excel sheet in a secure file held on the hospital server. If there was any uncertainty in the reading of the observation chart this field was left blank and verified by a second reviewer. If the second reviewer had changed the number and interpreted it differently this was noted. A third reviewer was also able to answer further queries. Vital signs were measured for all patients throughout their hospital stay. If patient stay was longer than 5 days a new sensor was placed.

3.3.4 Study design

A prospective cohort study was conducted so that the cohort of unwell patients could be followed up during their hospital admission. The real-time observational data taken by the nurses would act as a comparison for the vital signs taken by the sensor. Matched paired analysis was performed.

3.3.5 Study location

The study was based at West Middlesex University Hospital (WMUH) which is a busy acute district general hospital in West London. It serves a local population of 400,000 people and has around 400 beds. This was a single centre evaluation. All patients admitted to the acute medical unit (AMU), the acute surgical unit (ASU), Richmond (surgical ward), Syon 1 (surgical ward) and Syon 2 (surgical ward) were included in the study. The infrastructure costs vary depending on the number of wards engineered, the duration of time monitoring continues and the number of patients that are wearing the sensor. The study was funded by Sensium, the CW Plus Charity and the Royal College of Surgeons England through their research fellowship.

3.3.6 Participants

All acutely unwell medical and surgical patients were eligible to be included in the study. WMUH has a busy AMU with a high daily flux of unwell medical patients in the ward. AMU is where new general medical patients are admitted after accident and emergency. There is also a busy general surgical department. Patients are seen on the SAU (surgical admissions unit) and are either admitted there or transferred to another ward (Syon 1 or 2 ward). Several weeks were spent on the medical and surgical wards prior to the study as an initial feasibility assessment. It is understood on average the daily medical 24-hour intake has around 30 new

adult medical patient admissions. Most of these patients are eligible to be included. The number of acutely unwell patients seen by the medical team may be much higher than this but not all patients require a hospital admission and may be discharged home. These patients would not have been wearing the patch anyway. The number of patients reviewed by the surgical team in 24 hours is on average around 15 patients a day with approximately 7 admissions. There can, of course, be large variations in these numbers, but these were to act as a guide for the potential recruitment of patients. It was anticipated that there may be marked seasonal variation in recruitment numbers with greater pressures on the acute hospital intake during the winter season and this was accounted for with recruitment taking place over a year. The acutely unwell medical and surgical patients often have the greatest physiological derangement with many at risk of infection as treatment may not have yet fully commenced or be in the process of commencing. This is why this patient group has been targeted for recruitment.

3.3.7 Recruitment

A pilot study was conducted from November to December 2017 to ensure any potential system problems were identified prior to the main study starting. The recruitment in the pilot study was 10 patients. Following this, the main reliability trial commenced on January 2018 to January 2019. The anticipated sampling size was around 500 patients. As described previously a formal power calculation was not possible due to a lack of preliminary data with new wearable devices(149). A large sample size was used to recruit patients with adverse events and sepsis which will be reviewed in the following chapter.

All patients were identified by the medical or surgical consultant after they had reviewed the patient on the ward. There were several inclusion criteria for the study. Firstly, any acute patient placed on a general medical or surgical ward that was expected to remain in hospital for at least 24 hours was eligible for recruitment. The admitting consultant for both surgery and medicine were approached every morning by the research team after the ward round for a list of eligible patients. The surgical ward round normally finished around 10 am and the medical board round was later in the day at around 12pm. Secondly patients aged 18-95 were eligible for recruitment. An information sheet outlaying the sensor technology was given to all eligible patients (Appendix 3.1). Thirdly written consent (Appendix 3.2 patient consent form) was obtained for all patients taking part in the study to wear the sensor. It was mandatory that all patients gave written consent prior to recruitment. If any patient was unable to consent or withdrew their consent, they were excluded from the trial. All patients were made aware that they could withdraw from the study at any time and their clinical care would not have been affected if they did not take part. Additional exclusion criteria included patients with a skin condition on the chest wall, an open chest wound, those with a mental health problem, patients with a pacemaker or defibrillator and any condition in which the judgement of the clinical team excluded patching.

3.3.8 Study Procedure

Upon recruitment baseline demographic and admission data was collected by the research team. In addition, blood tests such as White Cell Count (WCC), C Reactive Protein (CRP) and blood culture results were recorded to identify patients with sepsis or infection. All blood tests were obtained from electronic health records.

Only patients on the pre-selected admitting wards that were engineered for sensor use were able to be monitored. If patients were relocated to other wards the sensor was removed. For the recruited patients the sensor was placed either by the research team or the trained healthcare professionals looking after the patient.

It was decided that in the reliability study only the Health Care Assistants (HCAs) would be trained. From a quality improvement study done at the hospital earlier in the year, the HCAs were the best at putting the sensor on patients. It is believed that the HCAs often have the longest time to spend with patients. Only those that had received the mandatory training were able to place the patch. All training and support were provided by the company Sensium. The company have several nurse champions which provided support for both patients and healthcare professionals if required. The training of HCAs on all wards took place between the 13th -24th November 2017. All HCAs were identified by the matron or senior sister on the ward. Only those that were long-term or permanent members of staff were trained (bank staff were not trained in this study). Placing the sensor on the patient takes approximately 5 minutes. The sensor is attached to a patient's chest using two standard disposable ECG electrodes (Red-Dot2560 3M, St Paul Minn). Medical tape is used to ensure that the temperature probe is secured correctly in the axilla. All patients continued to have normal bedside observations by the clinical team, and these were recorded as per standard practice described above. The battery life for the sensor was 5 days, after which a new sensor was placed for those patients requiring a longer hospital admission. The length of time patients were included in the study was highly variable and depended on how long patient stayed in that allocated ward area.

A member of the research team collected the patient observation charts 24 hours after the sensor had been placed. The ward vital signs observations were transcribed and recorded using Excel. All data was held in a secure file on the hospital server and only accessible by the research team. If there was any uncertainty in the reading of the observation chart this field was left blank by the transcriber and later independently verified by a second reviewer. A third reviewer was also able to further queries. If the second reviewer had changed the number and interpreted it differently this was noted. All ward observations were coded into categories of clear legible readings, illegible reading, no value written and patient off the ward. The patient discharge summaries were reviewed for any significant events of patient deterioration and the clinical course of events experienced by the patient whilst in hospital.

During a normal working day 9am to 6pm an alerting device was held by a member of the research team. No information on patient deterioration was provided; however, an alert was sent if there was no data received from the patient for an hour. This may have occurred if patients were transferred out of the ward for imaging or a procedure. The last 3 hours of data are held by the sensor and this data is uploaded onto the server as soon as the patient is transferred to the vicinity of a bridge. If patients are away from the ward for longer than 3 hours data loss will occur. There was no alerting to patient deterioration during this study and all deterioration alerts were switched off.

3.3.9 Signal Analysis & Statistical Analysis

The raw data from the wearable patch was extracted from West Middlesex University Hospital server and received from Sensium. The raw data from the sensor contained all measurements for HR, RR and temperature with associated time stamps. All invalid readings were assigned a -1 code. A minus 1 reading could be sent for a number of reasons: motion

artefact by ambulating patients, poor skin preparation, the sensor was removed from the patient and problems with the bridge or server.

The data was retrieved weekly in the form of a CSV file. All patients were matched via hospital numbers to the unique bar code on the sensor. These mapping files were reviewed weekly. Any minus 1 codes reflect invalid data readings, and these were removed in part of the analysis to allow for data to be continuous. All raw data was stored and processed in Excel format.

All files received were clean without any form of additional processing by the company. The first step of filtration was to make sure that the time and dates were adjusted and sequential. For patients that had stayed in hospital for longer periods of time data was found in separate files which required amalgamation. Some patients may have been patched several times if they remained on the ward for a long period of time. All of these files had to be combined into one allowing for continuous data flow, and this was all completed on Excel.

Once complete, ward data hitherto kept in separate files was incorporated into the Excel file to allow for sensor data and ward data to be compared. The accepted discrepancy between nurse measurements and the device was determined as per a previous study as heart rate of 5 beats per minute, respiratory rate of 2 breaths per minute and temperature of 0.5 °C(150).

The ward data was inserted at or the nearest corresponding time for the sensor data. This created a paired point for the sensor and the reference monitor. All sensor data and ward data were synchronised allowing for alignment of respective time stamps. No artefact removal or removal of any data was performed prior to the analysis. Data collected from the sensor was

statistically compared to data from manual observations to assess the reliability of the wearable patch in detecting changes in vital signs.

Whilst the exact times of the sensor can be compared to the ward observations it was likely that would lead to inaccuracies and significant alert fatigue for the nurses. A single change in a vital sign is unlikely to be clinically meaningful. A better way to generate an alert may be through several consecutive abnormal readings. The actual number of abnormal readings needed (time window) to generate an alert is unknown in the literature.

Based on the vital signs data being transmitted every 2 minutes, mean and median filters of the data were applied. Through observational study of nurses on the ward the average length of time for nurses to perform manual observations varied from 5-10 minutes per patient. It is unknown over what period of time an averaging filter should be applied. Consequently, several time filters were applied over a 6, 10, 12, 16 and 18 minutes. Only even numbers can be tested as the data is processed and transmitted in 2-minute intervals.

If a 10-minute window was used an average of 5 reading from the sensor were compared to the equivalent manual observation times. A mean and median filter were tested over a 10-minute period and applied to study the effect of HR, RR and temperature outliers. This investigates the capability of the wireless sensor in clinical practice. This is a similar method to one being used previously (141). For example, hypothetically if the ward observations show a HR of 70, RR of 14 and temperature of 36 the equivalent sensor times and averages may be shown in Figure 3.7.

Figure 3.7 The potential readings for HR, RR and temperature over a 10-minute time window which gives 5 actual data readings are shown.

A. Sensor Observation

Time	HR	RR	Temp
11.54	65	14	36
11.56	68	15	36.5
11.58	70	16	36.5
12.00	68	16	35.5
12.02	68	15	36

B. Average Sensor Observation

Time	HR	RR	Temp
11.54			
11.56			
11.58			
12.00	68	15	36.2
12.02			

C. Ward Observations

Time	HR	RR	Temp
11.54			
11.56			
11.58			
12.00	70	14	36
12.02			

A. = The raw sensor observations,

B = An average of the sensor observations taken over a 10-minute time window

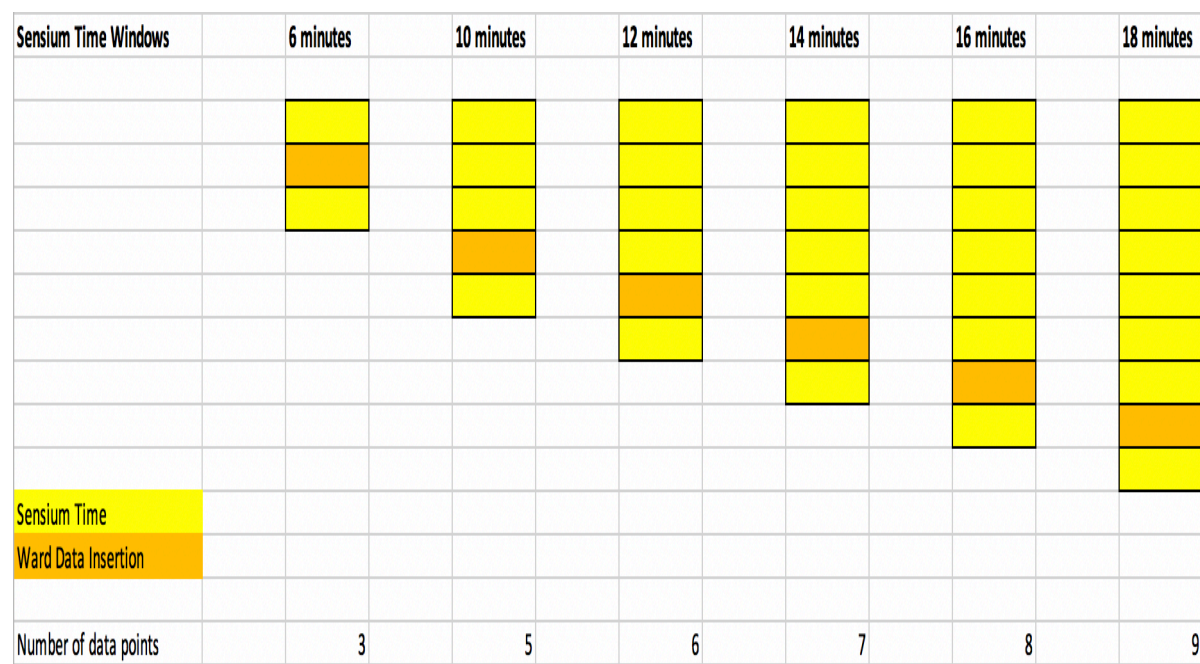
C = The actual time of the ward observations as written on the observation chart.

The exact time point where to average the data is also unknown. How many readings above or below the actual time point should the averaging be? It takes several minutes for healthcare professionals to take the observation itself and a few minutes to record it.

There needs to be a balance between too few data points and missing the actual time window in which the observations were taken and too many data points or averaging window in which there is the chance that another physiological process may occur and small changes in physiology missed. Thus, to our knowledge there has been no evidence base in the literature as to the best way to average such time windows and what the ideal time window there is to use. The ward data was inserted at the penultimate reading. An additional 2 minutes after was included for each averaging window to allow for the possibility the nurse may have been

transcribing at the time the ward observations were recorded. Figure 3.8 highlights the different Sensium time windows tested as well as the where the ward observations would have been inserted. Sensium averaging time windows are shown around the ward time.

Figure 3.8 Sensium averaging time windows around the ward data time



Empty or invalid readings reflected as a minus 1 reading were removed so that the averages of the continuous sensor readings could be compared to the corresponding time stamp on the manual observation charts. Sensor data and reference data were synchronised to ensure alignment of time stamps using STATA, this method has been described previously(141).

Pearson correlation coefficients was used to measure the correlation between sensor data and manual observations for HR, RR and temperature. One way that has been described in the literature as a statistical method for assessing agreement between two methods of clinical measurement is the use of Bland-Altman plots(151)(152)(141). This was used to visually

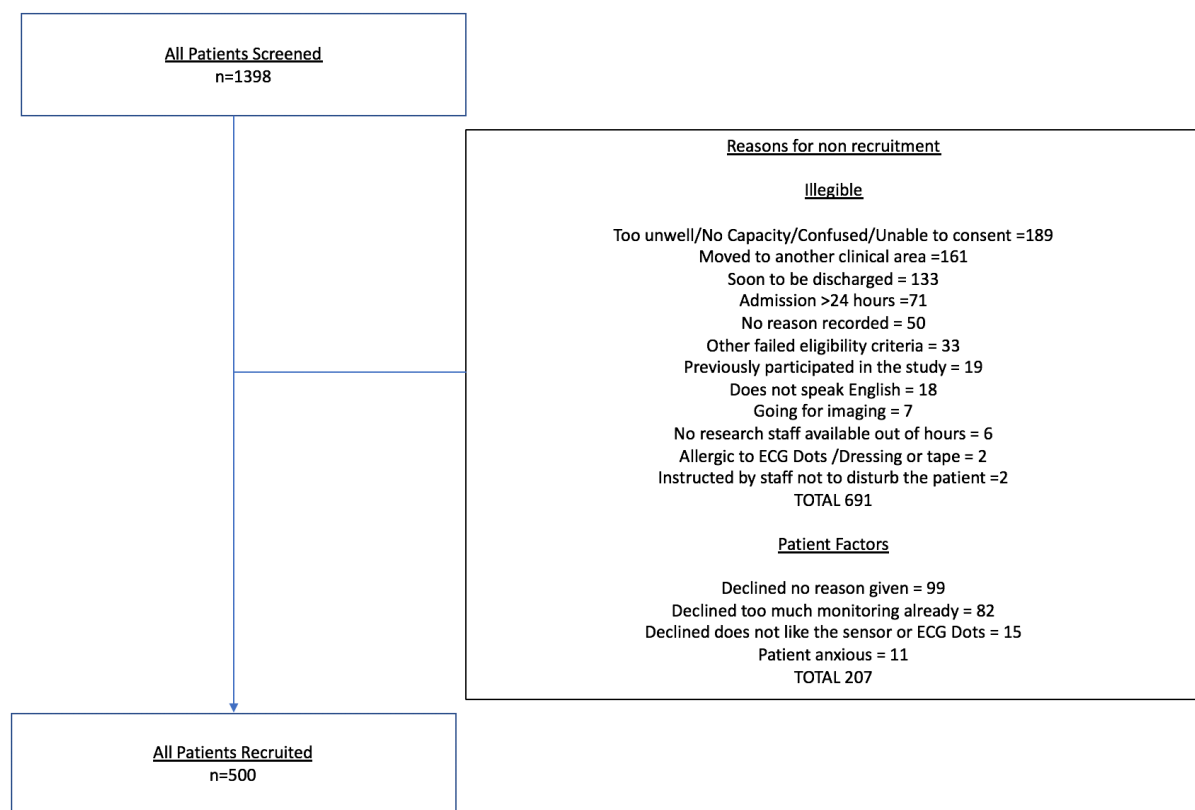
evaluate the consistency between sensor data and manual observations for HR, RR and temperature values. Each Bland-Altman plot mean value and 95% range of the differences were shown and calculated. Data was analysed using IBM SPSS Statistics (Version 25) and STATA(15). Dr Mansour Sharabiani (Lecturer in statistics in the Department of Primary Care and Public Health, Imperial College London) helped provide statistical support and helped in the analysis for chapter 3. Preliminary comparisons were performed by myself using IBM SPSS Statistics (Version 25) and this was checked by Dr Sharabiani using STATA.

3.4 Results

3.4.1 Patient Demographics

From January 2018 to January 2019 a total of 500 patients were enrolled into the study. A total of 1398 number of patients were screened to take part in the study and of these 500 were recruited into the trial. The screening and enrolment for the study can be found in Figure 3.9.

Figure 3.9 Screening and enrolment log for the study



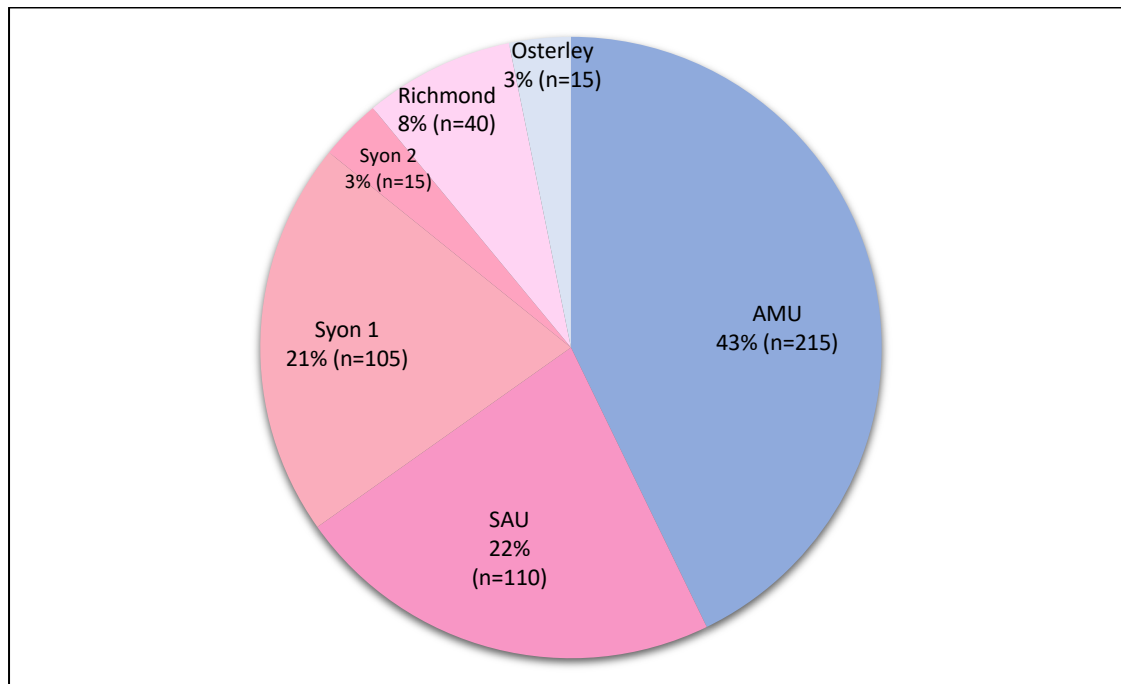
The main reasons for non-recruitment were patient illegibility (691 screened participants).

There were 207 patient factors in which patients were not recruited. Of these 99 patients declined with no reason given. Other patient reasons were already having too much

monitoring (n=82), not liking the sensor or ECG dots (n=15) and patient anxiety (n=11). The patients that already had too much monitoring were those on the AMU that had additional monitoring devices as per clinical care.

The number of surgical patients was 279 (55.8%) and the number of medical was 221 (44.2%). The total study population had 248 (49.6%) male and 252 (50.4%) female patients. The mean age for all patients was 56.7 years old (standard deviation 20.1) and ranging from 18 to 95. The mean age of medical patients was 64 years old whilst the mean age of surgical patients was lower at 52 years old. All medical patients were recruited on the acute medical unit and Osterley 2 ward. However, there were very few patients recruited on Osterley 2 ward as the recruitment on this ward was very late in the study. Surgical patients were recruited from SAU, Richmond, Syon 1 and Syon 2 wards. A pie chart identifying where patients were recruited is shown in Figure 3.10; all medical wards are in blue whilst all surgical wards are in pink. The highest medical recruiting ward was AMU whilst SAU and Syon 1 were the highest surgical recruiting wards.

Figure 3.10 A pie chart of patient recruitment by location



The ethnicity for all patients recruited can be shown in Table 3.1. Most participants recruited were White British (58.4%) and there was also a significant number from Asian British Indian (15.6%).

Table 3.1 – The ethnicity of all patients recruited in the study

All patient ethnicity groups	Total Number n (%)
White British	292 (58.4)
Other White Background	41 (8.2)
Black/ Black British Caribbean	3 (0.6)
Black/ Black British African	10 (2)
Other Black Background	2 (0.4)
Asian / Asian British Indian	78 (15.6)
Asian /Asian British Pakistani	15 (3)
Asian /Asian British Bangladeshi	2 (0.4)
Asian / Asian British Chinese	2 (0.4)
Other Asian Background	8 (1.6)
Mixed Background	7 (1.4)
Other (please state)	27 (5.4)
Not known	13 (2.6)
Total	500

3.4.2 Reliability of ward data

All of the ward data was reviewed, and a total of 27,397 ward data points were identified. All ward observations were coded into categories of clear legible reading, illegible reading, no value written and patient off the ward. These can be found in Table 3.2 below. The total numbers of valid readings for all 3 vital signs were high with 95.7% of HR readings, 97.2% of respiratory rate readings and 95% of all temperature readings. The highest numbers for illegible readings was for HR at 2.2%, then 2% for temperature and 0.8% for RR.

Temperature had the highest number of values not written at 2.4%, followed by HR at 1.6% and RR at 1.5%. The same number of patients off the ward were found in all 3 vital signs at 46 patients.

Table 3.2 –Documentation of Ward Observations for each vital sign in all patients

Vital Sign	Number of vital signs (%)
Heart Rate	
Clear legible Readings	8745 (95.7%)
Illegible	199 (2.2%)
Value not written	144 (1.6%)
Patient off the ward	46 (0.5%)
Total	9134
Respiratory Rate	
Clear legible Readings	8881 (97.2%)
Illegible	72 (0.8%)
Value not written	134 (1.5%)
Patient off the ward	46 (0.5%)
Total	9133
Temperature	
Clear legible Readings	8676 (95.0%)
Illegible	185 (2.0%)
Value not written	223 (2.4%)
Patient off the ward	46 (0.5%)
Total	9130

3.4.3 Review of different averaging time windows for the sensor

The ideal averaging time window to use when comparing sensor data to ward data is unknown to date with variation in the current literature. The ideal averaging method (mean or median) is also unknown. The 6, 10, 12, 16 and 18-minute time windows were assessed, and all can be found in Table 3.3 below.

There was little significant difference for correlation between ward observations and the sensor time windows that were compared. The 10-minute time window was chosen as it provides the smallest monitoring window with the least amount of data loss. Smaller time windows had less numbers of matched pairs compared to larger time windows. Whilst the 6-minute window was good, the number of matched pairs were considerably less than the 10-minute window resulting in significant data loss. In addition, not all ward staff can take observations in under 10 minutes and so it would be unfair to include ranges under 10 minutes. The concern with the higher averaging time windows is the chance that patients may enter a new physiological process and important early changes in physiology may be missed. The results for the 10-minute window can be found below whilst the results for the other time windows analysed are in the Appendix (6-minute window – Appendix 3.3, 12-minute window -Appendix 3.4, 16-minute window Appendix 3.5- and 18-minute window Appendix 3.6). There was also little variation when comparing the averaging method of the mean or median for the different time windows.

Table 3.3 - A comparison of the different averaging time windows for sensor readings with both means and medians given

	6-Minute Window		10-Minute Window		12-Minute Window		16-Minute Window		18-Minute Window	
Heart Rate	Mean	Median	Mean	Median	Mean	Median	Mean	Median	Mean	Median
Correlation	0.805	0.8034	0.7941	0.7925	0.7948	0.7902	0.7987	0.7967	0.7932	0.7922
P Value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
n-number of matched pairs	2731	2730	2849	2848	2873	2872	2910	2909	2927	2926
Limits of agreement	-26.715 to 21.370	-26.611 to 21.963	-27.684 to 21.896	-27.652 to 22.854	-27.521 to 21.712	-27.643 to 22.940	-27.164 to 21.349	-27.006 to 22.540	-27.528 to 21.715	-27.178 to 22.864
Mean difference	-2.672 (CI - 3.123 to - 2.221)	-2.324 (CI - 2.780 to -1.868)	-2.894 (CI - 3.349 to -2.439)	-2.399 (CI - 2.863 to -1.935)	-2.905 (CI - 3.355 to -2.454)	-2.351 (CI - 2.814 to -1.889)	-2.907 (CI - 3.348 to -2.466)	-2.233 (CI - 2.684 to -1.783)	-2.907 (CI - 3.353 to -2.461)	-2.157 (CI - 2.611 to -1.704)
Range	37.000 to 156.650	46.000 to 157.000	38.000 to 168.500	46.000 to 168.500	38.000 to 168.500	46.000 to 168.500	38.000 to 168.500	46.000 to 168.500	38.000 to 168.500	46.000 to 168.500
Respiratory Rate										
Correlation	0.2841	0.2845	0.3002	0.3042	0.3013	0.3069	0.2988	0.2944	0.2978	0.2943
P Value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
n-number of matched pairs	2129	2129	2510	2510	2610	2609	2762	2761	2808	2807
Limits of agreement	-11.099 to 14.421	-11.237 to 14.524	-10.315 to 13.975	-10.830 to 14.316	-9.849 to 13.787	-10.533 to 14.195	-9.472 to 13.418	-10.416 to 14.052	-9.273 to 13.292	-10.338 to 13.973
Mean difference	1.661 (CI 1.390 to 1.932)	1.644 (CI 1.370 to 1.917)	1.830 (CI 1.592 to 2.068)	1.743 (CI 1.497 to 1.989)	1.969 (CI 1.742 to 2.196)	1.831 (CI 1.594 to 2.069)	1.973 (CI 1.760 to 2.187)	1.818 (CI 1.590 to 2.047)	2.009 (CI 1.801 to 2.218)	1.817 (CI 1.593 to 2.042)
Range	10.000 to 45.500	10.000 to 45.500	7.500 to 42.500	7.500 to 42.500	8.500 to 43.250	8.500 to 43.250	8.500 to 42.000	8.500 to 42.500	8.500 to 42.000	8.500 to 42.500
Temperature										
Correlation	0.4267	0.467	0.4259	0.4254	0.4268	0.4265	0.4272	0.4271	0.4269	0.4273
P Value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
n-number of matched pairs	3151	3150	3236	3235	3271	3270	3320	3319	3353	3352
Limits of agreement	-1.486 to 2.501	-1.487 to 2.499	-1.483 to 2.519	-1.483 to 2.514	-1.482 to 2.523	-1.483 to 2.524	-1.475 to 2.525	-1.478 to 2.520	-1.478 to 2.534	-1.481 to 2.527
Mean difference	0.508 (CI 0.473 to 0.543)	0.506 (CI 0.471 to 0.541)	0.518 (CI 0.484 to 0.553)	0.516 (CI 0.481 to 0.550)	0.520 (CI 0.486 to 0.555)	0.520 (CI 0.486 to 0.555)	0.525 (CI 0.491 to 0.559)	0.521 (CI 0.487 to 0.555)	0.528 (CI 0.494 to 0.562)	0.523 (CI 0.489 to 0.557)
Range	33.850 to 39.750	33.850 to 39.750	33.800 to 39.750	33.850 to 39.750	33.850 to 39.800	33.875 to 39.775	33.850 to 39.750	33.900 to 39.775	33.850 to 39.750	33.900 to 39.750

3.4.4 Heart rate

A mean 10-minute averaging window for Sensium observations compared to ward observations provided a total of 2849 matched pairs over 500 recruited patients, whilst a median averaging window provided 2848 matched pairs. The correlation coefficient between the Sensium data and the ward observation data was 0.79($p=0.0001$). The Bland Altman plot with all 500 patients matched HR pairs for both means and medians can be seen in Figure 3.11.

Using the mean the limits of agreement were -27.684 to 21.896 and the mean difference between the Sensium HR and ward observations was 2.894 (CI -3.349 to -2.439). The range of heart rate was 38 to 168.5 beats per minute.

Using the median, the limits of agreement were -27.652 to 22.854 and the mean difference between the Sensium HR and ward observations was 2.399 (CI -2.863 to -1.935). The range of heart rate was 46 to 168.5 beats per minute.

Histograms using the mean and median when comparing the Sensium data to the ward observations for HR can be found in Figure 3.12. A normal distribution was found between the sensor and ward data for HR. The sensor overall was able to take much higher and lower readings compared to the nurses.

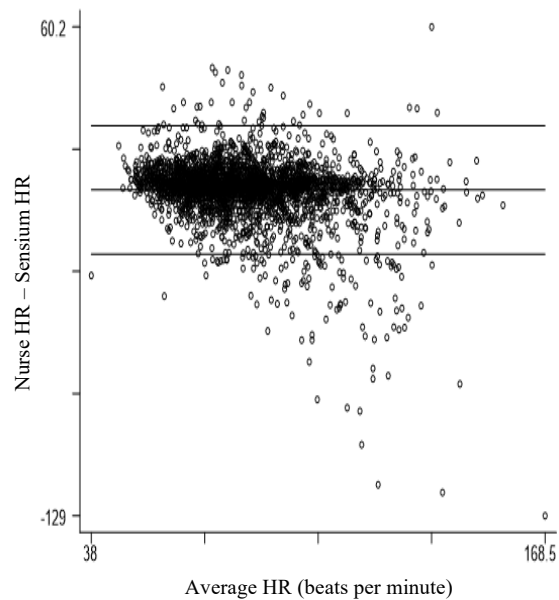
By reviewing both the Bland Altman results and Histograms it is clear that results near the average (either median or mean) are very close between the sensor and the nurse. However in

extremes of HR both either at the lower or upper end the difference between the sensor and the nurse increases.

There was a strong statistically significant direct relationship between the ward observations and sensor readings for HR. On average the difference between the ward measurements and the sensor reading for HR were between 2.4 – 2.9 beats per minute. The Kappa agreement between the nurses observations and the sensor for HR was 97%.

Figure 3.11 Bland Altman plots for the mean and median matched pairs of Sensium HR and ward observations in a 10-minute averaging time window

Bland Altman for 10-minute mean HR



Bland Altman for 10-minute median HR

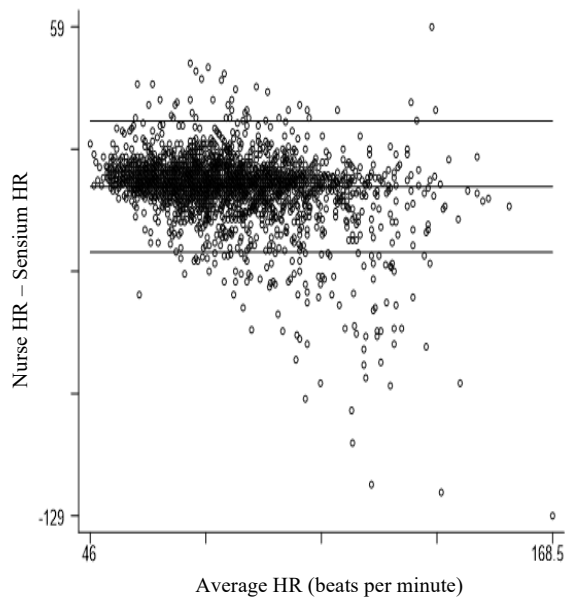
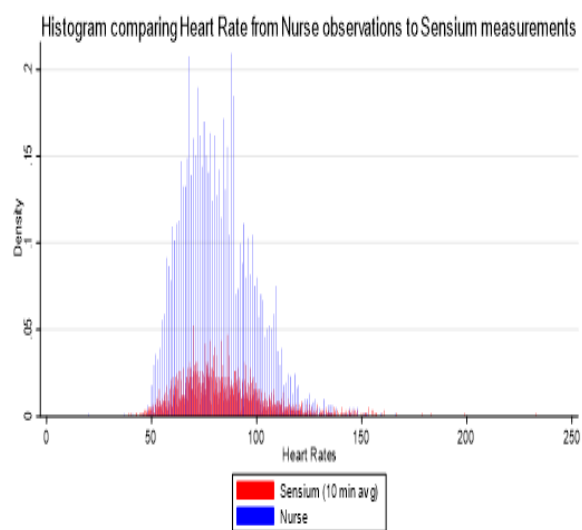
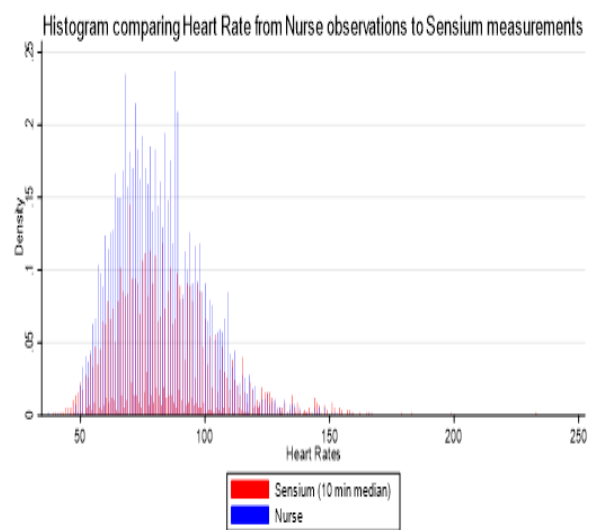


Figure 3.12 Histograms for the mean and median matched pairs of Sensium HR and Ward observations in a 10-minute averaging time window

Histogram for 10-minute mean HR



Histogram for 10-minute median HR



4.4.5 Respiratory Rate

Using both the mean and median 10-minute averaging window for the Sensium observations compared to the ward data there was a total of 2510 matched pairs over 500 recruited patients. The correlation coefficient between the Sensium data and the ward observation data was 0.3($p=0.0001$). The Bland Altman plot with all 500 patients matched RR pairs for both means and medians can be seen in Figure 3.13.

Using the mean the limits of agreement were -10.315 to 13.975 and the mean difference between the Sensium RR and ward observations was 1.830 (CI -1.592 to -2.068). The range of respiratory rate was 7.500 to 42.500 breaths per minute. Using the median, the limits of agreement were -10.830 to 14.316 and the mean difference between the Sensium RR and ward observations was 1.743 (CI -1.497 to -1.989). The range of respiratory rate was 7.500 to 42.500 breaths per minute.

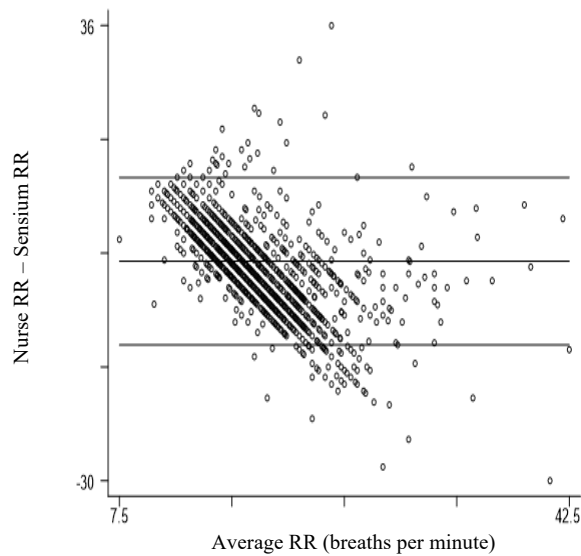
Histograms using the mean and median when comparing the Sensium data to the ward observations for RR can be found in Figure 3.14. For both mean and median the most common nurse RR readings were between 16 and 20 with the most frequent reading being 18 breaths per minute. In contrast the sensor showed more of a spread of data with much lower RR readings than the ward observations.

Although the respiratory rate between the sensor and ward observations were statistically correlated there was a weak positive linear relationship. To understand why there was only a weak positive relationship, more frequent observations by the nurses would have been required. On average the difference between the ward measurements and the sensor reading

for RR were between 1.7-1.8 breaths per minute. The Kappa agreement between the nurses observations and the sensor for RR was 82%.

Figure 3.13 Bland Altman plots for the mean and median matched pairs of Sensium RR and ward observations in a 10-minute averaging time window

Bland Altman for 10-minute mean RR



Bland Altman for 10-minute median RR

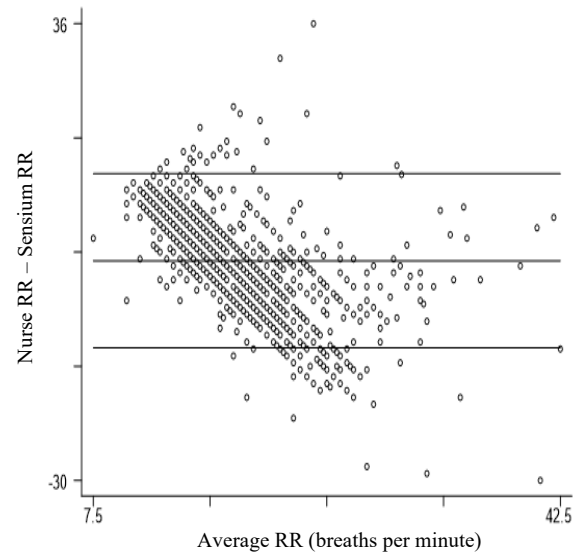
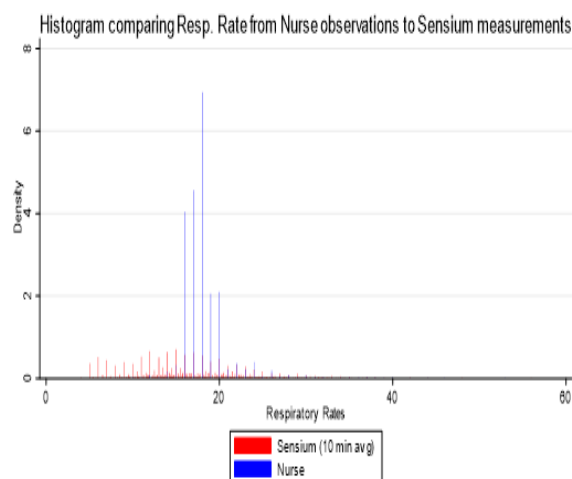
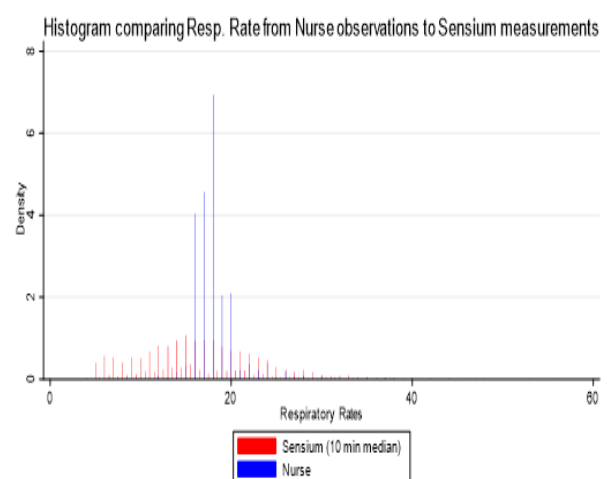


Figure 3.14 Histograms for the mean and median matched pairs of Sensium RR and Ward observations in a 10-minute averaging time window

Histogram for 10-minute mean RR



Histogram for 10-minute median RR



3.4.6 Temperature

Using a mean 10 mean minute averaging window for the Sensium observations compared to the ward data there was a total of 3236 matched pairs over 500 recruited patients and a median averaging window gave a total of 3235 matched pairs. The correlation coefficient between the Sensium data and the ward observation data was 0.43 ($p=0.0001$). The Bland Altman plot with all 500 patients matched temperature pairs for both means and medians can be seen in Figure 3.15.

Using the mean the limits of agreement were -1.483 to 2.519 and the mean difference between the Sensium temperature and ward observations was 0.5°C (CI 0.484 to 0.553). The range of temperature was 33.8 to 39.8°C .

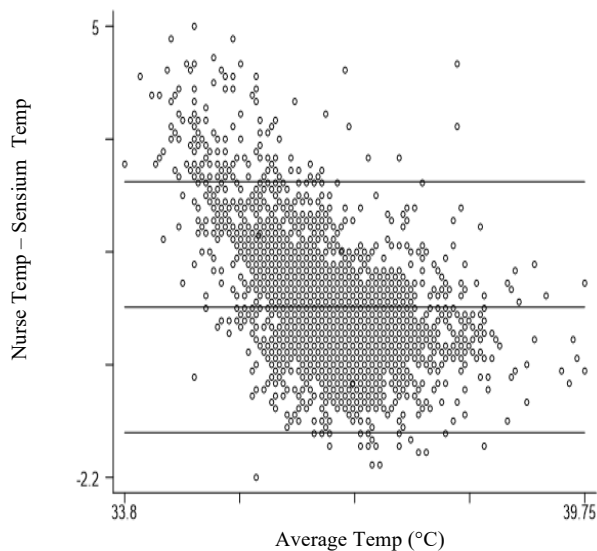
Using the median, the limits of agreement were -1.482 to 2.523 and the mean difference between the Sensium temperature and ward observations was 0.5°C (CI 0.486 to 0.555). The range of temperature was 33.9 to 39.8°C .

Histograms using the mean and median when comparing the Sensium data to the ward observations for temperature can be found in Figure 3.16. There is a skew of the red sensor temperature readings to the left when compared to the ward observations. This means the temperature taken by the sensor axillary temperature was lower than the tympanic temperature taken by the nurses. Overall the sensor identified much lower ranges in temperature than the tympanic probe used by the nurses.

There was a moderate statistically significant correlation between the sensor and ward temperatures using the 10-minute time window. The average difference between the sensor and ward observations was 0.5°C. The Kappa agreement between the nurses observations and the sensor for temperature was 60%.

Figure 3.15 Bland Altman plots for the mean and median matched pairs of Sensium temperature and ward observations in a 10-minute averaging time window

Bland Altman for 10-minute mean Temp



Bland Altman for 10-minute median Temp

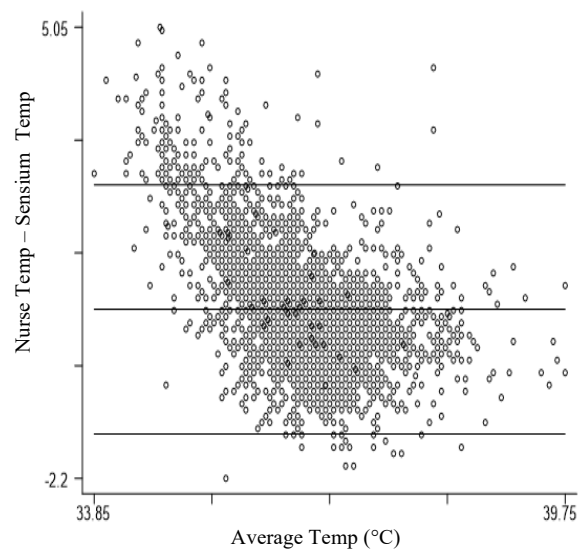
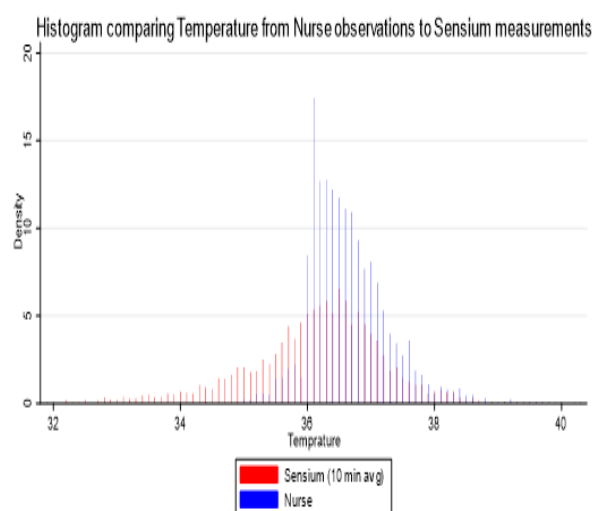
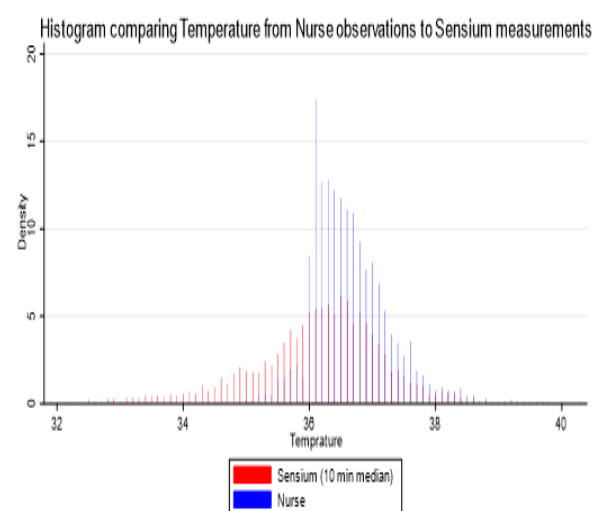


Figure 3.16 Histograms for the mean and median matched pairs of Sensium RR and Ward observations in a 10-minute averaging time window

Histogram for 10-minute mean Temp



Histogram for 10-minute median Temp



3.5 Discussion

To the best of our knowledge this is the largest prospective cohort study that investigated the reliability of continuous vital signs monitoring using a wearable wireless patch sensor for several days in acutely unwell admissions to hospital. The majority of previous studies have been obtained in controlled laboratory conditions(75)(153). Both medical and surgical patients were recruited over six clinical areas providing real-time information in several clinical settings. Patients recruited represent a range of ethnic groups reflecting the admitting population at the trust. This can often be missed in research studies with a selection bias. Additionally, the year-long study duration helped ensure patient recruitment was not affected by seasonality. We studied the performance of a wearable wireless sensor to monitor HR, RR and temperature. Whilst the device has regulatory CE marking approvals, the feasibility in a real-time ward setting was unknown. This unique study uses a wearable sensor to continuously monitor vital signs in an acute setting for patients on general wards.

3.5.1 Heart Rate

There was a strong positive correlation between the sensor readings and ward observations for HR with a mean difference in HR of only 2.4 – 2.9 beats per minute. Other studies have agreed HR to be acceptable if within a 5 beat per minute range against the reference standard (152). Whilst the ward monitoring for HR and temperature were defined as the current ‘gold standard’ all equipment will vary slightly in both functionality and inherent error(154).

3.5.2 Respiratory Rate

The RR correlation between the ward observations and sensor readings showed a weak positive correlation 0.3 ($p=0.0001$). This is concerning as RR is one of the first vital changes

to change early in patient deterioration. Similar studies reviewing wearable sensors have found differences between respiratory rates from sensor data to measurements by nurses(149). This may be explained by inaccuracies in the sensor or the HR and temperature having a digital reference standard whilst RR is calculated from manual counting from the nurse. Although, one can compare digital observations to digital observations, quite simple comparing digital to manual records has many limitations. There is a wide evidence base to show that RR one of the most sensitive markers of earlier deterioration and sepsis is often recorded inaccurately. The variation that has been found between the RR and the ‘gold standard’ of nursing observations may not have been correct. The discrepancies found may be attributable to an incorrect reference point, i.e. nursing observations. A phenomenon that may help explain any potential differences found between ward and sensor observations for RR is that of ‘data smoothing’(155). This is where staff may be ‘biased toward vital sign values that lie within the assumed limits of normality and record vital sign values that are incorrectly normal-‘smoothing’ the extremes of the vital sign record’(155). It may be difficult to do this with digital readings recorded with HR and temperature as these are readings that are given in a digital format with limited scope for ‘smoothing’. However, with the RR being a manual count by the nurses the effects of data ‘smoothing’ may be more likely. Data smoothing of ward vital signs has been described in the acute setting previously(156). Nursing data is more likely to have fewer extreme samples resulting in larger discrepancies between raw data of an extreme value(156). Despite this, the overall difference between the RR from the sensor compared to the ward observations was only on average between 1.7-1.8 breaths per minute. When reviewing the literature, accepted discrepancies between sensor readings for RR when compared to nurses is 2 breaths a minute(152).

3.5.3 Temperature

The temperature difference was only 0.5°C between the Sensium sensor and the reference standard. This is again an acceptable limit of agreement (152). The core body temperature range varies from <35°C (hypothermia) to >41.0°C (hyperpyrexia). There was a moderate correlation between the sensor and ward observations for temperature. The difference of 0.5°C was expected as there is known to be such a difference depending on which anatomical location the temperature was taken from(157). Significant variations in temperature of 0.5°C have been found between one ear and the other using tympanic temperature probes(157). Whilst the ward monitoring for HR and temperature were defined as the current ‘gold standard’ all equipment will vary slightly in both functionality and inherent error(154).

3.5.4 Alerting time windows

Wearable sensor technology generates an abundance of data. This data must be delivered to the clinical team in a fast and reliable way. A single change in a vital sign may not be meaningful and result in excess alert generation. Several vital changes over a number of minutes is more likely to be clinically significant. The ideal time for alerting has been largely unknown to date with wide heterogeneity in the literature. Comparing several alerting windows is highly clinically relevant and the 10 minute window may be used in the future for alerting regardless of the specific sensor used. The testing of 10 minute alerting in further randomised controlled trials is required.

A strength of this study is it is one of the first studies that has reviewed several averaging time windows when comparing sensor readings to other forms of monitoring. The data from this study shows that a 10-minute window may be best when comparing the data to ward

observations for all 3 vital signs HR, RR and temperature. When comparing the mean to a median reading there was little difference between the two forms of averaging, however a median averaging method will be less affected by outliers and skewed data when compared to the mean. A median filtering method was used in a previous small pilot study over a 15 minute time window (141). When reviewing the whole process of taking nursing observations this can take several minutes alone from chatting to the patient, attaching the monitoring, taking the reading and finally documenting the observations on the charts. The length of time that this can occur is typically over 5-10 minutes depending on the staff member taking the reading and whether there were any interruptions during this process. If too small an averaging window is taken, then there may be insufficient sensor readings and a greater chance of error if one of the readings is incorrect. If the averaging window is too long, then there is a chance that a new physiological process may occur in that time and consequently the comparison readings to the manual observations be incorrect. Therefore, an average filter time of 10 minutes has been selected to compare the sensor time to the ward observations.

Whilst attempts have been made to best understand the data through several averaging formats as wearable devices develop further, it is likely that even more sensing technologies will be added, and additional vital signs monitored. Large amounts of data can be generated from sensors already and these will require algorithms to analyse the data and help clinicians understand the outcomes(154). Algorithms used aim to achieve a balance of sensitivity and false alarms and minimising the power consumption of the device during algorithm execution(158).

There will need to be a balance for wearable technologies in which too little data may miss detection of unwell patients and too much data which may overwhelm clinical teams. The mining of data for clinical sensitivities and relevant outcomes is complex (154). In addition, the mining of data will require the algorithms to work at a lower power consumption ensuring that the sensors are both light weight and can be worn for longer time periods. A possible method that may help is to use wearable sensors which work in a low power state and only require high power consumptions when alarms are generated (154).

Although small in numbers, incomplete and illegible ward observations from the nurses were found. This can be shown in similar studies that have reviewed observation charts previously(159). Using current ward monitoring where some observations may only be measured a few times a day, there could be adverse serious consequences if vital signs are inaccurate or illegible. Early detection of unwell patients and sepsis may easily be missed due to incomplete or illegible data. A strength of monitoring through wearable sensors is due to the digital display of data, therefore it is unlikely that data transmitted will be incomplete or illegible.

Whilst track and trigger systems such as NEWS are routinely used, observations or patients triggering on these scoring systems are still poorly acted upon. This is one of the major problems with a failure to escalate an unwell patient. Unfortunately in clinical practice there is only partial adherence to escalation protocols and repeat assessment of unwell patients(65). The reasons as to why this may be are largely unconfirmed. For some this may be a lack of knowledge of observations and a problem with staff education. Whilst for others they may not be familiar with the charts themselves and feel either unable to ask or know who to contact for help(160). Staff members may also be scared to raise an alarm in a deteriorating

patient(160). Staff shortages and busy wards may be another factor that deterioration is not acted upon when realised and this has been shown to affect patient outcomes(161). Whilst it is difficult to address all of these issues, the use of continuous monitoring on real-time wards may help highlight unwell patients sooner.

3.5.5 Strengths

To the best of my knowledge this is the first clinical study that investigated the reliability of continuous vital signs monitoring using a wearable wireless patch sensor for several days in acutely unwell admissions to hospital. The majority of previous studies have been obtained in controlled laboratory conditions(75)(153). This study and the use of the device was approved by the medical staff involved as well as gaining full consent from patients. The large sample size compared to other studies can help not only with reliability but also in detection of patients who deteriorate on the ward or develop sepsis as reviewed in the next chapter.

This is the largest study of its kind to date. Another strength is the study included both medical and surgical patients recruited over six clinical areas providing real time information in a variety of clinical settings. Patients recruited in this trial represent a wide range of ethnic groups and so reflect the admitting population at the trust. This can often be missed in research studies with a selection bias. The yearlong study duration helped to ensure that patient recruitment was not affected by seasonality.

Although this study and others have reviewed the feasibility of the device in clinical practice, it cannot validate it. Much of the validation of these devices has occurred through the process to acquire CE marking and FDA approval. What may be of real benefit to the clinical team is not only the huge number of readily available data for HR, RR and temperature but also the

trends in these vital sign parameters. During a normal inpatient stay over 24 hours we have shown that most patients only have a few vital sign readings. Whilst it is possible to review trends over these data points a larger number of readings providing, they are accurate will be far more meaningful for trend analysis. A real strength of the wireless technology is not just the 'spot reading' for the vital sign but for trend analysis.

3.5.6 Limitations

This study was performed in a single hospital setting, and it may not be possible to generalise the results to other institutions or hospitals. As found in previous studies the results show the difficulty in confirming the accuracy vital signs particularly RR monitoring in a real-time ward setting(141). Ideally the project would have had additional observers checking the nursing observations as they occurred. However in a real-time ward setting this is impractical. Thoracic impedance is influenced by factors such as walking, talking, breathing, laughing and patient movement(141). This may have also affected the discrepancies found for respiratory rate.

Despite the large number of patients recruited it is possible that data saturation may not have been reached. As this is a feasibility pilot study the sample size calculations were difficult to perform. Whilst the study includes a wide number of ages and demographics there may have been a selection bias as not all participants approached agreed to partake in the study and this potentially may limit the generalisability of findings. Common reasons for failing to partake were already cited, e.g., having access to excessive monitoring, anxiety prior to a procedure such as an emergency operation and feeling too unwell.

However, a high proportion of those excluded were either very sick (unable to consent) or well enough to be considered for discharge. In this context, these patients are unlikely to be those that benefit from continuous monitoring. Unfortunately, the inability to recruit patients who are with either acute confusion or longer term dementia limits assessments in patients who may struggle to wear the sensors and/or report problems with them.

The Sensium wearable patch has pre-specified quality thresholds determined by the developer to exclude data that does not meet the threshold. The data that is not being transmitted is contaminated by artefact. The most prone to artefact is the RR as this requires correcting due to the interference from cardiac oscillations. The performance of the sensor during abnormal conditions of a heart rate arrhythmia is also unknown. The reliability of the sensor in patients with known arrhythmias needs to be assessed in future research studies.

Whilst all data points have been included in the analysis there is the potential that patient deterioration may have occurred and potentially be missed during those time periods where no data has been transmitted.

Whilst there was no real alerting occurring for patient deterioration, alerts were sent to the research team if there was a problem with the patch. This was key to the study as without this it was unknown if the patch was placed correctly. All alerts were sent to a smartphone for the study as well as a Sensium mailbox on a desk-based computer available to the research team. At times there were problems with the smartphone, for example, if a system update was required the phone became deactivated. It was during these times that the desk-based computer was used.

3.5.7 Conclusions

This is the largest prospective cohort study that investigated the reliability of continuous vital sign monitoring using wearable sensors for several days in acutely unwell hospital admissions. We have demonstrated strong agreement with heart rate between the sensor and ward observations. The temperature had moderate statistically significant correlation between the sensor and ward temperatures. Whilst the respiratory rate showed a weak positive linear relationship it was still statistically significant with less than 2 breaths per minute difference on average between the sensor and ward observations. This chapter supports the use of wearable sensors to reliably measure vital signs in an acute setting and identifies optimum time windows for alert generation. Wearable sensor use for monitoring ward patients will cause a paradigm shift resulting in safer smarter wards.

This chapter has reviewed the reliability of wearable sensors, but the use of wearable sensors to detect patient deterioration and sepsis is unknown. The next chapter will explore whether data from wearable sensors will be able to detect patient deterioration earlier than existing practice.

Chapter 4 Assessing speed of wearable sensors to detect patient deterioration and sepsis as compared to current monitoring

4.1 Introduction

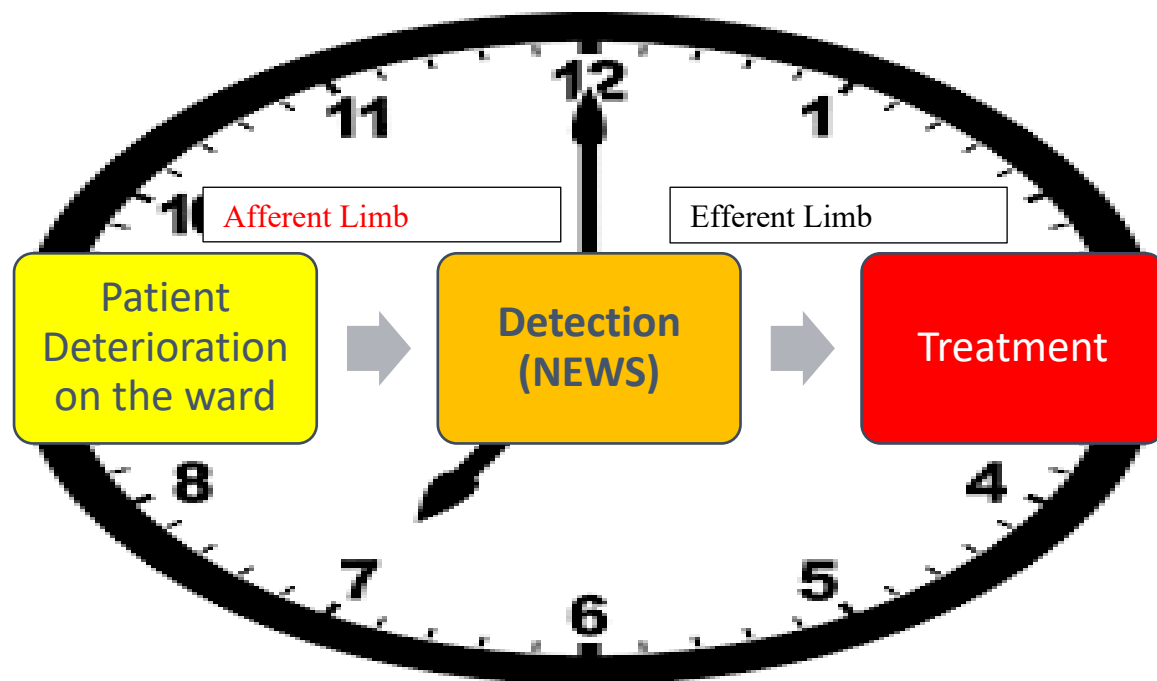
The speed with which patient deterioration is identified and acted upon has a significant impact on survival from that episode of deterioration. Chapter 1 demonstrated the need for earlier detection of unwell patients, how new innovative digital technology can be used to do this and reviewed a range of wearable sensors. The systematic review and meta-analysis in chapter 2 demonstrated the importance of digital alerting in sepsis and its improvement in some outcome measures with implementation. The reliability of wearable sensors was assessed in chapter 3. The use of wearable sensors to detect unwell patients more rapidly than current monitoring is unknown and will be explored in this chapter.

The demand in hospitals is increasing both within the UK and worldwide, both in terms of acuity and in terms of overall numbers of admissions. The treatment of ward based patients is now complex due to an increase in the aging population and individuals surviving with more co-morbid conditions. With limited resources in most hospitals, these complex patients are increasingly being monitored in a ward based settings. Unfortunately, during these admissions a significant proportion of patients experience serious adverse events such as cardiopulmonary arrest, respiratory failure and shock which can lead to transfer to higher levels of care and mortality(162). In a multicentre study, harm has been found to persist with little improvement over a 5 year time window(162).

Both early identification and treatment are required to improve outcomes in unwell patients. The early identification of patients is referred to as the afferent limb whilst treatment and escalation the efferent limb. Much of the research to date has been on the efferent limb. The best example showing improvements in the efferent limb is that of the use of outreach or rapid response teams. These are centrally based teams that attend when patients become unwell on the ward and help in the treatment of acutely unwell patients. These teams are summoned to attend to a deteriorating patient once deterioration is recognised. There has been much research on the use of the outreach or rapid response team for patients at risk of deterioration, and they have been shown to reduce the incidence and mortality from unexpected cardiac arrest in hospital(163).

Whilst such outreach teams are extremely useful, they rely on timely identification of unwell patients by healthcare staff, and this does not always occur. There is now a switch in focus to the afferent limb with alternative strategies to detect patient deterioration. It is only when worsening vital signs and clinical deterioration are correctly identified by those looking after the patient that the rapid response teams would be alerted. If there is a delay or inaccuracy in the afferent limb, there will be corresponding delays in the efferent limb. This can be shown in Figure 4.1

Figure 4.1 A flow diagram depicting the afferent and efferent limbs in detecting unwell patients.



Governments and healthcare providers are utilising the latest technology to identify patients earlier and to implement treatments(164). Much of the focus of this research has been the use of digital alerts as explored in chapter 2. The use of wearable sensors in sepsis detection is novel and has not been explored previously in the context of sepsis.

It is known that patient deterioration is preceded by changes in vital signs. A high proportion of vital sign abnormalities are found prior to ICU admissions, cardiorespiratory arrest and mortality(165)(166)(167)(163). In 60% of patients, abnormalities were documented 8 hours prior to their admission(166). Many patients in the study were hypotensive, tachycardic or tachypnoeic(166). Concerns were raised by nursing staff and junior medical staff in 70% of all ward patients 8 hours prior to the ICU admission(166). However subtle changes in vital

signs often remain undetected; missing opportunities to detect signs of deterioration. Early detection facilitates faster treatment which in turn reduces both transfer to the Intensive Care Unit (ICU) and mortality(168)(167).

This chapter will explore the use of wearable sensors to detect unwell patients and those that have sepsis.

4.1 Aims

To investigate the speed at which the wearable patch detects patient deterioration and the subset of patients with sepsis when compared to standard monitoring.

The null hypothesis states that continuous measurements is unable to detect the deteriorating patient and sepsis earlier than current methods.

4.3 Methods

4.3.1 Study design

A prospective cohort study was conducted. This study design was selected so that there would be real time observational data to act as a data comparison for the study, with such real-time data being the standard of care on general ward areas.

4.3.2 Study location

The study was based at West Middlesex University Hospital (WMUH) which is a busy acute district general hospital in West London. It serves a local population of 400,000 people and has around 400 beds. This was a single centre evaluation. All patients admitted to the acute medical unit (AMU), the acute surgical unit (ASU), Richmond, Syon 1 and Syon 2 wards were included in the study.

4.3.3 Participants

All deteriorating patients were identified from the patients recruited in the previous chapter 3. It is the acutely unwell patients, both medical and surgical, that often have the greatest physiological derangement and risk of infection as treatment may not have yet fully commenced or be in the process of commencing. Therefore, this patient group was targeted for recruitment.

4.3.4 Study Procedure

The data from the patients recruited in the previous chapter were reviewed. Upon patient recruitment into the study all admitting documentation was reviewed and a standard pro forma completed for each patient. This can be found in Appendix 4.1 Data reviewed included all demographic data, initial observations at presentation, suspected diagnosis on admission, whether there was a suspicion of infection or sepsis (if so the suspected source) and antibiotic use. All clerking notes were reviewed for any signs of sepsis, severe infection, infection or suspicion of infection. As per trust policy all patients with sepsis should have a sepsis risk score completed on admission (Appendix 4.2). The numbers of these completed scores was also reviewed. Patient drug charts were checked for both antibiotic use and the patient's BMI. All demographic sheets were completed at the time of patient consent. In addition the patients themselves were asked directly about symptoms, co-morbidities, place of residence and levels of independence. The dates and time of when the patient was admitted as well as the initial observations and NEWS score were recorded to act as a baseline for the patient.

All discharges at the trust are electronic and were reviewed to identify any significant adverse event experienced by the patient during their hospital admission. If any further details were required about the patient, the notes were requested and reviewed.

4.3.4.1 Identifying unwell patients

The average interval in measuring vital signs for most ward patients is between 4-6 hours.

The frequency of this may be increased for example if the patient is unwell or post-operative.

This is the ideal; however on a busy ward with stretched resources the time intervals may not be as close together as we might like. The first task normally performed by nurses or nursing auxiliaries if they suspect a patient is unwell is to take a set of bedside observations. These observations are time stamped and must be recorded by the nurse at the precise time the observations were taken.

All ward observation charts were reviewed and data was transcribed onto Excel sheets for HR, RR and temperature. If any readings were unclear these were checked by a second reviewer as described in the previous chapter. The ward observations were used as the gold standard to identify patient deterioration.

In this chapter the time of patient deterioration on ward observations was compared to when the Sensium device first detected abnormal vital sign changes and an alert generated using a 10 minute time window (as identified in the previous chapter). The thresholds for the alert are based on NEWS thresholds that have been set and are the same as those routinely used on the ward observation charts as per standard clinical care. NEWS was selected as it is the most widely adopted form of standardising acute illness severity in the NHS.

NEWS is used to standardise the assessment of the acutely unwell patient(53). NEWS has 6 physiological parameters(53). Each parameter is assigned a value from 0 to 3 and the NEWS may range from 0 to 20(53). The use of supplementary oxygen for a patient scores 2(53). AVPU (alert, voice, pain, unresponsive) is the score used to decipher a patient's level of consciousness and is also part of NEWS(53). The higher the NEWS the more unwell the patient is(53). There have been several recent updates and NEWS 2 was released earlier this year(169). The main updates have been an updated format of the NEWS chart including removing of green colour codes, a dedicated section for patients with hypercapnic respiratory failure (usually COPD) and the addition of a 'new confusion' score(169).

As per the NEWS score for HR to generate a red alert on the sensor there needs to be a reading of less than or equal to 40 or greater than or equal to 131 beats per minute(169). An amber alert for HR is sent if the HR is between 111-130 beats per minute(169). To generate a red alert for RR on the sensor there needs to be a reading of less than or equal to 8 or greater than or equal to 25 breaths per minute(169). An amber alert for RR is sent if RR is between 21-24 breaths per minute. To generate a red alert for temperature on the sensor there needs to be a reading of less than or equal to 35°C(169). An amber alert for temperature is sent if it is greater than or equal 39°C(170). A copy of the NEWS thresholds is found in Figure 4.2 below(169).

Figure 4.2 showing the thresholds used for alerting of the National Early Warning Score 2 and the Sensium device (169).

Physiological parameter	Score						
	3	2	1	0	1	2	3
Respiration rate (per minute)	≤8		9–11	12–20		21–24	≥25
SpO ₂ Scale 1 (%)	≤91	92–93	94–95	≥96			
SpO ₂ Scale 2 (%)	≤83	84–85	86–87	88–92 ≥93 on air	93–94 on oxygen	95–96 on oxygen	≥97 on oxygen
Air or oxygen?		Oxygen		Air			
Systolic blood pressure (mmHg)	≤90	91–100	101–110	111–219			≥220
Pulse (per minute)	≤40		41–50	51–90	91–110	111–130	≥131
Consciousness				Alert			CVPU
Temperature (°C)	≤35.0		35.1–36.0	36.1–38.0	38.1–39.0	≥39.1	

All ward vital signs were coded as per the NEWS scoring systems. Using the ward data, patients were risk-stratified to identify those with deterioration. All patients were put into several categories: no alerts on NEWS, pale yellow alerts, amber alerts or red alerts. The highest alert generated was used to risk stratify the patient so, for example, if a patient had an amber and a red alert the patient was coded as a red alert patient.

4.3.4.2 Identifying patients with sepsis

As discussed in Chapter 1 there are several ways to classify patients with sepsis in the absence of a single diagnostic test. A variety of classifications for sepsis were used including:

SIRS ≥ 2 with a suspicion of infection, a NEWS of 5 with a clinical suspicion of infection, QSOFA and ICD codes.

SIRS ≥ 2 & Clinical suspicion of infection

As identified in the meta-analysis in Chapter 2, a common scoring tool is the use of SIRS with a clinical suspicion of sepsis. Ward observations were used to identify any abnormal vital sign changes in heart rate, respiratory rate and temperature. The vital sign data were combined with a white cell count commonly taken in routine clinical investigation of unwell patients. All clerking notes were reviewed to identify those patients on admission with a clinical suspicion of infection. A SIRS score was calculated for all ward HR, RR and temperatures each time the ward observations were recorded.

NEWS of 5 & Clinical suspicion of infection

The recently updated NEWS 2 report suggests ‘the most effective approach to improving the early recognition of sepsis is one that builds on the routine vital signs monitoring systems that are already embedded into the healthcare system, i.e. NEWS’(169). NHS England’s recent guidance on early detection of clinical deterioration due to sepsis in adults recommends ‘NEWS as the early warning score to detect clinical deterioration in patients with suspected sepsis’(169)(171). A NEWS of 5 or greater and patients with a clinical suspicion of infection was used to help identify patients with sepsis. To allow a like for like comparison to the sensor technology only vital signs with a comparable vital signs on the sensor were used i.e. heart rate, respiratory rate and temperature. The above ward observations were used to

identify abnormal changes in HR, RR and temperature. The patient's admission notes were assessed to identify patients with a clinical suspicion of infection.

Quick Sequential Organ Failure Assessment (QSOFA)

The Quick Sequential Organ Failure Assessment (qSOFA) score was also used to help identify patients with sepsis(4). This score uses a combination of a respiratory rate of equal to or greater than 22 breaths per minute, altered mentation and a systolic blood pressure of less than or equal to 100mmHg. The qSOFA score was calculated on admission and throughout the patient stay.

International Classification of Disease (ICD codes)

Another system to identify patients with sepsis is the International Classification of Disease (ICD codes). The codes used for sepsis are the A41. All electronic discharge summaries were reviewed to identify ICD codes on patient discharge.

Clinician suspicion of infection was needed for a diagnosis and whilst blood culture results were reviewed for all patients a positive culture was not required to diagnose severe sepsis. This methodology of identifying patients with sepsis has been described previously(140). The Trust has a sepsis screening tool pro forma for all admitted patients and this was also reviewed (Appendix 4.2).

4.3.4.3 Reviewing alerting based on ward observations

There needs to be a balance between detecting an unwell patient sooner and preventing the alerts from firing unnecessarily and the subsequent risks of alert fatigue(172). One of the benefits of retrospective analysis is that the data can be reviewed and used to identify the optimum thresholds to use for alerting. The ideal alert is one that correctly identifies the deteriorating patient and excludes the well patient. The alert generating algorithms use data-driven approaches in identifying the number of alerts and frequency when identifying early detection of unwell patients(172).

Clinical deterioration detected on ward observations as per standard clinical practice was used to identify unwell patients. For all patients with a high risk alert (either an amber or red alert) a detailed analysis on alerting was performed. For patients with no alerts generated, or only pale yellow alerts without subsequent deterioration, further alerting analysis was not performed as these patients did not have clinically relevant deterioration on ward observations. In all patients with either an amber or red alert on ward observation charts, the times of sensor placement was reviewed to assess whether the episode of deterioration (red or amber NEWS) was known or unknown at the time of sensor placement and patients were coded accordingly. Patients with episodes of unknown deterioration at the time of patch placement were used to compare when the sensor first detected a change in comparison to the ward observations. The unknown deteriorating patients were further subclassified into those with a suspected infection and/or sepsis and those that were unwell for other reasons. The time at which the wearable patch first detects a change in any physiological observations was compared to ward-based patient observations charts. The times of patient deterioration on

both the ward observations and the sensor are known. This process of identifying patients with red or amber alerts on ward observations and known or unknown deterioration at the time of patch placement can be found in Figure 4.3.

Several rules were applied when the data were being reviewed to allow for standardisation. If for any reason the ward observation time was illegible, omitted or not clear this alert was not included in the comparison. Analysis was only performed when there was overlapping sensor periods of sensor and ward monitoring. At least an hour of valid sensor readings were needed after sensor placement to allow inclusion in further analysis. If patients had shown either an amber or red alert prior to sensor placement this was classified into a known patient with deterioration. If observations were increased by the clinical team anything up to hourly observations it was assumed the nurses were aware of patient deterioration and that episode of deterioration was known.

To generate an alert on the sensor there needed to be 5 abnormal alerts (10 minute window as described in the previous Chapter 3). These had to be consecutive without any normal readings in between. Minus one readings (a sensor timestamp without a valid vital sign reading) in between were acceptable and the alert still counted. The duration of the alert was also reviewed. To stop an alert 5 consecutive normal readings were needed or a period of 60 minutes of minus 1 data (without any valid amber or red sensor readings in between). For all readings from the sensor there is a 'leads on' or 'leads off' notification. If for any reason the sensor is not on the patient (has come off) any vital sign readings sent across will have a 'leads off' notification. Although no HR or RR notifications will be sent if the 'leads are off' (the sensor is not on the patient) there is the possibility that a temperature reading may be

sent as the sensor may record ambient temperature even when the sensor is not on the patient. The leads on and off function for temperature is very useful.

The hypothesis is that sensor data will lead to appropriate alerting of deterioration earlier than nursing ward observations. As all alerts were retrospective, a simulating alerting model was created on Excel to generate alerts. The alerting model was created by Mr Kenny McAndrew (Department of Information Technology at Chelsea Westminster Hospital NHS Foundation Trust). The times from the previous ward observations and the next ward observations were automatically calculated so that comparisons in time to alerting could be made. When calculating the duration of an alert, the alert was taken up to the next available ward observations, if the ward observations were still abnormal the alert was continued.

An example of the model using some hypothetical data is shown in Figure 4.4 with an alert for an abnormal heart rate and temperature. The time for the previous ward observations and next ward observations is automatically calculated. The alerting thresholds are set for that of the highest alert of NEWS for that parameter. These are changeable to separate thresholds and can be modified to fit the thresholds for an amber alert.

Figure 4.3 A Flow diagram identifying which patients to include in time to deterioration analysis

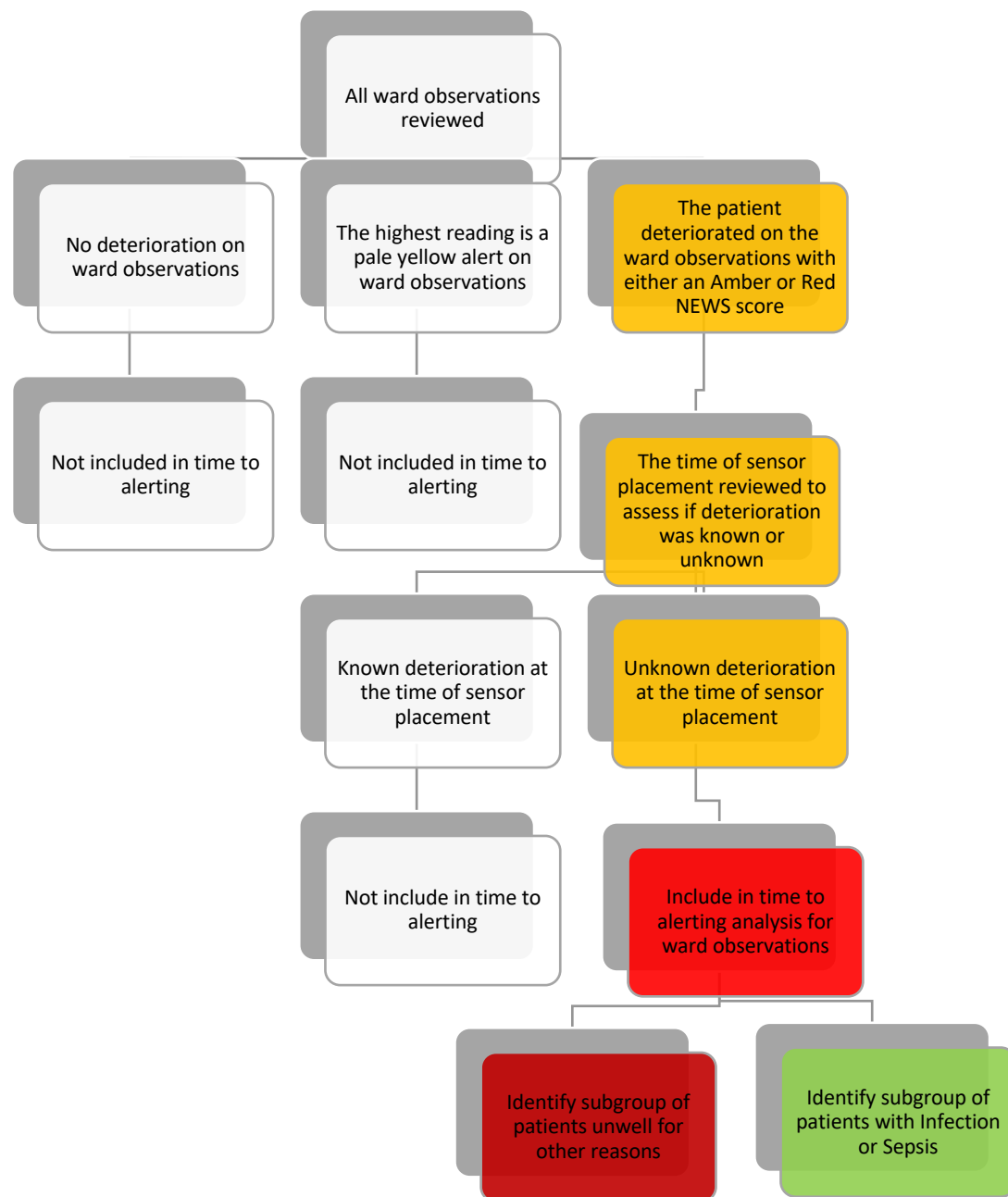


Figure 1 shows a screenshot of a patient monitoring dashboard with several annotations explaining its components:

- Deteriorating HR on the sensor to hit a Red alert:** Points to a red value in the HR column.
- Alerts set for a Red alert on NEWS for HR, RR & Temp:** Points to the NEWS column.
- Time from the previous ward HR:** Points to the 'Time' column under 'Heart Rate'.
- Time of next ward HR:** Points to the 'Next Ops' column under 'Heart Rate'.
- Time from the previous ward Temperature:** Points to the 'Time' column under 'Temperature'.
- Time of next ward Temperature:** Points to the 'Next Ops' column under 'Temperature'.
- No alerting for RR:** Points to the 'RR' column.

4.3.4.4 Analysis

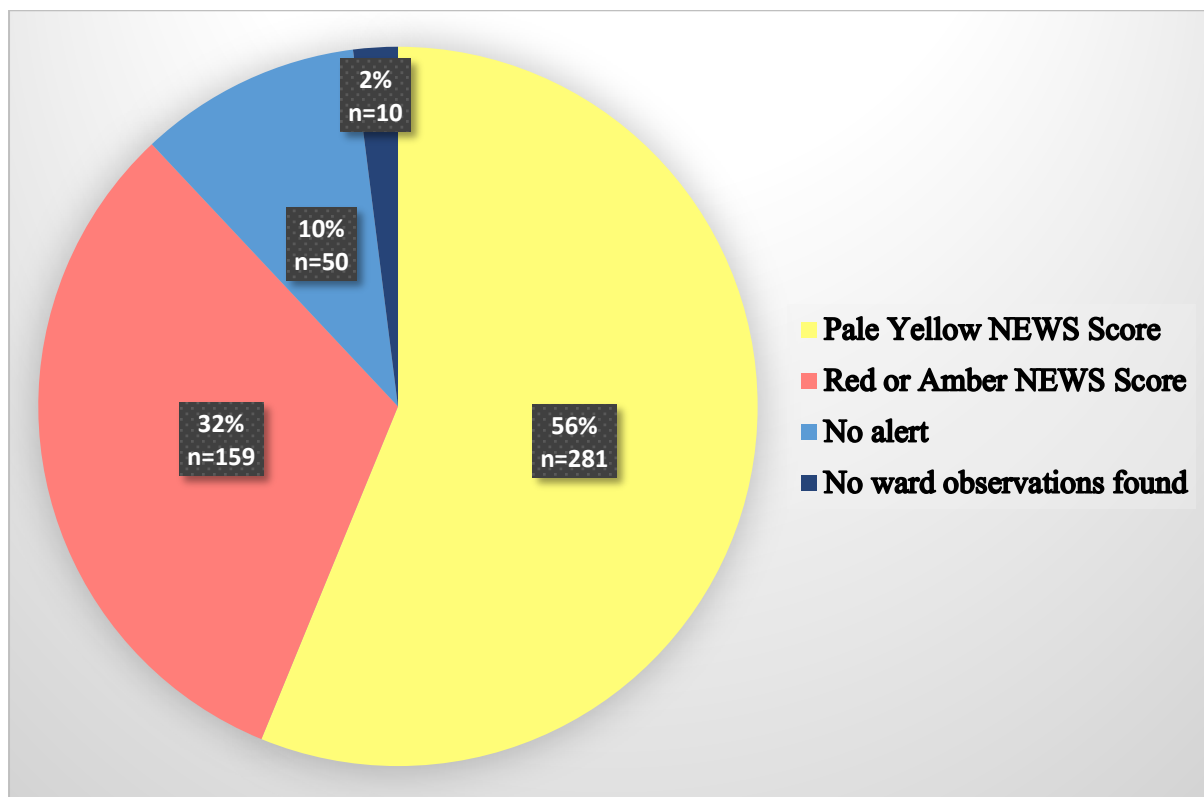
Data collected from the sensor were compared to data from manual observations to assess the speed at which the sensor detects deterioration and sepsis. Excel was used to calculate the mean change in detection of deterioration when comparing the sensor to the nurses ward monitoring. Separate subgroup analysis was performed in HR, RR and temperature for; all patients, those with infection or sepsis, those with a red NEWS score alert and those with an amber NEWS score alert. As descriptive statistics were applied, there was no statistical significance level set in the assessment of outcome measures.

4.5 Results

4.5.1 Risk stratification and coding of all patients based on NEWS

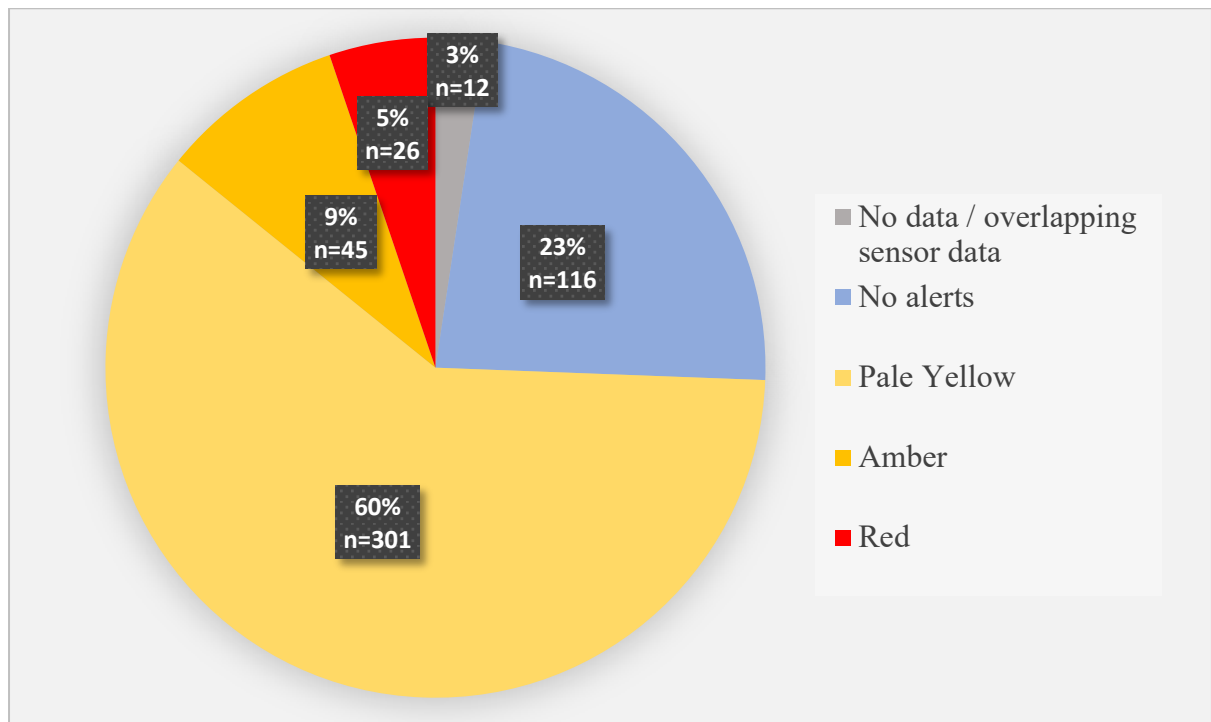
Ward observations were used to classify patients as these would also have been used by the clinical teams to identify unwell patients. All recruited patients were initially risk-stratified into those with no data, no alerts, pale yellow alerts on news score and those with either an amber or red score as high risk patients. The highest NEWS score reading was used to classify each patient so if a patient had both a red and amber alert, they were stratified into the red group. Out of the 500 patients recruited: 50 patients had no alert, 281 had a pale yellow alert and 159 had either an amber or red alert (Figure 4.5). Sensor alerting was reviewed in all patients with signs of deterioration on NEWS as shown by either an amber or red alert on NEWS score. Those patients with pale yellow alerts or no alerts were not reviewed as these did not go on to deteriorate. A total of 10 observation charts were not found for patients recruited in the study (2%).

Figure 4.5 The proportions of highest recorded NEWS categories on ward observation charts in all recruited participants



As well as risk-stratifying the patients based on all ward observation data patients were further risk-stratified based on the available data during the corresponding times the sensor was on. As above there was no data for 10 patients and no overlapping sensor and ward observation data for 2 patients. The number of no alerts had increased from 50 to 116. The number of pale yellow alerts were similar at 301 patients. The total number of deteriorating patients on ward observations was reduced to 71 (45 patients with an amber alert and 26 with a red alert). A pie chart of deteriorating patients at the time the sensor was on can be found in Figure 4.6 below.

Figure 4.6 The proportions of highest recorded NEWS categories on ward observation charts in all recruited participants from the time of sensor placement



4.5.2 Patients with Infection

Out of 500 patients, 302 (60.4%) acutely unwell patients presented with an infection and this was a common reason for patient admission. In the 302 patients with infection, 154 were surgical and 148 medical.

4.5.3 Patients with Sepsis

Out of all the 500 patients reviewed several ways to detect sepsis were used. One way of assessing patients with sepsis was through reviewing the initial baseline demographic data. Based on initial vital sign parameters at presentation, patients were stratified according to SIRS criteria or that of NEWS. The primary ICD codes on discharge were also reviewed. There was a discrepancy in identifying patients with sepsis based on the criteria used. Using a SIRS definition of sepsis, which is a combined score of greater than or equal to 2 with a suspicion of infection, 139 patients (27.8%) with sepsis were identified.

Using a NEWS of 5 and a suspicion of infection, as per current guidelines 51 patients (10.2%) with sepsis were identified. The total number of patients with a NEWS of 5 or more was 64 and out of these 51 patients were suspected to have sepsis.

To review the suspicion of infection for both the SIRS and NEWS scores all clerking notes were reviewed. Out of all the 500 recruited trial patients 64 (12.8%) had a diagnosis of sepsis written in the clerking notes. A review of discharge summaries showed 18 (3.6%) patients with sepsis written on discharge.

All adult patients at the trust should have a sepsis screening tool on admission. A copy of this can be found in the Appendix 4.2. A total of 37 patients were identified as high risk on the screening tool, which is 7.4% of all patients.

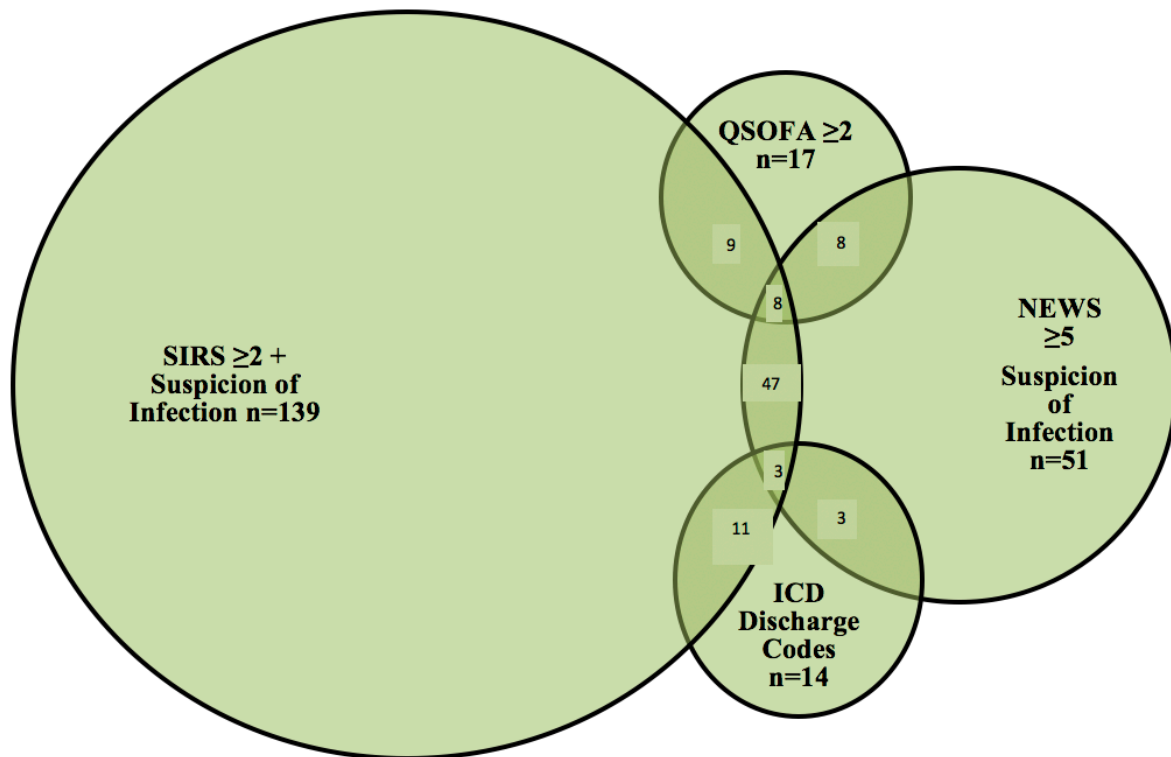
Another way of reviewing patients with sepsis is reviewing the ICD codes of all the patients recruited. According to this the number of patients with an official primary ICD code of sepsis was 14 (2.8%). There were some patients where sepsis was not written as a primary code. Table 4.1 shows how all patients were sepsis recruited in the study were identified. There is a high heterogeneity in the diagnosis of sepsis depending on which definition of sepsis was used.

Table 4.1 A table to show how patients with sepsis in the study were identified

Scoring system used to identify patients with sepsis	Number of patients, n (%)
SIRS ≥ 2 + suspicion of infection	139 (27.8%)
NEWS of ≥ 5 + clinical suspicion of infection	51 (10.2%)
QSOFA Score	17 (3.4%)
Sepsis on doctors clerking notes	64 (12.8%)
Trust sepsis screening tool identified Sepsis	37 (7.4%)
Trust sepsis screening tool High Risk Sepsis	25 (5%)
Discharge summaries sepsis written	18 (3.6%)
ICD Codes for Sepsis	14 (2.8%)

There were no patients that were identified as sepsis based on all the scoring systems used. SIRS identified the most number of patients with suspected sepsis, out of these 139 patients only 11 had an ICD discharge code of sepsis. Whilst a NEWS of 5 or greater and suspicion of sepsis identified 51 patients only 3 of these had an ICD code of sepsis. When comparing the patients with a NEWS of 5 and suspicion of infection, 47 patients would have also had sepsis on SIRS. The QSOFA score only identified 17 patients (3.4%) with sepsis. The relationship of patients defined as having sepsis using the different commonly used scoring systems can be demonstrated in the Venn diagram below (Figure 4.7).

Figure 4.7 Venn diagram of overlapping sepsis definitions



4.5.4 Alerting from ward observations stratification in unwell patients using a 10 minute alert

As identified in the previous chapter the 10 minute time window for sensor data was chosen to simulate alerts. A review of all ward observations was performed to identify those patients scoring on the highest NEWS for each vital sign parameter: HR, RR and temperature. A comparison was then made of these patients for the time the sensor would have triggered an alert based on the highest NEWS scores. For HR, an alert would have been generated for a HR of less than or equal to 40 beats a minute and greater than or equal to 131 beats per minute. For RR an alert would have been generated for a RR of less than or equal to 8 breaths per minute and greater than or equal to 25 breaths per minute. For temperature an alert would have been generated for a temperature of less than or equal to 35 °C. To generate a real alert to the nurse there would need to be 5 abnormal alerts for each vital sign parameter (equating to

a total 10 minutes of alerting as they are taken every 2 minutes). Sometimes there can be missed readings and so 10 minutes of alerts over a 22 minute range was used rather than 10 minutes of consecutive alerting.

For most patients the greatest deterioration (highest red alerts on the ward observations NEWS score) was on admission. In the initial period whilst the patient was in A&E etc there were no patched patients and recruitment of patients was only performed on the ward. Unfortunately due to patients being recruited the following day (after the consultant ward round assessment) some patients had normalised after treatment. Consequently, the number of patients with an abnormal alert on the ward observations and/or sensor was rare. Despite this there are cases where deterioration was found at the time of patch placement.

4.5.4.1 Heart rate alert comparison for all patients

There were 27 patients that had shown deterioration when the sensor was on for HR.

Of those 27 patients there were 41 amber or red alerts on the ward observations.

Of these 41 ward HR alerts 29 alerts (71%) **were picked up earlier by the sensor on average by 121 minutes (2.02 hours).**

In 9 HR ward alerts (21%) the ward detection was quicker.

The average time of detection of the nurse was 21 minutes quicker than the sensor.

In 3 patients there was no alert on the sensor when there was an alert on the ward.

The average duration of the alert on the sensor was 290 minutes.

The results for all HR alerting patients can be found in Table 4.2.

Table 4.2 Using a 10 minute HR alert the number of all patients with a Red or Amber alert on ward observations and comparison of Sensium

alerting times

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT HR DATE/TIME SENSUM	PRE ALERT SENSUM HR	DURATION OF ALERT	HR DATE/TIME WARD	FIRST ALERT DETECTED WARD HR	POST HR ALERT DATE/TIME SENSUM	POST ALERT SENSUM HR	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER?
18	RESPIRATORY + INFECTION	RED				24/01/2018 21:05	116	24/01/2018 22:09	146	10		64	NURSE
20	RESPIRATORY	AMBER				25/01/2018 02:00	125	25/01/2018 05:12	118	116		192	NURSE
55	IBD	AMBER	21/02/2018 17:46	111	10	21/02/2018 17:52	117				6		SENSOR
96	BOWEL OBSTRUCTION	AMBER	23/03/2018 17:31	121	322	23/03/2018 20:45	122				194		SENSOR
110	RECTUS SHEATH HAEMATOMA	AMBER	11/04/2018 13:39	136	406	11/04/2018 15:13	116				94		SENSOR
124	PARTIAL OBSTRUCTION OF STOMA	AMBER				20/04/2018 01:50	112	20/04/2018 01:53	118	20		3	NURSE
143	APPENDICITIS	AMBER	03/05/2018 06:14	111	34	03/05/2018 06:20	114				6		SENSOR
143	APPENDICITIS	AMBER				03/05/2018 17:30	111	03/05/2018 17:44	117	32		14	NURSE
143	APPENDICITIS	AMBER	04/05/2018 08:14	124	124	04/05/2018 10:00	111				106		SENSOR
153	CHOLECYSTITIS	RED	09/05/2018 14:02	115	716	09/05/2018 18:00	119				238		SENSOR
153	CHOLECYSTITIS	RED	10/05/2018 16:14	40	146	10/05/2018 17:24	115				70		SENSOR
180	PANCREATITIS	AMBER	22/05/2018 18:41	120	322	22/05/2018 20:45	118				124		SENSOR
190	CANCER AND NEOPLASMS	AMBER	30/05/2018 18:52	115	202	30/05/2018 21:50	119				178		SENSOR
193	RESPIRATORY + INFECTION	AMBER	04/06/2018 15:39	112	454	04/06/2018 18:40	119				181		SENSOR
201	RESPIRATORY + INFECTION	RED	07/06/2018 14:59	123	274	07/06/2018 17:30	112				151		SENSOR
201	RESPIRATORY + INFECTION	RED	08/06/2018 06:25	130	1012	08/06/2018 11:23	123				298		SENSOR
201	RESPIRATORY + INFECTION	RED	09/06/2018 07:37	111	256	09/06/2018 09:50	119				133		SENSOR
237	DIARRHOEA SECONDARY TO ABX	AMBER				13/07/2018 21:23	112						NURSE
289	SEPSIS	RED	13/08/2018 16:22	113	152	13/08/2018 17:13	114				51		SENSOR
289	SEPSIS	RED	13/08/2018 23:10	115	114	14/08/2018 00:00	120				50		SENSOR
298	RESPIRATORY + INFECTION	AMBER	17/08/2018 16:43	122	110	17/08/2018 18:04	129				81		SENSOR
305	EYE	AMBER				21/08/2018 18:00	114						NURSE
308	RESPIRATORY + INFECTION	RED	21/08/2018 19:29	162	612	21/08/2018 21:15	148				106		SENSOR
308	RESPIRATORY + INFECTION	RED	22/08/2018 07:11	144	220	22/08/2018 10:05	136				174		SENSOR
308	RESPIRATORY + INFECTION	RED	22/08/2018 14:09	137	158	22/08/2018 14:20	152				11		SENSOR
308	RESPIRATORY + INFECTION	RED	22/08/2018 17:33	129	76	22/08/2018 20:50	129				197		SENSOR
308	RESPIRATORY + INFECTION	RED	23/08/2018 06:09	149	312	23/08/2018 09:50	134				221		SENSOR
318	SEPSIS	RED	25/08/2018 01:09	111	50	25/08/2018 02:00	126				51		SENSOR
329	CANCER AND NEOPLASMS	RED	01/09/2018 08:37	115	244	01/09/2018 09:50	121				73		SENSOR
329	CANCER AND NEOPLASMS	RED	02/09/2018 16:53	136	242	02/09/2018 18:05	112				72		SENSOR
361	CARDIOVASCULAR	RED				18/09/2018 18:30	37						NURSE
397	RESPIRATORY + INFECTION	AMBER				13/10/2018 17:55	116	13/10/2018 17:59	118	70		4	NURSE
412	RESPIRATORY + INFECTION	RED	25/10/2018 16:56	117	188	25/10/2018 18:00	114				64		SENSOR
433	RESPIRATORY	AMBER	16/11/2018 08:54	115	282	16/11/2018 11:00	119				126		SENSOR
437	CARDIOVASCULAR	RED	16/11/2018 21:50	146	978	17/11/2018 02:40	119				290		SENSOR
466	DIVERTICULITIS	AMBER				07/12/2018 14:15	118	07/12/2018 14:20	117	14		5	NURSE
489	RESPIRATORY	AMBER				04/01/2019 09:02	114	04/01/2019 09:23	111	102		21	NURSE
489	RESPIRATORY	AMBER				05/01/2019 11:00	112	05/01/2019 11:27	111	38		27	NURSE
489	RESPIRATORY	AMBER	06/01/2019 09:29	121	156	06/01/2019 10:30	116				61		SENSOR
489	RESPIRATORY	AMBER	06/01/2019 14:35	117	230	06/01/2019 16:28	116				113		SENSOR
489	RESPIRATORY	AMBER				07/01/2019 14:15	113	07/01/2019 14:31	121	82		16	NURSE
AVERAGE					289.72					53.78	121	41	

4.5.4.2 Heart rate alert comparison for patients with infection or sepsis

Out of the 27 patients with HR deterioration, 12 patients (44%) had infection or sepsis.

In patients with infection or sepsis (as defined by the clinical team as the diagnosis on admission) there were 22 alerts and in 18 alerts (82%) the sensor was quicker on average by 122 minutes (2.03 hours).

The average duration of alerting was 278 minutes.

There were 4 alerts in which the ward observations were quicker and these on average were by 22 minutes.

The average duration of a post sensor alert was 32 minutes.

The results for all HR alerting patients with infection or sepsis can be found in Table 4.3.

Table 4.3 Using a 10 minute HR alert the number of patients with infection and or sepsis generating an amber or red alert on ward observations

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT HR DATE/TIME SENSUM	PRE ALERT SENSUM HR	DURATION OF ALERT	HR DATE/TIME WARD	FIRST ALERT DETECTED WARD HR	POST HR ALERT DATE/TIME SENSUM	POST ALERT SENSUM HR	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER?
18	RESPIRATORY + INFECTION	RED				24/01/2018 21:05	116	24/01/2018 22:09	146	10		64	NURSE
143	APPENDICITIS	AMBER	03/05/2018 06:14	111	34	03/05/2018 06:20	114				6		SENSOR
143	APPENDICITIS	AMBER				03/05/2018 17:30	111	03/05/2018 17:44	117	32		14	NURSE
143	APPENDICITIS	AMBER	04/05/2018 08:14	124	124	04/05/2018 10:00	111				106		SENSOR
153	CHOLECYSTITIS	RED	09/05/2018 14:02	115	716	09/05/2018 18:00	119				238		SENSOR
153	CHOLECYSTITIS	RED	10/05/2018 16:14	40	146	10/05/2018 17:24	115				70		SENSOR
193	RESPIRATORY + INFECTION	AMBER	04/06/2018 15:39	112	454	04/06/2018 18:40	119				181		SENSOR
201	RESPIRATORY + INFECTION	RED	07/06/2018 14:59	123	274	07/06/2018 17:30	112				151		SENSOR
201	RESPIRATORY + INFECTION	RED	08/06/2018 06:25	130	1012	08/06/2018 11:23	123				298		SENSOR
201	RESPIRATORY + INFECTION	RED	09/06/2018 07:37	111	256	09/06/2018 09:50	119				133		SENSOR
289	SEPSIS	RED	13/08/2018 16:22	113	152	13/08/2018 17:13	114				51		SENSOR
289	SEPSIS	RED	13/08/2018 23:10	115	114	14/08/2018 00:00	120				50		SENSOR
298	RESPIRATORY + INFECTION	AMBER	17/08/2018 16:43	122	110	17/08/2018 18:04	129				81		SENSOR
308	RESPIRATORY + INFECTION	RED	21/08/2018 19:29	162	612	21/08/2018 21:15	148				106		SENSOR
308	RESPIRATORY + INFECTION	RED	22/08/2018 07:11	144	220	22/08/2018 10:05	136				174		SENSOR
308	RESPIRATORY + INFECTION	RED	22/08/2018 14:09	137	158	22/08/2018 14:20	152				11		SENSOR
308	RESPIRATORY + INFECTION	RED	22/08/2018 17:33	129	76	22/08/2018 20:50	129				197		SENSOR
308	RESPIRATORY + INFECTION	RED	23/08/2018 06:09	149	312	23/08/2018 09:50	134				221		SENSOR
318	SEPSIS	RED	25/08/2018 01:09	111	50	25/08/2018 02:00	126				51		SENSOR
397	RESPIRATORY + INFECTION	AMBER				13/10/2018 17:55	116	13/10/2018 17:59	118	70		4	NURSE
412	RESPIRATORY + INFECTION	RED	25/10/2018 16:56	117	188	25/10/2018 18:00	114				64		SENSOR
466	DIVERTICULITIS	AMBER				07/12/2018 14:15	118	07/12/2018 14:20	117	14		5	NURSE
AVERAGE					278.22					31.50	122	22	

4.5.4.3 Heart rate alert comparison for patients with a red NEWS alert

When reviewing the alerting just for red HR alerts on the ward observations there were 19 alerts in 10 patients.

Infection or sepsis was defined by the clinical team as the diagnosis on admission and accounted for 15 (79%) out of the 19 HR red alerts.

In these red HR alerts the sensor identified patient deterioration 17 (**89%**) out of 19 times quicker than the ward observations; **on average 132 minutes (2.2 hours) quicker.**

The average duration of abnormal alerting continued for 338 minutes.

For patient 361 although the sensor detected deterioration it was not enough for an alert to be generated.

For patient 18 the ward observations were quicker by 64 minutes.

The results for all red HR alerting patients can be found in Table 4.4.

Table 4.4 Using a 10 minute HR alert the number of all patients with a red alert on ward observations and comparison of Sensium alerting times

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT HR DATE/TIME SENSUM	PRE ALERT SENSUM HR	DURATION OF ALERT	HR DATE/TIME WARD	FIRST ALERT DETECTED WARD HR	POST HR ALERT DATE/TIME SENSUM	POST ALERT SENSUM HR	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER?
18	RESPIRATORY + INFECTION	RED				24/01/2018 21:05	116	24/01/2018 22:09	146	10		64	NURSE
153	CHOLECYSTITIS	RED	09/05/2018 14:02	115	716	09/05/2018 18:00	119				238		SENSOR
153	CHOLECYSTITIS	RED	10/05/2018 16:14	40	146	10/05/2018 17:24	115				70		SENSOR
201	RESPIRATORY + INFECTION	RED	07/06/2018 14:59	123	274	07/06/2018 17:30	112				151		SENSOR
201	RESPIRATORY + INFECTION	RED	08/06/2018 06:25	130	1012	08/06/2018 11:23	123				298		SENSOR
201	RESPIRATORY + INFECTION	RED	09/06/2018 07:37	111	256	09/06/2018 09:50	119				133		SENSOR
289	SEPSIS	RED	13/08/2018 16:22	113	152	13/08/2018 17:13	114				51		SENSOR
289	SEPSIS	RED	13/08/2018 23:10	115	114	14/08/2018 00:00	120				50		SENSOR
308	RESPIRATORY + INFECTION	RED	21/08/2018 19:29	162	612	21/08/2018 21:15	148				106		SENSOR
308	RESPIRATORY + INFECTION	RED	22/08/2018 07:11	144	220	22/08/2018 10:05	136				174		SENSOR
308	RESPIRATORY + INFECTION	RED	22/08/2018 14:09	137	158	22/08/2018 14:20	152				11		SENSOR
308	RESPIRATORY + INFECTION	RED	22/08/2018 17:33	129	76	22/08/2018 20:50	129				197		SENSOR
308	RESPIRATORY + INFECTION	RED	23/08/2018 06:09	149	312	23/08/2018 09:50	134				221		SENSOR
318	SEPSIS	RED	25/08/2018 01:09	111	50	25/08/2018 02:00	126				51		SENSOR
329	CANCER AND NEOPLASMS	RED	01/09/2018 08:37	115	244	01/09/2018 09:50	121				73		SENSOR
329	CANCER AND NEOPLASMS	RED	02/09/2018 16:53	136	242	02/09/2018 18:05	112				72		SENSOR
361	CARDIOVASCULAR	RED				18/09/2018 18:30	37						NURSE
412	RESPIRATORY + INFECTION	RED	25/10/2018 16:56	117	188	25/10/2018 18:00	114				64		SENSOR
437	CARDIOVASCULAR	RED	16/11/2018 21:50	146	978	17/11/2018 02:40	119				290		SENSOR
AVERAGE					338.24					10.00	132	64	

4.5.4.4 Heart rate alert comparison for patients with an amber NEWS alert

When reviewing the alerting just for amber HR alerts on the ward observations there were 22 alerts in 16 patients.

Infection or sepsis was defined by the clinical team as the diagnosis on admission and accounted for 7 (32%) out of the 22 HR amber alerts.

In these amber HR alerts the sensor identified patient deterioration 12 (**55%**) out of 22 times quicker than the ward observations; **on average 106 minutes (1.77 hours) quicker.**

Upon deterioration the average duration of the alert was 221 minutes.

In 7 alerts (32%) the ward observations were quicker than the sensor by on average 38 minutes.

In the post ward observation detection, the average length of the alert was 59 minutes.

For patient 20 leads off from the sensor was present 73% of the time.

For patients 110 and 489 the detection of deterioration was equal between the sensor and the nurse.

There were **2 patients in which an abnormal HR was not detected by a HR alert on the sensor.**

The results for all amber HR alerting patients can be found in Table 4.5.

Table 4.5 Using a 10 minute HR alert the number of all patients with an amber alert on ward observations and comparison of Sensium alerting

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT HR DATE/TIME SENSUM	PRE ALERT SENSUM HR	DURATION OF ALERT	HR DATE/TIME WARD	FIRST ALERT DETECTED WARD HR	POST HR ALERT DATE/TIME SENSUM	POST ALERT SENSUM HR	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER ?
20	RESPIRATORY	AMBER				25/01/2018 02:00	125	25/01/2018 05:12	118	116		192	NURSE
55	IBD	AMBER	21/02/2018 17:46	111	10	21/02/2018 17:52	117				6		SENSOR
96	BOWEL OBSTRUCTION	AMBER	23/03/2018 17:31	121	322	23/03/2018 20:45	122				194		SENSOR
110	RECTUS SHEATH HAEMATOMA	AMBER	11/04/2018 13:39	136	406	11/04/2018 15:13	116				94		EQUAL
124	PARTIAL OBSTRUCTION OF STOMA	AMBER				20/04/2018 01:50	112	20/04/2018 01:53	118	20		3	SENSOR
143	APPENDICITIS	AMBER	03/05/2018 06:14	111	34	03/05/2018 06:20	114				6		SENSOR
143	APPENDICITIS	AMBER				03/05/2018 17:30	111	03/05/2018 17:44	117	32		14	NURSE
143	APPENDICITIS	AMBER	04/05/2018 08:14	124	124	04/05/2018 10:00	111				106		SENSOR
180	PANCREATITIS	AMBER	22/05/2018 18:41	120	322	22/05/2018 20:45	118				124		SENSOR
190	CANCER AND NEOPLASMS	AMBER	30/05/2018 18:52	115	202	30/05/2018 21:50	119				178		SENSOR
193	RESPIRATORY + INFECTION	AMBER	04/06/2018 15:39	112	454	04/06/2018 18:40	119				181		SENSOR
237	DIARRHOEA SECONDARY TO ABX	AMBER				13/07/2018 21:23	112						NURSE
298	RESPIRATORY + INFECTION	AMBER	17/08/2018 16:43	122	110	17/08/2018 18:04	129				81		SENSOR
305	EYE	AMBER				21/08/2018 18:00	114						NURSE
397	RESPIRATORY + INFECTION	AMBER				13/10/2018 17:55	116	13/10/2018 17:59	118	70		4	SENSOR
433	RESPIRATORY	AMBER	16/11/2018 08:54	115	282	16/11/2018 11:00	119				126		SENSOR
466	DIVERTICULITIS	AMBER				07/12/2018 14:15	118	07/12/2018 14:20	117	14		5	SENSOR
489	RESPRATORY	AMBER				04/01/2019 09:02	114	04/01/2019 09:23	111	102		21	NURSE
489	RESPRATORY	AMBER				05/01/2019 11:00	112	05/01/2019 11:27	111	38		27	NURSE
489	RESPRATORY	AMBER	06/01/2019 09:29	121	156	06/01/2019 10:30	116				61		NURSE
489	RESPRATORY	AMBER	06/01/2019 14:35	117	230	06/01/2019 16:28	116				113		SENSOR
489	RESPRATORY	AMBER				07/01/2019 14:15	113	07/01/2019 14:31	121	82			EQUAL
AVERAGE					221.00					59.25	106	38	

4.5.4.5 Respiratory Rate alert comparison for patients for all patients

There were 27 patients that had shown deterioration when the sensor was on for RR.

Of those 27 patients there were 31 amber or red alerts on the ward observations. Infection or sepsis was defined by the clinical team as the diagnosis on admission and accounted for 18 (58%) out of the 31 RR alerts.

For both red and amber alerts 25 alerts **(81%)** were picked up **quicker by the sensor on average by 109 minutes (1.82 hours).**

There was only **one patient** (patient number 110) in which **the nurse was faster by 76 minutes.**

There were **5 (16%)** deteriorating ward alerts for RR that were **not identified on the sensor.**

The results for all RR alerting patients can be found in Table 4.6.

Table 4.6 Using a 10 minute RR alert the number of all patients with a Red or Amber alert on ward observations and comparison of Sensium

alerting times

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT RR DATE/TIME SENSIMUM	PRE ALERT SENSIMUM RR	DURATION OF ALERT	RR DATE/TIME WARD	FIRST ALERT DETECTED WARD RR	POST RR ALERT DATE/TIME SENSIMUM	POST ALERT SENSIMUM RR	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER?
18	RESPIRATORY + INFECTION	RED	25/01/2018 09:33	25	120	25/01/2018 09:35	26				2		SENSOR
51	SEPSIS	RED	20/02/2018 05:49	6	52	20/02/2018 08:00	36				131		SENSOR
105	PANCREATITIS	AMBER	03/04/2018 18:00	24	182	03/04/2018 18:25	24				25		SENSOR
110	RECTUS SHEATH HAEMATOMA	RED				11/04/2018 15:13	23	11/04/2018 16:29	26	188		76	NURSE
116	INJURIES AND ACCIDENTS	RED	11/04/2018 17:06	28	78	11/04/2018 17:45	22				39		SENSOR
124	PARTIAL STOMA OBSTRUCTION	AMBER				19/04/2018 23:35	22						NURSE
177	UTI	AMBER	23/05/2018 14:07	6	148	23/05/2018 14:50	22				43		SENSOR
179	PANCREATITIS	AMBER	23/05/2018 13:48	26	246	23/05/2018 15:30	21				102		SENSOR
256	RESPIRATORY + INFECTION	RED	25/07/2018 15:46	21	114	25/07/2018 18:15	25				149		SENSOR
265	PANCREATITIS	AMBER	30/07/2018 16:10	23	158	30/07/2018 18:22	21				132		SENSOR
277	RESPIRATORY	RED	06/08/2018 16:20	27	604	06/08/2018 18:20	26				120		SENSOR
285	RESPIRATORY + INFECTION	AMBER	09/08/2018 19:12	21	208	09/08/2018 21:40	21				148		SENSOR
289	SEPSIS	RED	13/08/2018 20:42	6	400	13/08/2018 23:00	24				138		SENSOR
317	UTI	AMBER				25/08/2018 16:30	21						NURSE
318	SEPSIS	RED	28/08/2018 06:09	26	1620	28/08/2018 10:00	24				231		SENSOR
318	SEPSIS	RED	26/08/2018 17:59	29	2188	26/08/2018 22:25	30				266		SENSOR
326	SEPSIS	RED	30/08/2018 15:40	34	342	30/08/2018 17:00	28				80		SENSOR
340	APPENDICITIS	RED	07/09/2018 09:44	23	410	07/09/2018 13:00	29				196		SENSOR
366	CANCER AND NEOPLASMS	AMBER	24/09/2018 05:00	26	676	24/09/2018 10:10	21				310		SENSOR
393	RESPIRATORY + INFECTION	RED	09/10/2018 06:58	28	348	09/10/2018 08:00	24				62		SENSOR
393	RESPIRATORY + INFECTION	RED	13/10/2018 10:04	22	266	13/10/2018 11:15	22				71		SENSOR

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT RR DATE/TIME SENSUM	PRE ALERT SENSUM RR	DURATION OF ALERT	RR DATE/TIME WARD	FIRST ALERT DETECTED WARD RR	POST RR ALERT DATE/TIME SENSUM	POST ALERT SENSUM RR	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER?
412	RESPIRATORY + INFECTION	RED	25/10/2018 16:58	41	476	25/10/2018 18:00	22				62		SENSOR
420	APPENDICITIS	AMBER	02/11/2018 09:22	31	134	02/11/2018 09:30	22				8		SENSOR
427	APPENDICITIS	AMBER	12/11/2018 20:30	26	188	12/11/2018 21:20	24				50		SENSOR
481	RESPIRATORY + INFECTION	RED	21/12/2018 15:44	28	350	21/12/2018 16:00	21				16		SENSOR
482	INJURIES AND ACCIDENTS	AMBER				23/12/2018 04:20	22						NURSE
485	RESPIRATORY	AMBER				29/12/2018 14:20	22						NURSE
493	RESPIRATORY + INFECTION	AMBER	08/01/2019 16:41	6	106	08/01/2019 17:32	22				51		SENSOR
498	RESPIRATORY	RED	11/01/2019 03:11	27	258	11/01/2019 05:00	24				109		SENSOR
498	RESPIRATORY	RED	12/01/2019 23:35	26	266	13/01/2019 02:30	24				175		SENSOR
498	RESPIRATORY	RED				15/01/2019 06:00	24						NURSE
Averages					397.52					188	109	76	

4.5.4.6 Respiratory Rate alert comparison for patients with infection or sepsis

Out of the 27 patients with RR deterioration, 16 patients (59%) had infection or sepsis.

Infection or sepsis was defined by the clinical team as the diagnosis on admission. In patients with infection or sepsis there were 18 alerts in 16 patients.

On average the **sensor was quicker on average by 100 minutes (1.67 hours)**. Out of all 18 ward alerts for RR the sensor was quicker in 17 alerts (**94%**).

For patient 317 although deterioration was found for RR on the sensor no threshold was reached.

The results for all RR alerting patients with infection or sepsis can be found in Table 4.7.

Table 4.7 Using a 10 minute RR alert the number of patients with infection and or sepsis generating an amber or red alert on ward observations

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT RR DATE/TIME SENSUM	PRE ALERT SENSUM RR	DURATION OF ALERT	RR DATE/TIME WARD	FIRST ALERT DETECTED WARD RR	POST RR ALERT DATE/TIME SENSUM	POST ALERT SENSUM RR	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER?
18	RESPIRATORY + INFECTION	RED	25/01/2018 09:33	25	120	25/01/2018 09:35	26				2		SENSOR
51	SEPSIS	RED	20/02/2018 05:49	6	52	20/02/2018 08:00	36				131		SENSOR
177	UTI	AMBER	23/05/2018 14:07	6	148	23/05/2018 14:50	22				43		SENSOR
256	RESPIRATORY + INFECTION	RED	25/07/2018 15:46	21	114	25/07/2018 18:15	25				149		SENSOR
285	RESPIRATORY + INFECTION	AMBER	09/08/2018 19:12	21	208	09/08/2018 21:40	21				148		SENSOR
289	SEPSIS	RED	13/08/2018 20:42	6	400	13/08/2018 23:00	24				138		SENSOR
317	UTI	AMBER				25/08/2018 16:30	21						NURSE
318	SEPSIS	RED	28/08/2018 06:09	26	1620	28/08/2018 10:00	24				231		SENSOR
318	SEPSIS	RED	26/08/2018 17:59	29	2188	26/08/2018 22:25	30				266		SENSOR
326	SEPSIS	RED	30/08/2018 15:40	34	342	30/08/2018 17:00	28				80		SENSOR
340	APPENDICITIS	RED	07/09/2018 09:44	23	410	07/09/2018 13:00	29				196		SENSOR
393	RESPIRATORY + INFECTION	RED	09/10/2018 06:58	28	348	09/10/2018 08:00	24				62		SENSOR
393	RESPIRATORY + INFECTION	RED	13/10/2018 10:04	22	266	13/10/2018 11:15	22				71		SENSOR
412	RESPIRATORY + INFECTION	RED	25/10/2018 16:58	41	476	25/10/2018 18:00	22				62		SENSOR
420	APPENDICITIS	AMBER	02/11/2018 09:22	31	134	02/11/2018 09:30	22				8		SENSOR
427	APPENDICITIS	AMBER	12/11/2018 20:30	26	188	12/11/2018 21:20	24				50		SENSOR
481	RESPIRATORY + INFECTION	RED	21/12/2018 15:44	28	350	21/12/2018 16:00	21				16		SENSOR
493	RESPIRATORY + INFECTION	AMBER	08/01/2019 16:41	6	106	08/01/2019 17:32	22				51		SENSOR
Averages					439.41						100		

4.5.4.7 Respiratory Rate alert comparison for patients with a red NEWS alert

When reviewing the alerting just for red RR alerts on the ward observations there were 18 alerts in 14 patients.

Infection or sepsis was defined by the clinical team as the diagnosis on admission and accounted for 12 (67%) out of the 18 RR red alerts.

In these red RR alerts the **sensor** identified patient deterioration 16 (**89%**) out of 18 times quicker than the ward observations; **on average 115 minutes (1.92 hours) quicker.**

The average duration of abnormal alerting continued for 493 minutes.

There was only **one patient** (patient 110) in which **ward observations were quicker by 76 minutes.**

There was also **one patient** (patient 498) in which a there was a red alert on the ward observations, but this was **not detected on the sensor.**

The results for all red RR alerting patients can be found in Table 4.8.

Table 4.8 Using a 10 minute RR alert the number of all patients with a red alert on ward observations and comparison of Sensium alerting times

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT RR DATE/TIME SENSUM	PRE ALERT SENSUM RR	DURATION OF ALERT	RR DATE/TIME WARD	FIRST ALERT DETECTED WARD RR	POST RR ALERT DATE/TIME SENSUM	POST ALERT SENSUM RR	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER?
18	RESPIRATORY + INFECTION	RED	25/01/2018 09:33	25	120	25/01/2018 09:35	26				2		SENSOR
51	SEPSIS	RED	20/02/2018 05:49	6	52	20/02/2018 08:00	36				131		SENSOR
110	RECTUS SHEATH HAEMATOMA	RED				11/04/2018 15:13	23	11/04/2018 16:29	26	188		76	NURSE
116	INJURIES AND ACCIDENTS	RED	11/04/2018 17:06	28	78	11/04/2018 17:45	22				39		SENSOR
256	RESPIRATORY + INFECTION	RED	25/07/2018 15:46	21	114	25/07/2018 18:15	25				149		SENSOR
277	RESPIRATORY	RED	06/08/2018 16:20	27	604	06/08/2018 18:20	26				120		SENSOR
289	SEPSIS	RED	13/08/2018 20:42	6	400	13/08/2018 23:00	24				138		SENSOR
318	SEPSIS	RED	28/08/2018 06:09	26	1620	28/08/2018 10:00	24				231		SENSOR
318	SEPSIS	RED	26/08/2018 17:59	29	2188	26/08/2018 22:25	30				266		
326	SEPSIS	RED	30/08/2018 15:40	34	342	30/08/2018 17:00	28				80		SENSOR
340	APPENDICITIS	RED	07/09/2018 09:44	23	410	07/09/2018 13:00	29				196		SENSOR
393	RESPIRATORY + INFECTION	RED	09/10/2018 06:58	28	348	09/10/2018 08:00	24				62		SENSOR
393	RESPIRATORY + INFECTION	RED	13/10/2018 10:04	22	266	13/10/2018 11:15	22				71		SENSOR
412	RESPIRATORY + INFECTION	RED	25/10/2018 16:58	41	476	25/10/2018 18:00	22				62		SENSOR
481	RESPIRATORY + INFECTION	RED	21/12/2018 15:44	28	350	21/12/2018 16:00	21				16		SENSOR
498	RESPIRATORY	RED	11/01/2019 03:11	27	258	11/01/2019 05:00	24				109		SENSOR
498	RESPIRATORY	RED	12/01/2019 23:35	26	266	13/01/2019 02:30	24				175		SENSOR
498	RESPIRATORY	RED				15/01/2019 06:00	24						NURSE
Averages					493.25					188	115	76	

4.5.4.8 Respiratory Rate alert comparison for patients with an amber NEWS alert

When reviewing the alerting just for amber RR alerts on the ward observations there were 18 alerts in 13 patients.

Infection or sepsis was defined by the clinical team as the diagnosis on admission and accounted for 6 (46%) out of the 13 RR amber alerts.

In these amber RR alerts the **sensor** identified deterioration 9 (**69%**) out of 13 times quicker than the ward observations; **on average 97 minutes (1.52 hours) quicker.**

The average duration of abnormal alerting continued for 227 minutes.

There were **no patients identified by the ward quicker.**

However, there were **4 patients in which an alert was not generated.**

In patient 482 and 485 there were lots of minus 1 readings around the time of deterioration although leads were on.

The results for all amber RR alerting patients can be found in Table 4.9.

Table 4.9 Using a 10 minute RR alert the number of all patients with an amber alert on ward observations and comparison of Sensium alerting

times

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT RR DATE/TIME SENSUM	PRE ALERT SENSUM RR	DURATION OF ALERT	RR DATE/TIME WARD	FIRST ALERT DETECTED WARD RR	POST RR ALERT DATE/TIME SENSUM	POST ALERT SENSUM RR	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER?
105	PANCREATITIS	AMBER	03/04/2018 18:00	24	182	03/04/2018 18:25	24				25		SENSOR
124	PARTIAL STOMA OBSTRUCTION	AMBER				19/04/2018 23:35	22						NURSE
177	UTI	AMBER	23/05/2018 14:07	6	148	23/05/2018 14:50	22				43		NURSE
179	PANCREATITIS	AMBER	23/05/2018 13:48	26	246	23/05/2018 15:30	21				102		SENSOR
265	PANCREATITIS	AMBER	30/07/2018 16:10	23	158	30/07/2018 18:22	21				132		SENSOR
285	RESPIRATORY + INFECTION	AMBER	09/08/2018 19:12	21	208	09/08/2018 21:40	21				148		SENSOR
317	UTI	AMBER				25/08/2018 16:30	21						NURSE
366	CANCER AND NEOPLASMS	AMBER	24/09/2018 05:00	26	676	24/09/2018 10:10	21				310		SENSOR
420	APPENDICITIS	AMBER	02/11/2018 09:22	31	134	02/11/2018 09:30	22				8		SENSOR
427	APPENDICITIS	AMBER	12/11/2018 20:30	26	188	12/11/2018 21:20	24				50		SENSOR
482	INJURIES AND ACCIDENTS	AMBER				23/12/2018 04:20	22						NURSE
485	RESPIRATORY	AMBER				29/12/2018 14:20	22						NURSE
493	RESPIRATORY + INFECTION	AMBER	08/01/2019 16:41	6	106	08/01/2019 17:32	22				51		SENSOR
AVERAGES					227.33						97		

4.5.4.9 Temperature alert comparison for patients for all patients

There were 12 patients that had shown deterioration when the sensor was on for temperature.

Of those 12 patients there were 14 amber or red alerts on the ward observations.

Infection or sepsis was defined by the clinical team as the diagnosis on admission and accounted for 9 (64%) out of the 14 temperature alerts.

For both red and amber alerts only 4 alerts **(29%)** out of the 14 were picked up **quicker by the sensor on average by 132 minutes (2.2 hours)**.

There were **2 patients** (patient number 95 and patient number 340) in which the **nurse was faster on average by 17 minutes**.

In total there were **8 abnormal temperature alerts that were undetected on the sensor** (patient numbers 33, 51, 125, 148, 153, 355, 402 and 487).

The results for all temperature alerting patients can be found in Table 4.10.

Table 4.10 Using a 10 minute temperature alert the number of all patients with a Red or Amber alert on ward observations and comparison of

Sensium alerting times

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT TEMP DATE / TIME SENSUM	PRE ALERT SENSOR TEMP	DURATION OF ALERT	TEMP DATE/ TIME WARD	FIRST ALERT DETECTED WARD TEMP	POST TEMP ALERT DATE/ TIME SENSUM	POST ALERT SENSUM TEMP	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER?
33	Respiratory Infection	RED				10/02/2018 09:45	35						NURSE
51	SEPSIS	RED				20/02/2018 05:00	39.4						NURSE
95	Pancreatitis	AMBER				23/03/2018 17:35	39.2	23/03/2018 18:01	39.1	32		26	NURSE
125	Abdo Pain	RED	20/04/2018 08:52	34.8	16	20/04/2018 10:40	35				108		SENSOR
125	Abdo Pain	RED				21/04/2018 14:00	35						NURSE
148	Cholecystitis	AMBER				04/05/2018 18:10	39.7						NURSE
148	Cholecystitis	AMBER	05/05/2018 12:16	39.1	192	05/05/2018 13:30	40.2				74		SENSOR
153	Cholecystitis	RED				10/05/2018 12:00	39.6						NURSE
340	Appendicitis	RED				06/09/2018 15:35	39.1	06/09/2018 15:42	39.1	162		7	NURSE
355	Respiratory	RED				13/09/2018 02:00	39.3						NURSE
402	Appendicitis	AMBER				19/10/2018 17:58	39.2						NURSE
407	Pancreatitis	RED	25/10/2018 22:58	35	506	26/10/2018 01:30	35				152		SENSOR
487	Infection	AMBER				11/01/2019 21:17	39.4						NURSE
499	Diverticulitis	RED	12/01/2019 11:02	33.7	230	12/01/2019 14:15	34.9				193		SENSOR
Averages					236					97	132	17	

4.5.4.10 Temperature alert comparison for patients with infection or sepsis

Infection or sepsis was defined by the clinical team as the diagnosis on admission. In patients with infection or sepsis there were 9 alerts for temperature in 8 patients.

In **2 patients** (patient 148 and 499) the sensor **was faster than the nurse by 134 minutes (2.23 hours)** with an average duration of sensor alert at 211 minutes.

There was **one patient (patient 340) in which the ward observations were faster than the sensor by 7 minutes.**

In **6 alerts (67%) there was no threshold reached on the sensor** to send an alert.

The results for temperature alerts in patients with infection or sepsis can be found in Table 4.11.

Table 4.11 Using a 10 minute temperature alert the number of patients with infection and or sepsis generating an amber or red alert on ward

observations

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT TEMP DATE/TIME SENSUM	PRE ALERT SENSUM TEMP	DURATION OF ALERT	TEMP DATE/TIME WARD	FIRST ALERT DETECTED WARD TEMP	POST TEMP ALERT DATE/TIME SENSUM	POST ALERT SENSUM TEMP	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)
33	RESPIRATORY + INFECTION	RED				10/02/2018 09:45	35					
51	SEPSIS	RED				20/02/2018 05:00	39.4					
148	CHOLECYSTITIS	AMBER				04/05/2018 18:10	39.7					
148	CHOLECYSTITIS	AMBER	05/05/2018 12:16	39.1	192	05/05/2018 13:30	40.2				74	
153	CHOLECYSTITIS	RED				10/05/2018 12:00	39.6					
340	APPENDICITIS	RED				06/09/2018 15:35	39.1	06/09/2018 15:42	39.1	162		7
402	APPENDICITIS	AMBER				19/10/2018 17:58	39.2					
487	INFECTION	AMBER				11/01/2019 21:17	39.4					
499	DIVERTICULITIS	RED	12/01/2019 11:02	33.7	230	12/01/2019 14:15	34.9				193	
AVERAGES					211					162	134	7

4.5.4.11 Temperature alert comparison for patients with a red NEWS alert

When reviewing the alerting just for red alerts on the ward observations there were 8 alerts in 9 patients.

Infection or sepsis was defined by the clinical team as the diagnosis on admission. Infection or sepsis accounted for 5 (56%) out of the 9 temperature red alerts.

In these red temperature alerts the **sensor** identified patient deterioration 3 (**33%**) out of 9 times **quicker** than the ward observations; **on average 151 minutes (2.52 hours) quicker**.

The average duration of abnormal alerting continued for 251 minutes.

There was only **one patient** (patient 340) in which **ward observations were quicker by 7 minutes**. Although the change on the sensor was detected at the same time of the ward observations several readings were needed to generate an alert hence the ward observations were faster.

There were **5 alerts** in 5 patients (patient 33,51,125,153 and 355) in which a there was a red alert on the ward observations, but this was **not detected on the sensor**. Although changes were detected in temperature this was not enough to generate an alert.

The results for all red temperature alerting patients can be found in Table 4.12.

Table 4.12 Using a 10 minute temperature alert the number of all patients with a red alert on ward observations and comparison of Sensium

alerting times

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT TEMP DATE/ TIME SENSUM	PRE ALERT SENSUM TEMP	DURATION OF ALERT	TEMP DATE/ TIME WARD	FIRST ALERT DETECTED WARD TEMP	POST TEMP ALERT DATE/ TIME SENSUM	POST ALERT SENSUM TEMP	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER ?
33	RESPIRATORY + INFECTION	RED				10/02/2018 09:45	35						NURSE
51	SEPSIS	RED				20/02/2018 05:00	39.4						NURSE
125	ABDO PAIN	RED	20/04/2018 08:52	34.8	16	20/04/2018 10:40	35				108		SENSOR
125	ABDO PAIN	RED				21/04/2018 14:00	35						NURSE
153	CHOLECYSTITIS	RED				10/05/2018 12:00	39.6						NURSE
340	APPENDICITIS	RED				06/09/2018 15:35	39.1	06/09/2018 15:42	39.1	162		7	NURSE
355	RESPIRATORY	RED				13/09/2018 02:00	39.3						NURSE
407	PANCREATITIS	RED	25/10/2018 22:58	35	506	26/10/2018 01:30	35				152		SENSOR
499	DIVERTICULITIS	RED	12/01/2019 11:02	33.7	230	12/01/2019 14:15	34.9				193		SENSOR
Average					250.67					162	151	7	

4.5.4.12 Temperature alert comparison for patients with an amber NEWS alert

When reviewing the alerting just for red alerts on the ward observations there were 5 alerts in 4 patients.

Infection or sepsis was defined by the clinical team as the diagnosis on admission and accounted for 4 (80%) out of the 5 temperature amber alerts.

In these amber temperature alerts the **sensor only** identified patient deterioration once faster (patient 148) by **74 minutes quicker**.

The duration of abnormal alerting continued for 192 minutes.

There were **3 alerts in 3 patients** (patient 148, 402 and 487) in which there was an amber alert on the ward observations, but this was **not detected on the sensor**. Although changes were detected in temperature this was not enough to generate an alert.

The results for all amber temperature alerting patients can be found in Table 4.13.

Table 4.13 Using a 10 minute temperature alert the number of all patients with an amber alert on ward observations and comparison of Sensium alerting times

PATIENT ID	DIAGNOSIS	ALERT TYPE	PRE ALERT TEMP DATE/ TIME SENSUUM	PRE ALERT SENSUUM TEMP	DURATION OF ALERT	TEMP DATE/ TIME WARD	FIRST ALERT DETECTED WARD TEMP	POST TEMP ALERT DATE /TIME SENSUUM	POST ALERT SENSUUM TEMP	DURATION OF ALERT	PRE TIME DIFFERENCE (MINUTES)	POST TIME DIFFERENCE (MINUTES)	WHOS QUICKER ?
95	PANCREATITIS	AMBER				23/03/18 17:35	39.2	23/03/18 18:01	39.1	32		26	NURSE
148	CHOLECYSTITIS	AMBER				04/05/18 18:10	39.7						NURSE
148	CHOLECYSTITIS	AMBER	05/05/18 12:16	39.1	192	05/05/18 13:30	40.2				74		SENSOR
402	APPENDICITIS	AMBER				19/10/18 17:58	39.2						NURSE
487	INFECTION	AMBER				11/01/19 21:17	39.4						NURSE
Average					192					32	74	26	

4.5.5 Alerting from the sensor using a 10 minute alert

The total number of all sensor readings with a leads on for 500 patients was **1,328,085** (HR was 442695, RR was 442695 and temperature was 442695).

For HR the total number of valid readings were **379,090** (63604 were minus 1 data) resulting in a **HR given 85%** of the time.

For RR the total number of valid readings were **225,149** (217545 were minus 1 data) resulting in a **RR given 51%** of the time. This is a significant issue and much lower than HR and temperature.

For temperature the total number of valid readings were **372,729** (69965 were minus 1 data) resulting in a **temperature given 84%** of the time.

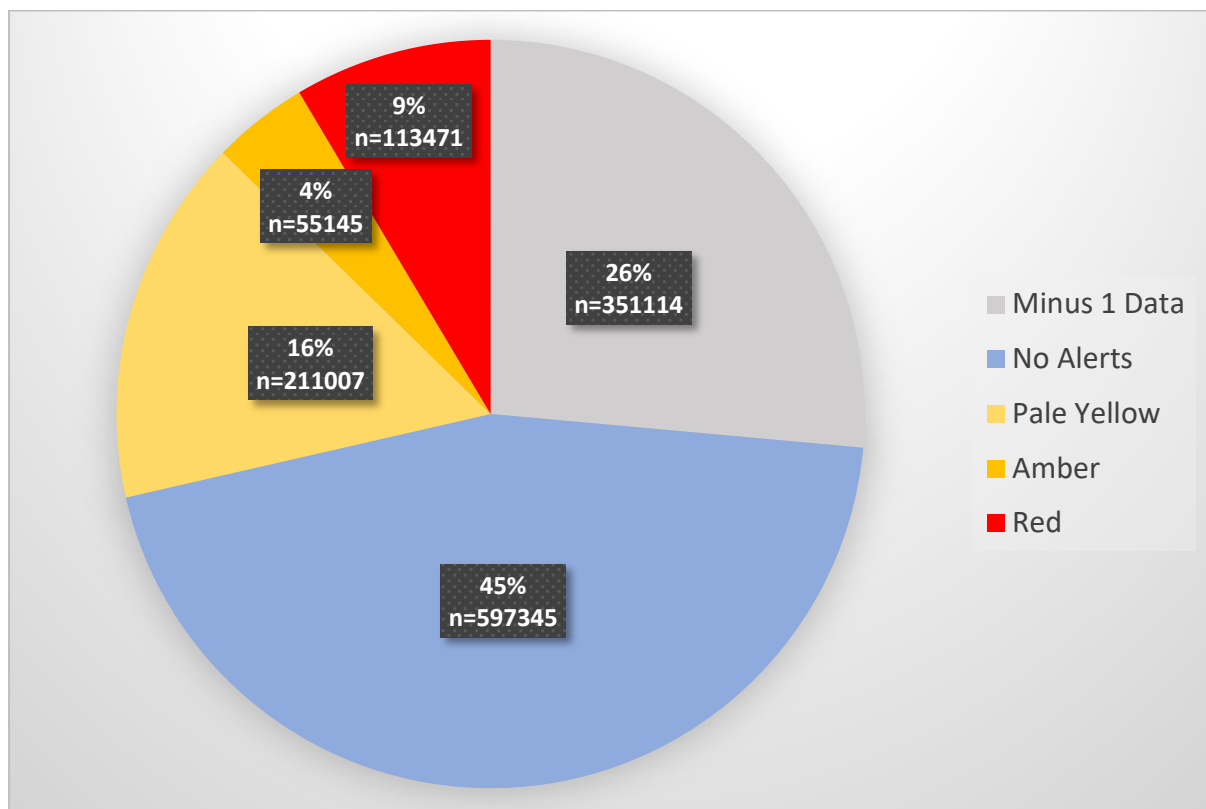
When reviewing the total monitoring time with the sensor there were 442,694 data time stamps in which the sensor was reported to be correctly placed. The sensor records and provides readings every 2 minutes so the total number of minutes of monitoring for all patients is **885,388 minutes** or **14,756 hours of monitoring**. On average this results in **29.5 hours** of monitoring per patient which is **1 day and 5.5 hours**.

Out of all 500 patients there were **346 patients that received alerts** (notifications) on the sensor based on the rules for a 10 minute alert. If reviewing the total number of alerts in all patients there would be **3.66 alerts per patient**. If reviewing the total number of alerts in the patients receiving notifications, there would be **5.22 alerts per patient**.

In the context of time as all patients were monitored for 885,388 minutes what would equal 0.12 alerts per hour. Alternatively, this could be written as **on average an alert every 487.28 minutes (or an alert every 8.12 hours)**. This means that the average **number of alerts per 24 hours is 3 (2.96)**.

All sensor data for the 500 patients for HR, RR and temperature was reviewed and the results showed: minus 1 readings accounted for 351,114 readings (26%), there were 597,345 readings (45%) with no alert, 211,007 readings (16%) with a pale yellow alert, 55145 readings (4%) were amber and 113,471 readings (9%) were red. A pie chart of this can be found in Figure 4.8 below.

Figure 4.8 A pie chart showing the NEWS score on sensor observations for all participants recruited in the study.



The results above describe any change in a single vital sign parameter. Just as with the alerting based on the ward observations above and from the previous reliability chapter the alerting was performed over a 10 minute averaging window (with 5 abnormal consecutive samples). An alert was generated for the fifth abnormal reading. The duration of alerting was calculated for each alert using both minutes and hours. An alert was stopped or reset if there were 5 consecutive normal readings. In addition to this, if the gap between valid readings (length of values reported as -1) for any given vital was bigger than one hour the alert state was reset and the counter of alert triggering readings set to 0. When calculating the duration of time of alerting if there was a large gap of greater than 1 hour of minus 1 or invalid readings the alert duration was reset.

The total number of red alerts was 492; of these 109 were for HR and 383 for RR. There were no red alerts for temperature (there is no red alert for a high temperature using NEWS). If a temperature alert was sent for a high reading the maximum high score on NEWS for temperature is an amber alert. The low alerts for temperature were switched off as it was not possible at times to know if the sensor was alerting for a low temperature even when not on the patient. Further analysis for low temperature alerts was not continued.

The total number of amber alerts was 987; of these 390 were for HR, 579 for RR and 18 for temperature.

The alerting for each individual vital sign parameter will be discussed below.

4.5.5.1 Alerting from the sensor for HR in all patients using a 10 minute window

The alerts were only reviewed from the sensor if there was regular monitoring on the ward observations at the time. The total number of alerts generated from the sensor for HR was **498 alerts in 136 patients**.

The average number of minutes before the sensor alert for HR on the ward was **139 minutes (2.32 hours)**.

The average alert duration was **123 minutes (2.05 hours)**.

The average number of minutes after the sensor alert for HR on the ward was **134 minutes (2.23 hours)**.

Out of all of the **498 sensor alerts only 68 (13.4%)** were also detected on the ward observations.

This means that there were **430 alerts (86%)** on the sensor that were not detected on the ward.

There were **9 patients (19 alerting sensor episodes)** that although did not have an alert for HR on the ward but these patients were on **hourly observations** which suggests that the clinical team knew that the patient was unwell, and they were being more closely monitored for other reasons.

4.5.5.2 Alerting from the sensor for HR in patients with infection or sepsis using a 10 minute window

The total number of sensor HR alerts in patients with infection were **272 alerts in 64 patients**. Out of all patients with infection alerting on the sensor **only 8 (12.5%) patients** were also **detected on the ward**.

Infection or sepsis was defined by the clinical team as the diagnosis on admission. For patients with infection or sepsis the average number of minutes before the sensor alert for HR on the ward was **133 minutes (2.22 hours)**.

The average alert duration was **123 minutes (2.05 hours)**.

The average number of minutes after the sensor alert for HR on the ward was **128 minutes (2.13 hours)**.

Out of all of the **310 sensor alerts for infection or sepsis only 51 (16.5%)** were also detected on the ward observations.

This means that there were **259 alerts (83.5%)** on the sensor that were not detected on the ward.

There were **5 patients (11 alerting sensor episodes)** that although did not have an alert for HR on the ward but these patients were on **hourly observations** which suggests that the clinical team knew that the patient was unwell, and they were being more closely monitored for other reasons.

4.5.5.3 Alerting from the sensor for RR in all patients using a 10 minute window

The alerts were only reviewed from the sensor if there was regular monitoring on the ward observations at the time. The total number of alerts generated from the sensor for RR was **969 alerts in 276 patients**.

The average number of minutes before the sensor alert for RR on the ward was **138 minutes (2.3 hours)**.

The average alert duration was **320 minutes (5.33 hours)**.

The average number of minutes after the sensor alert for RR on the ward was **139 minutes (2.31 hours)**.

Out of all **969 sensor alerts only 63 (6.5%)** were also detected on the ward observations.

This means that there were **906 alerts (93.5%)** on the sensor that were not detected on the ward or alternatively missed episodes of patient deterioration.

There were **9 patients (15 alerting sensor episodes)** that although did not have an alert for RR on the ward but these patients were on **hourly observations** which suggests that the clinical team knew that the patient was unwell, and they were being more closely monitored for other reasons.

4.5.5.4 Alerting from the sensor for RR in patients with infection or sepsis using a 10 minute window

Infection or sepsis was defined by the clinical team as the diagnosis on admission. The total number of alerts generated from the sensor for RR in patients with infection or sepsis was **591 alerts in 151 patients**.

The average number of minutes before the sensor alert for RR on the ward was **132 minutes (2.2 hours)**.

The average alert duration was **372 minutes (6.2 hours)**.

The average number of minutes after the sensor alert for RR on the ward was **141 minutes (2.31 hours)**.

Out of all **591 sensor alerts only 52 (8.8%)** were also detected on the ward observations.

This means that there were **539 alerts (91.2%)** on the sensor that were not detected on the ward or alternatively missed episodes of patient deterioration.

There were **5 patients (7 alerting sensor episodes)** that although did not have an alert for RR on the ward but these patients were on **hourly observations** which suggests that the clinical team knew that the patient was unwell, and they were being more closely monitored for other reasons.

4.5.5.5 Alerting from the sensor for temperature in all patients using a 10 minute window

The alerts were only reviewed from the sensor if there was regular monitoring on the ward observations at the time. The total number of alerts generated from the sensor for temperature was **18 alerts in 9 patients**.

The average number of minutes before the sensor alert for temperature on the ward was 64 minutes.

The average alert duration was **118.9 minutes (1.98hours)**.

The average number of minutes after the sensor alert for HR on the ward was **56 minutes**.

Out of all **18 sensor alerts 12 (66.7%)** were also detected on the ward observations.

This means that there were **6 alerts in 5 patients (33.3%)** on the sensor that were not detected on the ward or alternatively missed episodes of patient deterioration. None of these were on hourly observations.

4.5.5.6 Alerting from the sensor for temperature in patients with infection or sepsis using a 10 minute window

Infection or sepsis was defined by the clinical team as the diagnosis on admission. The total number of alerts generated from the sensor for temperature in patients with infection or sepsis was **15 alerts in 8 patients**.

The average number of minutes before the sensor alert for temperature on the ward was **67 minutes**.

The average alert duration was **135 minutes (2.25 hours)**.

The average number of minutes after the sensor alert for temperature on the ward was **52 minutes**.

Out of all **15 sensor alerts 11 (73.3%)** were also detected on the ward observations.

There were **4 alerts (26.7%)** on the sensor that were not detected on the ward or alternatively missed episodes of patient deterioration.

There no patients that did not have an alert for temperature on the ward and had hourly observations.

4.6 Discussion

This study shows that early detection of unwell patients and those with sepsis is possible through continuous monitoring with wearable sensors. In addition proactive alerting algorithms have been generated using the sensor and proactive alert design for algorithms in the literature is rare(172). To date the best way to present alerts and the ideal alerting time windows are largely unknown which may obstruct the use of alerts in clinical practice(173). The work from this study answers some of these questions.

4.6.1 Summary of main findings

Ward observation NEWS was used to risk stratify patients. When reviewing all ward observations prior to the sensor being placed there were red or amber alerts in 32% of all total ward observations. However when looking at ward observations when the patient had the sensor on the number of either a red or an amber alert reduced to 14%. The opportunity to detect the earlier deterioration in these patients may have been missed due to the sensor not being placed on the patient at that time or it may reflect that unwell patients are admitted as emergencies and receive rapid treatment.

Infection was a common cause of patient admission both for medical and surgical patients. Interestingly there were significant variations in the number of patients with suspected sepsis (i.e. SIRS greater than or equal to 2 with a suspicion of infection = 139 patients (27.8%) with sepsis and a NEWS of 5 and a suspicion of infection as per current guidelines 51 patients

(10.2%) had sepsis. The number of patients with sepsis using both QSOFA and ICD was significantly less at only 17 (3.4%) patients and 14 patients (2.8%). There is a problem with the definitions used in sepsis. Whilst some classifications for sepsis may not be sensitive enough, more concerning are the classifications systems in which the diagnosis of sepsis is missed altogether.

The sensor identified deterioration much faster than the nursing observations for both HR and RR. The results show that when reviewing the time to detection of infection or sepsis for changes in HR (based on ward observation deterioration) the sensor was faster in 82% of cases and on average by 122 minutes (2.03 hours). Likewise, for RR as compared to the ward observation deterioration the sensor was quicker in 94% of cases and by 100 minutes (1.67 hours). The findings for temperature were mixed as although 2 patients were quicker by 134 minutes (2.23 hours) there were 6 alerts where no threshold was reached for the sensor.

When reviewing patients with infection or sepsis, HR and RR were generally much quicker on the sensor than ward observations. Whilst some patients were picked up quicker on the sensor for temperature there were a greater number of patients in which the threshold required to generate an alert for temperature was not reached.

4.6.2 Wider Literature

Sepsis diagnostic challenges

One of the challenges in the study has been the identification of patients with sepsis and knowing which definition of sepsis is the gold standard. Variations in the definitions of sepsis consequently result in variations in numbers of patients identified. To tackle this several definitions of sepsis were used. Similar findings have been found in the literature with varying sepsis incidence using several sepsis definitions (174). A literature review of 23 primary publications reporting sepsis incidence found great variations in sepsis incidence in the general population between the different studies(174). Although a NEWS of 5 and suspicion of sepsis is used in the UK, standardised sepsis definitions although challenging are welcomed to allow comparisons worldwide (174).

Wearable sensors and time to detection

To date, in the literature, there are very few studies which have reviewed the use of wearable sensors to detect patient deterioration and sepsis. However a recent study has compared the use of wearable sensors to ward observations in patients with high early warning scores and found earlier detection using wearable sensors(149). Two different wearables sensors were used (ViSi Mobile and the HealthPatch) and compared to nurse measurements. They compared the time between a high early warning score on the sensors to the next nursing observations and found the time to the next regular nurse measurements ranged from 0-9 hours using the HealthPatch and up to 10 hours using ViSi Mobile. For patients with a high early warning score there was a delay of up to 10 hours before the next regular nurse

measurement(149). The wearable sensors on average also reported a higher early warning score than nursing observations predominantly due to RR measurement differences(149).

The use of sensors providing continuous monitoring has been explored in a controlled clinical trial(102). The Early Sense sensor was used and although it is not a wearable sensor it can provide some continuous vital sign monitoring of ward patients. It is placed under a patient's mattress and connected to a bedside processing unit(102). The HR and RR are continuously recorded whilst the patient was in bed(102). The study found that the use of the Early Sense sensor significantly decreased total length of stay both in the hospital and in intensive care unit days for transferred patients, as well as reducing 'code blue' rates(102). In this study 'Code Blue' indicated those patients that had a cardiac arrest(102). Whilst a cohort of these patients had an infectious disease process this was not explored in detail and it is unknown if any of these patients developed sepsis(102).

Whilst there are limited studies on the use of wearable and sepsis there are several studies reviewing the use of digital technology to aid sepsis diagnosis. In an ICU study HR data from electrocardiograms and blood pressure time series at 2 second resolutions were collected from ICU bedside monitors. In this study dynamic changes in both heart rate and blood pressure were present up to four hours before a clinical suspicion of sepsis(175). These changes were independent predictors of sepsis even when clinical values, patient demographics and co-morbidities were adjusted(175).

Other use of digital technology to identify patients with sepsis is through digital alerting in electronic records as described in chapter 2. Screening tools based on vital sign observations and a suspected infection have been utilised to enable sepsis detection(176). These tools have helped increase the number of patients receiving timely antibiotics and a decreased mortality(176). Whilst these alerts are useful when sufficient ward observations are recorded the challenge remains in detecting deterioration when there is less baseline data or ward observations recorded(177). This is where wearable sensors which provide more continuous monitoring can help.

Missing vital sign data

As identified in the previous chapter some of the vital signs recorded on the paper observations were missing or illegible. This can be shown in similar studies that have reviewed observation charts previously(159). As well as missing observations there were also entire observation charts that were missing in 10 patients (2%). Whilst this number may not be very high it is worrying that these charts were missing whilst the patient was in hospital and still being ‘monitored’. Missing vital signs can prevent the recognition of an unwell patient in a timely way. As such early detection of unwell patients may be missed due to incomplete data. The continuous monitoring of ward-based observations helps not only between observations but can be used if monitoring is missed or illegible for any reason. In addition in clinical practice there is only partial adherence to escalation protocols and repeat assessment of unwell patients(65). In this chapter as the data was reviewed retrospectively and there were no real time observers of clinical staff the adherence to escalation protocols were unfortunately unable to be reviewed.

Patients in which abnormal vitals and no adverse events

Whilst worsening vital signs help identify unwell patients. There may be some patients in which abnormal vital signs develop but there are no adverse events(178). There may be sub groups of patients with specific co-morbidities which have abnormal vital signs yet no clinical deterioration. Patients with Chronic Obstructive Pulmonary Disease (COPD) tend to have much lower arterial oxygen saturations than those without the condition. NEWS 2 helps improve the recording of the use of oxygen saturations in patients with hypercapnic respiratory failure (often due to COPD)(169). The percentage of hospital in patients with abnormal vital signs and no adverse events is unknown(178).

RR problems

There are problems in recording of some vital signs using current monitoring and not all vital signs are measured as accurately. In an observational ward based study of vital sign monitoring RR in particular often has very poor documentation(88). In contrast blood pressure, heart rate and temperature are diligently recorded(88). This may be partially explained by the fact that whilst HR and temperature rely on digital monitoring, RR is a recording based on manual counting by the healthcare professional. Although digital ways of measuring RR are found in the ICU setting this is not common practice on medical or surgical wards. Any small distractions or interruptions which are frequently present on the acute wards may decrease the accuracy of recording the RR. This may help explain why some episodes of deterioration may have been missed on ward observations as compared to the sensor. In addition when comparing all vital signs, abnormalities in RR have been found to be the greatest predictor for an adverse outcome(179).

Artefact

Continuous monitoring of patients results in huge amounts of data being generated which may have several artefacts that may not directly represent an individual's physiology(180). There are various causes of artefact generation(181). Firstly, there may be a problem with the sensor itself and missed readings detected(180). There may be problems with the sensor attachment resulting in it coming loose(180). For the Sensium sensor this may be for the patch itself or the temperature wire. Finally interference to the signal may occur through activities by the patient such as abnormal movement, talking, eating or excessive anxiety or perspiration(180). All of these reasons may result in artefacts in the data and signal interference which do not reflect real physiology.

One strength of the Sensium sensor is the embedded processing that occurs within the sensor itself which sets rules to determine the data quality. In the literature a common way of removing artefacts is the setting of upper and lower limits of vital signs such as for HR a lower limit of 30 and upper limit of 300. Such techniques have been criticised however as smoothing of data may occur and imprecise monitoring of vital signs may occur(34).

Real time algorithms constantly reviewing vital sign data may help remove any artefacts(180). Artefacts may be identified by values representative to adjacent measurements (34). It may be outlying measurements that do reflect the distribution of other measurements may be removed (34). The clinical benefit of such techniques are to improve the detection of patient deterioration and reduce any unnecessary false alerts(34).

Alarm fatigue

Alarm fatigue is a well-recognised phenomenon particularly on ICU(182). Additional alarms are due to a combination of inappropriate settings, patient condition (co-morbidities) and problems with algorithms(182). The highest cause of alarms are physiological monitors found at the patient's bedside(182). Most strategies in alarm fatigue have focused on the reduction in number of alarms rather than improvements in the quality of alarms themselves(183). Strategies to reduce alarm fatigue include using physiological data in combination with data from electronic health records to form sophisticated alarm algorithms have been suggested(183).

4.6.3 Strengths

This is one of the first studies of its kind using wearable sensors to identify early patient deterioration and sepsis. It addresses one of the fundamental questions of this thesis - can wearable sensors result in earlier detection of patient deterioration? As opposed to other studies in the literature, several definitions of sepsis were used to correctly identify those patients with sepsis. This study shows that wearable sensor technology is feasible in a clinical setting as opposed to use in well controlled laboratory conditions which may lead to more artificial results. A large number of patients were recruited in the trial to allow for greater numbers of patients with deterioration (14% based on ward observations). Similarly, in the literature a large cohort of patients is required to detect those patients with deterioration. A similar study using the Early Sense continuous monitoring system found of 113 patients recruited only 9 (8%) suffered major clinical deterioration(184). The cohort of patients recruited were those at risk of increased respiratory failure(184).

The recruitment of both medical and surgical patients is a strength highlighting that sensor technology is useful in a variety of patient groups. In addition, recruitment of patients was from 6 clinical areas improving applicability in range of clinical settings throughout the hospital. The study shows that there were many episodes of NEWS amber and red alert detected on the sensor that were not detected clinically. These opportunities for early detection and subsequent early treatment were missed.

4.6.4 Limitations

This was a retrospective non-intervention cohort study only used on some floors of the hospital. Due to the infrastructure set up required for the sensor to work if patients were moved to other clinical areas not included in the study the data was not transmitted and thus monitoring had stopped. This was a single centre study limiting its generalisability to other centres.

As described previously the diagnosis of sepsis can be subjective and variable. Some 94 intensivists were asked to review short clinical case vignettes and assess for agreement in diagnosing sepsis, severe sepsis or septic shock(185). The interrater agreement in sepsis diagnosis was found to be poor(185). Other studies have shown that the emergency doctors diagnosis of sepsis disagrees with international definitions of severe sepsis with significant underscoring in clinical judgement alone(186). Whilst previous studies have identified patients with sepsis using International Classification of Disease) ICD codes for sepsis, it is known through previous research that relying on ICD code documentation alone is known to be an inaccurate indicator of clinical diagnosis(187).

Although we have used several classification systems to diagnose sepsis it may be possible that cases of sepsis may not have been identified correctly. It is also possible that identifying patient deterioration may have been missed. Patient deterioration may have occurred prior to patch placement and recruitment of the patient into the trial. Initial treatment may have been started by the clinical team and the patient have been stabilised on recruitment. These episodes of early deterioration ward observations in these patients will have been missed.

There may have been selection bias in recruited patients. All patients were required to give informed consent to be recruited in the trial as stipulated by the ethics board. Unfortunately, the very unwell patients and those with a certain degree cognitive impairment (including patients with severe sepsis) may have been unable to consent and therefore were not included in the trial. This has also been the case for other studies in the literature(184).

The wearable sensor currently only measures HR, RR and temperature. When reviewing the NEWS score only 3 parameters could be assessed. As such the discriminatory power of NEWS may have been reduced. Instead of a potential maximum NEWS score of 20 it has been reduced to 9. Although NEWS is the scoring system that has been used in this study and is widely accepted in the UK other scoring systems exist. In a retrospective review of post-operative patients the eCART (electronic Cardiac Arrest Risk Triage) score was more accurate than NEWS or MEWS (Modified Early Warning Score)(179). The eCART score utilises both vital signs and laboratory data(179). The use of vital sign data with laboratory helps with the accuracy in prediction of adverse events(179).

4.6.5 Future

As wearable sensors become more sophisticated and incorporate other vital sign parameters particularly blood pressure newer definitions of sepsis such as qSOFA may be calculated more easily. For this method of monitoring to become established integration into electronic health records is crucial. Additional tests such as white cell count, neutrophils and blood cultures will be combined with results from wearable sensor vital sign monitoring to allow newer definitions of sepsis to be used. It is likely that future digital alerting may be more personalised or specific to a patient's condition such as sepsis(183). In future alert thresholds derived from continuous predictive analytics monitoring may be operationalised as a degree of change from the person's own baseline rather than arbitrary threshold cut-points (used in NEWS) and this may better account for the individual's own inherent acuity levels(188). In addition future digital alerting aims to be more predictive of patient deterioration rather than reactive which is currently what occurs(183).

The rate of alarms generated per patient is largely unknown. A small pilot study found using a wearable sensor found the average alarm rate for all alarms was 2.3 alarms/patient/day(189). The authors suggest the use of customised vital sign monitoring to reduce the high number of alarms and consequent reduction in rapid response team calls(189).

As well as the use of continuous electronic vital sign monitoring through wearable sensors the use of other technologies such as machine learning and free text monitoring may be used

to identify patients with sepsis using electronic systems. The role of natural language processing and free text is becoming more apparent(190). This may be used in addition to vital signs to help improve specificity in identifying patients with sepsis. Automatic monitoring of nursing notes have been developed to review free text for signs and symptoms of infection(190). Further research is required to develop these technologies further.

The number of patients with deterioration on ward observations that go on to have significant clinical events is largely unknown. Future work on wearable sensors should review this as well as outcome data such as hospital length of stay, transfer to higher levels of care and mortality.

Vital sign changes occur prior to clinical deterioration and early detection is key to timely intervention. However the best way to monitor and interpret vital signs is still unclear in the literature(191). A recent systematic review highlighted the value of trend analysis when reviewing vital signs(191). This may be more useful in the context of continuous monitoring however the studies used in the review were heterogenous and some imprecise(191). When reviewing the way vital signs should be displayed a small study on 42 intensive care nurses found that displays of vital signs which provide readily visible trends and data variability can improve the speed and accuracy of data interpretation when compared to just standard numerical values(192). Further research is still needed to review the best ways to monitor patients.

4.6.6 Conclusion

This chapter has shown for the first time that wearable sensors and continuous monitoring may be used to detect patient deterioration and sepsis quicker than current monitoring.

Although episodes of deterioration were missed both using the sensor and current monitoring, the number of missed deteriorating episodes was far greater using current monitoring. It is hoped that in future wearable sensor technology may be used to provide more continuous monitoring and support current monitoring systems to provide an adjunct to care. Whilst this chapter has focused on speed of detection the feedback from patients wearing the sensor is unknown and this will be reviewed in the next chapter.

Chapter 5 Patient experience of wearable sensors: a mixed methods evaluation

5.1 Introduction

For any new technology to succeed in both its uptake and implementation it must be welcomed by those who use it. The end-users in this wearable sensor study so far are patients. This thesis has identified the importance of the need for digital technology in identifying unwell patients as highlighted in previous chapters. Chapter 1 demonstrated the need for earlier detection of unwell patients, how new innovative digital tools can be used to do this and reviewed the latest wearable sensors. Chapter 2 reviewed the importance of digital alerting in sepsis and its effect on outcome measures such as mortality, length of stay and time to antibiotics. Chapter 3 demonstrated the reliability of the wearable device, and chapter 4 the speed of detection. Another key dimension for any new technology is the acceptability by end-users. As such, this chapter aims to explore the opinions of patients on wearable sensor technologies and continuous monitoring.

The latest development in lightweight wearable sensors offers the opportunity for measuring vital signs continuously for patients on a general ward. Several studies have reviewed the reliability of lightweight wearable devices(149)(141), Whilst we need to make sure that these devices are reliable, we also need to understand patient opinions as the end users. There are very few studies in the literature that have reviewed patient experience of wearable sensors (193)(141)(149). A systematic review of patient and staff experience of wearable sensors found a lack of high quality studies in the area(194). The end-user experience was often a secondary aim rather than primary focus of research. Additionally, the included studies had small sample sizes (most studies had less than 20 participants) and demonstrated limited reporting on methodology and the research process. Following the review, the authors

concluded that further research was required with a focus on end-user preferences, particularly in the design of wearable sensor technology(194).

Previous research on older types of wearable sensors identified them as bulky, larger in size and contained several wires in their design, reducing their acceptability to patients. In a study using the Hidalgo EQ02 Sensor Electronics Module (SEM) portable wearable monitor, one quarter of patients requested the patch to be removed within a day. This portable device was either worn around the neck or around the arm and has several wires attached to the patient for monitoring(195). The main reasons stated by patients for removal were discomfort, irritation and general unease about the monitoring process. The discomfort or annoyance from wearing the sensor has been suggested to decrease the perception of any advantage(195).

5.1.1 Importance of patient experience

The purpose of this chapter is to review the opinions of patients. Patient experience is an integral component of high quality care(196). Within the last 10 years there has been a huge increase in collecting feedback from patients about healthcare services worldwide(197). A mixture of quantitative and qualitative techniques are used from a local to national level feedback(197). Feedback collection may include: focus groups, complaints and compliments, interviews and surveys(197). Newer ways of collecting feedback are the use of social media and patient websites, such as www.iwantgreatcare.org or www.patientopinion.org.uk. However there are some concerns with the validity of the responses of the feedback and bias in those patients that do feedback(198).

Despite the challenges associated with different types of feedback, the NHS Confederation has found that higher levels of reported patient experiences in hospital are associated with good clinical outcomes, improved physical environment and better understanding of what patients feel about their care and staff interactions towards them(199). One way to gain feedback from patients is through involvement in both the design and feedback evaluation of new devices, which is becoming more commonplace within healthcare. The ability to empower patients to be involved in their care is a vital step in improving healthcare, and patients can play a very effective role in healthcare improvement (200)(201). Physicians now understand the importance of this role; the New Care Models within the NHS focus on the need to empower patients and communities (202)(203).

Patient technology adoption in general has been shown to be influenced by technical factors, trust and perceived risks(204). Although some patients may welcome the additional form of monitoring there may be a concern by others about unintended consequences such as invasion of privacy(205). It may be a cause of anxiety in some patients, for others it may act as a reminder or cause them to become more involved in their healthcare. In this study the wearable device only feeds back to staff members; there are no alarms on the sensor itself. This helps to minimise any perceived anxiety felt by patients on wearing the device. Despite the integration of wearables in society the use in medical practice has been limited. There is little known thus far about patient experience in continuous vital signs monitoring with wearable sensors. New technologies and wearable sensors allow the potential of continuous monitoring for ambulating patients admitted to a general ward.

There are very few studies in the literature that have reviewed the acceptance of wearable sensors amongst patients(193). This chapter aims to explore patient experiences of wearable sensor technology and continuous monitoring through questionnaire and interview studies.

5.2 Aims:

To explore patient experience of wearable sensor technology and continuous monitoring through questionnaire and interview studies.

5.3 Methods

5.3.1 Study design

A mixed methods approach was adopted to evaluate the breadth and depth of patient experience of a wearable sensor technology. To achieve breadth, all patients recruited into a wearable patch study were asked to complete a patient questionnaire; semi-structured interviews were completed with a subgroup of patients to better explore in depth their experience of the patch.

5.3.2 Ethics

Ethical approval was granted by Yorkshire & The Humber - Leeds East Research Ethics Committee (Reference number 17/YH/0296))

5.3.3 Patient recruitment

All patients were recruited as part of a wearable patch study performed at West Middlesex University hospital, which is a busy hospital located in northwest London serving an ethnically diverse population. All patients who had worn the sensor during the wearable patch study were invited to complete a questionnaire that had been piloted with volunteers prior to use (Appendix 5.1). The wearable patch study leaflet informed patients about the questionnaire. Written consent had been obtained for all patients during the consent process for the wearable patch study. In addition a subgroup of patients were selected to participate in patient interviews. These patients were given an additional information sheet (Appendix 5.3) and consent form (Appendix 5.4) .

Any new medical or surgical patient could potentially be included. All patients who had taken part in the main patching study were eligible to participate. The exclusion criteria were any patients that withdrew their consent or were no longer able to consent. Patient recruitment was either on the Acute Medical Unit, Acute Surgical Unit, Richmond Ward, or Syon 1 & 2 wards. Patients were required to wear the sensor for at least two hours prior to completing the questionnaire. All patient questionnaires were collected on patient discharge and were stored securely in a locked room; data was handled in accordance with the Data Protection Act.

Care was taken to include those patients in which English is not a first language through available translational services. The patients being admitted to these wards include a variety of case mix. For those patients who did not understand English (written or spoken) all efforts were taken to identify an appropriate translator (provided by the NHS). We asked these patients to consider taking part (using a translator). The research nurses in the study spoke several languages fluently including Greek, Hindi, Punjabi and Urdu. If there were any doubts that the prospective patients did not understand the information sheet or consent form, they were excluded from the study. We made as much effort as possible to prevent discrimination of non-English speaking patients.

5.3.4 Quantitative Research Methodology

The questionnaire was adapted from the systems usability scale which is shown to be a reliable tool in assessing reliability of a devices(206). This questionnaire has not been validated for use in wearable sensors previously. The questionnaire has 9 questions which are

on a 5-point Likert scale ranging from: strongly agree, agree, neutral, disagree and strongly disagree. The questionnaire covered topics including patient comfort, understanding, safety, whether patients would wear the device again at hospital or at home. It took approximately 10 minutes to complete.

5.3.5 Qualitative Research Methodology

Qualitative methods refer to an array of data collection and analysis techniques that purposefully use sampling, semi-structured and open-ended interviews(207). These can be used to provide an in-depth analysis which may be missed with other research methodologies(207). A strength of qualitative techniques is that there is a shift in the ‘balance of power and expertise away from the researcher to respondents’(207). Patients have the freedom to discuss priorities and concerns away from a researcher’s restrictions and assumptions (207). For this reason, qualitative research methodology in the form of semi-structured interviews were selected in addition to the questionnaire to allow for a more in-depth exploration of the opinions of wearables by patients. Semi-structured interviews allow a flexible approach to data collection and highlight ideas or concepts that may not have been identified during the questionnaire study. The semi-structured interview guide gives the researcher a framework for exploration but gives patients freedom to explore their own ideas and perceptions of wearable sensors and continuous monitoring.

A sample of patients was invited to take part in an in-depth semi-structured interview. Face-to-face interviews were conducted by the lead researcher (MJ) using a prepared topic guide (Appendix 5.2). The topic guide was prepared by MJ based on informal interactions with patients on the ward prior to the study commencing. A separate patient leaflet was given to

patients to review 24 hours previously (Appendix 5.3). Written consent was obtained from all those partaking in the interview study (Appendix 5.4). This was an additional separate consent form as requested by the ethics committee. The interviews took place in a quiet allocated room on the ward.

The questions were open-ended and focused on the topics of: patient understanding, continuous monitoring, comfort, any problems, potential future changes and what patients thought about potential future home monitoring. An example of a question is ‘How do you feel about being monitored with the wearable sensor?’. Interviews were audio-recorded and transcribed verbatim. The inclusion criterion was patients that had worn the wearable sensor. The exclusion criteria were any patients that had withdrawn their consent or no longer able to consent. An audio recording was made of all interviews and the interviewer also took field notes reflecting the verbal responses and reflections used to adapt the topic/study direction. All interviews were held at the study site (West Middlesex University Hospital). Interviewing was stopped once data saturation was reached, and the audio recordings were transcribed using the Page Six transcription. Page six is a secure transcription service used by Imperial College for audio file transcription and it has General Data Protection Regulation (GDPR) compliance(208). No patient details were given to the transcription service and individual patients were identified on the transcript by the study number which is only known to the research team.

5.3.6 Analysis

Quantitative data were analysed using parametric and non-parametric statistics with tests being conducted in IBM SPSS Statistics (Version25). As with previous similar studies

(15)(16)(17), the scores for each question were treated as continuous variables. As such, means and standard deviations were calculated per question.

Interview data were analysed using thematic analysis (209). Thematic analysis helps identify, analyse and report patterns (themes) within data sets as well as organising data and providing depth. All transcripts were reviewed multiple times. Initial codes were developed by MJ and were independently reviewed by a second coder Dr Abigail Morbi. Dr Morbi is a Clinical Research Fellow in the Department of Surgery and Cancer, Imperial College London and is a researcher familiar with qualitative research methodology. The codes were discussed and refined until final themes were generated.

5.4 Results

5.4.1 Questionnaire Patient demographics

Of the 500 patients who had worn the wearable sensor, 453 completed the questionnaire (90.6%); 51% of the participants were female and the mean age was 57 (ranging from 18-95).

5.4.2 Interview Patient demographics

Twelve patients consented to be interviewed; 6 male and 6 females. Patients were recruited from a range of clinical areas, SAU, Richmond, Syon 1 and 2 wards. The age range of included patients were 23 to 73 years old. The interviews were performed over several weeks with the first interview on 4th April 2018 and the final interview on the 19th July 2018. The demographics for patients interviewed can be found in Table 5.1.

Table 5.1 Patient Demographics for patient interviews

Patient Number	Specialty	Sex	Age	Employment Status	Ethnicity	Presenting Complaint	Frailty	Residence	Past medical history	Infection
1	Surgical	M	71	Retired	White British	Deranged renal function, high stoma output	Independent	Own home	Laparotomy, gall bladder and ascending colon removed 11/2017, post op leak and further laparotomy 3/52 after	N
2	Surgical	M	25	Student	White British	Perforation, had a laparotomy	Independent	Own home	Nil	Y
3	Surgical	M	20	Employed	White British	Appendicitis	Independent	Own home	Cyst removed from Jaw	Y
4	Surgical	F	33	Self Employed	Other White Background	Acute Cholecystitis	independent	Own home	Nil	Y
5	Surgical	F	27	Employed	Mixed Background	Terminal Ileal Crohn's	Independent	Own home	Nil	Y
6	Surgical	F	48	Employed	White British	Appendicitis had a laparotomy, thought to be Meckel's	Independent	Own home	Nil	Y
7	Surgical	F	73	Retired	White British	ERCP Pancreatitis	Independent walks with crutches (amputee has prosthesis)	Own home	Nil	N
8	Surgical	M	66	Employed	White British	Cholecystitis /Biliary colic	Independent	Own home	Nil	N
9	Surgical	M	70	Employed	Other White Background	Irreducible paraumbilical hernia, abdominal pain	Independent	Own home	Nil	Y
10	Surgical	F	54	Employed	White British	Unwell & diarrhoea	Independent	Own home	Appendicectomy, hysterectomy, breast lump removal	Y
11	Surgical	M	74	Unknown	White British	Rib fracture falling off a ladder	Independent	Own home	Nil	N
12	Surgical	F	40	Employed	Black / Black British African	Subacute bowel obstruction	Independent	Own home	Several bowel operations, repeated bowel obstructions	N

5.4.3 Questionnaire results

The results from the questionnaire were generally positive; descriptive statistics for each questionnaire item can be seen in Table 5.2. Patients agreed the wearable sensor was comfortable to wear (85.4%; n=427) and few reported that the sensor was cumbersome (5.4%; n=27). Only 2.2% (n=11) agreed that the system was complex, and the majority of patients agreed they knew who to contact if they had any problems (83.2%; n=416). Most patients disagreed they had much to learn before they used the sensor (79.4% (n=397)). The majority of patients (89.0%; n=445) agreed they understood what wearable patch was for and 69.2% (n=347) agreed they felt safer being monitored. For future use, most patients agreed they would wear the sensor again when in hospital (85.8%; n=429) and in their homes (79.6%; n=398).

The results for each individual question will be described in the paragraphs below.

Table 5.2 Descriptive statistics for each questionnaire item

Please rate your level of agreement with the following statements	Strongly Agree Number (%)	Agree Number (%)	Neutral Number (%)	Disagree Number (%)	Strongly Disagree Number (%)	No Data (%)	Total Number (%)	Means	Standard Deviation
1. The wearable patch was comfortable to wear	224 (44.8%)	203 (40.6%)	14 (2.8%)	11 (2.2%)	1 (0.2%)	47 (9.4%)	500 (100%)	1.59	0.690
2. I found this system unnecessarily complex	1 (0.2%)	10 (2.0%)	12 (2.4%)	277 (55.4%)	152 (30.4%)	48 (9.6%)	500 (100%)	4.26	0.636
3. I understood what the wearable patch was for	213 (42.6%)	232 (46.4%)	4 (0.8%)	3 (0.6%)	0 (0.0%)	48 (9.6%)	500 (100%)	1.55	0.553
4. I felt safer being monitored whilst wearing the wearable patch	132 (26.4%)	214 (42.8%)	90 (18.0%)	16 (3.2%)	0 (0.0%)	48 (9.6%)	500 (100%)	1.98	0.796
5. I knew who to contact if I had any problems with the wearable patch	154 (30.8%)	262 (52.4%)	15 (3.0%)	19 (3.8%)	2 (0.4%)	48 (9.6%)	500 (100%)	1.79	0.734
6. I would wear the wearable patch again when in hospital	175 (35.0%)	254 (50.8%)	12 (2.4%)	9 (1.8%)	0 (0.0%)	50 (10.0%)	500 (100%)	1.68	0.627
7. I found this system very cumbersome to wear	4 (0.8%)	23 (4.6%)	19 (3.8%)	263 (52.6%)	142 (28.4%)	49 (9.8%)	500 (100%)	4.14	0.788
8. I would wear the wearable patch in my home	163 (32.6%)	235 (47.0%)	17 (3.4%)	30 (6.0%)	6 (1.2%)	49 (9.8%)	500 (100%)	1.85	0.874
9. I needed to learn a lot of things before I could get going with this system	11 (2.2%)	32 (6.4%)	11 (2.2%)	263 (52.6%)	134 (26.8%)	49 (9.8%)	500 (100%)	4.06	0.907

5.4.3.1 The wearable patch was comfortable to wear

There were 427 patients (85.4%) patients that indicated they strongly agreed or agreed that the wearable sensor was comfortable to wear (bar chart in Appendix 5.5). There were 11 patients (2.2%) that disagreed and 1 patient (0.2%) that strongly disagreed. The number of patients with no data was 47 (9.4%).

5.4.3.2 I found this system unnecessarily complex

There were 429 patients (85.8%) that either strongly disagreed or disagreed that the wearable sensor system was complicated (bar chart in Appendix 5.6). There were 10 patients (2%) that agreed with the system being complex and 1 patient (0.25%) that strongly agreed it was complex. The number of patients with no data was 48 (9.6%).

5.4.3.3 I understood what the patch was for

There were 445 patients (89.0%) that indicated they strongly agreed or agreed that they understood what wearable patch was for (bar chart in Appendix 5.7). There were 3 patients (0.6%) that disagreed and did not understand the patch and no patients that strongly disagreed. The number of patients with no data was 48 (9.6%).

5.4.3.4 I felt safer being monitored whilst wearing the wearable patch

There were 347 patients (69.2%) that indicated they strongly agreed or agreed that they felt safer being monitored whilst wearing the wearable patch (bar chart in Appendix 5.8). There were 90 patients (18%) that were neutral and 16 patients (3.2%) that disagreed they felt safer.

No patients strongly disagreed with feeling safer wearing the patch. The number of patients with no data was 48 (9.6%).

5.4.3.5 I knew who to contact if I had any problems with the wearable patch

There were 416 patients (83.2%) that indicated they strongly agreed or agreed that they knew who to contact if they had any problems (bar chart in Appendix 5.9). There was a total of 19 patients (3.8%) that disagreed and 2 patients (0.4%) that strongly disagreed. The number of patients with no data was 48 (9.6%).

5.4.3.6 I would wear the patch again when in hospital

There were 429 patients (85.8%) that indicated they strongly agreed or agreed that they would wear the patch again when in hospital (bar chart in Appendix 5.10). There was a total of 9 patients (1.8%) that disagreed, and no patients strongly disagreed to wearing the sensor. The number of patients with no data was 50 (10%).

5.4.3.7 I found this system very cumbersome to wear

There were 405 patients (81.0%) that either strongly disagreed or disagreed that the system was cumbersome to wear (bar chart in Appendix 5.11). A total of 23 patients (4.6%) agreed the sensor was cumbersome and 4 patients (0.85%) strongly agreed. The number of patients with no data was 49 (9.8%).

5.4.3.8 I would wear the wearable patch in my home

There were 398 patients (79.6%) that indicated they strongly agreed or agreed that they would wear the wearable patch in their home (bar chart in Appendix 5.12). There were 30 patients (6%) that disagreed to wearing the patch at home and 6 patients (1.2%) that strongly disagreed. The number of patients with no data was 49 (9.8%).

5.4.3.9 I needed to learn a lot of things before I could get going with this system

There were 397 patients (79.4%) that either strongly disagreed or disagreed that they had to learn a lot of thing before they could get going with this system (bar chart in Appendix 5.13). There were 32 patients (6.4%) that felt they had to learn lots of things and 11 patients (2.2%) that strongly agreed. The number of patients with no data was 49 (9.8%).

5.4.3.10 Questionnaire comments

Comments from the free text box where patients could write their own comments were coded and grouped into positive, negative and neutral feedback. The total number of comments left were 215: of these 148 were positive, 46 negative and 21 neutral.

Overall the 215 positive comments were grouped into concept/device and patient comfort as these were the two main themes. There were 73 positive comments about the concept of monitoring, enhanced safety and a general good idea. The remaining 75 positive comments were around positive feelings of patient comfort with many patients stating they could not feel the sensor. The positive comments can be found in a table in Appendix 5.14.

The 46 negative comments were split into several categories. The largest categories were problems with the adhesive (15 patients), problems with the under-arm temperature wire (9 patients), generally uncomfortable (7 patients) and itchiness (5 patients). The other negative comments were problems sleeping (3 patients), hairy chest problems (2 patients), warmth from the sensor (2 patients), wearability (2 patients) and annoying (1 patient). The negative comments can be found in a table in Appendix 5.15.

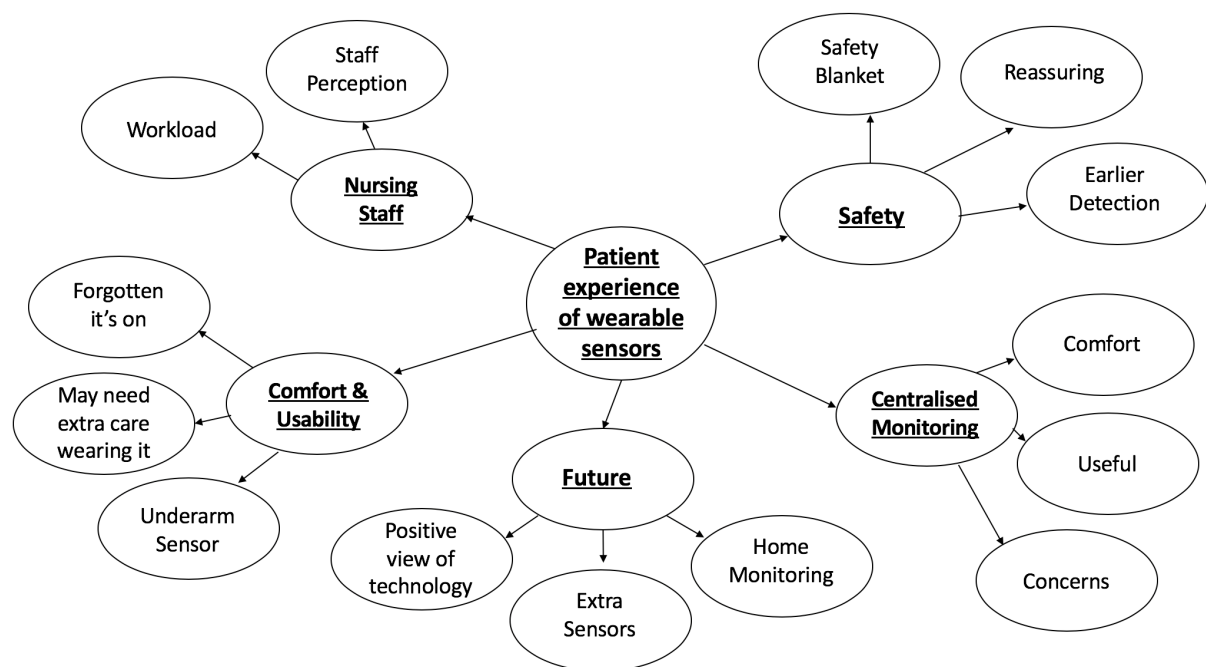
The neutral comments were largely related to the study design, supplementary research documents and positive feedback about the research team. Several suggestions for improvements to the sensor were made and these included a recyclable sensor, a display for the patient, vertical sensor position, different sensors for males and females, a smaller sensor and changes to the colour of the sensor. All of these comments were made by individual patients and form a minority view. The individual neutral comments can be found in the Appendix 5.16.

5.4.4 Main results: semi-structured interviews

Five main themes were evident from the interviews; 1) Centralised monitoring, 2) Safety, 3) impact on nursing staff, 4) comfort & usability and 5) the future and views on technology.

These themes and their contributing subthemes are summarised in figure 5.1.

Figure 5.1 Themes and subthemes from thematic analysis



Patient understanding of the wearable sensor was asked specifically for each patient. All patients wearing the sensor had a good understanding of why they were wearing it and understood the sensor was identifying vital signs to identify early patient deterioration. This replicates information gleaned from the questionnaire where 89% indicated they either strongly agreed or agreed to what the wearable sensor was used for.

5.4.4.1 Centralised monitoring

Centralised monitoring was consistently described by patients and was the underpinning of many of the other themes. Centralised monitoring provided patients with greater peace of mind and patients felt they were always amongst healthcare staff if a problem arose.

‘Remote monitoring so your doctor can sit at the desk and see his patients, how you’re doing’ (patient 9, male, aged 70).

However, one patient was concerned about the patch potentially not providing any monitoring as no feedback is given to patients:

‘I was worried it wasn’t really recording when it needed to be recording’ (patient 8, male, aged 66).

Central monitoring was discussed by all patients interviewed and helped provide patients with a greater peace of mind and reassurance. One patient was concerned about the lack of feedback given to the patient.

5.4.4.2 Safety

All patients commented on an enhanced feeling of patient safety while wearing the patch; the extra layer of support enabled a feeling of reassurance:

‘I felt like there was a second safety blanket around me, almost, and that I was constantly in amongst the nurses. I appreciate that the nurses do their obs as

frequently as they can, but they're very busy. So, for this to be on constantly, it's reassuring' (Patient 2, male, aged 25).

Patients identified there was a problem with the current monitoring systems through their experiences on the ward, particularly overnight where the perceived current monitoring by nurses was at a minimum:

'Reassuring, an extra layer, particularly at night where they don't do obs' (patient 10, female, aged 54).

Patients emphasised that the use indwelling lines (i.e. nasogastric tube) and a patient's ability to talk may prevent a patient's ability to raise a concern if there was a problem. They perceived that the addition of the wearable patch and continuous monitoring could help provide patients with a 'voice' at times of sudden worsening in their condition:

'Some people can't talk like if they've got tubes in and stuff but that could talk for them, like if they can't say I'm feeling hot or feeling ill' (patient 12, female, aged 40).

Patients described that wearable sensors would be of greater benefit in certain patient groups such as children, postoperative patients and the elderly. Patients were concerned that current systems may cause a delay in identifying unwell patients; therefore impairing patient safety. Conversely, patients believed that continuous monitoring of patients with conditions such as infection would improve patient safety and offer earlier detection of patient deterioration.

5.4.4.3 Nursing Staff

Patients described the impact that continuous monitoring might have on the workload of staff. Most patients believed that the technology would reduce workload for nurses especially as nurses were already perceived to be under considerable strain:

‘I missed my medication dose because they were so busy, and they didn’t get to me. So, like if this was something – Say, I know it’s not about medicine but they would have been alerted on their, you know, say if my temperature had gone up or – It’s just the fact that they’re so busy and there’s not enough of them, I think it’s good, it takes a lot of strain, it take some of the strain off of their workload. So, yeah, I think it’s very beneficial.’ (patient 12, female, aged 40).

Patients recognised that the nursing role was demanding and that staff shortages added further pressure on an already stretched workforce. Patients felt wearable sensors would improve nursing workload and free up nurses for other tasks:

‘Free nurses for an awful lot of routine stuff, you know they have been doing me every half an hour, am sure there are better things they can be doing in a busy place like this’ (patient 9, male, aged 70).

Whilst most patients agreed wearable sensors would improve nursing workload, one patient was concerned continuous monitoring may increase the demands placed on staff.

‘The nurses might be running away if they have got too much to do’ (patient 8, male, aged 53).

Another concern by one patient was if the sensors were too efficient, they would be used as a replacement for a regular nurse check-up:

‘Thought it was to see if it could replace the need to have regular nurse check-ups of heart rate and what not’ (patient 3, male aged 20).

All patients said that wearable sensors and continuous monitoring would affect nursing workload; most patients believed that there would be improvements in nursing workload. However, one patient was concerned the demands on staff would be increased. Another patient was concerned that sensors may be used as a replacement for nurse check-ups if too efficient.

5.4.4.4 Comfort & Usability

All patients described the patch as being comfortable to wear with many patients forgetting about the patch once it was on:

‘From about five minutes after it was on, I completely forgot it was there’
(patient 2, male, aged 25).

One patient described the sensor as being very comfortable but after a week found it to be a bit irritating.

‘I just find it a bit irritating now when I have to adjust it every now and then, but I had it on for a week’ (patient 8, male, aged 66).

Some everyday tasks such as changing clothes and washing required extra patient care to prevent dislodging the patch and reducing monitoring.

‘Only concern was when I wanted to get changed, I didn’t want to sort of move it off too quickly, in case I caught on the sensor when I had a wash. Easy to have on no issues with it’ (patient 9, male, aged 70).

Several potential changes to the patch were suggested on questioning which may make the patch more comfortable and improve overall usability. A few patients mentioned that the patch could be smaller but in doing so there were concerns that the patch consequently may not be as comfortable. Other potential changes identified for both utility and comfort were changes to the fixings and the under-arm temperature sensor.

‘The underarm sensor I managed to knock off in the shower so that might need some looking at, caught the spiral cable when towel drying, I knocked the patch off, fixings comparatively bulky’ (patient 1, male, aged 71).

All patients described the sensor as being comfortable to wear and comfort was a key theme mentioned by patients. Those patients that had worn the sensor for more prolonged use up to 1 week found it to be irritating at times. Certain day-to-day tasks required patients to be more careful when wearing the sensor and these included changing clothes and washing. Several suggestions were made by patients to improve the sensor further and these included a smaller size and changes to the under-arm temperature sensor.

5.4.4.5 The future

Patients described wearable sensors as the future and that wearable sensors were a 'step forward' (patient 3, male, aged 20). Future sensor use is likely to be at home; all patients interviewed agreed to wearable sensor monitoring in their own homes. High risks groups such as children and post-operative patients were identified to have most benefit from home monitoring and that it was as an enhancement of medical care:

'I think it would be brilliant if we can extend early developments into the home environment', identified patients like him post op, to help 'flagging dangerous symptoms' (patient 1, male, aged 71).

The use of sensors for home monitoring was particularly important as patients discussed current fears of going home after an operation and becoming unwell. One patient described how her friend developed an infection at home post-operatively and died:

'She developed an infection post her cancer surgery. But, so it wasn't even the actual surgery that killed her as such, but you know like these symptoms come on really quickly, you're starting to feel – because you get delirious when you get a temperature and you may not realise how sick you are, but if that was to send a message to somebody then I just think that's amazing' (patient 12, female, aged 40).

Patients felt future sensors should be smaller and have additional monitoring signs such as blood pressure and accelerometry data, and that this may be important in detecting falls particularly for high risk elderly people at home:

‘Yes I would imagine for old people it could be very valuable, particularly if it detected movement as well, maybe things that apply to old people having more incidents, I’ve got to 70 need to start thinking about these things’ (patient 9, male, aged 70).

Further sensor modalities such as implantable sensors were suggested for future use. It was felt that this would be the natural evolution of sensor technology and would be beneficial. Overall, patients held a positive view of technology in general and were reassured with the technological advancement in healthcare.

5.4.4.6 Further Concerns

Whilst the majority of patients were very supporting of the technology, a few concerns were raised by some. As this was only a minority view this was not raised as a central theme.

One patient was concerned that the new technology would be used as a tool to discharge the patient home too early. This patient allegedly had been discharged early and had a readmission. At the same time however the patient thought the wearable sensor was a great idea and also suggested that it be used to monitor patients at home even prior to an operation.

One patient was concerned about the recycling of the patch and whether the devices could be reused. It was suggested that ways to recycle the patch be considered. Another patient wanted to make sure that all the patient data was being stored correctly and the ‘IT side is being well looked after’. Patients identified that wearable sensors potentially generate huge amounts of data and wanted to make sure that all of this was stored both safely and securely.

5.5 Discussion

It has been suggested that the success of wearable technologies depends on ‘their usability, acceptability, and the willingness and active participation’ of wearers(210). As to our knowledge, this is the largest questionnaire study to date of wearable sensor use in an acute hospital setting. The large questionnaire sample size in this study coupled with additional patient interviews have helped ensure a richness in the responses.

5.5.1 Summary of findings and Existing Literature

Safety

In this study, most patients felt safe wearing the patch, describing the sensor to be an ‘extra safety blanket’ and felt safer with centralised monitoring systems; this is consistent with previous research(211). Previous studies have described how sensors provide patients with a sense of extra security(212). The sensors provide an increased monitoring frequency of vital signs and this adds to feelings of security.

Comfort

The majority of patients in this study found the wearable sensor to be comfortable; patients reported they had forgotten they were wearing the sensor. A previous study on elective surgical patients using the same Sensium wearable device again found the sensor so comfortable that they had forgotten it was on (10/12 patients)(211). Patient comfort of wearable sensors was also found to be of importance to patients; this has been highlighted in

other studies(211). Despite the apparent comfort, several patients highlighted in the interviews that extra care was needed at times with certain tasks such as washing.

Ease of sensor use an design

The simplicity of sensor use and design is important. Most patients in this study felt they did not have to learn a lot of things before they used the technology - reflecting ease of use by patients. Previous studies have revealed that technical problems and complicated designs can result in frustration and stress for patients (22). A simple sensor design is an important end user preference (8).

Potential for further use of wearable sensors both at hospital and home

This study found that most patients would wear the wearable sensors again when in hospital and would wear the sensor at home. This demand by patients is likely to encourage wearable sensor use in future. Patients had a very positive view of technology and felt that wearable sensors and continuous monitoring would certainly be used in the future. The idea of home monitoring by wearable sensors was welcomed by all patients and may be the next natural step in wearable sensing technology. A study using a wearable sensor called Vital Connect in the home setting has been identified in the literature(104). This study showed ‘encouraging positive feedback on wear ability and usability’ of the sensors for home use(104). Certain groups for monitoring were highlighted by patients in our study such as: children, the elderly and post-operative patients. Wearable sensor use in the elderly has been gaining interest(213). The use of vital sign monitors may be coupled with additional monitoring sensors such as fall detectors and physical activity monitors(210). These would alert to family members or caregivers in any cases of patient deterioration(214). With a world-wide

ageing population, the latest technologies can help create solutions to provide support for people yet enabling them to live as independently as possible.

Concerns of wearable sensor use

Some concerns about wearable sensors were raised although these were held by a minority view. One patient had been discharged from hospital too early in her opinion. This patient mentioned that whilst she welcomed the monitoring, she did not want it to be an excuse to discharge patients too early. Although data security was mentioned by only one patient, this has been highlighted in the literature previously(211). One of the key features with this wearable sensor is that data is only uploaded to the server if near the sensor hot spot (bridge). If for any reason the patient leaves hospital or accidentally takes the patch home, it will no longer work. It is hoped this feature would increase the security of the patch.

Ideas for future wearable sensor development

Patients identified a number of areas for future development. These included a smaller sensor size and changes to the under-arm sensor design. This is supported in the wider literature. A review of patient perspectives of wearable sensors found that there was a preference for small, compact devices that were not directly visible to others and so did not cause any stigmatisation(194). Regardless of whether the wearable sensor is used in a clinical setting or at home, user preferences must be taken into account(194).

Staff impact of wearable sensors

The impact on staff was a key emerging theme from the patient interviews. Patients believed that the sensor would be an overall adjunct to care and help nurses. However, some patients had raised concerns that wearable sensors may increase the burden of work on the nurses. The opinions from staff members must be highlighted in further work.

Patient understanding of wearable sensors

The patient understanding of the technology was impressive with most agreeing that they understood what the wearable patch was for. This may be a reflection of the time taken to consent each patient and the training of the researchers in explaining the sensor to patients. Patients are already familiar with the monitoring that occurs in hospital, particularly with vital signs, and this will have further improved understanding. All the patients recruited in the interviews had a firm understanding of the technology and the vital signs measured.

5.5.2 Strengths

This study has greatly expanded the literature of patient feedback on wearable sensors in an acute hospital setting. Studies reviewing patient feedback of wearable sensors until now have been limited. Unlike this study, previous studies have reviewed patient feedback as a secondary aim rather than the primary aim of the study (194). A key strength in this study are the high rates of questionnaire completion with feedback from 453 patients (90.6%). This high response rate helps enhance the reliability of the feedback generated and reduce potential biases. The themes and subthemes generated from the interviews have significant overlap between the findings from the questionnaire encouragingly supporting the use of both methods of research. The multiple data collection methods offered a comprehensive view of

patient feedback. Due to the diverse local patient population a wide range of ethnicities were eligible to be recruited in the study. The research nurses in this study were able to speak several languages; this helped with recruitment of patients across multiple ethnic groups. The feedback generated by patients was from many ethnic groups enhancing generalisability at a population level.

5.5.3 Limitations

There is the potential of bias in the patients recruited as we can only capture the feedback from patients who have agreed to wear the sensor. As such these patients may have a positive view of technology compared to others not recruited. The average number of days for sensor use in this study was 2 days. It is unknown whether patients required to wear the sensor for much longer time periods may have differing results particularly on comfort and usability. Only one sensor device (Sensium wearable sensor) was used in the study. Though the broad themes of sensor technology and continuous monitoring will also apply to other sensors, themes such as comfort may not be applicable to other sensor devices.

All members of staff on the wards that were patching patients knew about the wearable sensors and had specific training. General awareness of the study and wearable patches was raised throughout the hospital with articles in the trust magazine 'Going Beyond' and through many local oral and poster presentations. Despite this, one of the patients mentioned that when moved to another department in the hospital (radiology) not everyone there knew about the patch. It is thought that the general awareness of the sensor within the hospital could be promoted even further and this would be useful for future similar studies.

5.5.4 Future work

Only patients were included in this study. Further research to learn the opinions of patients' friends and relatives and see what they feel about the technology would be beneficial. This was not captured in this study but would be of great importance if the wearable sensors were being used at home by patients. Future studies should also review the opinions of healthcare staff another key end-user of wearable technology.

5.5.5 Conclusion

Overall, the feedback from patients was positive and the technology was welcomed. Whilst a few concerns have been raised, procedures can be put in place to help counteract these. It is believed that continuous monitoring of vital signs may be the future. The success of wearable sensor technology in future relies on patient and healthcare profession acceptability. This chapter has focused on patient feedback. The next chapter will highlight feedback from staff, the other key end-used user of wearable sensing technology.

Chapter 6 Staff perspective of the wearable sensor and continuous monitoring

6.1 Introduction

As discussed in the previous chapter for any new technology to succeed it must be welcomed by its end-users. The previous chapter explored patient opinions while staff opinions have been hitherto unexplored. This chapter will build on work so far and focus on staff opinions.

Patients being admitted to our surgical and medical wards are sicker, older and have a greater number of co-morbidities than ever before. For any new technology to be seriously considered and used routinely on the hospital wards the opinions of staff are crucial. In many hospitals the way that observations are being taken for general ward patients has not changed over many years. Often the vital signs are taken by a Health Care Assistant (HCA) on the ward or a junior nurse. The information is then transcribed, in most hospitals, onto a paper observations chart (although some hospitals are now using electronic observation tools). If the HCA or junior nurse is concerned about the patient's observations this is then escalated up to a more senior nurse. Senior nurses will then act on this information and escalate to either the relevant team managing the patient, the acute on-call team or rapid response teams in the hospital. All information should be accurate and given in a timely manner so patient deterioration can be acted on early and enable better outcomes. All of this requires great communication from all parties. This is concerning as failures in communication are universal and frequent(160). Delayed escalation of care is linked with poorer outcomes and greater mortality(215). A systematic review has shown that the frequent causes of delayed escalation of care for patients included hierarchy and failures in communication(215).

There have been concerns about the accuracy of the current technology being used to assess vital signs in the ward setting. A survey of predominantly nurses confirmed they were not confident about the accuracy of current equipment used to measure vital signs(216). In addition, although extra observations were conducted on patients when necessary, this was time-consuming and at times required rearranging nursing staff and patient assignments(216). The advent continuous monitoring on hospital wards hopes to cause a huge paradigm shift in monitoring, offering a more proactive detection of patient deterioration than current monitoring.

Although there are several studies documenting the reliability of wearable sensors on hospital wards, there is very little feedback on healthcare staff perspectives(141)(152). The opinions of all who use the technology must be reviewed. They may vary depending on the role staff members have in hospital. The largest impact of continuous monitoring may be on nurses as, in most settings, they will be placing the sensor on patients and will be the first to be alerted. One study interviewed nursing staff and doctors; both groups believed that continuous monitoring of vital signs may lead to earlier identification and response to patient deterioration as well as greater availability and accessibility to vital signs information(216). One concern held by both nurses and doctors was the potential of over-reliance on the continuous monitoring and reduced bedside interactions held between healthcare staff and patients(216). Currently there is very limited research in the clinical staff perceptions on patient monitoring systems and the impact this may have on staff. No study to date has conducted a comprehensive exploration of staff views of wearable sensor technology for ward patients. A pan-stakeholder review of wearable sensors for ward patients will be explored further in this chapter.

6.2 Aims:

To explore staff experience of wearable sensor technology and continuous monitoring through interview studies.

6.3 Methods

6.3.1 Participants and setting

Prior to the study commencing we held briefing sessions to explain the aims of the study. Awareness about the project was raised through the use of several local presentations, the intranet and hospital magazine. All junior nurses were trained to be able to place the sensor and remove it on patient discharge in case this was required out of hours when a member of the research team was unavailable. The research team had spent many months on the ward prior to the commencement of the study and were well known to staff members.

A wide range of participants were sampled from both junior nurses and doctors to senior nurses and senior surgeons. A band 6 nurse or higher was graded as a senior nurse. A senior surgeon was anything above an ST7 surgical grade or a consultant. This ensured a pan-stakeholder approach in the analysis of continuous monitoring of ward patients from the most junior to the most senior members of the inter-professional care team(160). To avoid any bias that this may have created, only those participants working on the surgical wards were included. All staff members were caring after general surgery patients. The surgical wards where surgical patients are inpatients at West Middlesex University Hospital are Syon 1&2, Richmond and the Surgical Assessment Unit (SAU). All participants included in the interviews had either applied the patch, had the training or managed a patient that had worn the wearable patch.

6.3.2 Qualitative Research Methodology

Qualitative research methodology in the form of semi-structured interviews was selected to allow for a more in-depth exploration of the opinions of wearables for clinical staff and the impact on patient safety. This topic guide helped to provide a framework for questioning but was not rigid in its approach allowing a rich understanding of staff perceptions. The semi-structured interviews allow a flexible approach to data collection and highlight ideas or concepts that may not have been identified elsewhere. The semi-structured interview guide can give the researcher a framework for exploration but gives participants freedom to explore their own ideas and perceptions of wearable sensors and continuous monitoring. The topic guide was developed and piloted prior to use with 6 members of the healthcare team. I performed all interviews. The topic guide for staff interviews is found in Appendix 6.3.

The following concepts were examined:

1. The positives and negatives of the wearable patch and continuous monitoring.
2. The role of the wearable patch on patient safety and sepsis detection.
3. The potential facilitators and barriers to routine wearable patch and continuous monitoring use on the wards.
4. For those members of staff (junior nurses) that were trained to use and place the patch the adequacy of their training was explored.
5. An assessment of the wearable patch affecting time with patients was also explored.

All staff that have been involved in the use of sensor technology on the wards were invited to take part. Ethical approval was obtained prior to the commencement of the interviews by

Yorkshire & The Humber - Leeds East Research Ethics Committee (Reference number 17/YH/0296)). A standard approach was used for all participant interviews. The staff rotas from nurses to senior surgeons were checked to ensure that all involved were invited to take part. All participants were contacted via telephone or in-person to request an interview. An information leaflet was given to staff to review prior to the interviews (Appendix 6.1). Written consent was obtained from all those participating in the interviews (Appendix 6.2). Semi-structured interviews were conducted by the primary lead researcher using the prepared topic guides (Appendix 6.3). Face-to-face interviews were performed with all members of the health care team from: junior nurses, senior nurses, junior doctors, and senior surgeons. An audio recording was made of all interviews. The interviewer also made field notes reflecting the verbal responses and reflections that were used to adapt the topic/study direction. All interviews were held in a quiet room off the ward at West Middlesex University Hospital. Interviewing was stopped once data saturation was reached, and the audio recordings were transcribed using the Page Six transcription. Page six is a secure transcription service used by Imperial College for audio file transcription and it has General Data Protection Regulation (GDPR) compliance(208). No participant details were given to the transcription service and individual participants were identified on the transcript by the study number which is only known to the research team. All interviews were reviewed to ensure reliability by a second independent researcher Dr Abigail Morbi (AM). Dr Morbi is a Clinical Research Fellow in the Department of Surgery and Cancer, Imperial College London and is a researcher familiar with qualitative research methodology. Any discrepancies in thematic codes were discussed with Mr Hutan Ashrafian (Chief Scientific Adviser in the Department of Surgery and Cancer, Imperial College London) until agreement was reached among all reviewers. The interviews continued until data saturation was reached, and to limit any bias, the same number of staff were used in each staff cohort.

All interviews staff interviews took place between 12th March 2018 to 22nd August 2018. The mean number of minutes for staff interview was; 7.1 minutes for junior nurses, 7.1 minutes for junior doctors, 7.4 minutes for senior nurses and 9.0 minutes for senior surgeons. The mean number of minutes for all interviews was 7.6 minutes.

6.3.3 Analysis

Just as in the previous patient chapter, all interview data were analysed using thematic analysis (209). Thematic analysis helps identify, analyse and report patterns (themes) within data sets as well as organising data and providing depth. All transcripts were reviewed multiple times. Initial codes were developed by MJ and were independently reviewed by a second coder Dr Abigail Morbi. The codes were discussed and refined until final themes were generated. Any discrepancies in thematic codes were discussed with Mr Hutan Ashrafian until agreement was reached among all reviewers.

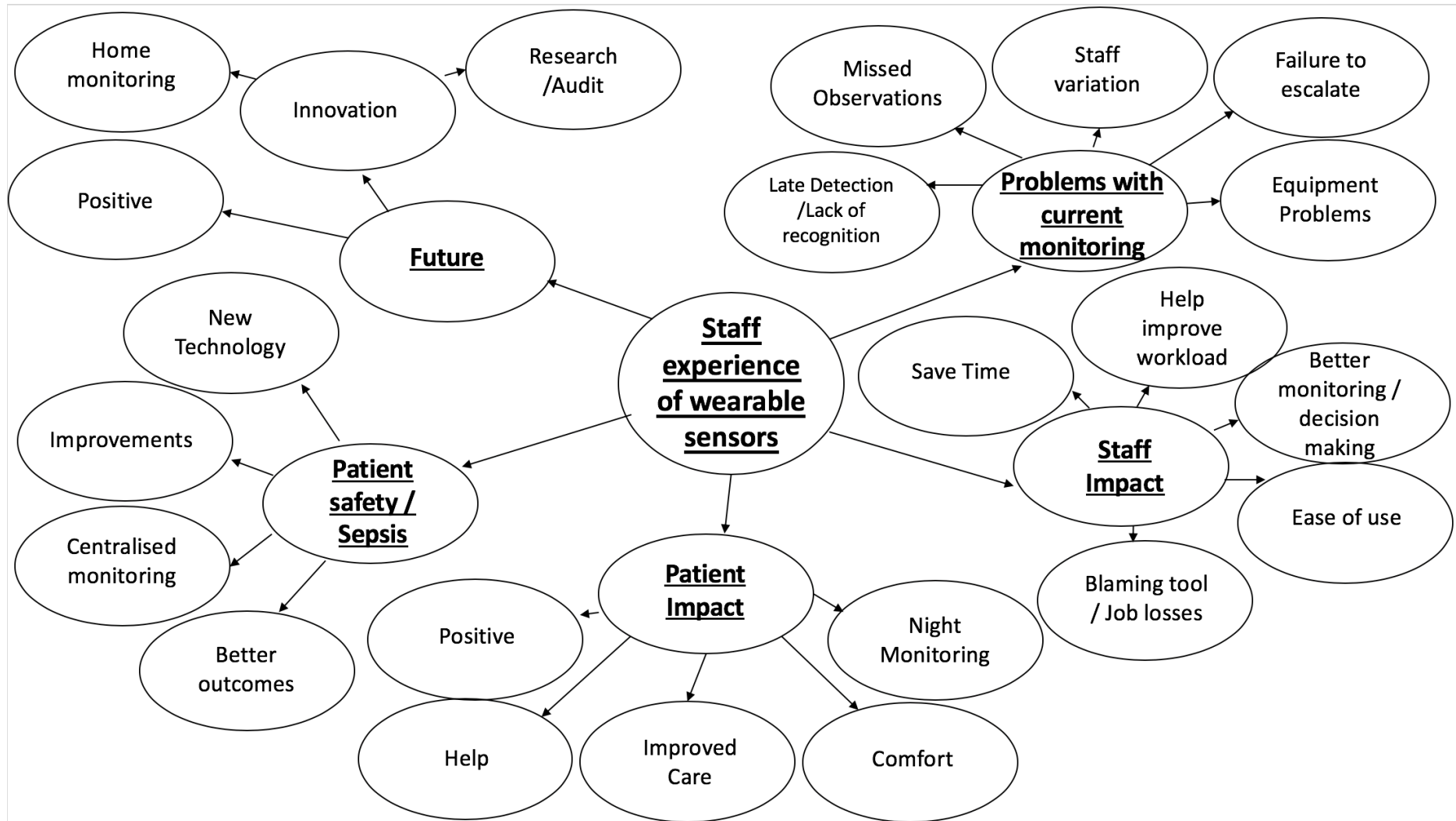
6.3.4 Assurance of qualitative rigour

Quality guidelines for research were strictly adhered to by all members throughout the study(217). Data collection and the analysis protocol were both clear and transparent with consistency throughout the study.

6.4 Results

A total of 48 interviews were performed with 12 senior surgeons, 12 junior doctors, 12 senior nurses, 12 junior nurses and health care assistants . Data saturation was reached in all staff groups with no new themes emergent in all groups. The senior surgeons had between 13-44 years of experience, senior nurses had between 5-20 years of experience, junior nurses had between 1-20 years of experience whilst the junior doctors were between 1-5 years following graduation. Figure 6.1 provides a list of all the themes and subthemes that have emerged after thematic analysis.

Figure 6.1 Themes and subthemes from thematic analysis



The sections below qualitatively summarise the themes that have emerged during the interviews and include verbatim quotations (S=Senior surgeon, SN = Senior nurse, J = Junior doctor, JN = junior nurse). During the interviews participants often refer to ‘Obs’: this is an abbreviation for ‘observations’ which is the routine measurement of vital signs performed by nurses as standard care during an inpatient stay.

6.4.1 Problems with current management

All staff groups interviewed believed that there was a problem with current monitoring techniques used for ward patients. It was identified that patient deterioration was often picked up very late. Even after the introduction of early warning scoring systems bought about to detect patient deterioration sooner, these patients were still being missed. In patients that had adverse events and significant harm prompting investigations, signs of deterioration were present several hours before.

‘Well, we know that deteriorating patients are often picked late, despite all of the scoring systems that we have. Actually, when you look back at cause analysis and a lot of deterioration, there's always a sign there that was present hours before they were picked up’(S,11).

Despite all members of staff aware of the importance of taking vital signs it was known that they were not always taken in a timely manner. Staff members identified that patients were currently falling through the ‘safety net’ because of this. Even when patients’ observations were taken on time, all staff groups interviewed suggested that patients were deteriorating between the observation rounds and this was not identified. Whilst patients on the ward routinely have their observations taken 4-6 hours apart there is the potential of patient

deterioration soon after the observations are taken. This leaves the potential of deterioration for several hours prior to be identified.

‘So patients are on four-hourly obs so there could be a deterioration that you miss for three hours, three and a half hours if nobody’s coming round to do obs’ (J,7).

One of the compounding issues in late detection of unwell patients is the number of missed observations. This has been identified as a significant issue by all staff groups. Over a 24 hour period patients on average have 4-5 observations. If one of these observation rounds is missed there may be significant deterioration till the next observation round. The use of agency staff has been highlighted by both senior and junior nurses as one of the factors in which observations may be missed.

‘We had a healthcare who was agency, doesn’t really work here much, where we thought things were up to date and when we went back to check, an observation hadn’t been done, that patient had spiked, so obviously there’s that time period in between we could have been acting sooner’ (SN,11).

Both senior surgeons, senior nurses and junior doctors have identified that junior nurses are not all the same quality. The variation in nursing staff may lead to delays and patients on the ward being missed. The doctors rely on the transmission of timely accurate information being relayed to them by the nursing staff. If variation occurs in the quality of information provided, discrepancies in detection and treatment of unwell patients will occur.

‘Healthcare assistants, they are not of the same quality, the detail is not complete’
(S,4).

One of the key concerns is the lack of recognition of an unwell patient. Despite various national early warning scores there is still a failure to recognise an unwell patient. Senior surgeons have identified this as being a common problem on the ward. The assessment of the unwell patient may not be accurate or complete.

‘I see this all the time still, you know, on the wards, is this failure to escalate’
(S,8).

Practical reasons for failures in monitoring and detection of escalation have been suggested. Staff shortages are an international problem within healthcare. Additional demands consequently placed on existing staff members can result in the inability to reach patients on time. Even for patients that are already known to be unwell more frequent observations are not always possible.

‘The worrying issue I guess, at the moment, is manpower. With nurses on the ward, you cannot expect them to do hourly obs on everyone, or even 20, 30 minute obs on everyone, there’s strictly not that number of people on the wards there’ (J,10).

The night shifts are when both nurses and doctors are often in short supply. When staff are on allocated breaks, particularly at night, observations are missed.

‘If on my break or during the night-time it’s most of the time. It’s only one HCA for two bays. It’s meaning if I’m on my break definitely nobody is doing instead of me’ (JN,12).

Faulty equipment and the lack of enough observation machines has also been described as an additional problem on already busy wards. Without the appropriate monitoring equipment and sharing of observation machines delays will occur. This is highlighted by those using observations machines the most - the junior nurses.

‘You know, you’re limited with the obs machines you know, and sometimes they don’t always work, and you’ve got to share one obs machine between eight or nine patients which isn’t easy have been found’ (JN, 9).

Problems with current monitoring were highlighted by all staff groups. It is known that ward observations are not taken in a timely manner and patient deterioration is often identified late. Variations in staff quality, agency staff, staff shortages and faulty monitoring equipment have been identified as being some of the reasons why this occurs.

6.4.2 Problems with current management and patients with sepsis

As well as problems with current management for general ward patients, there are similar problems with the management of patients with sepsis. Identifying patients with late sepsis is a key problem and has been identified by all staff groups interviewed. Several critical incident reviews have found the lack of recognition of the development of sepsis in patients as a key concern and common event.

‘Certainly from some of the serious incident investigations that I’ve been involved in, the lack of recognising the development of sepsis and the lack of recognising deteriorating new scores is a relatively common theme amongst serious incident patients’ (S,2).

The biggest causes in late sepsis detection are attributable to missed or delayed observations. This occurs when nurses are busy or when there are staff shortages or agency staff. Staff identify that often patients do not like to complain or mention when they have a fever or other relevant symptoms and this may exacerbate the problem.

‘So, yeah I mean, there possibly can be a bit of a delay maybe on the wards when we are doing observations like we are, and then if things aren’t identified, or patients don’t tell us that they feel unwell, or have got pain, or feel hot, that type of thing’(SN,4).

Another reason for delayed detection or undiagnosed cases of sepsis may be due to the nature of the ward itself. The acute surgical admitting ward or Surgical Assessment Unit (SAU) can have a high turnover of patients and staff. This frequent transition from the accident and emergency department through SAU and to the ward may leave some patients with sepsis or suspicion of sepsis being missed. The worst time periods are when several patients are admitted to the ward at the same time.

‘It’s like trying to balance your time, so sometimes in SAU it is quite high turnover, so you could get five or six patients in at one time, you’re trying to treat them all, so you are trying to go around and see everyone and try and do your bits

and pieces but obviously sometimes it is quite hard to try and pick up everything'(SN,7).

Even when patients with sepsis show a sign of deterioration, there appears to be an apparent failure to escalate. This may be caused by a lack of confidence of some staff members or lack of education. Greater and sustained education of staff members may combat this.

‘Part of the whole sepsis story, it’s all about education of staff, being able to have the confidence to institute treatment, so I just, I see it so often where the patient’s deterioration is accurately monitored but then nothing’s done about it’(S,8).

With the late identification and escalation of patients with sepsis, the treatment of sepsis is also delayed. Most hospitals use the Sepsis 6, guidelines which are the early sepsis treatment guidelines(218). Whilst there is good overall knowledge and awareness about Sepsis 6 the treatment of sepsis is still currently a concern.

‘Even though we know all about the Sepsis 6 and everything else that’s connected, we’re still not good at it’(S,8).

Problems in the identification of sepsis have been found by all staff members. Just as in the detection of unwell patients, missed or delayed observations often due to staff shortages or agency staff have been identified as contributing factors in the delay. Another factor is the transitioning of patients with sepsis across several clinical wards through a very short time frame. Even when patient deterioration has been detected, there are failures to escalate

patients with sepsis. A lack of confidence and education may be why this occurs. As a result of late detection and escalation a delayed treatment of sepsis has also been found.

6.4.3 Patient Safety

One of the largest emerging themes through the interview analysis is the concept of patient safety. The use of wearable sensors and continuous monitoring should make a big impact and alleviate some of the concerns identified with current ward monitoring. Several key subthemes were identified within the patient safety theme and these will be described below.

From the narrative above there appears to be significant delays in identifying unwell patients on the ward. The great strength of wearable sensors is the anticipation in identifying unwell patients earlier, and this has been highlighted though all staff groups. The use of wearable sensors reducing human error and improving time to detection of unwell patients is a key strength of the new technology. The use of digital prompts to even more junior nurses has been welcomed and helps provide them with encouragement in raising an alarm and timely escalation should a problem arise.

‘I would hope that ultimately the system will become infallible, that is to say the human error elements of recognising a deteriorating patient will be minimised, so if your data that you’re collecting from this machine is very clear and the algorithms are very clear, the program is very clear, your patient is deteriorating, there’s an alarm system, and more than that it’s not an alarm system when the patient’s on their last gasp, but it’s an alarm system which gives you time.’ (S,8)

‘I think it’s really good that it’s happening a lot quicker and obviously using technology so that the nurses can be alerted if something sort of is going wrong so that even the more junior nurses have that sort of prompt’ (J,5)

As well as earlier detection, the new technology hopes to improve the escalation pathways compared to current systems. There will be quicker escalation of an unwell patient to the nurse looking after the patient but also to the senior nurse in charge of the ward and other members of the team including acute outreach or ICU based teams. The simplicity, speed and accuracy of new digital alerts generated by wearable sensors hope to streamline the whole process of escalation to relevant staff members.

‘It just makes the whole process of nurses escalating to doctors a lot simpler, faster and more accurate.’ (J,1)

Observation charts in most hospitals are still held at the patient’s bedside and only visible if one is on the ward and at the patient’s bedside. Centralised monitoring offers the ability of all staff groups to identify unwell patients regardless of whether or not they are on the ward. In addition the abundance of extra data captured through wearable sensors permits further interpretation of the data through trend analysis rather than just a single set of observations taken at one point in time.

‘Like, if you are not physically there, present, and you can see anywhere in the screen if the patient is unwell or is deterioration in the patient observation.’
(SN,3)

As a consequence of earlier detection and escalation of unwell patients, it is likely that the treatment of unwell patients will also be faster particularly when waiting for the next 4 hour observations. Treatment of sepsis can occur in the period of time between observations.

‘Well, in picking up, it’ll be a great idea to do that, isn’t it? Because if you know that that patient is deteriorating for whatever reason, whether it’s like oedema(?) or where it’s sepsis or whatever, you know we can treat them sooner rather than having four-hourly observations and then missing out that window, period of fortunately where you can pick up sepsis earlier. It’s great.’ (S,7)

‘So, if someone’s you know, deteriorating often we don’t detect it until their next set of obs and then we see their scoring on the new score, whereas if we saw in real-time that their heartrate’s gone above 100 and they’ve spiked a temperature then we would probably act on it quicker than we would otherwise.’ (J,4)

A key in improved patient safety is fast and accurate data. All staff cohorts associated the wearable technology and alerting systems with having greater accuracy than current monitoring systems. Different nurses taking observations can result in high variability.

‘Being objective - less variability between the measurements as you will expect between different nurses taking the observations.’ (S,1)

Whilst current monitoring provides digital readings for many observations such as heart rate and temperature, the reading of respiratory rate is taken by manual count. Large variations in the practice of taking respiratory rate have been identified and current respiratory monitoring

is prone to inaccuracies. The benefits of using new digital technologies to detect respiratory rate in particular has been emphasised as a great strength. The new technology is less subjective than current monitoring and can be used to remove human error and reduce variability. In addition, the digital display when reporting vital signs is likely to be far clearer than current paper chart systems which the staff describe as at times being hard to read. The documentation of vital signs is likely to be better than the current paper chart systems used.

‘Well, we were discussing about the respiratory rate, so I mean I don’t know about the actual technology, the feasibility of that, but it would be great to have a way of actually accurately measuring respiratory rate.’ (J,7)

‘The good points in there is to give us exactly how much is the scoring, the numbering, of the patient, that we can get the temperature, the heart rate and respiratory, so that we will then, just like sometimes when you are counting, it’s just not really accurate.’(JN,2)

The wealth of data generated by the continuous monitoring of vital signs combined with alerting systems is likely to help improve the decision-making process when identifying an unwell patient. This would be more useful particularly for junior members of staff who may be unfamiliar with very unwell patients. Digital alerting may be used to help empower junior staff members to escalate patients sooner and provide them with the confidence to do so.

‘So, in many ways, although you might say that it might be a retrograde step but actually it’s going to actually take away some of the thinking process behind warning signs and I think, you know, I’m willing to be challenged but if the

machine says yes, I think there's going to be an element of people saying, "Well, yeah, actually I need to do something about this". It's an element of probably giving people I suppose empowerment is quite a good word but it gives them more confidence to make decisions.' (S,8)

With the earlier detection, faster escalation and quicker treatment, patient outcomes are likely to improve also. This has been suggested by the senior surgeons and nurses. The likely benefit of earlier intervention is improvements to patient outcomes and reductions in both morbidity and mortality. Patient outcomes, morbidity and mortality could not be assessed as there were no real time digital alerts during this study.

'It just means that hopefully it picks up things a lot earlier, sends the alerts and then we can actually intervene a lot earlier to actually improve their outcome and reduce morbidity and mortality' (S,6)

As well as improved outcomes, it is suggested the wearable sensors will improve overall patient care.

'Improve patient care by diagnosing the sick patient earlier, getting management earlier, improving outcomes.' (S,1)

The overall profile of patient safety is likely to be improved with suggestions of a culture change.

‘You know, innovative system I think can only raise the profile and if that’s the case, if it raises the profile of the deteriorating patient, then actually patients are going to benefit as a result.’(S,8)

‘It’s also a cultural change of actually acting on the abnormalities earlier rather than later’ (S,11)

Whilst the study was reviewing new acute surgical patients, high risk patient groups were identified by participants as having the most benefit from patient monitoring. These patients included acute orthopaedic patients (often elderly with multiple co-morbidities), post-operative patients requiring close monitoring and patients stepped down from ICU or HDU settings.

Overall there was a perceived increase in patient safety across all participant groups using wearable technology and alerting systems.

‘It’s just a far superior baseline to what we currently have on the wards when we do manual obs’ (J,1)

All members of staff believed that patient safety would be improved in a number of ways. The continuous monitoring provided by wearable sensors is thought to allow earlier detection of patient deterioration. Digital alerting to nursing staff aspires to improve the escalation of unwell patients. Staff welcomed that wearable sensors permit more centralised monitoring allowing those not directly at the bedside to detect a change. With earlier detection and escalation, members of staff believed that the treatment of unwell patients is likely to be

faster. A high variability in staff collecting vital signs has been identified. Interviewed staff believe wearable sensors, which provide digital alerts, should improve the accuracy of the data particularly for respiratory rate. In addition the digital alerts are likely to empower and give confidence when raising a concern particularly junior staff members. Staff believed that wearable sensors would help improve patient outcomes, improve overall care and create a culture change within the hospital. High risk patients, such as orthopaedic patients and post-operative patients, were identified as having the most benefit.

6.4.4 Patient Safety in patients with Sepsis

Whilst a review of patient safety in general patients was reviewed above, another key emergent theme was the use of wearable sensors and patient safety in patients with sepsis. Similar sub-themes were identified to general ward patients. Earlier sepsis detection was anticipated by all participant groups.

‘Now we have a patient with sepsis and we didn’t find out at the beginning. With this machine maybe we should get the result before that, so that’s why it’s much better than to find that later in every four hours’ (JN,12)

As well as earlier detection it is likely the wearable sensors will result in earlier escalation of care by senior staff members and other teams such as critical care outreach. This was also identified by all staff subgroups. The greatest benefit highlighted is the use of monitoring and escalation out of hours and at night where staffing numbers may be reduced.

‘So, for me it specifically means escalating the need for senior review quicker, which is particularly poignant at weekends and out of hours and may be missed whether it be due to a lack of attention to the obs chart, lack of juniors, lack of doctors being alerted, whatever it is.’ (S,12)

As well as improved detection and escalation it has been suggested that there will be improvements in the treatment of patients with sepsis.

‘That’s within the management, yes, so early recognition, early management, which is Sepsis 6, it includes antibiotics, fluids, lactate, temperature observations, urine output, everything else, and escalation of treatment accordingly sooner.’ (S,1)

‘So yes, it will make it faster for you to escalate any treatments or initiate any treatments as soon as you notice if anything is off.’ (J,2)

Faster detection, escalation and treatment is also expected to result in better outcomes in patients with sepsis with overall reductions in morbidity and mortality anticipated.

‘It will highlight the patients deteriorating quicker. So, we can start addressing, getting them fluids, antibiotics, you know act more appropriately quickly, and get better outcomes for the patients.’ (SN,1)

‘That if things are picked up quicker, then obviously they will get treated quicker hopefully, and seen sooner. And, everything will be hopefully a quicker process

to identifying and treating, and with a quicker, better outcome than those that might be sat on for a little while with something brewing and we may not recognise it' (SN,4)

Overall staff members expected that wearable sensors and continuous monitoring would help identify patient with sepsis earlier and have faster escalation and treatment. Staff expected that wearable sensors in patients with sepsis would enhance patient safety, resulting in better care and improved morbidity and mortality outcomes.

6.4.5 Impact on staff

Any new technology changing normal processes or procedures can impact staff. The impact on staff was a key theme that has emerged. Overall it was felt by all staff cohorts that the new technology would benefit staff in a positive way. Senior nurses described how there was no negative talk on the wards about the technology at all and members of staff were in strong support of it.

‘Everyone has been positive about it, I have not heard, you know because everyone talks, I have not heard any negative opinions or negative talk about it.’
(SN,1)

In an acute setting the demands on all members of staff can be great. One of the best benefits is that wearable sensors would help save time for all staff members involved.

‘It also saves doctors time as well in the sense that they know what’s appropriate and what they actually need to go’ (J,1)

The wearable sensors and continuous monitoring have been identified by the nursing staff as being an extra help to staff. This occurs through helping direct staff to those patients that are unwell as well as improving escalation and communication.

‘It gives us an idea of which patients we need to be looking at, you know, more promptly, who we need to be directing the nurses to, who we need to be sort of escalating to you guys, sort of more quickly, and just so we can try and avoid that deterioration, you know, of condition sooner, or the earlier we can pick things up, the better it is going to be for sort of all of us and the patient mainly.’ (SN,8)

As described above all staff cohorts identified problems with current monitoring platforms. A real strength of wearable technologies used in monitoring is the implied suggestion of better monitoring than current standards.

‘It will much better than what happens now you rely on healthcare assistants, they are not of the same quality, the detail is not complete, you come to see the patient, you see nurses get very busy and they have interval where there are no assessment done and by then you pick up, you pick that the patient is actually deteriorated, sick’ (S,4)

‘Sometimes the ward is really busy, and we cannot do their observations all the time, for some reasons. If the patient is monitored, that’s going to be much easier, and we’re going to see all the time.’ (JN,4)

Another crucial strength identified of wearable sensors is the ease of use and interpretation. The placement of the sensor and logging it onto the computer system takes around 5 minutes. Thereafter, little else is needed by nurses. The electrodes on the sensor are replaced every 24 hours and this is usually performed in the morning after patients have had a wash. If the patient remains in hospital for longer than 5 days, the wearable sensor will need to be replaced.

‘It’s not difficult. Stick it on, plug it in.’ (S,8)

In addition to the ease of use, the practicalities of monitoring were also another asset. The wearable patch is significantly reduced in size compared with normal monitoring systems. The current monitoring technology needs a power supply so the portable machines must have enough charge. The portable observation machines used currently are much larger in size and take up a great deal of room. The use of miniaturised wearable sensors is extremely beneficial when the space around a patient’s bed is limited.

‘Well, I think first and foremost it’s very, it’s very practical, you know, it’s not a big piece of equipment that, as we know, the bed spaces are really like small with patients’ bed and all that, with the machines that we have at the moment, but this is something really practical and handy that it’s just attached to the patient.’

(SN,6)

Junior members of staff may be unfamiliar in managing acutely unwell patients or those that suddenly deteriorate. Identifying an unwell patient can be challenging and stressful by all. Junior staff worry about the balance between not wanting to miss unwell patients yet at the same time not raising an alarm unnecessarily. Wearable sensors and digital alerting can help provide juniors with both empowerment and confidence in their decision making.

‘So, in many ways, although you might say that it might bit of a retrograde step but actually it’s going to actually take away some of the thinking process behind warning signs and I think, you know, I’m willing to be challenged but if the machine says yes, I think there’s going to be an element of people saying, “Well, yeah, actually I need to do something about this”. It’s an element of probably giving people I suppose empowerment is quite a good word but it gives them more confidence to make decisions.’ (S,8)

The impact of wearable sensors on staff workload was generally very positive. Most staff groups felt that workload would be reduced overall with the ability to allow for staff multitasking.

‘I think it lessens some of the work that the nursing staff need’ (J,1),

‘You have to do hourly yeah? It’s not enough staff for, sometimes for this, so this would be felt to take the workload from us’ (JN,1)

‘That you don’t need to be all the time close to the patient. You can manage a lot of jobs in the same times, and when the patient does change his pattern, you’re

going to see on the system quickly, because you're going to receive the message.

I think it's a very good point.' (JN,4)

However, there were a few concerns predominantly held by junior doctors that the workload of nursing staff may increase. The alerts generated from the wearable sensors would need to be actioned. If many alerts were generated it was felt this may add to the burden.

'When the nursing staff are busy and they are having to deal with more alerts and things like that, that is the only thing I can think of that would be ... not a barrier but if they are getting phone calls, they are doing this, that and the other and then they are getting the blip, the phones going off. If it is going off quite a bit, it is going to be difficult to triage, it might end up having to have a protocol for it I think, just to make that a bit easier for the staff, rather than having lots and lots of alerts going off and they are trying to do lots of different things at the same time, because usually they are quite busy as it is'.(J,11)

There were other concerns raised by junior doctors that were not found in the other staff groups. One concern was that the use of the new technology could in some way be used as a blaming tool particularly in cases where unwell patients had deteriorated, and when these alerts were not acted on in a timely manner.

'So, what I would be worried about is that it sends too many, too many alarms to staff and therefore staff gets bored of it and/or start to ignore it. They then become a blaming tool because it sort of you know, registered it as a problem, but then if it's not been acted on, then it becomes somewhere where it's more like a

legal sort of thing and people could use it towards that, when saying like oh, this machine picked it up but you didn't go for two hours and so and so, and such and such.' (J,3)

Another concern held by junior doctor groups was the potential concern over job losses if the new monitoring system through wearable sensors becomes too effective.

'There's always a new problem because number one that obviously if you introduce this thing, might actually put some people's job in danger for example Healthcare Assistants. There's no need to do observations on a regular basis because this thing does it for you, and I suspect that this can be you know, upgraded into blood pressure so in the future then these people will for example, lose their job.' (J, 3)

Most staff groups felt that wearable sensors would have a positive impact on staff.

Wearable sensors and continuous monitoring were thought to help save time for staff and allowed better monitoring than current standards. The ease of use of wearables sensors and their comparative miniaturisation were additional strengths. Overall it was felt that the deterioration alerts could be used to help empower staff members to escalate a patient and this may be most useful for junior staff members both nurses and doctors. Most staff groups felt there would be an improvement in the workload. However junior doctors were concerned that the workload for nurses might be increased if numerous alerts were generated and required actioning. Another concern by junior doctors was the device being used as a blaming tool particularly in cases of deterioration that were not actioned in time. In contrast if the technology was too efficient and worked well junior doctors were concerned that this may

lead to job losses particularly for junior nurses. Whilst these concerns were raised predominantly by junior doctors, the technology was still welcomed by all staff groups.

6.4.6 Impact on patients

All participant groups addressed the impact on patients and felt that it would help patients and offer improvements in patient care when compared to current monitoring techniques. This is found in several of the themes above with improved patient safety, earlier identification of unwell patients, earlier escalation of care and treatment. In addition, it was thought that specific patient factors would contribute to acceptability by patients.

The first emerging theme was that of patient comfort. It was felt by all participant groups that the wearable sensors would be far more comfortable than current monitoring. As to our knowledge, no specific complaints by patients were made to healthcare staff.

‘I never heard any patient complain, if they had any allergy or they found it uncomfortable, I never heard any patient complain about it.’ (JN,3)

Patient comfort was largely attributable to the smaller size of the monitoring unit than current technology and this was mentioned by all participant groups. The smaller size of the wearable sensor allowed for more discrete monitoring of patients and it was felt that this would improve patient compliance. There were no apparent complaints about the sensors falling off or having other problems.

‘I think they’re good, they’re very discreet, they’re sort of ... when patients have them on they’re not, you know, an inconvenience to them, none of the patients seem to complain about them. They seem to be, you know, they haven’t complained of any problems of them falling off or, you know, they seem to be sustaining well, so I think they’re good in that sense.’ (SN,12)

Both doctors and nurses commented that because the wearable patch was so discrete patients themselves had forgotten that the wearable sensor was on. This acceptability by patients and apparent comfort was identified as being important in future sensor use.

‘It doesn’t disturb patients much. Most of the ones that I’ve seen haven’t found that – they’ve even forgotten that it’s on them, so they don’t feel that it’s causing any particular distress or more pain for them’ (S,12)

The wearable sensor was thought to be easy to wear by staff cohorts. Practically there were no problems identified by patients carrying out their normal day to day tasks for example washing.

‘I do think it’ll be very beneficial; but no, it’s good, especially that it’s so small, you don’t even notice these things, even when they’re washing and things, there’s ... they’ve said they’re fine. We’ve had really good feedback from the patients about it.’ (SN,7)

As well as being discrete, the patients felt it was non-invasive and this was a real strength of its use. The patient did not have to do anything extra for the patch to be used.

‘Yeah, I mean it’s really inobtrusive, it doesn’t bother the patient, non-invasive’
(J,7)

A key theme was the use of wearable sensors in monitoring patients at night. It was felt that the benefits of wearable sensors and monitoring at night would cause overall less sleep disruption. Patients could be monitored whilst they were sleeping without having to be woken up thus minimising sleep disruption for patients. Junior nurses discussed their embarrassment at having to wake a patient up whilst sleeping for monitoring and the disruption current monitoring systems cause. The reassurance of sensor monitoring at night was found to be very important amongst junior nurses as these are often the staff groups that would have to wake up patients at night.

‘Everything, it looks like just perfect with this. Very small for the patient, it’s very comfortable, I don’t have to, if he’s sleeping, I don’t have to wake him up. Okay, just lift up your hand, I have to put over there. So many times it’s embarrassing for the patient if I put it over there during the night-time, for example, he’s coming out from the surgery or theatre and I have to wake him up every half an hour or every second hour or whatever. This is, my God, he’s sleeping it’s giving information right away so all the best.’ (JN, 12)

Staff members identified that one of the strengths of this wearable sensor system is that it does not cause any distress to patients by noises or alarms. The patch looks the same to the patient even when alerting. The signal is only transmitted to staff on any deterioration. Thereby any potential disruption caused to patients is minimised.

‘Quite discreet for the patients I suspect generally, for most of them. There is no noise comes from it.’ (SN,4)

Staff members have found that the overall the feedback from patients has been very positive. The small sensor size enabled more discrete monitoring with many patients informing staff members that they had forgotten the sensor was on. Patient comfort, ease of use and the potential for improved monitoring overnight with the least disruption to patients were identified as being the greatest facilitators to wearable sensor use. Based on their examinations the staff felt that the wearable sensors and continuous monitoring would have a positive impact on patients.

6.4.7 Changes

All staff members were questioned on the potential changes that may be made to the sensor. A total 54% (26/48) of participants thought no changes were required if we were planning to implement the technology again. Whilst the size of the patch was not identified as being a problem and far smaller than current monitoring, it was identified by all participant groups that the wearable sensor size was likely to change in future with a greater demand for reduced sensor size as technology advanced. Staff members believed that the smaller size would further improve patient acceptance and usability. The balance for a smaller size versus the practicalities of sufficient surface area for monitoring and to ensure adhesiveness was discussed.

‘I mean, the only thing that I can think of is that eventually as with all things, it will probably get slightly smaller. So, more for patient comfort you know, if they are hot and sweaty because they are running temperatures, it might be a bit more comfortable if it was smaller, but you need to have a good adhesive layer on it to keep it sticking. I know it’s press studs, but the underneath bit. But, yeah like everything, it will eventually get smaller and more easy, more comfortable to wear anyway’ (SN,1)

Whilst the current sensor is able to measure 3 vital sign parameters, staff participants felt that more parameters should be added in future to allow for a more complete form of monitoring. The addition of blood pressure was felt to be a real strength and the most common additional parameter identified, followed by the addition of oxygen saturations. Whilst the addition of blood pressure was welcomed, it was understood that continuous monitoring of blood pressure through lightweight wearable sensors may be difficult.

‘I guess the only thing that’s really missing is, like, the BP, but I think that would be quite hard to add in.’ (J,9)

Another suggestion was alternative placement for the patch itself. This was suggested only by the doctor participants asked. Alternative sensor placements suggested were the upper arm, wrist and necklace designed sensor.

‘I mean, the only thing is whether it can move to being a wearable technology on for instance the wrist, whether having a wrist wearable technology would help.

Because then you could snap them on the patient when they come in, and then it's not really that impeding, I guess' (J,10)

A change to the temperature wire was suggested by some of the junior nurses. At times it was felt the wire was hanging down; it was also suggested that a straighter wire might be more comfortable than a curly one.

'I think the wire. I think sometimes, because it was like down by the arm, sometimes that was a problem' (Jn,11).

Other suggestions were the addition of a hypoallergic patch for those patients who may have an allergy and that wearable sensors could be compatible with forms of imaging such as Magnetic Resonance Imaging.

Several changes were suggested by staff such as further miniaturisation, the additional of other vital signs sensors, alternative patch placement, i.e. wrist and changes to the temperature wire as mentioned by junior nurses. These changes to the sensor were recommended for future sensors.

6.4.8 The future

All staff participants strongly felt that this technology was the future and would replace the current monitoring systems.

'That's the future of healthcare.' (S,1)

‘You know, like I said I think the way the future is, everybody will be wearing them at some point’ (JN,9)

There was a feeling across all staff participants that this was a positive concept and an innovative tool. The staff participants welcomed the use of the new technology in healthcare and felt a need for the technology.

‘I think it will probably aid in a positive way, that we will be able to, because things will be maybe highlighted a bit sooner, that patient may not become as unwell as what they would if were just manually doing observations every four to six hours, or whatever’ (SN,4)

‘100%. I think the concept is needed.’ (J,10)

Suggestions were made by both senior and junior doctors on the use of wearable sensors in monitoring patients at home following discharge. Some patients may wish to have their own sensor readings particularly when in the home setting. This could be used to create further reassurance after patient discharge as well as providing them with confidence to seek a healthcare opinion if there was a problem.

‘Also if these could be rolled out to patients who actually go home, so they could monitor themselves at home, and maybe all of their information could be stored on some kind of database, so that the information, the patient basically feels that they own their own data. I think there is a lot of talk now about in the health tech industry about patient ownership of data, and I think quite a lot of the patients

would be quite interested to see trends in things like their heart rate for example, when they are recovering from an operation, it might give them peace of mind and might make them feel more able to go to their GP if they have got these parameters at home and they can see them for themselves. So I think basically what I am trying to say is rolling it out into maybe a community setting might be something to consider in the future. (J,12)

The use of monitoring in future of post-operative patients and step-down patients from higher levels of care was suggested. These patients were not given additional monitoring in this study as only acute admissions were eligible. However post-operative and step-down patients often need more frequent monitoring in a ward setting and are at a higher risk of sudden deterioration. Senior nurses identified them as being another patient group that may benefit from such close monitoring in future.

‘Since I am covering the surgical areas I do have a lot of surgical patient post-op, which is, I think, it is really important because these are the type of patients that can suddenly just become unwell following surgery. Also, obviously, it will help because when this patient comes back to the ward from, like, for example, an HDU step-down we have to monitor observations regularly, so, having this will obviously, will influence the action that we do and the plan of care that we do for the patient knowing that if there is an increase in the heart rate or, you know, or a decrease in the heart rate or any of the parameters that this sensor is recording it is very vital because obviously it can help us recognise any patient that is deteriorating on a specific time and plan in a timely manner as well’ (Sn,6)

Other suggestions were that the data in future be used for both research and audit purposes in addition to clinical use. Trends in the data could be used with clinical data to identify and monitor treatment strategies. The wearable sensor data could also be used for audit purposes.

‘So, for instance, if we ever wanted to have a look and see how our treatments are working and what the actual timeline or timeframe is for vital signs to actually normalise, grab all that data and use it for audits as well?’ (J,10)

Time with patients was thought not to be affected by the new technology with 40/48 participants saying there would be no effect on contact time with patients.

Wearable sensor use in future was highly likely and staff groups thought it would replace current monitoring techniques. The use of wearable sensors was recommended in all patients and not just the medical and surgical patients in the study. In addition the use of sensors at home was highly likely as well as use of data for research and audit purposes.

6.4.9 Staff training

Only the junior nurses underwent specific training on the placement of the wearable sensor and how to review monitoring. Out of all junior nurses asked, two did not receive formal training. There were no negative comments on the training. Overall the feedback from the training was positive with an appreciation of the practical training on placing a wearable sensor on the patient as well as a discussion on the patch. One participant mentioned that refresher training would be useful, particularly on clinical wards where the patch use had been limited. More practice was needed by one staff member and another participant felt that

the more staff that were trained the better. Whilst the new technology was welcomed by all the junior nursing staff, it was felt that some of the older nurses might not appreciate such technology and find it challenging.

‘I really like the new technology because I born and I grow up like this. But we have some of the 60 and over 60 years old nurse. I’m not pretty sure they can handle it and even they cannot absorb that. They’re going to a way – yes, they’re going to scare from this kind of new technology.’ (JN,12)

6.5 Discussion

To our knowledge this is the first study which provides a novel pan-stakeholder review of wearable sensors for surgical ward patients. Several key themes have emerged including; the current necessity for new technology, patient safety, patients with sepsis, impact on staff and patients, changes and the potential for the future.

6.5.1 The necessity for change

The necessity for changes to current monitoring methods was clearly identified by all staff groups. The highlighted problems were centralised around the current late detection of unwell patients. Failure to recognise and respond to patient deteriorating in hospitals is a major cause of morbidity and mortality (34)(35)(36)(37)(38). This was often attributed to missed observations and a lack of recognition of unwell patients. NCEPOD data shows that clinical deterioration may present several hours prior to an adverse event(34).

Staff factors were also highlighted including the use of agency staff, not all staff members being of the same quality and staff shortages especially overnight. Lower levels of registered nurses and high levels of admissions per registered nurse have been associated with increased risk of death during a hospital admission (219)(220). The nursing skill mix has also been associated with patient safety. A greater proportion of professional nurses is associated with better outcomes for patients and nurses (221).

The current working climate of surgical wards has the potential to cause delays in identifying unwell patients. As the demands for hospital beds grow, fewer beds are available causing a negative effect on acute admitting wards with acute patients staying longer on such wards.

Problems with current observations were also identified with not enough observation machines being available particularly at times when there were several unwell patients on the ward. The staff highlighted wearable sensors being used to fill in many of these gaps.

It was acknowledged that patients with sepsis were often missed with a lack of recognition. Delays were identified in detection, escalation and treatment. In patients with sepsis early detection is crucial. For every hours delay in sepsis the mortality goes up by 7.6% (12). Alternative ways to identify these patients are required.

6.5.2 Patient Safety

Wearable sensors provide continuous monitoring, and this hopes to make a huge positive impact on patient safety. As opposed to conventional observations taken at 4-6-hour intervals, the prospect of continuous monitoring is thought to result in earlier recognition of unwell patients, faster escalation and treatment. Centralised monitoring platforms providing remote monitoring of patients vital signs information offered staff reassurance. Poor documentation of vital signs has been consistently found using current monitoring techniques with respiratory rate being the vital sign that is often missed (63). With improved documentation and suggestions of better accuracy, staff were more confident about the observations recorded. Interpretation of the observations by the whole team was easier. It was hoped by staff participants that this would result in better patient outcomes, improved care and quicker discharges. The earlier discharges may result in significant cost savings which will be offset against the additional costs of the monitoring technology and supporting systems. With current surgical wards being overstretched, any potential assistance of new

technologies was welcomed and thought to improve prioritisation and multitasking. Overall the culture and awareness of unwell patients was thought to be improved.

6.5.3 Impact on staff and Nursing workload

There was overall very positive feedback by all staff members with the belief that wearable sensor monitoring would benefit staff and allow better monitoring than current systems used. The practical applications of small sensors being used where bed space was limited were identified. This was combined with the use of the new technology to provide easier interpretation, improved documentation and help with decision making. Overall it was felt that communication between the nurses and doctors would be significantly improved.

There was a conflicting view on nursing workload. Whilst many participants believed that the workload would improve using the new technology, it was the junior doctors who highlighted concerns of increased work load for the nursing staff particularly once the process was alerting. ‘Alarm fatigue’ is currently a problem in hospitals where various kinds of alerts are being generated not only from electronic health records but also inflatable mattresses and syringe drivers (222). With such frequent alarms there is the chance that nursing staff may become desensitised to them. Sensitive and specific alarms must be generated which correctly identify the unwell patient (222). Novel ways of interpreting such large quantities of data generated from wearable sensors may be required and one suggestion is through the use of trend analysis platforms. Whilst the sensor used in this study had specific vital signs transmitted, other monitoring technology may provide the opportunity to transmit waveform data from the ECG, for example, which may provide a more accurate picture of a patient’s physiological health.

A strength of the wearable sensor used in this study is the relatively long battery life compared to other sensor competitors. The sensor would only need to be replaced after 5 days during which most patients will have been discharged. This will help to reduce the workload on nurses by minimising the time needed to replace and recharge batteries.

There were a few concerns held by junior doctors that the technology might be used as a blaming tool if alerts were not acted on and if the technology were efficient the result might be job losses. These concerns were not echoed by other staff groups.

6.5.4 Impact on patients

All staff groups felt the technology to have a positive impact on patients and improved care. It was felt the wearable sensor was comfortable and well tolerated by patients. Staff groups reported that many of the patients had forgotten that they were wearing the sensor due to its small discrete nature and ease of wear. This reaction is unlike an earlier study on wearable sensors where 19% of patients took the sensor off prematurely due to patient discomfort (222). Patients had fed back to staff that strength of the device was no noise or alerts being fed back to the patient. Other strengths were the perception that patients may not need to be woken at night for routine sets of observations if all other vital signs telemetry was normal.

6.5.5 Suggested sensor improvements

Whilst the overall acceptability of the sensor was very good, there were a few suggestions on improvement. The first of which commented by all staff members is that the sensor is likely

to get smaller in future. Other suggestions were the inclusion of other parameters such as blood pressure. The continuous monitoring of blood pressure through a wearable device is challenging. A lightweight wearable sensor that is comfortable to patients and continuously measures blood pressure accurately is yet to be found. Another suggestion was the addition of pulse oximetry. Whilst pulse oximetry data would be very useful, it is often measured using a finger probe. This may be quite uncomfortable and distracting for patients if worn continuously. The ear has been used as an alternative site for a pulse oximeter but this is far less common. The balance between adding additional parameters and still maintaining a lightweight wearable sensor comfortable to patients is challenging.

Suggestions were made to change the way the sensor is worn. This was suggested by both senior surgeons and nurses. Possible wrist worn sensors or necklace sensors were suggested as possible alternatives but only if the chest-based sensor was not comfortable to patients. Other suggestions were the use of hypoallergic sensors available for patients at risk of allergy and sensors compatible with imaging, so patients were not required to have them removed when in radiology.

6.5.6 Future

All staff participants agreed that wearable sensors were the future of healthcare and likely to stay. This is an important finding considering all the new technology that is currently flooding healthcare. Participants viewed the technology as positive and innovating. It was anticipated that the sensor could be used for all patients in future. Certain groups of patients were identified as perhaps having the greatest benefit of this technology including post-operative surgical patients and patients recently stepped down from critical care. It may be

that further research reviews wearable sensor use in post-operative patients and those stepped down from higher levels of care in future.

Unlike traditional monitoring, which has several sets of observations a day, wearable sensors provide an enormous amount of data in comparison. It was highlighted by staff participants that another benefit of this technology is that it is likely that such wealth of data be used for research and audit purposes in future. It may be particularly useful when reviewing treatment options in patients.

6.5.7 Wider Literature

Whilst there is a limited evaluation of staff perception on wearable sensors and continuous monitoring in surgical patients, one recent study has been performed(216). In this study a wrist worn device was used (216). Similar findings were found to this research in which a clear need for the technology was identified. Staff were enthusiastic over the prospect of continuous monitoring and the perceived advantages it would allow through earlier identification of patient deterioration, patient reassurance, and support interdisciplinary communication (216). For successful implementation of new technologies, training and improved interdisciplinary communication were identified as key requisites (216). The study identified that staff training is a key requirement in the introduction of continuous monitoring devices(216). In particular education on placement of patches, device operation, interpretation of data and actions required in response to data(216). Staff training and good communication are pivotal to ensure successful implementation(223). Suggestions have been made for the use of ward champions in troubleshooting issues(216). Whilst the study by Prgomet et al added to the literature base on staff feedback there was a lack of a pan-

stakeholder approach with feedback from only 2 doctors being included, and it is unlikely that data saturation was met in this staff group (216).

6.5.8 Strengths

This is the first study of its kind to provide a pan-stakeholder review of the new technology including junior nurses, junior surgeons, senior nurses and senior surgeons. Staff participants were recruited from all 4 clinical wards with surgical patients. A clear need for the technology has been identified by all staff groups. All staff members approached were willing to take part in staff interviews. Staff engagement during the study was high and the feedback thus far has been overwhelmingly positive. Staff feedback also highlighted that patients found the monitoring comfortable with many forgetting they had it on. For the adoption of any new technology end-user feedback is very important both for staff and patients. From the results, we can see that the device was easy to use. For a continuous monitoring device to be widely adopted and useful it must be easy to use(75).

6.5.9 Limitations

Despite the fact this study was conducted over 4 clinical areas, the study was single centre and thus the findings may not be generalisable to other hospital settings. Though the Sensium wearable sensor was used in this study, findings on patient comfort and ease of use for staff may not be transferrable to other sensor technologies. In addition the wearable patches in the study were being used for research purposes and real-time alerting was not yet established. It may be useful in future to repeat the interview with staff members after digital alerting is established to review if any opinions about the technology should change. It might be that

feedback may not be so positive if real time alerting was being used and new problems may occur.

6.5.10 Conclusion

A pan-stakeholder approach has found wearable sensors to be a useful tool in identifying unwell patients and improving patient safety. In addition it is hoped by staff that wearable sensors will result in earlier escalation of care of unwell patients and treatments. It is hoped that the technology will help both staff and patients. Whilst limitations on use were identified, the feedback has been overwhelmingly positive and wearable sensors according to staff participants certainly will be the future of healthcare.

Chapter 7 A pilot study to investigate real digital alerting on the time taken to identify unwell patients and those with sepsis.

7.1 Introduction

The thesis has reviewed the role of digital alerts in sepsis outcomes and new wearable sensor technologies. The reliability of the chosen device as well as simulated time to alerting for unwell patients have been assessed. Patient and staff experience of this wearable sensor technology and continuous monitoring have been explored through questionnaire and interview studies. Through synthesis of the knowledge and learning in this thesis thus far, such as the use of the 10 minute window and models of alerting, the use of real-time digital alerts sent to the clinical teams will be explored in this chapter.

The utility of real-time alerting sent to the clinical team via a smartphone or handheld device is unknown. Wearable sensors that measure vital signs and send digital alerts to the clinical team when deterioration is suspected are not currently used in health care systems as part of routine clinical care. In chapter 4 all alerts were simulated and the time to alert acknowledgement reviewed.

This chapter describes a pilot study which reviews the average time to alert acknowledgement by nurses using real time alerts from wearable sensors.

7.2 Aims

To investigate if the use of real time digital alerts sent to healthcare staff can improve the time taken to identify unwell patients and those with sepsis.

7.3 Methods

7.3.1 Study Design

A prospective cohort pilot study was performed on the use of wearable sensors and digital alerts sent to members of the healthcare team in real time. There was a sequential recruitment of patients with no randomisation. The point of patient deterioration detected by the sensor was compared to the time of acknowledgement of deterioration on the application as completed by the healthcare team. It was hoped that by using this application and the wearable sensor all patients with abnormal vital signs for HR, RR and temperature would be promptly highlighted.

7.3.2 Study Location

The Surgical Assessment Unit (SAU) and Richmond wards were chosen for the digital alerting study for a number of reasons. Previous experience identified that there was a high chance that patients on AMU would be transferred to outlying wards within 24 hours, particular over the winter periods when bed capacity is tight and occupancy high. The length of monitoring for patients on AMU was less than on SAU. Syon 1 had many chronic surgical admissions and both Syon 2 and Osterley wards had very few recruited patients in previous studies. In addition, the staff on SAU & Richmond wards were very keen to be involved in the alerting phase.

7.3.3 Participants

All acutely unwell surgical patients admitted to SAU and Richmond wards were eligible to be included in the study.

7.3.4 Recruitment

The pilot study was commenced in May 2019 and was completed in August 2019. The same inclusion and exclusion criteria were used as reported in Chapter 4. All new surgical patients, aged 18-95, who were expected to remain in hospital for at least 24 hours were eligible for recruitment. An information sheet outlining the sensor technology was given to all eligible patients (Appendix 3.1). Written consent (Appendix 3.2) was obtained for all patients taking part in the study to wear the sensor and complete the patient questionnaire. It was mandatory that all patients give written consent, for recruitment to proceed. If any patient was unable to consent or withdrew consent, they were excluded from the trial. All patients were made aware that they could withdraw from the study at any time and their clinical care would not be affected if they did not take part. Additional exclusion criteria included patients with a skin condition on the chest wall, an open chest wound, those with a mental health illness, patients with a pacemaker or defibrillator and any condition in which the judgement of the clinical team excluded patching.

7.3.5 Staff Training

Unlike in chapter 4, where only the healthcare assistants were trained, in this study all nurses on SAU & Richmond wards received mandatory training. Only those who had received the mandatory training were able to place the patch. The training and support were provided by the manufacturer. A copy of all staff rotas for the nurses was obtained and staff training was

performed between April and May 2019. The manufacturer has several nurse champions who performed the training. Staff training consisted of a designated hour off the ward, free from clinical commitments. Training was performed in an adjacent room off the ward and consisted of an online training session and a hands-on training session in which staff were required to place the sensor on a participant (usually another member of staff) and enter the patient onto the Sensium system. A short online assessment was performed by all participants at the end of training to test appropriate levels of knowledge and understanding prior to sensor use.

7.3.6 Updating Software

All hospital servers required updating prior to the alerting stage. This required a request for change form to be completed and several reviews by the hospital board for this to be accepted. Any changes to software or hardware within the Trust are carefully managed to ensure the safety, quality and functionality of the Information Technology (IT) services within the trust.

7.3.7 The alerting device

The device providing the alerts to the clinical team is very important. Ideally the device should be well accepted by staff members and easy to use. Whilst previous studies on alerting device have focused on digital alerts through electronic medical records, this required healthcare professionals to log onto desktop-based computers removing them from a patient's bedside. Newer mobile devices are gaining popularity enabling data to be seen at a patient's

bedside and immediately reviewed without the need of logging onto a desktop-based computer. In addition, the focus is to keep the health care professional at the patient's bedside. On busy wards computer terminals are often in short supply, causing staff to wait. The Surgical Assessment Unit, a busy general surgical admissions unit at West Middlesex University Hospital is a prime example of this with only 3 desktop machines available for all nurses and doctors.

One of the alerting device platforms researched was that by Ascom which uses purpose built smartphones designed for healthcare(224). The ASCOM Myco was one of the devices explored as it has a secure messaging service, allows prioritised critical alert notifications and supports centralised management systems. An image of the Ascom Myco can be shown in Figure 7.1.

Figure 7.1 The Ascom Myco 2 alerting device



Sensium had collaborated with ASCOM previously at other sites and this partnership had worked. In the initial planning stages Sensium did not have a secure application or device for alerting. However, during the course of the year Sensium expanded and created a purposeful application that could be used on smartphones. Sensium were now increasingly using their application more and this was being tested in several other hospital sites for research purposes. It made more sense to use both the device and application provided by Sensium, so this application was chosen over the Ascom alerting system.

During the planning stages of the project there were several iterations of the application. One of the biggest challenges in the project was identifying the appropriate set of actions to be taken by staff.

The study required several key actions to be identified on the application:

1. The exact date and time stamp when the patient had deteriorated.
2. The time in which a member of staff acknowledged patient deterioration based on vital signs from the sensor.
3. The times for when the clinical team identified a patient with potential infection.
4. The times for when the clinical team identified a patient with sepsis.

The latest version of the Sensium application (version 2.6.1) was used for the alerting study.

The list of acknowledgements for the nurses could now be adapted on version 2.6.1 to include acknowledgements for sepsis or infection. The final list of all acknowledgements to be completed by the nurses can be found in Table 7.1

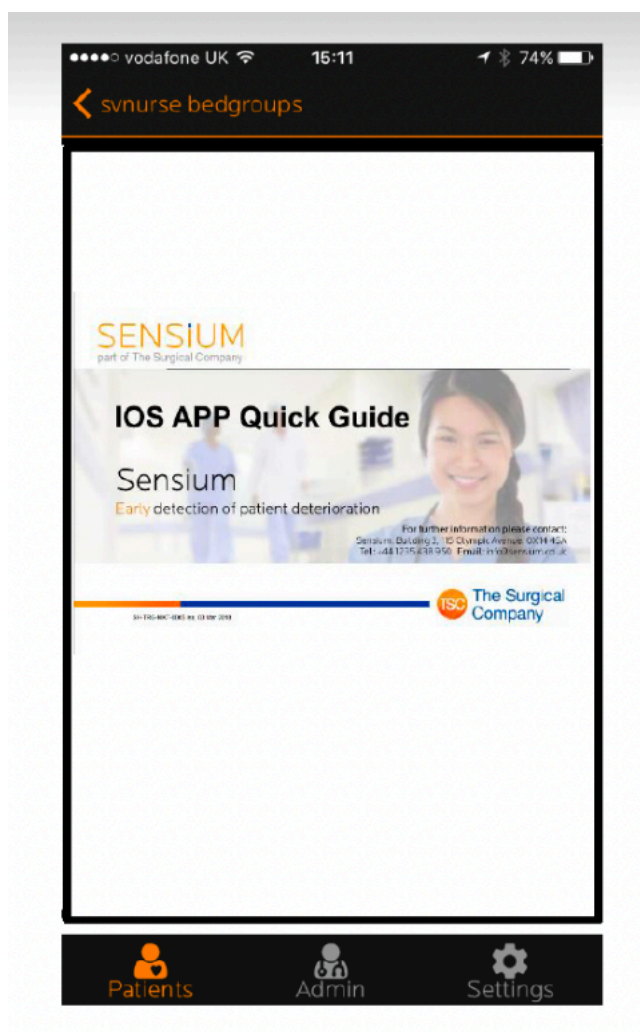
Table 7.1 List of actions on the application to be acknowledged by nurses when there are changes in vital signs.

<u>List of Actions</u>
Reapplied electrodes
Patient is off the ward
Patient is eating / talking / sleeping
No action taken
Observations recorded
Increased routine observations
Suspect patient is unwell
Refer to a senior clinician
Suspicion of Infection
Suspicion of Sepsis
Initiate Sepsis Pathway

All applications were installed onto a smartphone available for each staff member. Both SAU and Richmond wards were given 16 smart phones, 8 for the day team and 8 for the night team. The smartphone was picked up by all nurses at the start of the shift and left to charge at the end of the shift. All trained members of staff were given a secure username and password to log onto the application. As well as the handheld devices, there was also one central desktop with the application to be viewed on a larger screen if required by the nurses. This screen was only used for the study. The research team and the Sensium nurse champion were all available to support the healthcare team with the application and the sensor during normal working hours Monday to Friday. In the initial few months of the study the team were also

available to help at the weekends and on some nightshifts. In addition there is an online help section for all users of the application, which guides users on the functionality of the application. An image of the interface can be seen in Figure 7.2.

Figure 7.2 Online help section for end-users. The Sensium® App. Image used with permission from SENSIUM (Abingdon, United Kingdom)) (not real patient data)

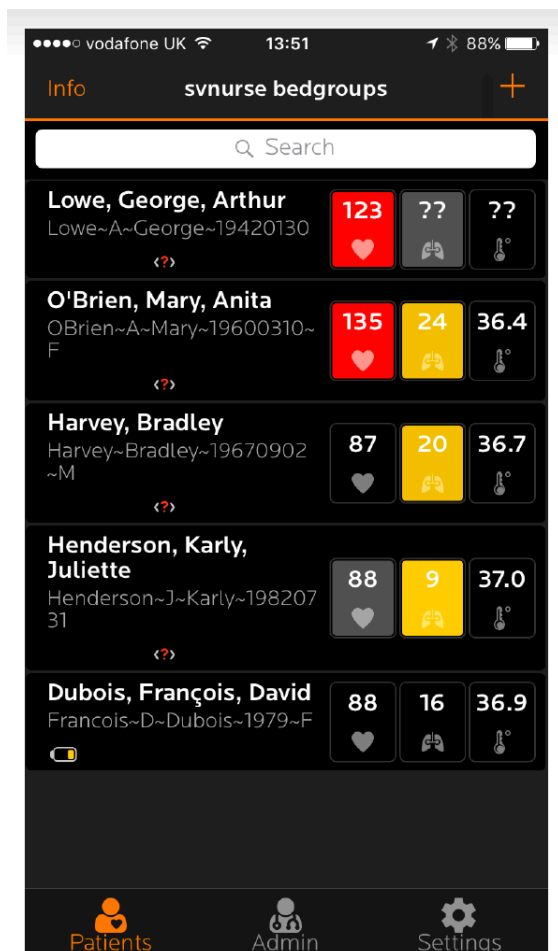


End-users typically interfaced with a home screen that showed all the patients within a certain bed group (Figure 7.3). The patients details, as well as bed numbers and placement on the ward, were highlighted. All names, bed numbers and vital signs shown in the display are

for demonstration purposes and not real patient data.

Figure 7.3 An image of the home screen with patients highlighted. The Sensium® App.

Image used with permission from SENSIUM (Abingdon, United Kingdom) (not real patient data)

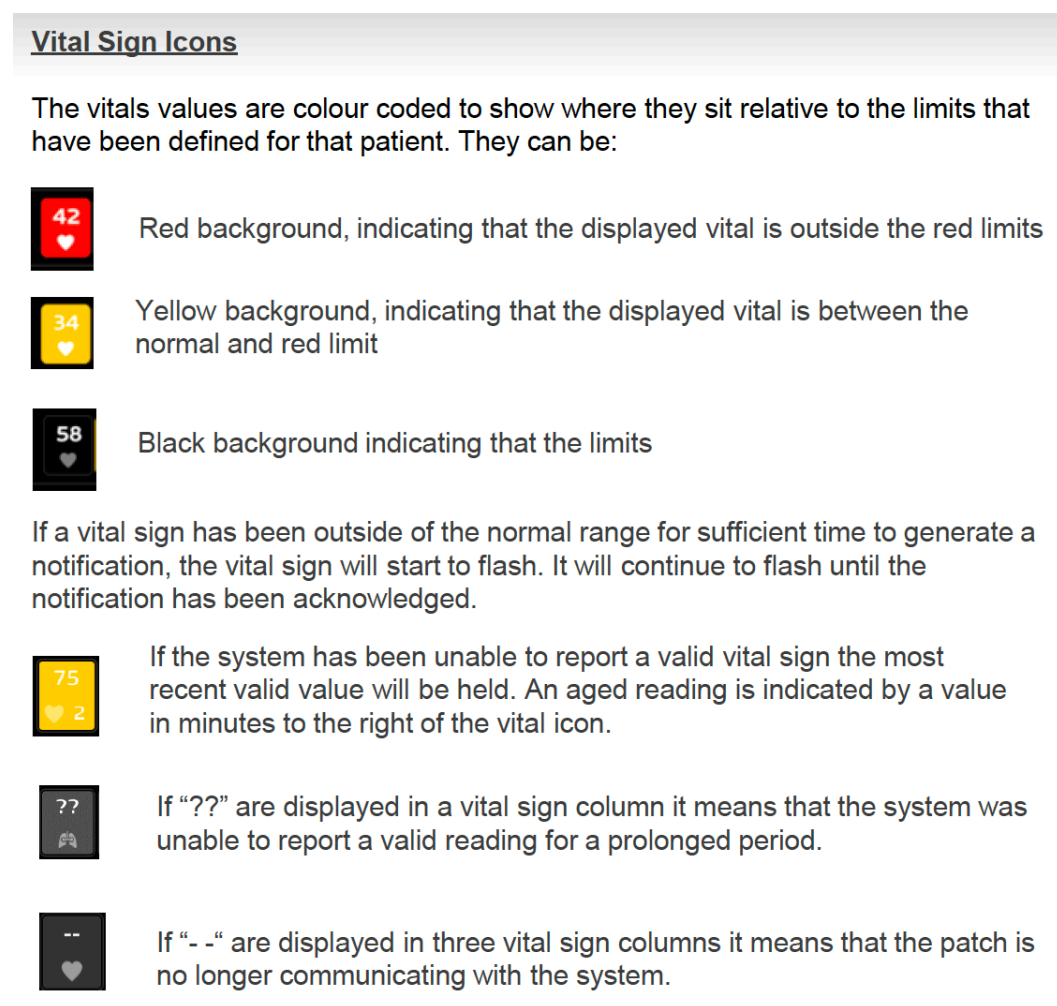


Vital signs with a red background highlight indicate the patient had a NEWS score of 3 for that particular vital sign. Vital signs with a yellow background indicate that the vital sign is between the normal and red limit and the patient is within the at-risk group. If vital signs are in black this indicates that the vital sign is within normal limits.

If there was a vital sign that was outside the normal range for 10 minutes (as identified in Chapter 3) an alert was generated and the vital sign would flash on the display screen. This sign would only stop flashing if the alert had been acknowledged by the nurses.

There are several other icon options such as a grey icon if the vital sign has not been recorded and a ‘- -’ sign if the patch is no longer communicating. All the vital sign icons and explanations are summarised in Figure 7.4.

Figure 7.4 An image showing all vital sign icons and their relevant meanings. The Sensium® App. Image used with permission from SENSIMUM (Abingdon, United Kingdom).



7.3.8 Study Procedure

After the surgical ward round a list of appropriate patients for selection was identified. As described in Chapter 3 an information sheet outlaying the sensor technology was given to the patient (Appendix 3.1). Written consent was obtained for all patients participating in the study (Appendix 3.2). All patients were made aware that they could withdraw from the study at any time and their care was not compromised if they did not take part in the study. Baseline demographic data was collected by a member of the research team.

If patients consented and enrolled to the study, a wearable sensor was placed by the member of the nursing team looking after the patient. As described in Chapter 3 placing sensors on patients takes approximately 5 minutes. The wearable sensor is attached to a patient's chest using two standard disposable ECG electrodes (Red-Dot2560 3M, St Paul Minn). Medical tape is used to ensure that the temperature probe is secured correctly in the axilla.

If a patient deteriorated on the ward an alert was sent to the designated nurse looking after that patient. As described in Chapter 3, a 10 minute window was selected for alerting. Often one nurse is assigned to one or two bays on the ward. If the alert was not acknowledged, a reminder notification was sent to the nurse again 15 minutes later. The alert continued until it was acknowledged by a member of the healthcare team. If there was no alert acknowledgement within 30 minutes, an alert was sent to the senior nurse in charge of the ward. For the purpose of this study the alerts were only sent to nurses on the ward and not doctors or other healthcare professionals.

All patients continued to have their normal ward monitoring and the wearable sensors were used in addition. Normal bedside observations were taken at 4-6-hour intervals by nurses and healthcare assistants, and more frequently if clinically indicated. The reference clinical device was a conventional bedside clinical monitor IntelliVue MP30, Philips, Amsterdam, The Netherlands). The observations were recorded on paper observations charts by the healthcare professional taking the observations. All patients continued to have the wearable sensor on during their admission on SAU and Richmond ward unless consent was withdrawn for any reason or the patient was either moved or discharged.

Upon patient discharge all ward observations were collected and transcribed to allow for further comparisons with sensor data. All ward observations, date and times were recorded on an Excel sheet in a secure file held on the hospital server. If there was any uncertainty in the reading of the observation chart this field was left blank and verified by a second reviewer. If the second reviewer had changed the number and interpreted it differently this was noted. If there was no entry on the charts or the writing was illegible this was also noted. A third reviewer was also able to help with further queries. After patient discharge all data was extracted from the hospital server. The discharge summary and clinical notes were reviewed for any significant events of patient deterioration and the clinical course of events experienced by the patient whilst in hospital. All alerts were reviewed for recruited patients to identify the exact time on the sensor that deterioration had occurred. The time to acknowledgement was then reviewed for each action and an average time to acknowledgement calculated. Dr Arti Sharma and Miss Antonia Koutsoukou, both research nurses from the National Institute for Health Research (NIHR) clinical research network that were assigned to the study assisted with patient recruitment, collection of ward observations and data entry.

7.4 Results

7.4.1 Total number of vital sign alert notifications

There were 50 patients recruited in the pilot study, for whom there were vital sign alerts in 18 patients (36%). The total number of vital sign alerts generated in these 18 patients was 51. Of these 51 alerts there 7 alerts for high HR (13.7%), 33 for RR (64.7%) and 11 for temperature (21.6%).

Figure 7.5 is of a patient wearing a sensor on the chest and deteriorating vital signs for respiratory rate detected on the sensor in real time. Permission was given by the patient for the picture to be used.

Figure 7.5 Real time detection of acute deterioration



In another example of patient deterioration, there was a patient with respiratory rate deterioration. To generate a red NEWS respiratory rate alert, 5 consecutive abnormal red NEWS respiratory rate readings were required. In contrast this patient had only 2 abnormal readings for heart rate and so a heart rate alert was not sent to the nurses (Figure 7.6). As well as individual vital sign readings the nursing staff were able to review the vital sign trends.

Figure 7.6 – Respiratory rate alerts sent to the mobile Sensium application for the clinical team. Image used with permission from SENSIMUM (Abingdon, United Kingdom).



For the 51 alerts generated, there were 27 alerts that were acknowledged and 23 notifications that were left unacknowledged. In those left unacknowledged there were 4 alerts for HR, 16 for RR and 3 for temperature.

Out of the 27 acknowledged alerts there were 2 alerts for HR, 17 for RR and 8 for temperature.

The average time to staff acknowledgement of the notification for all alerts was 154 minutes (2.6 hours).

The average time to staff acknowledgement for HR was 179 minutes (2.98 hours).

The average time to staff acknowledgement for RR was 162 minutes (2.7 hours).

The average time to staff acknowledgement for temperature was 165 minutes (2.75 hours).

All notifications sent, acknowledgements and timestamps can be found in Table 7.2.

The average time to an alert from previous wards observations was 164 minutes (2.7 hours) and the average time from the alert to the next ward observations was 197 minutes (3.3 hours).

7.4.2 Alert actions taken

There were 23 alerts that were left unacknowledged and 27 alerts that were acknowledged. The most frequent acknowledgement by nursing staff was to say that the patient was either eating, talking or sleeping (8 acknowledgements, 29.6% of all acknowledgements). The alerts prompted nurses to record a full set of manual observations in 6 cases. There was no action taken in 4 cases. Some acknowledgements were to say the patient was off the ward (3 cases) and sensor electrodes were replaced in 2 cases.

There were some patients that had shown signs of deterioration in the cohort. The frequency of routine observation monitoring was increased in 2 cases, 3 patients were referred to a senior clinician and 2 patients were initiated on the sepsis pathway.

Table 7.2 Sensor vital sign notifications, acknowledgements and actions taken by the clinical team

Study Identification Number	Notification Time Stamp	Acknowledgement Time Stamp	Acknowledgement Time Difference Minutes	Unacknowledged Notifications Time Stamp	Heart Rate & NEWS Colour Code	Respiratory Rate & NEWS Colour Code	Temperature	Alert Type Sent	Action Taken
505	25/05/2019 22:05	25/05/2019 23:46	101		74	7	36.3	RR	Patient is Eating / Talking / Sleeping - no action taken
507	29/05/2019 18:30	29/05/2019 18:58	28		101	27	36.3	RR	Observations Recorded
507	30/05/2019 03:10	30/05/2019 06:20	190		85	26	37.5	RR	Observations Recorded
507	31/05/2019 03:26	31/05/2019 06:09	163		83	29	37.4	RR	Patient is Eating / Talking / Sleeping - no action taken
505	31/05/2019 21:32	01/06/2019 00:01	149		68	27	35.6	RR	Patient is Eating / Talking / Sleeping - no action taken
507	31/05/2019 22:58			01/06/2019 00:21	89	28	37.3	RR	Unacknowledged alert
507	01/06/2019 00:20			01/06/2019 10:24	91	35	37.3	RR	Unacknowledged alert
506	01/06/2019 09:40				146	-1	-1	HR	No action taken
507	01/06/2019 10:24			01/06/2019 11:58	93	29	36.3	RR	Unacknowledged alert
507	01/06/2019 11:58			01/06/2019 20:37	104	38	36.9	RR	Unacknowledged alert
507	01/06/2019 20:36	01/06/2019 22:39	123		152	5	36.9	HR	No action taken
513	05/06/2019 07:37	05/06/2019 09:21	104		-1	25	36.4	RR	No action taken
512	05/06/2019 13:54	05/06/2019 14:06	12		100	-1	38.1	TEMP	Reapplied Electrodes
515	05/06/2019 16:09			05/06/2019 18:32	145	-1	35.5	HR	Unacknowledged alert
515	05/06/2019 18:31			05/06/2019 19:52	132	9	38.1	TEMP	Unacknowledged alert
513	05/06/2019 18:37			05/06/2019 20:38	-1	27	36.6	RR	Unacknowledged alert
515	05/06/2019 19:51	06/06/2019 08:15	744		123	8	37.7	RR	No action taken
513	05/06/2019 20:33	06/06/2019 05:45	552		84	35	36.6	RR	Patient is off the ward
513	06/06/2019 10:19	06/06/2019 11:10	51		82	25	36.3	RR	Patient is off the ward
513	06/06/2019 13:13	06/06/2019 15:28	135		-1	32	36.5	RR	Patient is Eating / Talking / Sleeping - no action taken
513	06/06/2019 15:41	06/06/2019 16:19	38		-1	33	37.4	RR	Patient is Eating / Talking / Sleeping - no action taken
513	07/06/2019 17:01	07/06/2019 20:19	198		93	27	36.7	RR	Patient is Eating / Talking / Sleeping - no action taken
517	08/06/2019 12:23	08/06/2019 12:28	5		85	24	38	TEMP	Observations Recorded
522	24/06/2019 19:12	25/06/2019 11:11	959		80	6	36	RR	Reapplied Electrodes

Study Identification Number	Notification Time Stamp	Acknowledgement Time Stamp	Acknowledgement Time Difference Minutes	Unacknowledged Notifications Time Stamp	Heart Rate & NEWS Colour Code	Respiratory Rate & NEWS Colour Code	Temperature	Alert Type Sent	Action Taken
522	26/06/2019 04:30	26/06/2019 05:18	48		78	8	36	RR	Patient is off the ward
526	28/06/2019 19:01	28/06/2019 19:04	3		91	19	38	TEMP	Initiated Sepsis Pathway
525	29/06/2019 11:44	29/06/2019 17:32	348		83	5	35.9	RR	Patient is Eating / Talking / Sleeping - no action taken
525	30/06/2019 10:24	30/06/2019 10:57	33		88	8	35.5	RR	Patient is Eating / Talking / Sleeping - no action taken
528	02/07/2019 12:55	02/07/2019 13:00	5		101	-1	38.6	TEMP	Observations Recorded
532	10/07/2019 03:14	10/07/2019 03:16	2		-1	-1	38.4	TEMP	Refer to Senior clinician, Suspicion of Infection, Observations Recorded, Increase Routine Observation
532	10/07/2019 05:20	10/07/2019 05:22	2		-1	-1	38.7	TEMP	Initiated Sepsis Pathway
541	24/07/2019 18:35			25/07/2019 08:08	74	6	-1	RR	Unacknowledged alert
543	25/07/2019 20:31			26/07/2019 04:55	61	26	37.4	RR	Unacknowledged alert
543	26/07/2019 04:55			26/07/2019 22:42	69	25	37	RR	Unacknowledged alert
544	01/08/2019 17:07			02/08/2019 08:40	105	27	36.1	RR	Unacknowledged alert
544	02/08/2019 08:39	02/08/2019 09:26	47		162	-1	-1	HR	Refer to Senior clinician
544	02/08/2019 09:31			02/08/2019 11:22	117	33	33.8	RR	Unacknowledged alert
544	02/08/2019 11:21			02/08/2019 11:40	137	-1	35.6	HR	Unacknowledged alert
544	02/08/2019 11:39			02/08/2019 12:18	124	32	36.1	RR	Unacknowledged alert
544	02/08/2019 12:17			02/08/2019 13:22	149	-1	35.9	HR	Unacknowledged alert
544	02/08/2019 13:21			02/08/2019 13:56	121	28	-1	RR	Unacknowledged alert
544	02/08/2019 13:55			02/08/2019 14:16	113	38	35.7	RR	Unacknowledged alert
544	02/08/2019 14:09			02/08/2019 14:38	154	-1	-1	HR	Unacknowledged alert
544	02/08/2019 14:37			02/08/2019 16:34	121	34	34.9	RR	Unacknowledged alert
546	06/08/2019 12:48	06/08/2019 13:05	17		63	8	34.4	RR	Observations Recorded
546	07/08/2019 08:18			08/08/2019 16:33	58	6	35.3	RR	Unacknowledged alert
548	12/08/2019 23:01			13/08/2019 02:12	80	33	32.7	RR	Unacknowledged alert
548	13/08/2019 02:11			13/08/2019 15:19	82	15	32	TEMP	Unacknowledged alert
550	16/08/2019 12:01			16/08/2019 16:08	104	-1	38.1	TEMP	Unacknowledged alert
550	16/08/2019 16:07	16/08/2019 17:40	93		100	20	38	TEMP	Increase Routine Observation
550	16/08/2019 17:45	16/08/2019 17:55	10		107	23	38.6	TEMP	Refer to Senior clinician
Average			154						

7.5 Discussion

This small pilot study used wearable sensors to generate real-time alerts to nursing staff when changes in vital signs were found. This study shows for the first-time clinical implementation of wearable sensors and offers practical clinical value. Research has highlighted that deterioration in vital signs especially HR and RR precede adverse events providing an opportunity to act on patients earlier, helping to provide treatment and even prevent more serious events occurring(225)(226)(166).

7.5.1 Summary of findings and context within the literature

Wearable sensors are not routinely used to measure vital signs within the NHS or in a wider setting. Research on the successful implementation of wearable sensors in vital sign monitoring in the literature is limited with small numbers of patients(149)(141). In addition the focus of these papers has been on sensor reliability with no review of time to clinical team acknowledgement(149)(141).

This chapter has shown for the first time that although digital alerts were sent to the nursing staff they were not always acknowledged and if they were acknowledged this was not done in a timely manner. The average time to alert acknowledgement was 154 minutes (2.6 hours). Whilst wearable sensors may be able to monitor at an increased frequency, it is important these digital alerts are acknowledged promptly.

There are several reasons that the delay in acknowledgement or failure to acknowledge the alerts may have occurred. The first possibility is that the alert prompted a member of staff to

review the patient but there was a failure to click the acknowledgement. The second possibility is through a lack of education and the clinical team being unaware that clicking the acknowledgement was important. The third possibility more worryingly is that the patient may not have been reviewed. Unfortunately, the only way that would have been known is if there were observers throughout the entire study period which was not possible.

The final possibility in which alerts may have not been acknowledged is through alarm fatigue. Alarm fatigue has been thoroughly documented in the literature and may help to explain some of the findings. Much of the work in alarm fatigue is based in critical care units due to high numbers of false alarms and non-actionable (true but clinically irrelevant) alarms(227). In alarm fatigue the clinical teams may ignore or silence alarms missing critical changes in the patient's condition(228)(229). There are new strategies being developed to help reduce the risk of alarm fatigue such as clinical decision software(227). The software is being increasingly used to provide to alert on individual patient data and being tested within the intensive care setting(227). Although alarm fatigue has been suggested it is unlikely that this is the main reason to explain the findings. In the intensive care setting all patients have increased monitoring however on the ward at any one time in the study there was a maximum of five patients that had the sensor on. Therefore, the number of alarms generated from these five patients is likely to be minimal.

There were some alerts that were not acknowledged by the clinical team. However in cases of deterioration or potential sepsis all alerts were acknowledged. In two patients the sepsis pathway was started and in three patients there was a referral made to a senior clinician. It is unknown whether the sepsis pathway was started due to the alert or if it may have occurred

without it however the alerts will have acted as a prompt to review the patient and act accordingly.

7.5.2 Strengths

This chapter has several key strengths and shows the successful implementation of wearable sensors and real-time alerting in acutely unwell surgical patients. This chapter for the first-time reviews real-time alert generation from wearable sensor technology and time to alert acknowledgement. All members of regular nursing staff within the clinical area received training and completed an assessment prior to the study starting. The training of staff members took several weeks however was very important if widespread use was to take place on the ward. The 10-minute alerting algorithm identified from the previous chapter was successfully deployed. All clinical areas were successfully engineered for use.

This chapter highlights that although wearable sensor technology allows more continuous monitoring the alerts generated to the nursing team were not always acknowledged. Further research is required to help better understand why this occurs. In the patients with alert acknowledgement there was often a delay. Why these delays are still occurring must be explored in further research. Despite this lack of acknowledgement and delays occurring many instances of deterioration on the sensor were acknowledged and actioned appropriately. Even in the small cohort of patients recruited 2 patients with sepsis were identified and started on the sepsis pathway and 3 patients were referred to a senior clinician. Although it is unknown whether this is solely due to the digital alerting from the wearable sensor it is likely that these alerts will have acted as a significant prompt for the actions performed.

7.5.3 Alerting challenges

There have been several challenges in the alerting phase before it could commence. The first phase of data collection (pre-alerting phase) finished in January 2019 and it was hoped that the alerting could start soon after however there were several factors that prevented this.

Firstly, the Ascom alerting device was no longer compatible with the Sensium application. An alternative alerting device needed to be found that could be used to provide real-time alerts for the nurses. The Chelsea Westminster Hospital Trust has an android policy only. Unfortunately, the Sensium application was not compatible with the android operating system. If Sensium were to create a new application for android operating systems, the project could have been delayed the study for at least a year. Fortunately, requests were submitted for the Chelsea Westminster Hospital Trust to review and special circumstances were given to use the Apple device for the study. The I-Pod touch device (6th generation) was selected for alerting to all nurses and healthcare assistants.

The second large delay came over the Sensium application. Unfortunately, the initial applications were fixed and the list of actions to be completed by the nurses could not be changed. In addition, in earlier versions of the Sensium application there was the inability to escalate patients to the senior nurses. The new changes required to the application for the study took a minimum of 6 months to complete. The latest version of the Sensium application also required server updates at the Trust. For any change in the hospital IT infrastructure a change of request had to be completed and approved by the Trust board which took time too.

The third delay in the study was due to ‘winter pressures on staff’. When there are substantial challenges for the nurses with extra demands being placed on them. Training each member of staff required up to an hour away from the ward was not possible and the alerting study could only commence when the winter pressure had eased (this was in March 2019).

7.5.4 Limitations

This chapter has several limitations which must be considered. Although just a pilot study the sample size is small with only 50 patients and is a single centre study.

Although changes in vital signs were detected using the wearable sensors it is hard to say that they would have remained undetected with manual ward observations. Unfortunately, many sensor notifications (23) were left unacknowledged. In these cases, it is unknown if nursing staff went on to review the patient and failed to acknowledge on the Sensium application or if they failed to register the change in vital sign at all and did not review the patient.

The temperature notification was set to 38 °C to account for the lower temperature skew highlighted in the reliability chapter. Overall the temperatures were lower for the sensor than they were for the tympanic form of temperature measurement used by the nurses. The average difference between the sensor and the nurse for temperature as seen in Chapter 3.

One of the challenges with the study which may help to explain some of the results is that nurses were reviewing the digital alerts from the sensor in addition to their current monitoring. They were using paper-based observation charts as well as having to review digital monitoring through smartphone technology. It is likely that this may have increased

their nursing workload. The SAU is a busy unit with a constant turnover of patients being either discharged or transferred to other surgical wards and new patients coming in. If nurses are reviewing digital alerts in addition to their ward monitoring, they may have felt this was an extra job in addition to their already busy workload. Ideally the nurses would have already been using digital vital sign monitoring with alerts from wearable sensors fully integrated into such systems. Once this occurs alerts from wearable sensors may be incorporated into a more standard operating procedure rather than being an additional task for nurses to review.

7.5.5 Further research

This pilot study needs much more research and review into why only some alerts were acknowledged by nursing staff. In addition, digital monitoring of vital signs is recommended to improve documentation as seen from earlier work in the thesis and also fully enable integration of wearable sensor alerts into vital sign monitoring systems. The use of paper observation charts in addition to wearable sensor digital alerts may have increased the workload and demands on nurses. More fully integrated systems may enable notifications to be acted upon and acknowledged in a timely manner.

As well as integration the other key to review in future is the effect of digital alerting through wearable sensors and patient outcome measures. There has been once such study in the literature which found continuous monitoring on ward patients through sensor technology resulted in a reduction in hospital and intensive care length of stay as well as lower rates of ‘code blue’ or cardiac arrest(102). In this study ‘Code Blue’ indicated those patients that had a cardiac arrest(102). This study has been welcomed and is the first to review patient outcomes measures(102). However, there are several significant limitations found. Firstly,

the sensor being used was not quite a wearable sensor, but the Early Sense sensor described in the introductory chapter. This sensor is placed under the patient's mattress and only records whilst the patient is in bed. For ambulating ward patients its use and applicability may be limited. In addition, only length of stay and code blue were reviewed, other outcome measures of interest such as mortality, transfers to intensive care and rapid response team involvement were unable to be reviewed. Further research is required to review wearable sensors and all outcome measures in a larger cohort of patients.

7.5.6 Conclusion

This chapter has seen the successful implementation of digital alerts based on developed alerting algorithms to nurses in real-time. Although not all alerts were acknowledged deterioration on the ward observations was detected and actions were taken accordingly. Patients were started on the sepsis pathway and escalation to senior clinicians occurred. Further research is required to review why only some alerts were acknowledged and the effects of digital alerting on patient outcomes. Full integration of paper-based ward observations and digital alerting from wearable sensors using electronic health systems is likely to improve results.

Chapter 8 Discussion and conclusion

In this final chapter of the thesis the work presented will be discussed. Firstly the aims of the thesis will be re-stated. This will be followed by a summary of how each aim was addressed. The key findings of the main studies have been summarised along with strengths, limitations and future directions for research. The overall implications for this research and further work are discussed and reviewed within a wider context. Lastly the chapter will conclude with my personal reflections of completing the research in this thesis.

The main aims of this thesis were addressed through the following body of evidence across the thesis chapters. The important research aims at the start of the study were:

1. *To review the latest wearable sensors measuring multiple vital signs.* This was performed through a review of the latest literature (Chapter 1).
2. *To explore the link between digital alerting and sepsis outcomes.* This was achieved through a systematic review and meta-analysis: Can digital alerting improve sepsis outcomes and hospital length of stay? (Chapter 2).
3. *To investigate the reliability of wearable sensors as compared to standard ward monitoring in acutely unwell patients.* This was achieved through a cohort study in which patients wore a wearable sensor as well as standard ward monitoring and vital signs readings were compared (Chapter 3)

4. *To assess the speed in which wearable sensors detect unwell patients and sepsis as compared to standard ward monitoring.* This was achieved through reviewing all the patients who had deteriorated in the above study and comparing the exact times of vital sign changes between the wearable sensor as compared to current monitoring standards (Chapter 4).
5. *To assess the opinions of patients who had worn the wearable sensor.* This was achieved through a mixed methods approach with both questionnaire and interview studies in patients who had worn the wearable sensor (Chapter 5).
6. *To assess the opinions of staff members who had either used the wearable sensor or treated patients wearing the sensor.* This was achieved through interview studies in with staff members (Chapter 6).
7. *To assess the use of wearable sensors and real-time digital alerting in identifying unwell patients and those with sepsis in an acute hospital setting.* This was achieved with a pilot feasibility study reviewing real-time digital alerting to identify unwell patients and those with sepsis (Chapter 7)

8.1 Findings of this research – Summary of key findings by aim

A summary of the main data chapters will be described below along with answers to the research questions proposed in the introduction.

8.1.1 To review the latest wearable sensors measuring multiple vital signs.

Chapter 1 was a review of the latest wearable sensor technologies measuring multiple vital signs. The sensor properties were compared and the evidence reviewed. A majority of the research performed was in controlled laboratory conditions with healthy volunteers. There is significant variation in the properties of these sensors and limited research in the real life applicability of these devices in a hospital setting with real patients. Greater research and larger clinical trials are required to review both reliability and usability. Following this review, the Sensium sensor was selected for further study in this thesis as it is a lightweight, low cost, waterproof, single use device, which measures HR, RR and temperature the vital signs which change early in sepsis. The battery life of the Sensium sensor at 5 days is longer than most of its competitors. It was thought most hospitalised patients would therefore only need one sensor per admission and this would help reduce costs.

8.1.2 To explore the link between digital alerting and sepsis outcomes.

Chapter 2 was a systematic review and meta-analysis on the use of digital alerting in sepsis outcomes. The digital alerts were intermittent and taken from routine nursing observations that had been entered into electronic systems. This review found that digital alerting in sepsis is associated with significant reductions in hospital LOS by 1.311 days ($p=0.014$) and ICU

LOS by 0.766 days ($p=0.007$). Both mortality and time to antibiotics showed no significant difference. This review also identified a wide variation in the diagnosis of sepsis and multiple measures used for this purpose. Many of the studies included in the review used the SIRS definition of sepsis or a modification of it. This is perhaps because it is the most practical in a clinical setting with readily available vital signs data and laboratory tests. This important meta-analysis paved the way for later work in this thesis. It led us to speculate on the use of more continuous monitoring of vital signs to see if improvements in the detection of sepsis or patient deterioration would occur.

8.1.3 To investigate the reliability of wearable sensors as compared to standard ward monitoring in acutely unwell patients.

Chapter 3 assessed the reliability of continuous digital monitoring of vital signs with a wearable sensor in acute hospital admissions. For any new technology to be embraced and used, the crucial question is reliability. Prior to the implementation of any new technology the fundamental question is does it really work? Most research into wearable devices to date has been in very controlled laboratory conditions. There is an absence in the literature of large-scale wearable sensor trials in patients. Real life reliability in clinical areas and with acute patients is largely unknown. The novel work from this chapter has been able to answer some important questions. I found that for all 3 vital signs the mean differences between the sensor and ward observations were small and within acceptable limits provided within the literature. Considering the differences in the monitoring technique these results are remarkable. To our knowledge with 500 patients recruited this is the largest prospective cohort study to have investigated the reliability of wearable sensor monitoring for several days in acutely unwell patients. We have demonstrated strong reliability of HR. The

temperature had moderate significant correlation and although the RR showed a weak positive correlation it was still statistically significant. The difference between the average number of sensor readings every 24 hours compared to nurse readings is huge. The average number of ward readings per patient is between 3-4 whilst for sensor readings it may be several hundred a day. This abundance of data may be overwhelming for busy clinicians. As such, a key issue going forward is the handling of the data and alerts generated.

If alerts are sent to the clinical team based on a single abnormal vital sign reading, it is likely that they will be bombarded with false alerts and be at risk of alert fatigue. Using an alert based on a single time point change in vital signs is likely to result in reduced diagnostic accuracy. Using alerts generated over time windows seems the best way to handle the large volumes of data in a meaningful way and reduce the volume of alerts generated.

To reduce alarm fatigue and improve diagnostic accuracy, a number of abnormal readings are needed to generate a digital alert to the health care team. Using the data collected from the 500 patients, several time windows were tested to identify how to configure the optimal alert. This research has for the first time compared different time windows to identify the most appropriate time window to use when generating an alert. If the time window over which the alert is generated is too small there was a risk of both data loss and the data being affected by outliers. If the time window is too large there is the potential risk of 'smoothing' of data and the chance that the patient may enter a new physiological state. This research has identified that there is little difference between the averaging windows tested.

The 10 minute window was selected for a number of reasons. In a practical sense not all nurses can take ward observations in less than 10 minutes, and many nurses will have difficulty acting on an alert which is less than 10 minutes. In addition when reviewing the number of data points any less than a 10 minute window has considerable data loss whilst a larger time window had a slightly higher mean difference between the nursing observations and the sensor readings.

8.1.4 To assess the speed in which wearable sensors detect unwell patients and sepsis as compared to standard ward monitoring.

Chapter 4 assessed the speed of detection of unwell patients and those with sepsis comparing standard ward monitoring to monitoring through the sensor. This chapter has shown for the first time that wearable sensors and continuous monitoring may be used to detect patient deterioration and sepsis quicker than current monitoring. Although episodes of deterioration were missed both by the sensor and current monitoring, the number of missed deteriorating episodes was far greater using current ward monitoring. It is hoped that in future wearable sensor technology will not only be able to measure HR, RR and temperature but also more vital signs providing more continuous monitoring. It is suggested the technology currently be used as an adjunct to care and aid earlier detection prior to ward monitoring.

8.1.5 To assess the opinions of patients who had worn the wearable sensor.

Chapter 5 was a quantitative and qualitative review of wearable sensors through questionnaire and interview studies with patients. End-user feedback is critical to ensure

sustained usability and future use. Whilst the questionnaire methodology provided a measure of occurrences and numerical calculations, the patient interviews provided a more in-depth exploration of opinions. The study strength was the 453-patient questionnaire feedback which provided a 91% response rate. This is the largest in the literature to date and unlike some previous sensor trials it is in real patients as opposed to healthy volunteers. Questionnaire findings showed that 85% of patients found the sensor to be comfortable and 86% would wear the sensor again in hospital. Furthermore 80% agreed they would wear such a sensor at home. Patient interviews identified problems with current monitoring and welcomed the wearable future sensor use. Changes to the sensor were suggested and it is likely that in future further miniaturisation of sensor technology will occur as well as the addition of other parameters such as accelerometer data. However, overall patient feedback was overwhelmingly positive. This research adds to the literature and explores the opinions of patients who are the key end-users of the technology.

8.1.6 To assess the opinions of staff members who had either used the wearable sensor or treated patients wearing the sensor.

Chapter 6 was a qualitative review of surgical staff perspectives on the use of wearable sensors and continuous monitoring. No study to date has conducted a comprehensive exploration of staff views of wearable sensor technology in acute hospital patients. A pan-stakeholder approach was used with 48 interviews performed in junior doctors, junior nurses, senior nurses and senior doctors. Results demonstrated all staff members identified problems with current monitoring used to detect deteriorating patients and those with sepsis. A clear need for the technology was articulated by all staff groups. Staff believed that wearable technology would enhance patient safety and improve outcomes. Most staff members

interviewed felt that wearable sensors and remote monitoring would improve workload. Several suggestions were made to improve the wearable sensor such as a smaller size, changes to the temperature wire and the addition of other vital signs. This is the first study in the literature providing a pan-stakeholder review of the wearable sensors in acute hospital patients.

8.1.7 To assess the use of wearable sensors and real-time digital alerting in identifying unwell patients and those with sepsis in an acute hospital setting

Chapter 7 was a pilot feasibility trial of real-time alert generation. This small pilot study used wearable sensors to generate real-time alerts to nursing staff when changes in vital signs were found. This chapter shows for the first time clinical implementation of wearable sensors and offers practical clinical value. Current research on the successful implementation of wearable sensors in vital sign monitoring in the literature is limited with small numbers of patients(149)(141). In addition the focus of these papers has been on sensor reliability with no review of time to clinical team acknowledgement(149)(141).

The 10-minute alerting algorithm identified from the previous chapter was successfully deployed. All clinical areas were successfully engineered for use. This chapter has shown for the first time that although digital alerts were sent to the nursing staff they were not always acknowledged and if they were acknowledged this was not done in a timely manner. The average time to alert acknowledgement was 154 minutes (2.6 hours). Whilst wearable sensors may be able to monitor at an increased frequency it is important these digital alerts are acknowledged promptly too to improve clinical value. A larger trial has been started to

improve alert acknowledgement by the nursing team and review the effect of digital alerts through the wearable sensor on patient outcomes. The trial is an extension of the work already completed. It is being performed in the same clinical area (SAU and Richmond wards) with the same research and nursing team. Currently the trial has recruited an additional 100 patients. The patient outcomes being reviewed are number and times of NEWS calls, time to antibiotics, transfer to higher dependency care, mortality, hospital readmissions and hospital length of stay.

8.2 Wider Literature

Wearable technology may soon transform healthcare and revolutionise biomedicine. There has been huge growth in wearable sensors throughout the course of this thesis from consumer grade devices to those being used in research studies. From the initial focus of enthusiastic consumers, healthcare professionals are beginning to adopt wearables for patient monitoring. The goal for smart sensors in healthcare is personalised monitoring intelligent systems which are ‘invisible’ to those that are wearing them(230). The ideal is not just for safe monitoring in the hospital setting but also at home for patients with chronic diseases and the elderly population. Whilst wearable sensors have been reviewed in this thesis to detect vital signs monitoring in hospital, wearable sensors have applicability in several areas of health research. Several of these will be described in the paragraphs below.

8.2.1 Wearable sensors in surgical patients

Over half of the patients in this thesis were surgical. The use of wearable sensors in surgical patients is gaining interest both in the pre-operative and post-operative period. Traditional outcome measures used to assess patients after surgery are hospital length of stay, readmissions and post-operative complications. Recently there is a new focus in optimising patients prior to surgery particularly in the elective setting. Wearable sensors might be useful in the perioperative period to enable physical activity monitoring and encourage mobilisation prior to surgery, which in turn hopes to improve outcomes post-surgery. A systematic review of wearable sensors found that they may be able to predict functional recovery post-operatively(231). As well as predicting recovery, wearable sensors may help promote functional recovery in patients(232).

8.2.2 Elderly people and wearable technology

The patients in this thesis were recruited up to the age of 95. One of the greatest uses of the technology will be in aiding elderly patients. One of the paramount challenges to healthcare world-wide is the aging population. The anticipated global projection of people over the age of 60 is due to rise from 10.0% in 2000 to 21.8% by 2050(233). Younger generations have exposure to technology from an early age making new technology adoption easier. However older generations may have had limited exposure to technology as well as fewer opportunities to partake in research which will have an influence on use(234).

One of the greatest uses of new technologies and wearable sensors in the future is the creation of smart homes. Whilst there are currently residential homes and nursing homes in many countries, these can be costly to run and create a loss of autonomy for many elderly residents. Most people would prefer to stay in their own homes and maintain independence as long as possible. The use of wearable sensors is likely to extend to the community in which the shift will change from reactive to predictive medicine. Those at home shall be able to live independently with the added security of wearable sensors and alarms.

There is an increasing focus of research on wearable devices in the elderly population particularly in the home setting. One of the greatest uses of wearables is in the use of fall detection. Falls in the elderly can result in mortality and significant morbidity(235). Serious negative consequences may occur if a person is left on the floor for a long period of time such as dehydration, pressure sores, rhabdomyolysis and pneumonia(236). Therefore older people with a fall need urgent attention to prevent further injury(158). Whilst there are personal emergency response systems - buttons that can be pressed to summon help - the alarm is only triggered when the participant presses it(237). However if someone has lost

consciousness, is confused or unwilling to summon help, there will be delays in fall detection(238). Research is underway reviewing a wearable sensor which detects if a patient has had a fall and alerts a family member or a member of the healthcare team(239).

Smart watch wearable use has been tested for the detection of pulse irregularities in older adults(240). When compared to the gold standard of Holter monitoring smart watch pulse recordings offered high accuracy in identifying pulse irregularities in older participants(240). Whilst this was in a simulated clinical environment, use within the home setting has great potential in the future(240). Despite the elderly participant group having a lack of familiarity with smart watches, they found them to be high acceptable(240).

8.2.3 Patients with cancer

Wearable sensors have been suggested for use in cancer patients. A feasibility trial has been performed with the use of activity monitors to measure functional status in patients with cancer(241). Feasibility was defined as those using the activity monitor for greater than 50% of the observational period(241). Although just a small study of 23 patients, 18 reported a positive experience using the activity monitors(241). In addition it was found to be a practical way of measuring long-term physical activity for patients receiving cancer treatments(241).

8.2.4 Patients with Peripheral Vascular Disease

Wearable sensors may be beneficial in patients with certain conditions such as Peripheral Vascular Disease (PVD)(242). In a small study of 37 patient's with PVD, the effect of wearable activity monitors (WAMs) was measured(242). Those with WAMs had set daily activity targets and could monitor their progress(242). The alternative treatment was a

supervised exercise programme(242). Despite the small study, sample the benefit of WAM-led technologies in patients with PVD and intermittent claudication showed a sustained benefit(242).

8.2.5 Patients with Chronic Obstructive Pulmonary Disease (COPD)

COPD is a common lung condition often managed in the community. Wearable sensors may be used to help manage this condition within that setting. Continuous peripheral blood oxygen saturations are assessed by pulse oximetry. Wearable finger pulse oximeters are being tested in the home. An early small study of 20 COPD patients has found significant peripheral blood oxygen saturation fluctuations between multiple days and nights(243). These pulse oximetry sensors could help monitor a patient's condition at home rather than static measurements taken within hospital.

8.2.6 Future sensor use in disaster setting and in places of remote monitoring

Whilst the Sensium sensor required a great deal of IT infrastructure, it is likely that wearable sensors in the future will require less. There may be opportunities for smart phones to act as a 'hot spot' or link bridges enabling monitoring outside of the hospital setting. As mentioned this may be used for people in the home setting but another potential use is to monitor patients in remote settings or during disaster situations. In one of the first studies of its kind a proof of concept study used a wireless sensor in an Ebola treatment centre in Sierra Leone(244). This wearable sensor was able to measure several vital signs and have data analytics applied to the signal allowing personalised alerting to assess changes in a patients

status(244). In places where healthcare workforce is scarce and digital infrastructure underdeveloped such technologies may help measure a patients physiological status continuously and support healthcare staff locally.

8.3 Thesis Strengths

This thesis has a number of strengths. The data generated are novel and a wide range of issues relevant to alerting from wearables has been covered in this thesis from sensor reliability and alerting to human factors. Thus far research on wearable sensors has largely been in controlled laboratory conditions. Whilst several proof of concept trials have been performed in hospital setting these have still been in controlled conditions with research nurses often performing ward observations. This limits the applicability of the findings to a real world hospital scenario which is often far more chaotic.

This has been the largest study to date of real time wearable sensors in acutely unwell patients in hospital with recruitment from several clinical areas. This thesis shows that recruitment of large numbers of patients is feasible in a clinical setting. This in itself is a significant strength because other studies reviewing wearable sensors in a clinical setting only have 25 patients or fewer (141)(149). Previous research has largely used wearable sensors in controlled laboratory conditions that may have limited its translational value in a clinical setting. In contrast this thesis focused purely upon acute care settings encompassing over 500 patients from different clinical areas, therefore lending strength to the reliability of the results within a wider healthcare setting.

For the first time this thesis attempts to use information from wearable sensors to be combined with other available data to help identify patients with sepsis. The literature shows that patients with sepsis are being identified late and novel digital solutions such as wearable sensors may be used to help bridge this gap. The findings from this thesis may be used as a step towards using wearable sensors to help identify sooner patients with sepsis.

The literature thus far has limited patient feedback of wearable sensor use in a hospital setting. For wearable sensors to be used and implemented in hospitals in future, feedback from patients is critical. However great the technology may be, if wearable sensors are not accepted by patients as the end-users, they will never be successful in full scale implementation within hospital. The large quantity of patient questionnaire feedback helps to ensure more reliable results and helps to minimise any bias that may be found with smaller sample sizes. In depth analysis of patient opinions was reviewed through interview studies.

There is also limited feedback from staff in the literature for wearable sensor use in a hospital setting. The first pan-stakeholder review of staff members on wearable devices has been performed. A need for the technology has been identified and there was a strong appetite by staff for future sensor use. The staff interviews were not only with key decision makers, such as senior consultants and matrons, but also with more junior doctors and nurses in equal numbers. Acceptability by health care staff is important for sustained use of wearable sensors in future.

The knowledge from this thesis has been applied and a pilot feasibility trial on real-time digital alerting has been set up in Chapter 7. Whilst the patient numbers in this study are small, more patients will be recruited; time to alerting as well as outcome measures will be reviewed in future work. This thesis has helped provide the platform for this further work.

The success of this thesis comes largely from an organisation and its team members that were receptive to change and innovation. The first step was acknowledging there was a problem

with current monitoring not only locally but nationally. The wearable sensor project at West Middlesex University Hospital has brought together a wide range of teams for true collaborative working. Very rarely do research studies or innovative projects cross the boundaries between medicine and surgery and yet we were able to do this. Having both surgical and medical supervisors was beneficial and productive.

A further strength is the collaborative team working behind this effort. Previous projects within healthcare have primarily just involved the clinical teams. The success of the work presented here is attributable to not only clinical teams, but also the wider workforce within the hospital such as the information technology (IT) team, engineers, finance and senior management within the organisation. This thesis is an example of true teamworking within an organisation. Future such projects within a hospital are unlikely to be limited to just healthcare team members within the centre; IT teams, finance, service managers and engineers, to name just a few, should be included. I have found that the success of such large projects within an organisation relies on both common goal alignment and good communication. For the meetings at the start of the project it was really important that the wider clinical team was present. During project meetings with Sensium, IT, finance and engineers within the trust were present. Understanding of the main goals of the project was really important so that everyone knew what I was trying to achieve. Throughout the course of the PhD, I have had a weekly meeting with IT and with Sensium. This has helped to both identify and address any problems in real-time as they occur and cement relationships which have been pivotal to the project being continued successfully.

8.4 Thesis Limitations

This section offers a broad critique of this thesis as individual study limitations have been described in the previous chapters.

8.4.1 Single Centre Design

The data from this thesis has been from a single centre and thus may not be generalisable to other hospitals. The only way to test the work from this thesis is through multi-centre study designs to test if the results can be replicated.

8.4.2 Scalability

The scalability in hospital is one of the study limitations. Ideally the whole hospital would have been bridged and engineered to permit wearable sensor use anywhere within the hospital. However, this would have required far greater resource and funding. Although six clinical areas were engineered for wearable sensor use, if patients moved out of these areas sensor data was no longer being transmitted to the server. The sensor is able to retain sensor data for the last 3 hours, but if patients are off the ward for longer some data may have been lost. This may have occurred for the some of the surgical patients in theatre. All steps were taken to reduce gaps in data loss. If patients were scheduled to go to theatre or imaging, consent was taken and the patients had the sensor placed on arrival back to the ward. For the medical patients there was a constant flux out of AMU to outlying wards. The bed manager and nurse in charge were consulted before any patients were patched. These team members were the most up-to-date about the movement of patients throughout the hospital. If patients

were due to move soon to outlying wards they were not recruited into the trial. Whilst all attempts were made to only recruit patients staying on the ward, at times this was not possible. This was due to the wider hospital infrastructure and patients were moved from the acute wards to downstream wards to create further admitting capacity. In the patients who were moved soon after sensor placement limited sensor data was available. Unfortunately the sensors did not work on outlying ward as these wards were not engineered for use.

8.4.3 Single sensor design

Whilst the general principles on continuous monitoring of vital signs are useful, only the Sensium wearable sensor has been used in this thesis. Many sensor companies were contacted at the start of the thesis during the planning stages. Unfortunately most did not reply back and others did not want the sensor to be used in a research study. Sensium was the only company contacted that was willing to take part in a research study and willing to share any research performed thus far. Comparability to other sensor designs, particularly for patient comfort and staff training feedback, has not been possible. The temperature wire in particular was identified by patients to be a problem and staff noted that in patients with a low body habitus the wire dangled down and was not correctly positioned in the axilla. This may partially explain why there is a skew of the data to lower temperature readings as demonstrated in the reliability chapter. For this reason, if a lower body habitus patient was recruited an adhesive dressing was placed over the wire in the axilla to help it keep in the correct position as noted in the alerting chapter.

One of the main problems with the device is the low number of total valid readings for RR. As seen in Chapter 4 section 4.5.5 when reviewing the alerting from the sensor, a valid RR was being reported only 51% of the time. This was considerably lower than HR (valid readings given 85% of the time) and temperature (valid readings given 84% of the time). Due to the inbuilt algorithm within the Sensium sensor not all of the sensor data could be accessed. The pre-processing stage may have eliminated some of the data resulting in data loss. The degree of data loss is largely unknown and should be compared to other sensor designs.

8.4.4 Number of patients with deterioration and or sepsis

As expected, in the literature the actual number of patients with real deterioration and sepsis is low. This is why large patient recruitment was needed in the trial to account for the small numbers of unwell patients or those with sepsis. Due to the comparative small sizes of deterioration, outcome measures were not able to be reviewed; further randomised controlled trials have been suggested. As no previous sensor data was available from other research studies, power calculations were unable to be performed. Several statisticians were consulted but with an unknown baseline there was significant variation in the numbers required for recruitment from a few hundred to several thousand patients. Attempts were made to recruit as many patients as possible in the short time available. Patients were recruited every working day for 1 year.

It is possible that some patients with sepsis may have been missed for two main reasons. The first is that very unwell patients may not have been admitted to a ward but gone straight from

the accident and emergency department to higher levels of care such as the HDU or ICU setting. The use of wearable sensors in this group of patients however is unlikely to have been of great benefit as these patients were already identified as being very unwell and escalated to higher levels of care as appropriate. The second is some patients that were unwell and had sepsis may have been missed due to the inability to consent. At the time of the original ethics submission it was advised by the ethics board that all participants should be able to consent. However with a proposed ethics amendment it is hoped that confused patients might be accepted into the trial in future to allow capturing this high-risk patient group if accepted confused patients may be recruited in future work. Patients would have the option of removing the sensor when they regained capacity if they no longer wished to be part of the trial and their data withdrawn from all analysis.

The sepsis literature is very heterogenous and defining sepsis has been challenging not only in wider research but also in this study. Many classifications of sepsis have been used in this thesis. ICD coding in the literature and in this study misses many patients with sepsis. Better coding of patients is required in future and defining sepsis should be consistent both academically and clinically in future work. Clinical coders in hospital review the diagnosis written on the discharge summary to code the patient. The discharge summary is often written by the most junior members of the team (junior doctors). Any inaccuracies in the summary will result in incorrect coding of the patient. Improvements in coding in future may occur through greater involvement of more senior clinicians in discharge summaries or junior doctors checking with senior colleagues prior to the discharge summary being written.

8.4.5 Data Processing

There were major challenges with processing the data in this thesis. Firstly all ward observations were written on paper charts found at the patient's bedside. These had to be manually written onto Excel sheets. This required much work and was time consuming as all data and queries were checked and verified. In future digitally recorded observations will make this process much easier going forward. Observation charts were easily misplaced or not filed in the notes. To reduce the risk of missing observation charts, a copy of each observation chart was taken each day as well as on patient discharge. All attempts were made to upload the ward observations daily, but on days when many patients were recruited, this was not always possible. At times there were 2 research nurses. On these days 1 research nurse would recruit whilst the other uploaded the data with myself.

The main patient recruitment started in January 2018. The data required much processing before any analysis could take place. I performed this processing daily for 8 months and this was incredibly time consuming and labour intensive. Most patients had several thousand data points to be processed into individual files after being extracted from raw data files from the server. Each patient would require a minimum of 5 hours to process. The matching of patients from sensor bar codes to hospital numbers and study numbers was only performed by me.

It was not until August 2018 that Sensium identified there was a problem with the data. The switch to summer time had not occurred, and all data from March was incorrectly time stamped. This was a hugely frustrating time as 8 months of work in processing and analysis were wrong and there was no way to salvage the work; the analysis had to be performed

again. This was a critical step in this thesis with relations with the company at a low point. However it became a catalyst for change. Sensium employed a new data analyst that I began to work closely with. All patient confidentiality was maintained at all times and no ward observations or other patient information was given to the company. However Sensium were able to help with some of the processing of sensor data by packaging it in a more user-friendly format for me to perform further processing and analysis. All original data still remained with me. I was able to provide the ward times stamps for the ward observations and Sensium were able to process the sensor data for those corresponding ward times in the way we needed. This was a better way of processing going forwards and gave me more time to perform the analysis.

8.4.6 Staff Education, Research nurses and the wider hospital team

The success in patient recruitment is largely attributable to my being present in the hospital every working day and assisted by the wider supportive team. Staff education is really important. Despite the initial training offered by the company, regular updates needed to be given to staff. In the first few weeks if a patient was recruited the patch was removed by staff members the following day. It was hard for nurses as the sensor was giving them no feedback in the initial stages. However with greater staff education and follow up on the wards this issue was largely resolved.

A strong relationship with the Information Technology (IT) team at the Trust was vital. A meeting was had every week for a year with myself and the Trust IT team. Changes to the wider hospital infrastructure had the potential to affect our study and all steps were taken to mitigate risk. The adoption by the Trust of Cerner (an electronic health record provider) on

May 4th required Sensium updates too. This did not affect the research in anyway as Cerner was only limited to the Accident and Emergency setting whilst all research was running. Checks were performed at the weekend when no live patients were patched to ensure the system was working correctly. Regular smaller issues were problems with the link bridges, hospital Wi-Fi and the handheld terminals were solved on a daily basis. A project of this size would not have been possible without a good relationship with IT.

The project gained 2 research nurses and this was a huge help. The nurses were valuable team members and helped in both patient recruitment, data entry and supporting the wider healthcare team with the technology. The consistency of having the same 2 research nurses throughout the year provided valuable continuity and they became known by the clinical teams. Initially we had one nurse part time but as the project grew it became clear we would need more support. I worked with the research nurses daily at the hospital and was on hand to answer any questions if they arose.

As mentioned in the reliability chapters of this thesis, it was difficult to know if a problem arose with the sensor or if no readings were provided. From patients 60-80 there were problems with data coming in and as the data was not being processed in real-time we did not know there was a problem. A way to solve this was through the setup of a separate alerting phone held by the research team (myself or the research nurses) Monday -Friday 9am to 6pm. If no data had been received on the patient for an hour a systems alert would be sent through to the research nurse or myself informing us of the need to check on the patient. A minor adjustment on the sensor position or replacing ECG electrodes was often all that was required and reduced the risk of potential further data loss in future.

8.5 Future research

It is known that patients admitted to general wards are still falling through the safety nets. Whilst there have been substantial improvements in patient safety, patient deterioration is often missed and referrals and escalation to more intense levels (such as ICU) are late. Some patient groups are typically presenting to hospital later and more unwell; the elderly population is increasing and many patients have co-morbidities. The acute admitting wards, such as the acute medical and surgical wards, have a high turnover of patients with altered physiology and rapid patient deterioration. This is coupled with increased pressures on nursing staff and high numbers of temporary staff. These factors can make the identification of early patient deterioration particularly challenging. Whilst the track and trigger approach to care has been helpful, the actual way that the vital signs are measured has not changed significantly over several decades and could benefit from fundamental enhancement.

Continuous monitoring through wearable sensor technologies may help provide some of the solutions to offer closer monitoring for patients. Wearable sensors have undergone a huge recent growth. The newer sensors are smaller, lighter, wireless, have longer battery lives and more processing power than their predecessors. The goal is for all patients that show signs of deterioration to be identified early so they can be given treatment sooner. This may help to prevent some of the adverse outcomes associated with delayed identification.

This thesis has answered the main research objectives set out at the start and is a good platform to build on for future work. The study design in this thesis has been single centre and using just one sensor design.

Further research should include larger randomised multicentre controlled trials using wearable sensors for continuous monitoring and sepsis. With larger multicentre trials a review of continuous monitoring on sepsis outcome should be possible. Work may build on the pilot alerting study in chapter 7 to review patient outcome measures. More patients will need to be recruited to identify the deteriorating patients and those with sepsis. Outcome measures such as time to antibiotics, morbidity, mortality and length of hospital stay should be reviewed. Ideally several wearable sensors should be tested. Since the advent of this thesis, novel sensor designs have been marketed but with limited research in a real patient setting.

Whilst the focus of this thesis has been identifying patients with sepsis within hospital the majority of sepsis is acquired in patients at home and in the community. The continuous monitoring of vital signs in the home setting seems the next natural transition for wearable sensor monitoring. For example they could be used for patients recently discharged from hospital to allow for further monitoring. This may be very useful in post-operative patients or those that have undergone a procedure. I believe the challenge now in home monitoring is not whether the technology is available but who monitors the data and responds if there are any signs of deterioration. The resources both in primary and secondary care are already overstretched. It may be that it is a transitional hospital at home team that may monitor and respond to such data. There are some areas within the UK that are already using such hospital at home teams. Such teams are already used to monitor patients and provide treatments within the home setting and may benefit from wearable sensors as an aid to monitoring. In areas where this is already established If patients have been recently discharged it may be advisable that monitoring of the patient through centralised monitoring occurs within a

secondary care setting. If monitoring is for patients with chronic health conditions managed in the community, centralised monitoring may be used by the primary care teams.

The goal is to have a discrete wearable sensor that is well tolerated by all patients and staff that correctly identifies acute deteriorating patients in real time. The sensor ideally should be able to measure all vital signs. Developing a sensor that can measure real-time blood pressure and level of cognition is a real challenge for the future. The first goal is to ensure that the sensors are reliable by independent researchers in large-scale high quality trials with appropriate clinical endpoints.

8.5.1 Future Digital Dashboards

It is hoped that wearable sensors in future will allow real-time detection of patient deterioration and sepsis. This might occur through a digital dashboard with the integration of other information such as blood test results. The dashboard will be available to the clinical team both at the patient's bedside and through centralised monitoring systems. The dashboard will provide real-time information for patients at an individual level.

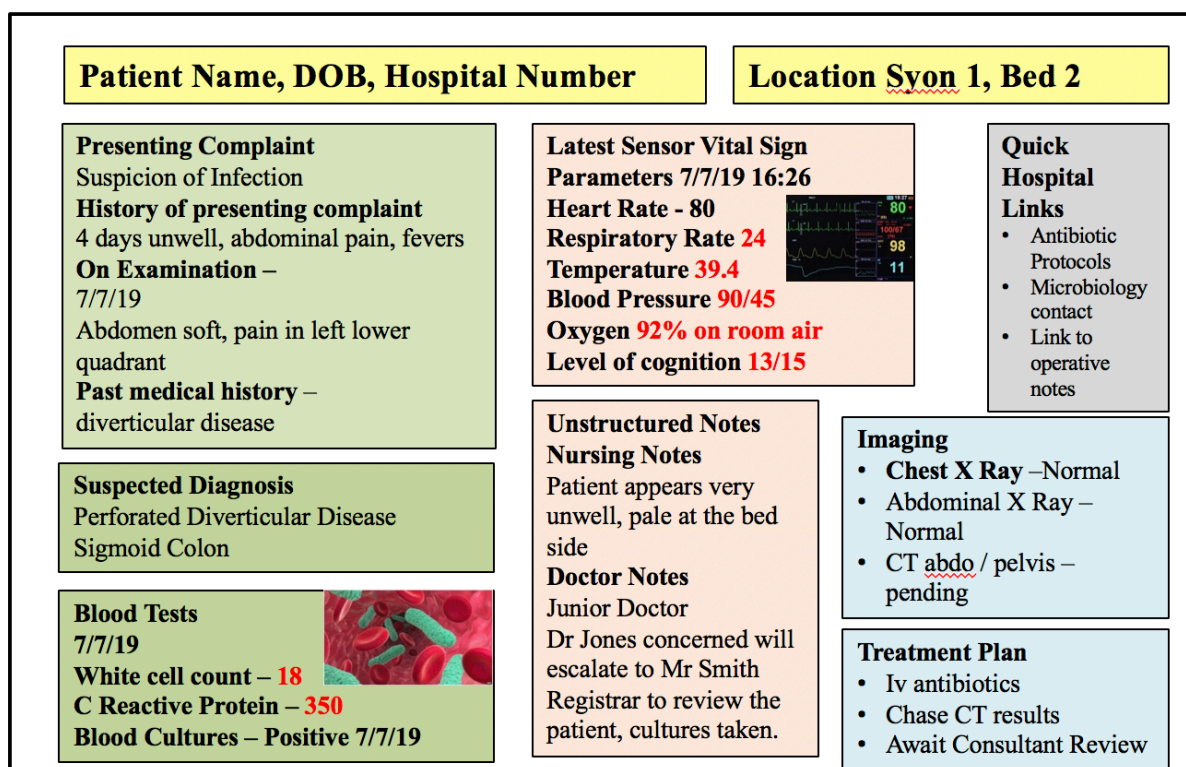
Currently ward patients have intermittent monitoring with a majority of hospitals using paper based observation charts completed by the nurse caring for that patient and held at the patient's bedside. Digital electronic observations can improve transparency and enable wider dissemination of a patient's status in real-time which may be at the fingertips of clinical teams. Through earlier identification of sick surgical patients, automatic digital alerts can be sent to clinical teams resulting in anticipated improved escalation and faster treatment.

Historically hospitals have lacked the infrastructure to support clinical decision units or dashboards(245). Previously clinicians have been reluctant to use digital systems as they have required both additional data entry and significant extra time(246). However digital technologies are being used increasingly worldwide and hospitals are turning to various electronic platforms to support care. The use of clinical decision units or dashboards has been highlighted to support the treatment of patients with infectious diseases(247). A clinical dashboard has been used in acute surgical patients in the intensive care setting(248). The sepsis screen score used SIRS and was composed of heart rate, respiratory rate, temperature and white blood count(248). Whilst this was a small study with only 7 patients with sepsis identified using the dashboard, the outcome results were encouraging(248). Using the dashboard the time to antibiotic administration was decreased (55.3 ± 15.5 h versus 16.2 ± 9.2 h; $P < 0.05$) compared to pre-implementation(248). ICU and hospital LOS was also decreased ($P < 0.01$) (248). Whilst the SIRS definition of sepsis is not specific and may lead to many false positives, the clinicians reviewed the positive alerts and used this to collect further data (such as physical examinations, and imaging) (248).

Future digital dashboards may also be able to utilise unstructured notes such as a healthcare professional's impression of the clinical condition of the patient. It may be possible to include the clinical suspicion from the healthcare professional, together with the vital signs, to create an overall impression of a patient's clinical condition. This would be very important for conditions such as sepsis or cases where patients may just not look right. Nurses may be the staff members that are most likely to benefit from this and often spend the most time at a patient's bedside when compared to other staff member groups. Studies have highlighted the importance of a nurse's worry or concern in the earlier detection of unwell patients(249).

An example of a screen of the patient dashboard has been created in Figure 8.1. The typical information provided in addition to wearable sensor vital signs are the patient presenting complaint, clinical examination findings, past medical history, suspected diagnosis, blood test results, unstructured notes, imaging results and a treatment plan.

Figure 8.1 An example of the interface of a digital dashboard



As well as dashboards to monitor individual patients, future dashboards may be used to track the conditions such as sepsis both locally and nationally. There is currently a project creating a suspicion of sepsis dashboard by Imperial College Health Partners through the Patient Safety Collaborative (PSC) with NHS Improvement's Patient Safety Measurement Unit (PSMU) and NHS England(250). This dashboard is used to see an overall picture of hospital admissions in the suspicion of sepsis category allowing the scale of sepsis to be reviewed at a

local, regional and national level(250). The use of such digital data may be used to review the epidemiology of sepsis as well as the impact of changes in sepsis treatment.

8.5.2 Managing digital data growth

There has been a huge growth in digital data over the recent years and output from sensors will be no different. The biggest future questions may not be how we can capture the data or whether it is reliable but do we have the analytical software required to process all the data. Wearable sensor development should be linked with analytical sensor development. The data should be provided to clinical teams in an easy and meaningful way. Sensor data should be easily structured and conveyed to the end-users who require it.

Due to the intermittent monitoring of ward observations which currently occurs, most early warning scores use single readings in individual vital signs to calculate a score. With the use of continuous monitoring of observations the trend generated from these observations will become more meaningful. Thus far trend analysis is poorly researched. A few studies are starting to review trend analysis and have shown to improve the accuracy of models designed to detect unwell patients(251). Further trend analysis of vital signs is likely to occur in future.

As well as trend analysis, the abundance of data generated may help facilitate algorithms in developing automated health event prediction, prevention and intervention(90). New technologies may be used to predict cases of sepsis rather than the seemingly reactive way sepsis is currently identified and treated. There is the strong emergence of wearable analytical platforms which are required with the sensor technologies. Whilst clinicians shall always need to make subjective decisions about the management of patients and treatments, computational models shall provide an additional insight to optimise decisions(252). It may

be possible to develop artificial intelligence platforms to aid the decision-making in the management of patient with sepsis. Forms of reinforcement learning may be applied to data from large cohorts of patients and used to guide the decision-making in the management of sepsis(252). Many of the current sepsis alerts utilise vital signs information, demographic information and blood test results. The future direction of alerting will likely incorporate the use of machine learning tools. Several machine learning algorithms are being tested retrospectively against big data sets to see if accurate prediction could take place. Whilst still in the relatively early stage tools such as InSight, have been shown to be effective in predicting sepsis onset. InSight, a machine learning classification system uses vitals, peripheral oxygen saturations, Glasgow coma score and age (253). A problem with the tools is the reliance on intermittent vital signs monitoring. This is why many of these tools have been used in a Intensive Care Setting, where through invasive monitoring, vital signs have a greater frequency. Whilst machine learning has been useful in intensive care the predictive performance is likely to reduce in a general ward setting due to more intermittent vital signs and in intensive care these patients are already being closely monitored and having been identified as being very unwell. The greatest benefit may be in the general ward setting with wearable sensors monitoring vital signs being utilised to improving prediction algorithms through the sheer abundance of data. One such prediction model for sepsis used free text analysis generated by nursing staff(254). The analysis was found to improve the discriminatory ability of identifying patients with infection(254).

Conceivably the next phase of differentiation and growth for wearable device companies is the software used(255). Smarter algorithms will be developed that can process large volumes of sensor data quickly using a variety of sensors and accurately. Commercially available sensors might monitor all daily activities from fitness routines, sleep, coffee and calorie

consumption. Huge streams of data will be captured every few minutes; this data not only needs to be stored but also processed from raw time series data points to data clinically useful to the end-user(154). Bespoke algorithms for each wearable device may be required to assess patients(256). The algorithms for these multisensor devices are likely to determine which wearable companies will succeed(255). Those applications which are more transparent as opposed to a black box design are most likely to be adopted in a clinical setting(154).

For this to happen all wearable sensors should be integrated into electronic health records allowing for real-time data collection. The current paper based ward observation sheets, largely being used both nationally and internationally, prevents this occurring. The use of both paper systems and wearable sensors incorporating into electronic health records may increase workload for clinical staff leading to an overreliance on one form of monitoring than the other.

8.5.3 Future wearable sensors

Through technological developments future sensors are likely to become more advanced. Further miniaturisation will allow the addition of other sensing parameters. Sensium are currently working on the addition of an accelerometer to their sensor in part due to the research in this thesis. Rapid changes in vital signs may be artificially produced by movement artefact if for example the patient is walking. Knowledge of levels of activity may further enhance the reliability of this and other devices as well as collecting an important additional parameter. Continuous blood pressure monitoring to wearable sensors will transform use so that a more complete assessment of the patient can be performed. As wearable sensors

become more sophisticated and incorporate other vital sign parameters particularly - blood pressure, patients with sepsis may be identified using classifications such as qSOFA not at a single time point when a clinician checks but more as a dynamic calculation over time. For this method of monitoring to become established, integration into electronic health records is crucial. Additional tests such as white cell count, neutrophils and blood cultures will be combined with results from wearable sensor vital signs monitoring to allow real-time sepsis alert generation using continuous monitoring. Changes in the scoring of a patient regardless of the definition used in sepsis may be more useful rather than a single static value(257). This is where wearable sensors can really come in to their own due to the sheer number of readings generated and the possibility of continuous scoring of a patient with sepsis. Whilst there are devices which claim to measure continuous blood pressure through wearable sensors, there appear to be few trials on real-time use, reliability of such devices is still largely unknown.

One of the greatest limitations of sensor technology thus far has been power consumption. Although the Sensium wearable sensor is better than most of its competitors for power consumption it still only lasts for 5 days. There are substantial cost implications for paying for another sensor particularly in those patients which require a longer hospital stay. On the other hand when patients are discharged home with sensors, the number of days the sensor lasts for might limit its use. Ideally the next revolution in sensor technology shall be sensors which have the ability to power themselves either through kinetic energy (motion) or solar power for example(258). This will allow more sustained use and help reduce costs particularly when used in the community.

As well as sensors monitoring vital sign parameters, future sensors may be combined with newer diagnostic devices able to identify bacterial pathogens directly from the blood at the point of care(259). As well as identifying the pathogen, new devices might be able to review the individualised host response with faster turnaround times than current methods(259). This data combined with data analytical software may help predict and identify those patients with sepsis who are most likely to deteriorate(259). This could lead to greater targeting of these patients and more aggressive treatment(259). Complex analytical digital platforms are likely to utilise pathogen data, individual patient data such as vital signs and patient demographics to highlight the patients which need more urgent attention(259).

There are at least 178 different biomarkers that have been tested in sepsis; however thus far none has sufficient specificity or sensitivity for routine use in clinical practice(260). The majority of these markers have been used as a prognostic marker for sepsis with few used for sepsis diagnosis(260). In the future it is hoped that not only will wearable sensors be used routinely to detect changes in vital signs and bacterial pathogens but they may also be used to detect new biomarkers in sepsis. Wearable sensors are looking to noninvasively measure biochemical markers in biofluids which are readily available such as sweat, tears, interstitial fluid and saliva(261). The correlation between biochemical processes in biofluids and its relation to blood biochemistry needs to be established to assess reliability (261). The development of a microelectrode for electrochemical detection of one sepsis biomarker interleukin-6 (IL-6) has been suggested(262). Whilst there have been many attempts at reviewing new biomarkers for sepsis there has yet to be one biomarker found that uniquely identifies sepsis alone.

The sensors themselves may look very different to the ones previously described in Chapter 1. Discrete sensors may be more appropriate in high-risk individuals, such as those with dementia, who may be at increased risk of removing the sensor. This was a concern raised by staff members in the interviews. Newer more discrete monitoring may be more helpful in such patients. There are researchers currently working on sensors that are designed as thin tattoos for patients to wear(263). Epidermal wearable biosensors have been tested which measure biomarkers in epidermal biofluids (sweat and interstitial fluid). The sensors are directly transferred onto the skin through patches of temporary tattoos(261). The methodologies of these sensors has been either electrochemical or colorimetric transduction(261). A thin disposable electrode has been developed that can last for several days, and data may be uploaded in cloud-based storage platforms which may be analysed from doctors in hospital through remote monitoring(264). There are saliva-based biosensors with the ability to wirelessly detect bacteria on tooth enamel(265). Whilst this is still in the early stages there is the potential that they can be used to detect sepsis in the future. Whilst a majority of research into wearable biosensors is currently proof of concept, large cohort validation studies will be required to review clinical applicability and acceptance (261).

Implantable sensors are likely to be more advanced in future. An example of an implantable wearable already in use is the pacemaker used to treat arrhythmias or irregular heartbeats. On detection of an arrhythmia, a low energy current is provided that causes the rhythm to go back to normal. Future implantable sensors may be able to monitor additional parameters such as additional vital signs.

Recommendations for future work in wearable sensors and sepsis are as follows:

1. Large scale randomised trials reviewing several wearable sensor types and effects on clinical sepsis outcomes.
2. Testing of wearable sensors in the community in elderly patients and those with chronic disease.
3. Cost analysis of wearable sensors.
4. Developing sepsis digital dashboards facilitating real-time monitoring and using algorithms to help identify those patients most at risk.
5. Assessment of new sepsis biomarkers which may be tested using wearable sensors.

8.6 Future Challenges & Implications

The expected challenges are several fold. The first is the sensors themselves; they may need to be smaller still with longer battery lives, with good reliability and accuracy. They also must have great diagnostic accuracy to reduce the number of false alerts and the potential for alert fatigue, and should, ideally measure all vital signs including blood pressure and level of cognition so track and trigger scores can be calculated. The integration of them into the existing medical health record is essential for long-term uptake.

The second is delivery. However great the sensor technology is, it is reliant on the way it is delivered to the medical team. It must be delivered to the clinicians in an easy user-friendly format to encourage use. Newer sensor technology enables digital alerts to be sent to handheld devices such as smartphones as shown in this thesis. The smartphone technology is readily available and often used by many in their everyday lives. In this way, it may be easily co-ordinated into the healthcare professional's lifestyle without the need for extensive training that could occur with alternative technology. The network capacity in sensor technology particularly within a hospital setting must withstand the large amounts of data generated both from the sensors and the communication device used to relay this information.

The third is the mode of use. The use of wearable sensor technology should be used as an adjunct to care rather than replacement. The continued levels of staff and patient interaction should be maintained. The continuous monitoring should in no way replace nursing clinical

judgement of patient deterioration. The simple recording of vital signs data is not enough and appropriate clinical judgement should always be used(266).

The fourth is risk assessment. A proactive risk assessment for the implementation of wearable sensors has been suggested(267). A carefully designed implementation will help ensure successful integration into clinical workflows preventing problems and potential harm to patients(267). An evaluation would be performed focusing on the normal procedures and actions required for sensor use. In this way potential challenges hope to be identified and addressed (267). A proactive assessment can help address which patients will wear the wearable sensors and which clinical areas may require them the most (267). The fifth is cost, the economic costs of the sensors must be reviewed and should be cost-effective prior to wide scale roll out.

The use of digital observations delivered through wearable sensor technology offers a timely accurate vital signs reading which is date stamped. This can avoid the inaccuracies commonly occurred with manual paper based observation charts. A review of our ward observation data has found that illegible writing and missing data is a frequent occurrence. Wearable sensor technology can avoid such biases and any potential artefact data.

However newer forms of error may arise such as information overload and alarm fatigue from digital alerting. There is an argument that the continual disruption to patients with alerts being generated and prompting reviews by the clinical team may be even harmful to health.

In a study on ICU patients, sleep disruption caused partly from noisy environments could lead to delayed recovery and worsening patient outcomes(268).

Maintaining data security with any form of data is paramount. Wearable sensors may use cloud-based technologies particularly if used in future in the community. The challenge is to make sure that digital data is secure. Patient safety could be compromised if the wireless patient data was intercepted in some way(269).

Not all patients will be able to tolerate wearable sensors. There are some groups of patients that are unable to tolerate wearable sensors at all. One vulnerable group of patients are those with certain types of mental health problems. Those with forms of paranoia, personality disorder or schizophrenia are less likely to adhere to this form of monitoring. Other forms of monitoring such as traditional monitoring may be more useful in this group.

Ultimately these sensors will provide a whole new archetype of real-time continuous patient physiological assessment; these will link into the digital and big-data analytical platforms for the next-generation of healthcare where they will act as a catalyst for even better early diagnostics, preventions and cures.

8.7 Personal Reflections

I have undergone significant growth and transition throughout the PhD process. Although I had experience of academia prior to the PhD with my BSc and other research, this was quite a daunting task.

Initially I wanted to know all the answers straight away. I found not having a project or chapter outline at the start very frustrating. The thesis plan was constantly changing based on meetings with my supervisors and my own reading. The evolution of my thesis was quite a journey and as I progressed, I realised it was me that ultimately took ownership of it and decided the path. This insightful concept transformed further work. I built a narrative and was able to visualise the PhD thesis both on a macro and micro level. Once the thesis was visualised with the support of my supervisors and supporting team it was all about making it happen.

The first 6 months were hard as there was a lack of structure to the day. Unlike my clinical training where I have a highly structured day. I found the PhD to be the total opposite. The only structured parts of the week were the mandatory clinical night shifts and clinics I had to do as a research fellow in our department. At the start of the PhD I wanted to learn everything immediately and was working incredibly hard including at nights and weekends. Before I knew it, I was exhausted and a short holiday in January 2017 during my first year was very helpful to both refocus and regroup. I realised the process of the PhD was more of a marathon than a sprint. Thereafter I learned to create my own structured timetable and utilised what I had learned during my clinical training and use it for my PhD. The mornings are the best time

for me to perform writing and any complex analysis. This time is precious, and all attempts were made to preserve it. Any meetings or other work was held in the afternoons.

8.7.1 Deep Mind

The early months in my first PhD year were spent at DeepMind. I was working with the designers on the Streams application under the supervision of Dominic King. The time at Deep Mind was very interesting and I am very grateful for this. Unlike working in the overstretched and under resourced National Health Service (NHS), Deep Mind had an abundance of highly skilled staff and resource. I assisted the Deep Mind designers and engineers to help with user testing of the Streams application. Working with Deep Mind was great and hugely insightful. I later used these learned usability skills to design the protocols for this thesis particularly for the patient and staff chapters. Unfortunately, the wearable department at google was not ready for a clinical trial at this stage which left me researching other wearable companies.

8.7.2 Sensium

Sensium is a small company in comparison to google with 75 UK staff members. The company is based in Oxfordshire and is owned by the parent company the Surgical Group. Learning to collaborate and work with an industrial partner was in many ways the key to this thesis. This was a process of trust and a journey. Initially I only had meetings with the company when my supervisors were present. However, I soon gained confidence and chaired these meetings independently.

The key to success was learning to align my research goals with that of the broader goals of the company. It helped that there were several academics within the company. This ensured

we were talking the same language and they understood our research processes. Good communication was essential to the partnership and regular updates from both parties were made throughout the three years.

There were several difficulties with the project itself. We started the pilot study in December 2017 and Phase 1 of the study in January 2018. From January 2018 to August 2018 I had spent most of my time processing and analysing the sensor data. Processing sensor data was a manual process which took at least 4-5 hours per patient. It was not until August 2018 that Sensium realised there was a real problem with the data. Sensium uses universal time stamps but the change to British summer time had not registered. Whilst the data we have received from Sensium seemed correct, all data time stamps were in fact out by an hour. This effectively meant that all of our data processing over 8 months (January 2018 – August 2018) was totally incorrect. The matching of the data to ward data was wrong as the time stamps were wrong. This was a major challenge, due to the complexities of processing the data, I was unable to just add an hour to all the data. Whichever way I tried to adjust the original data analysis, it was totally incorrect and would have led to even more inaccuracies. This was a really frustrating time as all of my analysis was wrong, and I felt this precious time had been wasted through no fault of my own. I had felt let down by the company and was losing trust. However co-incidentally the company had hired a new data scientist, Dr Carlos Pedreira to help with data processing around this time. This was a big turning point for both them and me. We found a way the data scientist could help with the sensor data formatting but not the processing. I was able to provide Sensium with the ward time stamps but not the confidential ward data. This arrangement prevented me from redoing much of the work I had just done and was a better plan going forward. I was able to give Sensium the nursing times for ward observations without giving them the actual data of the vital sign readings. Carlos

and I began working collaboratively so the setback was actually a catalyst for change and growth. The manual processing that I had been performing with the data on large Excel sheets was no longer required. Carlos was able to provide me Sensium data in a much better format that was easier for me to analyse and process. This was a huge help with the rest of our work. I have developed a good relationship with Sensium and this has really helped with the project going forwards and establishes a good foundation for future research collaboration.

8.7.3 Royal College of Surgeons Research Fellowship

Being awarded the Royal College of Surgeons Research Fellowship was a huge breakthrough. Writing the application and performing the viva helped me really consolidate the thesis both in a written format and in my mind. Firstly, it was acknowledgement at a national level, that the Royal College of Surgeons believed in the thesis plan and vision of the project. This is a highly competitive fellowship with only 20-25 fellowships awarded each year. The viva by eight professors of surgery and senior academics was both challenging and enjoyable. I used the funding from the fellowship in the final year of my PhD so that I no longer had to be on call every week. This extra day each week really helped me propel the thesis forward with both patient recruitment and analysis. Secondly, this competitive award enabled me to gain further support from the Clinical Research Network (CRN). I was allocated supporting research nurses to help with the study and recruit patients. Without this support the recruitment of large numbers of patients would have been very difficult. I am extremely grateful for the RCS research fellowship and the CRN for their support.

8.7.4 NHS England Sepsis Board

One of the greatest achievements I have had with this work is being invited to be an advisor on the NHS England Sepsis Board. I attended a Sepsis conference in my first year of the PhD and was interviewed by Ms Celia Ingham Clark who chairs the board and is the Medical Director for Clinical Effectiveness. I was selected as the only trainee representative to be on the board. I have had an active involvement on the Sepsis board for the last three years. I have contributed with not only knowledge learned through the work of this thesis but through other work such as national level sepsis codes in surgical patients. Having the opportunity to discuss research at a national level has been incredibly rewarding and insightful.

8.7.5 Achievements

I am proud of the success of this project and what I have achieved. From being invited as an international guest speaker at the European Resuscitation Council to receiving several awards, prizes and publications. The large patient recruitment and feedback from patients is due to hard work and discipline. Towards the end of my PhD I have been approached by a large multinational conglomerate. This company had already invested in millions of pounds into both wearable technology and sepsis algorithms. Despite their huge amounts of funding and resource, what I have achieved throughout this thesis has been more than they have been able to as they have yet to recruit a real hospital patient. This knowledge and awareness has been both motivating and satisfying and will help fuel my further research career going forwards.

8.8 Conclusions

Wearable sensors and remote monitoring have the potential to transform healthcare. When researching the top medical innovations in 2018, centralised monitoring for hospitalised patients was in the top 10(270). The work performed in this thesis has led me to truly believe in the potential benefits of wearable sensing technologies to both patients and healthcare staff.

There will be a dramatic change in the landscape of assessment of vital signs observations as these new technologies develop further. For decades, the way vital signs are measured have not changed. They are taken at static moments in time. Wearable sensors will cause a huge paradigm change. Patients will be continuously monitored which in turn will be combined with real time analytics helping to identify unwell or deteriorating patients much sooner than current technologies. The use of these sensors in high-risk patients and acutely unwell patients will be an early source of interest. Ultimately these sensors may provide a whole new archetype of real-time continuous patient physiological assessment; the sensors will link into the digital and big-data analytical platforms for the next-generation of healthcare where they will act as a catalyst for even better early diagnostics, preventions and cures. The potential of wearables to detect sepsis and patient deterioration earlier may be akin to penicillin in the era of digital health.

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The standardised observational chart for the National Early Warning Score

National Early Warning Score 2 (NEWS2) © Royal College of Physicians 2017

Appendix 2.1

Literature Review

The search was performed on 12/02/2019.

2.1.1 Medline Search

596 (plus 148) = 744

1	digital platform* or electronic platform* or electronic alert* or (Electronic or automated or digital) adj 2 (record* or system*) or machine learning* or AI* or Artificial Intelligence* or ((Electronic or automated or digital) and escalation) or Machine learning (MESH term) or Supervised machine learning (MESH term) or Decision theory (MESH term) or medical informatics (MESH term) or health information exchange (MESH term) or medical informatics applications (MESH term), decision making, computer –assisted (MESH term) or diagnosis, computer assisted (MESH term) or therapy, computer assisted (MESH term) or telemedicine (MESH term) or telepathology (MESH Term) or eHealth* or mhealth* or technology (MESH term) or internet (MESH term) or communications media (MESH term) or programmed as topic (MESH term) or computers, handheld (MESH term) or smartphone (MESH term) or mobile applications (MESH term) or cellphones (MESH term) or text messaging (MESH term) or ((mobile* or cell* or smart*) and phone*) or (digital adj health)*
2	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32
3	Sepsis (MESH term) or bacteremia (MESH term) or fungemia (MESH term) or shock, septic (MESH term), or sepsis* or septicaemia* or Systemic inflammatory response syndrome (MESH term) or systemic inflammatory response syndrome* or SIRS* or septic shock*
4	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
5	2 and 4

2.1.2 Embase search

2512 + 420 = 2932

1	digital platform* or electronic platform* or electronic alert* or (Electronic or automated or digital) adj 2 (record* or system*)) or machine learning* or AI* or Artificial Intelligence* or ((Electronic or automated or digital) and escalation) or Machine learning (SUBJECT HEADING) or data mining (SUBJECT HEADING), or supervised machine learning (SUBJECT HEADING) or medical informatics (SUBJECT HEADING) or artificial intelligence (SUBJECT HEADING) or telemedicine (SUBJECT HEADING) or telepathology (SUBJECT HEADING) or eHealth* or mhealth* or technology (SUBJECT HEADING) or internet (SUBJECT HEADING) or personal digital assistant (SUBJECT HEADING) or smartphone (SUBJECT HEADING) or mobile applications (SUBJECT HEADING) or mobile phone (SUBJECT HEADING) or text messaging (SUBJECT HEADING) or ((mobile* or cell* or smart*) and phone*) or (digital adj health)*
2	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
3	Sepsis (SUBJECT HEADING) or Systemic inflammatory response syndrome (SUBJECT HEADING) or bacteremia (SUBJECT HEADING) or fungemia (SUBJECT HEADING) or septic shock (SUBJECT HEADING), septicemia (SUBJECT HEADING) or sepsis* or systemic inflammatory response syndrome* or SIRS* or septic shock*
4	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
5	2 and 4

2.1.3 Health Management Information Consortium (HMIC) Search

4+1=5

1	digital platform* or electronic platform* or electronic alert* or (Electronic or automated or digital) adj 2 (record* or system*) or machine learning* or AI* or Artificial Intelligence* or ((Electronic or automated or digital) and escalation)* or decision theory (SUBJECT HEADING) or medical informatics (SUBJECT HEADING) or electronic patient records (SUBJECT HEADING) or medical information exchange (SUBJECT HEADING) or medical informatics (SUBJECT HEADING) or computer aided learning (SUBJECT HEADING) or artificial intelligence (SUBJECT HEADING) or telemedicine or medical telemetering equipment (SUBJECT HEADING) or telemetry (SUBJECT HEADING) or digital technology (SUBJECT HEADING) or internet (SUBJECT HEADING) or electronic data exchange (SUBJECT HEADING) or personal somputers. Or laptop computers (SUBJECT HEADING) personal digital assistant (SUBJECT HEADING) or tablet personal computer (SUBJECT HEADING) or mobile communication systems (SUBJECT HEADING) or mobile telephones (SUBJECT HEADING) or text messaging (SUBJECT HEADING) or ((mobile* or cell* or smart*) and phone*) or (digital adj health)*
2	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
3	Sepsis (SUBJECT HEADING) or sepsis* or septicaemia or septic shock or Systemic inflammatory response syndrome or SIRS
4	1 or 2 or 3 or 4 or 5 or 6
5	2 and 4

2.1.4 Psych Info Search

98+11=109

1	digital platform* or electronic platform* or electronic alert* or (Electronic or automated or digital) adj 2 (record* or system*)) or machine learning* or AI* or Artificial Intelligence* or ((Electronic or automated or digital) and escalation)* or machine learning (SUBJECT HEADING) or artificial intelligence (SUBJECT HEADING) or decision theory (SUBJECT HEADING) or telemedicine (SUBJECT HEADING) or computer assisted diagnosis (SUBJECT HEADING) or computer assisted therapy (SUBJECT HEADING) or eHealth* or Mhealth* or Technology (SUBJECT HEADING) or internet or computer applications or communications media or cellular phones (SUBJECT HEADING) or mobile devices (SUBJECT HEADING) or text messaging or ((mobile* or cell* or smart*) and phone*) or (digital adj health)*
2	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
3	Sepsis* or septic shock or bacteremia* or fungemia* or septicaemia* or Systemic inflammatory response syndrome or SIRS*
4	1 or 2 or 3 or 4 or 5 or 6 or 7
5	2 and 4

2.1.5 Cochrane

2+69 = 71

1	digital platform* or electronic platform* or electronic alert* or (Electronic or automated or digital) adj 2 (record* or system*) or machine learning* or AI* or Artificial Intelligence* or ((Electronic or automated or digital) and escalation) or Machine learning (MESH term) or Supervised machine learning (MESH term) or Decision theory (MESH term) or medical informatics (MESH term) or health information exchange (MESH term) or medical informatics applications (MESH term), decision making, computer –assisted (MESH term) or diagnosis, computer assisted (MESH term) or therapy, computer assisted (MESH term) or telemedicine (MESH term) or telepathology (MESH Term) or eHealth* or mhealth* or technology (MESH term) or internet (MESH term) or communications media (MESH term) or computers, handheld (MESH term) or smartphone (MESH term) or mobile applications (MESH term) or text messaging (MESH term) or ((mobile* or cell* or smart*) and phone*) or (digital adj health)*
2	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32
3	Sepsis (MESH term) or bacteremia (MESH term) or fungemia (MESH term) or shock, septic (MESH term), or sepsis* or septicaemia* or Systemic inflammatory response syndrome (MESH term) or systemic inflammatory response syndrome* or SIRS* or septic shock*
4	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
5	2 and 4

Appendix 3.1

Participant information sheet

WEARABLE PATCH VITAL SIGN MONITORING PROJECT

Participants information sheet for study

Contact

Dr Meera Joshi
10th Floor QEOM Building
St Mary's Hospital
Praed Street
London W2 1NY
United Kingdom
Email : meera.joshi03@imperial.ac.uk

You are being invited to take part in a research study. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Thank you

A large print version is available for those that require it, please ask the research team for a copy of this.

Summary

Why?

We are trying to find out if participants that suddenly deteriorate on the ward can be identified sooner by wearing a wearable sensor. This is an important study to see if the sensor works correctly in recording continuous vital observations of heart rate, respiratory rate and temperature. This information can help doctors and nurses identify unwell participants .

What?

We will ask you to wear a light wearable sensor on the chest that can be worn for 5 days. If you are still in hospital after this time the sensor can be changed. All sensors are disposable. You would not have to actively do anything to the sensor. We will also ask you to complete a short questionnaire about the sensor.

Who?

All participants on the ward that are admitted with a new medical or surgical problem can take part in the study. Anyone undergoing a surgical procedure that requires at least one overnight stay is eligible to take part in this study.

Where?

This study is being conducted at West Middlesex University Hospital and St Marys Hospital Paddington. Only certain wards are being included at both sites, if the participant moves wards the sensor will be removed.

How?

The study will last around 2 years and we aim to recruit 1000 participants.

1. What is the purpose of the study?

We are aiming to see if participant deterioration on the ward can be identified sooner by wearing the wearable sensor. We know that if we can identify sick participants quickly, participants are more likely to have better outcomes. The sensor measures heart rate, respiratory and temperature every 2 minutes and this can be reviewed by the clinical team of nurses and doctors looking after the participants. The participants will still have all their normal clinical care and bedside observations.

This research will also be used as part of a PhD thesis at Imperial College London.

2. Why have I been chosen?

You have been invited to take part in this study because you have had an acute medical or surgical problem that requires a stay in the hospital for at least one day.

3. Do I have to take part?

You do not have to take part in this study. You will have at least 2 hours to decide whether you wish to take part in the study and review the documentation but can have longer if needed. If you decide to take part, you will be asked to sign a consent form. Not participating or withdrawing from this study will not affect your current clinical care or any future clinical care.

4. What will happen to me if I take part?

If you are happy to participate you will be asked to read and sign a consent form. You will have opportunity to talk with the research team before signing the consent form and we can answer any questions you might have about the study.

Your paper and electronic medical notes may be looked at by responsible individuals from Imperial College, the NHS Trust or from regulatory authorities where it is relevant to your taking part in this research. In signing the consent form you give permission for these individuals to access your records that are relevant to this research.

Once you have given your consent, you will be asked to wear a small light weight wearable sensor. This is placed on your chest by the nurse or another healthcare professional. It can be worn continuously for up to 5 days. It is waterproof and can be worn whilst washing. It is a wireless sensor and you can move around as normal and do all your usual activities.

A picture of the wearable sensor is shown below.



If after 5 days, you are still in the hospital the sensor can be changed for another one. When you leave the hospital the sensor can be removed and handed back to the clinical team to be disposed of.

Taking part in this study in no way changes or affects the standard of clinical care you will receive now or in the future.

You will be asked to complete a questionnaire as part of the study that takes around 15 minutes. You will be given the questionnaire at the start of the study and this will be collected prior to discharge.

5. What happens to the data collected?

The data collected from the wearable sensor is heart rate, respiratory rate and temperature. This information will be used only by the clinical team and researchers in this project.

Data collected will be stored on a secure encrypted database. The data will be processed to allow the investigators to see if participants deterioration on the wards can be identified sooner than compared to standard observation taking. The data from the sensor may be used by the clinical team to help identify unwell participants

All paper records will be anonymous and paper questionnaire records will be kept securely in a locker in a locked office. Electronic data will be stored on a password protected computer at Imperial College and backed up regularly. No personal identifiable information will be used in any reports arising from this research. All paper records will be anonymous.

Whilst it is highly unlikely that you will lose mental capacity during the study but should you do so you will be withdrawn and no further data collected. Participating in the study does **NOT** increase chances of losing capacity. There are no risks associated with participation.

6. What are the possible benefits and disadvantages/risks of taking part?

Benefits

It is possible that by wearing the sensor unwell participants may be identified sooner. The questionnaire study will help us to understand more about people's views on the wearable sensor technology.

Disadvantages/risks

The Sensium vital signs sensor is a CE approved device and is completely safe. The monitor/sensor does not affect any other electrical equipment that you might carry. We will not ask you to attend any extra clinics or meetings above normal standard care. There is a small chance that talking about the issues raised in this questionnaire may make you feel a bit worried. If so, we can put you in contact with somebody who will be able to help you with your concerns. If you report serious incidents or unreported events, in the interests of safety, these may need to be reported to the appropriate clinical manager. If you have been affected by incidents that have happened at the hospital, we can put you in contact with the hospital PALS service. There is no financial incentive to participate.

7. What will happen if I don't want to carry on with the study?

The decision to take part in this study is entirely voluntary and you can change your mind at any time. Any decision you take to withdraw from the study will not affect the care you receive now or in the future.

If you do withdraw from the study information already collected may still be used. To withdraw from the study please tell the nurse looking after you and the wearable patch will be removed immediately.

8. What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service

complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

9. Will my participation in this study be kept confidential?

All information collected about you during the research is strictly confidential. Any information about you which leaves the clinical setting will have your name and details removed. All participants will be given a unique code number to anonymise the data. Questionnaires and other study documents will be kept in a combination locker in a locked office in the Academic Surgical Unit, 10th Floor, QEOM, St Marys Hospital, London, W2 1NY. Data will be backed up with secure storage for a period of 10 years for purpose of reference to data requested regarding any research published.

10. What will happen to the results of the research study?

The results of the research will be analysed and published in scientific journals. No individual participants will be identifiable from any report or publication.

The study data will also be used as part of a PhD thesis by Dr Meera Joshi.

11. Who is organising and funding the research?

The research is being organised and funded by Imperial College London.

12. Who has reviewed the study?

This study has been reviewed and approved by the Research Ethics Committee.

13. Who to contact about this study

Contact Dr Meera Joshi (details above) for further information and support,

Alternatively, Dr Sadia Khan (Principle Investigator West Middlesex University hospital), Consultant Cardiologist, West Middlesex University Hospital, Twickenham Road, Isleworth, TW7 6AF, Tel 020 8321 5336, Fax 020 8321 5394

OR for independent advice please contact:

Patient Advice and Liaison Service (PALS) West Middlesex University Hospital, Twickenham Road, Isleworth, TW7 6AF, Telephone 020 8321 6261
Patient Advice and Liaison Service (PALS) St Marys Hospital London Paddington, Queen Elizabeth the Queen Mother (QEOM) building, St Mary's Hospital, South Wharf Road, London W2 1NY, Telephone 020 3312 777

Participants will be given a copy of the consent form and information sheet for their own records.

Appendix 3.2

Participant consent form

Imperial College
London

IRAS ID 222979

WEARABLE PATCH VITAL SIGN MONITORING PROJECT
Consent form for patient enrolment in study and for questionnaires
Version 3 31/08/2017

Name of Researcher: Miss Meera Joshi

Supervisors: Professor Ara Darzi, Dr Sadia Khan, Dr Richard Kwasnicki

Participant ID:

Instructions for the participant:

Please read each of the sections below. In the box next to each section, please write your initials to show that you agree with what the section says.

When you have written your initials, please write your name, today's date and add your signature in the spaces at the bottom.

		Initials
1	I have read and understand the information sheet for the above study version 1.	
2	I have had the opportunity to think about the information and to ask questions about it if I want to. If I have asked questions, I am happy with the way my questions have been answered.	
3	I understand that I will be wearing a wearable monitoring patch.	
4	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
5	I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College, the NHS Trust or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research.	
6	I understand that I will be asked to fill out a questionnaire.	
7	I understand what will happen in the study.	
8	I understand that if I was to lose capacity to consent during the study, I will be withdrawn from the study and further data no longer collected.	
9	I have been informed that anything I say on the questionnaire will remain anonymous; my name will not be used, nor any other information that could be used to identify me.	
10	I understand that the information from the questionnaire will be saved on a computer at Imperial College London and the questionnaire will be safely stored at Imperial College London.	
11	I agree to take part in this study.	

Name of Participant

Date

Signature

Name of Person taking consent

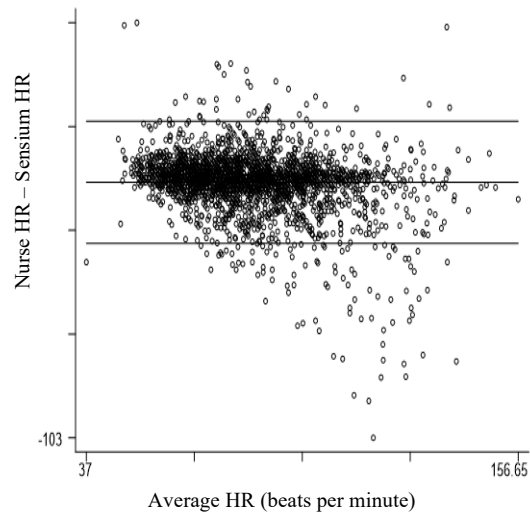
Date

Signature

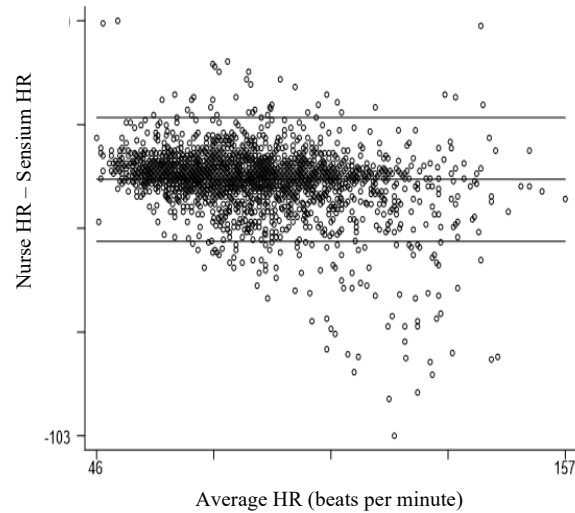
Appendix 3.3

Bland Altman Plots and histograms for the 6-minute time window for HR using both the means and medians

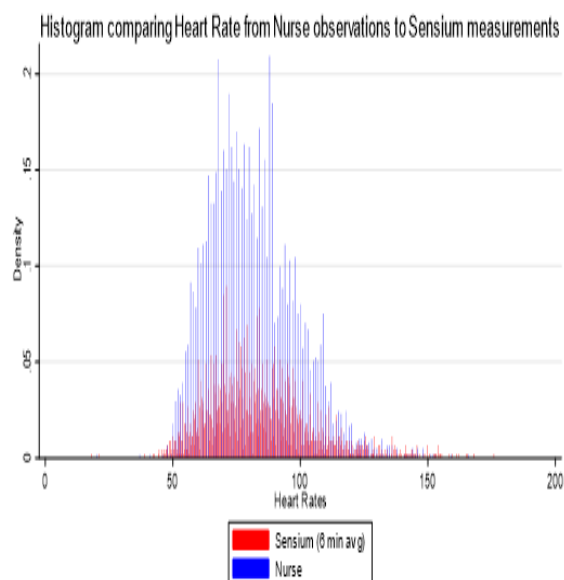
Bland Altman – 6-minute mean HR



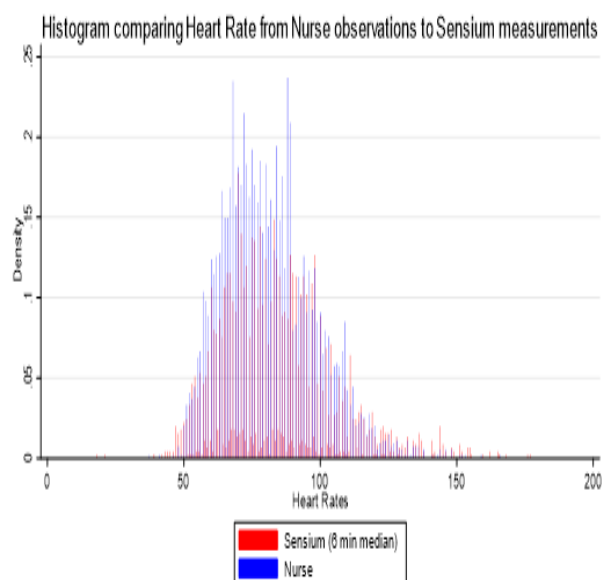
Bland Altman – 6-minute median HR



Histogram for 6-minute mean HR



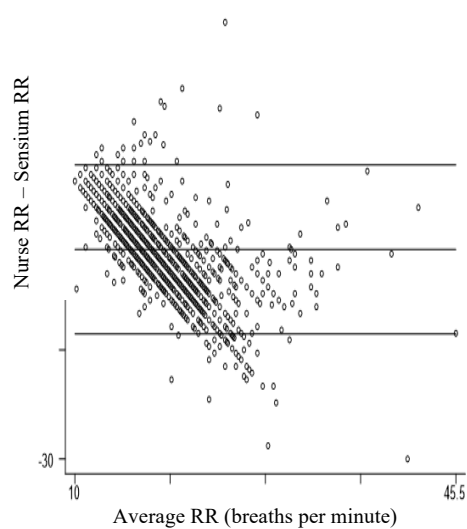
Histogram for 6-minute median HR



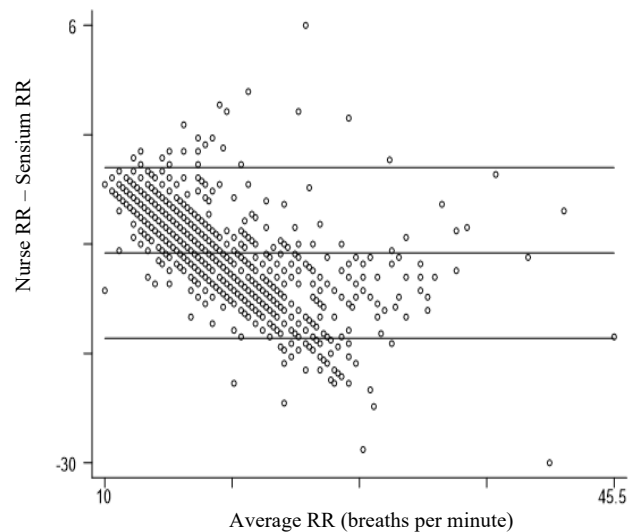
Appendix 3.3

Bland Altman Plots and histograms for the 6-minute time window for RR using both the means and medians

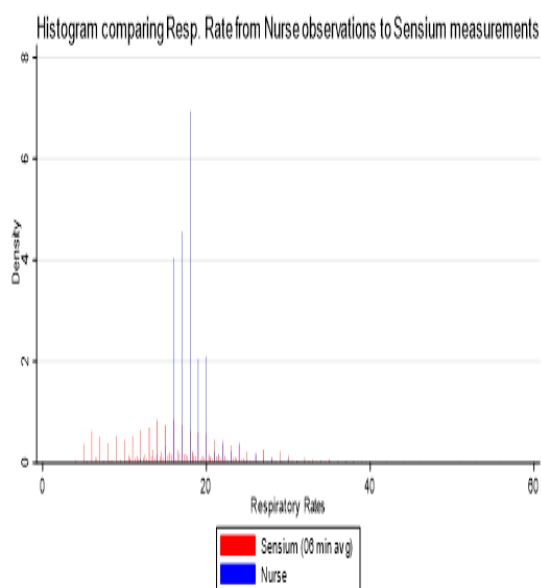
Bland Altman – 6-minute mean RR



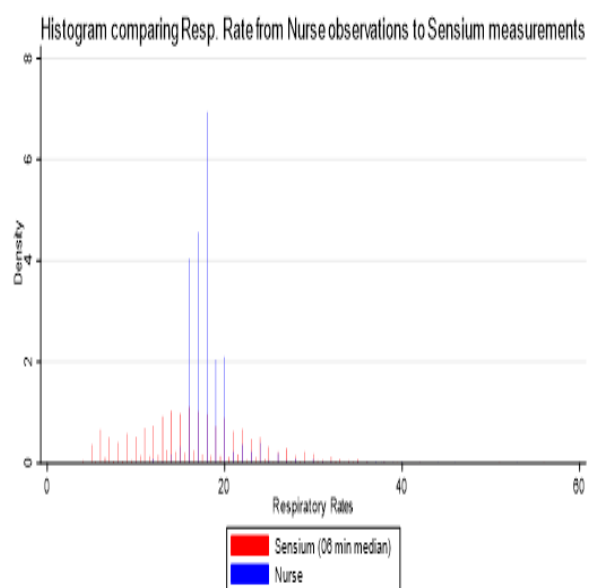
Bland Altman – 6-minute median RR



Histogram for 6-minute mean RR



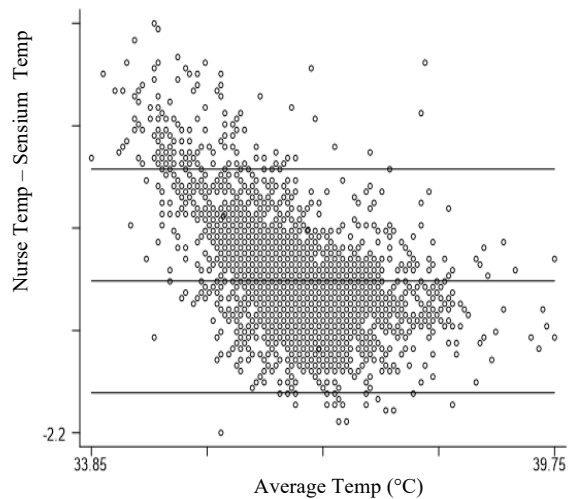
Histogram for 6-minute median RR



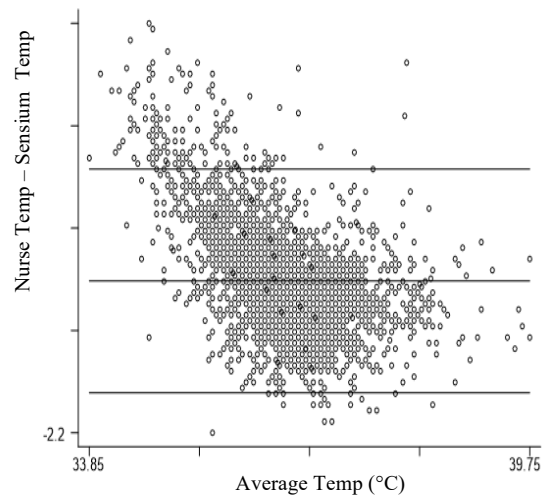
Appendix 3.3

Bland Altman Plots and histograms for the 6-minute time window for temperature using both the means and medians

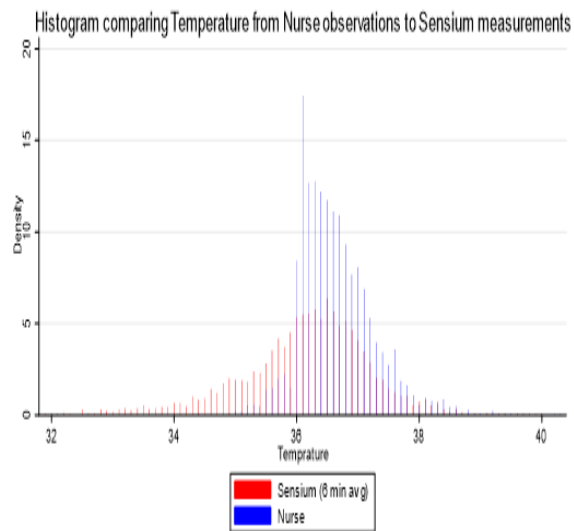
Bland Altman-6-minute mean Temp



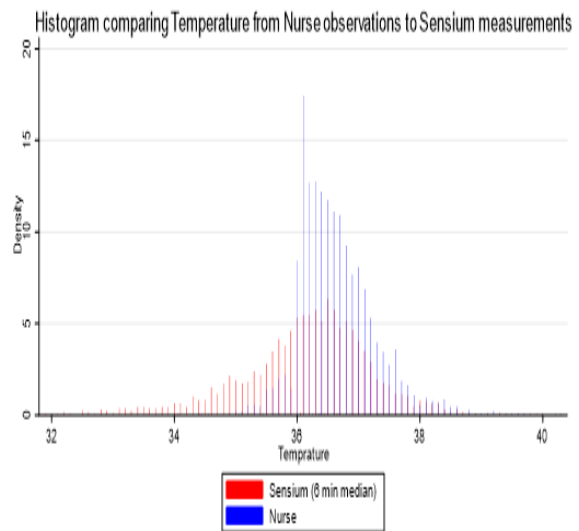
Bland Altman-6-minute median Temp



Histogram for 6-minute mean Temp



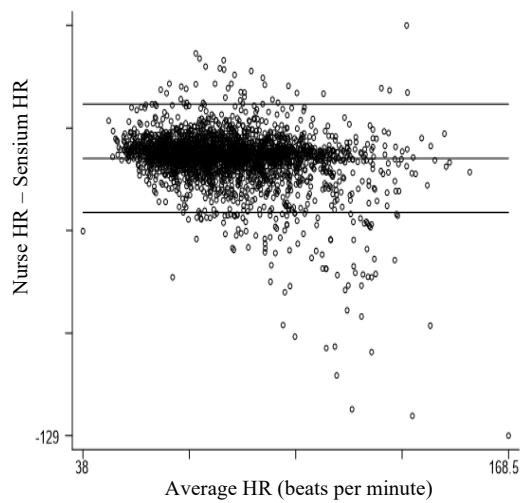
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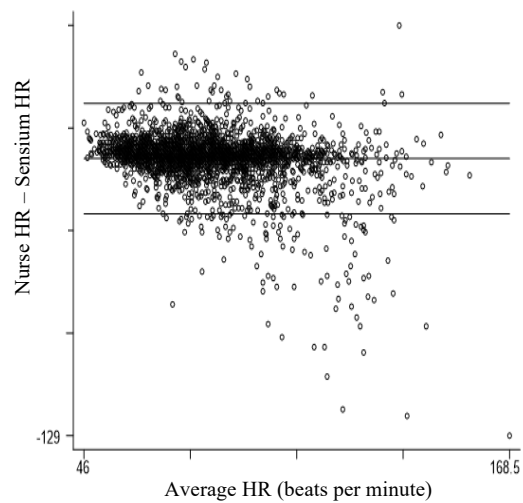
Appendix 3.4

Bland Altman Plots and histograms for the 12-minute time window for HR using both the means and medians

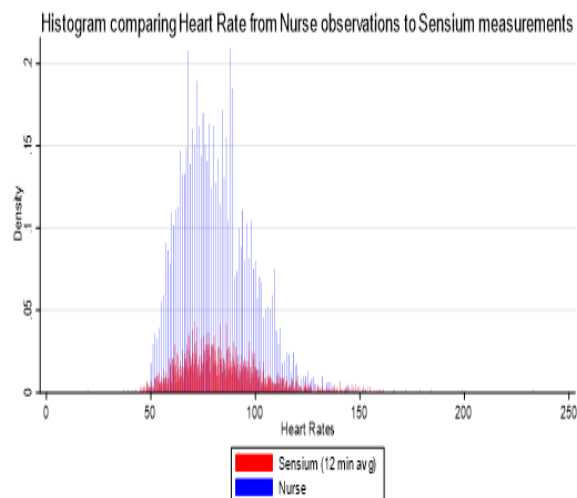
Bland Altman-12-minute mean HR



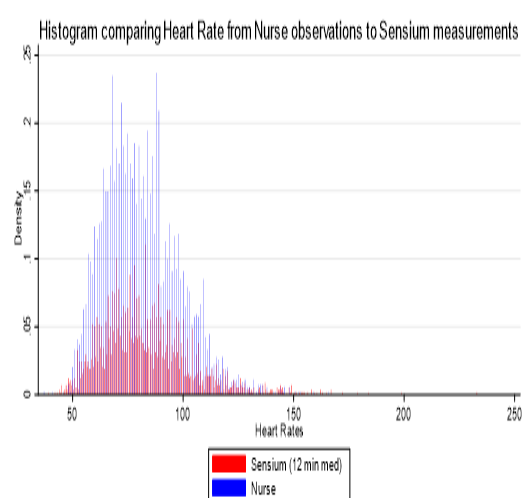
Bland Altman-12-minute median HR



Histogram for 12-minute mean HR



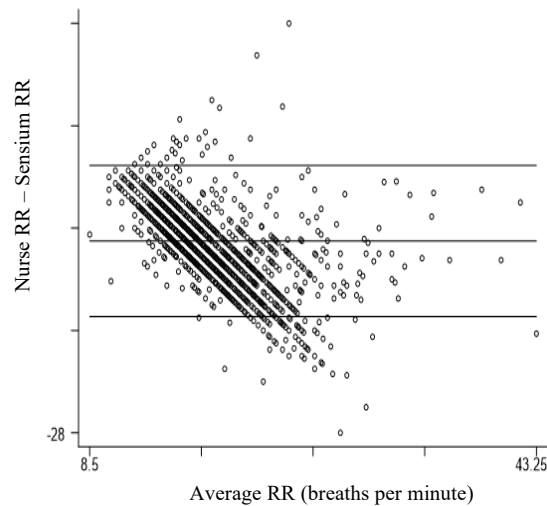
Histogram for 12-minute median HR



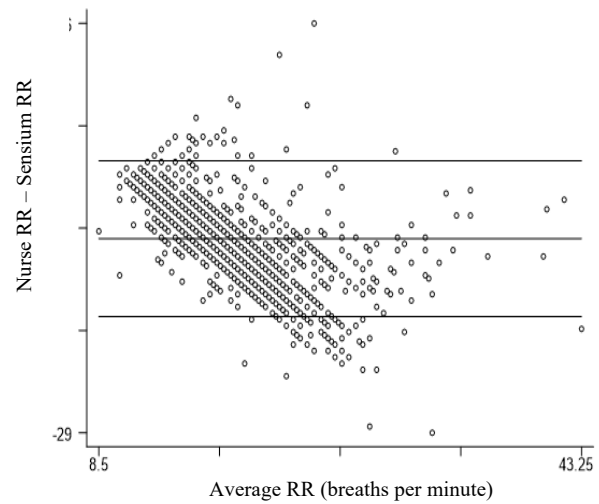
Appendix 3.4

Bland Altman Plots and histograms for the 12-minute time window for RR using both the means and medians

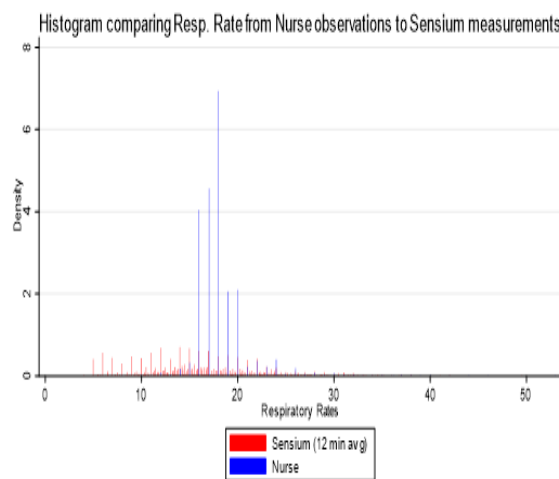
Bland Altman-12-minute mean RR



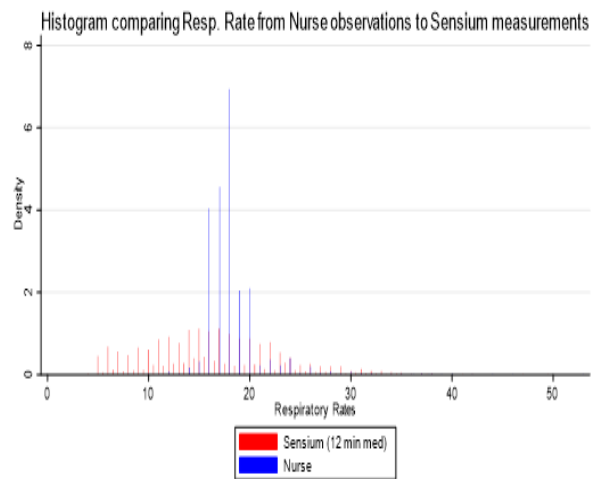
Bland Altman-12-minute median RR



Histogram for 12-minute mean RR



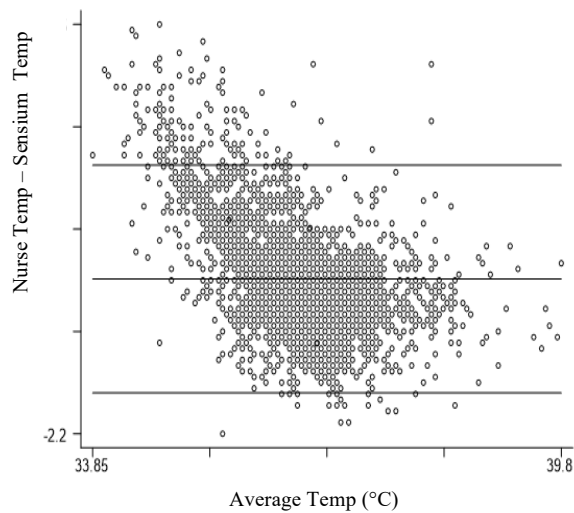
Histogram for 12-minute median RR



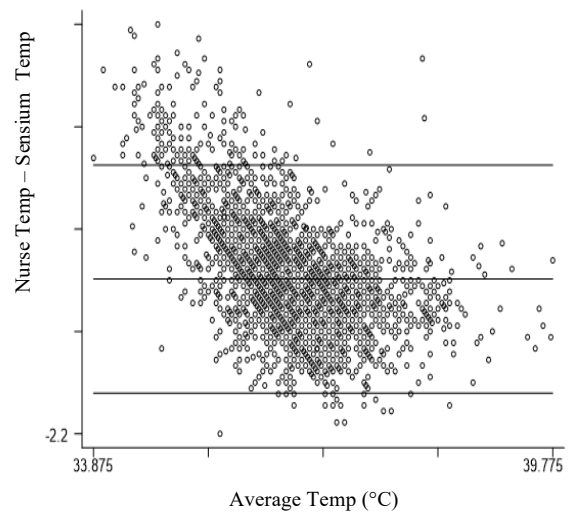
Appendix 3.4

Bland Altman Plots and histograms for the 12-minute time window for temperature using both the means and medians

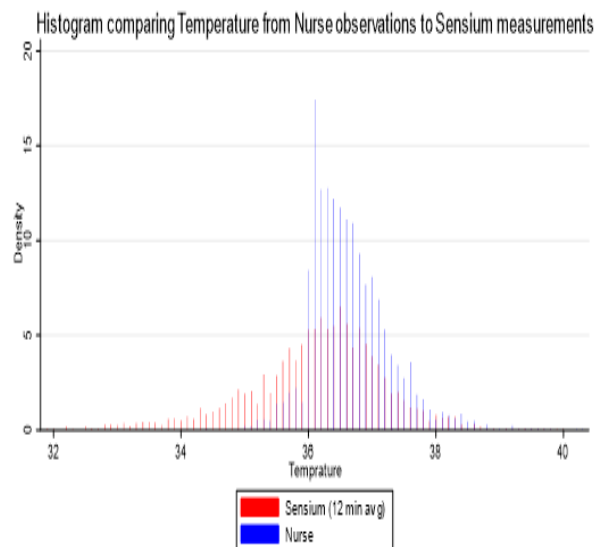
Bland Altman-12minute mean Temp



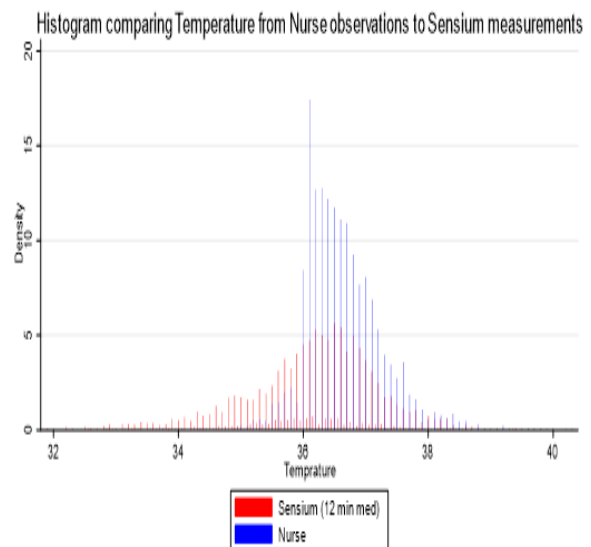
Bland Altman-12minute median Temp



Histogram for 12-minute mean Temp



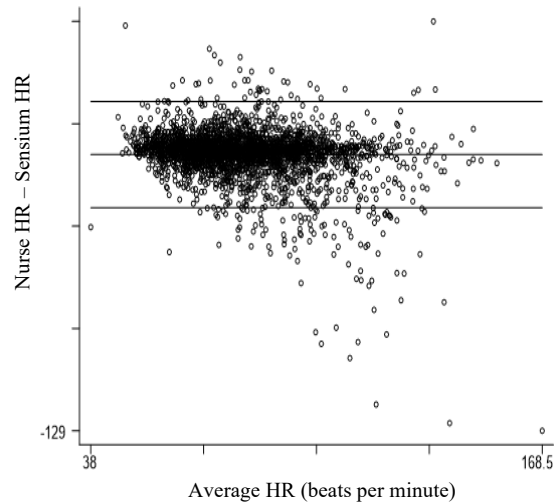
Histogram for 12-minute median Temp



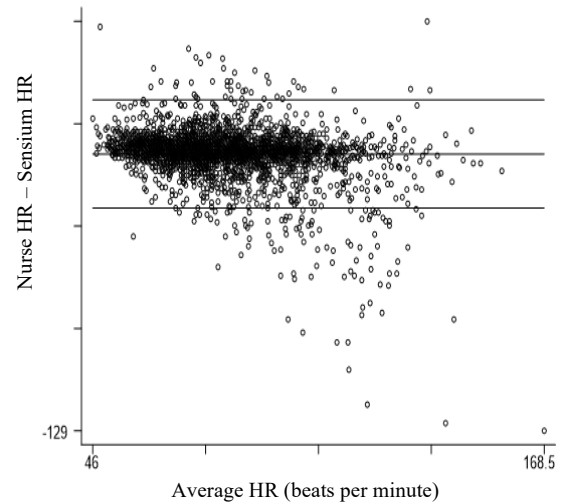
Appendix 3.5

Bland Altman Plots and histograms for the 16-minute time window for HR using both the means and medians

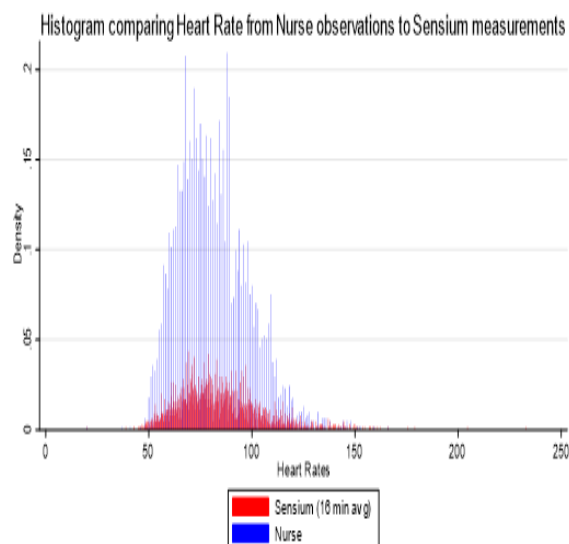
Bland Altman-16-minute mean HR



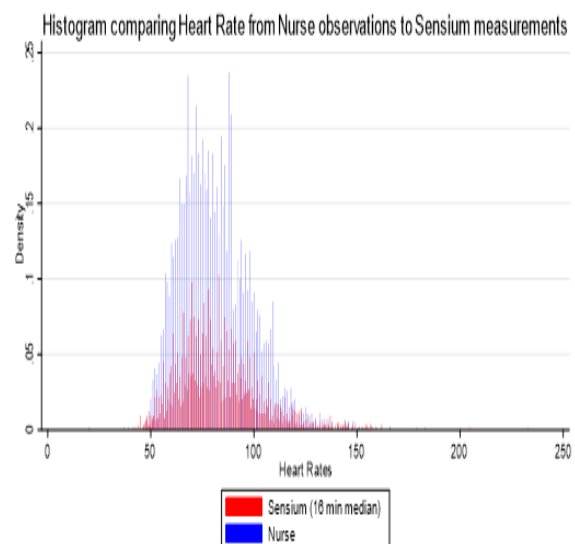
Bland Altman-16-minute median HR



Histogram for 16-minute mean HR



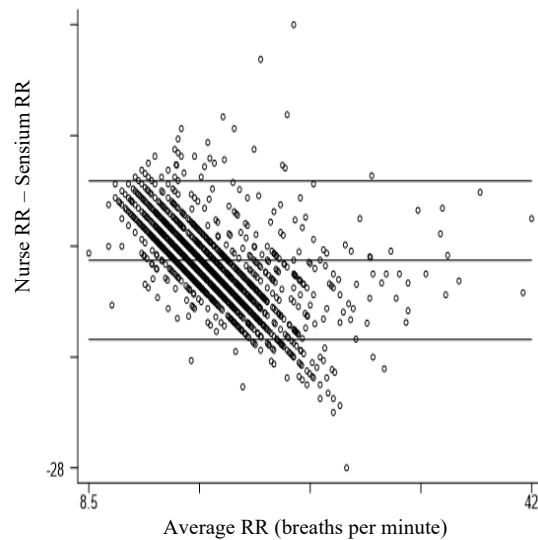
Histogram for 16-minute median HR



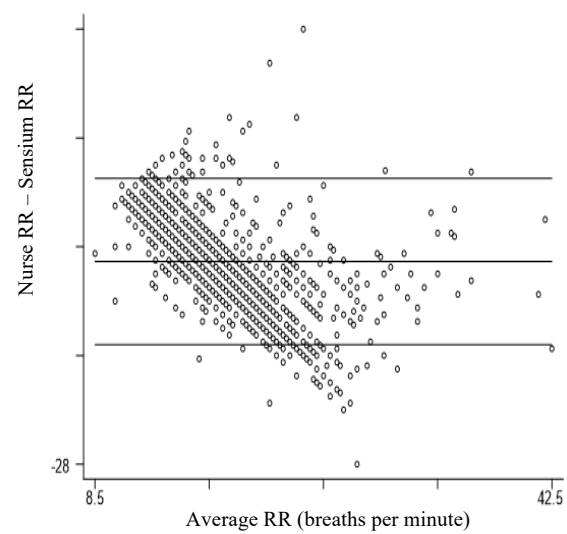
Appendix 3.5

Bland Altman Plots and histograms for the 16-minute time window for RR using both the means and medians

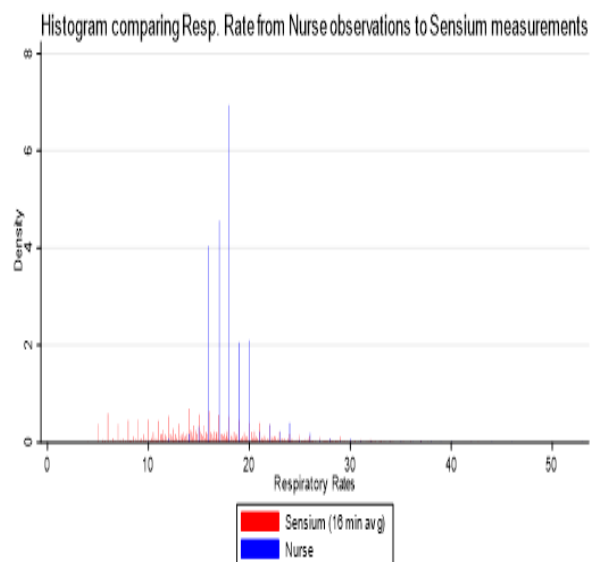
Bland Altman-16-minute mean RR



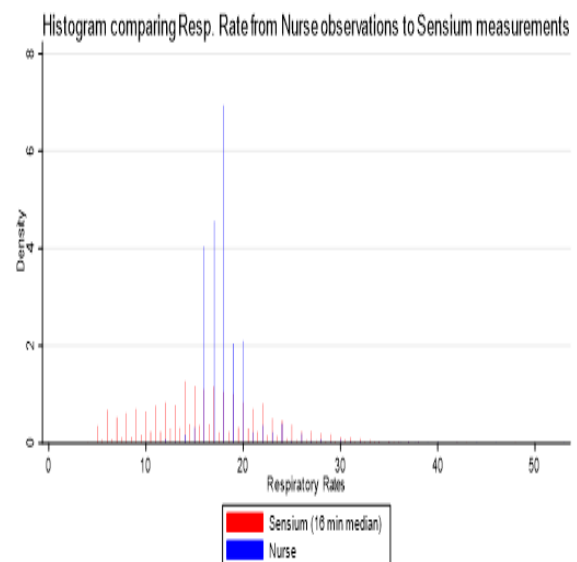
Bland Altman-16-minute median RR



Histogram for 16-minute mean RR



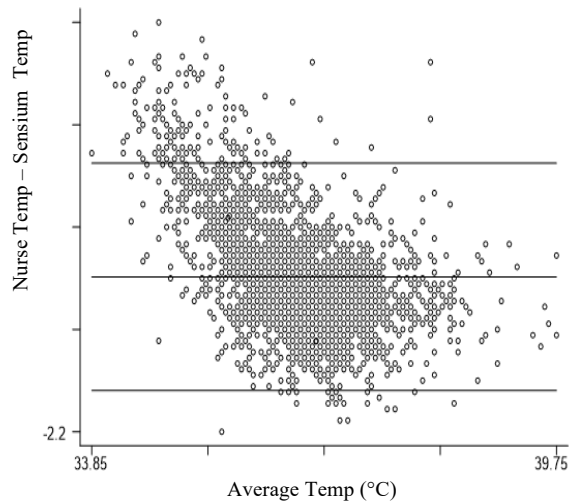
Histogram for 16-minute median RR



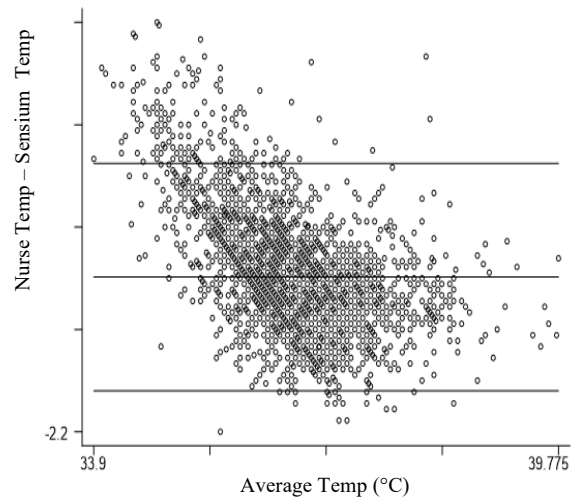
Appendix 3.5

Bland Altman Plots and histograms for the 16-minute time window for temperature using both the means and medians

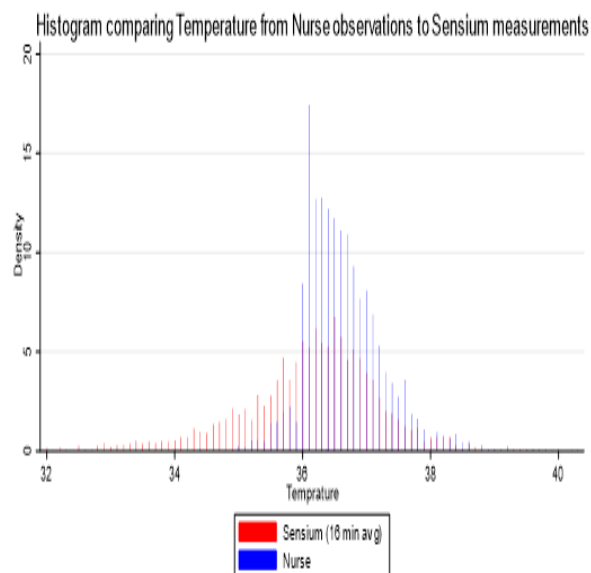
Bland Altman-16-minute mean Temp



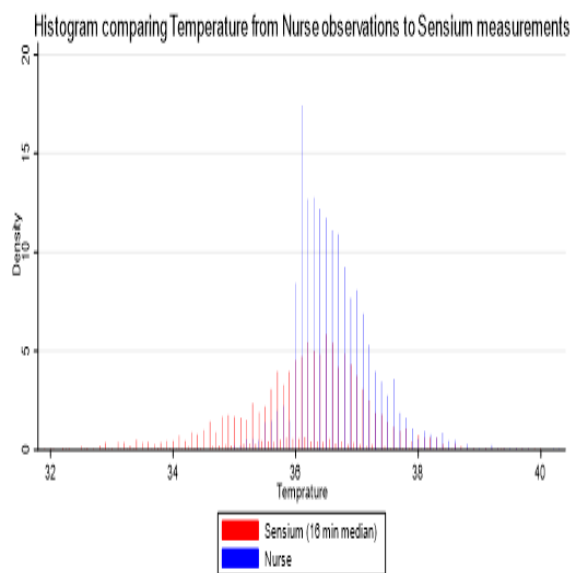
Bland Altman-16-minute median Temp



Histogram for 16-minute mean Temp



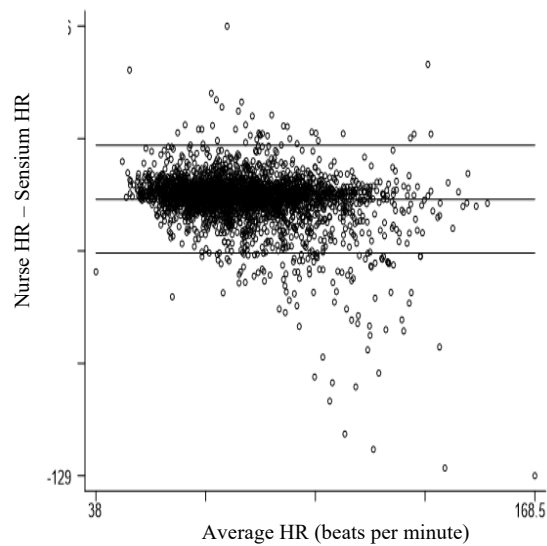
Histogram for 16-minute median Temp



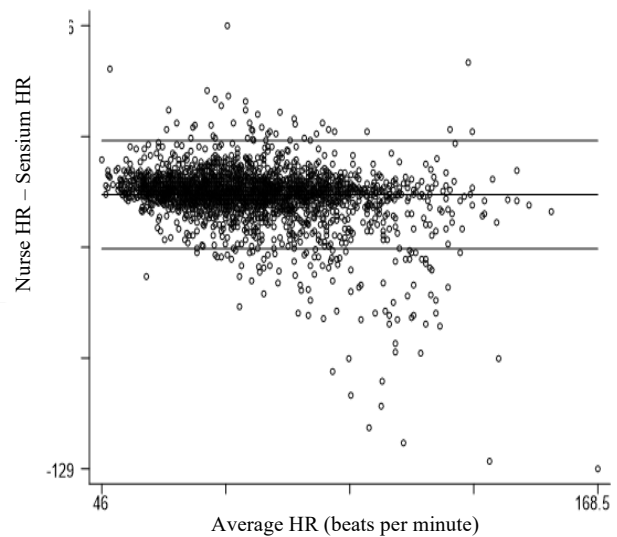
Appendix 3.6

Bland Altman Plots and histograms for the 18-minute time window for Heart Rate using both the means and medians

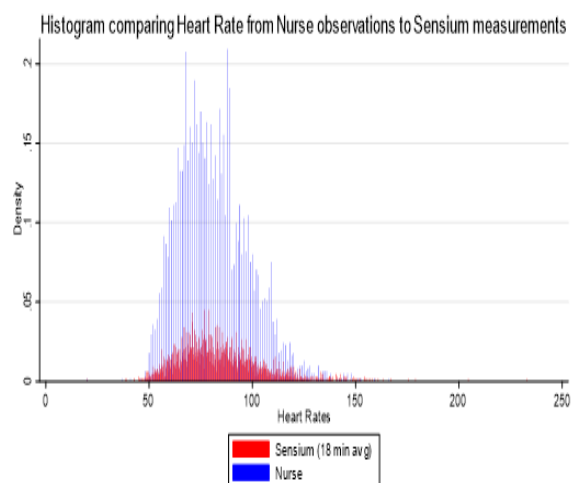
Bland Altman-18-minute mean HR



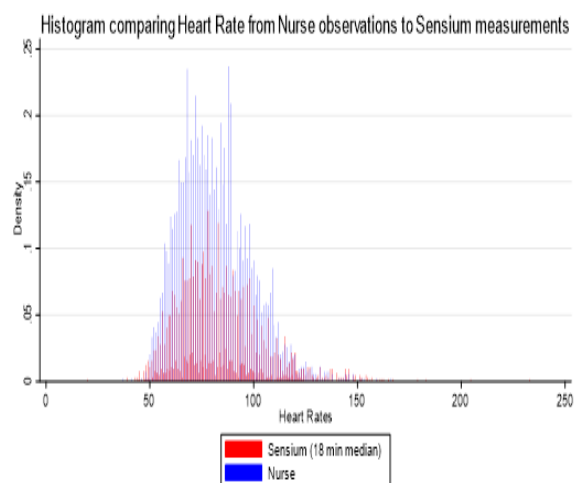
Bland Altman-18-minute median HR



Histogram for 18-minute mean HR



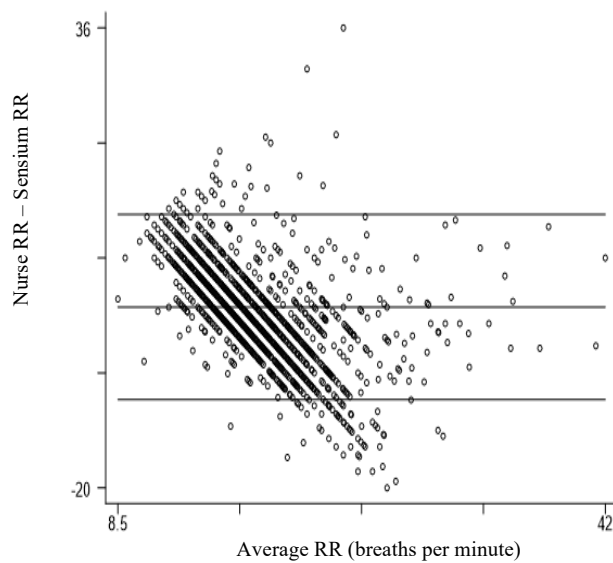
Histogram for 18-minute median HR



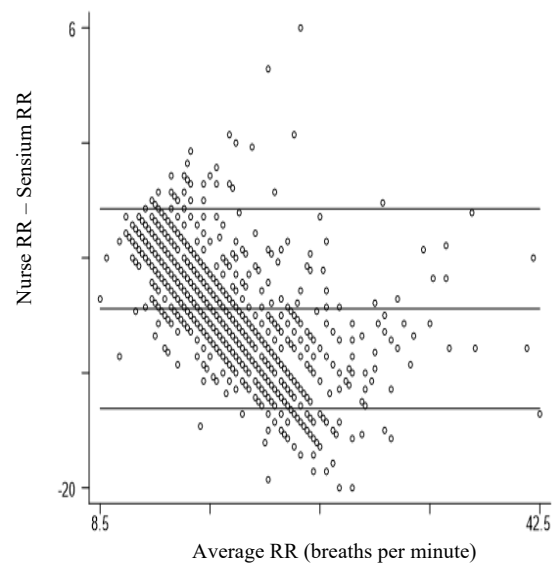
Appendix 3.6

Bland Altman Plots and histograms for the 18-minute time window for Respiratory Rate
using both the means and medians

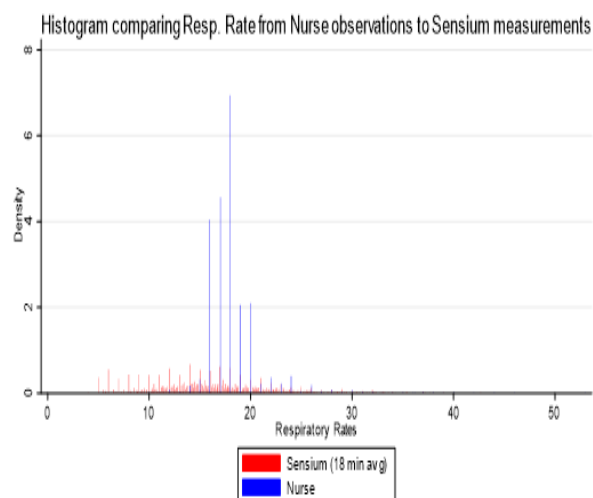
Bland Altman-18-minute mean RR



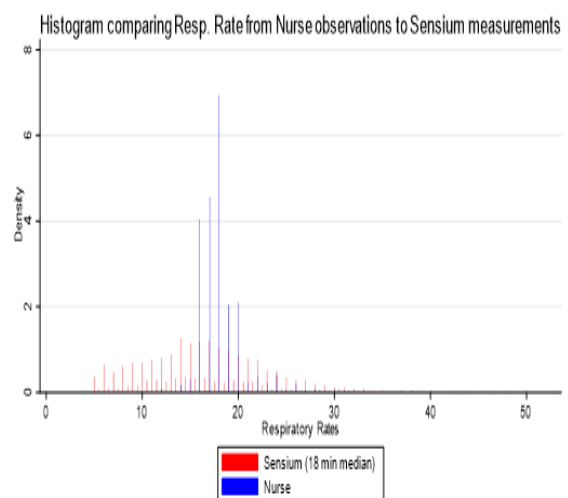
Bland Altman-18-minute median RR



Histogram for 18-minute mean RR



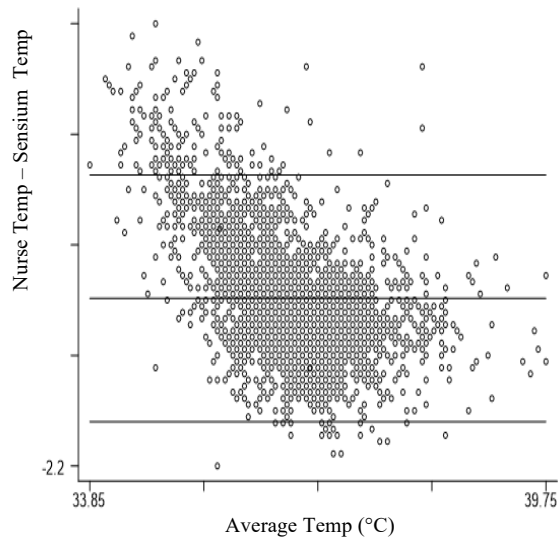
Histogram for 18-minute median RR



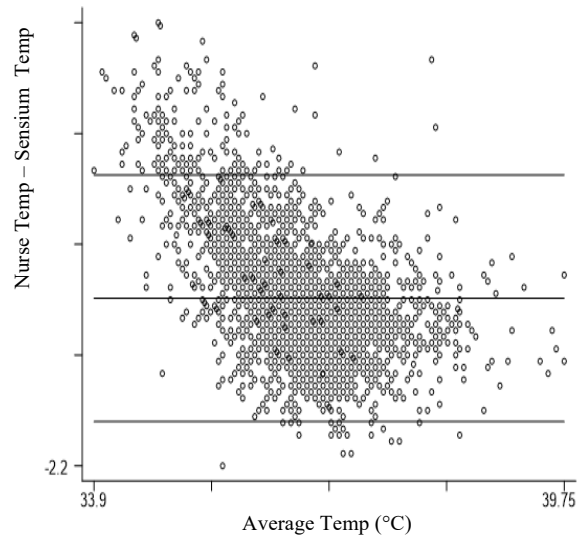
Appendix 3.6

Bland Altman Plots and histograms for the 18-minute time window for Temperature using both the means and medians

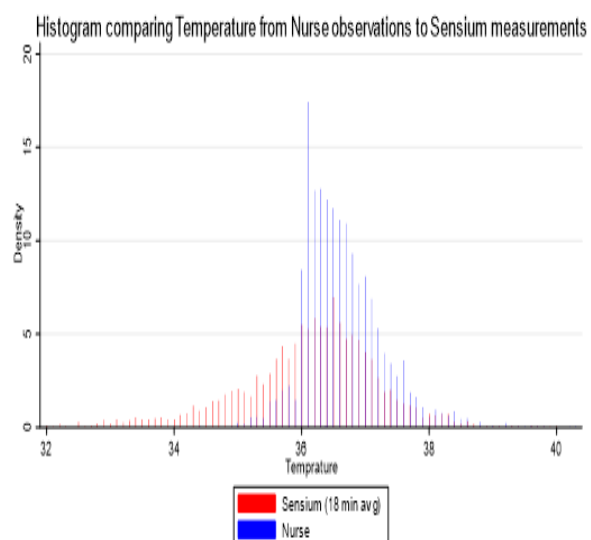
Bland Altman-18-minute mean Temp



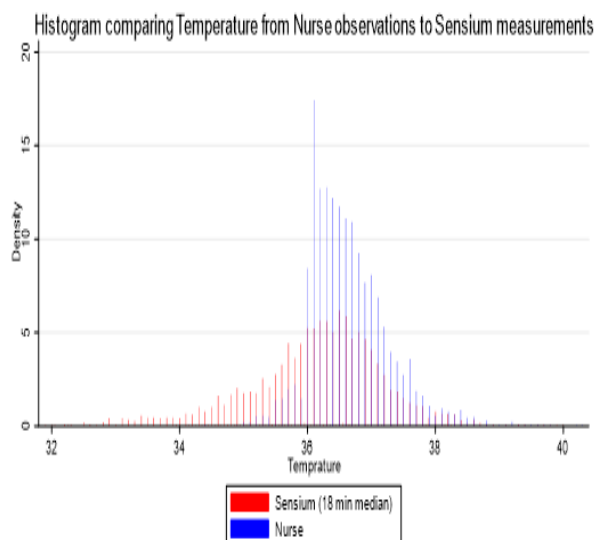
Bland Altman-18-minute median Temp



Histogram for 18-minute mean Temp



Histogram for 18-minute median Temp



Appendix 4.1

Patient demographic data collection sheet

<u>Patient Demographic Sheet</u>					
Name	Dob	Age	M/F		
Occupation	Ethnicity				
Date of admission			Time of presentation (24hr)		
Mode of admission	GP	A&E	Other please specify	Medical / Surgical	
Time of first observations.....			At presentation Observations:		
HR	RR.....	O2 Sats..... onL	Temp....	BP....	GCS...
NEWS SCORE		NEWS>5...Y/N			
Non blanching Rash/ mottled/ashen/ cyanotic Y/N					
Not passed urine for 8 hours Y/N			Urine output less than 0.5ml/kg/hr		
Blood tests Date	WCC.....	Neutrophils	CRP.....		
Blood cultures Taken Y/N	Date Cultures Taken				
Suspected diagnosis on admission					
Place of residence Own home / Residential home /					
Frailty – (Y/N please specify if present)			Number of careers daily.....		
PMHX					
AF, DM, HIGH BMI , HTN, COPD, Asthma, CRF, RA, Inflammatory arthropathy, Prev Ca, Current Ca treatment, Recent Chemo, Surgery, Other.....					
Patient BMI (weight on drug chart)					
Suspected or present source of infection Y / N					
Sepsis mentioned anywhere in initial clerking proforma/ suspicion of sepsis Y/N					
Risk of sepsis Low / Medium / High					
On Abx at admission ? Y/N Had one shot of antibiotics ? Y/N					
Which antibiotic					
IV/Oral ..	Date	Time first dose			
Abx continued on admission Y/N Duration of Abx					
Could this be an infection (please circle as appropriate)					
- Yes but source unclear			- Device /implant related infection		
- Pneumonia			- Meningitis		
- UTI			- Surgical		
- Abdo Pain or Distension			- Other		
- Cellulitis or septic arthritis or infected wound					
Date Sensor placed			Time Sensor Placed (24 hr)		

Appendix 4.2

Trust sepsis risk assessment proforma



Sepsis screening tool (adult)

To be applied to all adults ≥ 16 years of age in emergency department and inpatient areas (excl maternity areas)

Patient details (affix label)		Staff member completing form	
		Date/time: Name (print): Designation: Signature:	
1. Is the NEWS ≥ 5? or NEWS 3 in one parameter? or is there an acute change or clinical concern?		Low risk sepsis Continue to monitor and escalate as per NEWS Policy	
2. Could this be due to an infection? Yes, but source unclear at present Pneumonia Urinary tract infection Abdominal pain or distension Cellulitis/septic arthritis/infected wound Impaired immune system (eg illness or drugs) Device-related infection Meningitis Other (specify):		Is ONE or more amber flag present? Relatives concerned about mental status Acute deterioration in functional ability Immunosuppressed Trauma/surgery/procedure in last 6 weeks Respiratory rate 21–24 or breathing hard Systolic BP 91–100mmHg Heart rate 91–130 or new arrhythmia Not passed urine in last 12–18hrs Temperature $<36^{\circ}\text{C}$ Clinical signs of wound, device or skin infection	
Is ONE or more red flag present? Responds only to voice or pain/unresponsive New confusion Systolic BP $\leq 90\text{mmHg}$ (or drop $>40\text{mmHg}$ from normal) Heart rate >130 per minute Respiratory rate ≥ 25 per minute Needs oxygen to keep $\text{SpO}_2 \geq 92\%$ Non-blanching rash, mottled/ashen/cyanotic Not passed urine in last 18hrs Urine output less than 0.5ml/kg/hr Recent chemotherapy		Send bloods (include FBC, U&Es, LFTs, clotting, lactate)	
		Urgent senior review by ST3/SpR (must review with results)	
		Is AKI present? (tick) Yes No	
		Clinician to make antimicrobial prescribing decision within 3hrs If senior clinician happy, may discharge or de-escalate	
Red flag sepsis! Start 'Sepsis Six' pathway NOW (see overleaf) Time is critical—immediate action is required			

Sepsis Six pathway

To be applied to all adults ≥ 16 years of age with suspected or confirmed sepsis (excl maternity areas)

- Make treatment escalation plan and check DNACPR status
- Inform ST3/SpR/consultant patient has sepsis

Sepsis Six start time	consultant informed? (tick)	initials

Action (complete all within 1hr)

1. Take blood cultures

At least a peripheral set—consider eg CSF, urine, sputum
Think source control! Call surgeon/radiologist if needed
CXR and urinalysis for all adults

time complete	If not done, state reason
initials	

2. Give IV antibiotics

According to Trust protocol
Consider allergies prior to administration

time complete	List antibiotics given
initials	

3. Give IV fluids

If hypotensive/lactate $>2\text{mmol/l}$, 500ml stat
May be repeated if clinically indicated—do not exceed 30ml/kg

time complete	If not done, state reason
initials	

4. Check lactate

Corroborate high VBG lactate with arterial sample
if lactate $>4\text{mmol/l}$, call Critical Care and recheck after each 10ml/kg fluid challenge

time complete	Result/time	Result/time
initials	Result/time	Result/time

5. Administer oxygen

Aim to keep saturations $>94\%$
(88–92% if at risk of CO_2 retention, eg COPD)

time complete	If not done, state reason
initials	

6. Measure urine output

- ☐ Requires urinary catheter (tick if required)
☐ Fluid balance chart commenced and completed hourly (tick if required)

time complete	If not done, state reason
initials	

Escalation

Escalated to (SpR/ST3 or above)	
Date/time	Initials

Management plan

--

If after delivering Sepsis Six patient still has:

- systolic BP $<90\text{mmHg}$
- reduced level of consciousness despite resuscitation
- respiratory rate over 25 breaths per minute
- lactate not reducing

Or if patient not responding to treatment/deteriorating

Urgent senior clinician review (SpR/ST3 or above)

Appendix 5.1

Patient Questionnaire

WEARABLE PATCH VITAL SIGN MONITORING PROJECT

Participant Questionnaire on Wearable Vitals Patch Monitoring

Yes	No
I received an information sheet prior to applying the wearable patch and was invited to ask questions?	

Please tick the appropriate boxes below on a scale from strongly agree to strongly disagree.

Please rate your level of agreement with the following statements	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. The wearable patch was comfortable to wear					
2. I found this system unnecessarily complex					
3. I understood what the wearable patch was for					
4. I felt safer being monitored whilst wearing the wearable patch					
5. I knew who to contact if I had any problems with the wearable patch					
6. I would wear the wearable patch again when in hospital					
7. I found this system very cumbersome to wear					
8. I would wear the wearable patch in my home					
9. I needed to learn a lot of things before I could get going with this system					
We welcome any additional comments you may have: THANK YOU					

Contact

Dr Meera Joshi Clinical Research Fellow & Surgical Registrar, 10th Floor QEOM Building, St Mary's Hospital, Praed Street, London, W2 1NY, United Kingdom, Email meera.joshi03@imperial.ac.uk

Patient Advice and Liaison Service (PALS) West Middlesex University Hospital, Twickenham Road, Isleworth, TN7 6AF, Telephone 020 8321 6261
Patient Advice and Liaison Service (PALS) Ground floor of the Queen Elizabeth the Queen Mother (QEOM) building, St Mary's Hospital, South Wharf Road, London W2 1NY. Telephone 020 3312 7777

Appendix 5.2

Semi structured interview guides for patients

WEARABLE PATCH VITAL SIGN MONITORING PROJECT

Participant semi structured interview guide

Demographics – Age... Gender - M/F Worn a sensor before? Y/N Wear a sensor regularly? Y/N

1) Did you understand what the patch you were wearing was used for?

Prompts:

- Detection of unwell ward patients?

2) How do you feel about being monitored with the patch?

Prompts:

- Peace of mind?
- Invasion of privacy?

3) How comfortable was the patch to wear?

Prompts:

- Heavy?
- Inconvenience?
- Temperature wire

4) Were there any problems wearing the patch?

Prompts:

- Washing?
- Sleeping?

5) If you could change this patch in some way how would you change it to make it better?

6) Would you wear this patch again whilst in hospital?

Prompts:

- If yes or no why?

7) Would you consider wearing this patch or a similar patch at home?

Prompts:

- If yes or no why?

Appendix 5.3

Participant information sheet for semi structured interviews

WEARABLE PATCH VITAL SIGN MONITORING PROJECT

Participant information sheet for semi structured interviews

Contact

Dr Meera Joshi
10th Floor QEOM Building
St Mary's Hospital
Praed Street
London W2 1NY
United Kingdom
Email : meera.joshi03@imperial.ac.uk

You are being invited to take part in a research study. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

A large print version is available for those that require it, please ask the research team for a copy of this.

1.What is the purpose of the study?

The participant feedback from this sensor is very important to the use of sensor technology in hospitals. It is vital that the experiences of participants wearing the sensor are considered. We aim to explore this through interviews with participants. The sensor must be comfortable for participants to wear before the technology is widely used in hospitals. It is important that your views, experiences and use of the sensors are known.

This study forms a part of a PhD research project, being undertaken by Dr Meera Joshi at Imperial College London.

2.Why have I been chosen?

You have been invited to take part in this study because you had agreed to wear the wearable sensor during a hospital inpatient stay.

3.Do I have to take part?

You do not have to take part in this study. If you decide to take part, you will be asked to sign a consent form. You will have at least 2 hours to decide whether you wish to take part in the interviews and review the documentation but can have longer if needed. Not participating or withdrawing from this study will not affect your current clinical care or any future clinical care.

4. What will happen to me if I take part?

If you agree to participate you will be asked to read and sign a consent form. You will have opportunity to talk with the research team before signing the consent form and we can answer any questions you might have about the study. Once we have written consent we will arrange a time and place that suits you for the interview to take place. You will be asked some questions about your experiences, views and understanding of the wearable sensor that you

wore during your inpatient hospital stay. We will take some notes during the discussion and this will also be audio recorded. The interview will last approximately 20-30 minutes and take place prior to your hospital discharge. The data from the interview will be reviewed to allow a greater understanding about the use of the sensor by participants. The interviews will be transcribed using a transcription service. This information may be used to develop the sensor further or as part of a business case to explore the larger use of sensor technology within the NHS. The results will be published in journal articles and as part of a PhD thesis. All participant feedback will be anonymised and no participant will be identified through any feedback given in the interview.

5. Is taking part anonymous and confidential?

Yes, all information gathered will be anonymous. Paper records will be kept securely in a locker in a locked office. Electronic data will be stored on a password protected computer at Imperial College and backed up regularly. No personal identifiable information will be used in any reports arising from this research; we will use a pseudonym in reporting. A transcription service will be used to transcribe the information from the interview and all interview data will be anonymised.

5. I do not speak English. Can I still take part?

Yes. You can have an interpreter to help you.

6. What are the possible benefits of taking part in this study?

There may not be any direct benefit of you taking part in this study. The information we get from this study will help us to understand more about people's views on the wearable sensor technology.

7. What are the possible risks of taking part in this study?

There is a small chance that talking about the issues raised in this interview may make you feel a bit worried. If so, we can put you in contact with somebody who will be able to help you with your concerns. If you report serious incidents or unreported events, in the interests of safety, these may need to be reported to the appropriate clinical manager. If you have been affected by incidents that have happened at the hospital, we can put you in contact with the hospital PALS service.

8. What will happen after this study?

We hope that the results will allow us to understand more wearable sensors measuring vital signs. The results will be published in journal articles.

9. Can everyone take part?

We may not be able to talk to everyone who wants to take part in the study as there are lots of participants that will be wearing the patch. Some participants may be too unwell to take part. All participants must be able to consent to take part in the study.

10. Can I stop taking part?

You can decide to stop participating at any time up till the anonymised recordings are sent for transcription. If you would like to withdraw from the study before or after the interview, please contact Dr Meera Joshi. You can stop the interview at any time; just tell the researcher.

11. What if there is a problem?

We do not expect that this study will cause harm or worry for anyone taking part. If you have concerns, inform the researcher.

The study has been reviewed and approved.

12. Who has reviewed the study?

This study has been reviewed and approved by the Research Ethics Committee.

13. Who to contact about this study

Contact Dr Meera Joshi, Chief Investigator and Principle Investigator (details above) for further information and support

Alternatively, Dr Sadia Khan (Principle Investigator West Middlesex University hospital), Consultant Cardiologist, West Middlesex University Hospital, Twickenham Road, Isleworth, TW7 6AF, Tel 020 8321 5336, Fax 020 8321 5394

OR for independent advice please contact:

Patient Advice and Liaison Service (PALS) West Middlesex University Hospital, Twickenham Road, Isleworth, TW7 6AF, Telephone 020 8321 6261

Patient Advice and Liaison Service (PALS) St Marys Hospital London Paddington, Queen Elizabeth the Queen Mother (QEQM) building, St Mary's Hospital, South Wharf Road, London W2 1NY, Telephone 020 3312 7777

Participants will be given a copy of the consent form and information sheet for their own records.

Appendix 5.4

Consent form for patient interviews

WEARABLE PATCH VITAL SIGN MONITORING PROJECT

Consent form for participant interviews

Version 2 23/08/2017

Name of Researcher: Miss Meera Joshi

Supervisors: Professor Ara Darzi, Dr Sadia Khan, Dr Richard Kwasnicki

Participant ID:

Instructions for the participant:

Please read each of the sections below. In the box next to each section, please write your initials to show that you agree with what the section says.

When you have written your initials, please write your name, today's date and add your signature in the spaces at the bottom.

		Initials
1	I have read and understand the information sheet for the above study version 1.	
2	I have had the opportunity to think about the information and to ask questions about it if I want to. If I have asked questions, I am happy with the way my questions have been answered.	
3	I understand what will happen in the interview	
4	I understand that what I say to the researcher will be recorded using a digital voice recorder and saved on a computer at Imperial College London.	
5	A transcription service will be used to transcribe the information from the interview and all interview data will be anonymised.	
6	I understand that it is my right to refuse to take part in this study or withdraw at any time up till the anonymised recordings are sent for transcription.	
7	I have been informed that anything I say during the interview will remain anonymous; my name will not be used, nor any other information that could be used to identify me.	
8	I agree to take part in this study.	

Name of Participant

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

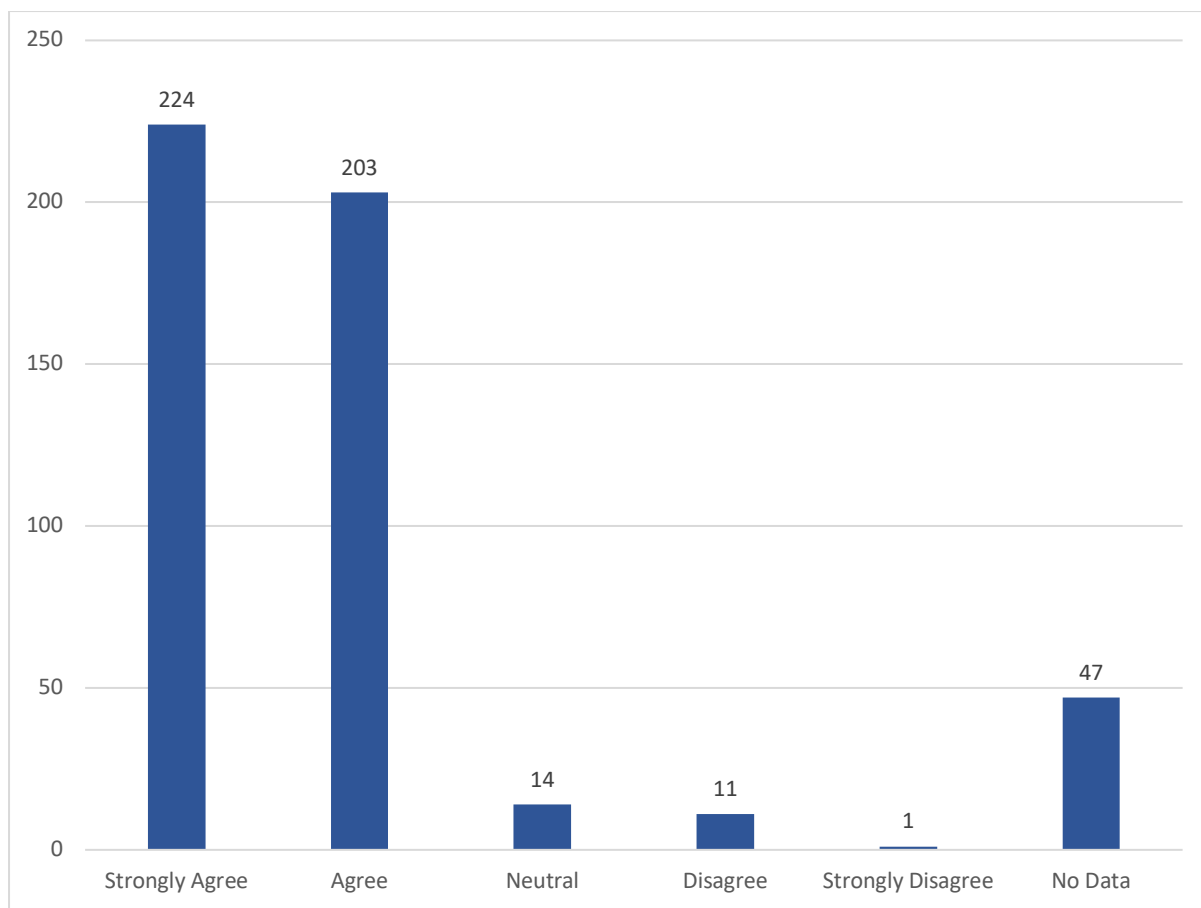
Researcher

Date

Signature

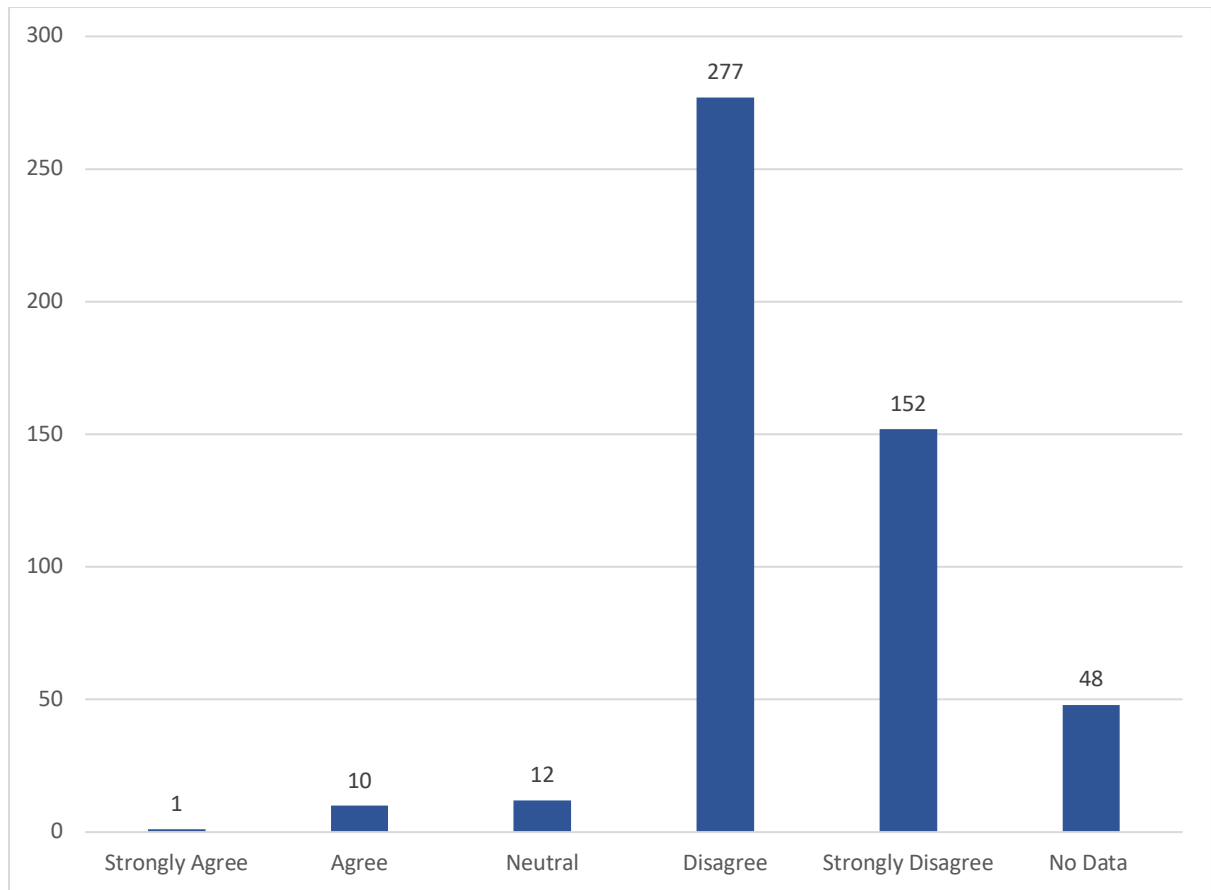
Appendix 5.5

The wearable patch was comfortable to wear



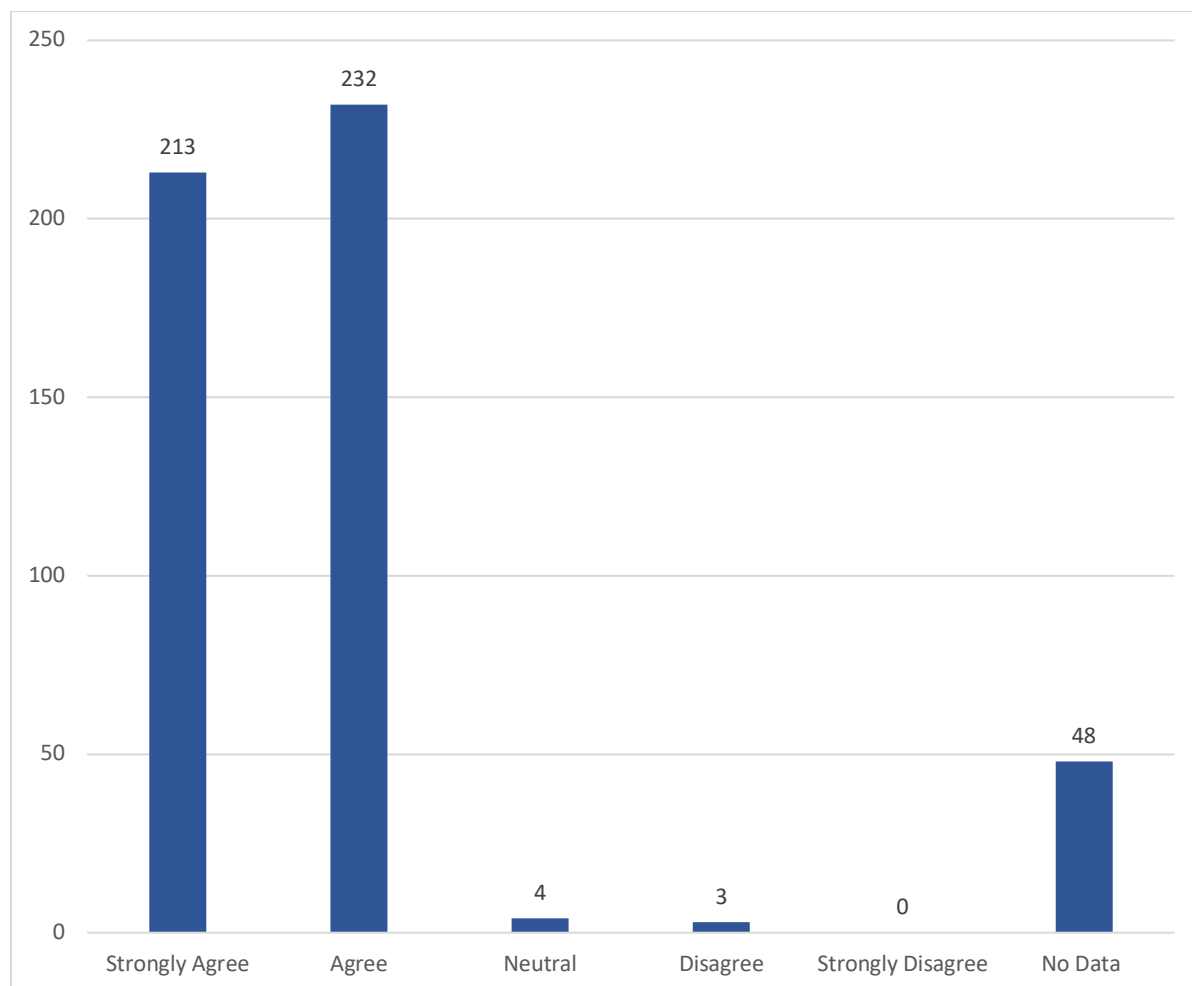
Appendix 5.6

I found this system unnecessarily complex



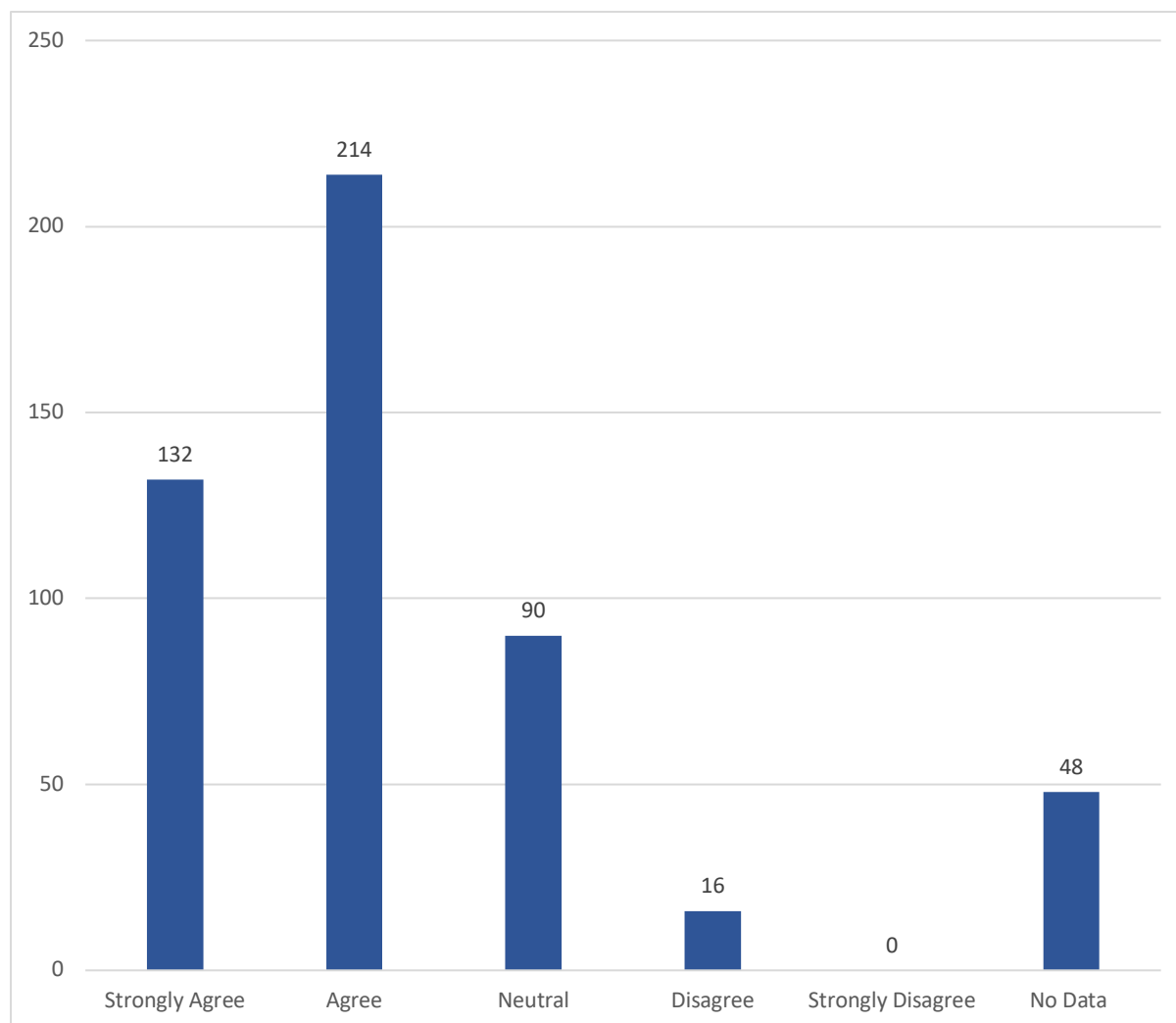
Appendix 5.7

I understood what the patch was for



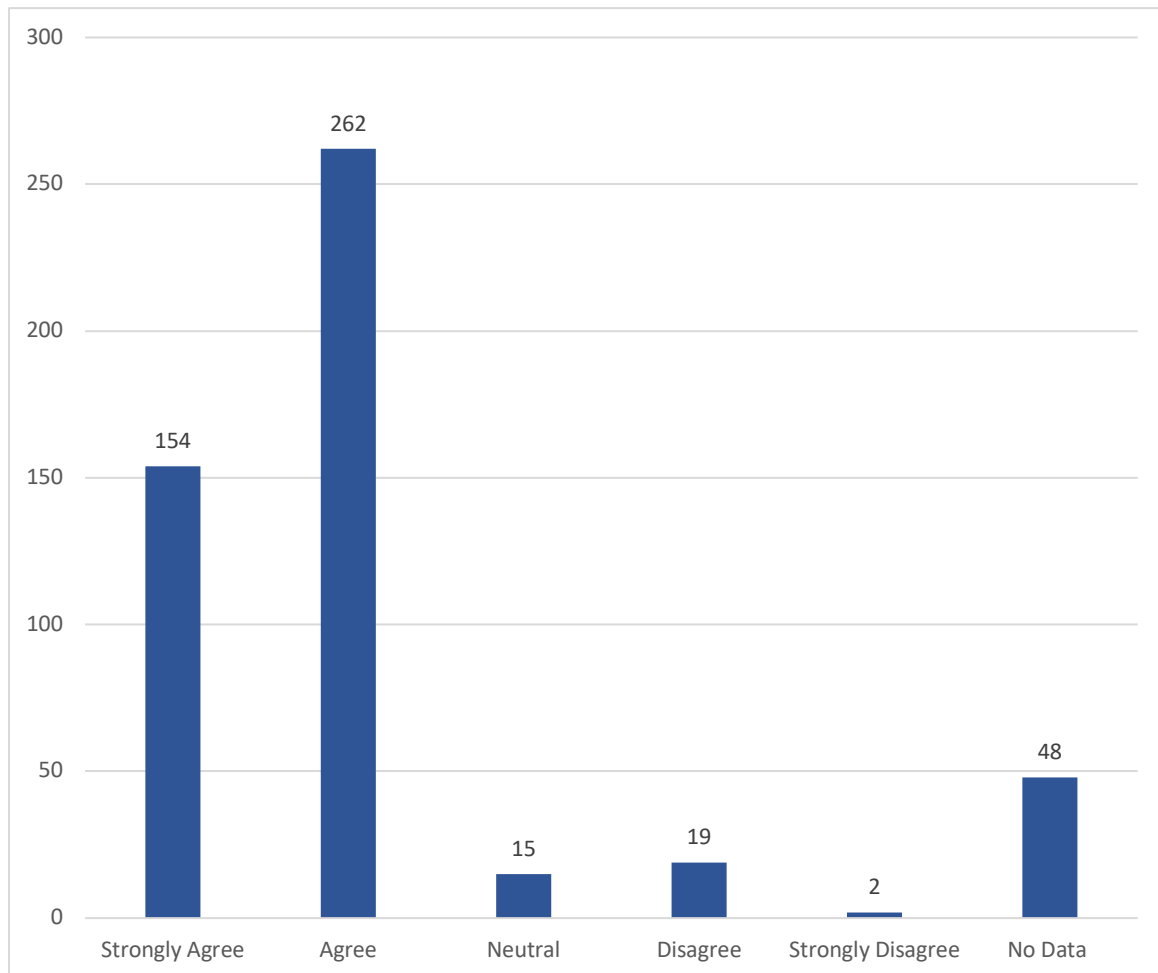
Appendix 5.8

I felt safer being monitored whilst wearing the wearable patch



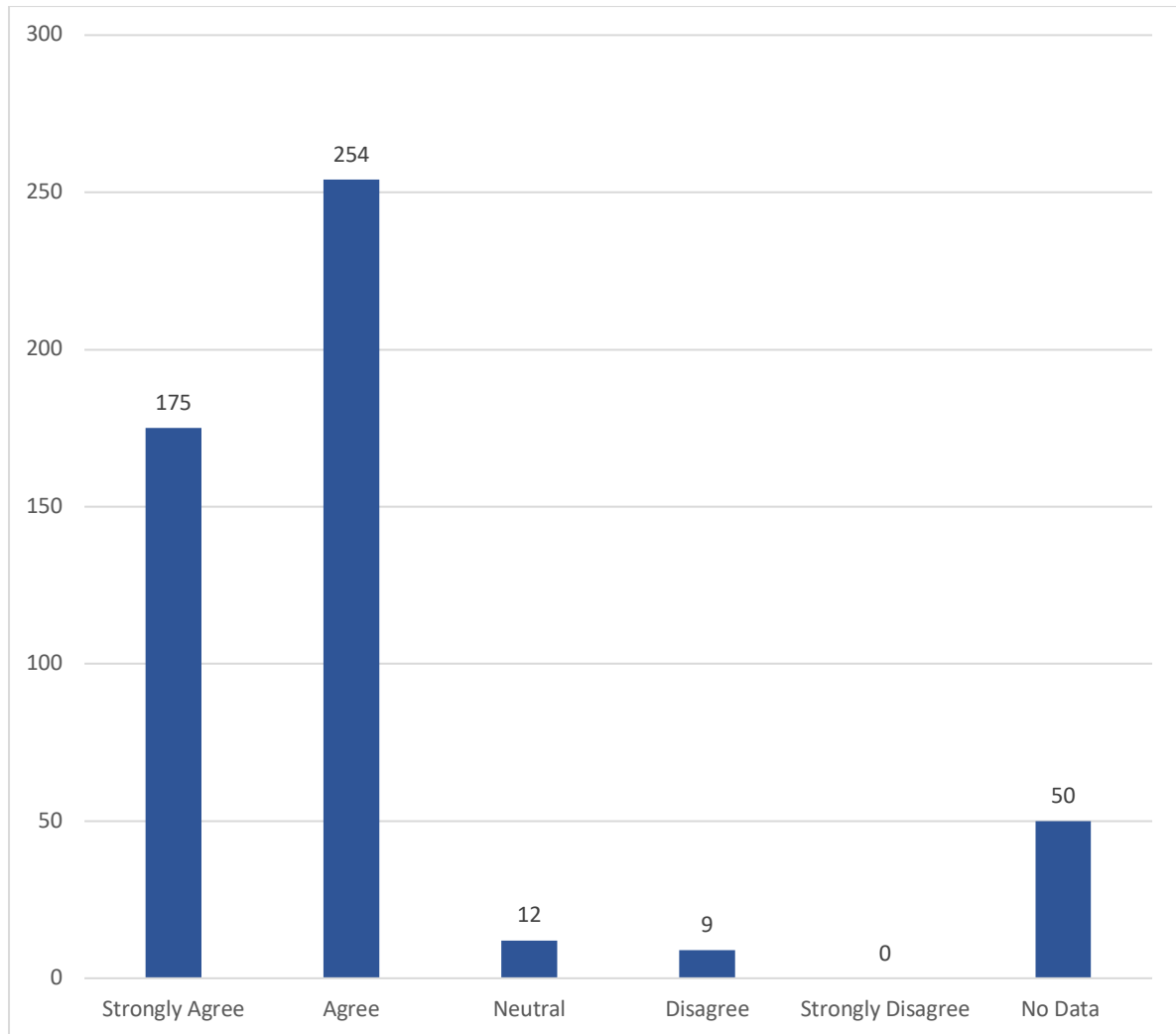
Appendix 5.9

I knew who to contact if I had any problems with the wearable patch



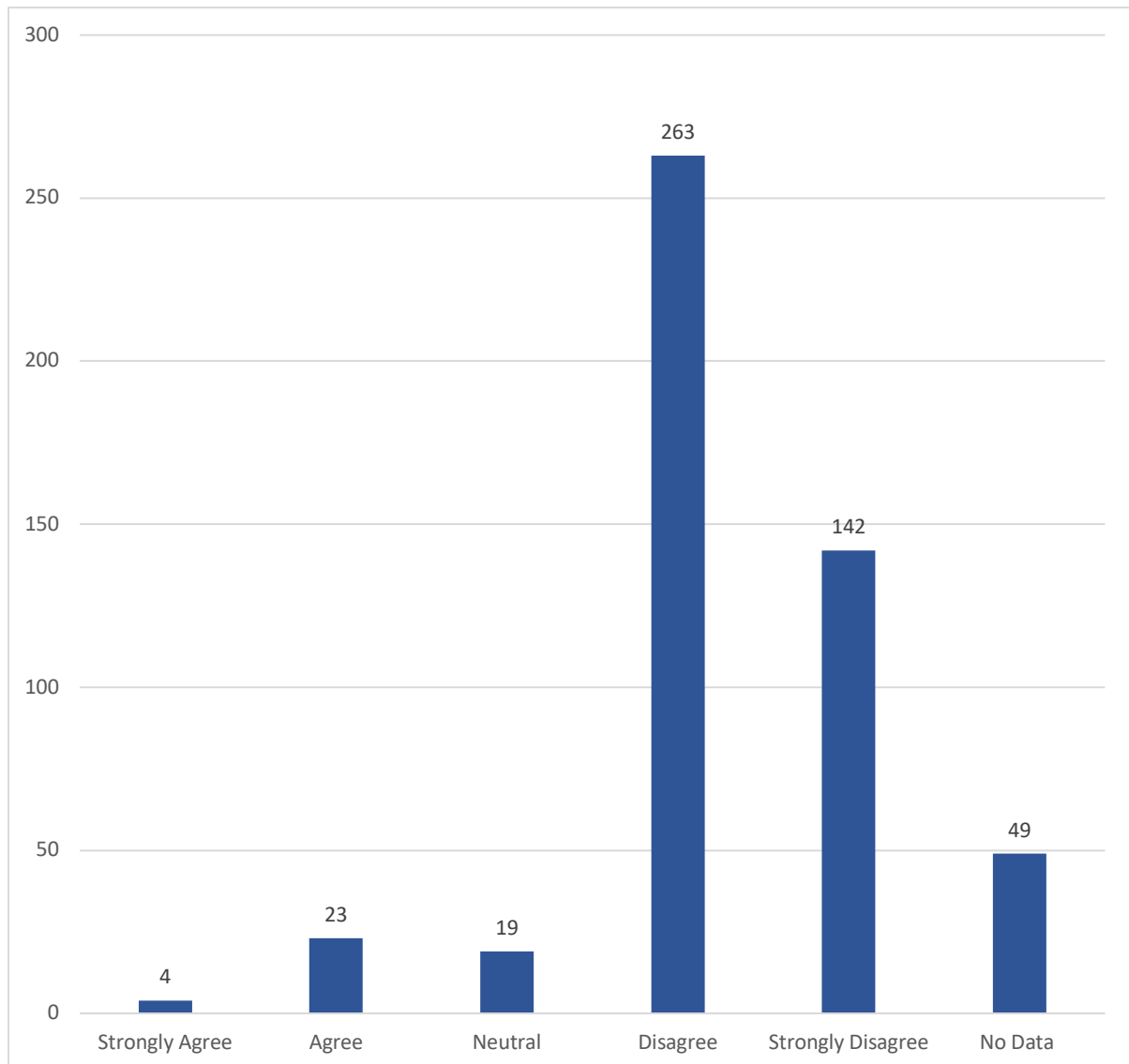
Appendix 5.10

I would wear the patch again when in hospital



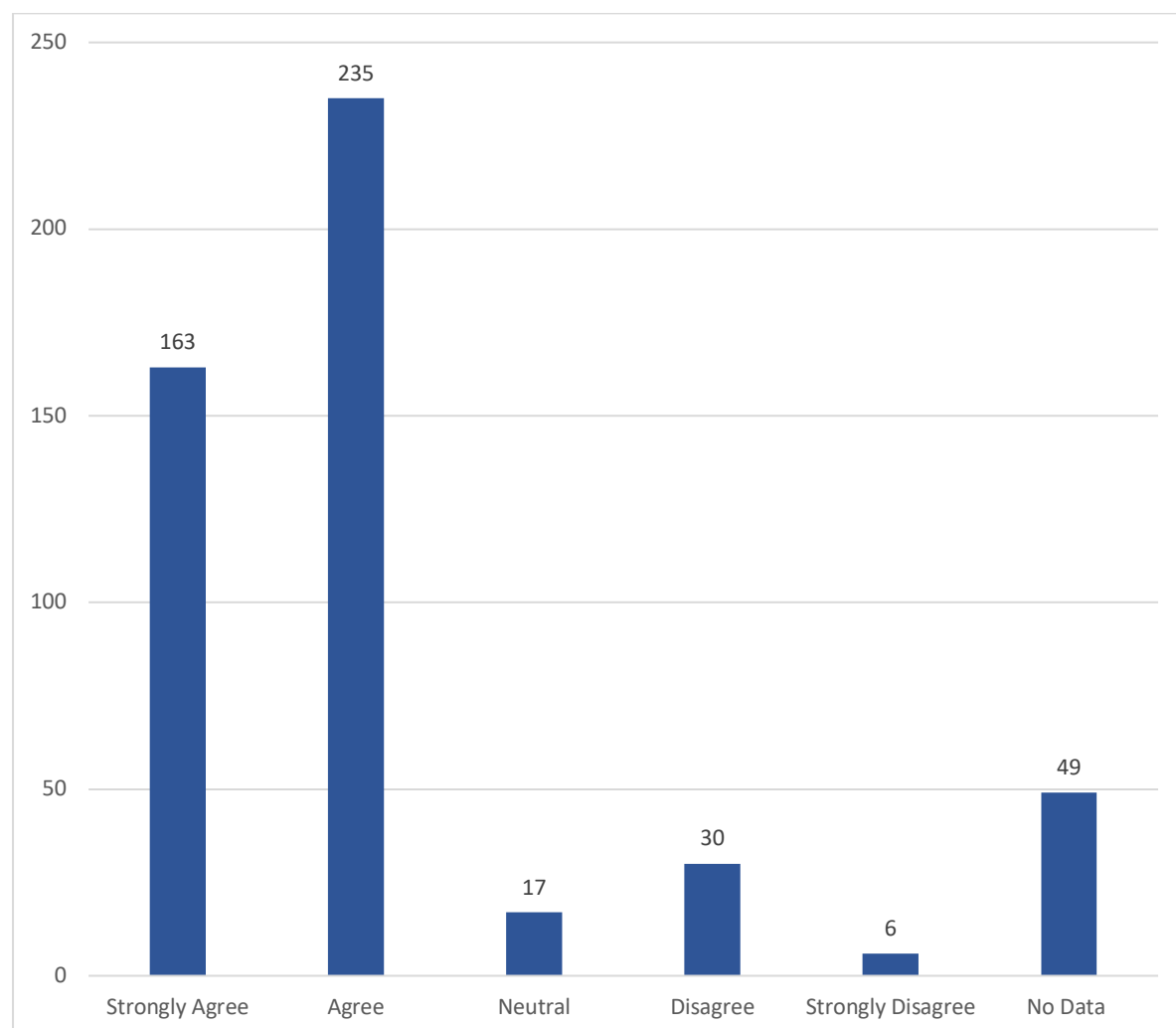
Appendix 5.11

I found this system very cumbersome to wear



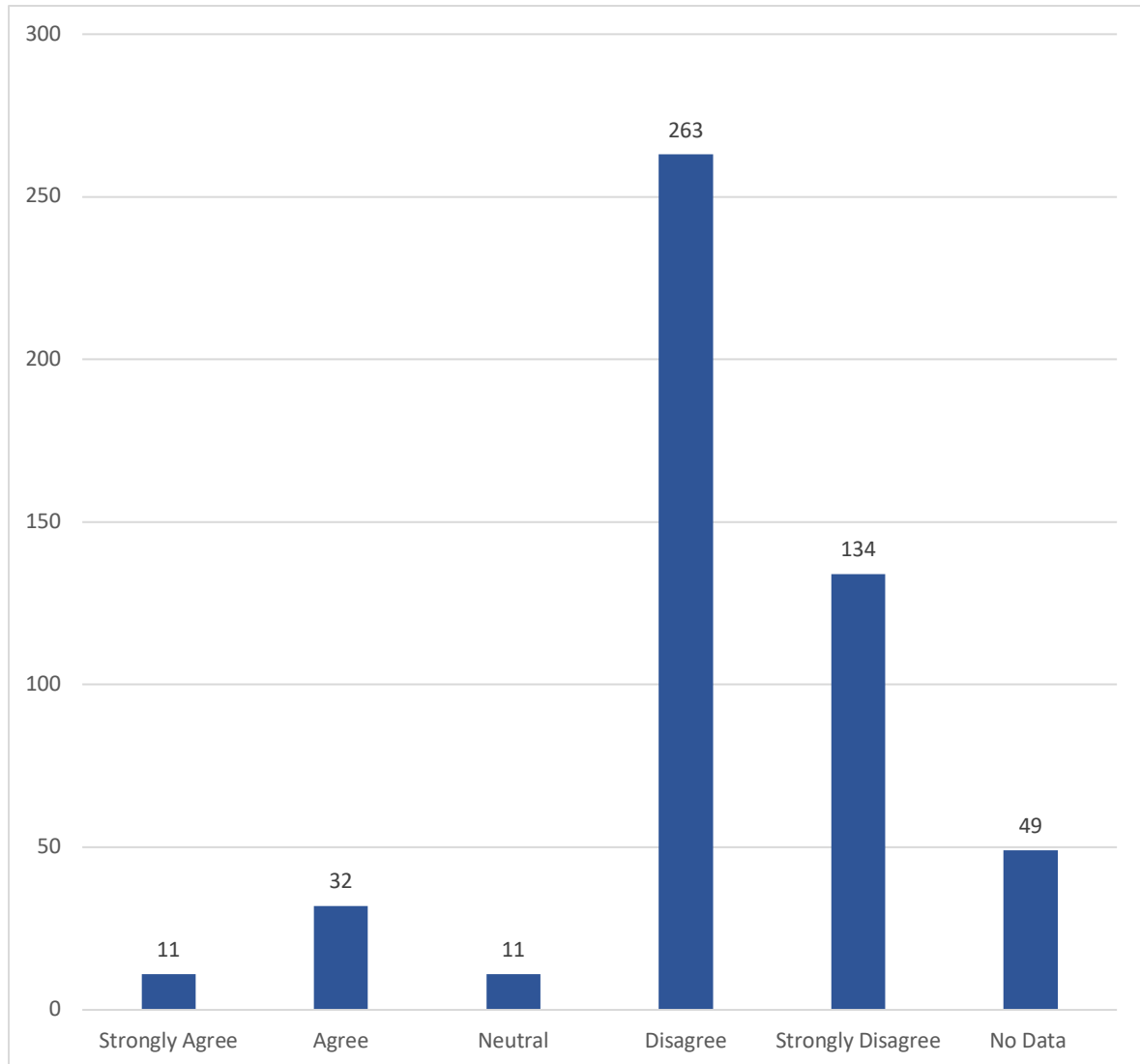
Appendix 5.12

I would wear the wearable patch in my home



Appendix 5.13

I needed to learn a lot of things before I could get going with this system



Appendix 5.14

Questionnaire free text positive comments

PATIENT STUDY ID	QUESTIONNAIRE POSITIVE COMMENTS
13	GIVES PEACE OF MIND
20	GOOD DEVICE, GREAT FOR THE FUTURE, FEEL SAFER BEING MONITORED
27	GOOD IDEA
38	GOOD IDEA - IDEA OF BEING MONITORED AT HOME
45	GREAT
53	VERY SIMPLE
66	WORKED WELL NO PROBLEM, WOULD REPEAT IF NECESSARY
82	GOOD SYSTEM
94	PATCH WAS OK
96	IT'S A GOOD THING
114	A GOOD IDEA
115	ITS FINE
130	GOOD IDEA
150	APPRECIATE THE SYSTEM
153	GREAT IDEA!!!
160	SEEMS EASIER TO HAVE PATCH THAN DOING OBS EVERY FEW HOURS
163	HOPE IT WORKS
164	GOOD IDEA
165	HOPE THE SYSTEM WORKS
170	IT IS A HELPFUL CONCEPT

PATIENT STUDY ID	QUESTIONNAIRE POSITIVE COMMENTS
184	VERY UNINTRUSIVE FACILITY WHICH POTENTIALLY WILL CONTRIBUTE TO THE PATIENT WELL BEING
187	ITS GOOD AND ITS GOING TO HELP OTHER PEOPLE
198	LIKES THE IDEA
200	EXCELLENT IDEA, THE WAY FORWARD, PIECE OF MIND, MUCH BETTER
203	WAS HAPPY WITH PATCH TO HAVE IT ON BEFORE MOVING TO MARBLE HILL WARD
208	GOOD IDEA, BENEFICIAL TO EVERYBODY
213	GOOD IDEA
214	IT WAS EXPLAINED VERY WELL AND IS A GOOD IDEA
240	VERY GOOD IDEA
254	GOOD PROJECT FOR RESEARCH
259	I FEEL THIS IS A GREAT INITIATIVE AND IT WILL HELP PATIENTS REMAIN WELL WHEN IN HOSPITAL BETWEEN CONTINUOUS MONITORING
260	WILL GIVE MORE INFO ABOUT PATIENTS TO NURSES, NOT BOTHERING ME AT ALL
267	IF IT WORKS IT WOULD BE A GOOD IDEA
272	GREAT DEVICE
279	GOOD, EXCELLENT IDEA
281	I AM VERY HAPPY TO BE PART OF THIS PROJECT. I COMPLETELY SUPPORT THE WEARABLE PATCH, WHICH I THINK IS A GREAT IDEA WITH A LOT OF POTENTIAL. I FEEL PRIVILEGED TO BE PART OF THE DEVELOPMENT OF THIS DEVICE AT ITS EMBRYONIC STAGES.
290	FANTASTIC
304	I THINK ITS WORTH TRYING
306	I THINK IT WILL BE A GOOD IDEA TO HAVE
320	I THINK IT'S A VERY GOOD IDEA ESPECIALLY ON A WARD LIKE THIS

PATIENT STUDY ID	QUESTIONNAIRE POSITIVE COMMENTS
323	IT'S NICE, SMALL AND EASY TO CARRY
325	IT'S A WONDERFUL IDEA, HAPPY TO HELP
331	SHE THINKS IT IS A GREAT IDEA
340	IT'S GOOD THAT IT IS CONSTANTLY MONITORING, DIDN'T EVEN REALISE IT WAS THERE
341	IT WAS GREAT AND IT WAS EXPLAINED TO ME VERY WELL.
343	GOOD CAUSE
348	GREAT IDEA
350	LAUDABLE RESEARCH STUDY
352	IT'S A GREAT IDEA AND THE WAY FORWARD. COMPLIMENTS TO THE TEAM
358	GOOD IDEA
365	I WOULD PROMOTE THE PATCH AND ENCOURAGE MORE PEOPLE TO USE IT
370	WHY WASN'T THIS THOUGHT OF BEFORE
374	ITS ALL FINE
388	IT WILL BENEFIT A LOT OF PATIENTS
390	GOOD IDEA, HAPPY TO SUPPORT IT
395	I THINK IT'S A VERY GOOD IDEA
396	VERY SIMPLE AND EASY I DIDN'T HAVE ANY PROBLEMS AT ALL
407	I THINK IT IS A VERY GOOD IDEA, IT SHOULD BE INTRODUCED IN THE HOSPITALS ASAP AND ALSO FOR USE AT HOME. IT'S A SIMPLE THING FOR THE PATIENT , IT IS NOT INVASIVE AND IT CAN MAKE A BIG DIFFERENCE
417	I THINK IT IS A VERY GOOD IDEA AND I AM HAPPY TO WEAR THE PATCH.
432	GOOD IDEA IF IT WORKS
440	PROGRESS

PATIENT STUDY ID	QUESTIONNAIRE POSITIVE COMMENTS
443	GOOD IDEA, WORTH DOING
445	I THINK IT IS FINE. THE TEAM EXPLAINED EVERYTHING REALLY WELL.
450	IT'S ALL RIGHT
457	I COULDN'T FEEL IT BUT IT CAME OFF DURING THR NIGHT. THE MATERIAL IS VERY GOOD, GREAT DEVICE
461	EVERYTHING WAS EFFICIENT, EXPLAINED WELL, PERFECTLY ALL NIGHT, DIDN'T HINDER AT ALL, HAD A SHOWER TWICE, SECOND TIME PATCH LIFTED SLIGHTLY
478	GOOD PRODUCT
479	IT'S A GREAT IDEA
481	ITS BRILLIANT
483	NEW THING, ITS OKAY
487	QUITE A FEW TIMES HAVE DIPS AT HOME, UNWELL QUICKLY, WHEN HAVE SEPSIS HAPPENS QUICKLY, WOULD BE USEFUL SOMEONE KNOWS WHATS GOING ON. HAD LOTS OF LINE INFECTIONS IN THE PAST
491	NO PROBLEMS AT ALL
494	IT'S GOOD AND IT HELPS
24	FORGOTTEN ITS ON, GOOD IDEA, BRILLIANT IF CAN HAVE IT AT HOME
35	FORGOTTEN HAD IT ON
49	PATCH WAS FINE AND COMFORTABLE
52	DIDN'T KNOW IT WAS THERE, REALLY CLEVER IDEA, IS A NURSE AND FROM A CLINICAL VIEW ITS VERY USEFUL
54	DIDN'T NOTICE IT WAS ON
75	DIDN'T REALLY NOTICE IT ON
80	COMFORTABLE BARELY NOTICED IT
88	REALLY COMFORTABLE, LIKES THE INNOVATION OF IT, REALLY GOOD IDEA

PATIENT STUDY ID	QUESTIONNAIRE POSITIVE COMMENTS
90	DIDN'T REALLY FEEL IT ON
108	IT'S COMFORTABLE AND SAFER, THE OTHER ONES ARE BIG AND BULKY, WIRES ATTACHED
109	DON'T KNOW IT'S THERE
110	DIDN'T NOTICE IT ON, V LEIGHT TO WEAR, TAKEN HOME VARIOUS THINGS FOM THE HOSPITAL BUT THIS IS THE BEST
111	DIDN'T NOTICE IT ON
117	FOUND IT VERY COMFORTABLE, COMPLETELY FORGOT ABOUT IT
121	FORGOT I HAD IT ON - FANTASTIC
122	ONCE ITS ON DON'T REALLY THINK ABOUT IT, ONLY THE UNDERARM BIT BUT NOT HUGELY UNCOMFORTABLE
123	I DON'T EVEN FEEL IT
131	VERY COMFORTABLE
133	VERY CONVENIENT VERY EASY
135	DIDN'T NOTICE IT WAS ON
136	DIDN'T NOTICE IT ON
149	DON'T REALLY KNOW ITS THERE
155	ITS AN IDEAL DEVICE AND DEPENDS ON EACH INDIVIDUAL, HARDLY REALISED IT WAS ON EXCEPT FOR THE PATCH ON THE BACK
159	I HAVENT NOTICED IT
161	FOUND IT VERY COMFORTABLE
169	FOUND IT COMFORTABLE, FORGOT SHE WAS EVEN WEARING IT
176	DIDN'T KNOW HAD IT ON
182	HADNT EVEN NOTICED IT WAS ON
185	I DIDN'T NOTICE I HAD IT ON
186	DIDN'T NOTICE I HAD IT ON, FORGOT ALL ABOUT IT

PATIENT STUDY ID	QUESTIONNAIRE POSITIVE COMMENTS
191	DIDN'T KNOW WAS WEARING IT, GOOD CONCEPT
192	FEELS COMFORTABLE TO WEAR
195	FOUND IT COMFORTABLE
197	NOT AWARE ITS ON
201	DIDN'T FEEL IT ON
209	DIDN'T NOTICE THAT IT WAS ON
212	DIDN'T NOTICE IT WAS ON
237	NOT NOTICED ITS THERE
244	DIDN'T EVEN NOTICE IT. I FELT SAFER AS IT REMOVES HMAN ERROR, NOT EVERYONE SPEAKS ENGLISH, IMPROVES COMMUNICATION ISSUES, MONITORED FOR A LONGER PERIOD.
245	I FORGOT IT WAS EVEN THERE
246	DIDIN'T NOTICE IT OR FEEL ITEVEN IN SHOWER I ABSOLUTELY FORGOT IT WAS THERE
251	ITS COMFORTABLE, I DIDN'T EVEN FEEL ITS THERE
256	DON'T EVEN KNOW ITS THERE
261	WAS FNE; COMFORTABLE TO WEAR
266	I FORGOT IT WAS EVEN THERE
273	SEAL DOESN'T SEEM SECURE OTHERWISE YOU CANT FEEL ITS THERE
277	JUST SO SIMPLE,NOT DOING ANYTHING, COMFORTABLE
305	ITS NO BOTHER WHAT SO EVER
307	HAVENT NOTICED IT ON
313	REALLY NON INVASIVE FORGET ITS THERE
316	IT IS VERY COMFORTABLE, I FORGOT IT WAS THERE, I WOULD RECOMMEND IT TO ANYBODY
360	DON'T KNOW THAT ITS THERE

PATIENT STUDY ID	QUESTIONNAIRE POSITIVE COMMENTS
363	DIDN'T NOTICE THE PATCH WAS THERE, I FOUND THE PRESENTER VERY HELPFUL
372	CANNOT FEEL ANYTHING, GOOD IDEA
381	DIDN'T FEEL IT ON
385	IT IS PERFECT, DIDN'T EVEN NOTICE IT WAS THERE. VERY COMFORTABLE.
403	VERY EASY TO USE, YOU JUST PUT IT ON AND FORGET ITS EVEN THERE. PEACE OF MIND
404	DIDN'T EVEN KNOW IT WAS THERE
408	DIDN'T EVEN KNOW IT WAS THERE
413	NICE AND EASY
439	USER FRIENDLY
444	IT REALLY FEELS LIKE IT IS NOT EVEN THERE. IT DID NOT CAUSE ME ANY DISCOMFORT AND I EVEN FORGOT I HAD IT ON
448	FORGOTTEN IT WAS THERE, ONCE PUT IT ON DIDN'T KNOW
452	IT'S GOOD, COMFORTABLE
454	I DIDN'T EVEN KNOW I HAD IT ON
463	I HAD FORGOTTEN I HAD IT ON, I THINK IT'S FANTASTIC. RECOMMEND TO OTHER PATIENTS, PARTICULARLY IF CARDIAC PROBLEMS
464	I DIDN'T REALISE IT WAS THERE, I COMPLETELY FORGOT ABOUT IT, IT'S NOT HARD PLASTIC, IT'S SPONGY AND THE LOCATION WHERE IT IS PLACED CONVENIENT. I WOULD RECOMMEND TO FAMILY MEMBERS. IF IT WORKS WILL MAKE PEOPLE FEEL MORE SAFE.
465	DIDN'T KNOW IT WAS THERE
466	REALLY COMFY, FORGOTTEN IT WAS THERE
473	I FORGOT IT WAS ON
475	I HAVEN'T EVEN NOTICED IT'S THERE
486	FORGOTTEN I HAD IT ON

PATIENT STUDY ID	QUESTIONNAIRE POSITIVE COMMENTS
495	I CAN'T FEEL I HAVE IT ON, IT'S BRILLIANT
496	DON'T REALLY FEEL IT
497	WOPULDN'T KNOW I HAD IT ON. JUST PUT IT ON, THAT WAS IT; BUT TAKEN OFF WHEN IT WAS ITCHY

Appendix 5.15

Questionnaire free text negative comments

PATIENT STUDY ID	QUESTIONNAIRE NEGATIVE COMMENTS
6	LONG FEEDBACK, MAIN PROBLEM SWEAT BETWEEN PATCH + SKIN, COIL UNDER ARM IRRITATION, SUGGEST COVER COIL WITH A SLEEVE
11	NEED TO FIND A BETTER WAY OF ATTACHING THE TEMPERATURE GAUGE, AS THIS IS A LITTLE RESTRICTIVE WHEN TAPPED TO THE BODY
12	VERY EASY AND UNDERSTANDABLE BUT KEPT FALLING OFF WHEN I MOVED! WHEN LYING ON SIDE FRONT PATCH WOULD FALL OFF
39	BIT ITCHY
47	FOUND WIRE PRICKLY UNDER THE ARMPIT,
74	TAPE MIGHT COME OFF
76	STICKY TAPE NOT COMFORTABLE
78	WIRE SLIGHTLY UNCOMFORTABLE ON MOVEMENT
81	STICKY BITS ON PATCH CAME OFF WHILST SLEEPING
84	WHILST SLEEPING A LITTLE BIT UNCOMFORTABLE
93	GREAT IDEA BUT NEEDS TO BE MORE COMFORTABLE
113	NEEDS IMPROVEMENT WITH REGARDS TO WEARABILITY
119	WHEN YOU MOVE IN BED IT FEELS A LITTLE UNCOMFORTABLE
120	WHEN YOU MOVE AROUND AT NIGHT IT SOMETIMES COMES OFF
140	HAIRS ON THE CHEST GOT IN THE WAY
141	GLUE COMES OFF SOMETIMES
152	CHEST HAIRS GET IN THE WAY AND WHEN SWEATY MAKES IT COME OFF
156	THE THERMOMETER WIRE NEEDS TO BE IN A CASE, THE INFO SHEET SHOULD BE IN BRAILLE

PATIENT STUDY ID	QUESTIONNAIRE NEGATIVE COMMENTS
158	IT WAS UNCOMFORTABLE FOR HER ESPECIALLY THE WIRE UNDER THE ARMS
162	THE PLASTER MAKES IT UNCOMFORTABLE
166	THE WIRE AND THE TAPE IS UNCOMFORTABLE
168	WIRE UNDER THE ARM WAS VERY UNCOMFORTABLE, CONCEPT IS VERY GOOD
178	FELT A SHOCK FROM RIGHT ECG DOT, HAPPENED TWICE TAKEN IT OFF
194	FOUND IT UNCOMFORTABLE IN THE ARMPIT BECAUSE OF SURGERY
196	WHEN YOU TURN OVER IT FOLDS UP A BIT
205	IT DIDN'T SURVIVE THE SHOWER, ADHESIVE NOT STRONG
215	FELT SOMETHING TIGHT ON CHEST BUT OTHERWISE PATCH OKAY
236	UNCOMFORTABLE WHEN LEANING OVER TO THE SIDE
249	IT FEELS A BIT UNCOMFORTABLE WHEN I PUT MY ARM ON TOP OF MY CHESTAS IT FOLDS. I CANNOT EVEN FEEL THE THERMOMETER
257	THE BACK IS A BIT UNCOMFORTABLE
262	IT FELL OFF QUICKLY
270	PATCH WAS FALLING OFF
297	IT MAKES YOU QUITE WARM ON YOUR CHEST
322	IT COMES OFF WHEN PT BECOMES SWEATY AND IN THE SHOWER. BEING SO BIG IS A BIT CUMBERSOME, IT WOULD BE MORE COMFORTABLE IF IT WAS SMALLER. THE WIRE SHOULD NOT GO ALL THE WAY BACK , IT IS A BIT UNCOMFORTABLE
334	IT IS A BIT ITCHY AROUND THE ECG DOTS
405	IT WA A BIT UNCOMFORTABLE DURING SLEEP
415	THE PATCH CATCHES ON CLOTHING WHICH MAKES IT UNCOMFORTABLE AND THE STICKERS KEPT FALLING OF
416	IT IS A LITTLE ANNOYING BUT IT IS ALRIGHT

PATIENT STUDY ID	QUESTIONNAIRE NEGATIVE COMMENTS
425	STICKER DOES NOT STICK PROPERLY
431	IT STARTED TO ITCH ON THE BACK WHERE THE TAPE IS
438	PATIENT FOUND IT ITCHY AND HAD TO REMOVE IT
456	TOOK OFF THE PATCH DURING THE NIGHT BECAUSE IT WAS ITCHY
458	IT FELT HEAVY AT FIRST BUT IT WAS OK ONCE I GOT USED TO IT. IT ALSO FELT A BIT WARM.
462	PATCH FELL OFF ON SHOWER AROUND 8-9AM ON 05/12/2018
472	FELL OUT IN THE SHOWER ON 13/12. I FELT THAT I HAD AN EXTRA SAFETY AND THAT IT WILL BENEFIT PATIENTS. I FORGOT I HAD IT ON.
498	WIRE CAME UNDONE, GREAT IDEA

Appendix 5.16

Questionnaire free text neutral comments

PATIENT STUDY ID	Comments
21	GOOD COMMUNICATION WINS, V INFORMATIVE RESEARCHER
65	PATIENT WOULD LIKE TO SEE THE RESULTS
86	PLEASE REDRAFT THIS QUESTIONNAIRE THE DIFFERENCE BETWEEN AGREE AND STRONGLY AGREE NOT VERY CLEAR
181	PLEASE RECYCLE THE PATCH AND MAKE IT REUSEABLE, THE INSIDE BIT NOT THE OUTER BIT CAN BE REUSED
193	HAPPY TO HELP THE MEDICAL PROFESSION
219	IT WOULD BE NICE TO HAVE A USER DISPLAY FOR THE PATIENT AND SOME INTERPRETATION FOR IT
239	COULD THE PATCH BE VERTICAL INSTEAD OF HORIZONTAL
248	I AM HAPPY TO PARTICIPATE IN SOMETHING THAT WILL HELP PEOPLE
265	HAPPY TO HELP
275	LOOK INTO ANY SIDE EFFECTS
293	ARTI WAS A FANTASTIC WORKER
298	HAPPY TO HELP
332	MAYBE COULD HAVE DIFFERENT ONES FOR MALES AND FEMALES
346	DIFFERENT COLOURS OF PATCHES
349	THE LITERATURE WAS VERY WELL WRITTEN, IT WAS EXPLAINED WELL AND EASSY TO TAKE IN
371	ARTI DID HER JOB WELL

PATIENT STUDY ID	Comments
375	VERY PLEASED TO BE PART OF THE RESEARCH
470	PLACE OF PATCH NOT IDEAL
484	NICE LADY DOING THE SURVEY
485	COULD MAKE THE PATCH SMALLER
500	HAPPY TO BE NUMBER 500 PATIENT!

Appendix 6.1

Staff Information Sheet

WEARABLE PATCH VITAL SIGN MONITORING PROJECT

Staff information sheet for semi structured interviews

Contact

Dr Meera Joshi
10th Floor QEOM Building
St Mary's Hospital
Praed Street
London W2 1NY
United Kingdom
Email : meera.joshi03@imperial.ac.uk

You are being invited to take part in a research study. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

1.What is the purpose of the study?

We are aiming to see if patient deterioration on the ward can be identified sooner by wearing the wearable sensor. We know that if we can identify sick patients quickly patients are more likely to have better outcomes. The sensor measures heart rate, respiratory and temperature every 2 minutes and this can be reviewed by the clinical team of nurses and doctors looking after the patient. The patient will still have all their normal clinical care and bedside observations.

This research will also be used as part of a PhD thesis at Imperial College London.

It is vital that the feedback from staff using the sensor are considered before the technology is widely used in hospitals. It is important that your views, experiences and use of the sensors are known. We hope to do this by conducting individual interviews with healthcare staff that have managed patients using the wearable sensor.

2.Why have I been chosen?

You have been invited to take part in this study because you were involved in the care of a patient that was wearing a wearable sensor during their hospital inpatient stay.

3.Do I have to take part?

You do not have to take part in the study. You will have at least 2 hours to decide whether you wish to take part in the interviews and review the documentation but can have longer if needed. If you decide to take part, you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason.

4. What will happen to me if I take part?

We will arrange a time and place that suits you for the interview to take place. You will be asked some questions about your experiences, views and understanding of the wearable sensor technology that patients wore in hospital. Questions will also be around the escalation of care and the role of the new technology in the management of acutely unwell ward patients. We will take some notes during the discussion and this will also be audio recorded. The interview will last approximately 20-30 minutes. The interviews will be transcribed using a transcription service.

5. Is taking part anonymous and confidential?

Yes, all information gathered will be anonymous. Paper records will be kept securely in a locker in a locked office. Electronic data will be stored on a password protected computer at Imperial College and backed up regularly. No personal identifiable information will be used in any reports arising from this research; we will use a pseudonym in reporting. Data will be backed up with secure storage for a period of 10years for purpose of reference to data requested regarding any research published.

6. What are the possible benefits of taking part in this study?

There may not be any direct benefit of you taking part in this study. The information we get from this study, will help us to understand more about staff views on the wearable sensor technology in the management of unwell ward patients.

7. What are the possible risks of taking part in this study?

There is a small chance that talking about the issues raised in this interview may make you feel a bit worried. If so, we can put you in contact with somebody who will be able to help you with your concerns. If you report serious incidents or unreported events, in the interests of safety, these may need to be reported to the appropriate clinical manager. If you wish to complain, or have any concerns about any aspect of the way you have been treated during this study then you should immediately inform the investigator: Dr Meera Joshi (meera.joshi03@imperial.ac.uk). If you have been affected by incidents that have happened at the hospital, we can put you in contact with the occupational health team at the trust.

8. What will happen after this study?

We hope that the results will allow us to understand more wearable sensors measuring vital signs. The results will be published in journal articles and will also be used as part of a PhD thesis at Imperial College London.

9. Can everyone take part?

We may not be able to talk to everyone who wants to take part in the study. At least 20 members of staff will be interviewed. These will include all members of clinical staff, 4 health care assistants, 4 ward nurses, 4 senior nurses, 4 junior doctors and 4 senior doctors.

10. Can I stop taking part?

You can decide to stop participating at any time without giving a reason by informing the researcher. If you would like to withdraw from the study, please contact Miss Meera Joshi. You can stop the interview at any time; just tell the researcher.

11. What if there is a problem?

We do not expect that this study will cause harm or worry for anyone taking part. If you have concerns, inform the researcher.

12. Who has reviewed the study?

This study has been reviewed and approved by the Research Ethics Committee.

13. Who to contact about this study

Contact Dr Meera Joshi (details above) for further information and support

OR for independent advice please contact:

Occupational Health Service West Middlesex University Hospital: Occupational Health Service, West Middlesex University Hospital, Twickenham Road, Isleworth, TW7 6AF

Occupational Health Service St Marys Hospital Paddington: Lower Ground Floor, Mary Stanford Wing Praed Street, London, W2 1NY

Appendix 6.2

Staff Consent Sheet

WEARABLE PATCH VITAL SIGN MONITORING PROJECT

Consent form for staff interviews

Version 2 23/08/2017

Name of Researcher: Miss Meera Joshi

Supervisors: Professor Ara Darzi, Dr Sadia Khan, Dr Richard Kwasnicki

Participant ID:

Instructions for the participant:

Please read each of the sections below. In the box, next to each section, please write your initials to show that you agree with what the section says.

When you have written your initials, please write your name, today's date and add your signature in the spaces at the bottom.

		Initials
1	I have read and understand the information sheet for the above study (Version 1)	
2	I have had the opportunity to think about the information and to ask questions about it if I want to. If I have asked questions, I am happy with the way my questions have been answered.	
3	I understand what will happen in the interview	
4	I understand that what I say to the researcher will be recorded using a digital voice recorder and saved on a computer at Imperial College London.	
5	A transcription service will be used to transcribe the information from the interview and all interview data will be anonymised.	
6	I understand that it is my right to refuse to take part in this study or withdraw within two weeks of the date of participation without having to give a reason. I understand that I can withdraw without my legal rights being affected.	
7	I have been informed that anything I say during the interview will remain anonymous; my name will not be used, nor any other information that could be used to identify me.	
8	I agree to take part in this study.	

Name of Participant

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

Appendix 6.3

Semi structured interview guide

WEARABLE PATCH VITAL SIGN MONITORING PROJECT

Healthcare staff semi structured interview guide

Role in hospital must be clearly stated at the start and frequency of use: (daily, weekly, monthly)

Experience – years in healthcare

Role in Healthcare -

- 1) What are the good points about the wearable patch?
- 2) How do you think that the wearable patch can affect patient safety for ward patients?

Prompt:

- Please explain in what way
- Can you give specific examples of this?
- Patient deterioration?

- 3) How do you think that the wearable patch can affect the care of patients with sepsis?

Prompt:

- Please explain in what way
- Can you give specific examples of this?
- Time to antibiotics?
- Escalation of care for patients with sepsis?

- 4) How was your training to use the wearable patch?

Prompt:

- Was this adequate?
- Anything you would change?
- Did you have support if you had problems?
- Where did the support come from?

- 5) Were there any barriers or facilitators to wearable patch use on your ward?

- 6) Were there any problems with the new technology?

Prompt:

- Time spent with patients?

- 7) If you could improve the wearable patch what would you change?

Prompts:

- Design? (weight, temperature probe)
- Attachment on patients?

- 8) Did the wearable patch technology affect your time spent with patients?

Prompts:

- Specific examples, in what way?

