

SMARTPHONE TOOLS FOR ANAPHYLAXIS MANAGEMENT

By

LUIS ULISES HERNÁNDEZ MUÑOZ

A thesis submitted to
The University of Birmingham
For the degree of

DOCTOR OF PHILOSOPHY (Ph. D.)

School of Electronic, Electrical and Computer Engineering
College of Engineering and Physical Sciences
University of Birmingham

February 2015

UNIVERSITY OF
BIRMINGHAM

University of Birmingham Research Archive

e-theses repository

This unpublished thesis/dissertation is copyright of the author and/or third parties. The intellectual property rights of the author or third parties in respect of this work are as defined by The Copyright Designs and Patents Act 1988 or as modified by any successor legislation.

Any use made of information contained in this thesis/dissertation must be in accordance with that legislation and must be properly acknowledged. Further distribution or reproduction in any format is prohibited without the permission of the copyright holder.

Abstract

Anaphylaxis is a severe life-threatening allergic condition which has dramatically increased in prevalence in recent years and now affects more than 2% of UK children. Anaphylaxis management requires the avoidance of allergen triggers and preparation in readiness for an emergency, i.e., for an anaphylactic reaction. People with anaphylaxis and their carers carry Adrenaline Auto-Injectors which need to be administered immediately in the event of an anaphylactic reaction. But, unfortunately, many people often do not know how to use the injectors and fail to use them or fail to use them correctly. This is due in part to deficiencies in training and also to a lack of a system encouraging continuous practice and providing feedback on that practice.

Pervasive healthcare research has demonstrated potential in supporting the management of chronic conditions such as diabetes, cardiovascular disease and asthma. However, research into assistive technology applications for the support of anaphylaxis management has been significantly neglected.

This thesis sought to answer three research questions: What assistive smartphone tools have potential to supplement anaphylaxis management? Could a smartphone tool improve adrenaline injection performance in training and positively influence self-efficacy, and what is the clinical evaluation of allergy specialists regarding the use and deployment of such tools?.

The research used a multi-stage prototype methodology that evolved prototypes from design to laboratory proof-of-concept and on toward a smartphone and wireless sensor near-clinical proof-of-concept prototype with expert clinical evaluation. The functionality, usability and ease-of-use of prototypes were assessed, and, the final system, AllergiSense, was designed with participatory design and the embedding of self-efficacy sources. The randomised, controlled testing of AllergiSense is presented with results demonstrating significantly improved injection training skills and a positive influence on self-efficacy. In addition, the results provide insights into possible self-efficacy failings in traditional training and benefits of embedding self-efficacy into the design process. The thesis also summarises qualitative evaluation from interviews with clinical staff who were provided AllergiSense for one week and which expressed positive feedback regarding the potential of the technology.

This thesis is dedicated to the following people:

To my wife Margarita, my daughter Carolina Elizabeth and my son Luis Emiliano.

To my parents Avelino and Maria Teresa.

To my brothers Lilian, Jorge and Hugo.

To Catalina and Felipe who will be always remembered.

To the people living with Anaphylaxis and their families.

Acknowledgements

I am very grateful with Dr. Sandra I. Woolley for being an outstanding supervisor. Her quality as a person and as an expert in the field of pervasive healthcare computing was present always along this research. I deeply appreciate her wise and professional advice that increased my academic self-efficacy. It has been a pleasure to work with such a remarkable researcher.

I thank very much my wife Margarita, my daughter Carolina Elizabeth and my son Luis Emiliano for their astonishing support. It has been an amazing and very challenging time in our lives. This thesis would not have been possible without all your love, patience and advice (I am sorry for limiting the family time together in the writing up stage of this thesis).

I express thankfulness to my parents Avelino and Maria Teresa who have always motivated me to be responsible, honest and to never give up in achieving my goals. Thanks for your example and support.

I also thank the University of Birmingham for all the support and facilities received during my studies.

I am grateful to my sponsors, the Mexican National Council of Science and Technology (Conacyt), the Mexican Secretariat of Public Education (SEP), the Anaphylaxis Campaign UK and the Cadbury Schweppes Foundation for their support. Likewise, I will be eternally thankful to the Mexican people who invested their money in my postgraduate studies.

I sincerely thank Dr. Lavanya Diwakar, Ms. Cathryn Melchior, Ms. Mary Winkles, Mr. David Infante-Sanchez and Mr. Ben Clarke for all their advice and support; and all the anaphylactic people, carers, allergy specialists and non-anaphylactic people who participated in the experiments of this thesis.

I sincerely thank the people who provided me with a job to support my family while I was writing up this thesis and who gave me the opportunity to be more self-efficacious as a researcher: Professor Chris Baber, Dr. Eugene Ch'ng, Dr. Susan Bull and the Guild of Students of the University of Birmingham.

I express my appreciation to the people of The National Autonomous University of Mexico (UNAM) for developing me as a student in my undergraduate studies, laying the foundation of my postgraduate studies.

Many thanks to Catalina and Antonio for taking the time to come to Birmingham and looking after us while this work was undertaken.

Thanks also to Fazira Ku Ku Azir, Victor Landasurri, Monica Jaime, James Knight, Daniel Andrews, Manish Parekh, Mark Blyth and Matthew Johnson for being my friends. Thanks also to those people who I am not listing here but who were friendly and gave me their hand in testing moments.

Last but not least, I would like to thank God our lord, for giving me the strength to continue my studies in the most challenging moments of this thesis and for taking care of my family and myself while we have been abroad.

I thank you all very much.

Luis.

Content List

1. Introduction..... 1

2. Literature Review 12

3. Multi-Stage Proof-of-Concept Prototyping and Evaluation..... 33

4. AllergiSense Design 60

5. Evaluation of AllergiSense Adrenaline Injection Training Tools 84

6. Clinician Evaluation 96

7. Conclusions and Further Work..... 103

8. List of References..... 108

Appendix 1. Publications..... 120

Appendix 2. Research Authorisations 172

Appendix 3. AllergiSense Sensing Unit 178

Appendix 4. Injection Models 182

Appendix 5. Questionnaires 186

Appendix 6. Chapter 5 Extra Information..... 197

Table of Contents

Abstract ii

Dedication iii

Acknowledgementsiv

Content List.....vi

Table of Contents vii

List of Figuresxi

List of Tables..... xiii

List of Symbols and Abbreviationsxiv

List of Publicationsxv

1. Introduction 1

 1.1. Motivation1

 1.2. Anaphylaxis.....2

 1.3. Anaphylaxis management and unmet needs.....4

 1.4. Self-efficacy theory8

 1.5. Research questions9

 1.6. Contribution to knowledge.....10

 1.7. Thesis structure11

2. Literature Review12

 2.1. Introduction12

 2.2. Pervasive Healthcare – opportunities and challenges12

 2.3. Evaluation, prototyping and participatory design methodologies in pervasive
 healthcare research13

 2.4. Pervasive Healthcare with mobile devices15

 2.4.1 Supporting well-being and healthcare16

 2.4.2 Supporting diabetes management17

 2.4.3. Supporting the management of cardiovascular diseases19

 2.4.4 Supporting dementia.....20

 2.4.5 Supporting the management of asthma21

 2.4.6 Health and well-being “apps” and issues of evaluation22

 2.5. Pervasive healthcare research in anaphylaxis management24

 2.5.1 Smartphone “apps” for anaphylaxis management.....24

 2.6. Self-efficacy27

 2.6.1 Self-efficacy sources of information27

2.6.2 Rational for incorporating self-efficacy theory in the management of chronic diseases	28
2.6.3 Self-efficacy in pervasive healthcare research studies with mobile devices	30
2.7. Summary of this chapter	32
3. Multi-Stage Proof-of-Concept Prototyping and Evaluation.....	33
3.1. Introduction.	33
3.2. Methods.....	34
3.3. Anaphylaxis management scenarios	35
3.4. Study one – PervaLaxis 1.....	37
3.4.1. User needs and preferences.	37
3.4.2. PervaLaxis 1 hardware (created in 2009).....	40
3.4.3. Methodology	41
3.4.4. Results	43
3.5. Study two – PervaLaxis 2.....	45
3.5.1. PervaLaxis 2 design	45
3.5.2. Methodology	48
3.5.3. System usability scale results.....	51
3.5.4. Workload results	52
3.5.5. Results from ISO 9241-11 usability measures	53
3.5.6. Analysis of observations and comments	55
3.6. Study three – PervaLaxis 3.....	56
3.6.1. Methodology	57
3.6.2. Participants	58
3.6.3. Results and conclusions.....	58
3.7. Summary	58
4. AllergiSense Design.....	60
4.1. Introduction	60
4.2. Design of AllergiSense application	61
4.2.1. Research procedure	61
4.2.2. Results of the first focus group.....	64
4.2.3. Results of the second focus group.....	69
4.2.4. AllergiSense	71
4.3. Injection sensing.....	74
4.3.1. Preliminary results.....	75

4.3.2. Hardware and sensing method	75
4.3.3. Creating a classification algorithm with WEKA software	78
4.3.4. Classification algorithm accuracy	81
4.3.5. Providing feedback about the steps of the injection	82
4.4. Summary	83
5. Evaluation of AllergiSense Adrenaline Injection Training Tools.....	84
5.1. Introduction	84
5.2. Methods.....	84
5.2.1. Statistics	85
5.2.2. Participants	85
5.2.3. Assessment of performance and administered questionnaires	86
5.2.4. Materials.....	87
5.2.5. Experimental procedure	87
5.2.6. Assessment of performance and administered questionnaires	88
5.3. Results	90
5.4. Discussion of results.....	93
5.5. Summary	95
6. Clinician Evaluation.....	96
6.1. Introduction	96
6.2. Methods.....	96
6.2.1. Research procedure	96
6.2.2. Research authorisations.....	97
6.2.3. Participants	97
6.3. Results	98
6.4. Discussion	102
6.5. Summary	102
7. Conclusions and Further Work	103
7.1. Conclusions	104
7.2. Further work.....	106
8. List of References	108
9. Appendices	120
Appendix 1. Publications	120
Appendix 2. Research Authorisations	172
Appendix 3. AllergiSense Sensing Unit.....	178

Appendix 4. Injections Models	182
Appendix 5. Questionnaires	186
Appendix 6. Chapter 5 Extra Information.....	197

List of Figures
Chapter 3

Fig. 3.1 PervaLaxis 1: (L-R) Main screen; AAI's expiry date list screen; injection detection and emergency text messaging support	39
Fig. 3.2 PervaLaxis 1 components: a) GPS module; b) Smartphone device; c) AAI trainer with three-axis Bluetooth™ accelerometer; d) Size comparison with a pen	41
Fig. 3.3 NASA TLX results.	44
Fig. 3.4 PervaLaxis 2 support in everyday life (left) and emergency (right) scenarios.	46
Fig. 3.5 (a) PervaLaxis 2 smartphone device; (b) AAI trainer with a three-axis Bluetooth™ accelerometer; (c) Pen size comparison.....	46
Fig. 3.6 (a) PervaLaxis 2 welcome screen and emergency button; (b) Expiry date list; (c) Videos; (d) Step-by-step AAI trainer tool.	47
Fig. 3.7 Mechanism used to detect adrenaline injection events through an AAI trainer tool and a sensor mounted on an Epipen® AAI trainer device	48
Fig. 3.8 System usability scale comparison between the traditional system and PervaLaxis 2 (N=32, there were significant differences in all the SUS questions, $p < 0.05$).....	51
Fig. 3.9 NASA TLX scales results.....	52
Fig. 3.10 (a-c) Measures of usability according to ISO 9241 part 11. (d) Amount of navigation assistance provided to participants Human-Centred Design activities cycle	54
Fig. 3.11 AAI trainer tool for adrenaline injection training: a) Step-by-step trainer interface; (b) Video animation with subtitles	57

Chapter 4

Fig. 4.1 PICTIVE set up of the focus groups	63
Fig. 4.2 Storyboard style used in the design of the smartphone tools.....	63
Fig. 4.3 Participant paper mock-ups of everyday life tools. A list of videos as an educational tool (left), a barcode reader tool for allergen avoidance support (right).	67
Fig. 4.4 Support in emergency (left), AAI use and management with emergency button (right). Usability activities and associated documents mentioned in ISO 9241-11	68
Fig. 4.5 a) Anaphylactic emergency button location; b) Decision between using smiley faces over tick and crosses in a injection training tool; c) Choosing between bar type buttons over icons type buttons; d) Decision to place a cancel button on top instead of at the bottom to avoid mistakes.	70

Fig. 4.6 AllergiSense tools for everyday life.....72

Fig. 4.7 AllergiSense tools for emergency73

Fig. 4.8 AllergiSense sensing unit mounted on an EpiPen® AAI trainer device.....76

Fig. 4.9 Creating and using a model for adrenaline injection feedback.77

Fig. 4.10 XYZ acceleration data with all the steps of the injection (top), gold standard injection from the clinical collaborator with a simplified version of steps (bottom)80

Fig. 4.11 AllergiSense injection training feedback83

Chapter 5

Fig. 5.1 Research procedure for session one (duration: 30 minutes)89

Fig. 5.2 Research procedure for session two (two weeks after session one - duration: 30 minutes).....90

List of Tables

Chapter 2

Table 2.1 Smartphone apps for anaphylaxis management (June 2014)	25
--	----

Chapter 3

Table 3.1 Functions implemented in PervaLaxis 1	40
Table 3.2 Tasks undertaken in the usability evaluation of PervaLaxis 2	42
Table 3.3 Tools implemented in PervaLaxis 2	49
Table 3.4 Table 3.4 Tasks undertaken in the usability evaluation of PervaLaxis 2	50

Chapter 4

Table 4.1 Profiles of focus groups participants	62
Table 4.2 Anaphylaxis management needs	64
Table 4.3 AllergiSense tools	71
Table 4.4 Self-efficacy sources supported by suggestions from user needs inputs, by the traditional care paper documents, by AllergiSense tools excluding an injector tool with feedback and by AllergiSense.	74
Table 4.5 List of features per segment of acceleration data	79
Table 4.6 Confusion Matrix of the model created by WEKA	81

Chapter 5

Table 5.1 Primary outcome: Number of people correctly completing the four injection Steps.	91
Table 5.2 Secondary outcomes: Self-efficacy, usefulness, ease-of-use, attitudes towards use, system usability and workload PervaLaxis hardware and software.....	92

Chapter 6

Table 6.1 Participants' profile	97
---------------------------------------	----

List of Symbols and Abbreviations

AAI: Adrenaline Auto-Injector.
AllergiSense: Allergy Interactive Sensing System.
BSACI: The British Society for Allergy and Clinical Immunology.
CPoC: Clinical Proof-of-Concept.
C#: Programming language included in Microsoft Visual Studio®.
ECG: Electrocardiogram.
GP: General Practitioner (family doctor).
GPRS: General Packet Radio Service.
GPS: Global Positioning System.
GSM: Global System for Mobile Communication (Groupe Spécial Mobile).
HCD: Human-Centred Design.
HCI: Human-Computer Interaction.
HIV: The Human immunodeficiency Virus.
IDE: Interface Development Environment.
ISO: International Organisation for Standardisation.
JTEHM: IEEE Journal of Translational Engineering in Health and Medicine.
MHRA: Medicines and Healthcare Products Regulatory Agency.
NICE: National Institute for Health and Care Excellence.
NHS: National Health Service.
OS: Operating System.
PDA: Personal Digital Assistant.
PervaLaxis: Pervasive Anaphylaxis System.
RCPCH: Royal College of Paediatrics and Child Health.
SMS : Short Message Service.
SUS: System Usability Scale.
WHO: World Health Organisation
WAO: World Allergy Organisation

Brands with trademark and copyright notice:

Android
Arduino
Apple
Blackberry
Bluetooth
Google
HTC
iPhone
iPad
iPod
EpiPen
Jext
Anapen
Microsoft
Linux
SPSS
Windows Mobile

ZigBee

List of Publications

The following table shows a list of peer-review publications that contain ideas, concepts and figures used partially or fully in this thesis. They are the work of the first author under the supervision of Dr. Sandra I. Woolley (supervisor) or/and Professor Chris Baber (internal supervisor). A copy of these publications can be found in appendix one.

Year	Publication
2007	Hernandez-Munoz, L.U., Woolley, S.I. and Baber, C. “A Mobile Context-Aware Device to Help People with Anaphylaxis” . Second European Conference EuroSSC, Kendal, UK.
2008	Hernandez-Munoz, L.U., Woolley, S.I. and Baber, C. “A Mobile Health Device to Help People with Severe Allergies” . 2 nd International Conference on Pervasive Computing Technologies for Healthcare 2008. Pervasive Health ‘08. Tampere, Finland.
2009	Hernandez-Munoz, L.U. and Woolley, S.I. “A User-Centred Mobile Health Device to Manage Life-Threatening Anaphylactic Allergies and Provide Support in Allergic Reactions” . 9 th International Conference on Information Technology and Applications in Biomedicine. ITAB’09. Cyprus.
2010	Hernandez Munoz, L.U. and Woolley, S.I. “A Personal Handheld Device to Support People with Life-Threatening Anaphylactic Allergies (PervaLaxis)” . International Journal of Handheld Computing Research. Vol. 1. No. 1. IGI Publisher. January-March 2010.
2011	Hernandez-Munoz, L.U., Woolley, S.I. and Baber, C. “PervaLaxis Two: Encouraging Anaphylactic People Manage Their Own Healthcare with a Touchscreen Personal Mobile System” . International Conference on Ambient Intelligence on Healthcare and Social Wellness. 5 th International Symposium on Ubiquitous Computing and Ambient Intelligence, UCAmI 2011. Riviera Maya, Mexico.
2013	Hernandez-Munoz, L.U. and Woolley, S.I. “Mobile Phone Tools with Ambient Intelligence for the Management of Life-Threatening Allergies” . Chapter 10. Book on Human Aspects in Ambient Intelligence. Atlantis Press - Springer.
2014	Hernandez-Munoz, L.U., Woolley, S.I. and Diwakar, L. “Pilot Evaluation of Smartphone Technology for Adrenaline Injection Training” . The British Society for Allergy and Clinical Immunology –BSCAI- Annual Meeting, 28 th – 30 th September, 2014. Telford UK.

Note: Three additional journal papers (including the results of chapters 4, 5 and 6) are being prepared for publication at the time of thesis submission.

Chapter 1

Introduction

1.1 Motivation

This research was motivated by the increasing prevalence of life-threatening anaphylaxis (Gupta et al., 2007; Lieberman et al. 2006; Lin et al., 2008; Poulos et al., 2007; Sheikh & Alves, 2000; Sheikh & Strachan, 2003; Simon & Mulla, 2008) and the ambition to support improved anaphylaxis management, in particular, to improve on the poor performance of Adrenaline Auto-Injector (AAI) use (Arga et al., 2011; Diwakar 2010; Pumphrey, 2011). Advances in pervasive and assistive health technology research have contributed toward improved management of other chronic health conditions (Free et al., 2013; Fjeldsoe et al., 2009; Belisario et al., 2013), but anaphylaxis has been neglected (Vavoula & Lonsdale, 2007). This is unfortunate because people with anaphylaxis really need good management skills to avoid life-threatening allergic reactions and to respond correctly in the event of such a reaction (NICE, 2011). Additionally, people with anaphylaxis and their carers are motivated more than most to carry mobile phones because they may need to make emergency calls, and so the technology needed for a pervasive healthcare solution is already available.

The following sections of this chapter introduce subjects relevant to this thesis, namely, anaphylaxis and its management, anaphylactic people's unmet needs and self-efficacy theory. This chapter also outlines the research questions, the contribution to knowledge and the methodology of this research. Finally, at the end of the chapter, the structure of the thesis is summarised.

1.2 Anaphylaxis

“Anaphylaxis is a serious allergic reaction that is rapid in onset and may cause death” (Sampson et al., 2006:392). Reactions may occur rapidly after contact, ingestion or inhalation of an allergen which may be a food, a wasp or bee sting, or a substance such as latex or a prescription drug (Lieberman et al., 2005). Reactions to allergens can also be delayed and can occur several hours after exposure (Ellis & Day, 2007). The Anaphylaxis Campaign UK (2010) explains that reactions occur when *“the body’s immune system reacts inappropriately in response to the presence of a substance that it wrongly perceives as a threat”*. Not surprisingly, anaphylaxis has implications not just for the individual affected but also for their family and friends. For example, *“invitations to dinner parties and social gatherings become a source of embarrassment and anxiety rather than enjoyment. A simple trip to the supermarket can become a lengthy series of food label examinations and a family trip abroad, if even considered, a delicate military operation”* (Sherwood, 2007:6)

The National Institute for Health and Care Excellence (NICE) in the UK (2011) has reported a lack of robust figures on anaphylaxis prevalence due, in part, to misdiagnosis and ambiguity in reporting, for example, cases of anaphylaxis reported as allergy or asthma. Anaphylaxis significantly affects developed countries (Sicherer & Sampson 2010) with an increase in occurrence that has elicited debate of an epidemic magnitude (Simons & Sampson, 2008). Gold & Sainsbury (2000) reported anaphylactic reactions with a frequency of 0.98 events per anaphylactic person per year and The Anaphylaxis Campaign UK (2010) has reported that around a million people in the UK suffer from anaphylaxis and as many as one in 52 children have anaphylaxis in the UK, i.e., that 2% of all children are now anaphylactic. For younger children, severe allergic reactions occur mostly in the home, while for adults, reactions occur more often outside the home (e.g., at parties, family gatherings, at restaurants and on flights) (Clark & Ewan, 2008; Jaervinen, 2011; Sicherer & Sampson, 2010).

The Royal College of Physicians (2003) suggests that severe allergic reactions are probably caused by environmental factors acting on a genetic predisposition. In addition, the “Hygiene Hypothesis” (Strachan, 1989), highlights the fact that declining family size, better household amenities, and improved standards of personal cleanliness have contributed to a reduction in cross

infections in young families and a missing opportunity to educate their immune systems to recognise and handle real threats.

According to the World Allergic Organisation (Kemp et al., 2008) an allergic reaction involves an abrupt release of chemical substances such as histamine from cells in the blood. The substances are released because of the reaction between the allergen and an antibody (e.g., Immunoglobulin E or Immunoglobulin G), and this mechanism is so sensitive that it can be caused by minute quantities of the allergen. The released substances affect the blood vessels to cause allergic symptoms. These can be mild symptoms such as itchy nose, flushing or rashing of the skin, headache or they can be more severe such as swelling of throat and mouth, difficulty in swallowing or speaking, change in voice, alterations in heart rate, severe asthma, abdominal pain, vomiting, a sudden drop in blood pressure or loss of consciousness (Allergy UK, 2011; Kemp et al., 2008; The Anaphylaxis Campaign UK, 2010). In people with anaphylaxis, allergic symptoms can be so severe that they can cause death (Sampson et al., 2006).

The reported mortality caused by anaphylaxis varies widely per country and per study. For example, the World Allergic Organisation (2006) has reported that approximately 29,000 food-anaphylactic events occur each year in the USA, resulting in approximately 2,000 hospitalisations and 150 deaths. However, a higher USA mortality rate has been estimated by Tang (2003) as approximately 1,500 deaths per year. Moneret-Vautrin et al. (2005) reported anaphylactic death rates of 0.65-2% while, in a meta-study, Umasunthar et al. (2013) estimated fatal food anaphylaxis rates at less than those due to accidental death. Pumphrey (2000) reported only 20 fatal anaphylactic reactions per year in the UK, but anaphylactic deaths are under-reported (Pumphrey, 2004). They can be difficult to identify and may be misreported as respiratory distress or cardiac arrest (Brown, Mullins & Gold, 2006).

The World Allergy Organisation (2009) and The Anaphylaxis Campaign UK (2010) report that the most common triggers of anaphylaxis “*include foods such as peanuts, tree nuts (e.g., almonds, walnuts, cashews, brazil nuts), sesame, fish, shellfish, dairy products and eggs. Non-food causes include wasp or bee stings*”, pollens, animals (e.g., contact with cats or dogs), latex and prescription medicines (e.g., penicillin). Reactions can be exacerbated by non-immunological

mechanisms, for example, exercise, sun exposure, air temperature and medication (Sheikh, 2011).

Foods are the most common allergens for children, adolescents and young adults but for older people, non-food allergens such as prescription medications and insect stings, are more common (Simons et al, 2011). Children frequently develop tolerance to milk, egg, soya and wheat allergens by school age, however, allergies to nuts and shellfish are more likely to be lifelong (Allen, Hill & Heine, 2006).

The first-line treatment for an anaphylactic reaction is the immediate administration of adrenaline (epinephrine) given by a pre-loaded Adrenaline Auto-Injector (AAI) (e.g., Epipen®, Jext®, etc.) into the outer thigh (NICE, 2011). The injection must be given “*as soon as a serious reaction is suspected and an ambulance must be called*” (Anaphylaxis Campaign UK, 2010) and if symptoms do not improve in five to ten minutes a second injection should be given (*ibid*; Muraro et al., 2007). Adrenaline is used because “*during anaphylaxis, blood vessels leak, bronchial tissues swell and blood pressure drops, causing choking and/or collapse. Adrenaline acts quickly to constrict blood vessels, relax muscles in the lungs to improve breathing, increase heart rate and help to stop swelling around the face and lips*” (Anaphylaxis Campaign UK, 2010). Anaphylactic people and their carers should carry one or more AAIs (RCPCH, 2008; Kemp et al., 2008; Lieberman et al., 2010) and also a mobile phone to call emergency services and alert family or friends in the event of a reaction (Simons et al., 2011).

1.3 Anaphylaxis management and unmet needs

Following a first anaphylactic event, patients typically meet with a family doctor or clinician, who may make a referral for diagnosis and advice on managing their allergies and preventing reactions (Ewan & Clark, 2005). Patients should then be provided with AAIs and trained in their use (NICE 2011; Royal College of Physicians, 2003). This is usually done by family doctors, allergy specialists, allergy nurses or pharmacists (Xu et al., 2010). The AAIs are packaged with patient information leaflets showing how they are used. Further information documents may be provided to the patients or they may obtain them themselves, for example, on-line resources of AAI manufacturers or allergy support groups such as the

Anaphylaxis Campaign UK or Allergy UK. We refer to this conventional style of care, learning, training and support as the “*traditional*” care system.

Since reactions might be provoked by inhalation, ingestion or skin contact with minute amounts of an allergen, and so can be unpredictable (Pumphrey, 2004), it is important that people at risk learn about anaphylaxis management. The management of anaphylaxis requires allergen avoidance and emergency preparedness (Walker & Sheikh, 2003; Wang, 2010; NICE, 2011; Simons et al., 2011). Allergen avoidance requires careful inspection of ingredients in food product labels to look for allergens (Walker & Sheikh, 2003; Umasunthar et al., 2013) as well as awareness of contamination risks, for example, ensuring food has not been cut with a knife that has been in contact with an allergen. Emergency preparedness involves training in the use of AAIs (Simons, 2009), wearing medical identification (Muraro et al., 2007) and having an emergency Allergy Action Plan: a plan that provides a summary of symptoms, emergency actions including AAI use, allergy details and emergency contacts (BSACI, 2014; NICE 2011; Royal College of Physicians, 2003).

Unfortunately, people with anaphylaxis have unmet needs and lack satisfactory levels of anaphylaxis management (Royal College of Physicians, 2003). After initial medical advice there may be little further reinforcement or support of the necessary on-going learning and management processes beyond the traditional care documents available to the patient. Warner et al. (2006) has reported a global lack of specialists, the need for improved patient care, training and expertise in this area, and the lack of appropriate clinical services to support people with anaphylaxis. Xu et al. (2010) has reported a lack of training for nurses and school staff. Carlisle (2010) has reported that patients can find allergen-free eating difficult and may not have an Allergy Action Plan or fail to follow it or fail to have an AAI available at the time of a severe reaction. Xu et al. (2010) has reported that training can be delayed or incomplete and that only a minority of families feel confident avoiding allergens and knowing when and how to use an AAI, and that they do not receive enough information about their allergies or about support groups. Kastner, Harada & Wasserman (2010) have observed that the management of anaphylaxis is inadequate and, in particular, that little attention has been given to the long-term management aspects of the condition. For example, there can be a lack of access to AAIs and specialist advice, a lack of preventive strategies for patients and carers and

a lack of education and training in diagnosis and treatment and a lack of consistent information about management.

Pumphrey (2000; 2004) reported that very poor outcomes in anaphylaxis involve, avoidance failure (e.g., rules broken, risks taken, contamination and cross contamination), poorly controlled asthma (co-morbidity), and, during a reaction, failure to lie down (the patient should lie down with legs raised), inhalation of vomit after giving adrenaline, incorrect use, delay or reluctance (perhaps caused by embarrassment) in the injection of adrenaline and delay in making the emergency call.

The correct use of AAIs is significant in anaphylaxis management (Lieberman et al., 2010). However, there are significant gaps in use, practice and training (Arga et al., 2011; Brown et al., 2013; Carlisle, 2010; Diwakar, 2010; Gallagher et al., 2011; Luckhurst et al., 2013; Macadam et al., 2012; Mehr, Robinson & Tang, 2007; Nguyen et al., 2012; Noimark et al., 2012; Sicherer, Forman & Noone, 2000). Many patients and carers do not know how to use AAIs (Diwakar, 2010; Sicherer, Forman & Noone, 2000), either because they were not trained correctly at the outset or they did not have a system of continuous practice and forgot (Sicherer, Forman & Noone, 2000). For example, Brown et al. (2013) found that a concerning low percentage of only 15% of 100 mothers could inject an AAI properly after being shown how to do it. Similarly, in a comparison of three AAIs from different manufacturers with 120 adults and children over 12 years old with no experience in their use, Luckhurst et al. (2013) found that regardless of the type of injector, only 28% of the participants performed all the injections steps correctly. Likewise, in a randomised study carried out in a Canadian school settings with 343 staff participants who had attended training, Nguyen et al. (2012) found that only 26.3% of the participants (the best of three groups involved) demonstrated a good performance. Additionally, Noimark et al. (2012) found that of 245 paediatric allergy patients who reported anaphylactic reactions in the previous year, only 41 used an AAI. The commonest reasons for not using an AAI were that they ‘thought adrenaline unnecessary’ (54.4%) and were ‘unsure adrenaline necessary’ (19.1%) other reasons included that they had already called an ambulance or that they went to an emergency department, that an AAI was not available, they were afraid to use it, were not trained to use it, or that it had expired. Similarly, Gallagher et al. (2011) interviewed 26 adolescents and 28 parents and identified that main barriers to AAI use were failure to

recognise anaphylactic symptoms, uncertainty about the injection steps and fear of using the AAI. In addition, Macadam et al. (2012) interviewed 20 anaphylactic teenagers and observed that most were making quite complex risk decisions about carrying their AAIs but noted that not all decisions were rational. Some teenagers reported not carrying their AAI because of concerns about size of the AAI and how it looks, uncertainty about its use and the hassle of it, e.g., managing the AAI expiry date and temperature (adrenaline should be stored at room temperature – it can degrade if, for example, it is stored in a fridge or in a hot car).

Unfortunately, it is not only users who have difficulties with AAI use. Many physicians, including paediatricians, are not familiar with AAIs (Arga et al., 2011; Sicherer, Forman & Noone, 2000). For example, Mehr, Robinson & Tang (2007) have suggested that the reason parents and children cannot use their AAIs may be because their doctors do not know how to demonstrate correct use. The authors recruited 100 doctors including residents, registrars and consultants (half of them had already prescribed an AAI), but unfortunately only 2% of them correctly demonstrated all the injection steps. Even after reading the injection steps, only 41% were able to demonstrate the steps correctly and one in five doctors self-injected their finger. Similarly, Arga et al. (2011) found in a study with 151 general physicians, residents and consultants that only 35 (23 %) were able to demonstrate how to use an AAI before receiving extra training. Typical injection errors can include: not injecting with enough force, carrying out unintentional self-injections and not holding the AAI in the site of the injection for the required time (Carlisle, 2010).

Although new AAI brands have appeared on the market and there have been some proposals to improve adrenaline injections e.g., modifying AAI design and labelling (Bakirtas et al., 2011; Gosbee, 2004) or simplifying the steps required (Kranke et al., 2011), there is, as yet, no ideal solution (Arga et al., 2012). Meanwhile, the consensus recommended in the clinical literature is that training should be improved and should ensure correct injection techniques are used and that training is continuous, monitored and assessed so that skills are refreshed and maintained in readiness for emergency events (Bina et al., 2006; Brown et al., 2013; Frew, 2011; Macadam et al. 2012; Mehr et al., 2007; NICE, 2011; Nguyen et al., 2012; Noimark et al., 2012). The proposal made in this thesis is the use of technology to provide supplementary support of anaphylaxis management, and in particular, the maintenance and monitoring of AAI training.

1.4 Self-efficacy theory

Glanz & Bishop (2010) observed that health-promotion interventions grounded on social and behavioural science theories are more effective than those not having a theoretical base. The design and evaluation phases of this thesis were informed by Bandura's (1977) self-efficacy theory. Self-efficacy refers to the "*beliefs in one's capabilities to organize and execute the courses of action required to produce given levels of attainments*" (Bandura, 1998:624). In other words, self-efficacy is related to the beliefs that one person has to carry out specific activities and behaviours in order to achieve their goals. This theory was used because evidence suggests that self-efficacy is a significant predictor of behavioural change and the levels and duration of sustained effort that a person invests in a task or behaviour (Bandura, 1997). Self-efficacy is also a major contributor to performance; it affects levels of motivation, perseverance, goal setting, outcome expectations, emotional states, vulnerability to stress and depression, and optimistic or pessimistic points of view (Bandura, 2012). Self-efficacy can be modified by four sources of information (Bandura, 1977): from *enactive experience* (i.e., experiencing attainment through mastery and practice), from *vicarious experience* (i.e., modelling other people having success in challenging activities), from *social persuasion* (i.e., receiving encouraging or discouraging information from other people) and from the perception of one's *physiological states* (i.e., the interpretation of one's physiological responses as indicators of personal competency).

Once a goal is achieved, people with "*high self-efficacy set even higher goals for themselves and mount a vigorous effort to realize these goals; those of somewhat lower efficacy believe they can achieve the original goal, stick to it, and work a bit harder; and those who distrust their efficacy to even repeat what they had accomplished lower their goals and slacken their efforts*" (Bandura, 2012:18). In this way, self-efficacy is a significant predictor of adherence to management plans, for example, plans for the self-management of chronic conditions (Lorig and Holman, 2003). Where medical or healthcare self-management is the individual's ability to manage their medical condition, its treatment and the physical and emotional consequences that result from it (Barlow et al., 2001). And where patients and carers themselves take a central role, with responsibility moving away from the healthcare system and towards themselves (Von Korff et al. 1997). Self-management is fundamental to good

anaphylaxis management so that people with anaphylaxis can take control of their condition and its consequences.

The reason for including self-efficacy theory in this research was that helping improve adrenaline injection performance and patient self-efficacy could translate to better anaphylaxis management. More specifically, higher levels of self-efficacy, together with improved training may imply better injection skills, better preparedness, improved confidence and, potentially, better outcomes in the self-management of anaphylaxis.

1.5 Research questions

The three research questions of this thesis arose from the hypothesis that pervasive healthcare technology, informed by self-efficacy theory could provide opportunities to support adrenaline injection training and anaphylaxis management; an application which presents challenges but could offer significant rewards but, as yet, has been little supported by pervasive healthcare technology. The research questions of this thesis are:

1) What assistive smartphone tools have potential to supplement anaphylaxis management?

The objective of this question was to map the needs of anaphylaxis management onto possible technology solutions: Firstly, investigating the tools needed for anaphylaxis management according to the needs presented in clinical literature and from anaphylactic people, carers and allergy specialists. And secondly, investigating the feasibility and usability of management tools implemented in functional smartphone prototypes.

2) Could a smartphone tool improve adrenaline injection performance in training and positively influence self-efficacy?

Adrenaline injection performance is a key component of anaphylaxis management. This research question addresses the potential effect of technology (smartphone tools and wireless sensors) on AAI training and self-efficacy.

3) What is the clinical evaluation of specialists regarding the use and deployment of such tools?

The objective of this research question was to investigate the opinions of allergy specialists (clinicians and allergy nurses) toward the use of everyday and emergency smartphone tools for anaphylaxis management.

1.6 Contribution to knowledge

The contribution of this thesis is three-fold:

- It defines tools desirable in the support of anaphylaxis management.
- It provides evidence about the ability of smartphone tools to improve AAI training *and* positively affect injection self-efficacy.
- It provides evidence of support from expert clinical evaluation regarding use and deployment.

First, this thesis argues that smartphone tools, informed by self-efficacy theory, may have the potential to enhance adrenaline injection training by supplementing the traditional care documents. And second, that clinical specialists can have positive attitudes towards the use of smartphone tools for anaphylaxis management and their possible deployment in patient settings.

The contribution of this thesis involved the use of a “*multi-stage prototyping*” methodology proposed in (Matthews et al., 2008). This methodology was used because it integrates the iterative approach suggested by Human-Centred Design (ISO 9241-210, 2010); the production of usable prototypes proposed by the “*Clinical Proof of Concept (CPoC)*” methodology (Bardram, 2008); and the involvement of healthy volunteers as per phase zero clinical trials (NHS, 2012). The methodology involved three stages: design of the smartphone tools, peer-study-evaluation with healthy volunteers and clinical assessment with medical staff.

1.7 Thesis structure

This thesis is organised as follows:

Chapter 2 reviews the relevant literature. It summarises pervasive healthcare research aims, opportunities and challenges and comprises research examples of mobile devices for the management of chronic diseases including diabetes, cardiovascular disease and asthma. Later, pervasive healthcare applications and online smartphone "apps" for anaphylaxis management are discussed. And, at the end of the chapter, self-efficacy theory, its benefits and examples of research involving this theory are reviewed

Chapter 3 presents the design and evaluation of a series of multi-stage proof-of-concept pre-clinical laboratory prototypes (PervaLaxis 1-3). The needs of people regarding anaphylaxis management are identified from the clinical literature and from workshops organised by a support group. Results from laboratory usability studies and from a pilot evaluation of smartphone adrenaline injection training tools are presented and discussed.

Chapter 4 provides details of the AllergiSense design; a clinical proof-of-concept prototype created in participatory design focus groups with allergy specialists, anaphylactic people and carers. Design stages explained in this chapter comprised group brainstorming exercises, paper prototyping and paper mock ups. Additionally, an algorithm for wireless adrenaline injection sensing is explained.

Chapter 5 presents the results of a three-arm, pre-post, randomised, controlled study aimed at identifying and quantifying the benefits that AllergiSense smartphone tools may have to enhance adrenaline injection training and AAI self-efficacy, in comparison with traditional care paper documents.

Chapter 6 shows results of a qualitative companion study with clinicians who were provided with AllergiSense technology for at least one week. Results include opinions and attitudes of the allergy specialists about smartphone technologies for anaphylaxis management and about their deployment in patient settings.

Finally, chapter 7 summarises the conclusions of this research and discusses future work issues and directions.

Chapter 2

Literature Review

“Pervasive healthcare may be defined from two perspectives: first, as the application of pervasive computing—or ubiquitous computing, proactive computing, ambient intelligence—technologies for healthcare, health, and wellness management; second, as making healthcare available everywhere, anytime— pervasively. Essentially, pervasive healthcare addresses those technologies and concepts that integrate healthcare more seamlessly into our everyday lives, wherever we are.” (Korhonen & Bardram, 2004:229)

2.1 Introduction

This chapter presents a review of the literature relevant to mobile devices in pervasive healthcare. To provide a context for this thesis, because there has been almost no pervasive healthcare research applied to anaphylaxis, the review includes research supporting the management of other chronic diseases. The chapter also reviews self-efficacy and its application to healthcare and anaphylaxis management.

2.2 Pervasive healthcare – opportunities and challenges

Pervasive healthcare ambitions include the design and deployment of solutions to enhance healthcare outcomes by providing healthcare to “anyone, anytime and anywhere” (Bardram, 2008; Varshney 2003; Varshney 2007), with solutions for both clinicians and patients, and described by Jakob Bardram as follows:

“Pervasive healthcare encompasses research on ubiquitous technologies both for supporting clinicians working in a hospital or other health institutions, as well as patients—and more generally citizens—themselves. The goal in the former case is to create technologies that help clinicians better treat and care for patients; in the latter case that patients become more capable and resourceful in their own disease management. Pervasive healthcare technologies can of course also be a hybrid of these two types of systems—that is, having systems that help patients manage health-related issues in close cooperation with clinical staff at a hospital.” (Bardram, published in Dey & Estrin, 2011:4)

Medical care has evolved over time from physicians visiting patients in their own homes to a more centralised model where clinicians and medical equipment are concentrated in hospitals and clinics (Arnrich et al., 2010). However, this centralised model faces significant challenges from the increasing costs and care quality demands made by populations that are aging and in which chronic conditions such as diabetes, arthritis and cardiovascular diseases, have increased in prevalence (Dall et al., 2013; Lehnert et al., 2011) have become leading causes of death (WHO, 2014). Pervasive healthcare has been proposed as means to enable a shift away from the centralised healthcare model toward a User-Centred model supporting proactive and preventative health management (Arnrich et al., 2010). However, this vision of pervasive healthcare presents technological, methodological and administrative challenges (Arnrich et al., 2010). The technological challenges include the development of devices that are intuitive and easy-to-use; the development of reliable infrastructure and interoperable systems to support seamless communication between different devices and networks; and the development of security technologies and mechanisms to protect confidential data (Varshney, 2007). Methodology challenges include the development of procedures that provide standardised, reliable and comparable results in controlled and uncontrolled environments (Bardram, 2008). And administrative challenges include the ethical and regulatory challenges involved in developing, evaluating and certifying solutions (Varshney, 2007).

2.3 Evaluation, prototyping and participatory design methodologies in pervasive healthcare research

In clinical studies the evaluation of a medicine or a treatment is typically carried out in staged clinical trial phases (NHS, 2013). Phase zero trials (early research) assess the effects of a new treatment on small numbers of healthy human subjects. Phase one trials (dose-ranging

studies) involve a small number of people, who may be healthy participants, to determine safe dosages and identify side effects. Phase two trials are short-term studies which test the effectiveness of the new treatment (usually compared with a placebo) on larger groups. With good results from phases one and two, phase three trials can proceed. Phase three trials involve longer-term evaluations with large groups of patients taking the medicine or acting as controls taking an existing treatment or placebo. Phase four (post-marketing) trials continue investigating safety, side effects and effectiveness of the treatment while it is being used in practice.

Clinical trials are expensive, long-term endeavours which require substantial commitment to legal and regulatory processes. Before a clinical trial can begin a research protocol must be submitted and approved by a specialised Research Ethics Committee (REC), funding must be secured, liability insurance obtained, a hospital or a research institute must agree to provide a home base for the study and researchers must obtain certification (e.g., good clinical practice certificates) and access permissions (research passports). For studies involving medical device technologies which may be commercial progenitors, Medicines and Healthcare products Regulatory Agency (MHRA) processes must also be followed. This long-term investment in formal testing is at odds with the rapid evolution of advances in mobile technology and also in user expectation. Years invested in formal testing may well provide important clinical evaluation, but the technology may then be out-dated and users may not want to use it. If the tested system were updated to a more current platform, and possibly improved with functionality provided by that platform, then the old evaluation may have no relevance.

Much of the early research in pervasive healthcare has involved the production of laboratory (or technological) proof-of-concept systems which has provided useful evidence to support the technological feasibility of the approach but has done little to further future clinical application. The creation of a new academic journal, IEEE Journal of Translational Engineering in Health and Medicine (JTEHM, 2014) focusing on the “intersection of engineering and clinical translation” evidences the need for work at the boundary to translate engineering technology into clinical practice with effective outcomes.

In pervasive healthcare research a methodology involving a “*Clinical Proof-of-Concept*” (CPoC) has been recommended as a compromise between the two extremes; clinical trials and laboratory proof-of-concepts (Bardram, 2008; 2010). The recommendation being that the

CPoC is a working usable prototype and is evaluated by real users for an appropriate amount of time (possibly one to three months) *ibid*. Though, of course, access to “real users”, i.e., to patients, involves rigorous, complex and time-consuming clinical study permissions similar to those involved in clinical trials and which pose substantial obstacles to individual researchers and small research teams.

In early stage research, where there is no working prototype, “multi-stage prototyping” methodology has been proposed (Matthews et al., 2008; Doherty, Coyle & Matthews, 2010). The methodology involves three stages: *Focus group*, *peer study* and *clinical evaluation*. These stages overlap with the iterative approach recommended by the Human-Centred Design standard (ISO 9241-210, 2010), the production of usable prototypes proposed in the CPoC methodology (Bardram, 2008), and the involvement of healthy volunteers recommended for phase zero and phase one clinical trials (NHS, 2013). The *focus group* stage comprises the use of qualitative research such as interviews, focus groups and direct observation to create paper and working prototypes, and to carry out usability evaluations. Participatory design, i.e., design with the participation of users, designers and programmers (Muller, Wildman & White, 1993) can also benefit the design of working prototypes. User participation can benefit design by improving the quality of the proposed solution (Muller, 1991) and improving user satisfaction (Kujala, 2003). The *peer study* stage involves assessment of prototypes with small groups of healthy participants. And the *clinical assessment* stage consists of evaluating a working prototype in collaboration with clinical specialists.

2.4 Pervasive healthcare with mobile devices

The following sections review mobile device examples of pervasive healthcare for chronic health conditions¹. While some of the examples include deployments of the technology in clinical trials and provide evidence of clinical effectiveness, the majority of the literature presents research outcomes that are much less mature. For example, evaluations are frequently limited to feasibility and usability studies of laboratory proof-of-concepts or involve limited assessment of short-term outcomes. And, as mentioned earlier, there is very little in the literature relevant to the self-management of anaphylaxis supported by pervasive healthcare

¹ The websites consulted for the literature review were: Web of knowledge/Web of Science, PubMed, ACM Digital Library, IEEE xplore and Google Scholar.

research². While, in contrast, there are myriad healthcare “apps” for which there is often little or no evidence of formal evaluation.

2.4.1 Supporting well-being and healthcare

In a review of assistive mobile phone applications, Blake (2008) observed promising results across a broad range of healthcare interventions including dietary management, promotion of physical activity and smoking cessation; and opportunities in chronic disease management, in particular for health monitoring in cancer, asthma, diabetes and dementia. Challenges reported included support for people less familiar with mobile technology or for people with low literacy. Blake observed that more evidence is needed regarding the effectiveness of these interventions and the long-term impact of mobile applications on health outcomes, health knowledge, healthcare delivery and changes in lifestyle behaviours.

Detailed usability results for three health promotion applications were reported by Athinen et al. (2009). The study was notable for being controlled and randomised and having a large sample size. One-hundred and nineteen technology participants (Finnish public-service employees) were provided with three mobile applications: a wellness diary (for self-observation of weight, exercise and steps taken), a mobile coach (for physical activity support) and a relaxation program. Participants reported some habit changes and the feedback was generally positive. The technology was generally perceived as intuitive, motivating and effective, but required a learning period, was sometimes monotonous, complicated or inconvenient and, in parts, lacked persuasion. The users liked the ability to observe progress over time but wanted adaptive, easy-to-use interfaces and applications with flexible schedules of use (allowing for gaps in use, for example, over weekends, busy times or during holidays).

In a review of mobile phone text message reminders for treatment adherence, Fjeldsoe, Marshall & Miller (2009) identified positive short-term behavioural outcomes in 13 of 14 randomised controlled trials. These included positive behaviours for smoking cessation, physical activity, anti-obesity behaviour modification, bulimia nervosa care and the self-management of diabetes, asthma and hypertension. However, the authors concluded that

² The websites consulted to search for pervasive health applications in anaphylaxis management were: Web of knowledge/Web of Science, PubMed, ACM Digital Library, IEEE xplore and Google Scholar. And the search terms were: “anaphylaxis management”, “smartphone AND anaphylaxis”, “m-Health AND anaphylaxis”, “mobile phone AND anaphylaxis”, “mobile phone AND allergies”, “pervasive computing AND anaphylaxis”, “anaphylaxis AND self-efficacy”.

much more research is required to build on the “first generation studies”, many of which were pilot tests or feasibility studies. They recommended improved research methodologies (they particularly noted a lack of theory-based interventions) and the testing of intervention efficacy with larger samples.

In a systematic review of smartphone applications for healthcare, Mosa, Yoo & Sheets (2012) classified solutions from the literature according to their functionality. They documented a total of 83 applications: 57 for medical professionals and 15 for patients. The former were grouped in seven categories according to their functionality, for example, for drug diagnosis, as medical calculators, as drug reference applications, for clinical communication or for medical training. While the latter included smartphone solutions for the management of chronic conditions, for patient monitoring and for patient education. The authors concluded that smartphone applications have potential in healthcare settings but that more research is needed to investigate clinical benefit. The authors also concluded that *“smartphones can play a very important role in patient education, disease self-management, and remote monitoring of patients”*. They observe that the work of healthcare professionals is very mobile in nature and that the functionality of applications is growing day by day and that *“the full potential of smartphones has yet to be exploited”*. They also observed that a substantial amount of medical applications are available for download in online web sites such as Google Play or Apple’s App stores, but note that most of them have not been analysed in the clinical literature.

2.4.2 Supporting diabetes management

Diabetes is a chronic condition that has received much attention in pervasive healthcare. Diabetes is a metabolic condition affecting blood sugar levels. Type I diabetes is the less common form and occurs when insulin, the regulating hormone, is not created by the body. Type II diabetes (known as insulin resistance) is much more prevalent and takes place when not enough insulin is produced or when there is a failure of cells to respond to this hormone. Gómez et al. (2008) developed the INCA (Intelligent control assistant for diabetes) system which provides an example of pervasive healthcare research evolving from the development of a laboratory prototype through to feasibility evaluation with small sample sizes and on to larger scale evaluation. INCA used a PDA with GPRS communication, an insulin pump and a glucose measurement device and could be used by patients as an “artificial pancreas”, calculating the dose of insulin according to glucose readings. In addition, the PDA provided

information to the patient (e.g., glucose level visualisations) and sent data for clinical review (e.g., current insulin dosage, glucose levels, diet and health data). The feasibility of the system and the clinical effect were evaluated in separate studies. In the first study, four patients with type I diabetes used the system and reported very high levels of satisfaction, but experienced technical issues with data transmission, mobile coverage and battery consumption. The second study involved a cross-over clinical trial with ten type I diabetic patients. Patients used the system for four weeks then had a control period of four weeks without the system. Improvements in participant blood glucose levels were observed during the intervention and patients reported that they felt more secure in managing their diabetes while using the system.

In a randomised controlled study Faridi et al. (2008) evaluated the impact of a mobile phone intervention with 30 type II diabetic patients over three months. The solution, called NICHE (i.e., Novel Interactive Cell-phone technology for Health Enhancement) implemented tailored text message feedback and reminders to participants. Intervention patients attended a one-day technology training workshop and were asked to measure their blood glucose levels and upload these together with pedometer data once a day. Control patients received no additional support but did count their steps with a pedometer. Lower, but non-significant, blood glucose levels were observed in the intervention group but only 25% of intervention patients used the system for at least 75% of the time. Faridi et al. reported that non-significant intervention effects were possibly due to the small sample size of the study and the low utilisation of the system, likely due to usability issues and user inexperience with the pedometer and the mobile phone.

Feasibility studies on diabetes management with mobile devices are frequent in the literature. For example, Yung-Hsiu et al. (2009) evaluated a PDA system supporting diabetic patients. The PDA was connected to a set of physiological measurement devices to quantify blood glucose, blood pressure and body weight. The system was used by 27 type II diabetic participants for one month. However, though the study used technology acceptance questionnaires for system usefulness, ease-of-use and attitudes towards, it was limited to investigating the viability of sending physiological data to a care centre and there was no control group. In common with other studies, positive reactions regarding the technology were obtained but no outcomes, clinical or otherwise, were evaluated.

In a feasibility study entitled “Enhanced 911/GPS Wizard for the Prevention of Severe Hypoglycaemia-Monitor, Alert and Locate” Dassau et al. (2009) described the idea of a smartphone alarm with GPS and Google maps online links to send automated text messages to physicians and emergency services about people experiencing low and very low blood glucose levels. They implemented staged alarm functionality depending upon the severity of the glucose readings. However, their test data was limited to glucose levels in clinical records and no real testing or evaluations with participants were made.

2.4.3 Supporting the management of cardiovascular diseases

Since cardiovascular diseases are a major cause of death (WHO, 2014), their management and support is a significant concern in healthcare and they have continued, from the outset, to be of interest in pervasive healthcare research. For example, in a technological proof-of-concept Hong et al. (2007) developed a ZigBee® wireless three-channel electrocardiogram (ECG) with a three-axial accelerometer. Data were transmitted to a remote server using a personal digital assistant (PDA), where medical specialists could observe and analyse the data. In an early clinical proof-of-concept system Salvador et al. (2005) utilised a mobile phone with Internet connectivity for cardiac out-patient follow-up. They evaluated the technology with 89 patients who had the system for 50 days. Patients collected physiological data (ECG, blood pressure, pulse oximetry and weight) depending upon their risk group. Results indicated that use of a mobile phone to transmit physiological out-patient data was feasible. However, the study had a number of limitations such as not having a control group, comprising only participants in stable conditions and not evaluating health outcomes.

In a five-year randomised controlled clinical trial called MOBITEL, Scherr et al. (2009) evaluated the impact of mobile phone devices on outcomes (hospitalisation and mortality) of chronic heart failure patients. Fifty-four patients were allocated to a control group receiving pharmacological treatment for six months, while another 54 patients in a “tele-group” (the intervention group) received pharmacological treatment *and* medical surveillance via a mobile phone for six months. Tele-group patients measured their blood pressure, heart rate and body weight daily and used the phone to send these together with medication dosage information to a monitoring centre. Physicians could analyse the data and call patients if necessary. Physicians could also receive email and text message notifications when data surpassed specified limits. Results showed that patients in the control group had more negative events (1 death, 17 hospitalisations) compared with the tele-group (0 deaths, 11

hospitalisations); and that tele-group patients spent significantly less time in hospital. However, the authors of the study reported difficulties with some patients, particularly elderly patients, in managing the materials (the mobile phone, weight scale and sphygmomanometer) and performing the necessary measurements.

2.4.4 Supporting dementia

Pervasive healthcare research has been active in the support of mental health, in particular, in the support of people with dementia. For example, a multidisciplinary European FP6 consortia, COGKNOW Mulvenna et al. (2007;2010), researched and developed pervasive healthcare technologies for people with mild dementia. Their aim was to develop a system for the elderly to help them remember to take their medicine, to maintain social contact with their relatives and carers, and to support the activities of daily living and feelings of safety with a variety of reminders and warnings, for instance, reminding them to take their keys and their mobile phone with them when leaving home. COGKNOW prototype development included four main components: sensors placed in the home (e.g., on the fridge and on the doors) for activity monitoring; a tablet computer for assistance in the home (e.g., picture dialling, reminders and for listening to the radio); a handheld device for assistance outside the home (e.g., for telephony and location services) and a location monitor (with a service for carers and relatives providing status information about the person with dementia). The results of the COGKNOW study showed that elderly people with mild to moderate dementia could make use of, and obtain benefit from, handheld devices, and that their involvement in the design process improved the outcomes in terms of meeting their needs.

Another example of technology support for dementia was presented by Taub et al. (2011). They described “The Escort” system and its twelve-week study evaluation in a care home. The Escort monitors people suffering from Alzheimer’s disease and informs carers about potentially unsafe locations or situations that may cause an accident. For example, passing through specific doors to exit the building. Selected patients based on mobility level and incident history wore LED ZigBee®-networked badges to report their location. Carers could be alerted of possible risky situations via automatic SMS messages with information about the patient’s context. Although the system appeared to work as expected in an actual patient’s residence, slow transmission of location information (the pagers used by carers took between 90 to 120 seconds to receive messages, while a mobile phones takes 5 to 10 seconds to receive a message) resulted in a delay in the carer response. Additionally, there were some

issues with battery life and with usability (device size and comfortability). But despite the challenges, with elderly populations increasing, this technology could have significant future benefits if, for example, more patients could be monitored with fewer carers and if the incidence of risky situations could be decreased.

2.4.5 Supporting the management of asthma

Asthma is a common chronic inflammatory disease of the airways. It is commonly comorbid (i.e., co-occurs with a primary disease) with anaphylaxis and significant in poor anaphylaxis outcomes (Pumphrey, 2004). For example, a study in children found that 90% of those who died from anaphylaxis had asthma (Lee & Vadas, 2011).

A number of pervasive health studies have investigated how mobile phones might support people with asthma. For example, Chu, Huang, Lian, & Tsai (2006) demonstrated technological feasibility with a proof-of-concept system for asthma management. It included the use of a PDA with GPS receiver to check local air quality. The PDA connected to a web server that consulted air quality stations, and the web server was able to return warning messages to the user's PDA. Nevertheless, this study was limited to recorded data from pollution-reporting stations and participants were not neither in design nor in testing. Similarly, in a month-long feasibility study, Holtz & Whitten (2009) tested mobile phone support of asthma treatment. Patients submitted their peak flow readings and could view charts of their readings over time. Participants received text message reminders to send their readings and confirmation messages with an action plan in case of abnormal readings. While participants reported good levels of satisfaction, usefulness and effectiveness, the study was limited in terms of viability with a sample size of only four patients. In a more thorough evaluation, Ryan et al. (2005) carried out a nine-month observational study using an electronic peak flow monitor connected to a mobile phone. Ninety-one patients including children and adults were asked to measure peak flows in the morning and afternoon and send their readings via the mobile phone. Users received prompt reading feedback with peak flow trends of their readings graphed over time. A helpline was also available to provide personalised feedback to patients. Participants indicated the system helped them to manage their symptoms, improve their awareness of asthma and their self-monitoring skills. Good levels of utilisation were found, and the system was perceived as a valuable tool. However, its use presented a level of technical inconvenience such as loss of battery power and GPRS

connectivity; and lacked a control group to provide a comparison with traditional asthma self-management programs, to which adherence has been often low (Clatworthy et al., 2009).

Continuing with Ryan et al.'s (2005) work, Cleland, Caldow & Ryan (2007) carried out semi-structured interviews with 12 participants after they used a similar system (a mobile phone connected to a peak flow monitor) for 40 weeks. Their results indicated that the mobile phone technology was perceived as convenient, especially when wireless technology such as BluetoothTM was used; patients felt more aware of their asthma symptoms and perceived the system as being a more accurate mechanism for recording and transmit peak flow readings. However, although this study provided good insights about participants' opinions, it lacked a control group and did not measure clinical outcomes.

In an effort to evaluate clinical outcomes, Ryan et al., (2012) carried out a six-month randomised clinical trial with 288 teenagers and adults, comparing a mobile phone application with a paper-based method for monitoring peak flow and control of asthma. But contrary to expectations, they found no significant differences in asthma outcomes. For example, both groups experienced improvements, similar number of exacerbations and unscheduled consultations; but with the technology group's care being more expensive. The authors suggest their results could be due to both groups receiving the same initial educational intervention, which, in other studies, is often less intensive for the control group. The study did not report on usefulness and ease-of use of the technology; important factors that can affect the long-term acceptance of interventions (Davis, 1989).

Pinnock et al. (2006) and Holtz & Whitten (2009) have suggested that future studies of pervasive healthcare technologies for asthma monitoring and control should involve evaluations with patients and practitioners and involve non-invasive methods of tele-monitoring breathing (e.g., using breath sound) to investigate compliance with action plans and thereby decrease asthma events.

2.4.6 Health and well-being "apps" and issues of evaluation

There are now myriad online smartphone applications for health and well-being that can be readily downloaded online. These applications (commonly called "apps") are provisioned by various sources including manufacturers, service providers and independent software

developers. They are typically simple providers or collectors of information and can often lack any formal evaluation. To distinguish these tools from the more formally documented application technology documented in the literature, I refer to these as apps rather than applications. Of course, not all freely downloadable apps are unevaluated. Medscape (2014) for example, is a mature, professional clinical web resource that is well documented in the literature and, for which, an app can be freely downloaded. Similarly, there are professional NICE (National Institute for Health and Care Excellence) guidance apps: NICE BNF (2013) and NICE guidance (2013). However, the majority of health-related apps do not provide any information about the involvement of users in their design nor about any evaluation, and only a few have provided evidence of effectiveness and user acceptance (Sarasohn-Kahn, 2010). Naturally there is concern regarding the content of these apps and a concern regarding a lack of regulation for the technology (Rosser and Eccleston, 2011).

Huckvale et al. (2012) have observed there is no conclusive evidence that mobile apps for asthma self-management are better than existing document-based methods and that most of the mobile apps available for asthma self-management are not able to combine reliable and detailed information; many of them providing inadequate or imprecise information and some providing unsafe tools. Similarly, Chomutare et al. (2011) revealed that despite the enormous growth in apps for diabetes self-management, evidence of the effectiveness of these applications is limited; education features are missing in most of them; and evidence-based recommendations are commonly overlooked. Likewise, Rosser and Eccleston (2011) in a review of pain management apps (typically providing information and supporting diary tracking) noted a lack of clinical involvement in their design and in the creation of their content; they also observed that the majority of reviewed apps claim to provide pain relief, but their effectiveness has not been evaluated, nor have their secondary effects been assessed; the authors conclude that there is a risk of individuals being misled. Also Visser, Korevaar & Nolan (2013) have pointed out that since mobile applications for healthcare are freely available, there is a lack of control in their use, and they can contain unreliable, out-of-date or misleading information. The authors foresee a need for "certification of approval" so that clinicians and users could determine if app designs have involved medical expertise and if they provide accurate information, are clinically safe and free from bias, and have been developed and evaluated according to regulated practices. But, of course, this vision is enormously challenging: potentially eradicating healthcare apps by inflicting the full burden, expense and delay of clinical trial evidence on to the app developers and researchers who

could probably never support the expense nor, perhaps, could their solutions survive the delay without a risk of obsolescence.

2.5 Pervasive healthcare research in anaphylaxis management

Despite the potential of pervasive healthcare and the breath of applications reported in the literature, there is comparative neglect for allergy and, in particular, for anaphylaxis (Vavoula & Lonsdale, 2007), a condition which has increased worldwide to near epidemic prevalence (Simons and Sampson, 2008).

Some of the few pervasive health applications for allergy found in the literature are early evaluations of functional prototypes such as the Smart Food (Gassner et al., 2005) and the ScanAvert (Badinelli, 2006) applications, which were personalised PDA applications designed to read product barcodes. The aim being that allergy sufferers could check ingredients for their allergens. Unfortunately, these solutions did not overcome the challenges of connecting to reliable and updated product databases which would have required cooperation between food manufacturers and retailers. Another research effort, similar to reading barcodes, was presented by Jara et al. (2010). It was a mobile phone system designed to avoid adverse drug effects on patients by checking for allergens in their electronic health record. Although this research demonstrated the feasibility of such a system, its usability, user acceptance and health effectiveness were not reported.

2.5.1 Smartphone “apps” for anaphylaxis management

Recently, a number of smartphone apps have been created to support anaphylaxis management. A search of the Android (Google Play) and the Apple (App store) stores with the word "anaphylaxis" returned nine such apps; none of which have reported evidence of their evaluation in the literature. They are summarised in Table 2.1.

All the smartphone apps for anaphylaxis management shown in table 2.1 provide information in English. Six applications are free and three require a download fee. Most of them have been developed by healthcare or anaphylaxis organisations: Anaphylaxis (2013) was developed by a UK university with support from the Anaphylaxis Campaign UK. Two apps (Jext UK, 2013 and Auvi-Q, 2013) were developed by AAI manufacturers. React! (2013) was developed by an NHS hospital in Newcastle, UK. WhyRiskIt? (2013) was developed by a Canadian anaphylaxis organisation and the remaining three apps (Anaphylaxis 101, Anaphylactic shock, AllergySense and alert5) were developed by independent companies.

Table 2.1 Smartphone apps for anaphylaxis management (June 2014).

Mobile application	Customer rating	Number of downloads	Benefits	Limitations
Anaphylaxis (Coventry University, UK., 2012) Free	Not reported (i.e., it does not have enough reviews to display an average rating) (Apple)	Not reported	-Contains emergency procedure information (including video). -Users can press a button to dial 999. -Saves emergency contacts. -Supports AAI reminders. -Can locate nearest hospital. -Clinically informed design and developed in collaboration with the Anaphylaxis Campaign UK. -Supports different AAls.	-Only available for Apple devices.
Jext UK (ALK-Abello Ltd, 2013) Free	5 stars/6 reviews (Android) Not reported (Apple)	100-500 (Android)	-Can save a personal profile. -Shows step-by-step instructions to use Jext AAI. -Supports one Jext AAI expiry alert. - Contains audio instructions to use the Jext AAI.	-Customised for Jext AAI.
React ! (Great North Children's Hospital, Newcastle upon Tyne, 2013) Free	Not reported	Not reported	-Designed for teenagers. -Based on emergency simulated scenarios. -Contains video-animation about adrenaline injection steps. -Supports different AAls. -Clinically informed design.	-It is a web application, not available for download (runs in a web browser only).
Auvi-Q (Sanofi-Aventis U.S. LLC, 2013) Free	3.3 stars/13 reviews (Android) 4.5 stars/16 reviews (Apple)	1000-5000 (Android)	-Contains audio step-by-step instructions for the Auvi-Q AAI. -Can dial to 911 and notify contacts using text messages. -Can store a personal profile. -Provides AAI expiration and training reminders.	-Customised for Auvi-Q AAI.
WhyRisKit? (Anaphylaxis Canada, 2013) Free	5 stars/7 reviews (Android) 5 stars/17 reviews (Apple store)	100-500 (Android)	-Comprises facts on food allergies and anaphylaxis. Information on allergies, common causes, signs & symptoms and treatment. -It is linked to the "Why Risk It?" Blog (stories, articles and tips written by teenagers and young adults with food allergies).	-Only provides information about anaphylaxis but there is not any other type of interaction with the user.
Anaphylaxis101 (Mylan, 2012) Free	2 stars/2 reviews (Android)	100-500 (Android)	-Contains a short educational video about anaphylaxis.	-Only available for Android devices. -Not reported if it was clinically informed.
Anaphylactic shock (Small cog, 2011) £1.00	Not reported	10-50 (Android)	-Shows information about first aid response (animation) to allergic reactions.	-Only available for Android devices. -Not reported if it was clinically informed.
AllergySense (DNR Consulting Australia Pty Ltd, 2013) £3.99	Not reported	Not reported	-Provides AAI expiry date reminders. -Contains allergen tables and ingredient substitutes. -Provides food recipes.	-Focused on food allergies more than anaphylaxis. -Only available for Apple devices.
alert5 (4Productions Limited, 2014) £4.99 (standard version is free)	5 stars/1 review (Android) Not reported (Apple store)	10-50 (Android)	-The standard version sends text messages to five emergency contacts with the user's GPS location and supports dial to emergency services. -The anaphylaxis version provides standard version functionalities and shows on screen personal health data and a note to ask for assistance. -This version was developed in collaboration with "what allergy?" blog (food allergies eczema and asthma.)	-Apart from emergency messages and GPS location, it does not provide any other type of support for anaphylaxis management. -The anaphylaxis version is not free.

Anaphylaxis (2013) was developed with medical input; it provides tools to save personal information about allergies, medications and emergency contacts. It supports emergency reminders for different AAI manufacturers. For emergency situations, it contains information about anaphylactic symptoms and emergency procedures; supports 999 dialling and provides information about medical services nearby. React! (2013) was designed to be viewed in a web browser and is not available as an app for download. It was aimed at educating teenagers in anaphylaxis management through simulated video scenarios and contains information on the use of different AAIs. It can also save a personal profile with information about allergies and the type of injector used. Jext UK (2013) supports the creation of personal profiles that can be emailed to other people. It uses text and video to show the steps required to inject adrenaline using their own Jext AAI. It can provide expiration reminders for one Jext AAI and offers audio and step-by-step instructions for that injector. Similarly, Auvi-Q (2013) is a customised application that supports the use of its Auvi-Q AAI with audio instructions. For emergencies, it offers 911 dialling and text messaging to emergency contacts. It can also provide AAI expiration and training reminders and can store a personal profile. However, it does not support other AAIs, nor does it provide information about anaphylaxis management. WhyRisKit? (2013) provides only information about food allergies and anaphylaxis, Anaphylaxis101 (2012) contains only a short educational video about anaphylaxis, Anaphylactic shock (2011) is limited to an animation with first aid instructions and AllergySense (2013) provides food recipes and ingredients substitutes and AAI expiry date reminders. alert5 (2014) is a free application that supports text messages with GPS location to five emergency contacts, but it has an anaphylaxis version that is not free but extends on the standard version with emergency service dialling and on-screen information with personal health data and a note to ask for assistance.

In general, apps stores report good levels of popularity for anaphylaxis apps (as stars), but the number of reviews is very low and the numbers of downloads are imprecise or not reported. For example, Auvi-Q (2013) appears to be the most popular anaphylaxis app at the time of writing, ranging from 1000-5000 downloads and 4.5 stars (out of 5) in the Apple store and 3.3 stars (out of 5) in the Android store, but it has had only a limited number of reviews (13 and 16 reviews, respectively). The number of downloads for Jext UK (2013), WhyRisKit? (2013) and Anaphylaxis 101 (2013) ranged from 100 to 500, but they had only a very few

reviews. While, the number of reviews and the number of downloads of Anaphylaxis (2010) and AllergySense (2013) apps have been reported as too low to display in the Apple store.

In summary, although most of the anaphylaxis smartphone apps appear to have been informed by expert input from anaphylaxis organisations or AAI manufacturers, there is, as yet, no evidence of their evaluation. In addition, none provide feedback about adrenaline injection technique.

2.6 Self-efficacy

Self-efficacy refers to the “*beliefs in one’s capabilities to organize and execute the courses of action required to produce given levels of attainments*” (Bandura, 1998:624). Self-efficacy theory establishes an association between people’s belief’s and behavioural change, and hypothesises that expectations of personal self-efficacy determine if a specific behaviour will begin, the amount of effort that will be invested in the behaviour and the length of the behaviour in the presence of obstacles and challenging experiences (Bandura, 1977). The theory was developed by Albert Bandura, a famous psychologist and long-term Stanford professor. He is the fourth most-cited psychologist of all time and the most cited living psychologist (Haggbloom et al., 2002). He is known for the theoretical construct of self-efficacy and for the development of social cognitive theory, subjects about which, in his eighties, he continues to write.

2.6.1 Self-efficacy sources of information

Self-efficacy is defined as having four sources of information (Bandura, 1977):

1) Enactive experience (performance accomplishments) is a source of self-efficacy grounded on personal mastery experience. Mastery expectations are enhanced by repeated success and they are the most effective way to acquire higher levels of self-efficacy (Bandura, 1998). Performance accomplishment can cause significantly more changes in behaviour (in less time) than any other source of self-efficacy. Occasional failures do not diminish self-efficacy when persistent effort helps overcome difficulties (Bandura, 1977). Persistence, through mastery, minimises defensive behaviours and improves self-efficacy which can then generalise to other activities, for example, Bandura (1977) found that overcoming phobias to

specific animals can improve efforts in social situations, decrease worries about other animals, and improve levels of anxiety and stress.

2) Vicarious experience also known as modelling enhances self-efficacy through observing other people performing challenging activities with success (Bandura, 1977). This can enhance the expectations of the observer and ‘persuade’ them that they can do it *ibid*. In particular, observing models, who required great determination and persistence, can enhance the self-efficacy perception of the observer *ibid*.

3) Social persuasion or verbal persuasion can increase levels of self-efficacy when, for example, people say something encouraging (e.g., “you can do it”) in order to motivate a behavioural change, though this type of intervention may be weak if past or negative experiences are present (Bandura, 1977). Vicarious experiences and social persuasion can modify levels of self-efficacy independently of enactive experiences (Bandura, 2012)

4) Physiological states such as stress or emotional arousal can be perceived by some people in some circumstances as indicators of personal competency, but in others, a state of alert to a threatening situation (Bandura, 1977). High emotional arousal or stress levels may diminish self-efficacy, performance and success, but it can be decreased by vicarious and mastery experiences (Bandura, 1969).

2.6.2 Rationale for incorporating self-efficacy theory in the management of chronic diseases

The main reason for using self-efficacy theory in the management of chronic diseases is that research in healthcare (as well as research in academic achievement and psychology) has shown that self-efficacy beliefs are contributors of performance, are strong predictors of behaviour and are major determinants of action (Bandura, 2012). And action is required in the management of chronic medical conditions (Bandura, 1998). The influence of self-efficacy in human health is twofold: first, self-efficacy beliefs regarding one’s capacity to handle stressors affects the regulation of the immune system (Bandura, 2012). The higher the self-efficacy, the higher the capacity to manage the biochemical reactions caused by stress hormones and the higher the performance of the individual. Second, self-efficacy beliefs help manage health behaviours. They determine habit change, motivation and perseverance toward success, as

well as maintenance, susceptibility to decline and success in recovering from challenges (Bandura, 2012). It is important to note, though, that self-efficacy is different from self-esteem. Self-efficacy is a judgment of capability, while the latter is a judgment of self-worth (Bandura, 2012). Self-esteem has no significant effect on self-efficacy (Bandura, 1997).

Barlow et al. (2001) reports self-management as referring "*to the individual's ability to manage symptoms, treatment, physical, psychosocial consequences and life style changes inherent in living with a chronic condition*", with the aim of maintaining an acceptable quality of life, and establishing a permanent process of self-regulation. The self-management approach can be a generic model that can be adapted to different chronic conditions and can further increase health benefits through mastery mechanisms of self-efficacy (Bandura, 1998). For example, in the context of self-management, mastery skills could be improved through action; vicarious experience could be provided by written instructions, photos, actors, trained peers, health professionals or videos to model health management tasks. While carers, support groups, psychologists and medical specialists could provide encouraging feedback that can enhance the social experience and improve physiological states (Lorig & Holman, 2003).

In the context of health self-management, self-efficacy increases adoption and maintenance of health habits (Bandura, 1997). These habits include the management of treatment (e.g., drug adherence) and symptoms, psychological consequences, lifestyle (e.g., exercise, nutrition, diet or smoking), social support, communication with doctors and decision making (Barlow et al., 2002).

It has been found that self-management programmes based on self-efficacy theory can improve health status while reducing hospitalisations of people with diabetes, arthritis, asthma, stroke, lung disease and heart disease (Lorig et al., 2001). For example, self-management programmes for diabetes types I and II have shown that self-management education correlates with improved glucose levels (Norris et al., 2002), treatment acceptance and maintenance of correct glucose levels (Gregg, 2007), and weight loss and smoking cessation (Davies et al., 2008).

Lorig & Holman (2003) report that self-management education for arthritis management grounded in self-efficacy theory can offer significant and continuous benefits to patients at a lower cost than traditional carer education programmes. The benefits include improved patient

behaviours, for example, an increase in the number of minutes per week of exercise and in symptom management techniques such as relaxation and communication with physicians.

Despite the benefits demonstrated by self-management programmes based on self-efficacy theory, little has been applied to studies for anaphylaxis management. One of the few exceptions was a study carried out by Litarowsky, Murphy & Canham (2004), who designed a training program for high school staff. The program utilised experiences of mastery, social persuasion and vicarious experiences to train 53 people in recognising anaphylaxis and using AAIs. The programme used slide presentations, videos, AAI “face to face” demonstrations, AAI “hands-on” practice and verbal feedback. Symptom recognition and adrenaline injection knowledge and self-efficacy were measured before and after the training. The study authors reported significant improvements in knowledge and self-efficacy, but noted the absence of a control group. It is worth noting that, at the time of the study, Bandura’s (2006) recommendations on self-efficacy questionnaires had not been published and there was no other self-efficacy questionnaire for anaphylaxis management in the literature. Thus, the study authors created a questionnaire with a response scale ranged from 1 to 4. Bandura (2006) recommended a more sensitive scale from 0 (i.e., cannot do) to 10 (i.e., highly certain can do). The study was later replicated by Lee (2011) but using the same questionnaire.

2.6.3 Self-efficacy in pervasive healthcare research studies with mobile devices

There have been studies in pervasive healthcare research with mobile devices that have evaluated self-efficacy levels, but only a few of them have been grounded in self-efficacy theory (Free et al., 2013).

For example, in a three-month phase one randomised control trial, Faridi et al. (2008) assessed the use of mobile phones on type II diabetes self-care. The intervention group (15 participants) received daily tailored text messages to improve their diabetes self-care while the control group continued with their usual self-management program. Non-significant improvements in glucose levels were found in the intervention group and non-significant deterioration in the control group. However, self-efficacy levels (measured with a diabetes self-efficacy scale) improved significantly in the technology group. Likewise, Haapala et al. (2009) investigated whether a one-year controlled randomised text messaging program could improve weight loss. The intervention included customised text messages to 62 overweight

adults that reported their weight daily and received immediate feedback. The authors reported that the technology group had significantly higher weight loss and higher waist circumference diminution. They also identified that self-efficacy in dieting (quantified with a questionnaire), attitudes towards the technology and work and family life were strong predictors of weight loss. Similarly, Fukuoka et al. (2010) piloted a mobile phone intervention to assess the potential to motivate 41 sedentary women to increase their physical activity. Pedometer step count was used as input to the mobile phone application which provided immediate and daily feedback, and motivational messages and prompts highlighting benefits of exercise. The study lasted three weeks. There was no control group. The self-efficacy for physical activity survey (SEPA) was used to quantify the degree of confidence that participants had in doing physical activity. Results showed that participants were motivated to carry out physical activity and the daily amount of steps and average caloric expenditure improved. However, self-efficacy levels were similar before and after the study. The authors suggested this was likely due to the short term nature of the intervention.

In a review, Krishna, Boren & Balas (2009) evaluated 25 clinical controlled studies involving text messages and mobile phone voice interventions in healthcare applications including diabetes, HIV, asthma, anxiety and smoking cessation. The authors concluded that standard care supplemented with text message reminders, disease monitoring and mobile phone voice interventions can help improve patient self-efficacy and outcomes such as behaviour modification, medication compliance, medication adherence, symptom improvements and quality of life and also can help improve processes of care such as communication with patients and appointment attendance.

Examples of studies grounded on self-efficacy theory are less common. For instance, in a review of 26 controlled trials of mobile devices for healthcare that implemented behavioural change or disease management interventions, Free et al. (2013) identified only four studies based on self-efficacy theory and only three more based on other theories of behavioural change. The four studies grounded in self-efficacy theory involved interventions for type II diabetes education, smoking cessation for people living with HIV/AIDS, exercise intention enhancement with text messages and text messages for monitoring physical activity. The authors concluded that behavioural change interventions with text messages that encourage smoking cessation and antiretroviral medication adherence are effective and their implementation should be considered for inclusion in clinical services.

Finally, in a recent University of Utah Ph. D. thesis on the infusion of self-efficacy theory in a walking encouragement application, Koyle (2013) used SMS text messages to investigate whether this technology may encourage walking for exercise and affect levels of walking and self-efficacy. The author found that a mobile application may have potential to promote walking and changes in walking self-efficacy in the short term. However, the work did not involve participatory design and provided little information about how the components of self-efficacy were implemented in the mobile application and in the text messages and there is no report of benefits in outcome measures such as weight loss or body mass index.

2.7 Summary of this chapter

Chapter one looked at anaphylaxis management and how day-to-day management of anaphylaxis involves allergen avoidance and being prepared for an emergency. It considered the unmet needs, in particular, needs regarding adrenaline injection training. This chapter has shown that pervasive healthcare research with mobile devices provides opportunities to support people with chronic diseases and also to support self-management. The chapter also reported a lack of solutions grounded in self-efficacy theory despite the benefits of incorporating it into the design of pervasive healthcare solutions.

Chapter 3

Multi-Stage Proof-of-Concept Prototyping and Evaluation

3.1 Introduction

This chapter presents the results of early multi-stage proof-of-concept prototyping that helped to understand how anaphylaxis management needs and people's preferences might translate into usable and beneficial tools to supplement traditional care documents. As shown in the literature review, pervasive healthcare technology has the potential to support chronic disease management, but little research has been done for its application to anaphylaxis. The laboratory prototyping work described here evolves from a first study exploring technological possibilities through to a study with a functional smartphone prototype design with support for adrenaline injection training.

As a new application of technology to anaphylaxis management, the research involved here was aimed at producing pre-clinical testing results that might usefully inform phase one testing. Of specific interest was an appreciation of the usability issues relating to the use of this technology. Though, of course, the aim was not to supplant the traditional system of anaphylaxis management (i.e., the advice, training and documentation provided to anaphylactic people), but rather to supplement it. For example, it was not anticipated that a mobile phone solution would replace the in-person clinical advice and training that forms the basis of the traditional system of care, but rather that it would supplement the traditional document-based support.

3.2 Methods

The “multi-stage prototyping” methodology proposed by Matthews et al. (2008) recommends a three-stage evaluation: focus group, peer study and clinical evaluation. This chapter presents results from the first two stages, focus group and peer study evaluation through three studies. The methods used in each study are as follows:

Study one involved direct observation and questionnaire feedback regarding user needs and preferences from 19 families attending anaphylaxis training workshops organised by the Anaphylaxis Campaign UK. The aim of the study was to investigate technological possibilities. The needs analysis (Smith, 2011) informed the design of a first laboratory keypad smartphone and wireless injection-sensing AAI prototype, *PervaLaxis 1* (from *Pervasive anaphylaxis*), and a formative usability evaluation performed with a small number of anaphylactic and non-anaphylactic people.

Study two was designed to evaluate the usability of an improved prototype, *PervaLaxis 2*, implemented in a touchscreen smartphone with an improved interface informed by feedback from study one. The study was carried out with a group of 32 non-anaphylactic participants using traditional care paper documents and *PervaLaxis 2* smartphone materials. The purpose was to continue assessing formative usability and begin to investigate measures of summative usability (effectiveness, efficiency and satisfaction). Questionnaires of self-reported workload and usability were used in the assessment of different tasks. A thematic analysis of debrief interviews was also carried out to investigate aspects of usability and identify advantages and disadvantages of traditional care paper-documents materials vs the smartphone tools.

Study three was designed as 'early research' (phase zero) investigative pilot testing as per clinical trial methodology (NHS, 2013). The *PervaLaxis 3* prototype used in this study comprised the same phone and wireless sensing hardware and software as *PervaLaxis 2*, but incorporated video animation tools (recommended in study two evaluation). A two-arm, laboratory, randomised controlled study with groups of 11 non-anaphylactic participants was undertaken to investigate the benefits on adrenaline injection training. One group used traditional care paper documents (control group) and the other group (the intervention group)

used the tools implemented in the PervaLaxis 3 prototype. Participant injection performance and self-reported usability were assessed¹.

3.3 Anaphylaxis management scenarios

The work underpinning the studies required consideration of the people involved in anaphylaxis management and possible scenarios of use to illustrate the context of the activities, as recommended in the Human-Centred Design standard (ISO 9241-210, 2010). Based on the clinical literature², effective management of anaphylaxis requires cooperation between the anaphylactic person, health providers and supporting people, for example, from carers, family and friends.

- *The anaphylactic person* (depending on age and capacity) is responsible for management tasks such as managing medication and diet, avoiding allergens, attending medical appointments, having an emergency "Allergy Action Plan" (a plan that provides a summary of symptoms, emergency actions including AAI use, allergy details and emergency contacts) (BSACI, 2014) and educating and training others about AAI use and emergency procedures (NICE, 2011; Simons et al., 2011).
- *Health providers* are the practitioners or specialists responsible for diagnosing, establishing treatment, maintaining records, providing advice and encouraging self-management. (Resuscitation Council UK, 2008; Carlisle et al., 2010).
- *Supporting people* may be carers, trained supporters and untrained supporters. Their level of responsibility may vary. For example:
 - *Carers* such as family members or close friends are more likely to be trained to support emergency and everyday life activities and to have some responsibility for care and anaphylaxis expertise (RCPCH, 2011). Helping, for example, with avoiding allergens, managing medications, following an emergency Allergy Action Plan and, where appropriate, encouraging independence (Simons, 2006).
 - *Trained supporters* such as health providers, school nurses and teachers, first

¹ The number of participants having a smartphone increased over the time of the studies as follows: Focus group (2008): 21.1 %, Study one (2009): 25% , Study two (2010): 21.1 %; Study three (2012): 86%. This mirrors levels of smartphone penetration in the USA in those years, though globally the increase has been somewhat slower (Statista, 2014).

² The websites consulted to search for clinical literature on anaphylaxis management were: Web of knowledge/Web of Science, PubMed and Google Scholar. And the search term were: "anaphylaxis management" and "anaphylaxis",

aiders, friends and co-workers, are examples of the people who would be familiar with the emergency Allergy Action Plan and trained to support the person in an emergency, for example, trained in adrenaline injection (Kemp, Lockey & Simons, 2008).

- *Untrained supporters*, such as classmates or colleagues, may be familiar with the person's anaphylactic condition but not explicitly trained (Simons, 2006). These people may be in attendance in an emergency and might, for example, recognise a possible reaction event and understand the need to summon help quickly (RCPCH, 2011).

From anaphylaxis guidelines (National Institute of Allergy and Infectious Diseases, USA, 2010; NICE, 2011; Resuscitation Council UK, 2008; Simons et al., 2011) and the relevant medical literature (Lieberman et al., 2010; RCPCH, 2011; Wang, 2010) two main types of scenarios regarding anaphylaxis management in the community can be proposed: emergency scenarios and everyday life scenarios.

Emergency scenarios may result from touch, inhalation or ingestion of an allergen. Reactions can occur anywhere: at home, in restaurants, at school or on vacation, at the homes of relatives and friends, children's nurseries, hospitals or clinics (NICE, 2011) (Clark and Ewan, 2008). People with anaphylaxis should follow their Allergy Action Plan (BSACI, 2013) and, after detecting anaphylactic symptoms, should inject adrenaline and an ambulance should be called (Pumphrey 2004). The allergen should, where possible be identified, contact removed and other triggers like exercise should be avoided (RCPCH, 2011). If there is no improvement in 5 to 10 minutes, a second injection should be given (The Anaphylaxis Campaign UK, 2010). The patient should lie flat with their legs raised (Pumphrey, 2004). Antihistamines and steroids are the second line of treatment (Resuscitation council UK, 2008). After suffering an anaphylactic event the patient should be transferred to an emergency department for observation and, as appropriate, carers contacted (Simons et al., 2011).

Everyday life scenarios in the management of anaphylaxis involve a range of activities requiring training and continuous practice (Kemp, Lockey & Simons, 2008). For example, anaphylactic people need to avoid allergens (Simons, 2009) and check product labels and ingredients (Walker & Sheikh, 2003). They should carry AAIs and know how to use them

(Simons et al., 2011). The AAIs should be in-date (not expired) and always at hand (Walker et al., 2010; Baral & Hourihane, 2007). Patients and carers should know how to recognise anaphylactic symptoms (RCPCH, 2011; Resuscitation council UK, 2008) and have an emergency Allergy Action Plan outlining the correct emergency procedure (Lieberman et al., 2010; Sicherer et al., 2010; Simons, 2010; Simons et al., 2011). They also need to manage risks (RCPCH, 2011), maintain a nutritious diet (Carlisle et al, 2010), attend medical appointments (NICE, 2011), have ready access to information about allergies and, ideally, wear medical ID such as a medic alert bracelet (Sicherer et al., 2010; Simons, 2010). Importantly, people with anaphylaxis need to interact with others, (supporting people and carers), explaining about their allergies and training them as appropriate, for example, about their Allergy Action Plan and in the use of AAIs (Kemp, Lockey & Simons on behalf of the WAO, 2008).

3.4 Study One – PervaLaxis 1

3.4.1 User needs and preferences

The task of gathering the user needs that led to tools implemented in PervaLaxis 1 involved observations and discussions with 19 anaphylactic children and young adults (from 8 to 25 years old) and 21 parents/carers in two training workshops organised by the Anaphylaxis Campaign UK. In addition to observations and discussions during the workshops, questionnaire feedback was obtained. The purpose of the questionnaire was to investigate users' needs and preferences, for example it asked about their allergic reactions, the number (and manufacturer) of AAIs carried, their familiarity with and usage of smartphones, and their suggestions for support in everyday life and emergency scenarios. Nineteen questionnaires were returned (one per family).

Questionnaire feedback indicated that at the time of the workshops (2008) only four families had used a smartphone or a PDA (21%). In that year the usage of smartphone devices was not as high as at the time of writing this thesis (in 2008 the global smartphone penetration was 12% (Statistica, 2014)). Most of the anaphylactic people that attended the workshops carried two Epipen® AAIs (69% - 13 families), or one Epipen® AAI (21% - 4 families) and only two families mentioned having more than two Epipen® AAIs (10.5 %). Nobody had an

Anapen® AAI or any other manufacturer's AAI. Respondents typically carried two AAI and a mobile phone. Their parents, or family and friends often also carried a mobile phone specifically for contact in emergencies and they also sometimes carried spare AAIs. Regarding the use of pervasive healthcare technology, questionnaire results indicated that only eight families (42%) were interested in receiving SMS food alerts (warnings about wrongly labelled foods in the supply chain). Nevertheless, most of them, 14 families (73.7%) were interested in receiving alerts when an AAI was opened or used.

The workshops were guided by trained instructors of the Anaphylaxis Campaign UK. The first workshop was a short two-hour training session attended by five families. The second workshop was a full day training workshop for families with teenage children. Fourteen families attended. This workshop involved broad coverage of self-management activities and also "risky situation" role play opportunities for the teenagers. The researcher was allowed an ethnographic opportunity as a workshop assistant and group leader; helping, observing and note-taking for the teenage activities, and was also provided with 20 minutes to discuss ideas with attendees about how technology could support anaphylaxis management.

The suggestions proposed in discussion and in questionnaire feedback about technological implementations that they wanted included: an emergency alarm to call an ambulance and contact/message family, a tool to help with AAI use and to manage AAI expiry dates, educational videos about anaphylaxis, food alerts and also a variety of other suggestions including a tool to detect nearby AAIs, to automatically detect AAI opening or use, and messages in different languages for travel abroad. In general, parents of pre-teen children wanted control over emergency settings and information, whereas parents of teenagers wanted less control and instead wanted to resource the children to take control of their allergies. Nevertheless, it was observed that people had difficulties imagining how new technology could support their anaphylaxis management needs, perhaps because only a few of them had experience with smartphones and perhaps because they were still learning about anaphylaxis management at that time. These reasons also precluded the use of participatory design which requires user understanding of the subject domain (Muller, 1991).

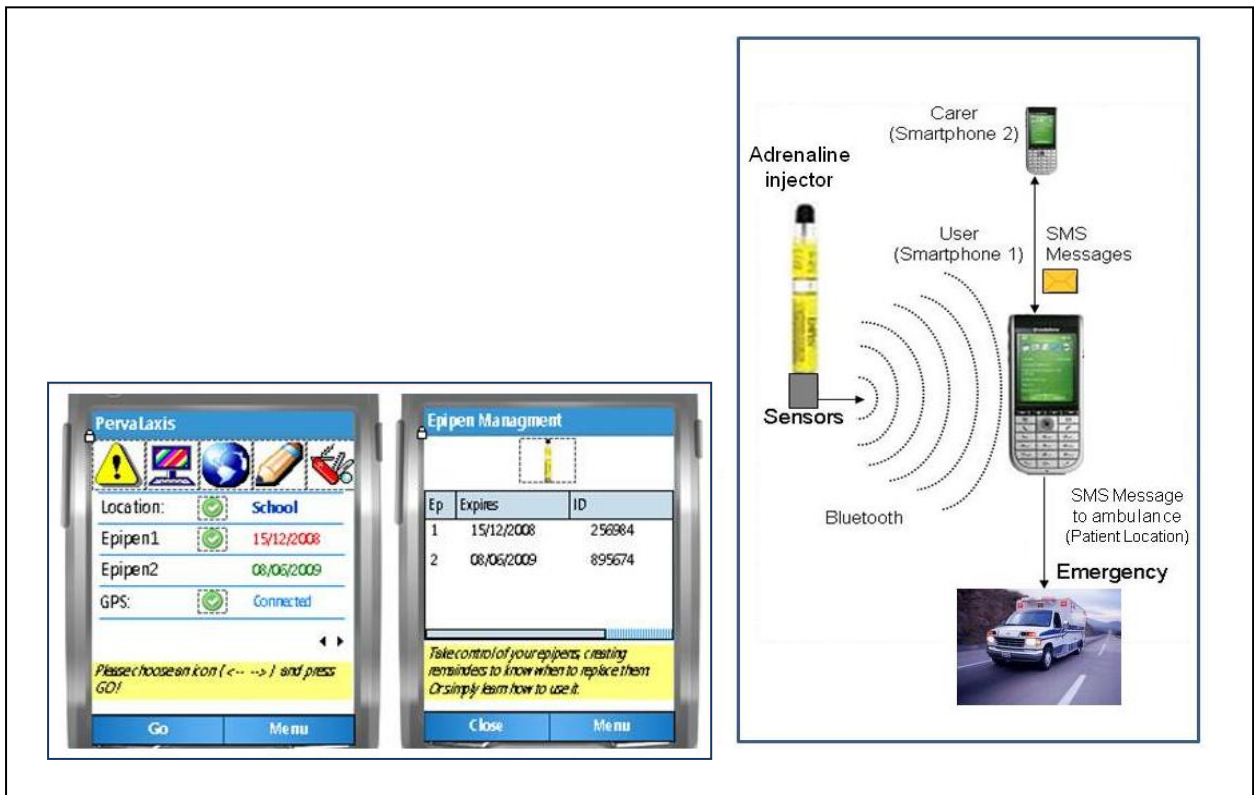








Fig. 3.1 PervaLaxis 1: (L-R) Main screen; AAIs expiry date list screen; injection detection and emergency text messaging support.

Fig. 3.1 shows screenshots from PervaLaxis 1 and a schematic of the emergency text idea. Table 3.1 summarises the tools implemented. They included the more popular suggestions of the workshop participants such as the AAI expiry date list, AAI training support (a tool for sensing injection “jab” motions), educational videos, an emergency text message and a list of emergency contacts (who would receive automatic text messages in an emergency). In addition, an emergency location tool was implemented to explore if text messages could have more meaningful location names rather than just GPS locations, for example, “Mary has used an Auto-Injector at *school*” or “John has opened an Auto-Injector at *Grandma’s house*”. The technical objectives of this prototype were fairly ambitious, for example, attempting to automate injection detection was computationally demanding (given excessive false positives

would need to be avoided) and also very demanding over the long-term in terms of power consumption.

Table 3.1 Functions implemented in PervaLaxis 1.

Scenario User	Need Supported	Tool Implemented	Description
Everyday life Patient/supporting people	Help injecting adrenaline	Injector trainer 	This function informed users if they have injected with enough force.
Everyday life Patient/supporting people	Warning about adrenaline expiry dates	Injectors expiry date list 	It kept a list of expiry dates and reminders to replace AAI them before they expired.
Everyday life Patient/supporting people	Learning about allergy and AAIs	Information (Videos) 	It contained a video showing how to use an EpiPen® AAI.
Emergency Patient/supporting people	Detects injections and sends messages to emergency services and carers Adrenaline injector status	Emergency alarm 	After detecting a possible injection of adrenaline, it sent SMS messages to emergency services and carers.
Emergency (created in everydaylife) Patient/supporting people	Emergency messages to ambulance and carers	Locations 	It allowed the creation of personal locations based on GPS coordinates to be embedded in emergency messages.
Emergency (created in everydaylife) Patient/supporting people	Maintain a list of contacts Parents emergency settings	Contact list 	It helped manage a personalised list of important people to inform in case of emergency.

3.4.2 PervaLaxis 1 hardware (created in 2009)

The PervaLaxis 1 hardware and Windows 5.0 keypad smartphone (v1240, 200 MHz HTC-Vodafone) are shown in Fig. 3.2 The PervaLaxis 1 application was created using Visual Studio 2005, C#. The smartphone received wireless data from a three-axis accelerometer mounted on an EpiPen© AAI trainer and also from an external GPS module (GPS-BN90 BlüeNext). It was not clear at this early stage of technology exploration whether this sensor

could be for mounting on real (adrenaline-filled) AAIs as well as trainers, but for the purposes of testing the injector needed to be a trainer. The rather ambitious idea was that sensed information could be used to detect possible emergencies and respond, for example, with generating SMS messages to carers and emergency services. Emergency messaging services that support mobile phone SMS communication have emerged in recent years, for example, there is Emergency-SMS in the UK allowing deaf and speech-impaired people, to register mobile phones from which they can send SMS messages to emergency services (www.emergencysms.org.uk, 2012). A text-to-911 service in the USA was introduced in 2014 and now has “limited availability” (www.fcc.gov/text-to-911, 2014).

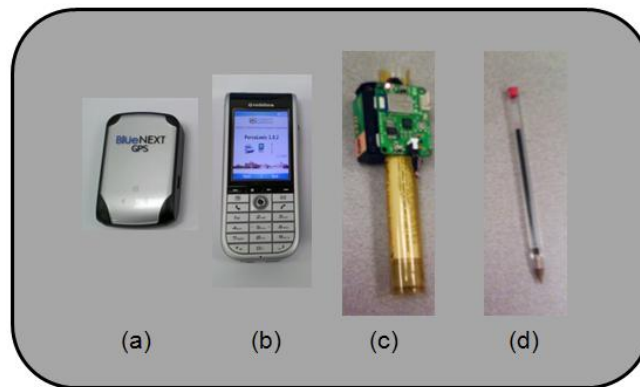


Fig. 3.2 PervaLaxis 1 components: a) GPS module; b) Smartphone device; c) AAI trainer with three-axis Bluetooth™ accelerometer; d) Size comparison with a pen.

3.4.3 Methodology

User interface inspection, System Usability Scale (SUS) (Brooke, 2006) and NASA TLX (NASA, 2003) questionnaires were used for evaluation. The SUS questionnaire was used to provide a measure of perceived usability, covering aspects of acceptance, need for support, training and system complexity (Jones & Marsden, 2006; Preece, Rogers & Sharp, 2002). NASA TLX questionnaires were used to quantify levels of mental, physical and temporal demands, and self-reported levels of performance, effort and frustration. Each scale has 21 vertical marks that divide it from 0 to 100 in increments of 5. Low demand levels could indicate that a task would be more likely to be successful in a real scenario (Brewster et al., 2003). Eight participants were involved in the evaluation. Two participants were anaphylactic people already trained in anaphylaxis management, an eight year old child (who used the system with his mother) and a twenty-one year old nurse. The remaining six people were

adults between 27 and 40 years old, three with knowledge of allergy and anaphylaxis and three without. After signing consent forms and agreeing to participate, they were first introduced to traditional care paper-documents provided by the anaphylaxis campaign and an AAI manufacturer and then shown PervaLaxis 1. Later, they carried out six tasks (Summarised in table 3.2) to inspect and use the implemented tools: familiarisation with the user interface, adrenaline injection training, emergency messaging, using information tools with videos, managing injector expiry dates and creating locations for text messages. Questions and communication with the researcher were allowed. Additionally, in a debrief discussion participants had the opportunity to make suggestions and comments about their evaluation experience.

Table 3.2 Tasks undertaken in the usability evaluation of PervaLaxis 2.

Task 1 User interface	Participants were asked to familiarise themselves with the smartphone user interface and explore the different menus, to open and close screens and open the PervaLaxis 1 application.
Task 2 Injector trainer	Participants opened the AAI trainer tool and perform several injection attempts in different directions and with different forces and observe whether the system could detect them
Task 3 Set Up emergency scenario	Participants were asked to keep PervaLaxis 1 in the main window, make an injection with the trainer and observe if text messages were sent (these were text messages sent to the same number).
Task 4 Using videos	Participants were asked to open the information tool and play a video (produced by the Anaphylaxis Campaign UK) on how to use an EpiPen(R) AAI.
Task 5 Injector expiry date	Participants were asked to open the AAI expiry date tool, add a new expiry date to the list, edit it and remove it. And also to verify the alarms created in the screen about AAI renewal.
Task 6 Creating locations	Participants were asked to open the location tool and add new location to the list.

3.4.4 Results

System Usability Scale (SUS) results. To make a comparison between the traditional care paper-documents (provided at the beginning of the evaluation) and PervaLaxis 1, SUS questionnaires (Brooke, 2006) were completed for both. Participants reported that PervaLaxis 1 was easier to use and more user-friendly. However, participants considered that the use of this new technology needed extra support, at least at the beginning of its use to become familiar with the smartphone interface. They felt that there was little difference in the time spent learning how to use the new system compared with reading traditional sources of information. They reported that PervaLaxis 1 was more consistent and more integrated because they did not have to spend time looking for information in several places nor carry paper everywhere. They also expressed an increased confidence in their ability to manage an emergency situation with PervaLaxis 1. The SUS score for the traditional paper-based method was 50.3, while for PervaLaxis 1 it was 79.6, suggesting that PervaLaxis had improved usability. According to Bangor, Kortum & Miller (2008:592) this translates to between poor and ok usability for the traditional paper-based method, and good to excellent for PervaLaxis 1.

NASA TLX results. After completing each task participants completed a NASA TLX questionnaire about their perception of the implemented functionality. It can be seen in Fig 3.3 that the initial use of the smartphone *interface* was demanding with participants reporting the highest effort and the highest frustration for this task. This may have been because participants either felt unfamiliar with the Windows Mobile 5.0 smartphone or because it was difficult to use. The *injection training* tool was reported as physically demanding. It required participants to practice injections (pushing and pulling the AAI on the outer thigh). Despite this, participants reported a degree of satisfaction about performing the injection correctly and about the potential the tool could have to help train others. "*SetUp emergency scenario*" was a task that participants perceived as easy, injections were recognised and SMS text messages were sent. Participants liked this feature but wanted explicit and clear confirmation about the messages so that they could be confident these were sent. Low TLX scores for the *videos tool* agreed with participant reports that this tool was easy to use and that the video was more useful than reading the equivalent information on the instruction leaflet, however, some

participants mentioned that the screen was small. The injector *expiry date list* also had a fairly low TLX score. One of the anaphylactic participants reported that this tool could be especially useful since they had forgotten several times to replace expired AAIs. *Creating locations* had a high TLX score. It had the highest mental demand, the lowest self-reported performance and a high level of frustration. Creating location names was a more advanced feature of PervaLaxis 1 requiring more navigation and more key presses, and it proved the most polemic, separating the users into those who found it easy and useful and those who found it difficult to understand and difficult to implement. Here, the need to navigate menus, look and search for textboxes and follow on screen instructions proved too difficult for the latter.

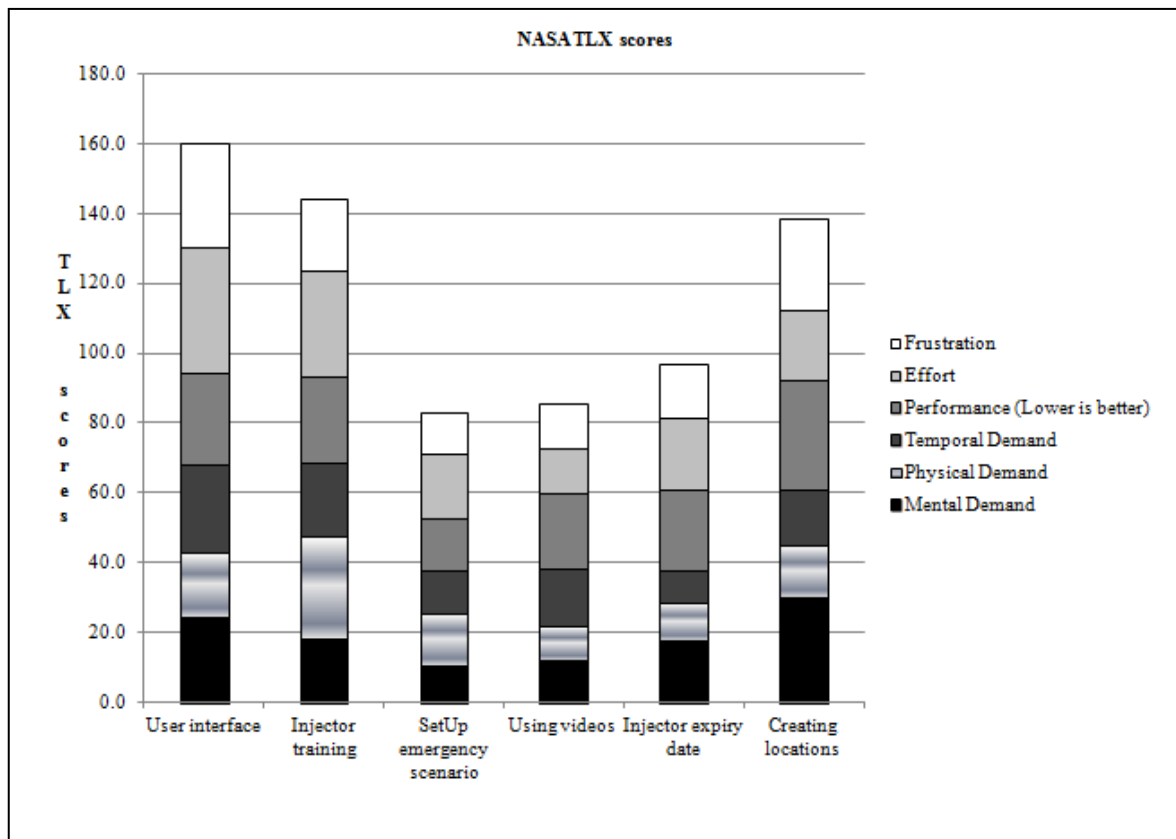


Fig. 3.3 NASA TLX results.

Comments and feedback. Although positive feedback was received from participants regarding the tools and potential of PervaLaxis 1, it was clear that there were both global and local (Dumas & Redish, 1999) usability issues. Global in the sense of the inherent limitations of the underlying technology, which although typical of smartphones at the time, were that the

joystick and the small keypad buttons were difficult to use, the screen was too small and the icons were not intuitive. Local in the sense of the PervaLaxis application which participants suggested could be improved with the addition of step-by-step injection instructions, confirmations for messages sent, a “panic button”, a mechanism to avoid false alarms for injections, more intuitive menus and icons, an easier way to add and remove AAIs in the expiry date list and a redesign of the locations tool which several found too difficult to use.

In summary, while the study was fairly informal, limited to only a few participants and without a control group, it provided some useful insights into the technological feasibility of smartphone tools and wireless sensing for anaphylaxis management and some useful formative feedback for the design of an improved prototype, PervaLaxis 2.

3.5 Study two – PervaLaxis 2

The purpose of this study was to evaluate formative and summative usability of an improved technological proof-of-concept prototype, PervaLaxis 2, with a larger sample of participants. PervaLaxis 2 implemented the usability improvements identified in the first study. It was created in a newer touchscreen smartphone (HTC Diamond 2 with Windows Mobile 6.1) with a re-designed user interface.

3.5.1 PervaLaxis 2 design

Fig. 3.4 (left) depicts the use cases implemented in PervaLaxis 2 in the context of everyday life scenarios. PervaLaxis 2 included re-designed video tools (information about anaphylaxis), a re-designed expiry date tool with traffic light colouring (AAI management) and, importantly, the adrenaline injection sensing tool from study one developed into a more focused tool to support training together with an accompanying step-by-step guide (adrenaline injection training). The idea of generically sensing *any* injection events with *real* injectors may be something that could, in the future, be designed into next generation “smart AAIs” or smart add-ons for conventional AAIs, but the idea presents significant technological and implementation issues (not least concerns regarding false positive messaging). In addition, the

literature and the user feedback in study one identified a need for injection training support – something which could be more reasonably achieved and more readily implemented.

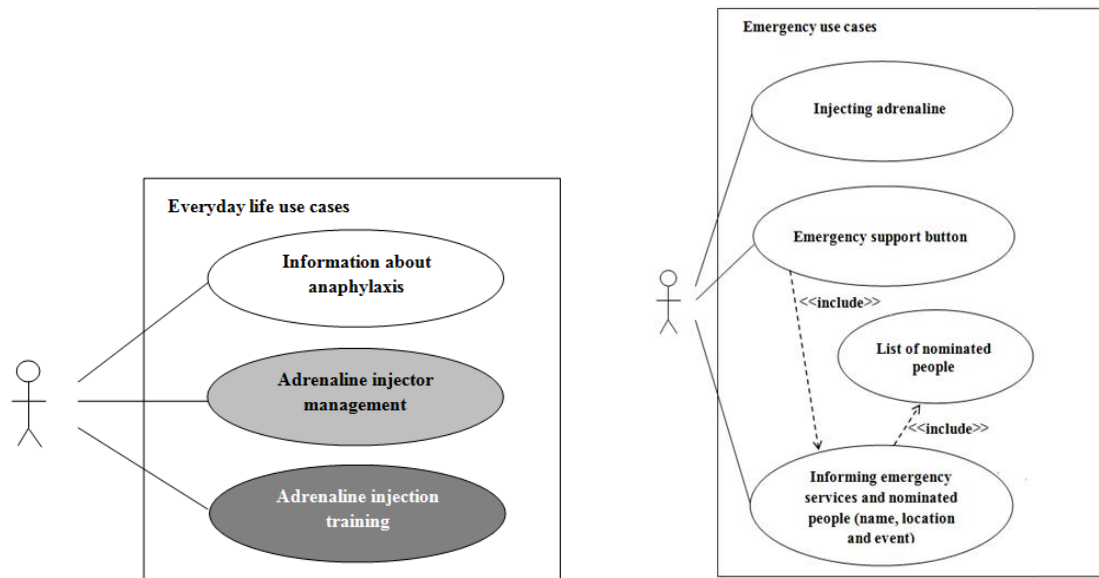


Fig. 3.4 PervaLaxis 2 support in everyday life (left) and emergency (right) scenarios.

Fig. 3.4 (right) shows the use cases implemented in PervaLaxis 2 in the context of an emergency scenario. PervaLaxis 2 tools were designed to support the user in case of emergency with videos about how to inject adrenaline and provided functionality with an emergency support button to send automatic SMS messages to emergency services and to nominated people.



Fig. 3.5 (a) PervaLaxis 2 smartphone device; (b) AAI trainer with a three-axis Bluetooth™ accelerometer; (c) Pen size comparison.

The PervaLaxis 2 prototype was implemented in an HTC Diamond 2 touchscreen smartphone running Windows Mobile 6.1. Fig. 3.6 illustrates the PervaLaxis 2 Touchscreen smartphone and AAI trainer with wireless accelerometer unit, containing a SparkFun Bluetooth® Wireless 3D Tilt Sensing unit, battery and an LM7805 voltage regulator. The unit was configured to sample X, Y and Z channels at 10 Hz. Empirical thresholding limits were used to detect possible injections. The tools were developed using Visual Studio 2008, C#.

Fig. 3.6 shows screenshots of the PervaLaxis 2 user interface. The emergency button on the home screen (Fig. 3.6a) sends emergency SMS messages to emergency services and selected contacts with embedded location information. Fig. 3.6b shows the new AAI expiry date list with the traffic light colouring (red for out-of-date, yellow for near-date and green for in date) and equivalent emoticons; and Fig 3.6c shows the information tool with videos about anaphylaxis, injecting adrenaline, symptoms and what to do in an emergency. Fig. 3.7d shows the new injector trainer step-by-step tool showing simple steps about how to give an injection. This tool included sensing to help users practice injections by providing feedback on the force applied. The feedback was provided in step five of the guide after the trainer tool recommended 'swing and jab' of the AAI trainer. A 'happy face' icon was shown if the injection data (received from the wireless accelerometer on the trainer) indicated sufficient force (as shown in Fig. 3.7).

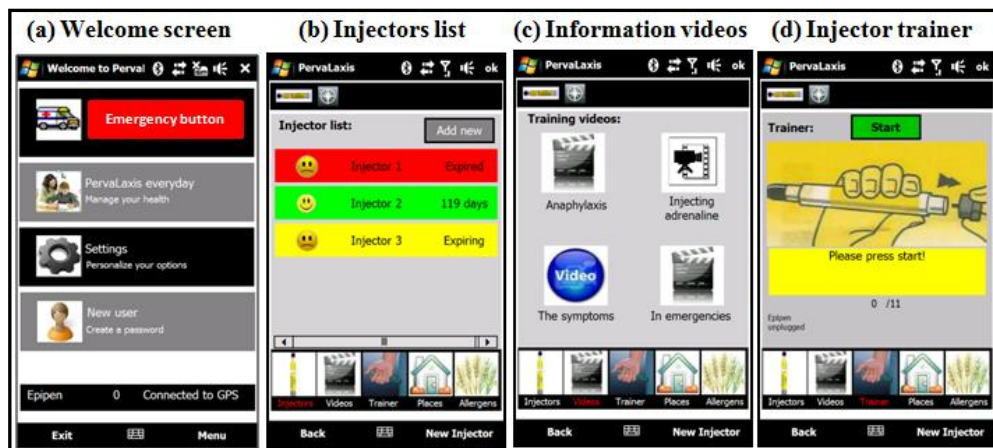


Fig. 3.6 (a) PervaLaxis 2 welcome screen and emergency button; (b) Expiry date list; (c) Videos; (d) Step-by-step AAI trainer tool.

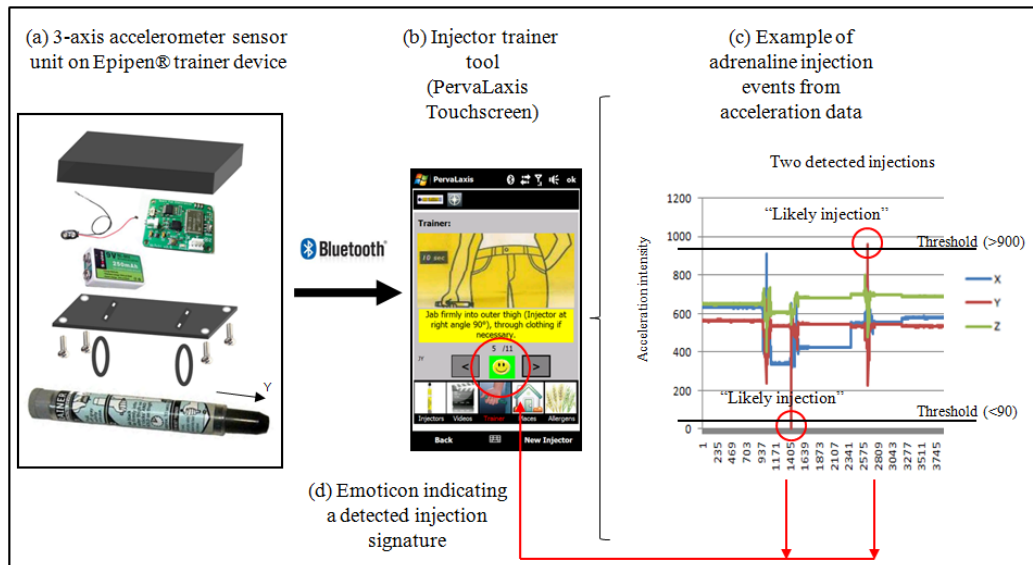



Fig. 3.7. Mechanism used to detect adrenaline injection events through an Auto-Injector trainer tool and a sensor mounted on an Epipen® AAI trainer device.

Table 3.3 summarises the full set of everyday and emergency tools implemented in PervaLaxis 2.

3.5.2 Methodology

A usability study was undertaken with 32 participants aged 18 to 40 years old. While testing with healthy volunteers is appropriate for pre-clinical testing, and there is the further issue that the vast majority of anaphylactic people are still preteen minors, the opinions of test volunteers with allergy experience was of interest. For this reason volunteers were asked about their allergy experience and the group of 32 constituted 16 people without allergies and 16 people with experience of allergies, i.e., were allergy sufferers themselves or caregivers of a person with allergies. The reported allergies ranged from mild to significant but no participants were carriers of AAIs and none had experience of their use. All 32 followed the same test procedure but, for interest only, the results of those who had experience of allergy were compared to those who had no experience.

Table 3.3 Tools implemented in PervaLaxis 2.

Scenario				
User	Needs	Use cases	Tool implemented	Description
Everyday life Allergic person/supporting people	Manage the expiry dates of AAIs.	AAI management.	Injector expiry date list	It was designed to manage (checking and modifying) a list of AAIs expiry dates.
	Keep injectors in-date at all the times.			
Everyday life and Emergency	Training to use AAIs.	Adrenaline injection training.	Injector trainer	It was designed to provide AAI injection instructions with step-by-step tool and feedback on sensed injection motion.
	Inform emergency services and carers about an emergency event.	List of nominated people.	Contact numbers (within settings)	
Allergic person/supporting people	Get informed about anaphylaxis management. Encourage continuous training about how to detect symptoms, how to avoid allergens, how to avoid contamination and cross contamination.	-Information about anaphylaxis. -Injecting adrenaline.	Information (Videos)	It was designed to provide information about anaphylaxis and how to use an EpiPen® AAI.
	Inform emergency services and carers about an emergency event.	- Emergency support button. - Informing emergency services and nominated people (name, location and event). - Sensing possible injections.	Emergency support button	

After signing consent forms, participants were provided with an explanation about anaphylaxis and adrenaline injections and were provided with documents on which this explanation was based. These included the manufacturer’s injector information leaflet showing how to inject adrenaline and two information leaflets produced by the Anaphylaxis Campaign UK about anaphylaxis, its causes, symptoms, treatment and emergency recommendations.

After consulting the documents, participants completed a system usability scale questionnaire (Brooke, 2006). They were then required to carry out four tasks with PervaLaxis 2 (Table 3.4). After finishing each task, they completed a NASA TLX workload questionnaire (NASA, 2003) and at the end of the evaluation they completed a system usability scale questionnaire.

Table 3.4 Tasks undertaken in the usability evaluation of PervaLaxis 2.

Task 1 Videos	The user was required to open PervaLaxis 2, select a specific video about anaphylaxis and return to the tools menu.
Task 2 Injector list	The user was required to use the injector expiry date tool to create a list of three AAI expiry dates (one non-expired, one expiring and one expired), delete one expiry date from the list and to edit another.
Task 3 Trainer	The user was asked to open the trainer tool, run the injection demonstration steps and practise injecting adrenaline with the injector trainer.
Task 4 Emergency action simulation	The user was required to press the emergency support button, watch an adrenaline injection video and simulate an injection using the injector trainer device.

ISO 9241-11 (Ergonomic of human system interaction– Part 11: Guidance on usability) (ISO 9241-11, 1998) guidelines were used to measure effectiveness, efficiency, and satisfaction.

During the tasks, participants could request assistance at any time. The number of requests was counted by the researcher. All requests were simple navigation queries. User keystrokes were automatically counted and logged by the system, and the task time was measured by the researcher.

While undertaking the tasks, participants were encouraged to “think aloud” about their interaction with the system. They were particularly encouraged to make suggestions and to identify usability issues. All comments were recorded. Additional comments and suggestions were obtained from the completed workload and usability questionnaires and in a debrief talk.

A Shapiro-Wilk test was used to test if results were samples of a normally distributed population (significance level = 0.05) (Field, 2000). Parametric t-tests were used on normally

distributed results; and Mann-Whitney and Friedman Rank tests for results not normally distributed. The statistical tests were undertaken using SPSS® version 17.

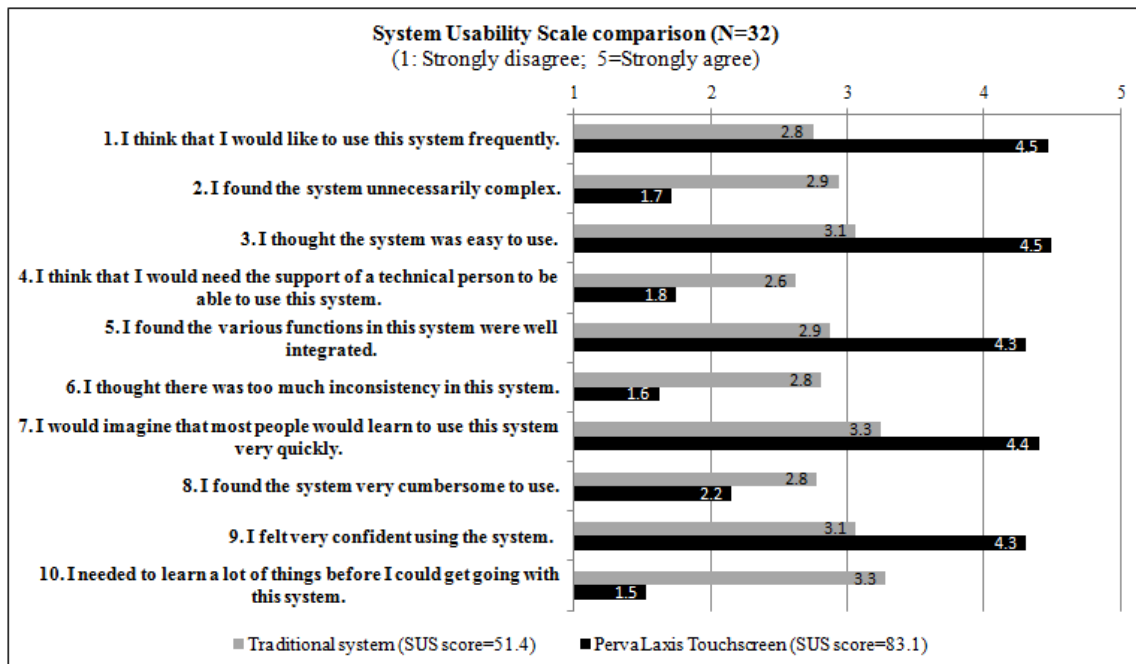


Fig. 3.8 System usability scale comparison between the traditional system and PervaLaxis 2 (N=32, there were significant differences in all the SUS questions, $p < 0.05$).

3.5.3 System usability scale results

Fig. 3.8 shows the results of the system usability scale. These results revealed significant differences between PervaLaxis 2 and the traditional system for all 10 questions. Here references to the traditional system mean the traditional system *alone*, i.e., the initial in-person advice and training and provision of hardcopy documentation. References to PervaLaxis 2 mean the PervaLaxis 2 prototype *supplementing* the traditional system. Participants rated PervaLaxis better than the traditional system when they were asked whether they thought that they would like to use the system frequently. They found the traditional system more complex, more difficult to use, less consistent and less integrated than PervaLaxis 2. They felt more confident using PervaLaxis 2 and felt they needed to learn less to get going with it.

There were no significant differences between the results of allergic and non-allergic participants, with the exception of questions 4 and 10 where non-allergic participants reported

more difficulty with the traditional system which, given their lack of allergy background, it might be anticipated.

The average SUS score for the printed instructions was 51.4, while the SUS for PervaLaxis 2 was 83.1. Rated according to Bangor, Kortum & Miller (2008:592), the results were encouraging; the traditional system SUS score was unacceptable (between poor and OK) and PervaLaxis 2 was acceptable (between good and excellent).

3.5.4 Workload results

Fig. 3.9 shows the mental, physical and temporal demands, and the self-reported levels of performance, effort and frustration quantified using the NASA TLX scales. There were no significant differences between allergic and non-allergic participant results. Significant differences were found in the different scales for each task, as might be anticipated due to difference in keystrokes and actions required of each. But, although the time to complete each task was different, there were no significant differences in the temporal demand, suggesting participants felt no difference in time pressure.

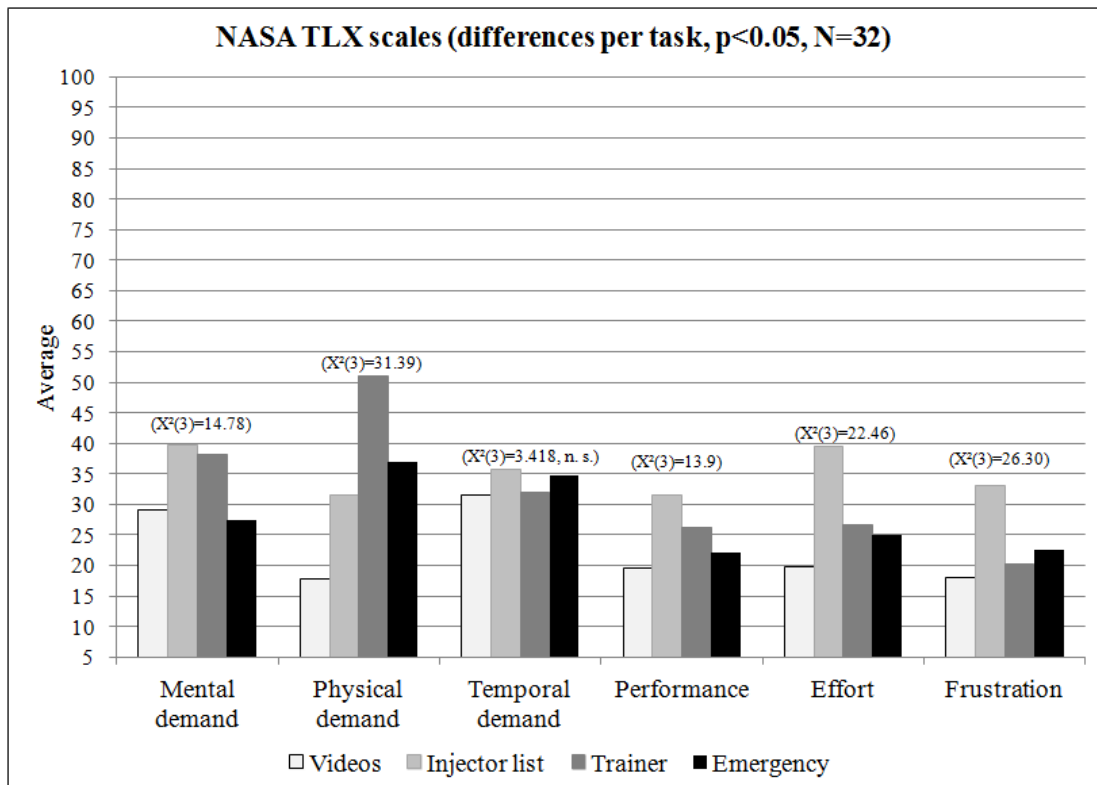


Fig. 3.9 NASA TLX scales results.

Creating a list of injectors had a higher mental demand in comparison with using the emergency support button. Significant differences in physical demand ($X^2(3)=31.39$, $p<0.05$) were shown for different tasks, with the injection trainer and emergency action simulation tasks requiring the greatest demand. Both these tasks required participants to simulate an injection. Furthermore, significant differences in performance ($X^2(3)=13.9$, $p<0.05$), effort ($X^2(3)=22.46$, $p<0.05$) and frustration ($X^2(3)=26.3$, $p<0.05$), indicated that using the videos was an undemanding task, but creating an injectors expiry date list was much more demanding. The injector list task had the highest demand in four out of six TLX scales. This was somewhat expected since this task required the greatest numbers of steps, however, usability issues with the touchscreen keyboard were identified (e.g., the resistive screen of the smartphone device was too sensitive and caused participants to type incorrect characters).

3.5.5 Results from ISO 9241-11 usability measures

The Mann-Whitney test showed, again, that there was no significant difference between allergic and non-allergic participants using PervaLaxis 2 in the ISO 9241-11 measures of effectiveness, efficiency, satisfaction and the amount of help provided to them. While satisfaction of allergic participants might have been expected to be higher than non-allergic participants, the satisfaction was high for both.

The Friedman Rank test revealed significant differences between the effectiveness, efficiency and number of requests for assistance for tasks (Fig.3.10). For example, it can be seen in Fig. 3.10 that for task 1, using videos about anaphylaxis information, participants had significantly better effectiveness, better efficiency and asked for less help. This would mean that participants made less keystroke errors (i.e., were closer to the optimal number of keystrokes) and carried out this task quicker than the other tasks. In contrast, it is noticeable that the creation and editing of an injector list produced on average more keystrokes than the optimal number, needed more time to complete and required more navigation advice in comparison with the other tasks. The test also suggested that the perceived satisfaction was not significantly different within tasks with a visible average level around 80%. This would indicate that participants were satisfied with the implemented functionalities.

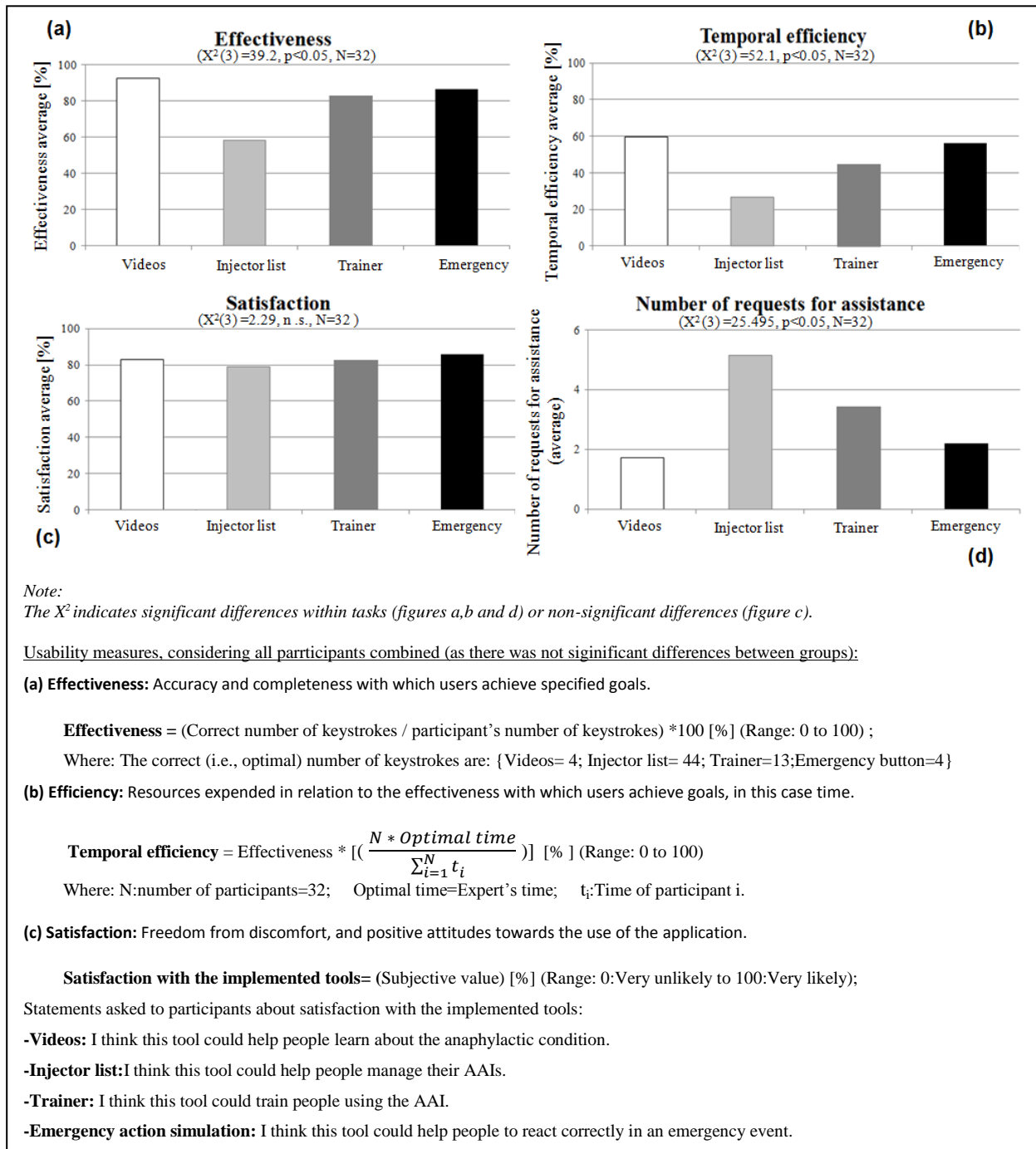


Fig. 3.10. (a-c) Measures of usability according to ISO 9241 part 11. (d) Amount of navigation assistance provided to participants.

3.5.6 Analysis of observations and comments

A content analysis was performed on the 257 comments transcribed and collated from participants “think aloud” commentary, questionnaire submissions and debrief. A thematic analysis was carried out. Comments were categorised according to their respective task and identified as one of the following themes: (1) positive statements about PervaLaxis 2; or comments or suggestions regarding (2) the user interface; (3) the hardware and (4) the Smartphone processing speed. A trained independent coder carried out a categorisation for reliability evaluation. The reliability between coders had a satisfactory Cohen’s kappa coefficient above 0.7.

Positive statements comprised 25% of the total. Participants reported that PervaLaxis 2 was interesting, useful for allergy management, preferable to the documents of the traditional system and that the information and functions were more accessible by being integrated in the mobile phone.

Thirty-four percent of the total comments provided suggestions related to the user interface and 33% related to functionality. Seven percent commented on low processing speed of the Smartphone (which was worsened by a monitoring connection with the researcher's computer). Participants commented on font size and colours, suggesting larger fonts and higher contrast colours, and suggested subtitles for the videos. Comments reflected that the smartphone navigation was initially demanding but soon became easier.

The injector list task had positive reactions in, for example, the use of emoticons to provide a simple indicator of injector expiry date (a happy face for each in-date injector and a sad face for an out-of-date injector), but participants suggested to improve the usability of the touchscreen keyboard. The emergency support button received positive comments. Participants liked the possibility of sending the SMS messages with a single button press, including the name, GPS location and event. Their suggestions included provision for recorded voice messages and that the emergency function might also involve making a phone call after sending the SMS message.

In recording results of participants' injection attempts, errors were observed (deviations from the information and instructions provided) in injection site, not applying sufficient force, not holding the injector in place for ten seconds and not massaging the injection site. It was interesting to observe a reduction in these errors on the subsequent injection required in task 4 (emergency action simulation), suggesting that practice and feedback from PervaLaxis 2 may have helped users improve their performance. For example, in the first injection in task 3, two participants held the injector the wrong way around and would have injected their own thumbs if the trainer had been a real injector. There were no such errors in the subsequent injection. Similarly, four participants failed to hold the injector trainer in place for 10 seconds after the first injection, but all performed correctly on the next injection. However, there were 5 in 32 attempts in task 4 which failed to make sufficient force to make the correct "jab" type injection motion.

The injector trainer testing demonstrated that the simple thresholding detection method was limited. For example, only 20 (out of 32) of the injection attempts were correctly detected on the first occasion (task 3); and 25 out of 32 in the second occasion (task 4), with only five potentially accounted for by user error. An improved method of detection would not only improve reporting of possible injections but would reduce the possibility of false positive events.

3.6 Study three – PervaLaxis 3

PervaLaxis 3 implemented suggestions collected from the previous study; aesthetic changes in background colour, increased font sizes, including the ability to begin a phone call with the emergency button, the inclusion of an Allergy Action Plan, and, importantly, the addition of an AAI manufacturer video animation with added subtitles within the injection trainer step-by step tool (Fig 3.11). The enhanced step-by-step tool was used in this third study to evaluate its potential for adrenaline injection training in comparison with traditional care paper-documents. This was a slightly more formal evaluation of the functions implemented in PervaLaxis 3 to quantify the benefits of smartphone tools designed for adrenaline injection training. It was hypothesised that smartphone tools with video animations may produce better adrenaline injection performances.

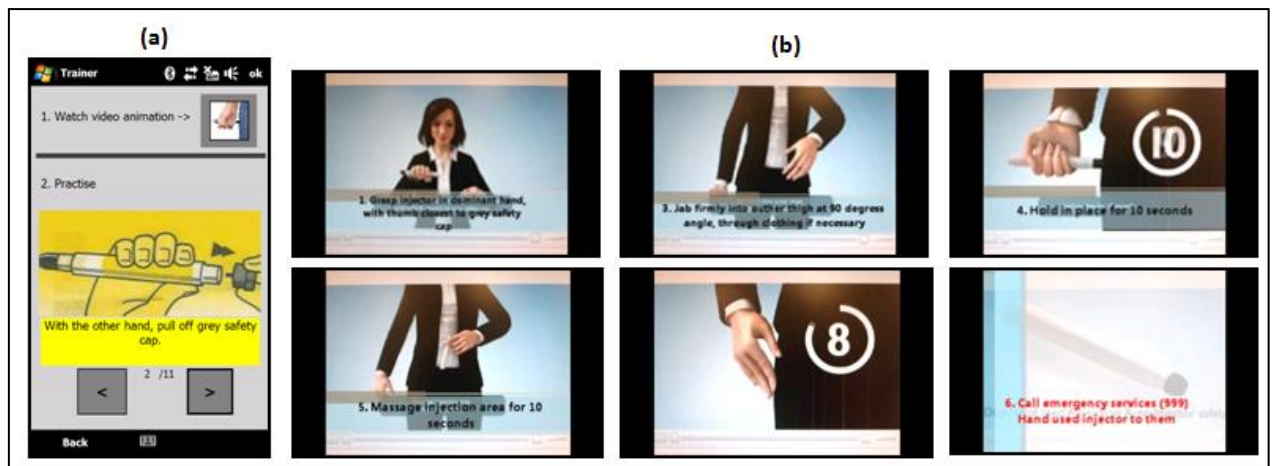


Fig. 3.11 AAI trainer tool for adrenaline injection training:
 (a) Step-by-step trainer interface; (b) Video animation with subtitles.

3.6.1 Methodology

Twenty-two healthy adult participants signed a consent form and answered a questionnaire about mobile phone usage. They were briefed on anaphylaxis and AAI use and randomly assigned into two groups (balanced in a first come first served basis) as follows: a control group provided with manufacturer paper-document injection instructions and a technology group provided with the same manufacturer instructions, but implemented with a video demonstration and a visual step-by-step guide in PervaLaxis 3. Participants used their allocated practice material with an AAI trainer before demonstrating use and completing a technology acceptance questionnaire. Correct technique required each of four steps recommended by the AAI manufacturer and used in previous studies (Arga et al., 2011; Sicherer, Forman & Noone, 2000) as follows: removal of the injector trainer safety cap, 'swing and jab' motion of the injector trainer to outer thigh, holding the trainer in place for 10 seconds and massaging the site of the injection for 10 seconds

The evaluation sessions were video recorded. Sessions lasted a maximum 30 minutes. The videos were analysed using ELAN annotation software. Another postgraduate researcher carried out an independent review of a random sample of videos (Cohen's Kappa above 0.7). A Shapiro-Wilk test was used to test if results were samples of a normally distributed population (Significance level = 0.05) (Field, 2000). Parametric t-tests were used on

normally distributed results; and X^2 and Mann-Whitney (U) tests for results not normally distributed. The statistical tests were undertaken using SPSS® version 21.

3.6.2 Participants

Twenty-two healthy participants were recruited from the University of Birmingham, UK. People with prescribed AAIs, anaphylactic people and their carers were not included in the study. Participants were all students, the average age in both groups was 22 years old. Some participants reported having mild allergies (i.e., hay fever) but none of them reported having an AAI or having experience of their use. All but three of the participants had smartphones.

3.6.3 Results and conclusions

Significantly more people in the technology group (63.6%) completed all injection steps correctly compared to those in the control group (18.2%) ($X^2=4.701$, $p<0.05$). The technology group (81.8%) also performed significantly more correct the 'swing and jab' step than the control group (45.5%) ($X^2=3.143$, $p<0.05$). Technology acceptance questionnaire results showed that the technology group reported more usefulness of their smartphone practice material than the control group ($U=7.5$, $p<0.001$), they also reported better ease of use ($U=10$, $p<0.01$) and more willingness about future use ($t(20)=5.661$, $p<0.001$). Feedback from the technology group suggested the visual demonstrations helped in modelling the correct technique.

In summary the results suggested that smartphone technology may help improve AAI training.

3.7 Summary

The first study provided useful insights into technological function and feasibility as well as user needs and usability issues which all usefully informed improvements made in PervaLaxis 2. The second study demonstrated the potential of this new prototype to support anaphylaxis management and training by supplementing the system of traditional care. The final study was more informative about the potential for AAI training through a step-by-step tool and a video animations.

However, the studies presented in this chapter were more technological proof-of-concepts rather than clinical proof-of-concepts. They provided encouraging results, helped understand user needs, helped map these onto smartphone tools and helped identify usability issues. But the prototypes did not benefit from participatory design and there was no collaboration or participation with expert clinicians and, hence, no clinical evaluation of the systems. In addition the designs were not purposefully grounded in self-efficacy theory, though sources of self-efficacy were contained in the tools. For example, the use of video animations was a source of vicarious experience (modelling) and the step-by-step training tool contained a source of enactive experience (mastery skills). The limitations outlined here were addressed in further work involving the design and evaluation of a prototype, AllergiSense, that was closer to a clinical proof-of-concept prototype. AllergiSense design and evaluation results are presented in the next chapters.

Chapter 4

AllergiSense Design

4.1 Introduction

This chapter describes the design of AllergiSense, a mobile application for anaphylaxis management designed with a more formal methodology and evaluated in more detail. The PervaLaxis studies presented in the previous chapter were technological proof-of-concepts. They provided encouraging results, helped provide insights into user needs, helped map these into smartphone tools and helped identify usability issues. But PervaLaxis prototypes did not benefit from participatory design and there was no collaboration or participation with expert clinicians and, hence, no clinical evaluation of the systems. In addition the designs were not purposefully grounded in self-efficacy theory.

AllergiSense started afresh in terms of design and in terms of clinical collaboration, and with an ambition to produce something closer to a clinical proof-of-concept prototype. The AllergiSense design methodology adopted is not one that has been reported in the literature. It is tentatively proposed as an incremental improvement to prototyping methodology and, in particular, for pervasive health prototyping. The methodology involves the development of near-clinical proof-of-concept prototypes from a combination of participatory design together *with* the embedding of self-efficacy sources.

The AllergiSense participatory design involved focus groups comprising allergy specialists, a trained anaphylactic person, carers and a smartphone app designer. The tools proposed via the process were supplemented with embedded sources of self-efficacy that were evolved through further participatory design.

This chapter is organised as follows: Section 4.2 presents the methods used in the design of AllergiSense, provides results of the participatory design focus groups and explains the tools and functionalities implemented in the mobile application. Section 4.3 explains the simple algorithm developed to use wireless sensor data from adrenaline EpiPen® trainer injections to assess injections in the AllergiSense trainer feedback tool. And section 4.4 summarises the main findings of the design process.

4.2 Design of AllergiSense application

4.2.1 Research procedure

Two focus group sessions were convened at the University of Birmingham UK. The participants included allergy specialists, an anaphylactic person, carers of anaphylactic people and a smartphone app designer. Each focus group session lasted one hour and the two sessions were one month apart. The aim of the focus groups was to gain a deeper understanding of anaphylaxis management needs and to involve the participants, as potential users and stakeholders, in the design a mobile application to support those needs. The aim was not to reach a consensus but to elicit rich and varied accounts from different perspectives. All participants were encouraged to participate and the discussion was generally well-balanced between the participants. The researcher acted as the moderator to ensure this balance and another researcher took notes. The format was generally relaxed and informal and participants were provided with coffee and refreshments.

The focus group participant profiles are presented in table 4.1. There was an allergy clinician, an allergy nurse, a trained anaphylactic person, two carers and a healthy participant (who researched anaphylaxis prior to the sessions) with an engineering background and with interest in smartphone app design.

Table 4.1. Profiles of focus groups participants

Participant	Gender	Age	Status	Smartphone use
1	Female	31-40	Allergy clinician	Reported using an iPhone, social networking, e-mail and media apps.
2	Female	41-50	Allergy nurse	Reported using an iPhone, mapping and social media apps.
3	Female	51-60	Trained anaphylactic person	Reported using a Nokia smartphone using social networking apps.
4	Female	41-50	Carer of an anaphylactic person	Reported using a Samsung smartphone and several apps.
5	Male	41-50	Carer of an anaphylactic person	Reported using a non-smartphone, (but with communication and programming expertise)
6	Male	21-30	Healthy participant with an engineering background and experience in smartphone apps. (Researched anaphylaxis before the sessions)	Reported using a Google smartphone and several apps and using SMS messages and phone calls very frequently.

First focus group. Participants were provided with a short introduction about the aim of the meeting. After agreeing to participate, they read and signed consent forms. Participants were then asked to briefly introduce themselves to the other group members. A detailed explanation of mobile apps was provided and PowerPoint® slide examples of apps for allergies and for anaphylaxis were presented. Participants were allocated in groups of two (three pairs), group one was formed by participants one and five (the allergy clinician and a carer), group two included participants two and three (the allergy nurse and the anaphylactic person) and participants four and six formed group three (a carer and a healthy participant). The first activity in this focus group was to undertake a brainstorming needs analysis exercise about anaphylaxis management. Ideas were summarised on a white board by the researcher (moderator) and notes were taken by another researcher. Participants were asked the following questions: who would use mobile apps for anaphylaxis management?, what or how could those tools support? and where would they be used?. All participants were encouraged to participate. The second part of this focus group consisted of each group designing paper prototypes for two different tools identified in the brainstorming exercise. They used the paper mock-up PICTIVE¹ participatory design technique (Muller, 1991), for which they were provided coloured pens and paper, post-it notes, “smiley faces” and “star” stickers, glue,

¹ Plastic interface for collaborative technology initiatives through video exploration (Muller, 1991)

scissors and other stationery (as shown in Fig. 4.1) to stimulate their imagination. The session was video recorded for analysis. Users were asked to write on a large piece of paper the anaphylaxis management challenges, the goals of the tools and the tasks involved with the tool. They used post-its to create a storyboard of the tool design in a domino style (i.e., a sequence of post-its representing the order in which the screens would appear) and used an old PDA cover to frame and size the post-it screens (as shown in Fig 4.2). Finally, each group was asked to explain their tools to the group using the PDA cover framed screens. Group members then provided suggestions and comments.

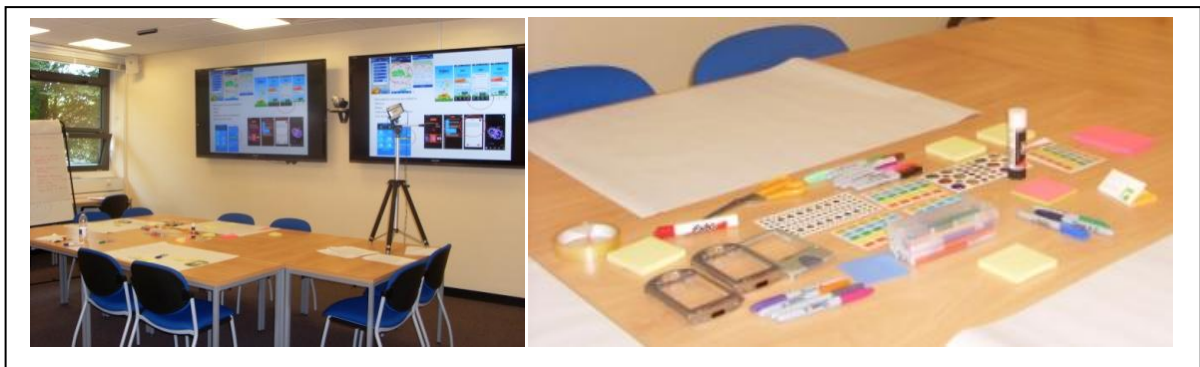


Fig. 4.1 PICTIVE set up of the focus groups.

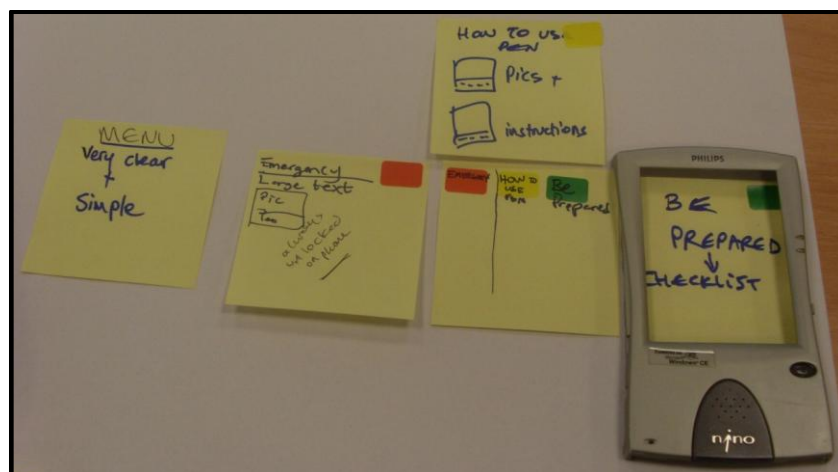


Fig. 4.2 Storyboard style used in the design of the smartphone tools.

Second focus group. The aim of this focus group was to receive suggestions and identify preferences for user interface designs incorporating the ideas and tools described by participants in the first focus group session one month before. The user interface mock-ups produced for this session were created with Balsamiq® software for higher fidelity user interface prototyping of screenshots with the look of a smartphone app (examples are shown later in Fig. 4.5). The same six participants attended the session. The initial activity was a brief review of the ideas and suggestions identified in the first focus group. Then, participants reviewed the look of the implemented mock-up tools and gave their suggestions. At the end of the focus group participants were asked to decide among different user interface styles and were asked to suggest a name for the mobile application.

4.2.2 Results of the first focus group

The anaphylaxis management needs identified and discussed by participants in the first focus group are summarised in table 4.2. These were generally consistent with the user needs established less formally in the PervaLaxis studies, but were provided with more supporting detail as outlined below.

Participants identified two main contexts: emergency and everyday life. And they identified five main needs in anaphylaxis management, the need for: help educating others, help with communication, help with AAI use and management, help with food label checking and help with emergency situations.

Table 4.2 Anaphylaxis management needs.

User need	Who	About what	How (with technology)	Where
Educate people	-Patient (child and adult), carers, relatives, friends, physician, nurse, schools teacher, work colleague [anyone]	-The condition -The treatment -The management -Emergency	Using: -Text -Video -Audio -Instructions -Reminders	Clinic Home Outside home: Airplane Restaurant Holiday School
Help with communication	-Patient (child and adult), carers, relatives.	The management in -Everyday life	Emergency: -Contacting emergency services -Know what to do '999' +	Home Outside home: Holiday School

User need	Who	About what	How (with technology)	Where
		-In Emergency	Location -Say Anaphylaxis -Receive instructions Everyday life: -Day to day management -Support groups (->Link to the Anaphylaxis campaign website) -Contact number of allergy specialist	
Help with the management of the treatment (AAI)	-Patient (child and adult), carers, relatives, physician, nurse , friends, school teacher, work colleague.	Manage the treatment in Emergency and regularly (everyday life)	-Know when to inject (detect symptoms) -How to use it -When to use it -What to do next -What not to do (self-inject) -Instructions for emergency Emergency plan: -Remove the allergen -Re-assess (inject after 5 minutes) -Go to hospital -How to manage AAI in everyday life with reminders about: - the AAI -in date -have it -check colour	Home Outside home: Supermarket Restaurants Holiday Airplane School
Support food label reading	-Patient (child and adult), carers, relatives, school teacher.	-Detect ingredients with harmful allergens on food labels and products with latex.	-Barcode reading -Central database -Everyone can contribute -Link to support groups -Allergen avoidance.	Home Outside home: Supermarket Restaurant Holiday Airplane School
Help with emergency situations	-Patient (child and adult), carers, relatives, friends, teacher, work colleague.	-In an actual emergency -In everyday life for training	-Improving communication -Using AAI correctly -Assessment of the situation	Home Outside home: Supermarket Restaurants Holiday Airplane School

Help educating others. Participants explained that people who might need to support the anaphylactic person needed to be educated about the condition, the treatment, the management and what to do in an emergency. They reported that this education could usefully take place in the allergy clinic, and also at home, at the school or anywhere as needed outside home (e.g., in an airplane or restaurant). They suggested this could be supported with text, video, audio, or any type of instructions and reminders.

Help with communication. According to participants, anaphylaxis management in an emergency and in everyday life requires supporting patients, carers, and relatives in communications with emergency services (e.g., knowing what to do and what to say), with support groups and with allergy specialists. They suggested implementing a mechanism to contact emergency services and links to support group web sites and contact numbers for allergy services.

Help with AAI use and management. People in the focus group reported the needs relating to AAI use and management in emergency and in everyday life, for example, tools for emergency situations to help decide when to use an AAI, how to use it, what to do after the injection, know what not to do (e.g., to avoid self-injecting the thumb), and to have emergency actions that includes instructions about removing the allergen, use of another AAI after 5 minutes and to go to hospital. For everyday life situations they suggested reminders to keep AAIs in-date, to have AAIs with them, to check the colour of the adrenaline (to check it is not cloudy which could indicate spoilage).

Help with food label checking. Participants reported a need to detect harmful allergens in food ingredient labels and, to a lesser extent, in other products (e.g., contact allergens like latex in gloves). They mentioned food label checking could be supported with barcode reading and a central database that collects, stores and maintains records. They suggested that everyone could contribute. They also suggested a link to support groups and an information tool to support allergen avoidance.

Help with emergency situations. Focus group participants mentioned that patients, carers, relatives, friends, school teachers and work colleagues need a solution that supports them in emergency situations, for example, helping with AAI use, improving communication with emergency services and assessing the situation. In addition they needed a mechanism in everyday life to support them prepare for an emergency, e.g., training in AAI use, knowing how to assess an anaphylactic situation and knowing what to do.

After discussing anaphylaxis management needs, participants worked in groups of two to design the tools that supported their needs as follows:

Group one designed a simple education tool comprising a list of videos (their notes are shown in Fig. 4.3). They also designed a tool supporting food label checking. They envisioned the idea of using barcode reading to automatically detect allergens in food ingredients, informing the user if something contained an allergen, and also reporting any commonly cross reactive allergens (allergens that frequently co-occur, for example, other nuts with peanuts), processing large amounts of database products and ingredients with product alerts and with moderation from food manufacturers, users and support groups.

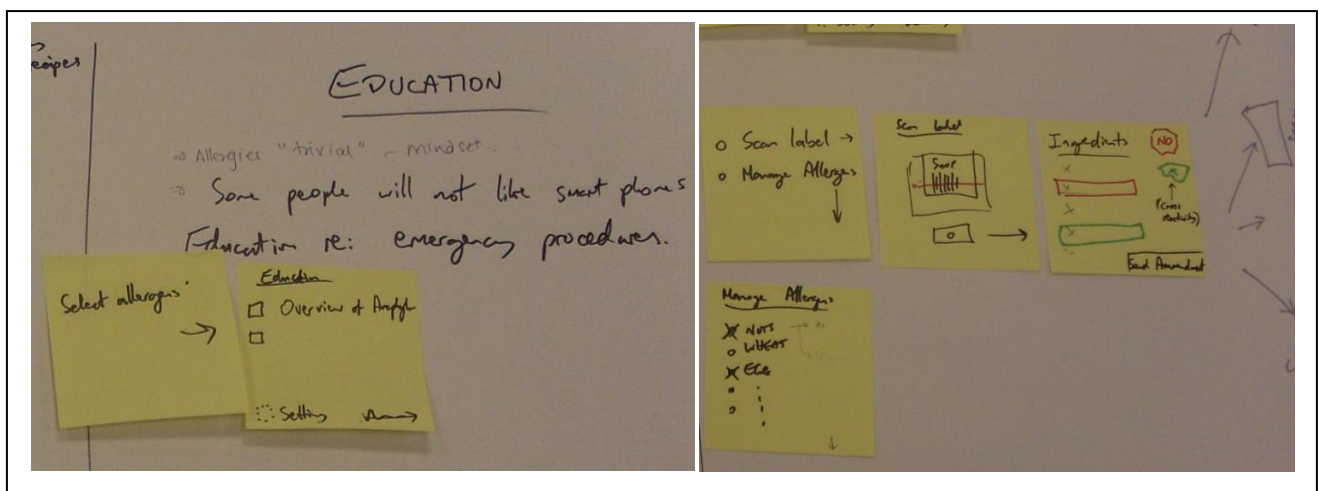


Fig. 4.3 Participant paper mock-ups of everyday life tools. A list of videos as an educational tool (left), a barcode reader tool for allergen avoidance support (right).

Group two designed a tool for the assessment and treatment of emergency situations (Fig. 4.4 left). They created a list of possible symptoms that could indicate an anaphylactic reaction. This group suggested the implementation of video animations and step-by-step AAI instructions. They also suggested support for contacting emergency services with either automated calling support or sending a message with the GPS location of the patient.

Group three designed a tool for AAI management (Fig. 4.4 right). They wanted to support users in having their AAI/s available, not expired, knowing when to use them, trained in the correct steps of AAI use and knowing how to obtain help after using it. This tool overlapped the management of the AAI in everyday life and in emergency. They made a three-button menu screen comprising traffic-light coloured buttons: a yellow button to explain AAI use through pictures and instructions, a green button to be prepared for emergency with a checklist and a red emergency button to summon help.

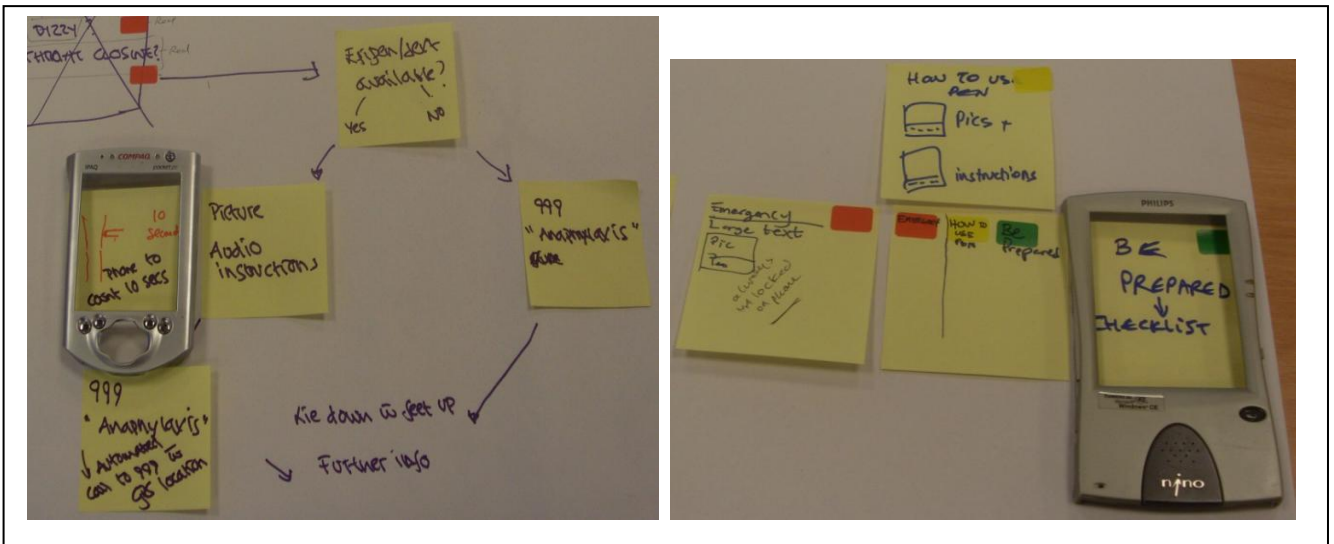


Fig. 4.4 Support in emergency (left), AAI use and management with emergency button (right).

4.2.3 Results of the second focus group

The user interface mock-ups produced for the second focus group were created with Balsamiq® software for higher fidelity user interface prototyping of screenshots with the look of a smartphone app. The participant feedback and paper mock-ups informed the designs. It was a challenging task to develop designs incorporating the many different ideas given by the participants. The solution to this was to create different alternatives for the participants to compare and choose from.

In addition to the tools suggested in the first focus group, an AAI injection training tool was created. A simplified version of an injection force sensing tool had been tested in the PervaLaxis prototypes, but while help with AAI use had been suggested, a sensing tool with feedback had not been explicitly suggested in the first participatory design session. This new version of the AAI injection training tool was designed purposefully to increase self-efficacy sources: it encouraged mastery and provided social persuasion (via encouraging assessments). The tool was included in mock-ups presented in the second focus group for participant feedback and is described in more detail in the section 4.3.

Fig. 4.5 shows some of the alternatives that participants were provided with. For example, the placing of the menus and the emergency buttons at the top or at the bottom of the screen (Fig. 4.5a and d), the use of “smiley faces” or tick and crosses in the training tool feedback (Fig. 4.5b) and the use of bar type buttons over the use of icon type buttons (Fig. 4.5c). Participants preferred to put the anaphylactic emergency button (Fig. 5.5a) and the cancel button (Fig 5.5d) at the top of the screen to improve their visibility and to avoid pressing them by mistake. They decided to have horizontal bar coloured buttons on the everyday life tools screen instead of icons (Fig. 5.5c). And for the injection training feedback tool, they preferred ticks and crosses rather than happy or unhappy faces because they thought they were clearer, as depicted in Fig. 5.5b.



Fig. 4.5 a) Anaphylactic emergency button location; b) Decision between using smiley faces over tick and crosses in a injection training tool; c) Choosing between bar type buttons over icons type buttons; d) Decision to place a cancel button on top instead of at the bottom to avoid mistakes.

Although participants suggested names for the application, for example, Ana-Smart, AllergyMate, Anadroid, EpiTOME (Training, organisation, management and emergency), it was decided, that AllergiSense was best because it combined three important characteristics of the mobile application that differentiate it from others: “Allerg” from anaphylactic allergies, “i” from interactive and “sense” from the use of wireless sensors in the AAI trainer.

4.2.4 AllergiSense

Six tools suggested by participants were implemented in AllergiSense. Four tools for everyday life and two for emergency scenarios. These tools were selected as those which could be more reasonably and more readily implemented. For example, the barcode scanning of ingredients was not implemented. This was suggested to help with food label checking by automatically recognise the allergens. It is an idea that was announced as a future service in the UK, but has since been abandoned. Perhaps because it is an idea that requires cooperations and infrastructures that do not exist. Table 4.3 shows a summary of the tools and the functionality implemented for each.

Table 4.3 AllergiSense tools.

Scenario	Tool implemented	Description
Everyday life	AAI expiry date manager	It was designed to manage (checking and modifying) a list of AAIs expiry dates with “smiley” and “unhappy” faces and reminders. It implemented a traffic light colours code for the icons.
	Information: AAI step-by-step instructions	It provides step-by-step injection instructions and a video.
	Information: videos	It provides information videos about AAI use and how to recognise the symptoms of anaphylaxis
	AAI injection training (with feedback)	It was designed to provide feedback about the steps of a simulated injection. The smartphone tool connects to wireless sensors mounted on an AAI trainer device.
Emergency	Emergency messages tool and call to 999 button	They send text messages to emergency contacts and call 999 respectively. The name of the user, GPS location and event are embedded in the text messages.
	Emergency information: emergency what to do tool and AAI injection stepstool	They provide information about emergency procedures and how to use and AAI device, respectively.

Fig. 4.6 shows screenshots of AllergiSense tools implemented for everyday life including an expiry date list, information about AAI use with step-by-step instructions, information in videos and injection training with feedback. While tools for an emergency, included information about emergency procedures and AAI use (in a list and with step-by-step instructions), and communication with emergency services and emergency contacts (SMS text messages and a button to call 999).

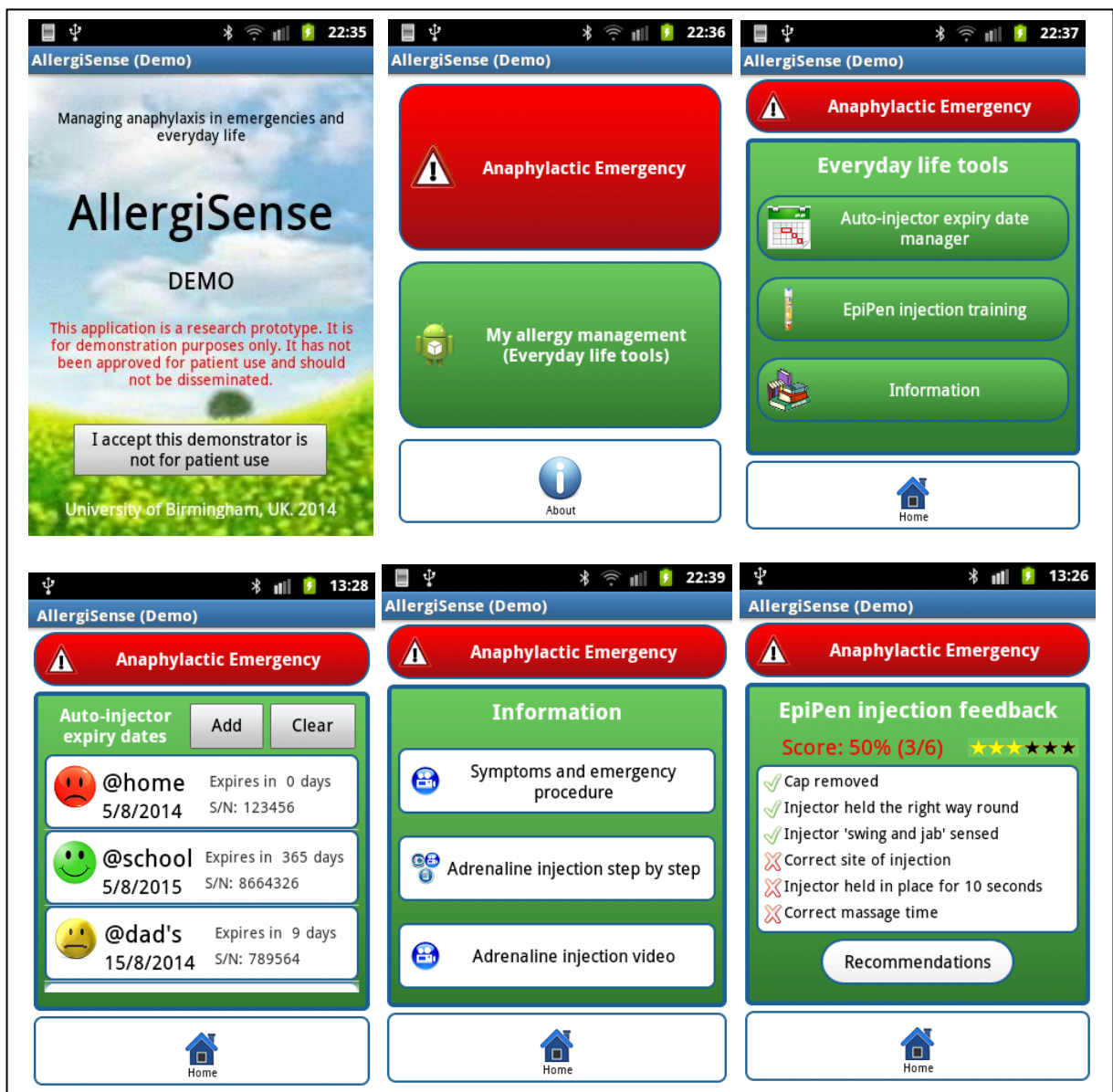


Fig. 4.6 AllergiSense tools for everyday life.

Fig 4.7 shows the tools for emergency. The colouring of screens and buttons indicates if they are for emergency management (red) or for everyday life management (green). They were implemented in an Android smartphone. Android platform was chosen for three reasons: because at the time of writing Android was a very popular OS in the smartphone market, because the development tools and the smartphone devices cost were more accessible for research purposes and because it supported multiple Bluetooth™ connections.

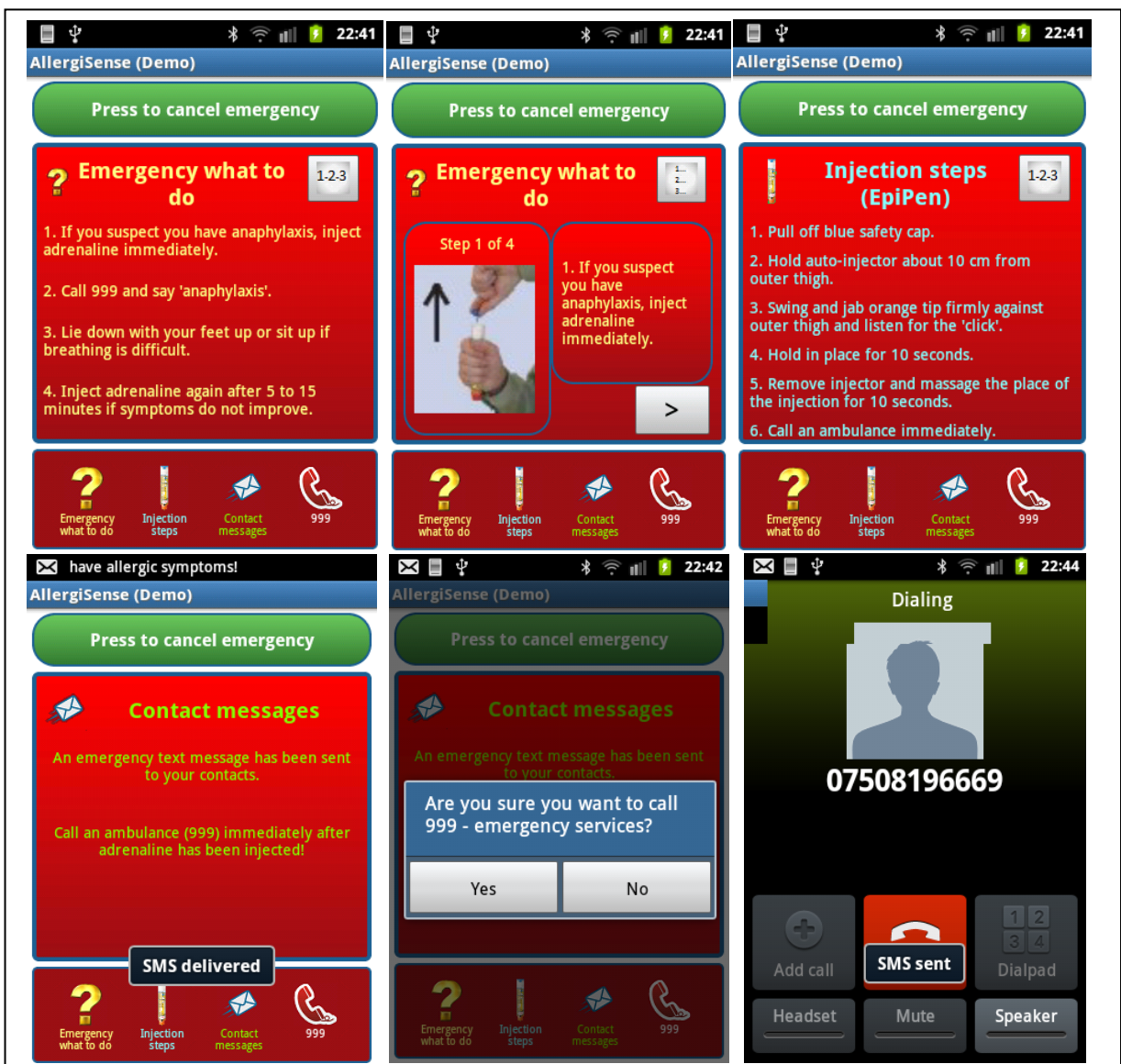


Fig. 4.7 AllergiSense tools for emergency.

Table 4.4 compares the self-efficacy sources suggestions from the user needs inputs (from last chapter studies one to three, and from this chapter both participatory design sessions), by the traditional care paper documents, by AllergiSense tools excluding an injector tool with feedback and by AllergiSense. It can be seen that the user suggestions improve on the self-efficacy sources compared to traditional care paper documents.

Very possibly without realising, participants proposed tools that could enhance their levels of self-efficacy. But, of course, people might intuitively ask for pictures or videos so that they can more easily copy (model) something they need to do. This suggests that participatory design in pervasive healthcare might more naturally ground solutions in self-efficacy theory, or at least help with contributing some sources of self-efficacy.

Table 4.4 Self-efficacy sources supported by suggestions from user needs inputs, by the traditional care paper documents, by AllergiSense tools excluding an injector tool with feedback and by AllergiSense.

	Everyday				Emergency	
	AAI expiry date manager	Information		AAI Injection training with feedback	Emergency information, including step-by-step tools	Communication including texts and call to 999
		AAI Step-by step instructions	AAI Videos			
User needs (studies one to three + focus groups)	Social persuasion	Modelling	Modelling	-----	Modelling	Physiological states
Paper	-----	Modelling		-----	Modelling	-----
AllergiSense without feedback	Social persuasion	Modelling	Modelling	-----	Modelling	Physiological states
AllergiSense	Social persuasion	Modelling	Modelling	Mastery and social persuasion	Modelling	Physiological states

4.3 Injection sensing

This section describes how the steps of practice adrenaline injections with a trainer can be automatically recognised and evaluated. The functionality described here was implemented in the AllergiSense adrenaline injection training tool.

A wireless three-axis accelerometer sensor mounted on a trainer device was used to sense injection motion. Acceleration data was transmitted to AllergiSense application via Bluetooth™.

4.3.1 Preliminary results

Previous implementation results from attempts at injection sensing were useful in informing the design of this tool. These earlier implementations used an accelerometer sample rate of 10 Hz and a binary tree model for detection but achieved an accuracy of only 63%. Improved detection was desirable. The sample rate was increased and a sensor was added to the safety cap of the trainer to detect if the cap was removed, rather than relying only on acceleration data that did not provide precise information about this step of the injection.

4.3.2 Hardware and sensing method

In the preliminary testing, the SparkFun sensing unit (described in chapter 3) comprised a PIC® microcontroller, a three-axis accelerometer and a Bluetooth™ transceiver. However, their size and shape was not convenient for evaluation purposes and was rather bulky for people to handle. Therefore, a new sensing unit, shown in Fig. 4.8, was designed and implemented. It included an Arduino "Pro mini" microcontroller, a three-axis accelerometer, a Bluetooth™ transceiver and a push button sensor under the blue safety cap to sense when it was removed. The sensing unit was encased in a slim plastic cover that was more easily handled. The accelerometer sensor unit was configured to sample X, Y and Z acceleration channels at 70 Hz. The communication with the smartphone device used a Serial Port Profile (SPP). A sampling rate of 70 Hz, was empirically selected as sufficiently high to improve sensing fidelity and that could be sustained in terms of battery life (approximately 3 hours of continuous sensing, with a single practice injection in the order of 25 seconds).

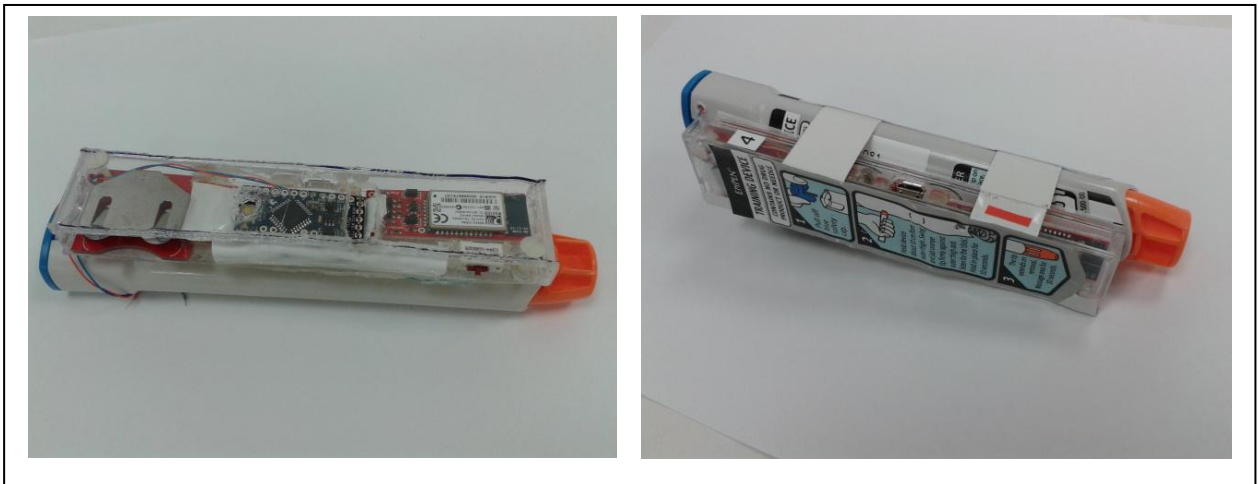


Fig. 4.8 AllergiSense sensing unit mounted on an EpiPen® AAI trainer device.

In chapter 3, PervaLaxis studies, the injector sensing tool using acceleration data to detect possible injections was received very positively. However, it was limited to the detection of a 'swing and jab' motion with a simple thresholding method that did not provide any information about two of the other important steps (removing the blue safety cap and holding the injector firmly in the place of the injection for 10 seconds). Therefore, a simple binary tree model that informed the status of the sensing unit was created and later implemented in AllergiSense smartphone (illustrated in Fig. 4.9) as follows:

1. Creating the model

- 1.1 Sensing data (from the allergy specialist collaborator) were collected by the AAI sensing unit and sent to a PC hyperterminal using Bluetooth™ protocol (training data).

- 1.2 Features of acceleration data were calculated in the PC and saved in a CSV (i.e., comma separated value) file. The features of acceleration data were a set of statistical parameters representing continuous segments of X, Y and Z acceleration data over the time domain (they are described in the next section).

- 1.3 The features were introduced into WEKA software (WEKA, 2012) to create a model that could classify features of acceleration over time into injection steps.

2. Using the model

- 2.1 The model created previously was implemented in AllergiSense.

- 2.1 XYZ data from the user's training injection were collected and sent to AllergiSense

through the AAI sensing unit.

2.2 Features of user's acceleration data were calculated in AllergiSense

2.3 The model created previously classified the features of acceleration user's data into segments of injection steps over time.

2.4 Three types of motion could be detected: A 'swing and jab' motion (when the features of data represented the signature of a sudden and strong motion), a 'still' status (when the features of data represented a motionless sensing unit) and other motion labelled as 'moving' (when the features of data represented a random type of movement).

2.5. The array of segments of injection steps over time were later provided to a *higher level decision tree model*. The higher level model looked for the correct segments of injection steps over time and verified that they were in the sequence required by a successful injection.

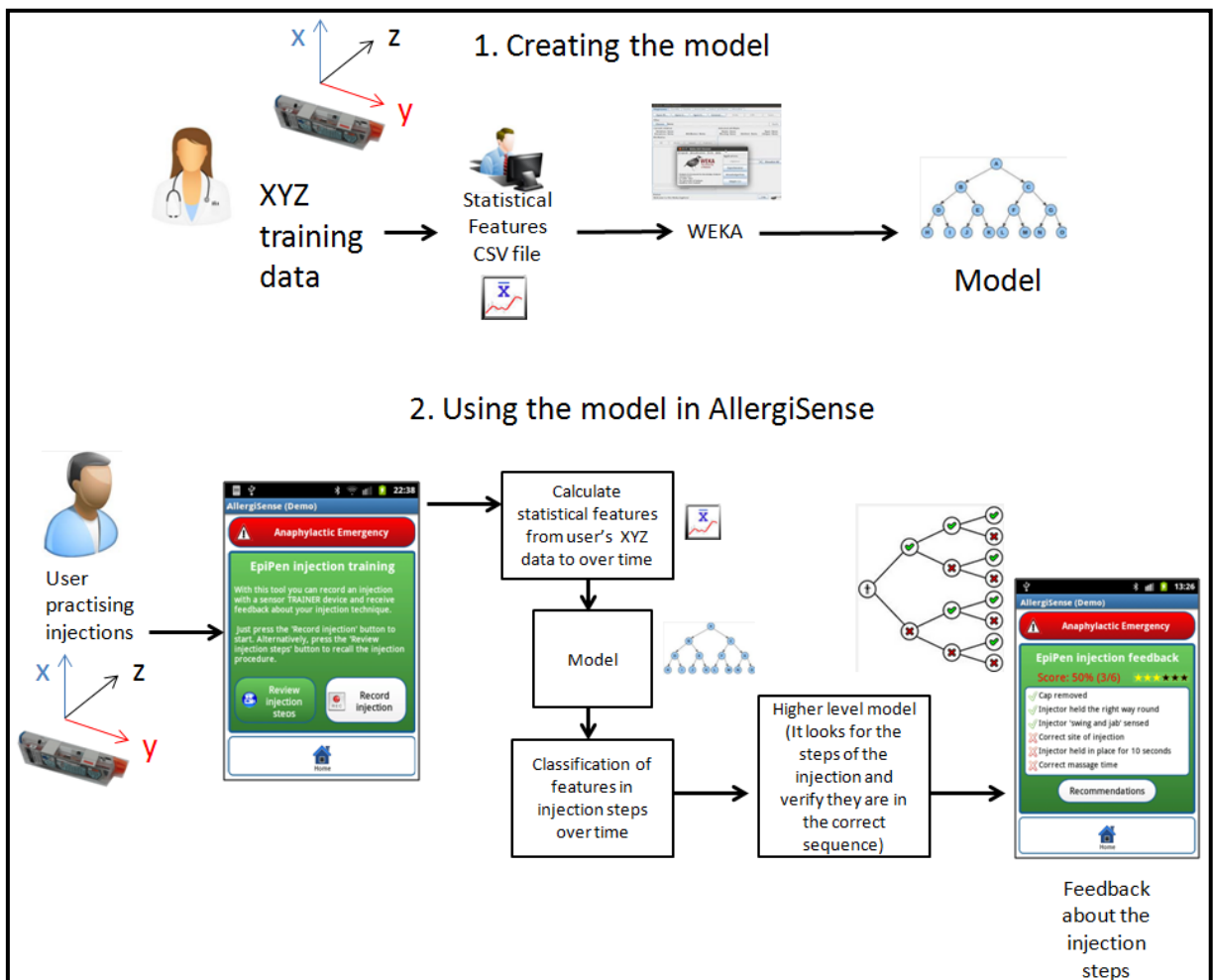


Fig. 4.9 Creating and using a model for adrenaline injection feedback.

4.3.3 Creating a classification model with WEKA software

The creation of a classification model was needed to translate X, Y and Z acceleration into injection steps. For this, acceleration data (training data) was required from a reliable person serving as gold standard for the injection steps. These were provided with the expert clinical collaborator. Classification algorithms can be based on different data mining techniques (e.g., binary trees or Bayesian classifiers), which can vary in complexity and in processing demands. Methods can be implemented in different programming languages (e.g., C# or Java), however, there are several research tools available that optimise this process. WEKA (2012) is one such popular freeware data mining tool. It provides a large variety of data mining techniques and was useful to obtain a classification model needed in this research.

Recording training data. Training accelerometer data from 12 practice injections made by the expert clinical collaborator were recorded in a laptop using a hyperterminal interface wirelessly connected to the sensing unit. The injections were performed with the right hand, both sitting down and standing up to collect a range of training data that reflected usual body postures in adrenaline injection training scenarios. The injections included all the steps of the injection, namely remove the blue safety cap, inject firmly into the outer thigh at 90 degrees, hold in place the device for 10 seconds, remove the injector trainer and massage the area of the injection for 10 seconds.

Extracting the features from the training data. In order to create a classification model with WEKA software, features of XYZ acceleration data in the time domain had to be calculated (since standard classification algorithms cannot take XYZ acceleration data directly). Therefore, the XYZ acceleration data of the training injections were transformed in a series of time segments of data with associated features (Kwapisz, Weiss and Moore, 2010). A sampling frequency of 70 Hz enabled a good trade-off between battery consumption and noise level, thus the use of filtering techniques like those in (Zhang et al., 2010) were avoided to decrease calculation demands in the smartphone.

A set of 24 features of data were generated per segment of 70 samples of XYZ acceleration (25 for the training data, which included a pre-selected class). Each segment had a sliding

window of one second and a 50% overlap. One second was considered enough to detect the “swing and jab” step (the moment of the injection) with 70 rows of XYZ samples, while the 50% overlap was chosen because it was useful to avoid the loss of meaningful data located on window edges (Wang and Chen, 2005; Devaul and Dunn, 2001).

Table 4.5 lists the features calculated per segment of XYZ acceleration data. Average, standard deviation, and maximum and minimum values have been used in activity classification research using accelerometers (Saponas et al. 2008, Kwapisz, Weiss and Moore, 2010). Nevertheless, an extensive list was considered to identify other possibly beneficial features.

Table 4.5 List of features per segment of acceleration data.

Feature (70 xyz samples; 1 second of data)	Features generated from XYZ data	Description
Average	xaverage, yaverage, zaverage	Average acceleration per axis
Standard deviation	xsd, ysd, zsd	Standard deviation per axis
Average resultant	Raverage	$Raverage = \frac{\sum_{i=1}^{70} \sqrt{(Xi^2 + Yi^2 + Zi^2)}}{70} = \frac{\sum_{i=1}^{70} Ri}{70}$
Standard deviation of the average resultant	Rsd	$SD(Raverage) = \frac{\sum_{i=1}^{70} (Ri - Raverage)^2}{70}$
Maximum value	xMax, yMax, zMax, RMax	Maximum value per axis and per resultant
Minimum value	xmin, ymin, zmin, Rmin	Minimum value per axis and per resultant
Average absolute difference (average of the distance to the mean per axis and resultant)	dXaverage, dYaverage, dZaverage, dRaverage	$E.g.: dXaverage = \frac{\sum_{i=1}^{70} xi - xaverage }{70}$ Same expression per dYaverage, dZaverage and Raverage
Max - min	xMax-xmin yMax-ymin zMax-zmin RMax-Rmin	Maximum value minus minimum value per axis and resultant
Class	jab, still, moving	Classes representing the steps of an adrenaline injection.

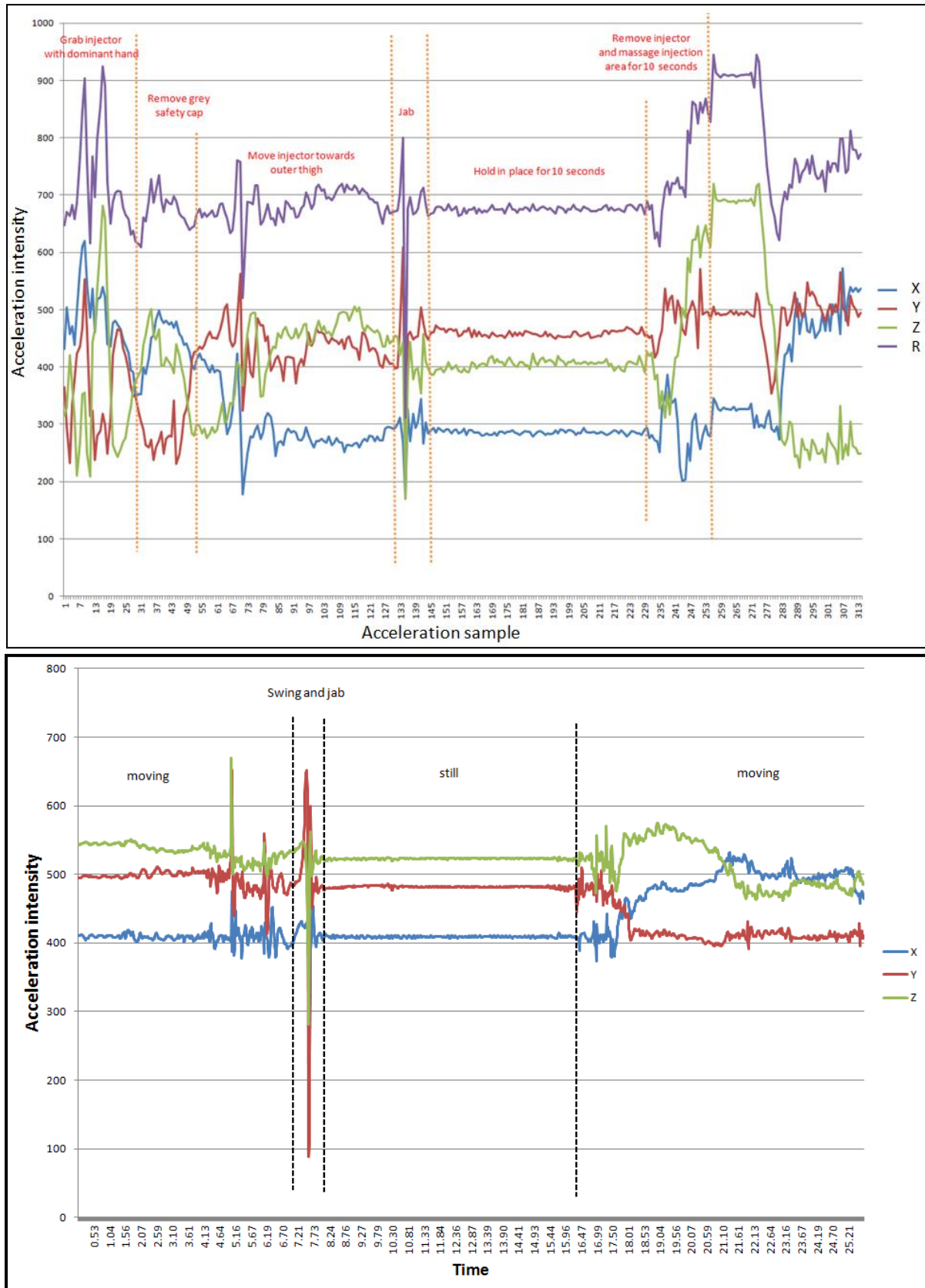


Fig. 4.10 XYZ acceleration data with all the steps of the injection (top), gold standard injection from the clinical collaborator with a simplified version of steps (bottom).

In the preliminary injection pilot study, mentioned before, all the steps of the injection (removing the safety cap, moving the injector towards the outer thigh, 'swing and jab', stay still for ten seconds and remove the injector) were considered for sensing and classification (see the top of Fig 4.10). However, a low accuracy of 63% was found and many of the steps were confused in the model. Therefore, to increase the accuracy of the classification algorithm, and to minimise the confusion among steps, only three types of motion were further considered: The 'swing and jab' movement when the injection is done, the motionless state when the person hold the injector still for 10 seconds and any other type movement (labelled as 'moving') (see the bottom of Fig. 4.10). While the removal of the safety cap was sensed with a specific purpose sensor (a push button placed under the safety cap).

4.3.4 Classification model accuracy

Once the features of the acceleration training data were calculated, a binary decision tree (J48) data mining technique was chosen in WEKA software. J48 is the Java implementation of popular data mining C4.5 decision tree algorithm. It was chosen because it can be feasible to implement in the resource constraints of mobile devices, such as smartphones. The accuracy of the model created in WEKA was 88%. This accuracy was considered sufficient for AAI training scenarios (unlike the much higher accuracy that would be needed of real injection sensing) but, of course, other contributions to the area could be useful in improving further. This accuracy was obtained with a simplified version of steps (illustrated at the bottom of Fig. 4.10) in direction of the Y-axis, which is the axis along the length of the trainer. Axes X and Z were discarded from the model as they provided limited information in the sensing of the injection.

Table 4.6 Confusion Matrix of the model created by WEKA.

moving	jab	still	classified as
48	2	4	moving
5	12	0	jab
10	2	104	still

The classification model implemented in the AllergiSense was as follows:

=== Classification model ===

```
dYaverage <= 1.933061: still
dYaverage > 1.933061
| ymin <= 153
| | dYaverage <= 37.37602: jab
| | dYaverage > 37.37602: moving
| ymin > 153
| | ysd <= 12.774451
| | | yMax-ymin <= 50: moving
| | | yMax-ymin > 50
| | | | dYaverage <= 4.609694: still
| | | | dYaverage > 4.609694
| | | | | yMax-ymin <= 99: moving
| | | | | yMax-ymin > 99: still
| | | | | ysd > 12.774451: moving
```

It can be seen that the number of features required by the model to detect the steps of the injection was considerable less than the original features proposed in table 4.5 (only 6 out of 24). This was a benefit obtained by the utilisation of the J48 decision tree algorithm, which removed ('pruned') the less useful features (under the consideration that Y was the main axis affected in the injection motion).

4.3.5 Providing feedback about the steps of the injection

After creating the classification model, it was implemented in AllergiSense. The process of providing feedback involved three steps:

1. Collect acceleration data from the user injection and calculate their features.
2. Provide the features to the classification model.
3. Use a higher level model to know if the sequence of steps, in segments of injection steps over time resulted from the classification model, reflected a possible injection.

The higher level model was a simple implementation that looked first for the steps of the injection over time, and later, verified they were in the following sequence:

moving + swing and jab + still (for 10 seconds) + moving,

which represented a possible injection of adrenaline.

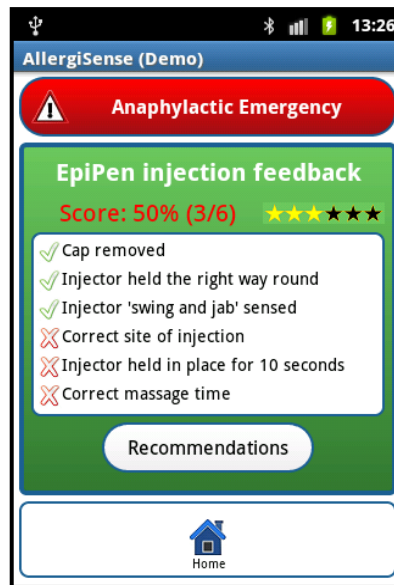


Fig. 4.11 AllergiSense injection training feedback.

AllergiSense users received injection feedback as illustrated in Fig. 4.11, including information about the safety cap removal, the way the injector was held, whether the 'swing and jab' motion was detected and if the injector was held in place for 10 seconds. Information about the place of the injection and the correct massage time were collected with a short questionnaire before providing feedback.

4.4 Summary

This chapter showed how AllergiSense was designed based on participatory design focus groups with allergy specialists, anaphylactic people, carers and smartphone users. Participants expressed their user needs and created and refined paper prototypes based on these needs. Later, AllergiSense tools that incorporated suggestions from the focus groups together with purposefully added sources of self-efficacy were presented. These included a novel tool for adrenaline injection training feedback. Results from the evaluation of the AllergiSense tools are presented in the following two chapters.

Chapter 5

Evaluation of AllergiSense Adrenaline Injection Training Tools

5.1 Introduction

The purpose of this chapter is to provide the results of formal laboratory evaluation of AllergiSense, the final anaphylaxis management smartphone prototype whose design was described in the last chapter. AllergiSense was designed with embedded sources of self-efficacy and, in particular, to support AAI training by sensing injection practice with wireless Bluetooth® sensors mounted on a trainer.

5.2 Methods

The aim of this evaluation was to carry out a three-arm, pre-post (two-week), randomised controlled study with healthy participants to investigate whether smartphone tools for adrenaline injection training could improve adrenaline injection performance and positively influence injection self-efficacy.

The **main hypothesis** of this evaluation was that using *AllergiSense* (in addition to traditional care paper documents training) would provide better adrenaline injection skills in comparison with training supported by traditional care paper documents alone.

The **primary outcome** of this research was an assessment of the effect of different training materials on adrenaline injection skills through the evaluation of the injection steps based on the manufacturer's instructions. The **secondary outcomes** were to evaluate participants' self-reported AAI self-efficacy, workload, usability, system usefulness, ease-of-use and attitudes towards use.

The study received ethical approval from the Science, Technology, Engineering and Mathematics Ethical Review Committee of the University of Birmingham UK (ERN_13-1496) and was funded by The Anaphylaxis Campaign's Small Grant Scheme (04-13-LHM). Additionally, the training provided was clinically approved and the procedure overseen by an expert clinical collaborator.

5.2.1 Statistics

A Shapiro-Wilk test was used to test if results were samples of a normally distributed population (Significance level = 0.05) (Field, 2000). Parametric t-tests and ANOVA were used on normally distributed results; Friedman's Rank and Mann-Whitney (U) tests for results not normally distributed and X^2 for comparing frequencies of data. The statistical tests were undertaken using SPSS® version 21.

5.2.2 Participants

Twenty-one adult participants per group (63 in total) were trained in the use of an Epipen® AAI with an Epipen® trainer injector. Participants were recruited from the University of Birmingham, UK. Anaphylactic people and their carers were excluded from the study¹.

¹ The recruitment of anaphylactic people and their carers, i.e., of patients, would have required extensive NHS and ethical permissions. Approval for testing of technology with real patients would be more likely in the event of positive outcomes from testing with healthy participants.

5.2.3 Assessment of performance and administered questionnaires

Assessment of adrenaline injection performance. The assessment of AAI performance was based on the marking scheme used in other studies (Sicherer, Forman & Noone, 2000; Arga et al., 2011), which, in turn, was based on the steps recommended by the EpiPen® AAI manufacturer. These are:

1. Remove the blue safety cap.
2. 'Swing and jab' the orange tip of the AAI trainer against the outer thigh until it 'clicks'.
3. Hold firmly against the thigh for 10 seconds.
4. Remove the Auto-Injector from the thigh. The orange tip will extend to cover the needle and massage the injection area for 10 seconds.

The AllergiSense system separates step two into two by i) sensing “swing and jab” and ii) explicitly asking the user to select the correct injection site from a randomly ordered list. In addition it senses for the injector being held the right way around. This means that while AllergiSense assesses the four step injection performance it reports out of six rather than out of four.

Workload and self-reported usability. The NASA TLX (NASA, 2003) and the System Usability Scale (SUS) (Brooke, 2006) questionnaires were used for evaluation of workload and self-reported usability, respectively. NASA TLX questionnaires were used to quantify levels of mental, physical and temporal demands, and self-reported levels of performance, effort and frustration. Each scale has 21 vertical marks that divide it from 0 to 100 in increments of 5. Low demand levels could indicate that a task would be more likely to be successful in a real scenario (Brewster et al., 2003). The SUS questionnaire was used to provide a measure of perceived usability, covering aspects of acceptance, need for support, training and system complexity (Jones & Marsden, 2006; Preece, Rogers & Sharp, 2002).

Self-efficacy. A self-efficacy questionnaire for adrenaline injection was created using a ten-point scale as recommended in guidelines by Bandura (2006). The selection and phrasing of the questions was first reviewed by the clinical collaborator of the study, checked by another

senior allergy clinician and later by other 16 allergy specialists (allergy immunologists and trained allergy nurses) who rated the questions according to their importance.

Usefulness, ease-of-use and attitudes towards use. Self-reported measures of usefulness, ease of use and willingness regarding use were collected from technology acceptance questionnaires (Davis, 1989).

5.2.4 Materials

The materials used in the three groups (subsequent to their clinically approved training outlined below) are summarised as follows:

Paper (traditional care paper documentation). Participants in all groups received a paper copy of the EpiPen® AAI instruction leaflet (the instructions for use provided in the EpiPen® AAI patient information). This document provides information about injector use and step-by-step pictures for each of the four injection steps. Participants in the paper-only (control) group received only this information. Participants in the other groups had this material supplemented with AllergiSense materials as described below.

AllergiSense without feedback. This was the AllergiSense smartphone system without the injection practice feedback functionality, i.e., not using wireless sensor data and not providing out-of-six feedback, but with smartphone AAI step-by-step instructions and an AAI usage video. Thus participants with AllergiSense without feedback were provided with the paper instructions (the same as the control paper group) supplemented with smartphone video (an instructional EpiPen video produced by the manufacturers (and available online in the EpiPen® AAI website) and a step-by step tool (text + pictures as per paper steps).

AllergiSense. This was the complete AllergiSense smartphone system using wireless sensor and providing out-of-six injection feedback. Thus, participants in this group were provided paper instructions (the same as the control paper group) supplemented with smartphone AAI step-by-step instructions and an AAI usage video (the same as the AllergiSense without feedback) *and* the mark out-of-six injection feedback.

5.2.5 Experimental procedure

People who elected to participate were randomised and allocated to one of the three groups. Block randomisation (Alman & Bland, 1999) was carried out in blocks of three people to keep groups balanced. Participants were allocated to groups on a first-come-first-serve basis. On the day of the first session participants read and signed consent forms. They were then all provided with clinically approved training: an explanatory video about anaphylaxis and how to use an AAI (including demonstrations of correct use) delivered by the study's clinical collaborator. Participants were then provided with the material/s appropriate to their group.

The experimental phase comprised two sessions. The tasks involved in these sessions are summarised in Figs 5.1 and 5.2. All sessions were video recorded. All injections were made with trainers fitted with wireless sensors and all this sensor data was logged. The sensor data from all demonstrated injections was used to assist subsequent assessment of injection performance. Only in the AllergiSense group was this data also used for smartphone feedback during the training.

In session one, participants were trained as described above then asked to demonstrate injections using the trainer. They then completed AAI self-efficacy questionnaires before using their allocated materials to practice three training injections before demonstrating another injection after which they completed another self-efficacy questionnaire and also a technology acceptance and an SUS questionnaire.

In session two, two weeks later, participants were recalled to demonstrate injections and complete the AAI self-efficacy questionnaire. They then retrained by practicing three injections with their allocated material/s before making a final demonstration and completing a NASA TLX questionnaire.

Only the participants in the AllergiSense group received feedback on their injection performance. No other feedback was provided to any participants until after the completion of session two of the experiment. All participants were informed that the experiment was not a

first-aid course and that they should seek and follow clinical instruction and patient information regarding any future AAI use. All participants received a £10 Amazon voucher for their participation at the end of session two.

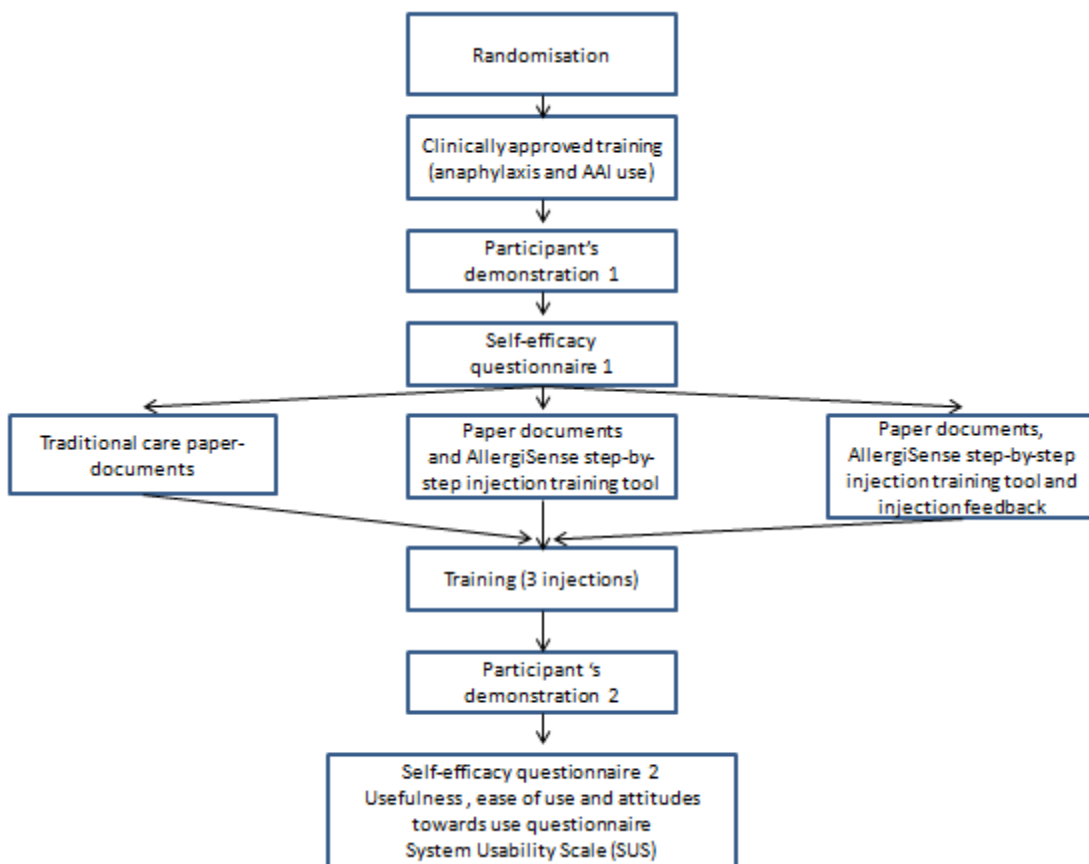


Fig. 5.1 Research procedure for session one (duration: 30 minutes)

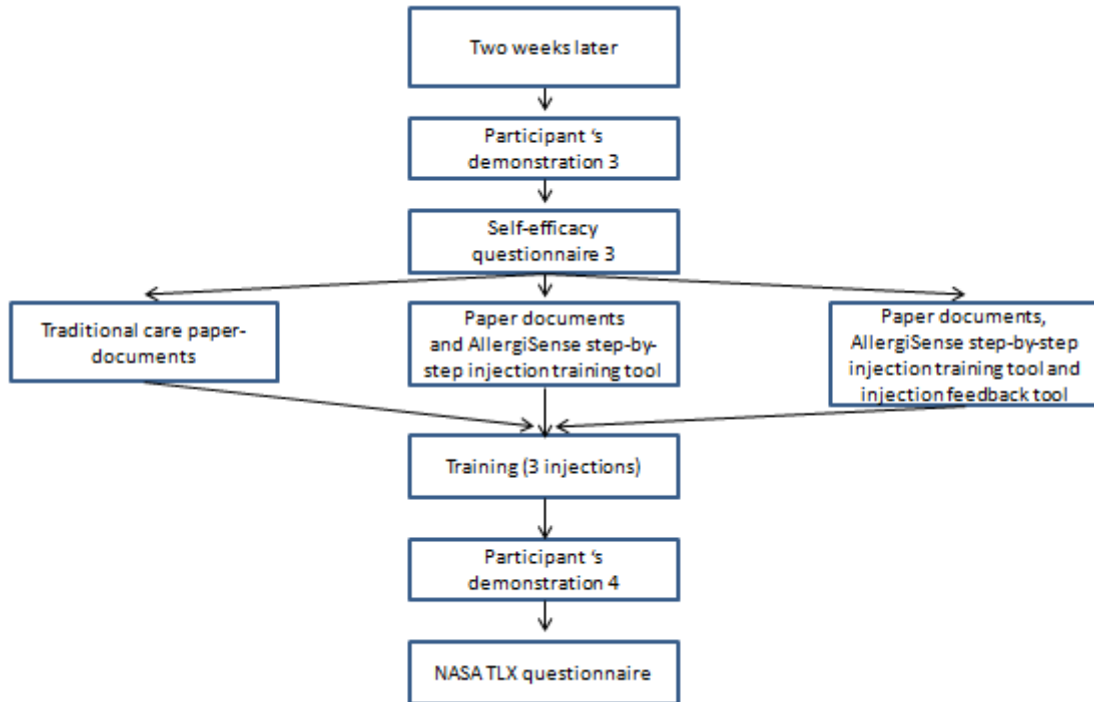


Fig. 5.2 Research procedure for session two (two weeks after session one - duration: 30 minutes).

The performance of all participants' adrenaline injections was evaluated via video observation. An inter-rated test with an independent researcher was carried out with a sample of injections (Cohen's Kappa > 0.8). Injection step differences were discussed and analysed with the independent researcher using the recorded video and data from the AAI sensors.

5.3 Results

Sixty-three participants completed the two-week study. All were healthy participants and 60 of them (95%) reported having a smartphone. Groups were balanced in all categories after randomisation ($P > 0.05$)².

Table 5.1 shows the number of people in each group that correctly completed the four injection steps. Although more people in the AllergiSense group performed all steps correctly after the initial training (i.e., in demonstration 1), there were no significant differences

² Significance level= 0.05

between groups: 5 vs 4 ($p=0.707$), 5 vs 7 ($p=0.495$) and 4 vs 7 ($p=0.242$). Similarly, after training in session 1 (i.e., in demonstration 2) although more people in the AllergiSense group correctly completed all the steps, there were no significant differences between the groups: 5 vs 9 ($\chi^2=1.714, p=0.19$), 5 vs 10 ($\chi^2=2.593, p=0.107$) and 9 vs 10 ($\chi^2=0.96, p=0.757$). However, after training in session two significantly more people in the AllergiSense and AllergiSense without feedback groups completed the four steps correctly compared to the control (paper-only) group: 6 vs 19 ($\chi^2=16.701, p<0.001$) 6 vs 14 ($\chi^2=6.109, p=0.013$) respectively, while the difference between AllergiSense and AllergiSense with feedback showed a trend towards significance: 14 vs 19 ($\chi^2=3.535, p=0.060$).

Table 5.1 Primary outcome: Number of people correctly completing the four injection steps.

	Session 1		Session 2	
	Demonstration 1 (After watching clinical video)	Demonstration 2 (After training)	Demonstration 3 (After two weeks)	Demonstration 4 (After training)
Group 1: Paper	5 (23.8 %)	5 (23.8 %)	8 (38.1 %)	6 (28.6 %)
Group 2: AllergiSense without feedback	4 (19.0 %)	9 (42.9 %)	8 (38.1 %)	14 (66.7 %)
Group 3: AllergiSense	7 (33.3 %)	10 (47.6 %)	9 (42.9 %)	19 (90.5 %)

The number of people correctly completing the steps in the paper only group did not change significantly across the four demonstrations ($p>0.05$), i.e., there was no significant change in their injection ability despite the training opportunities. However, the AllergiSense group improved significantly, from 9 to 19, after training in session two: ($\chi^2=10.714, p=0.013$), and the AllergiSense without feedback group showed a trend towards significance: from 8 to 14 ($\chi^2=3.436, p=0.064$). For the two AllergiSense groups the number of errors made decreased with training. Only 3.1% of all errors (225) involved a failure to remove the safety cap and all of these occurred in demonstration 1. Not injecting with sufficient force comprised 24.9%, not holding the AAI trainer in place for 10 seconds comprised 19.1% and not massaging the injection site for 10 seconds comprised 52.9% of all errors.

Table 5.2 shows the questionnaire results for self-efficacy, usefulness, ease-of-use, attitudes towards use, system usability and workload. Self-efficacy differences *within* groups were seen after training with their allocated material(s) in session one. The paper-only group increased from 7.5 to 8.5 ($\chi^2=-1.405$, $p<0.001$), the AllergiSense without feedback group increased from 7.6 to 8.6 ($\chi^2=-1.429$, $p<0.001$) and the AllergiSense group increased from 7.1 to 8.5 ((F,2)=47.321, $p<0.001$). Self-efficacy remained high for the three groups for two weeks, and no significant differences were found between the three groups ($p>0.05$).

Table 5.2 Secondary outcomes: Self-efficacy, usefulness, ease-of-use, attitudes towards use, system usability and workload

		Material		
		Group 1 Paper	Group 2 AllergiSense without feedback	Group 3 AllergiSense
Self-efficacy:				
Before using material (after Demonstration 1)	average score	7.5	7.6	7.1
	standard deviation	1.4	1.2	1.4
After using material (after Demonstration 2)	average score	8.5	8.6	8.5
	standard deviation	1.2	1.0	0.9
After two weeks (after Demonstration 3)	average score	8.5	8.7	8.4
	standard deviation	1.4	1.1	1.0
Usefulness	average score	5.1	6.1	6.2
	standard deviation	1.5	0.6	1.0
Ease-of-use	average score	4.7	6.2	6.0
	standard deviation	1.5	0.6	1.0
Attitudes towards use	average score	5.1	6.1	6.1
	standard deviation	1.1	0.6	0.7
System Usability Scale (SUS)	average score	68.5	86.3	82.7
	standard deviation	14.5	9.0	15.9
Workload (NASA TLX)	average score	34.1	31.9	31.5
	standard deviation	17.1	13.9	12.2

Participants in the AllergiSense and AllergiSense without feedback groups gave significantly higher average scores for the usefulness, the ease-of use and in the willingness to use their training materials compared to the paper-only group. **Usefulness:** paper vs AllergiSense without feedback ($\chi^2=-14.167$, $p=0.012$); paper vs AllergiSense ($\chi^2=-19.333$, $p=0.001$); **Ease-of-use:** paper vs AllergiSense without feedback ($\chi^2=-18.690$, $p=0.001$);

paper vs AllergiSense ($\chi^2=-15.667, p=0.005$); **Willingness towards use:** paper vs AllergiSense without feedback ($p<0.001$) and paper vs AllergiSense ($p<0.001$).

Also, both AllergiSense groups reported significantly higher system usability scores (SUS) than the paper-only group: paper vs AllergiSense without feedback ($\chi^2=-20.810, p<0.001$); paper vs AllergiSense ($\chi^2=-18.190, p=0.001$). While the workload was not significantly different between groups ($(\chi^2, 2)=0.018, p=0.991$).

5.4 Discussion of results

The purpose of this study was to compare the three different materials. Results support the main hypothesis that smartphone tools supplementing traditional care paper documents could improve adrenaline injection training. There was no significant improvement in the paper-only performance throughout the study. The results supporting the hypothesis are: i) the significant difference between the number of participants correctly completing all steps of their final demonstration in the paper only group (28.6%) vs. the two AllergiSense groups: (AllergiSense without feedback (66.7%) and AllergiSense (90.5%)) and ii) in the greater within group improvement of the AllergiSense groups in Session 2 (AllergiSense without feedback (from 38.1 % to 66.7%) and AllergiSense (from 42.9% to 90.5)) compared with the paper-only group (which actually deteriorated from 38.1% to 28.6%, i.e., from eight people to six injecting correctly). The improved results for AllergiSense could be a consequence of improved training through the implementation of mastery, vicarious and social experiences of self-efficacy in the smartphone tools with videos, step-by-step instructions and visual feedback. In comparison the paper instructions only provides limited modelling opportunity via text and pictures.

Results also appear to support other reports in the literature regarding the inadequacy of the current approach to adrenaline injection education (i.e., expert explanation and AAI demonstration), in particular that it does not monitor practice nor provide feedback and does nothing to encourage or support continuous practice. This was observed after the first demonstration in session one when, at best, only one third of people in the three groups could correctly complete all four steps of the injection (23.8%, 19% and 33.3% for control,

AllergiSense without feedback and AllergiSense, respectively). These very low results concur with other extremely poor findings reported in the literature, for example, Brown et al's. (2013) findings that only 15% of mothers could correctly use an AAI after being shown how to do it.

One interesting and unexpected result in the testing was the significant increase in self-efficacy in the paper-only group after they first used their material for training. This increase was less than the increase for the AllergiSense groups but not significantly less. The paper-only group retained their increased self-efficacy throughout the study despite the lack of any significant improvement in their performance. This was exemplified at the end of session two by one paper-only participant who expressed surprise for each and all of the demonstrated injections they had made incorrectly. Bandura (2012) has reported in the literature that improved self-efficacy in the absence of improved performance indicates a problem in the system. Perhaps then, the experiment revealed something of the problem with the current system, i.e., that in the absence of monitoring and feedback people have elevated self-efficacy based on incorrect assumptions about their mastery skills. This could have several consequences, not least the lack of motivation for continuous practice.

Secondary outcome results showed participants reported no significant differences in workload for the three different materials. Interestingly, compared to the paper-only group both AllergiSense groups scored significantly better for usefulness and ease-of-use of their materials and also reported significantly more willingness towards use. Additionally, average self-reported usability scores for AllergiSense were very positive. The paper-only participants reported, according to (Bangor, Kortum & Miller, 2008:592) definitions, a marginally acceptable SUS score of 68.45 (between OK and good), while the SUS score for AllergiSense without feedback was 86.31 and was 82.74 for AllergiSense (both between good and excellent).

Self-efficacy results showed that adrenaline injection self-efficacy improved after the first training session and then was not significantly different two weeks later. Perhaps if participants had been recalled six weeks or six months later these self-efficacy results might be substantially different. Further work involving longer-term studies is recommended to

validate the injection training self-efficacy questionnaire and to investigate how self-efficacy and adrenaline injection skills attenuate over time and how these are impacted by the training materials used.

5.5 Summary

This chapter presented a randomised, controlled, pre-post study to compare smartphone tools for anaphylaxis management to the paper instructions used in traditional care. Although the study was limited to healthy participants simulating adrenaline injections with an AAI trainer, it provided useful insights into how smartphone tools and wireless sensors could supplement traditional care paper documents and positively affect injection performance in training and user self-efficacy.

Chapter 6

Clinician Evaluation

6.1 Introduction

This chapter provides results of the evaluation of AllergiSense by clinical staff. The reason for conducting this study was to ascertain the expert opinion of allergy specialists about AllergiSense and, more generally, to smartphone technology designed to support anaphylaxis management, and particularly, to support adrenaline injection training.

The following section explains the research procedure, the research authorisations and the participant profiles. Later, results are presented and discussed. Finally, a summary of the chapter is provided.

6.2 Methods

6.2.1 Research procedure

After signing consent forms clinical staff participants were provided with an introduction to the research and demonstrations in the use of the AllergiSense system. Each participant was then provided with an AllergiSense system for a one-week evaluation period after which a short semi-structured interview was carried out to receive their feedback. The systems (the smartphone, AAI trainers and mobile application software) were clearly labelled as research prototypes for evaluation and not for clinical use. The semi-structured interviews were audio recorded for analysis purposes. The interview questions asked the participants about their

previous experience with smartphone apps, and their opinions of the potential benefits, limitations or difficulties relevant to technology solutions for anaphylaxis management and to AllergiSense in particular. One researcher performed the interview and a second researcher assisted in taking notes. After the interview the two researchers made a summary of the session and identified significant themes. Later, an analysis of the recorded audio was performed to further clarify the main themes and ideas discussed.

6.2.2 Research authorisations

This study required commitment to legal and regulatory processes. Before starting the study a risk assessment was performed and approved by the School of Electronic, Electrical and Systems Engineering and a research protocol was submitted and approved by the Science, Technology, Engineering and Mathematics Ethical Review Committee of the University of Birmingham UK (ERN_13-1496). Funding was provided by The Anaphylaxis Campaign's Small Grant Scheme (04-13-LHM) and liability insurance was provided by the University of Birmingham (RG_14-090). The Leicester Royal Infirmary (University Hospitals of Leicester NHS Trust) agreed to provide a home base for the study and the researcher obtained certification (a good clinical practice certificate) and access permissions (a research passport).

Table 6.1 Participants' profile.

Participant (Age interval)	Clinical status (gender)	Smartphone use
1 (50-60)	Allergy clinician (male)	Reported having an iPhone and using mobile apps such as news and sports. Considered himself having moderate experience with smartphone (limited to Internet use and apps)
2 (30-40)	Allergy clinician (male)	Reported using an iPhone and many apps such as BBC iPlayer, and audible train times. Considered himself having moderate smartphone experience (i.e. use of web browser and apps).
3 (40-50)	Allergy nurse (female)	Reported using a Sony smartphone and communication apps (e.g. Skype and WhatsApp) but considered herself a beginner in smartphone app use.

6.2.3 Participants

Two allergy clinicians and an allergy nurse participated in the AllergiSense evaluation. They were senior clinical allergy staff of the Leicester Royal Infirmary. Their profiles are described in Table 6.1. Participants reported using smartphones and smartphone apps. They considered themselves as having low to moderate experience with smartphones (limited to communication functionalities, and Internet and apps use).

6.3 Results

The study was carried out at the Leicester Royal Infirmary, a medical facility located in the English Leicester of England. Leicester is located in the centre of England; it has a total population of 329,839, of which 33.6% are foreign born (UK Census, 2011). Leicester Royal Infirmary has 890 beds and provides accident and emergency services. The Children's Hospital has an allergy clinic (NHS, 2014) staffed with research-active senior allergy clinicians.

The clinical staff agreed to have a group interview one week after receiving AllergiSense. The interview lasted 1.5 hours and took place in the Paediatric Department of the Leicester Royal Infirmary. An allergy clinician and the allergy nurse attended the full interview, the second allergy specialist (the senior of the two) arrived half way through. However, he was provided with extra time to review the missing questions. The three clinicians answered all the questions.

The following discussion themes summarise the analysed recorded audio. They are: experience with smartphone apps, challenges in anaphylaxis management, how clinicians envisaged the use and delivery of those tools in the future, who could take the associated responsibility of the tools, how AllergiSense technology could be used by anaphylactic people, barriers that may affect the adoption of AllergiSense, using AllergiSense to tele-monitor people's injections skills, and finally, the advantages and disadvantages of AllergiSense and suggestions for improvement.

Experience with smartphone apps. One participant expressed that he did not use apps frequently but that he had a smartphone, so he knew how to use them. Other participants declared using apps such as the BNF (British National Formulary) medical guidelines which is an app that provides guidance for prescribing, dispensing and administering prescribed drugs, and that they had downloaded some anaphylaxis apps for personal interests (e.g., Jext® and React), but mentioned that some of apps were difficult to find online (e.g., React app is

available in a web browser but not available for download). One allergy clinician mentioned medical apps as valuable references.

Challenges in anaphylaxis management. Clinical staff mentioned that they considered two main issues as the main challenges in anaphylaxis management: anaphylaxis symptoms recognition and the management and use of AAIs. They mentioned that the recognition of symptoms, even after receiving explanations, was a difficult task for clinicians, paramedics and patients. An example was cited of a child in a school having only tingling lips (a very mild symptom) had been injected with three AAIs.

In regard to AAI use and management clinical staff highlighted that patients often do not carry AAIs and often do not use their AAIs when they need to, or otherwise delay their use. They also explained that possible reasons were a lack of confidence in the use of AAI, that patients were scared of using AAIs in the clinic for practice and outside the clinic for emergencies, maybe because they think that using an AAI could cause harm instead of a benefit. Furthermore, interviewees highlighted that patients with prescribed AAIs often arrived at the clinic not knowing how to use them. This was often when their GPs (i.e., general practitioners or family doctors) had prescribed them but nobody had showed the patients how to use them. It was also pointed out in the interview that many medical students and clinicians do not know how to use AAIs because their courses do not include information on AAI use and management. In summary, carriage of AAI, recognition of symptoms and treating of anaphylaxis were considered issues to be addressed in anaphylaxis management.

How clinicians envisaged the use of smartphone tools for anaphylaxis management in the future. Clinicians expressed that smartphone tools could be useful in an allergy clinic as “aid memoires” for patients, and making the clinic more efficient and more interactive. They said that injection training tools could be used for training medical staff (e.g., nurses), childminders and other people. Thus, through the feedback about their injection technique, people could be more attentive to training (interviewees expressed their desire to train other people with AllergiSense training tools). They also mentioned that outside the clinic, smartphone tools can have a certain role to inform patients, carers and relatives because a lot of people have a smartphone. They also suggested that there might be a dynamic process

where the tools could be renewed to avoid users, especially children, getting bored and not using them anymore.

How clinicians imagine the delivery of this technology in the future. First of all they mentioned that distribution is a difficult issue because if the tools are tailored to one AAI manufacturer, they will be limited to their product. Secondly, clinical staff imagined GPs providing basic training to patients and carers and recommending them to download the app to learn how to use their prescribed AAI in a safe way. They highlighted that injection training tools could be a useful resource in that way since, usually, GPs make the diagnosis and then prescribe an AAI, but they have limited time to train patients.

Who could take the associated responsibility in the maintenance of smartphone applications supporting anaphylaxis management. Clinical staff suggested that ideally the responsibility should be shared in a partnership among patients, carers, patient's support groups, national societies, representatives from schools and a group to coordinate the work. In addition, they suggested that there should be meetings twice or three times a year to verify how matters were evolving and improving.

How AllergiSense technology could be used by anaphylactic people. Clinical staff said that some families could take the tools very seriously and that the tools will be very useful, for example, in training other people such as grandparents and babysitters. They also highlighted that AllergiSense could supplement the materials people have outside the clinic, where the role of AllergiSense would be to promote better management and the proper and timely use of AAIs. They also discussed if AllergiSense may have an impact in improving carriage and usage of AAIs.

Barriers that may affect the adoption of AllergiSense tools. Interviewees mentioned that they did not see major barriers because AllergiSense tools would be easy to use, but that if patients were asked to purchase the tools, that could be, potentially, a barrier. Moreover, they mentioned that AllergiSense integrated many functionalities, thus additional information about the tools should be provided to understand their goals and know how and when to use them. They said the tools should be in English, but they could support other languages,

especially Asian languages such as Urdu, Hindi and Arabic. They mentioned that many of their patients or carers were non-English speakers.

Using AllergiSense to tele-monitor people's injection skills. Clinical staff said that they have used technology to tele-monitor people with diabetes. But that in anaphylaxis management they would not think it would be appropriate, due to privacy issues, to “police” patients’ skills. They mentioned that people could supplement their traditional training, outside the clinic, with AllergiSense, using it as a self-help tool and that it could also be useful inside the clinic to help with training while people wait for their appointments.

How AllergiSense may support anaphylaxis management challenges. Clinical staff said that AllergiSense tools can be used to train novice people or as a reminder service for AAI practice, for example, they explained that the injection training tool could provide a good reinforcement and useful feedback about the injection steps to avoid possible mistakes. Also they pointed out that the injection training tool could be useful as an educational mechanism for medical students to provide them a “ground floor” about how to use an AAI because they will have, eventually, to prescribe AAIs to patients. Interviewees also mention that AllergiSense tool could help as a way to call emergency services promptly without dialling, so that patients and carers would have a sense of confidence that “they are not exactly on their own”. They also expressed that AllergiSense could be a tool to address the fear factor that people have on AAI use.

AllergiSense advantages and disadvantages and suggestions for improvement. Participants provided many useful, interesting and insightful ideas for improvement. They mentioned that the AAI injection training tool with the sensing unit as a reminding service was useful, they liked the ticks, crosses and stars to provide feedback about the steps of the training injection, which was considered a novel way to provide injection training. They also liked the idea of having a button that dials the 999 emergency number and the text messages to emergency contacts. However, they said that the information contained in the videos could be improved (the videos were produced by the Anaphylaxis Campaign and the EpiPen® AAI manufacturer). There were also suggestions to improve usability issues including not having different paths of information in the emergency tools and avoiding repetition in the “what to

do” tool. They said that a good addition could be the detection of the thumb on top of the AAI trainer device and the addition of a talking voice tool that calls emergency services (because people experiencing an anaphylactic reaction can lose their voice) and talking voice that explains the steps of the injection. In addition they suggested improving the reliability of the injection sensing for injections done when lying down (this condition was omitted from the training data). They also mentioned that a note should be added to the emergency information tools saying that an AAI can be injected through the trousers. Training reminders and the use of scenarios that provide aids for education were also suggested.

6.4 Discussion

Four major findings were found in this study: First, clinicians expressed that smartphone tools for anaphylaxis management could be used to train people in AAI use inside and outside the clinic supplementing the traditional care system. Second, that AllergiSense tools could support patients and carers in the day-to-day anaphylaxis management and in emergency situations. Third, that medical staff and medical students could be trained with the tools implemented in AllergiSense (as training the trainers). And four, that there are no major barriers to adoption of the technology because people have already smartphones.

This study was, however, limited to a qualitative evaluation with three clinical staff participants in a one-week intervention. Nevertheless, the feedback was positive and insightful ideas about the future use of the tools were identified. Allergy specialists suggested that further work should evaluate the effects of those tools with healthy participants such as medical students and further work should consider studies with a larger number of clinicians.

6.5 Summary

This chapter presented the opinions and attitudes of clinical staff about the tools implemented in AllergiSense after having the system (smartphone and sensing unit) for one week. The opinions and suggestions collected in a semi-structured interview were positive. They highlighted that those tools could encourage AAI carriage and use, and expressed their willingness towards the use of the technology in clinical settings and outside the clinic, for example, training medical staff, medical students, patients, carers, relatives, school teachers and baby sitters and supporting patients and carers in emergencies.

Chapter 7

Conclusions and Further Work

The contribution of this thesis is three-fold: i) it defined tools for the support of anaphylaxis management; ii) it provided evidence about the ability of smartphone tools to improve AAI training and positively affect injection self-efficacy; and iii) it provided evidence of support from expert clinical evaluation regarding use and deployment. The research questions were:

What assistive smartphone tools have potential to supplement anaphylaxis management? The thesis addressed this question in two ways: i) with multi-stage prototyping that showed that step-by-step tools supporting adrenaline injection may be more effective than the traditional care system alone. And ii) through the more substantial design and evaluation of AllergiSense which provided evidence of significant benefit and also received positive opinions from three allergy specialists.

Could a smartphone tool improve adrenaline injection performance in training and positively influence self-efficacy? The results presented in the thesis showed that healthy participants using smartphone tools for injection training had significantly better performance than participants using traditional care paper documents alone. Furthermore, the results showed that participants using the technology had improved levels of self-efficacy that better reflected their actual performance, in comparison with paper-only participants that did not improve in their performance and had misguided perceptions of self-efficacy.

What is the clinical evaluation of specialists regarding the use and deployment of such tools? Interviews with three clinicians that had AllergiSense smartphone tools for one week provided positive evidence about the potential for their use in the clinic and also in the community. They also expressed encouraging attitudes towards the use and deployment of smartphone applications for anaphylaxis management. They posited that such applications could supplement the traditional care system to train people in AAI use both inside and outside the clinic, supporting patients and carers in day-to-day anaphylaxis management and also in emergency situations. They also recommended that medical staff and medical students be trained with the tools implemented in AllergiSense (i.e., training the trainers) and reported that there were no major barriers to adoption given the ubiquity of smartphones amongst patients, carers and clinical staff.

7.1 Conclusions

Anaphylaxis management has been a neglected subject in pervasive healthcare research. There are just a few simple anaphylaxis “apps” for which, like the majority of health-related “apps”, evaluation is not reported in the literature. Despite the demonstrated potential of pervasive healthcare technology and the breath of applications reported in the literature, there is comparative neglect for allergy and, in particular, for anaphylaxis, a condition which has increased worldwide to near epidemic prevalence. Although in other pervasive health applications there has often been an element of technology imposition which can present barriers to adoption, for anaphylaxis management this would be minimal since anaphylactic people and their carers already carry mobile phones (increasingly smartphones with built-in GPS) to call emergency services and they already carry AAIs.

This thesis has considered the difficulties associated with both technological prototyping and formal clinical trial evaluation. The clinical proof-of-concept prototyping proposed by Bardram (2008) provides a compromise between the two but still sets a very high goal, at least in terms of ethics and formal permissions, by recommending longitudinal studies with real users. The methodology developed and used in the design of AllergiSense has not been reported in the literature and is tentatively proposed as an incremental improvement for pervasive healthcare development. The methodology incorporates participatory design with embedded self-efficacy sources to develop a near-clinical proof-of-concept prototype, i.e., a

prototype tested by healthy participants but designed, tested and evaluated with clinical collaboration. This testing and evaluation provides results that can help support a case for further longer-term testing and testing with other larger groups of healthy participants, e.g., medical students. With positive outcomes a good case could then be made for testing with real patients.

The results of this research suggest that pervasive healthcare research has significant potential to support anaphylaxis management for people with anaphylaxis and their carers. In addition, clinician evaluation feedback identified further potential to support the training and education of medical students, practicing clinicians, health workers, childminders and school staff.

Experimental results from AllergiSense testing with healthy participants supported the main hypothesis that smartphone tools supplementing traditional care paper documents could improve the adrenaline injection performance in training and AAI self-efficacy. These improved results could be a consequence of improved training materials resulting from grounding of the design in self-efficacy as a behavioural change theory. AllergiSense included the implementation of mastery, vicarious and social experience sources of self-efficacy. In comparison the paper-only participants had only a limited modelling source of self-efficacy via text and pictures. Very possibly without realising it, participatory design focus group attendees asked for tools that could enhance levels of self-efficacy. Of course, people might intuitively ask for pictures or videos so that they can more easily copy (model) something they need to do. This suggests that participatory design in pervasive healthcare might more naturally ground solutions in self-efficacy theory, or at least help with contributing some sources of self-efficacy. These can then be enhanced further by the designer purposefully adding self-efficacy sources to tools (like the feedback injection tool in AllergiSense) that support the user requirements but might not have been explicitly proposed in the participatory design process.

Secondary outcome results showed participants reported no significant differences in workload for the different materials and interestingly, compared to the paper-only group both AllergiSense groups scored significantly better for usefulness and ease-of-use of their

materials and also reported significantly more willingness towards use. Additionally, average self-reported usability scores for AllergiSense were very positive. These results suggest really good potential usability for the technology.

Test results appeared to support other reports in the literature regarding the inadequacy of the current approach to adrenaline injection education, i.e., expert explanation and AAI demonstration and then documents for on-going support. In particular that the current approach does not monitor practice nor provide feedback and does nothing to encourage or support continuous practice. The increased level of self-efficacy in people using the traditional system in the control group was interesting and not expected, and it was not compatible with their performance. They retained this increased self-efficacy throughout the study despite the lack of any significant improvement in their performance. This could be a consequence of the lack of monitoring and feedback and it suggests that people were unable to identify their own errors and assessed their competence on incorrect assumptions about their mastery skills. This could have severe consequences, not least increased complacency and a lack of motivation for continuous practice.

7.2 Further work

Since anaphylaxis management with smartphone tools has been neglected, the amount of research that could be undertaken is vast. There is so much that could be done and so little that has been done. In every aspect of the work presented here there is scope for much more contribution. Over 2% of children are now anaphylactic in the UK and the most common allergen, peanuts, is not generally outgrown. This new generation will need support in the management of their anaphylaxis.

This thesis was limited to short-term evaluations with healthy participants in training scenarios. The clinician evaluation was limited to qualitative evaluation with three clinical staff participants in a one-week intervention. Although the results and feedback were positive, the clinical recommendation is that further work is needed to evaluate the tools with healthy participants such as medical students and with a larger number of clinicians in patient settings. Further work is also needed to populate solutions with content and define tools aimed at supporting symptom recognition and allergen avoidance. Further work could also consider the issues of

responsibility for the support and maintenance of the technology and the information contained within it. In addition, further work is needed for the creation and validation of self-efficacy questionnaires for anaphylaxis management and adrenaline injection and, importantly, much further work is needed for evaluation of tools in longitudinal studies with patients in and outside the clinic. Finally, future research could investigate how to improve injection sensing for training and perhaps also prototype new “smart” AAI designs with emergency sensing.

List of References

- Anaphylaxis Campaign UK, 2010. Helping People With Severe Allergies Live their Lives. *The anaphylaxis Campaign UK*. Available at: www.anaphylaxis.org.uk.
- Alert5, 2014. Alert5 App. *February*. Available at: <https://itunes.apple.com/fr/app/alert5/id662086772?l=en&mt=8> [Accessed June 14, 2014].
- Allen, K.J., Hill, D.J. & Heine, R.G., 2006. Food Allergy in Childhood. *Medical Journal of Australia*, 185(7), pp.394–400.
- AllergySense, 2013. AllergySense App. *May*. Available at: <https://itunes.apple.com/gb/app/allergysense/id873915095?mt=8> [Accessed June 14, 2014].
- Altman, D.G. & Bland, J.M., 1999. How to Randomise. *BMJ (Clinical research ed.)*, 319 (7211), pp.703–4.
- Anaphylactic Shock (Small Cog), 2011. Anaphylactic Shock App. *March2*. Available at: https://play.google.com/store/apps/details?id=air.Anaphylaxis&hl=en_GB [Accessed June 14, 2014].
- Anaphylaxis (Coventry University), 2013. Anaphylaxis App. *February*. Available at: <https://itunes.apple.com/gb/app/anaphylaxis/id583861393?mt=8> [Accessed June 14, 2014].
- Anaphylaxis101 (Mylan), 2012. Anaphylaxis101 App. *October*. Available at: https://play.google.com/store/apps/details?id=com.aurasma.skinned.anaphylaxis101&hl=en_GB [Accessed June 14, 2014].
- Arga, M. et al., 2011. Training of Trainers on Epinephrine Auto-Injector Use. *Pediatric allergy and immunology*, pp.1–4.
- Arga, M. et al., 2012. Effect of Epinephrine Auto-Injector Design on Unintentional Injection Injury. *Allergy and Asthma Proceedings*, 33(6), pp.488–492.
- Arnrich, B., Mayora, O., Bardram, J., et al., 2010. Pervasive Healthcare: Paving the Way for a Pervasive, User-Centered and Preventive Healthcare Model. *Methods of information in medicine*, 49(1), pp.67–73.
- Arnrich, B., Mayora, O. & Bardram, J., 2010. Pervasive or Ubiquitous Healthcare? *Methods of information in medicine*, 49(1), pp.65–66.
- Athinen, A. et al., 2009. User Experiences of Mobile Wellness Applications in Health Promotion. In *International Conference on Pervasive Computing Technologies for Healthcare. PervasiveHealth*. Tampere, Finland: IEEE, pp. 1–8.
- Auvi-Q (Sanofi-Aventis U.S. LLC), 2013. Auvi-Q App. *February*. Available at: <https://play.google.com/store/apps/details?id=com.sanofiaventis.AuviQCompanion> [Accessed June 14, 2014].

- Badinelli, E., 2006. Scanavert: Detection and Alarm Against Ingredient Harm. *CCNC 2006. 2006 3rd IEEE Consumer Communications and Networking Conference, 2006.*, 2, pp.1286–1287.
- Bakirtas, A. et al., 2011. Make-up of the Epinephrine Auto-Injector: The effect on its Use by Untrained Users. *Pediatric Allergy and Immunology: Official Publication of the European Society of Pediatric Allergy and Immunology*, 22(7), pp.729–733.
- Bandura, A., Blahard, E.B. & Ritter, B., 1969. Relative Efficacy of Desensitization and Modeling approaches for Inducing Behavioral, Affective, and Attitudinal Changes. *Journal of Personality and Social Psychology*, 13(3), pp.173–99.
- Bandura, A., 2012. On the Functional Properties of Perceived Self-Efficacy Revisited. *Journal of Management*, 38(1), pp.9–44. .
- Bandura, A., 2006. Guide for Constructing Self-efficacy Scales. In *Self-Efficacy Beliefs of Adolescents*. pp. 307–337.
- Bandura, A., 1998. Health Promotion from the Perspective of Social Cognitive Theory. *Psychology & Health*, 13(4), pp.623–649.
- Bandura, A., 1997. *Self-efficacy: The Exercise of Control*, New York, USA: W.H. Freeman.
- Bandura, A., 1977. Self-efficacy: Toward a Unifying Theory of Behavioral Change. *Psychological Review*, 84(2), pp.191–215.
- Bangor, A., Kortum, P.T. & Miller, J.T., 2008. An Empirical Evaluation of the System Usability Scale. *International Journal of Human-Computer Interaction*, 24(6), pp.574–594.
- Baral, V.R. & Hourihane, J.O., 2005. Food Allergy in Children. *Postgraduate Medical Journal*, 81(961), pp.693–701.
- Bardram, J.E., 2008. Clinical Proof-of-Concept – An Evaluation Method for Pervasive Healthcare Systems. *UbiComp '08. Workshop W2 - Ubiquitous Systems Evaluation (USE '08)*, Seoul, Korea.
- Bardram, J.E., 2008. Pervasive Healthcare as a Scientific Discipline. *Methods of Information in Medicine*, pp.178–185.
- Barlow, J., 2001. How to Use Education as an Intervention in Osteoarthritis. *Best Practice & Research. Clinical Rheumatology*, 15(4), pp.545–58.
- Barlow, J., Wright, C., Sheasby, J., Turner, A. & Hainsworth, J., 2002. Self-management Approaches for People with Chronic Conditions : A Review. *Patient Education and Counseling*, 48, pp.177–187.
- Blake, H., 2008. Innovation in Practice: Mobile Phone Technology in Patient Care. *British Journal of Community Nursing*, 13(4), pp.160, 162–5.
- Brewster, S. et al., 2003. Multimodal “ Eyes-Free ” Iteraction Techniques for Wearable Devices. In *Computer Human-Interaction CHI*.

- Brooke, J., 2006. System Usability Scale. *Usabilitynet.org*. Available at: www.usabilitynet.org/trump/documents/Suschapt.doc [Accessed June 1, 2007].
- Brown, J. et al., 2013. A Randomized Maternal Evaluation of Epinephrine Auto-Injection Devices. *Pediatric Allergy and Immunology: Official Publication of the European Society of Pediatric Allergy and Immunology*, 24(2), pp.173–7.
- Brown, S.G.A., Mullins, R.J. & Gold, M.S., 2006. Allergy - 2. Anaphylaxis: Diagnosis and Management. *Medical Journal of Australia*, 185(5), pp.283–289.
- BSACI, 2014. BSACI Allergy Action Plan. Available at: <http://www.bsaci.org/about/download-paediatric-allergy-action-plans?EID=33016898&CID=5385780> [Accessed June 20, 2014].
- ISO, 1998. ISO 9241-11. Ergonomic Requirements for Office Work with Visual Display Terminal (VDTs) - Part 11: Guidance on Usability.
- Carlisle, S.K. et al., 2010. Food Allergy Education for School Nurses: A Needs Assessment Survey by the Consortium of Food Allergy Research. *The Journal of School Nursing: The Official Publication of the National Association of School Nurses*, 26(5), pp.360–367.
- Chomutare, T. et al., 2011. Features of Mobile Diabetes Applications: Review of the Literature and Analysis of Current Applications Compared Against Evidence-Based Guidelines. *Journal of Medical Internet Research*, 13(3).
- Chu, H.T. et al., 2006. A Ubiquitous Warning System for Asthma-Inducement. In *IEEE International Conference on Sensor Networks, Ubiquitous, and Trustworthy Computing, 2006*. pp. 186–191.
- Clark, A.T. & Ewan, P.W., 2008. Good Prognosis, Clinical Features, and Circumstances of Peanut and Tree Nut Reactions in Children Treated by a Specialist Allergy Center. *The Journal of Allergy and Clinical Immunology*, 122(2), pp.286–9.
- Clatworthy, J. et al., 2009. The Value of Self-Report Assessment of Adherence, Rhinitis and Smoking in Relation to Asthma Control. *Primary Care Respiratory Journal: Journal of the General Practice Airways Group*, 18(4), pp.300–305.
- Cleland, J., Caldow, J. & Ryan, D., 2007. A Qualitative Study of the Attitudes of Patients and Staff to the Use of Mobile Phone Technology for Recording and Gathering Asthma Data. *Journal of Telemedicine and Telecare*, 13(2), pp.85–89.
- Dall, T.M. et al., 2013. An Aging Population and Growing Disease Burden will Require a Large and Specialized Health Care Workforce by 2025. *Health affairs (Project Hope)*, 32(11), pp.2013–2020.
- Dassau, E. et al., 2009. Enhanced 911/Global Position System Wizard: A Telemedicine Application for the Prevention of Severe Hypoglycemia-Monitor, Alert, and Locate. *Journal of Diabetes Science and Technology*, 3(6), pp.1501–6.
- Davidson, N. & Vance, G., 2013. React! App. Available at: <http://react-app.com>

- Davies, M.J. et al., 2008. Effectiveness of the Diabetes Education and Self- Management for Ongoing and Newly Diagnosed (DESMOND) Programme for People with Newly Diagnosed type 2 Diabetes: Cluster Randomised Controlled Trial. *BMJ*, 336 (7642), pp.491–495.
- Davis, F.D., 1989. Perceived Usefulness, Perceived Ease of Use, and User Acceptance of Information Technology. *Management Information Systems*, 13(3), pp.319–340.
- Devaul, R.W. & Dunn, S., 2001. Real-Time Motion Classification for Wearable Computing Applications.
- Dey, A.K. & Estrin, D., 2011. Perspectives on Pervasive Health from Some of the Field’s Leading Researchers. *IEEE Pervasive Computing*, 10(2), pp.4–7.
- Diwakar, L. et al., 2010. Self-Injectable Adrenaline Devices: Is Training Necessary? *Journal of Investigational Allergology and Clinical Immunology*, 20(5), pp.446–453.
- Doherty, G., Coyle, D. & Matthews, M., 2010. Design and Evaluation Guidelines for Mental Health Technologies, 22 (4).
- Dumas, J.S. & Redish, J.C., 1999. *A Practical Guide to Usability Testing*, Portland, Oregon. USA: Intellect Books.
- Editors, C. et al., 2005. The Diagnosis and Management of Anaphylaxis: An Updated Practice Parameter. *The Journal of Allergy and Clinical Immunology*, 115 (3 Suppl 2), pp.S483–S523.
- Ellis, A.K. & Day, J.H., 2007. Incidence and Characteristics of Biphasic Anaphylaxis: A prospective Evaluation of 103 Patients. *Annals of Allergy, Asthma & Immunology: Official Publication of the American College of Allergy, Asthma, & Immunology*, 98 (1), pp.64–69.
- emergencySMS.org.uk, 2012. SMS to the Emergency Services. Available at: <http://www.emergencysms.org.uk/>.
- Ewan, P.W. & Clark, A.T., 2005. Efficacy of a Management Plan Based on Severity Assessment in Longitudinal and Case-Controlled Studies of 747 Children with Nut Allergy: Proposal for Good Practice. *Clinical and Experimental Allergy*, 35(6), pp.751–756.
- Faridi, Z. et al., 2008. Evaluating the Impact of Mobile Telephone Technology on Type 2 Diabetic Patients’ Self-Management: The NICHE Pilot Study. *Journal of Evaluation in Clinical Practice*, 14(3), pp.465–469.
- fcc.gov, 2014. Text-to-911. Available at: <http://www.fcc.gov/text-to-911>.
- Field, A., 2000. *Discovering Statistics Using SPSS for Windows*, London: SAGE Publications Ltd.
- Fjeldsoe, B.S., Marshall, A.L. & Miller, Y.D., 2009. Behavior Change Interventions Delivered by Mobile Telephone Short-Message Service. *American Journal of Preventive Medicine*, 36(2), pp.165–173.
- Free, C. et al., 2013. The Effectiveness of Mobile-Health Technology-Based Health Behaviour Change or Disease Management Interventions for Health Care Consumers: A Systematic Review. *PLoS Medicine*, 10(1).

- Frew, a J., 2011. What are the “Ideal” Features of an Adrenaline (Epinephrine) Auto-Injector in the Treatment of Anaphylaxis? *Allergy*, 66(1), pp.15–24.
- Fukuoka, Y. et al., 2010. Innovation to Motivation-Pilot Study of a Mobile Phone Intervention to Increase Physical Activity Among Sedentary Women. *Preventive Medicine*, 51(3-4), pp.287–289.
- Gallagher, M. et al., 2011. Epinephrine Auto-Injector Use in Adolescents at Risk of Anaphylaxis: A Qualitative Study in Scotland, UK. *Clinical and Experimental Allergy*, 41(6), pp.869–877.
- Gassner, K. et al., 2005. Smart Food: Mobile Guidance for Food-Allergic People. In *seventh IEEE International Conference on E-Commerce Technology, 2005. CEC 2005*. pp. 531–534.
- Glanz, K. & Bishop, D.B., 2010. The Role of Behavioral Science Theory in Development and Implementation of Public Health Interventions. *Annual Review of Public Health*, 31, pp.399–418.
- Gold, M.S. & Sainsbury, R., 2000. First Aid Anaphylaxis Management in Children Who Were Prescribed an Epinephrine Auto-Injector device (EpiPen). *Journal of Allergy and Clinical Immunology*, 106(1), pp.171–176.
- Gómez, E.J. et al., 2008. The INCA System: A Further Step Towards a Telemedical Artificial Pancreas. *IEEE Transactions on Information Technology in Biomedicine: A publication of the IEEE Engineering in Medicine and Biology Society*, 12(4), pp.470–479.
- Gosbee, L.L., 2004. Nuts ! I Can't Figure Out How to See my Life-Saving Epinephrine Auto-Injector! *Joint Commission Journal on Quality and Safety Human*, 30(4), pp.220–223.
- Gregg, J.A. et al., 2007. Improving Diabetes Self-Management Through Acceptance, Mindfulness, and Values: A Randomized Controlled Trial. *Journal of Consulting and Clinical Psychology*, 75(2), pp.336–343.
- Gupta, R. et al., 2007. Time Trends in Allergic Disorders in the UK. *Thorax*, 62(1), pp.91–96.
- Haapala, I. et al., 2009. Weight Loss by Mobile Phone: A 1-year Effectiveness Study. *Public health Nutrition*, 12(12), pp.2382–2391.
- Haggbloom, S.J. et al., 2002. The 100 Most Eminent Psychologists of the 20th Century. *Review of General Psychology*, 6(2), pp.139–152.
- Holtz, B. & Whitten, P., 2009. Managing Asthma with Mobile Phones: A Feasibility Study. *Telemedicine Journal and E-Health: The Official Journal of the American Telemedicine Association*, 15(9), pp.907–909.
- Hong, J.H. et al., 2007. A Wireless Three-Channel ECG Transmission System Using PDA Phone. In *International Conference on Convergence Information Technology, 2007*. pp. 462–465.
- Huckvale, K. et al., 2012. Apps for Asthma Self-Management: A Systematic Assessment of Content and Tools. *BMC medicine*, 10(1), p.144.
- ISO, 2010. ISO 9241-210:2010, Ergonomics of Human-System Interaction - Part 210: Human-Centred Design for Interactive Systems, pp.32. Available at:
http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=52075.

- Jaervinen, K.M., 2011. Food-Induced Anaphylaxis. *Current Opinion in Allergy and Clinical Immunology*, 11(3), pp.255–261.
- Jara, A.J. et al., 2010. A Pharmaceutical Intelligent Information System to Detect Allergies and Adverse Drugs Reactions Based on Internet of things. In *2010 8th IEEE International Conference on Pervasive Computing and Communications Workshops (PERCOM Workshops)*. pp. 809–812.
- Jara, A.J., Zamora, M. a. & Skarmeta, A.F., 2012. Drug Identification and Interaction Checker Based on IoT to Minimize Adverse Drug Reactions and Improve Drug Compliance. *Personal and Ubiquitous Computing*.
- Jext (ALK-Abelló), 2013. Jext App. *June*. Available at: https://play.google.com/store/apps/details?id=com.androidapp.alkabello.jext_uk&hl=en_GB [Accessed June 14, 2014].
- Jones, M. & Marsden, G., 2006. *Mobile Interaction Design*, London: John Wiley & Sons, Ltd.
- JTEHM, 2014. *IEEE Journal of Translational Engineering in Health and Medicine*. Available at: <http://health.embs.org/>
- Kastner, M., Harada, L. & Wasserman, S., 2010. Gaps in Anaphylaxis Management at the Level of Physicians, Patients, and the Community: A Systematic Review of the Literature. *Allergy*, 65(4), pp.435–444.
- Kemp, S.F., Lockey, R.F. & Simons, F.E.R., 2008. Epinephrine: The Drug of Choice for Anaphylaxis. A statement of the World Allergy Organization. *Allergy*, 63(8), pp.1061–70.
- Von Korff, M. et al., 1997. Collaborative Management of Chronic Illness. *Annals of Internal Medicine*, 127(12), pp.1097–1102.
- Korhonen, I. & Bardram, J.E., 2004. Guest Editorial: Introduction to the Special Section on Pervasive Healthcare. *IEEE Transactions on Information Technology in Biomedicine: A Publication of the IEEE Engineering in Medicine and Biology Society*, 8(3), pp.229–234.
- Koyle, A.E., 2013. *The Value of Infusing Self-efficacy Theory with Smartphone Technology to Sustain Walking for Exercise in a Worksite Population*.
- Kränke, B. et al., 2011. How to Improve the Safety of Adrenaline (Epinephrine) Auto-Injectors. *The Journal of Allergy and Clinical Immunology*, 127(6), pp.1645.
- Krishna, S., Boren, S.A. & Balas, E.A., 2009. Healthcare Via Cell Phones: A Systematic Review. *Telemedicine Journal and E-health: The Official Journal of the American Telemedicine Association*, 15(3), pp.231–40.
- Kujala, S., 2003. User Involvement: A Review of the Benefits and Challenges. *Behaviour & Information Technology*, 22(1), pp.1–16.
- Kwapisz, J.R., Weiss, G.M. & Moore, S.A., 2010. Activity Recognition using Cell Phone Accelerometers.

- Lee, C., 2011. *Being prepared for an Anaphylactic Reaction at School: The Unlicensed Assistive Personnels' Perspective*.
- Lee, J.K. & Vadas, P., 2011. Anaphylaxis: Mechanisms and Management. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology*, 41(7), pp.923–938.
- Lehnert, T. et al., 2011. Review: Health Care Utilization and Costs of Elderly Persons with Multiple Chronic Conditions. *Medical Care Research and Review: MCRR*, 68(4), pp.387–420.
- Lieberman, P. et al., 2006. Epidemiology of Anaphylaxis: Findings of the American College of Allergy, Asthma and Immunology. Epidemiology of Anaphylaxis Working Group. *Annals of Allergy, Asthma & Immunology*, 97(5), pp.596–602.
- Lieberman, P. et al., 2010. The Diagnosis and Management of Anaphylaxis Practice Parameter: 2010 Update. *The Journal of Allergy and Clinical Immunology*, 126(3), pp.477–480.
- Lin, R.Y. et al., 2008. Increasing Anaphylaxis Hospitalizations in the First 2 Decades of Life: New York State, 1990 -2006. *Annals of Allergy, Asthma & Immunology: Official Publication of the American College of Allergy, Asthma, & Immunology*, 101(4), pp.387–393.
- Litarowsky, J. a., Murphy, S.O. & Canham, D.L., 2004. Evaluation of an Anaphylaxis Training Program for Unlicensed Assistive Personnel. *The Journal of School Nursing*, 20(5), pp.279–284.
- Lorig, K. & Holman, H., 2003. Self-Management Education: History, Definition, Outcomes, and Mechanisms. *Annals of Behavioral Medicine*, 26(1), pp.1–7.
- Lorig, K.R. et al., 2001. Chronic Disease Self-Management Program - 2-year Health Status and Health Care Utilization Outcomes. *Medical Care*, 39(11), pp.1217–1223.
- Lorig, K.R. & Holman, H., 2003. Self-Management Education: History, Definition, Outcomes, and Mechanisms. *Annals of Behavioral Medicine: A Publication of the Society of Behavioral Medicine*, 26(1), pp.1–7.
- Luckhurst, H. M., Tuthill, D., Brown, J., Spear, E., & Pitcher, J., 2013. Anapen, EpiPen and Jext Auto-Injectors: Assessment of Successful Use After Current Training Package. *Archives of Disease in Childhood*, 98 (Suppl 1), pp.A42–A43.
- Macadam, C. et al., 2012. What Factors Affect the Carriage of Epinephrine Auto-Injectors by Teenagers? *Clinical and Translational Allergy*, 2(1), p.3.
- Marcano Belisario, J.S., Huckvale, K., Greenfield, G., Car, J. & Gunn, L.H., 2013. Smartphone and Tablet Self-Management Apps for Asthma (Review). *The Cochrane Library* 2013, Issue 11.
- Matthews, M. et al., 2008. Designing Mobile Applications to Support Mental Health Interventions, (1), pp.635–656.
- Medscape (WebMD, L.), 2014. Medscape App. *May*. Available at: https://play.google.com/store/apps/details?id=com.medscape.android&hl=en_GB [Accessed June 4, 2014].

- Mehr, S., Robinson, M. & Tang, M., 2007. Doctor - How Do I Use My EpiPen? *Pediatric Allergy and Immunology*, 18(5), pp.448–452.
- Moneret-Vautrin, D. et al., 2005. Epidemiology of Life-Threatening and Lethal Anaphylaxis: A Review. *Allergy*, 60(4), pp.443–51.
- Mosa, A.S.M., Yoo, I. & Sheets, L., 2012. A Systematic Review of Healthcare Applications for Smartphones. *BMC Medical Informatics and Decision Making*, 12(67), pp.1–30.
- Muller, M.J., 1991. PICTIVE -An Exploration in Participatory Design. In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*. New York, USA: ACM, pp. 225–231.
- Muller, M.J. & Kuhn, S., 1993. Participatory Design. *Communications of the ACM*, 36(4), pp.24–28.
- Mulvenna, M. et al., 2007. COGKNOW: Translating Research Innovation into Products and Services. In *Expanding the Knowledge Economy, Issues, Applications, Case Studies*. pp. 575–583.
- Mulvenna, M.D. et al., 2010. Supporting People with Dementia Using Pervasive Health Technologies. In M. D. Mulvenna & C. D. Nugent, eds. *Advanced Information and Knowledge Processing*. London: Springer London, pp. 3–14.
- Muraro, a et al., 2007. The Management of Anaphylaxis in Childhood: Position Paper of the European Academy of Allergology and Clinical Immunology. *Allergy*, 62(8), pp.857–871.
- NASA, 2003. NASA TLX: Task Load Index. NASA. Available at: <http://humansystems.arc.nasa.gov/groups/TLX/>.
- National Institute of Allergy and Infectious Diseases (USA), 2010. *Guidelines for the Diagnosis and Management of Food Allergy in the United States*.
- Nguyen, N. et al., 2012. Immunology Management of Anaphylaxis in Schools: Evaluation of an Epinephrine Auto-Injector (EpiPen W) Used by school Personnel and Comparison of Two Approaches of Soliciting Participation, pp.1–8.
- NHS, 2013. Clinical Trials and Medical Research - Clinical Trials. *January*. Available at: <http://www.nhs.uk/conditions/clinical-trials/pages/clinical-trial.aspx> [Accessed June 15, 2013].
- NHS, 2014. Leicester Royal Infirmary. Available at: <http://www.leicestershospitals.nhs.uk/aboutus/our-hospitals/leicester-royal-infirmary/> [Accessed August 10, 2014].
- NHS, 2012. Expert Patients Programme. Available at: <http://www.nhs.uk/conditions/Expert-patients-programme-/Pages/Introduction.aspx> [Accessed March 15, 2012].
- NICE, 2011. Anaphylaxis Assessment to Confirm an Anaphylactic Episode and the Decision to refer after Emergency Treatment for a Suspected Anaphylactic Episode. *NICE Clinical Guideline*.
- NICE BNF (NICE), 2013. NICE BNF App. *September*. Available at: <https://itunes.apple.com/gb/app/nice-bnf/id523093958?mt=8> [Accessed July 15, 2014].

- NICE Guidance (NICE), 2012. NICE Guidance App. *November*. Available at: <https://itunes.apple.com/gb/app/nice-guidance/id505146575?mt=8> [Accessed June 7, 2014].
- Noimark, L. et al., 2012. The Use of Adrenaline Auto-Injectors by Children and Teenagers. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology*, 42(2), pp.284–92.
- Norris, S.L. et al., 2002. Self-management Education for Adults with type 2 diabetes - A Meta-Analysis of the Effect on Glycemic Control. *Diabetes Care*, 25(7), pp.1159–1171.
- Norris, S.L., Engelgau, M.M. & Narayan, K.M. V., 2001. Effectiveness of Self-Management Training in Type 2 Diabetes - A Systematic Review of Randomized Controlled Trials. *Diabetes care*, 24(3), pp.561–587.
- Patel, B.M., Bansal, P.J. & Tobin, M.C., 2006. Management of Anaphylaxis in Child Care Centers: Evaluation 6 and 12 months After an Intervention Program. *Annals of Allergy, Asthma & Immunology: Official Publication of the American College of Allergy, Asthma, & Immunology*, 97(6), pp.813–5.
- Pinnock, H. et al., 2006. Professional and Patient Attitudes to Using Mobile Phone Technology to Monitor Asthma: Questionnaire Survey. *Primary Care Respiratory Journal: Journal of the General Practice Airways Group*, 15(4), pp.237–245.
- Poulos, L.M. et al., 2007. Trends in Hospitalizations for Anaphylaxis, Angioedema, and Urticaria in Australia, 1993-1994 to 2004-2005. *The Journal of Allergy and Clinical Immunology*, 120(4), pp.878–84.
- Preece, J., Rogers, Y. & Sharp, H., 2002. *Interaction Design, Beyond Human-Computer Interaction*, New York: Wiley & Sons, Inc.
- Pumphrey, R., 2004. Anaphylaxis: Can We Tell Who is at Risk of a Fatal Reaction?, *Current Opinion in Allergy and Clinical Immunology*, 4(4), pp.285–90.
- Pumphrey, R., 2011. Deaths from Anaphylaxis. British Society for Allergy and Clinical Immunology. Annual Meeting.
- Pumphrey, R.S., 2000. Lessons for Management of Anaphylaxis from a Study of Fatal Reactions. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology*, 30(8), pp.1144–1150.
- Resuscitation Council (UK), 2008. Emergency Treatment of Anaphylactic Reactions. *Guidelines for healthcare providers*.
- Rosser, B.A. & Eccleston, C., 2011. Smartphone Applications for Pain Management. *Journal of Telemedicine and Telecare*, 17(6), pp.308–312.
- Royal College of Paediatrics and Child Health (RCPCH), 2011. *Allergy Care Pathways for Children. Anaphylaxis*.
- Ryan, D. et al., 2012. Clinical and Cost Effectiveness of Mobile Phone Supported Self-Monitoring of Asthma: Multicentre Randomised Controlled Trial. *BMJ*, 344 , pp.1–15.

- Ryan, D. et al., 2005. Mobile Phone Technology in the Management of Asthma. *Journal of Telemedicine and Telecare*, 11 (Suppl 1), pp.43–46.
- Salvador, C.H. et al., 2005. Airmed-cardio: A GSM and Internet Services-Based System for Out-of-Hospital Follow-Up of Cardiac Patients. *IEEE Transactions on Information Technology in Biomedicine: A Publication of the IEEE Engineering in Medicine and Biology Society*, 9(1), pp.73–85.
- Sampson, H. et al., 2006. Second Symposium on the Definition and Management of Anaphylaxis: Summary Report - Second National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network Symposium. *Annals of Emergency Medicine*, 47(4), pp.373–380.
- Saponas, T.S. et al., 2008. iLearn on the iPhone: Real-Time Human Activity Classification on Commodity Mobile Phones, Seattle.
- Sarashon-Kahn, J., 2010. How Smartphones are Changing Healthcare for Consumers and Providers.
- Scherr, D. et al., 2009. Effect of Home-Based Telemonitoring Using Mobile Phone Technology on the Outcome of Heart Failure Patients After an Episode of Acute Decompensation: Randomized Controlled Trial. *Journal of Medical Internet Research*, 11(3).
- Sheikh, A. & Alves, B., 2000. Hospital Admissions for Acute Anaphylaxis: Time Trend Study. *BMJ*, 320(7247), pp.1441.
- Sheikh, A., 2011. Managing Anaphylaxis in Primary Care. British Society for Allergy and Clinical Immunology. Annual Meeting.
- Sherwood, A., 2007. *Allergy-Free Cookbook*, London, UK: Dorling Kindersley Limited.
- Sicherer, S.H., Forman, J. A. & Noone, S. A., 2000. Use Assessment of Self-Administered Epinephrine Among Food-Allergic Children and Pediatricians. *Pediatrics*, 105(2), pp.359–362.
- Sicherer, S.H. & Mahr, T., 2010. Management of Food Allergy in the School Setting. *Pediatrics*, 126(6), pp.1232–9.
- Sicherer, S.H. & Sampson, H.A., 2010. Food Allergy. *Journal of Allergy and Clinical Immunology*, 125(2), pp.116–125.
- Simon, M.R. & Mulla, Z.D., 2008. A Population-Based Epidemiologic Analysis of Deaths from Anaphylaxis in Florida. *Allergy*, 63(8), pp.1077–83.
- Simons, F.E.R. et al., 2011. 2012 Update: World Allergy Organization Guidelines for the Assessment and Management of Anaphylaxis. *World Allergy Organization*, 12(4), pp.13–37.
- Simons, F.E.R., 2006. Anaphylaxis, Killer Allergy: Long-Term Management in the Community. *The Journal of Allergy and Clinical Immunology*, 117(2), pp.367–77.
- Simons, F.E.R., 2010. Anaphylaxis. *The Journal of Allergy and Clinical Immunology*, 125(Suppl 2), pp.S161–S181.

- Simons, F.E.R., 2009. Anaphylaxis: Recent Advances in Assessment and Treatment. *The Journal of Allergy and Clinical Immunology*, 124(4), pp.625–36.
- Simons, F.E.R. & Sampson, H. A, 2008. Anaphylaxis Epidemic: Fact or Fiction? *The Journal of Allergy and Clinical Immunology*, 122(6), pp.1166–1168.
- Smith, T.K., 2011. Needs Analysis: Or, How Do You Capture, Represent, and Validate User Requirements in a Formal Manner/Notation Before Design. In N. A. Karwowski W, Soares M M, Stanton, ed. *Human Factors and Ergonomics in Consumer Product Design: Methods and Techniques (Handbook of Human Factors in Consumer Product Design)*.
- Statista, 2014. Global Smartphone Penetration from 2008 to 2014 (In Percent of New Handset Sales). Available at: <http://www.statista.com/statistics/218532/global-smartphone-penetration-since-2008/> [Accessed July 25, 2014].
- Strachan, D.P., 1989. Hay Fever, Hygiene, and Household Size. *BMJ* 299 (6710), pp.1259–1260.
- Tang, A.W., 2003. A Practical Guide to Anaphylaxis. *American Family Physician*, 68(7), pp.1325–1332.
- Taub, D. et al., 2011. The Escort System: A Safety Monitor for People Living with Alzheimer’s Disease. *IEEE Pervasive Computing*, 10(2), pp.68–77.
- The Royal College of Physicians, U.K., 2003. *Allergy: The Unmet Need*.
- The World Allergic Organization, 2006. Anaphylaxis: Synopsis. Available at: http://www.worldallergy.org/professional/allergic_diseases_center/anaphylaxis/anaphylaxisynopsis.php [Accessed April 21, 2012].
- Allergy UK, 2011. Available at: <http://www.allergyuk.org/>.
- UK Census, 2011. Available at: http://www.ons.gov.uk/ons/guide-method/census/2011/index.html?utm_source=twitterfeed&utm_medium=twitter [Accessed August 5, 2014].
- Umasunthar, T. et al., 2013. Incidence of Fatal Food Anaphylaxis in People with Food Allergy: A Systematic Review and Meta-Analysis. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology*, 43(12), pp.1333–1341.
- Varshney, U., 2003. Pervasive Healthcare. *Computer*, 36(12), pp.138–140.
- Varshney, U., 2007. Pervasive Healthcare and Wireless Health Monitoring. *Mobile Networks and Applications*, 12(2-3), pp.113–127.
- Vavoula, G. & Lonsdale, P., 2007. Mobile Learning for Young Allergy Sufferers: A Report Exploring Research Opportunities, Challenges, Methods and Best Practices.
- Visser, B.J., Korevaar, D. a & Nolan, T., 2013. Mobile Medical Apps: Dangers and Potential Solutions. *Journal of Telemedicine and Telecare*, pp.1–2.

- Waikato Environment for Knowledge Analysis, 2012. *WEKA*. Available at: http://www.cs.waikato.ac.nz/ml/weka/index_downloading.html [Accessed January 15, 2012].
- Walker, S. et al., 2010. Primary Care Training for Adults and Children with Confirmed Anaphylaxis Requiring Treatment with Adrenaline. *Primary Health Care*, 20(7), pp.33–40.
- Walker, S. & Sheikh, a, 2003. Managing Anaphylaxis: Effective Emergency and Long-Term Care are Necessary. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology*, 33(8), pp.1015–1018.
- Wang, J., 2010. Management of the Patient with Multiple Food Allergies. *Current Allergy and Asthma Reports*, 10(4), pp.271–277.
- Wang, S. et al., 2005. Human Activity Recognition with User-Free Accelerometers in the Sensor Networks. *2005 International Conference on Neural Networks and Brain*, 2, pp.1212–1217.
- Warner M.A. et al., 2006. Allergy Practice Worldwide: A Report by the World Allergy Organization Specialty and Training Council. *Journal of the World Allergy Organization*, 18(1), pp.4–10.
- WHO, 2014. The Top 10 Causes of Death. *May*. Available at: <http://www.who.int/mediacentre/factsheets/fs310/en/> [Accessed June 3, 2014].
- WhyRiskIt? (Anaphylaxis Canada), 2014. WhyRiskIt? App. *March*. Available at: <https://play.google.com/store/apps/details?id=com.anaphylaxiscanada.whyriskit2> [Accessed June 14, 2014].
- Xu, Y.S. et al., 2010. Food Allergy Management from the Perspective of Patients or Caregivers, and Allergists: A Qualitative Study. *Allergy, Asthma, and Clinical Immunology: Official Journal of the Canadian Society of Allergy and Clinical Immunology*, 6(1), p.30.
- Yung-Hsiu, L. et al., 2009. Developing Diabetes Self-Care Supporting Service: A Systemic Approach. In *IEEE International Conference on Service-Oriented Computing and Applications (SOCA)*, 2009.
- Zhang, S. et al., 2010. Activity Monitoring Using a Smart Phone's Accelerometer with Hierarchical Classification. *2010 Sixth International Conference on Intelligent Environments*, pp.122–127.

A Mobile Context-Aware Device to Help People with Anaphylaxis

Luis U. Hernandez-Munoz, Sandra I. Woolley and Chris Baber.

Electronic, Electrical and Computer Engineering, University of Birmingham.
Edgbaston, Birmingham B15 2TT, United Kingdom.
{LXH615, S.I.Woolley, C.Baber} @bham.ac.uk

Abstract. This paper presents PervaLaxis, a Personal Ubiquitous Health Device that can help patients with life-threatening allergies to manage their health in normal life and in emergency scenarios. With mobile Context-Aware smartphone technology and web-based interfaces, it is being designed to encourage the patient and their carers to learn about and safely manage their allergies and health. The design also includes an alarm that can be generated from sensed context-awareness if an anaphylactic reaction occurs.

Keywords: Ubiquitous computing, anaphylaxis, context-aware healthcare.





A Mobile Health Device to Help People with Severe Allergies

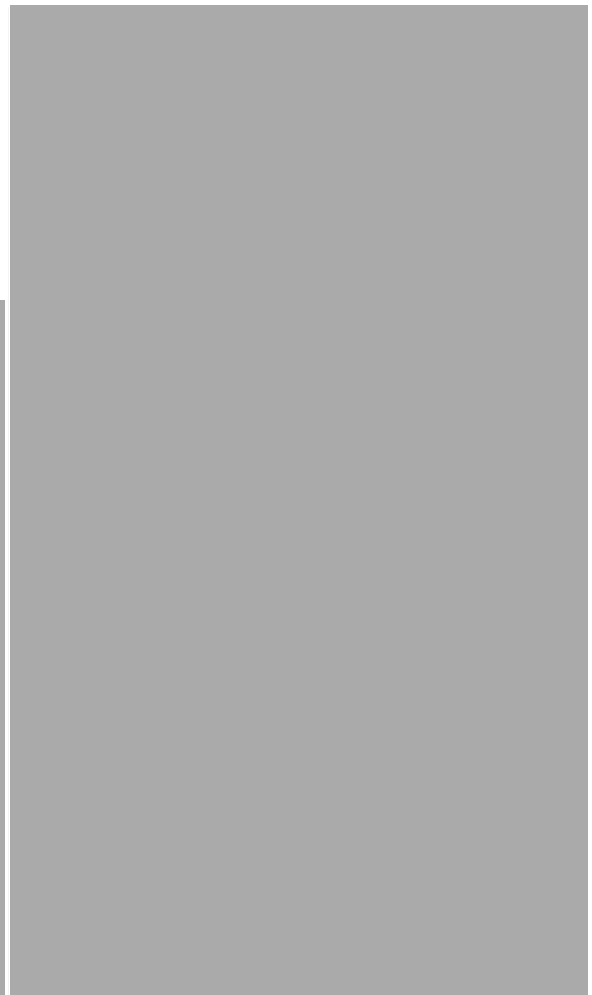
Luis U. Hernandez Munoz, Sandra I. Woolley and Chris Baber

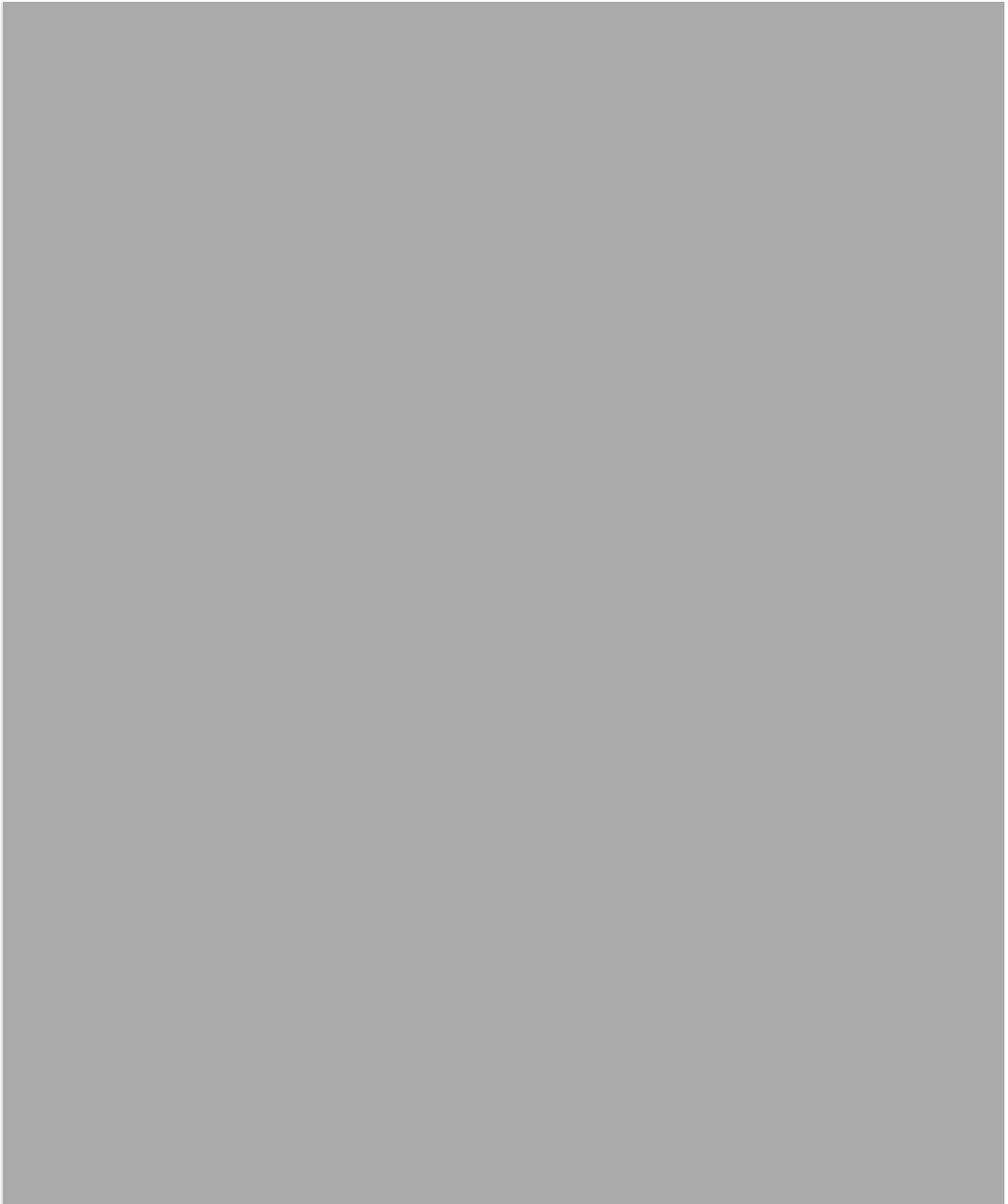
Electronic, Electrical and Computer Engineering
University of Birmingham

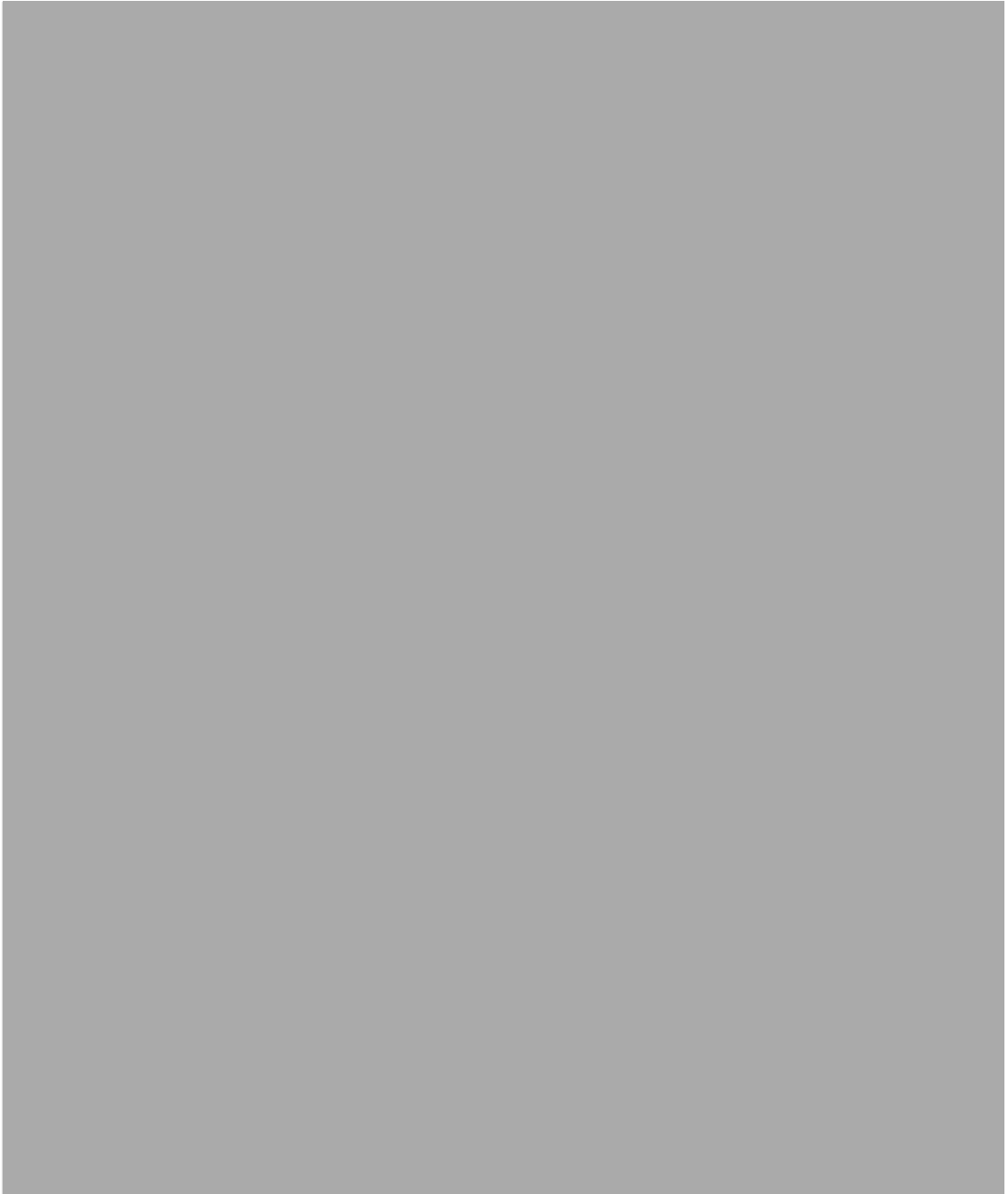
Birmingham, United Kingdom, B15 2TT
{LXH615, S.I.Woolley, C.Baber}@bham.ac.uk

Abstract— This paper presents, a Pervasive Mobile Health Device that can help patients with life-threatening allergies to manage their health in normal life and in emergency scenarios. With mobile context-aware smartphone technology, personal wireless networks and web-based interfaces, it is being designed to encourage the patient and their carers to learn about and safely manage their allergies and health. The design also includes an alarm that can be generated from sensed context so that if an anaphylactic reaction occurs, carers could be alerted or emergency services could be contacted.

Keywords- *Pervasive Computing, allergies, context-aware healthcare.*







Proceedings of the 9th International Conference on Information Technology and Applications in Biomedicine, ITAB 2009, Larnaca, Cyprus, 5-7 November 2009

A user-centered mobile health device to manage life-threatening anaphylactic allergies and provide support in allergic reactions

Luis U. Hernandez Munoz and Sandra I. Woolley

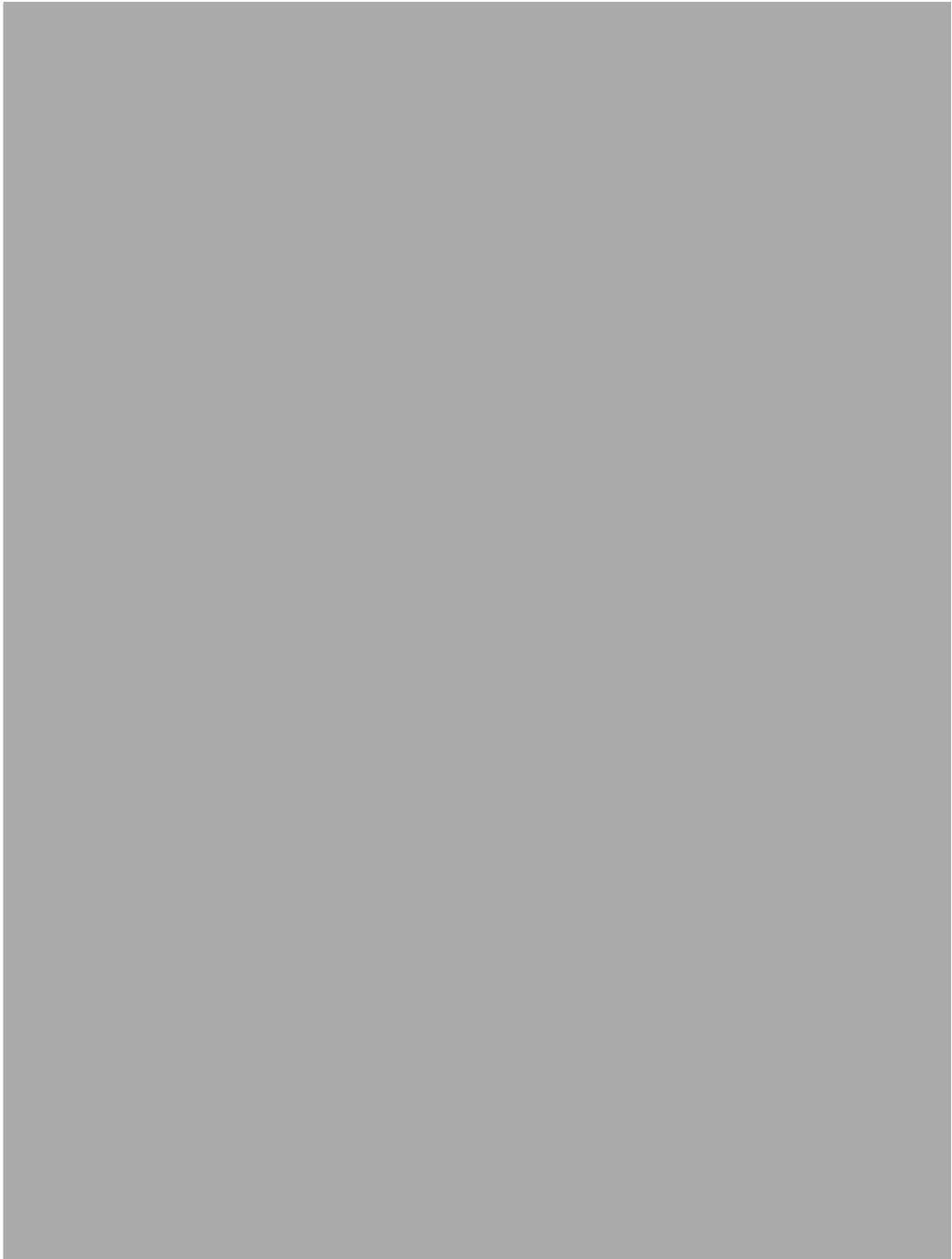
Abstract—This paper presents a user-centered mobile health device to help people with life-threatening allergies request emergency services in the case of an anaphylactic attack. The device was designed as a support tool to directly assist anaphylactic people and their carers, as opposed to a medical resource designed for practitioners. It makes use of multimedia technology, for example, with first aid video demonstrations showing how to deliver life-saving adrenaline injections using the injectors typically carried by anaphylactic people.

A 3-axis accelerometer mounted on the adrenaline injector sends data via Bluetooth to the Smartphone platform and injections events can be automatically sensed and communicated together with personal information and GPS location. Emergency services can receive an alarm and a web-based application can show a patient record and provide a map of their location. This paper describes the health management and alarm functions of the device and presents usability test results from real anaphylactic users.

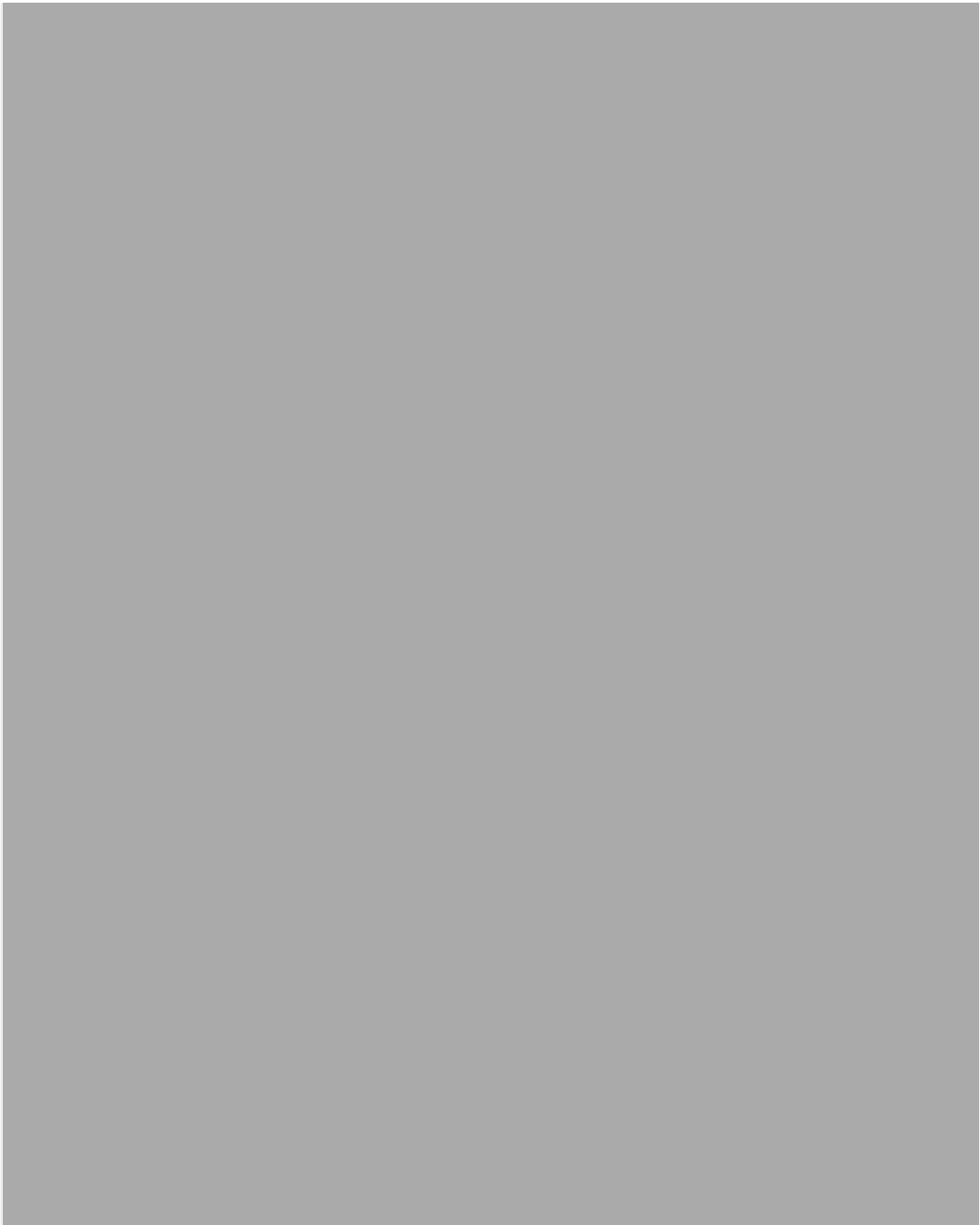
Index Terms— *Mobile phone, user-centered design, allergies, handheld, healthcare computing.*

978-1-4244-5379-5/09/\$26.00 ©2009 IEEE

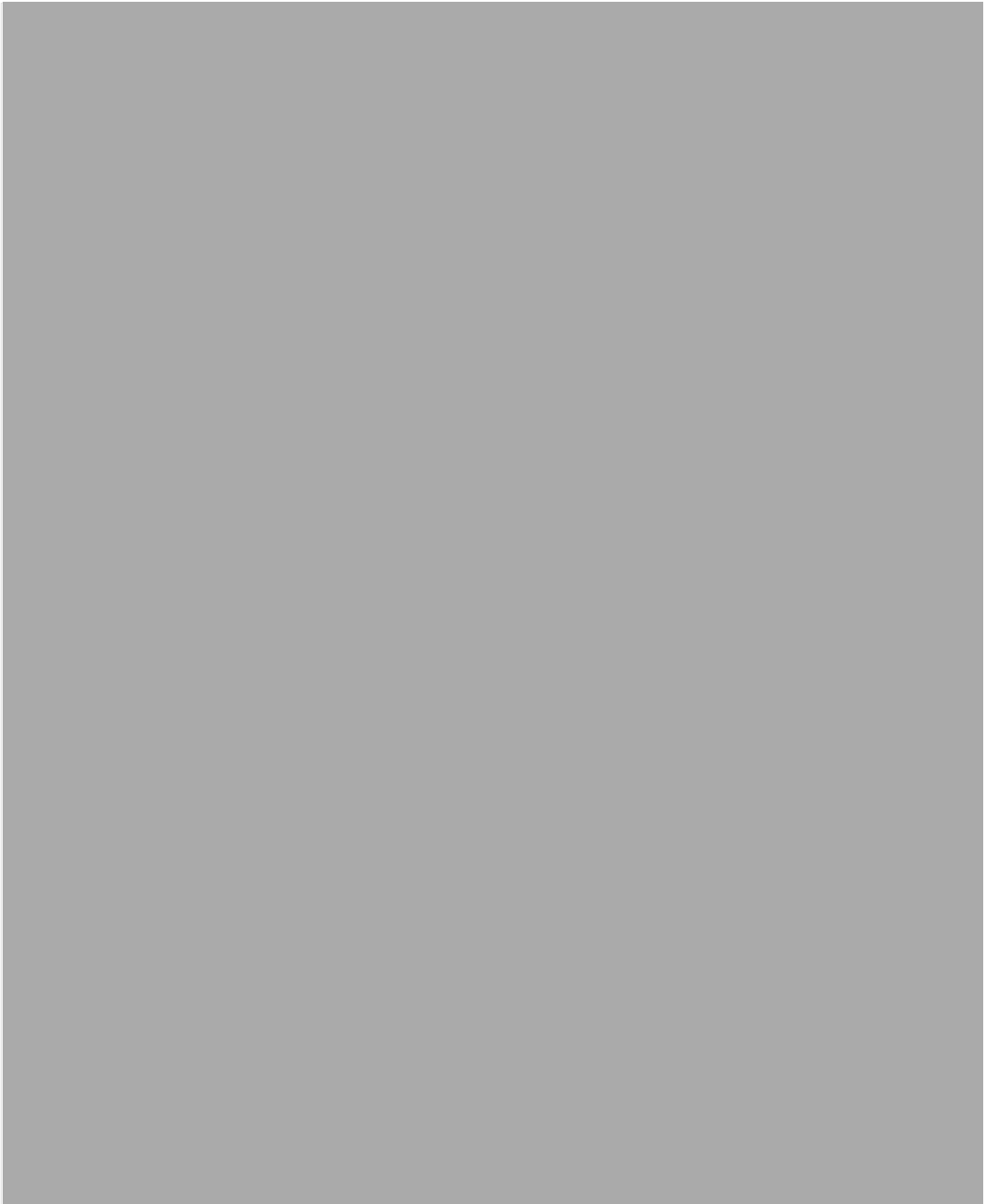
Authorized licensed use limited to: UNIVERSITY OF BIRMINGHAM. Downloaded on May 12, 2010 at 08:55:30 UTC from IEEE Xplore. Restrictions apply.



Authorized licensed use limited to: UNIVERSITY OF BIRMINGHAM. Downloaded on May 12, 2010 at 08:55:30 UTC from IEEE Xplore. Restrictions apply.



Authorized licensed use limited to: UNIVERSITY OF BIRMINGHAM. Downloaded on May 12, 2010 at 08:55:30 UTC from IEEE Xplore. Restrictions apply.



Authorized licensed use limited to: UNIVERSITY OF BIRMINGHAM. Downloaded on May 12, 2010 at 08:55:30 UTC from IEEE Xplore. Restrictions apply.

A personal handheld device to support people with life-threatening anaphylactic allergies (PervaLaxis)

*Luis U. Hernandez Munoz
University of Birmingham, UK*

*Sandra I. Woolley
University of Birmingham, UK*

ABSTRACT

This paper presents PervaLaxis, a personal mobile health device designed to help anaphylactic people manage their life-threatening allergies. PervaLaxis was designed to support allergic patients both in everyday life and in emergency scenarios where an injection of adrenaline may be vital. PervaLaxis is implemented on a Smartphone platform and communicates wirelessly with adrenaline injectors. In emergency scenarios, PervaLaxis can detect an injection of adrenaline and send a message automatically to emergency services; in normal life PervaLaxis can support adrenaline injector training, for example with video demonstrations and can support medication management, for instance, managing adrenaline expiration dates.

In this paper we present user requirements and evaluation results for PervaLaxis, furthermore we explore the issues associated with the patient-oriented focus of the device (as opposed to health devices designed for expert use) and how this could benefit personal health management. We evaluate usability performance and propose directions for future work based on user feedback.

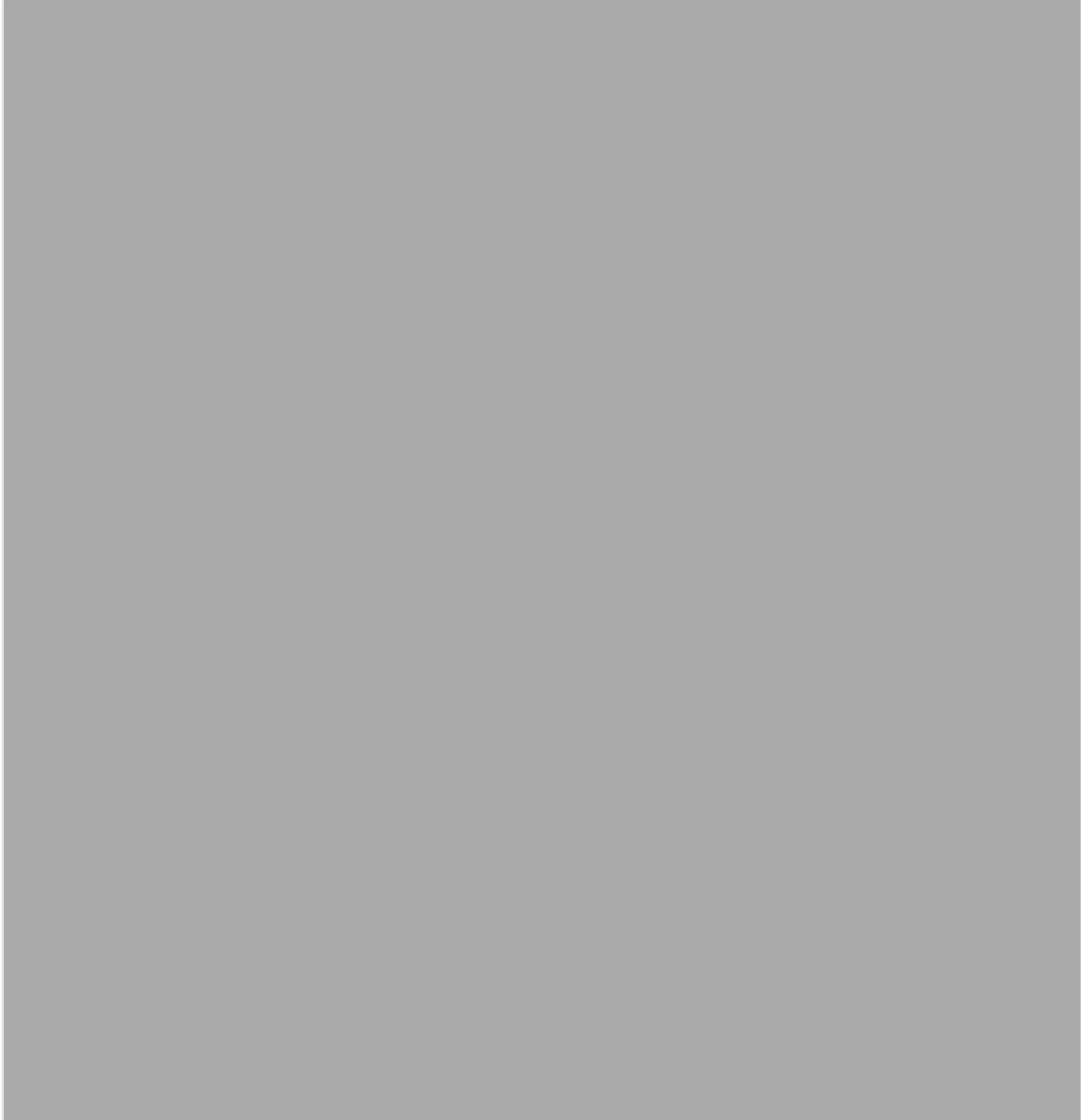
Keywords: Handheld computing, mobile technologies, pervasive healthcare, anaphylaxis, allergies, mobile learning, wireless networks.



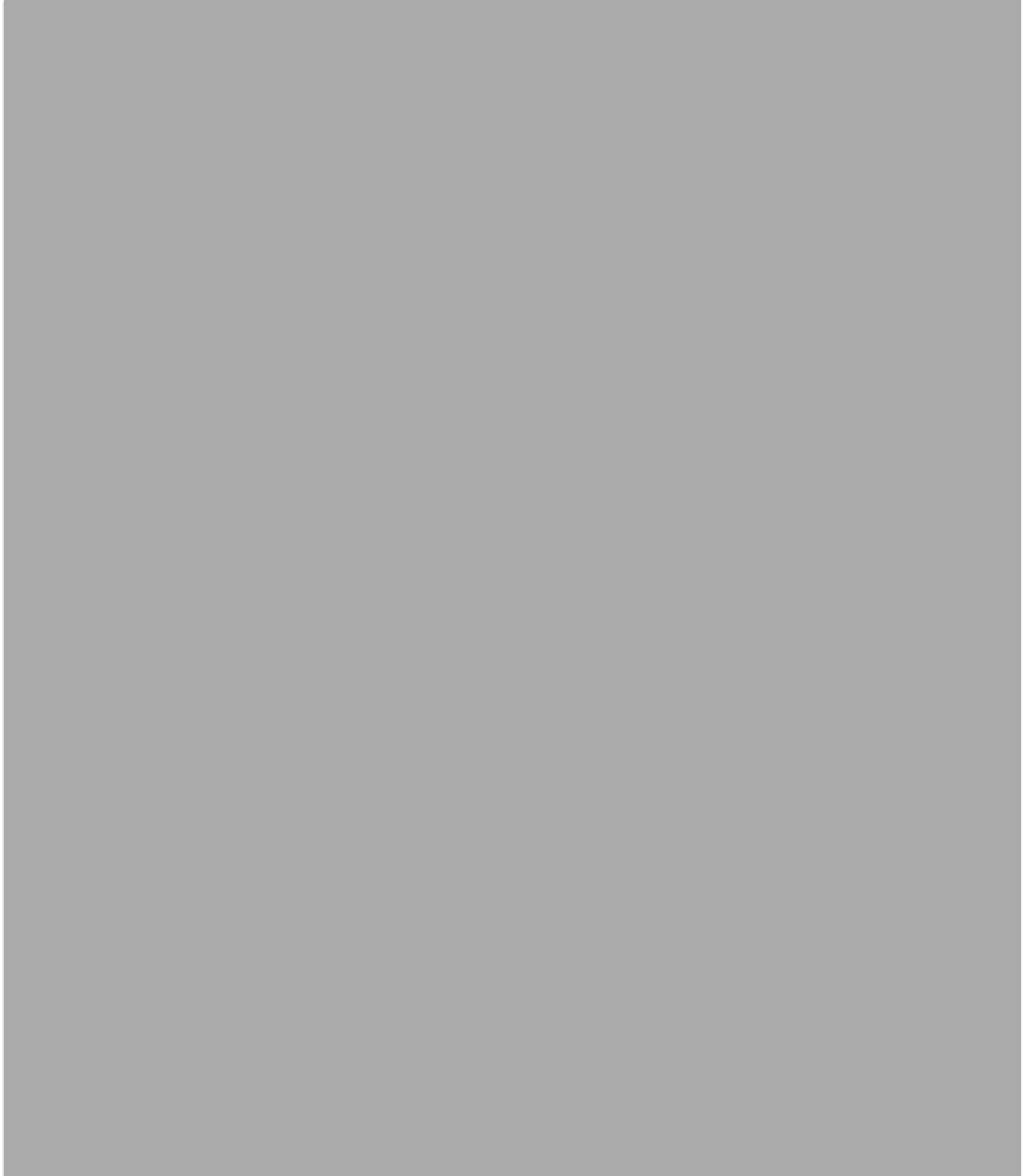


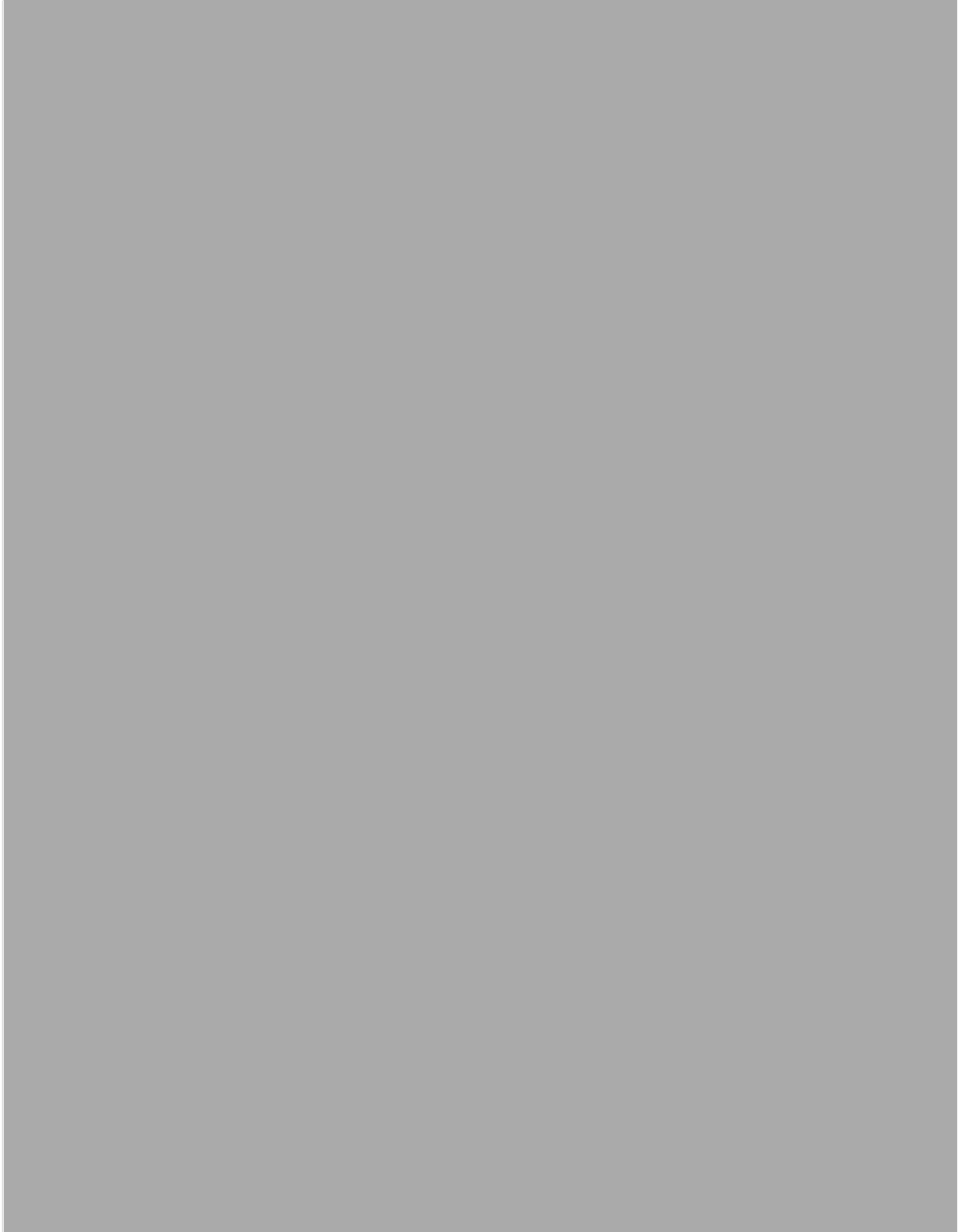


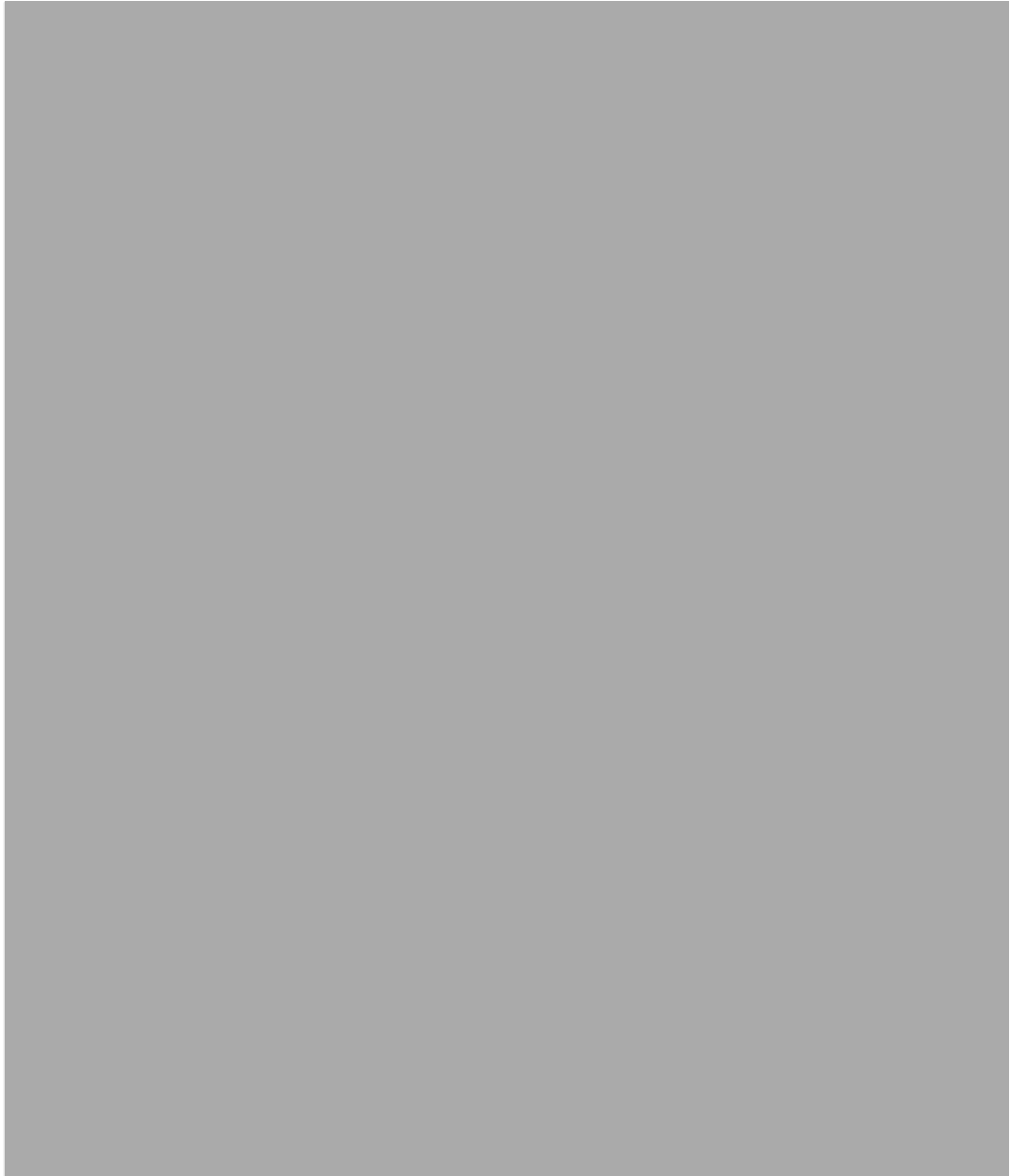




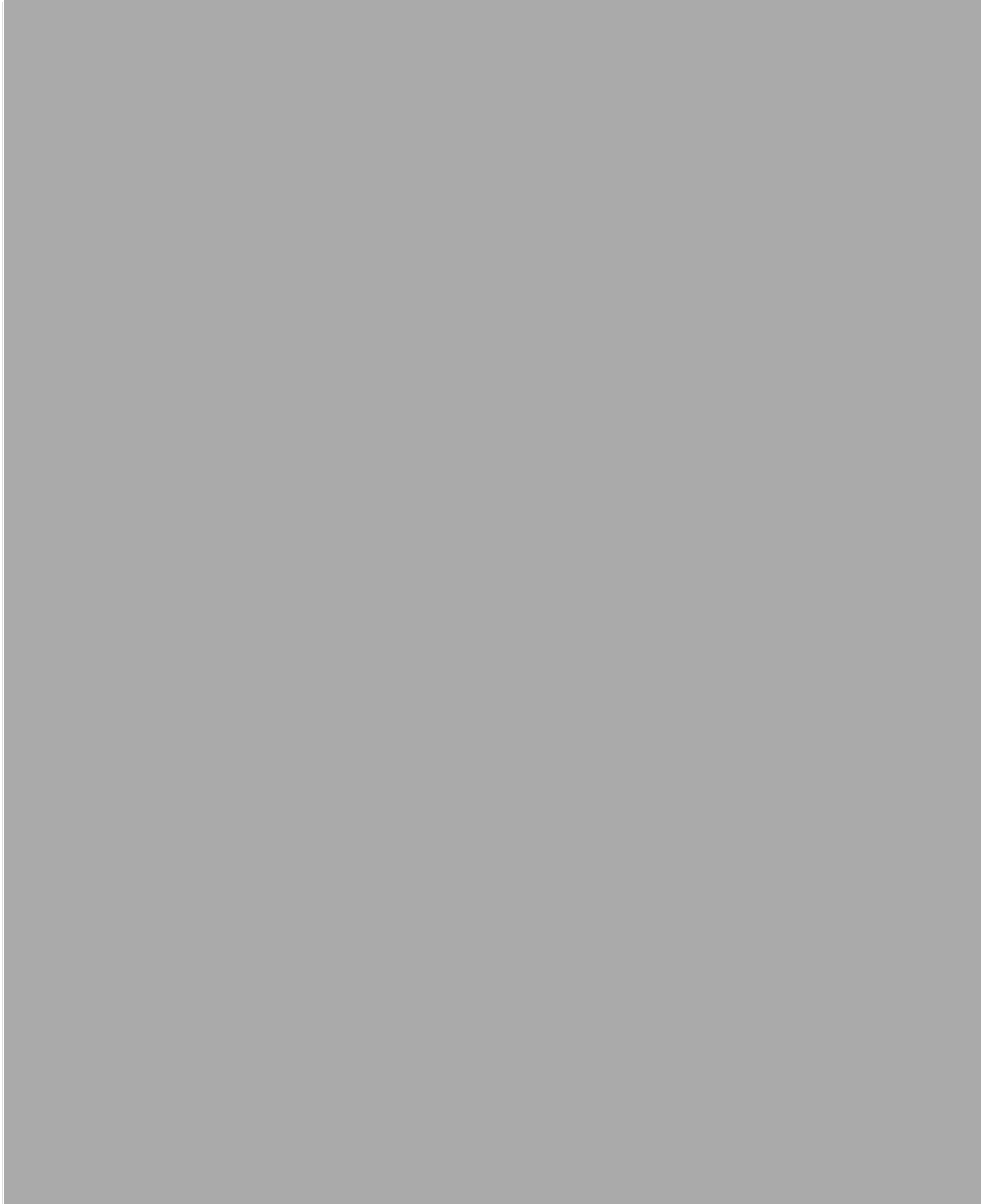


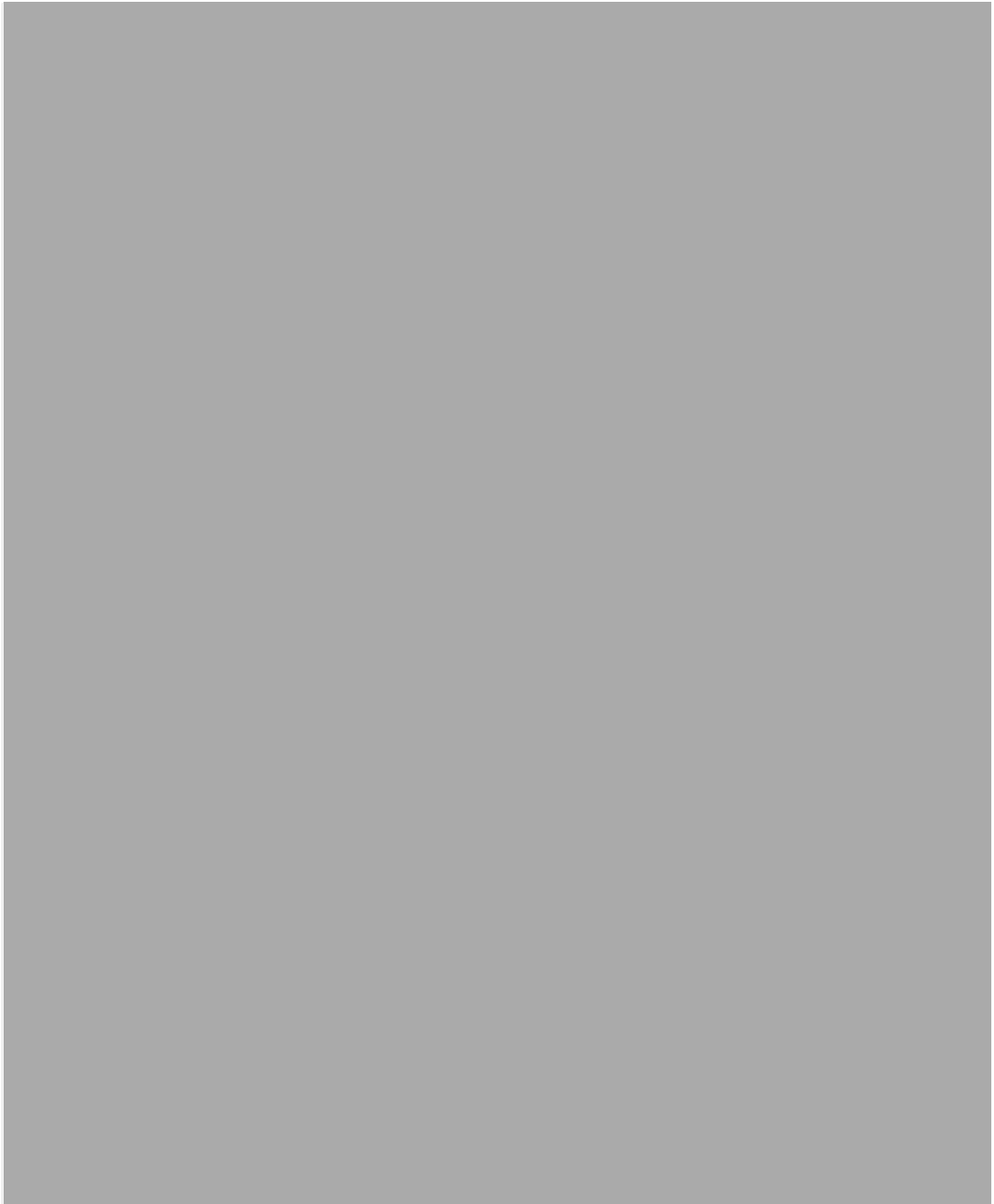


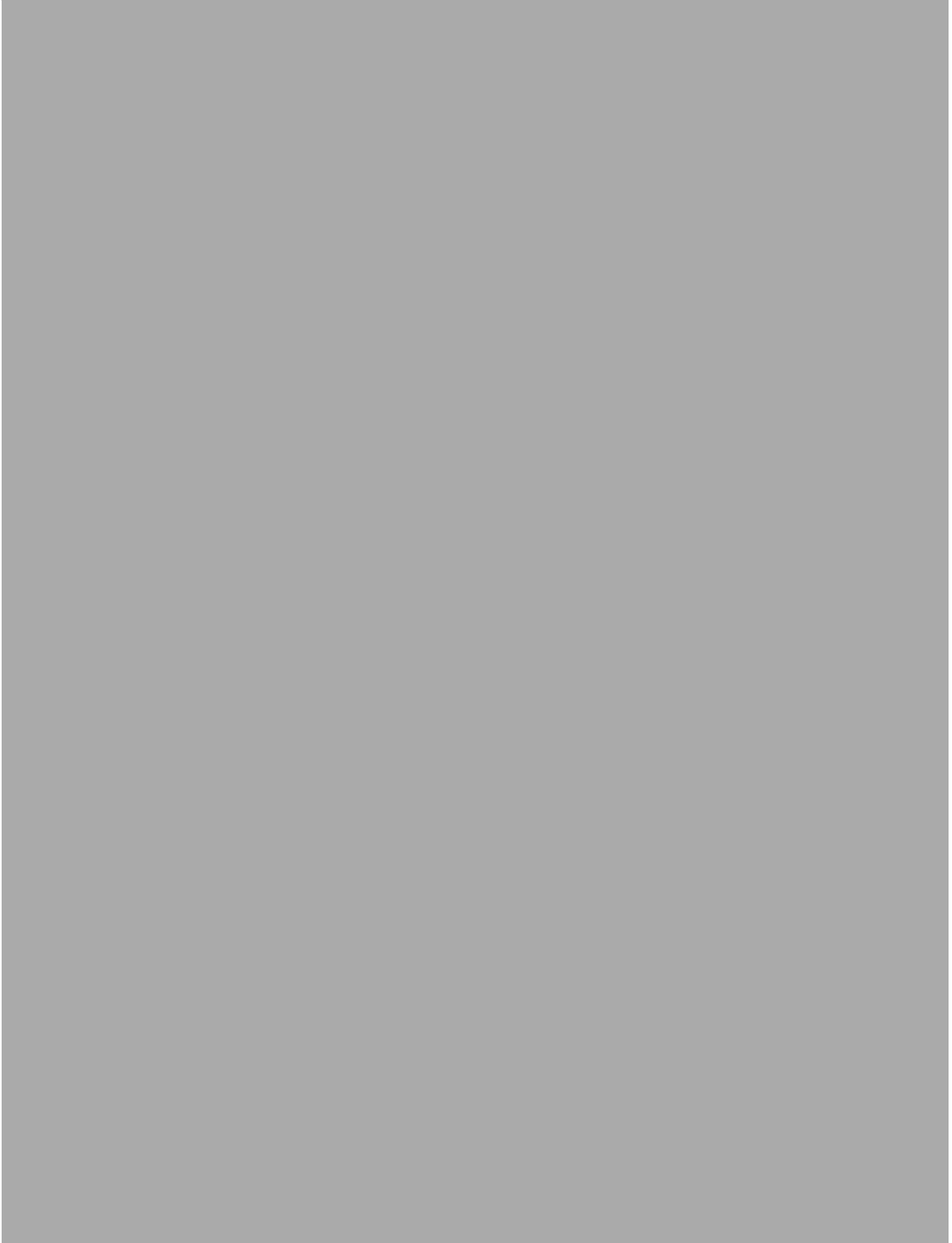


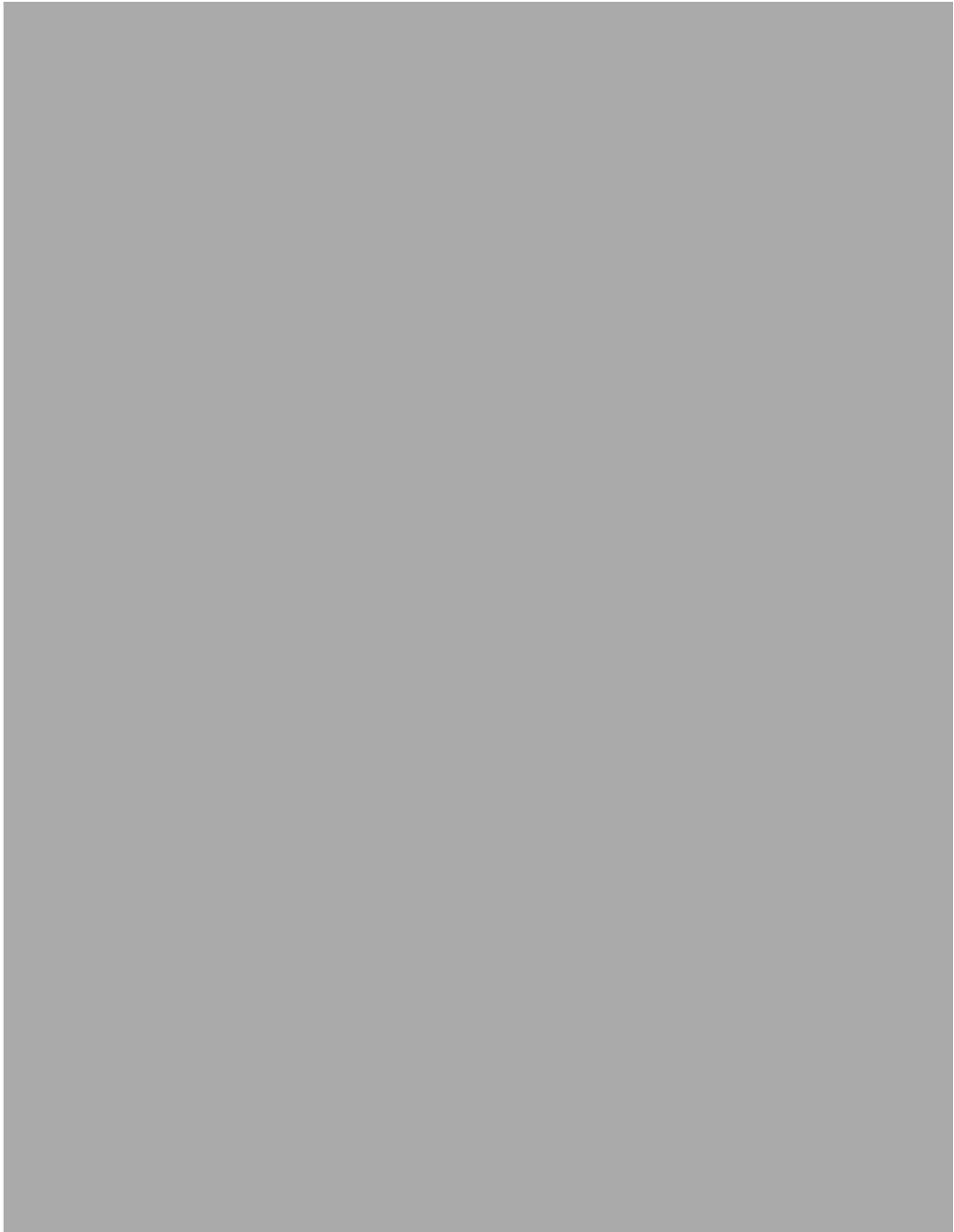


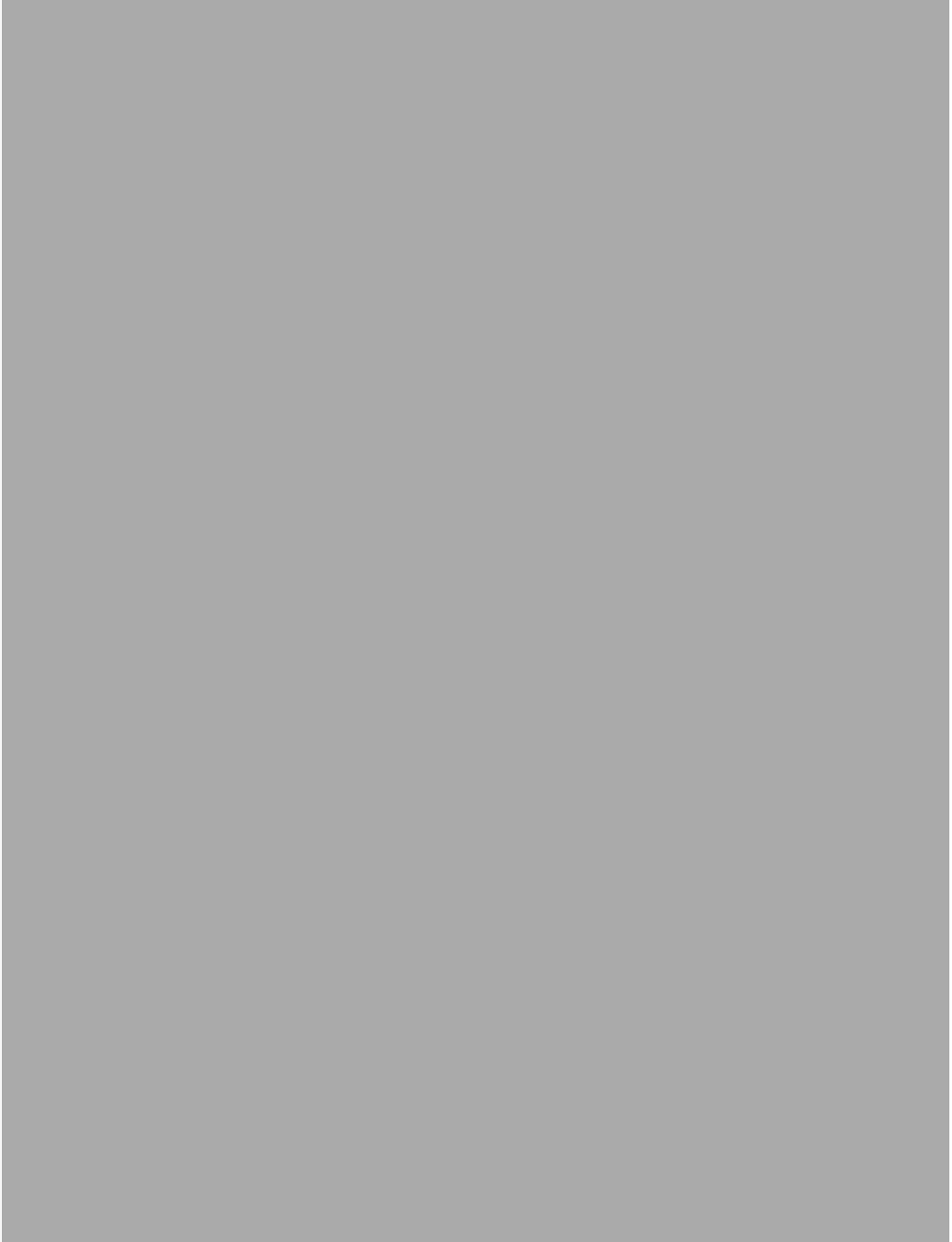


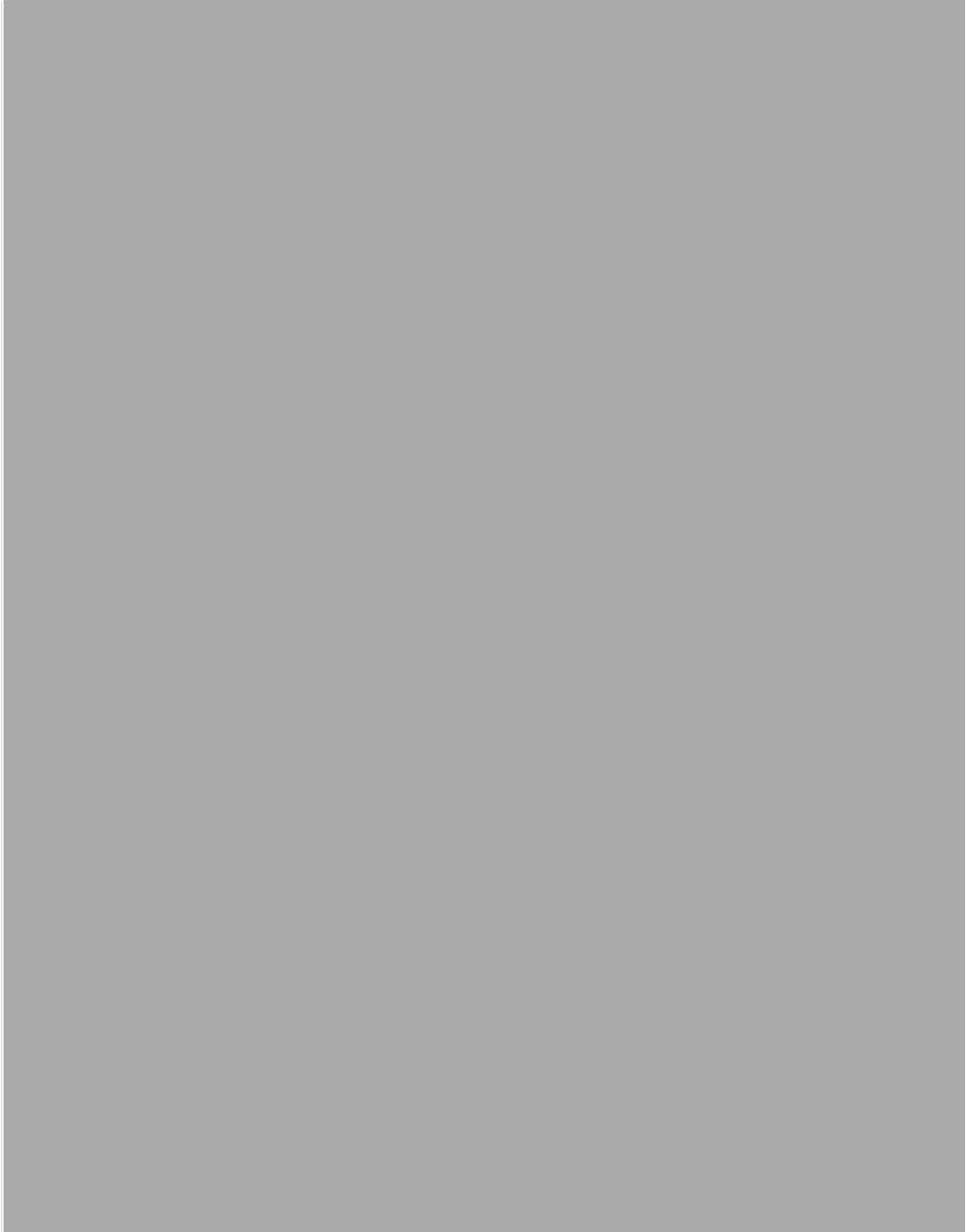


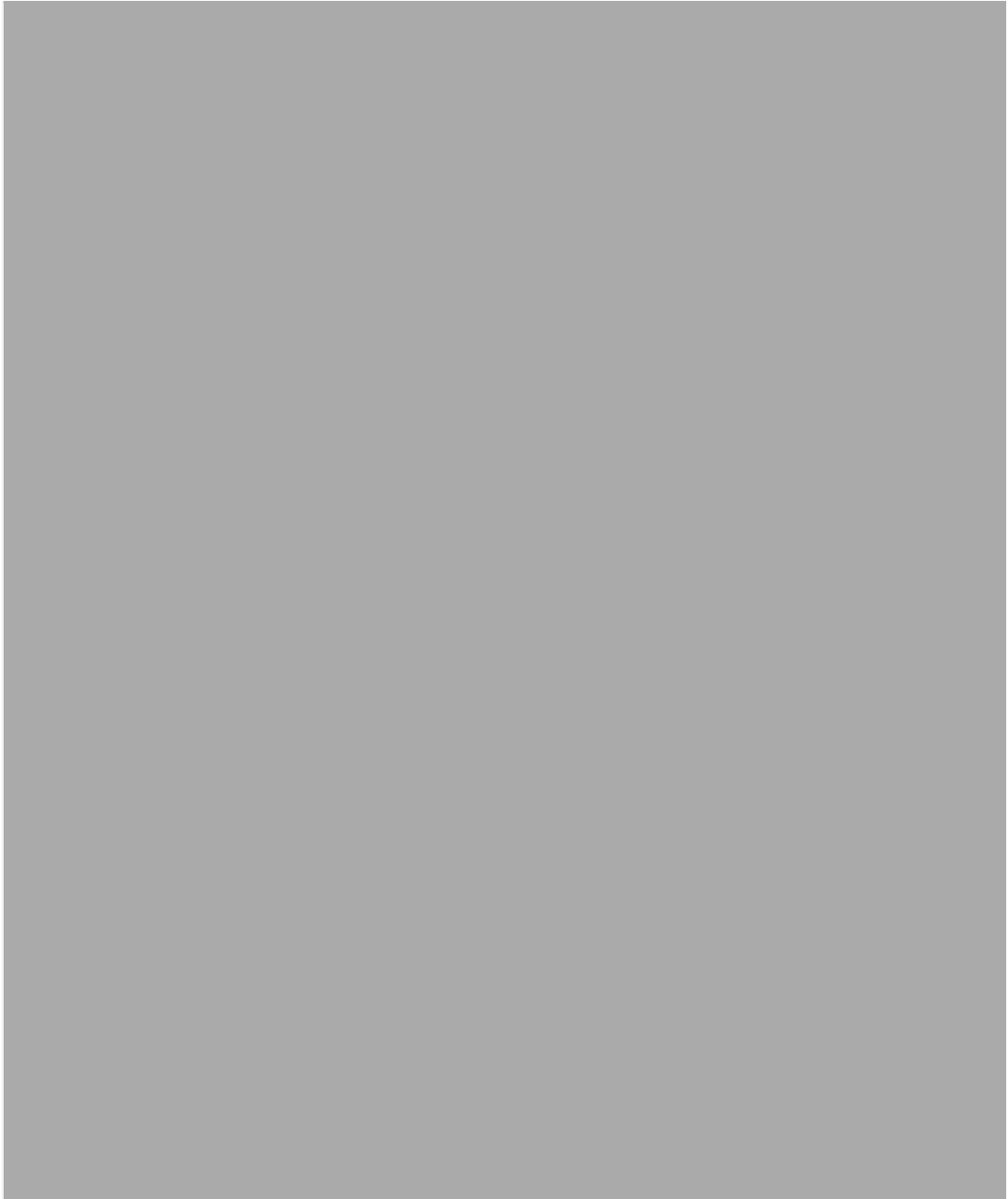












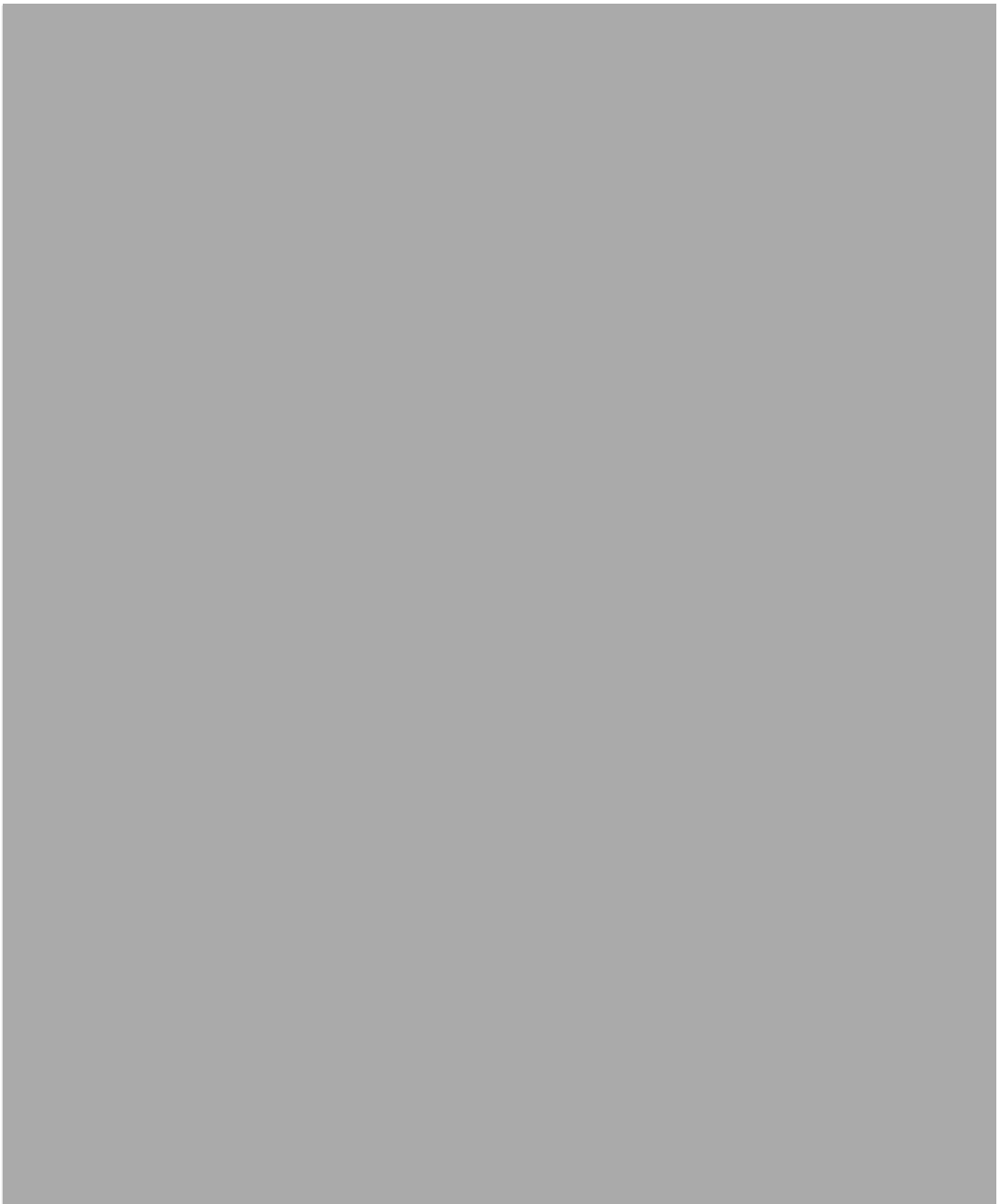
PervaLaxis Two: Encouraging anaphylactic people manage their own healthcare with a touchscreen personal mobile system

Luis U. Hernandez-Munoz
School of Electronic, Electrical and Computer
Engineering
University of Birmingham
Birmingham, United Kingdom
LXH615@bham.ac.uk

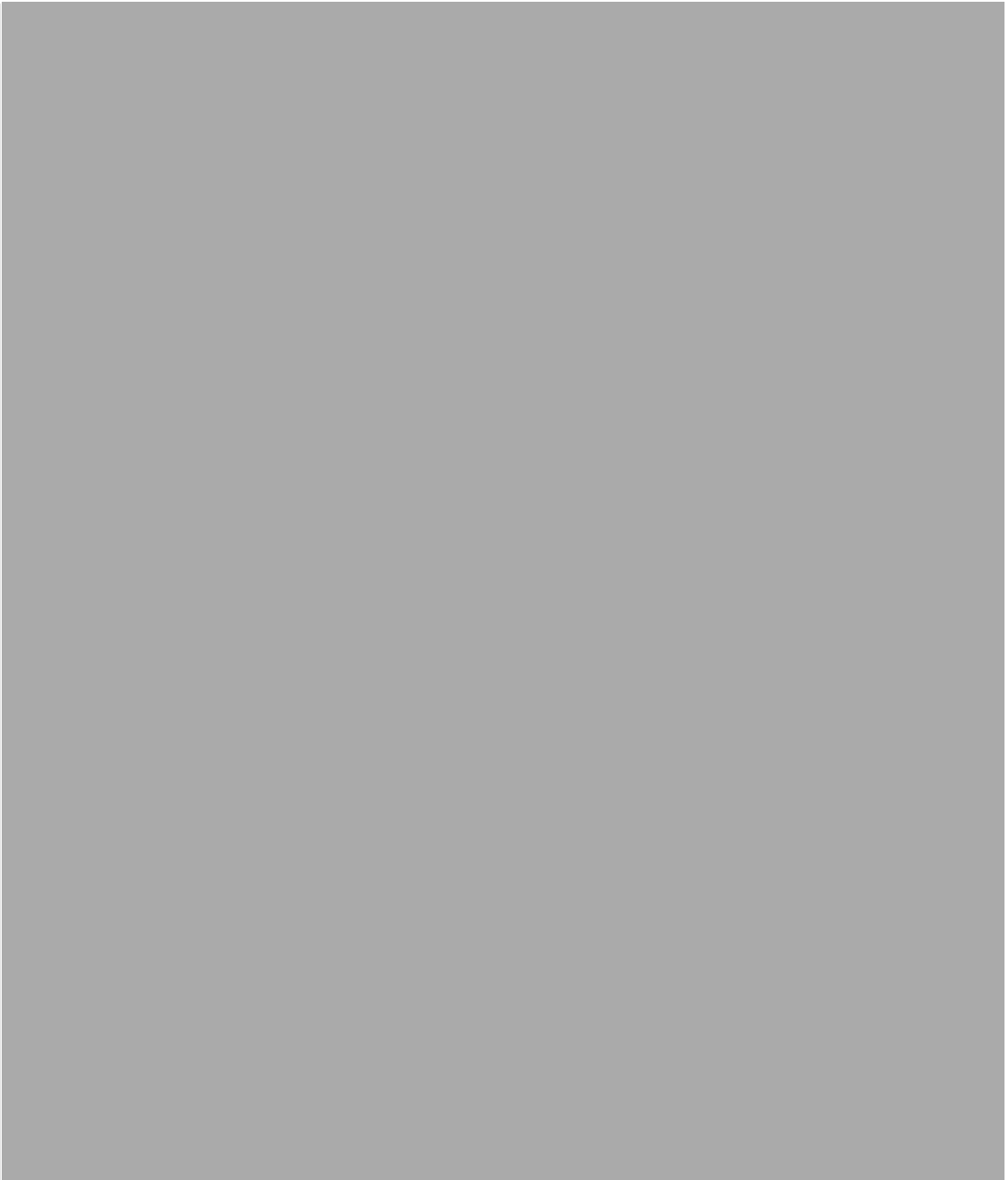
Sandra I. Woolley
School of Electronic, Electrical and Computer
Engineering
University of Birmingham
Birmingham, United Kingdom
S.I.Woolley@bham.ac.uk

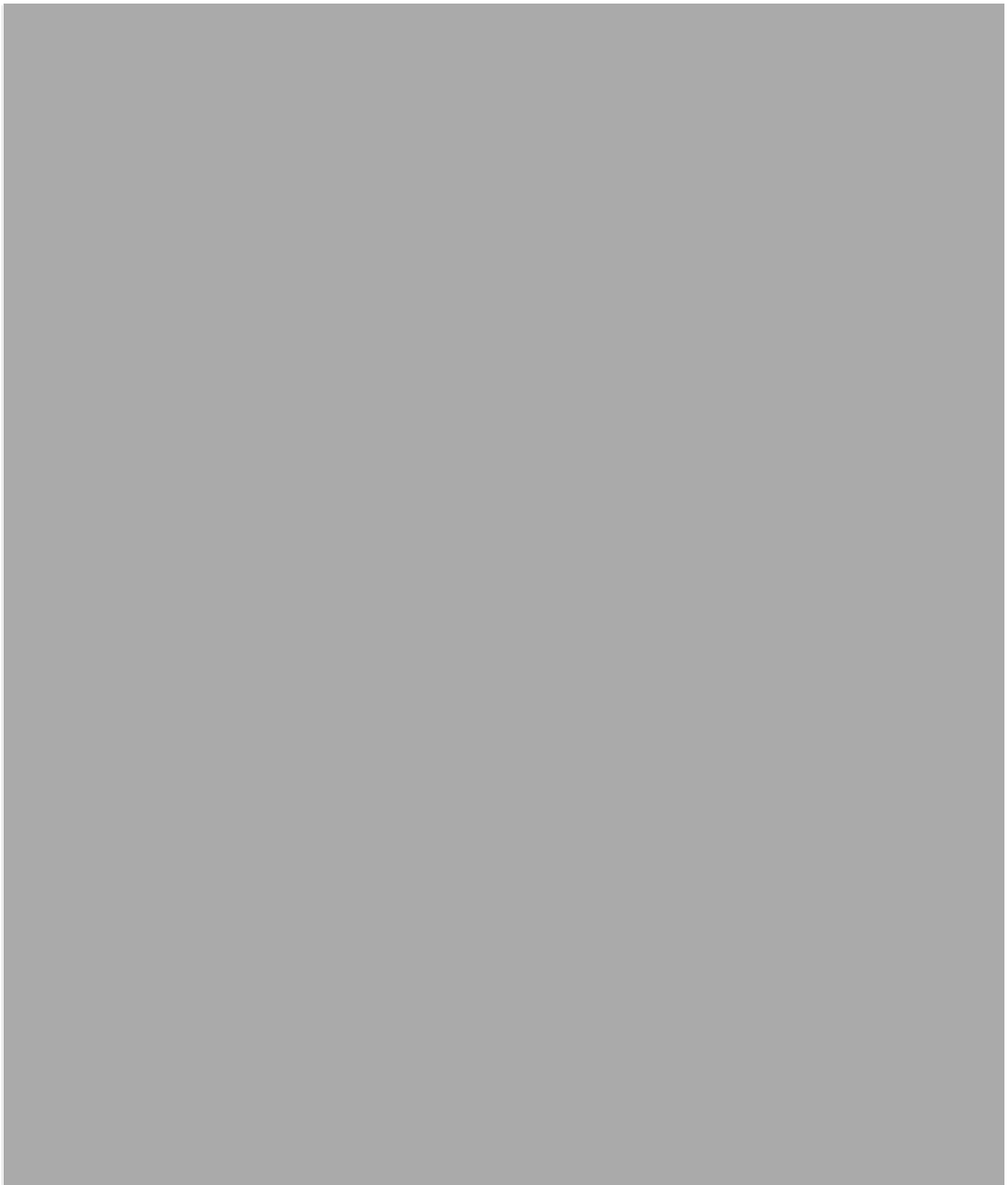
Abstract—This paper presents PervaLaxis Two, a touchscreen personal mobile health system with the potential to add value and function to the mobile phones and injectors that anaphylactic people typically carry. Anaphylaxis is a life-threatening allergic reaction which treatment involves the injection of adrenaline and the management of allergens. User requirements and evaluation results for PervaLaxis Two are presented, issues associated with the patient-oriented focus of the device (as opposed to health devices designed for expert use) are explored and how this could benefit personal health management. After testing the system, users suggested PervaLaxis Two is preferred and more usable than the paper-based traditional healthcare method and that the emergency messaging and training support of PervaLaxis Two is desirable and it is perceived with the potential to support allergy and personal health management. Evaluation findings indicated PervaLaxis Two seems to be able to help allergic people and non-allergic people (such as carers) manage allergies and take responsibility of the medical condition in everyday life with training-support applications and in emergency situations with a panic button embedded in the Smartphone device.

Keywords- Healthcare; anaphylaxis; m-health; allergies; pervasive computing; social wellness.









CHAPTER 10

**MOBILE PHONE TOOLS WITH AMBIENT INTELLIGENCE FOR THE
MANAGEMENT OF LIFE-THREATENING ALLERGIES**

Luis U. Hernandez-Munoz & Sandra I. Woolley
School of Electronic, Electrical and Computer Engineering
University of Birmingham
Birmingham, United Kingdom
E-mails: LXH615@bham.ac.uk ; S.I.Woolley@bham.ac.uk

This chapter describes the unmet needs of people with anaphylactic allergies and considers how pervasive technologies and ambient intelligence might support them in allergy management tasks. A working prototype solution, PervaLaxis Touchscreen, is presented which provides allergy management tools on a mobile phone and communicates with a wireless sensor to detect adrenaline injections. The results of usability testing are presented and demonstrate potential for mobile phone tools with ambient intelligence to provide useful and usable functionality to supplement the traditional system of training and education provided for allergy management. Test participants reported PervaLaxis Touchscreen tools, such as adrenaline injectors expiry date list, emergency support button and adrenaline injection sensing, as useful and stated the information and functions as more accessible by being integrated in the mobile phone.























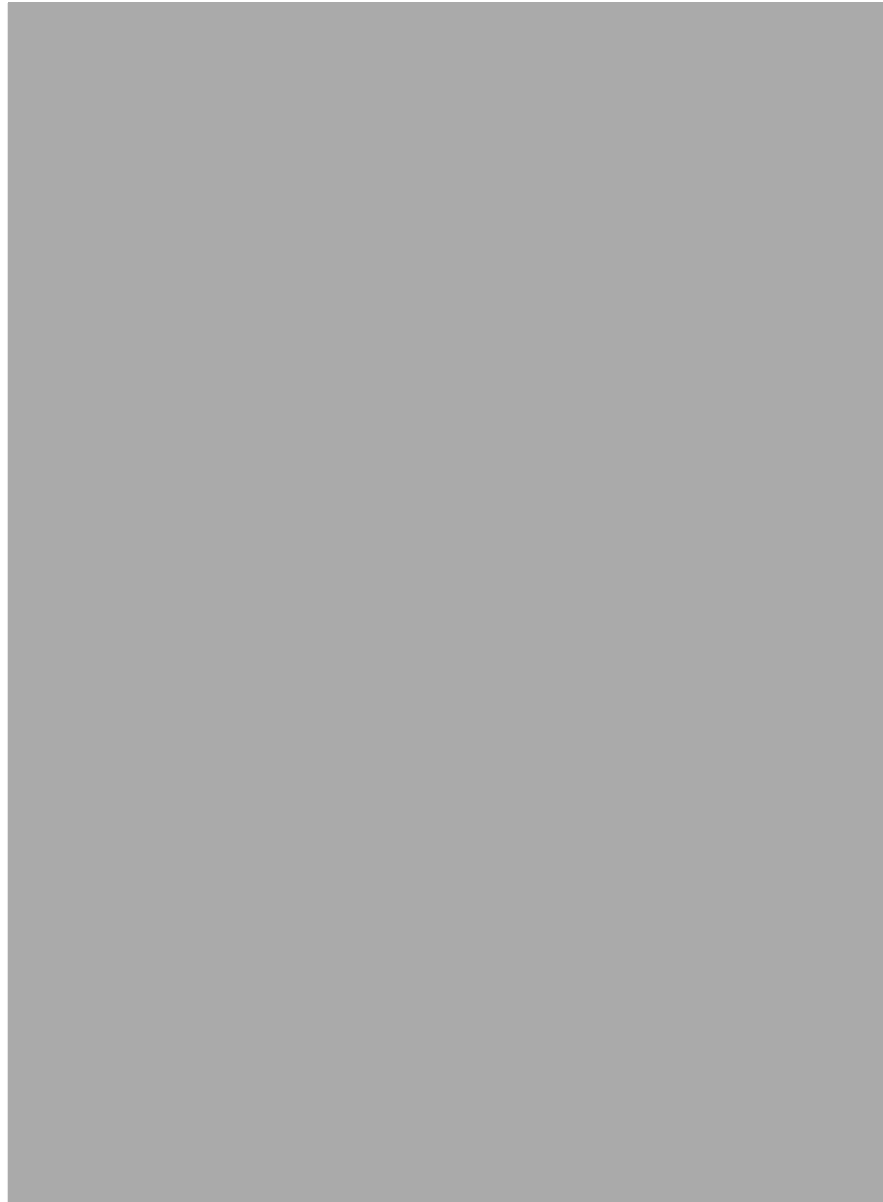


















Abstract accepted for publication in the proceedings of The British Society for Allergy and Clinical Immunology –BSCAI- Annual Meeting, 28th – 30th September, 2014. Telford UK.

Category : Allied Health

Pilot evaluation of Smartphone technology for adrenaline injection training.

L. Hernandez-Munoz; S. Woolley; L. Diwakar
University of Birmingham

Background: The importance of training in adrenaline auto-injector (AAI) use is well established. Inadequate training and lack of regular practice can lead to failure of use of AAIs by patients or their caregivers with potentially serious consequences.

Smartphone assistive technologies have demonstrated potential across a range of healthcare disciplines. However, assistive technology for AAI use in anaphylaxis currently lacks both development and evaluation.

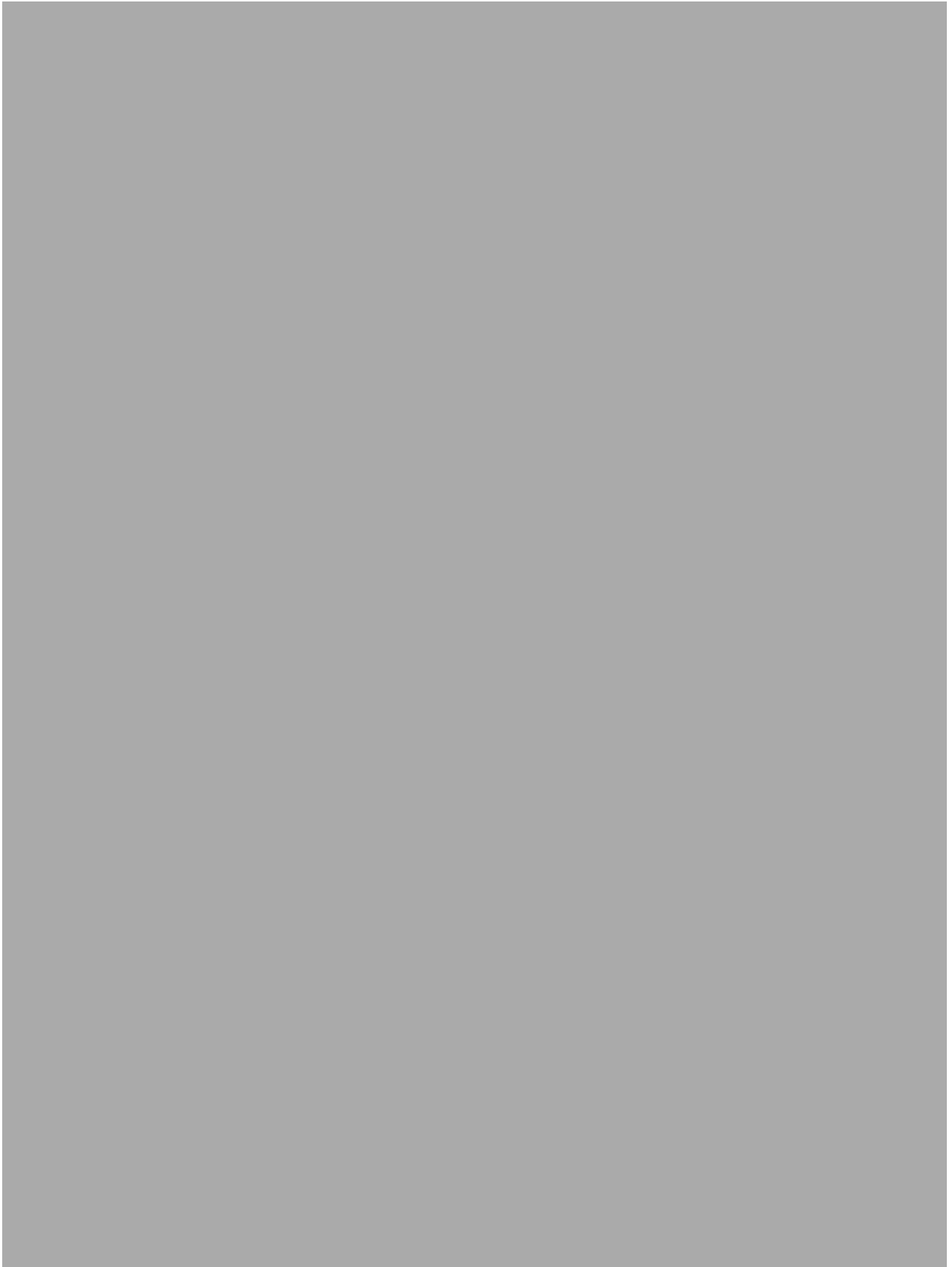
Objective: Pilot laboratory experimentation to investigate Smartphone technology for AAI practice versus printed instructions.

Methods: Twenty-two healthy adult participants were briefed on anaphylaxis and AAI use and randomly assigned into two groups; a control group provided with printed manufacturer instructions and a technology group provided with a Smartphone app with video demonstration and visual step-by-step guide. Participants used their allocated practice material with an AAI trainer before demonstrating use and completing a technology acceptance questionnaire. Correct technique meant each of four steps: removal of cap, swing and jab motion to thigh, holding in place for 10 seconds and massaging for 10 seconds were completed.

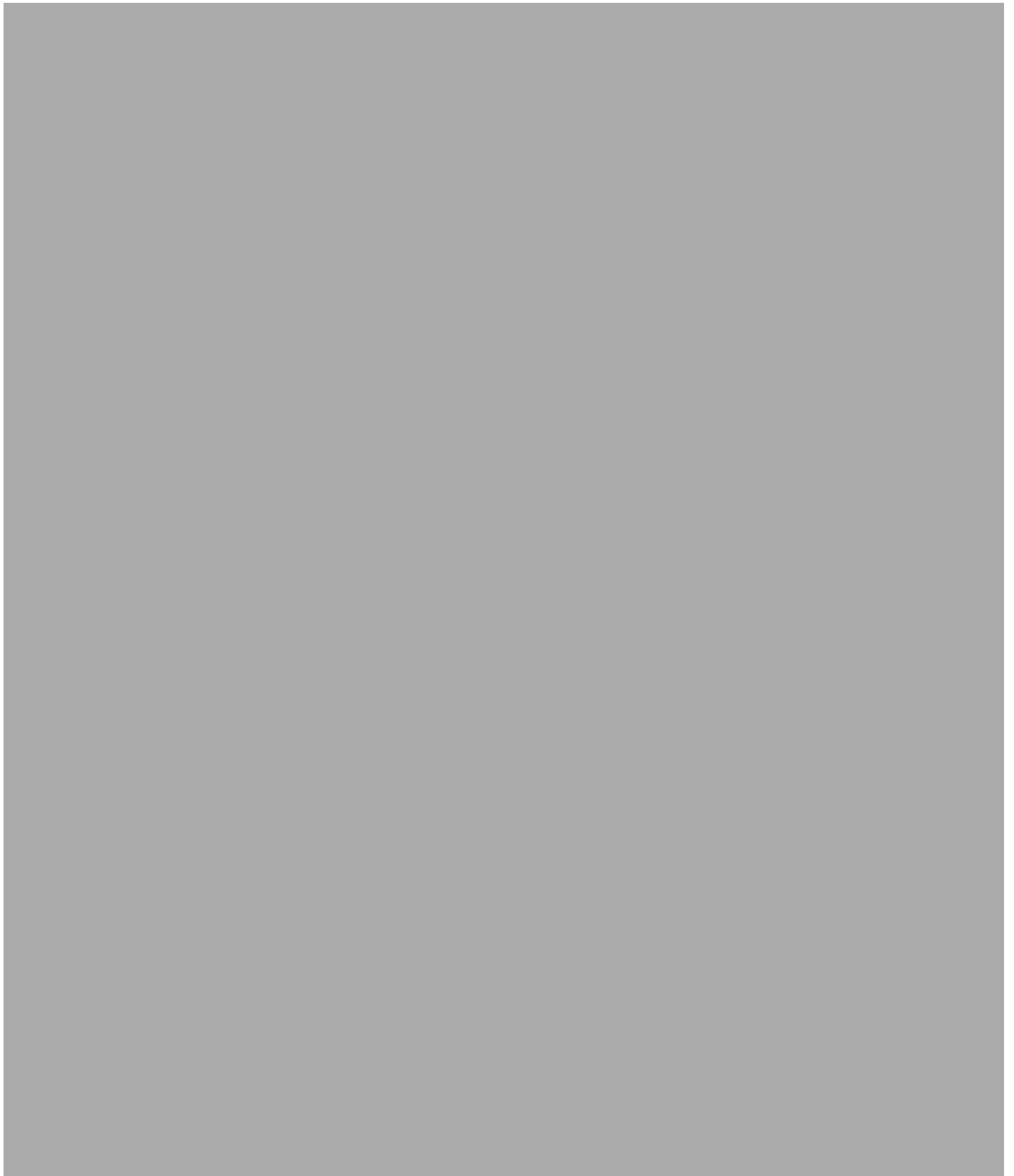
Results: Significantly more people in the technology group (63.6%) completed all injection steps correctly compared to those in the control group (18.2%) ($X^2=4.701$, $p<0.05$). The technology group (81.8%) also performed significantly more correct 'swing and jab' steps than the control group (45.5%) ($X^2=3.143$, $p<0.05$). Technology acceptance questionnaire results showed that the technology group reported more usefulness of their Smartphone practice material than the control group ($U=7.5$, $p<0.001$), they also reported better ease of use ($U=10$, $p<0.01$) and more willingness about future use ($t(20)=5.661$, $p<0.001$). Feedback from the technology group suggested the visual demonstrations helped in modelling the correct technique.

Conclusions: The results suggest that Smartphone technology may help improve AAI training.

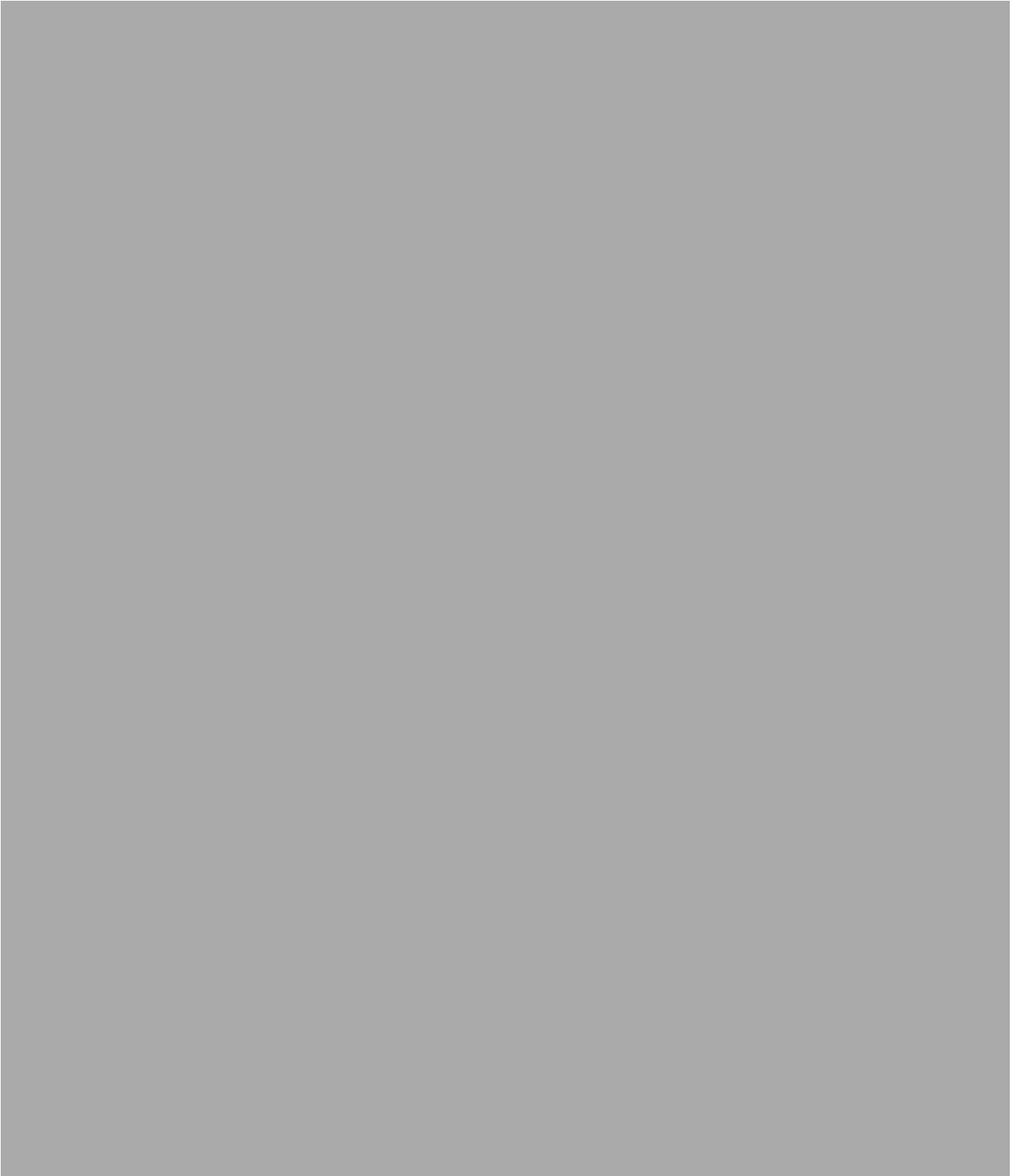
Further work, funded by the Anaphylaxis Campaign UK, is underway to assess an *AllergiSense* app that provides sensed practice feedback.

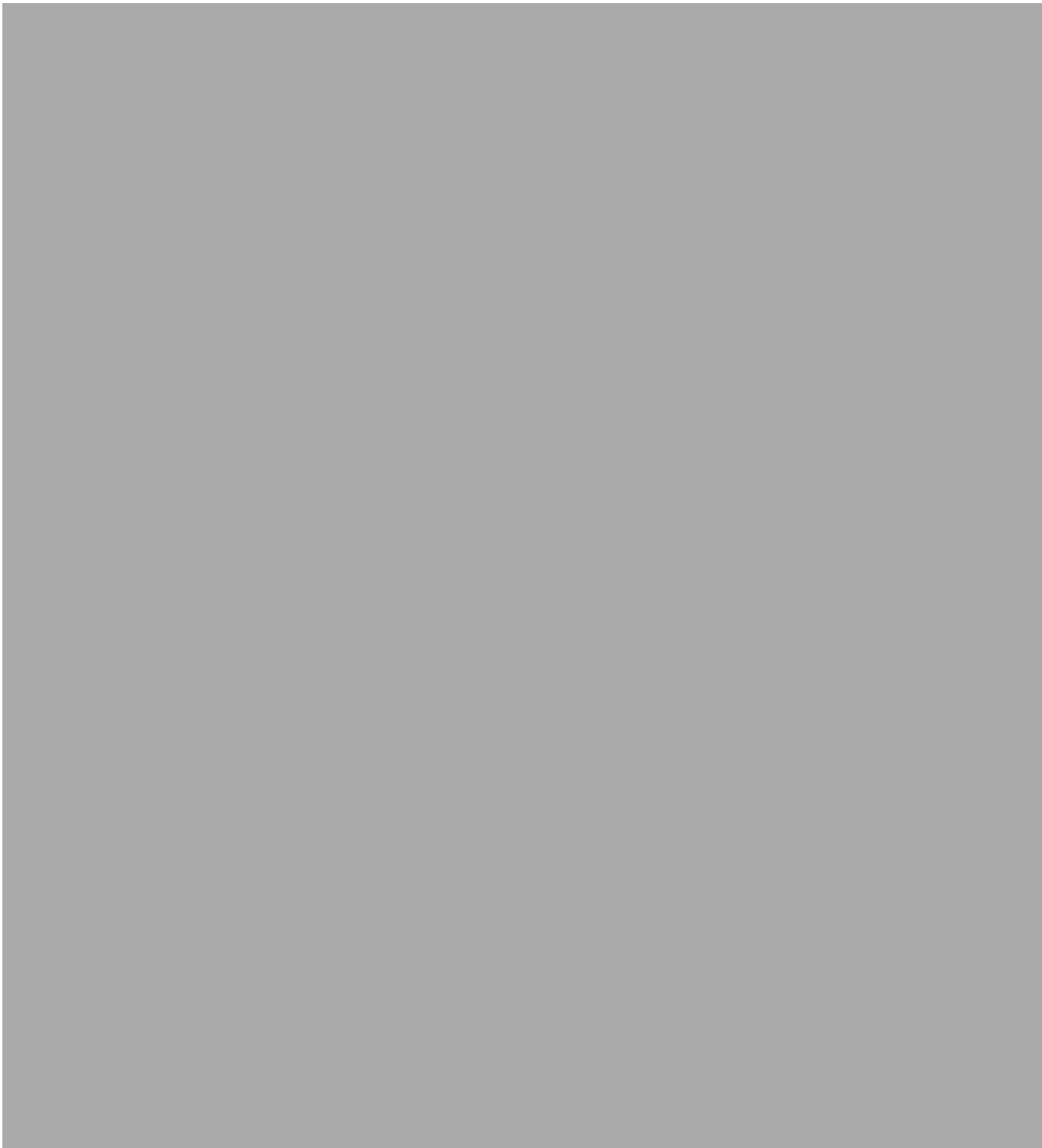




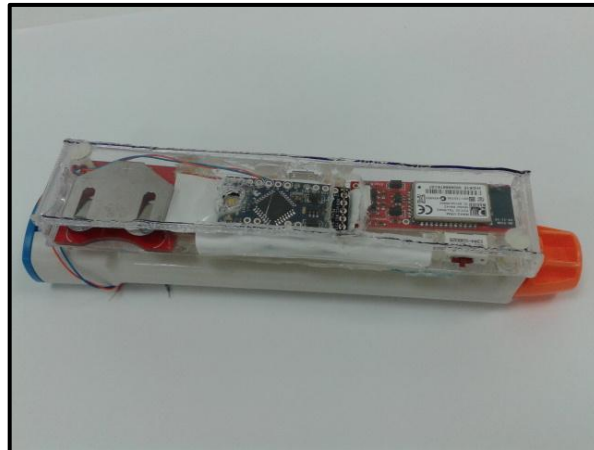








AllergiSense Sensing Unit



Components:

- Arduino Pro Mini 328 3.3V/8Mhz
- Triple Axis Analogue Accelerometer Breakout - ADXL335
- Coin Cell Battery Holder Breakout - 24.5mm
- Coin Cell Battery Rechargeable - 24.5mm
- USB micro connector
- Bluetooth™ transceiver, BlueSMiRF Silver RN-42

Arduino program:

/*

This program amends generic code (adding additional input and sensing) to read an analogue ADXL3xx accelerometer and communicate the acceleration intensity to a Bluetooth paired device using Serial Port Profile (SPP). The original code was created on 2 Jul 2008 by David A. Mellis modified 30 Aug 2011 by Tom Igoe, which code is in the public domain.
<http://www.arduino.cc/en/Tutorial/ADXL3xx>

The circuit:
analog 0: x-axis
analog 1: y-axis
analog 2: a-axis
pin 2: push button

*/

```
#include <SoftwareSerial.h>
```

```
//configure Bluetooth Serial port
```

```

// Pin 10 Arduino_vRX to BlueSmirf_Tx,
// Pin 11 Arduino_vTX to BlueSmirf_Rx

SoftwareSerial BTSerial(10, 11);

//Connection between the accelerometer and the Arduino Pro Mini

const int xpin = A0;           // x-axis of the accelerometer
const int ypin = A1;           // y-axis
const int zpin = A2;           // z-axis
const int capButton = 2;       // push button placed under
                                the blue safety cap (AAI
                                trainer device)

//X, Y and Z reading registers
int X=0;
int Y=0;
int Z=0;
int S=-1;

//data incoming from the Bluetooth transceiver
char ch;

void setup()
{

// initialise serial communications between Arduino and PC at 9600 //baud for debugging purposes

  Serial.begin(9600);

//Send a string from the Arduino to the PC using the Micro UART (Rx, //Tx)

  Serial.println("Hi PC");

//Set up a pull up internal resistor to sense a push button placed //under the blue safety cap of the AAI
device.
//resistor activated: switch open=>pin 2 = 1(Vcc);
//switch closed =>pin 2 = 0(GND)

  pinMode(capButton,INPUT_PULLUP);

// set the data rate for the SoftwareSerial port Arduino to the Bluetooth transceiver to 19200 for 70Hz
transmission

  BTSerial.begin(19200);

}

//keep polling all the time, start when an 'x' is received and stop when a 'y' is received

void loop()
{

```

```

if(BTSerial.available() >0)
{

  ch=BTSerial.read(); //Read serial port
  Serial.print(ch); //For debugging send it to the PC if it
                    //is available
  int i=0;          //declare an index to control the
                    //the number of each row of data

  //if an 'x' is received, start sensing acceleration data and send them to a Bluetooth paired
  //device.

  if(ch == 'x')
  {
    do
    {

      X=analogRead(xpin); //Read X axis and start creating
                          // the output.
                          // the output will look like D[i]=X,Y,Z,S. this is going to //be processed in the paired
                          //device

      BTSerial.print(" D[");
      BTSerial.print(i);
      BTSerial.print("]=");
      BTSerial.print(X);
      BTSerial.print(",");

      Y=analogRead(ypin); //Read Y axis and add it to the
                          // output.

      BTSerial.print(Y);
      BTSerial.print(",");

      Z=analogRead(zpin); //Read Z axis and add it to the
                          // output.
                          //

      BTSerial.print(Z);
      BTSerial.print(",");

      S=digitalRead(capButton); //Read the status of the blue
                                //safety cap button and
                                //add it to the output.

      BTSerial.println(S); // read the input pin:

      i++;                  //increase index

      if(i>3500)           //Maximum number of rows to send=3500
        ch='y';           //This is 90 seconds of data

    }

  }

  if(BTSerial.available() >0)

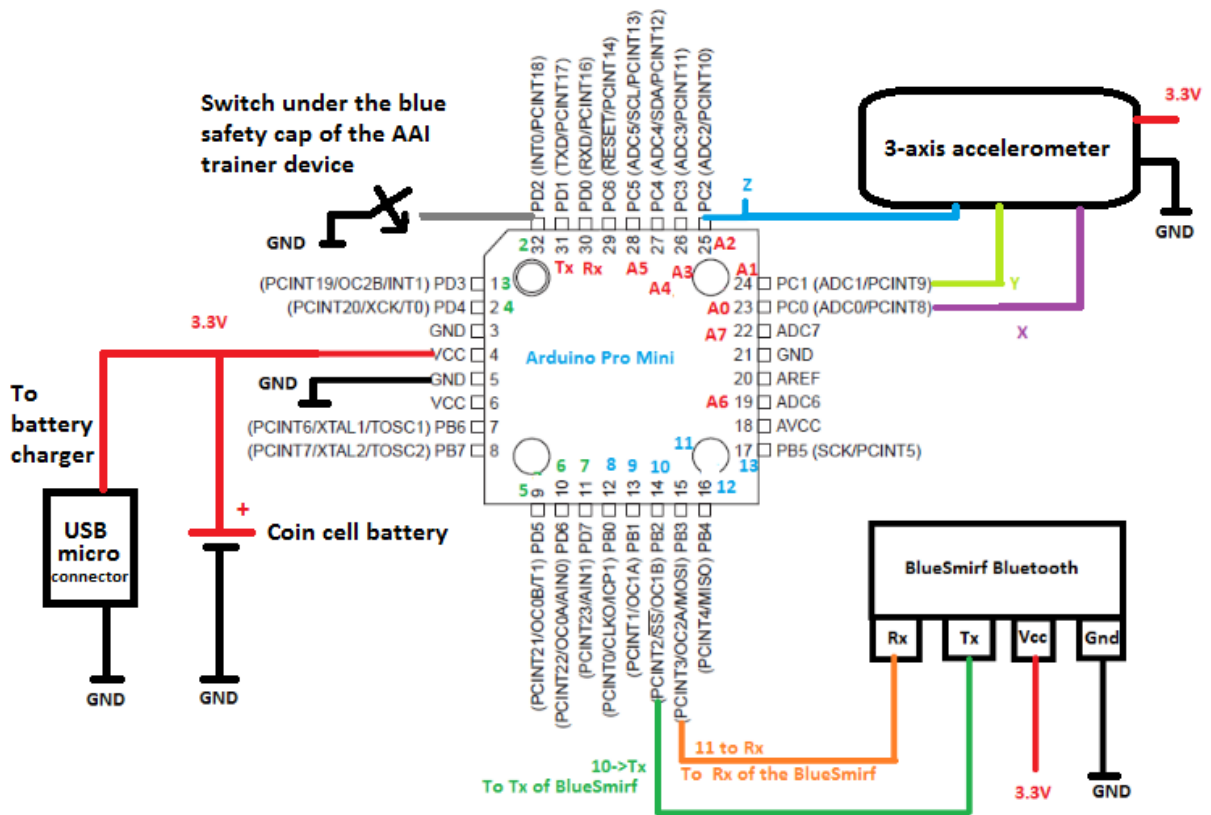
```

```

{
  ch=BTSerial.read();    //real serial port
  Serial.print(ch);      //Debugging
}
}while (ch!='y'); //if a 'y' is received from the paired
                          //device stop sending data.
i=0;                      //re-start index
}
}

```

AllergiSense Sensing unit schematic



First Model

(Twenty-five features, classifying 6 types of motion, 12 training injections)

Binary decision trees (J48)

		Cross validation (10-fold)						Average accuracy per class
		Predicted class						
		grab	removecap	towardsthgh	jab	still	removeinjector	
Actual class	grab	49	9	13	0	1	10	60 %
	removecap	20	28	13	4	2	8	37 %
	towardsthgh	15	12	90	6	12	13	61 %
	jab	4	2	8	20	4	8	43 %
	still	2	1	10	1	196	4	92 %
	removeinjector	10	9	26	4	8	26	12 %
Average accuracy		63%						

Naive Bayes

		Cross validation (10-fold)						Average accuracy per class
		Predicted class						
		grab	removecap	towardsthgh	jab	still	removeinjector	
Actual class	grab	35	19	4	7	4	13	43 %
	removecap	15	26	4	3	9	18	35 %
	towardsthgh	18	17	17	6	51	39	11 %
	jab	3	6	0	26	5	6	57 %
	still	0	3	1	3	204	3	95 %
	removeinjector	10	7	8	9	21	28	12 %
Average accuracy		52%						

RandomForest

		Cross validation (10-fold)						Average accuracy per class
		Predicted class						
		grab	removecap	towardsthgh	jab	still	removeinjector	
Actual class	grab	57	9	10	0	0	6	70 %
	removecap	18	37	13	1	1	5	49 %
	towardsthgh	18	8	96	2	9	15	65 %
	jab	5	2	9	22	3	5	48 %
	still	3	0	9	0	200	2	93 %
	removeinjector	9	9	23	5	6	31	11 %
Average accuracy		68%						

Second Model

(Seven features, classifying only 3 types of motion, injection in direction of the Y-axis, 12 training injections)

Binary decision trees (J48)

		Cross validation (10-fold)			Average accuracy per class
		Predicted class			
		moving	jab	still	
Actual class	moving	48	2	4	89 %
	jab	5	12	0	71 %
	still	10	2	104	90 %
Average accuracy		87.7%			

Naive Bayes

		Cross validation (10-fold)			Average accuracy per class
		Predicted class			
		moving	jab	still	
Actual class	moving	34	4	16	63 %
	jab	0	17	0	100 %
	still	1	2	113	97 %
Average accuracy		87.7%			

RandomForest

		Cross validation (10-fold)			Average accuracy per class
		Predicted class			
		moving	jab	still	
Actual class	moving	47	4	3	87 %
	jab	4	12	1	71 %
	still	10	2	104	90 %
Average accuracy		87.2%			

=== Run information ===

Scheme: weka.classifiers.trees.J48 -C 0.25 -M 2

Relation: FeaturesaCSVYaxis

Instances: 187

Attributes: 7

- yaverage
- ysd
- yMax
- ymin
- dYaverage
- yMax-ymin
- Class

Test mode: 10-fold cross-validation

==== Classifier model (full training set) ====

J48 pruned tree

```
dYaverage <= 1.933061: still (108.0/1.0)
dYaverage > 1.933061
| ymin <= 153
| | dYaverage <= 37.37602: jab (19.0/3.0)
| | dYaverage > 37.37602: moving (4.0/1.0)
| | ymin > 153
| | | ysd <= 12.774451
| | | | yMax-ymin <= 50: moving (12.0)
| | | | yMax-ymin > 50
| | | | | dYaverage <= 4.609694: still (3.0)
| | | | | dYaverage > 4.609694
| | | | | | yMax-ymin <= 99: moving (13.0/2.0)
| | | | | | yMax-ymin > 99: still (2.0)
| | | | | ysd > 12.774451: moving (26.0)
```

Number of Leaves : 8

Size of the tree : 15

Time taken to build model: 0 seconds

==== Stratified cross-validation ====

==== Summary ====

Correctly Classified Instances	164	87.7005 %
Incorrectly Classified Instances	23	12.2995 %
Total Number of Instances	187	

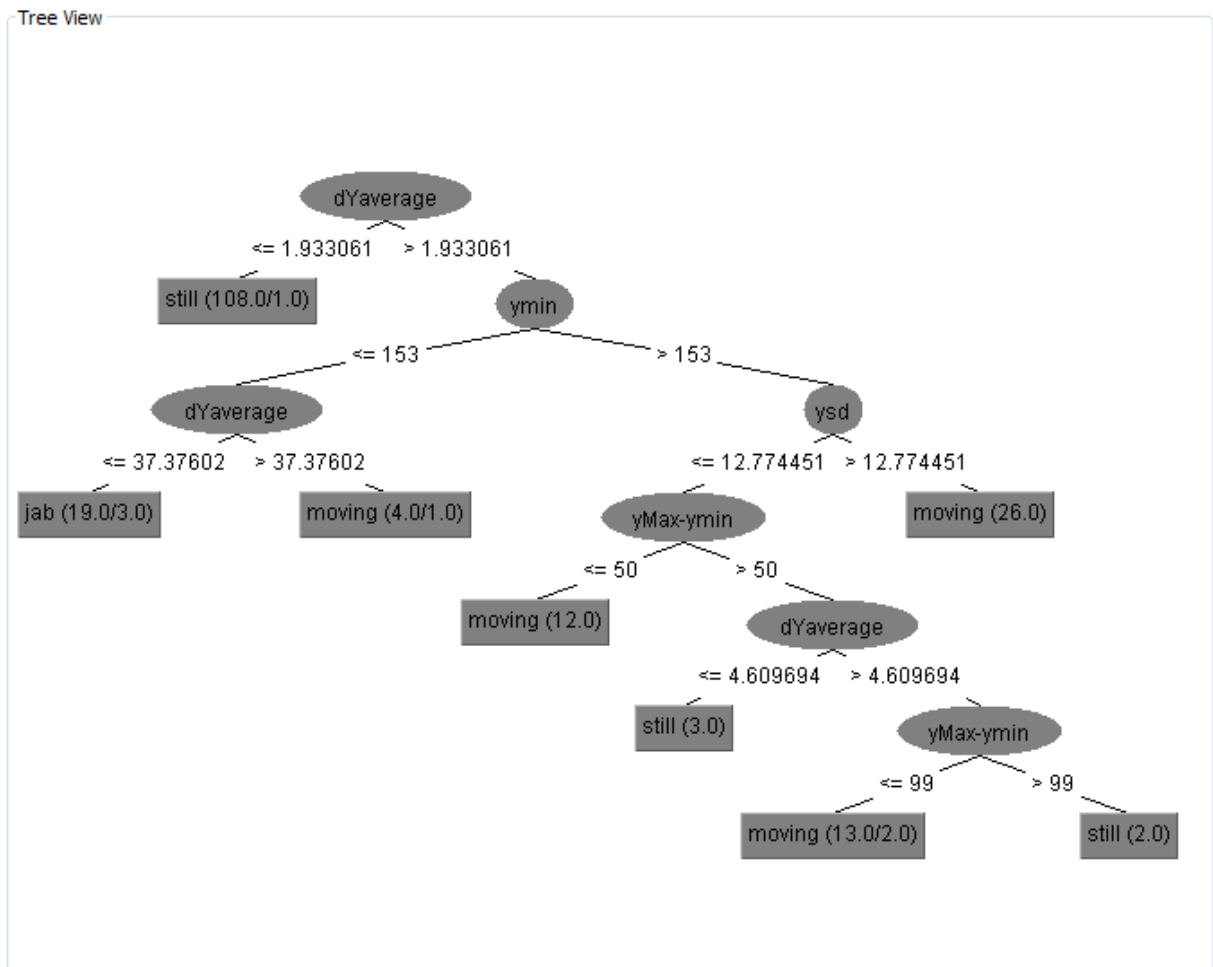
==== Confusion Matrix ====

a b c <-- classified as

48 2 4 | a = moving

5 12 0 | b = jab

10 2 104 | c = still



Self-efficacy Questionnaire for Adrenaline Injection

The aim of this questionnaire was to create an instrument to measure self-efficacy for adrenaline injection. The questions were based on the needs expressed by focus group participants presented in chapter 4 of this thesis, the manufacturer's EpiPen® AAI instructions and from sources of self-efficacy (mastery, modelling, social persuasion and physiological factors). The questions were selected (from a long list of candidate questions) by the clinical collaborator and checked by another senior allergy clinician.

Please read each statement and rate with an 'X' your degree of confidence in the scale that goes from 0 to 10.

Statement	Not at all confident				Moderately confident				Totally confident			
	0	1	2	3	4	5	6	7	8	9	10	
1. I am confident that I know what anaphylaxis is.	0	1	2	3	4	5	6	7	8	9	10	
2. I am confident that I know the possible causes of anaphylaxis.	0	1	2	3	4	5	6	7	8	9	10	
3. I am confident that I know the symptoms of anaphylaxis.	0	1	2	3	4	5	6	7	8	9	10	
4. I am confident that I know the treatment for anaphylaxis.	0	1	2	3	4	5	6	7	8	9	10	
5. I am confident that I can recognise an adrenaline Auto-Injector.	0	1	2	3	4	5	6	7	8	9	10	
6. I am confident that I know how to use an adrenaline Auto-Injector.	0	1	2	3	4	5	6	7	8	9	10	
7. I am confident that I know the difference between an Auto-Injector trainer and a real Auto-Injector.	0	1	2	3	4	5	6	7	8	9	10	
8. I am confident that I know what medication an Auto-Injector contains.	0	1	2	3	4	5	6	7	8	9	10	
9. I am confident that I know why an Auto-Injector should always be carried.	0	1	2	3	4	5	6	7	8	9	10	
10. I am confident that I know if an Auto-Injector can be injected through clothing.	0	1	2	3	4	5	6	7	8	9	10	
11. I am confident that I could correctly use an Auto-Injector in an allergic emergency.	0	1	2	3	4	5	6	7	8	9	10	
12. I am confident that I can correctly use an Auto-Injector trainer in a practice session.	0	1	2	3	4	5	6	7	8	9	10	
13. I am confident that I can demonstrate how to hold an Auto-Injector.	0	1	2	3	4	5	6	7	8	9	10	
14. I am confident that I can identify the safety release cap.	0	1	2	3	4	5	6	7	8	9	10	
15. I am confident that I know how to remove the safety release cap.	0	1	2	3	4	5	6	7	8	9	10	
16. I am confident that I can identify the end of the Auto-Injector where the	0	1	2	3	4	5	6	7	8	9	10	

Statement	Not at all confident			Moderately confident				Totally confident			
	---	---	---	---	---	---	---	---	---	---	---
needle comes out.											
17. I am confident that I can demonstrate which Auto-Injector end should point towards the injection site.	0	1	2	3	4	5	6	7	8	9	10
18. I am confident that I can identify the correct injection site.	0	1	2	3	4	5	6	7	8	9	10
19. I am confident that I can apply the correct force when injecting.	0	1	2	3	4	5	6	7	8	9	10
20. I am confident that I can demonstrate the correct time required to hold the injector in the injection site.	0	1	2	3	4	5	6	7	8	9	10
21. I am confident that I can demonstrate for how long the injection site should be massaged.	0	1	2	3	4	5	6	7	8	9	10
22. I am confident that I know what to do in an emergency after completing an injection.	0	1	2	3	4	5	6	7	8	9	10
23. I am confident that I know when to call emergency services	0	1	2	3	4	5	6	7	8	9	10
24. I am confident that I know when to use a second Auto-Injector.	0	1	2	3	4	5	6	7	8	9	10
25. I am confident that I know who to ask to obtain more information about Auto-Injectors.	0	1	2	3	4	5	6	7	8	9	10
26. I am confident that I have access to information beyond the printed manufacturer instructions. (e.g., I have access to instructional videos or automatic injector expiry date reminders).	0	1	2	3	4	5	6	7	8	9	10
27. I am confident that I can tell other people how and when to use an Auto-Injector.	0	1	2	3	4	5	6	7	8	9	10
28. I am confident that I am prepared to retrain periodically (or as needed).	0	1	2	3	4	5	6	7	8	9	10
29. I am confident that I can perform a successful adrenaline injection by copying a demonstration I have observed.	0	1	2	3	4	5	6	7	8	9	10
30. I am confident that I could learn from expert guidance or feedback about how to use an Auto-Injector correctly.	0	1	2	3	4	5	6	7	8	9	10
31. I am confident that I can obtain feedback to improve adrenaline	0	1	2	3	4	5	6	7	8	9	10

Statement	Not at all confident [---]			Moderately confident [---]			Totally confident [---]				
	0	1	2	3	4	5	6	7	8	9	10
injection skills.											
32. I am confident that I would not feel very anxious when demonstrating an adrenaline injection.	0	1	2	3	4	5	6	7	8	9	10
33. I am confident that I would not feel very anxious when injecting adrenaline in a real emergency situation.	0	1	2	3	4	5	6	7	8	9	10
34. I am confident that I would inject correctly in an emergency even if I was very anxious.	0	1	2	3	4	5	6	7	8	9	10
35. I am confident that I would feel confident when demonstrating an adrenaline injection.	0	1	2	3	4	5	6	7	8	9	10
36. I am confident that I would feel confident when injecting adrenaline in a real emergency situation.	0	1	2	3	4	5	6	7	8	9	10

Questionnaire Reliability

Table A5.1 Cronbach’s alpha for the internal reliability of the self-efficacy questionnaire.

		Material		
		Group 1 Paper	Group 2 AllergiSense without feedback	Group 3 AllergiSense
Self-efficacy:				
Before using material (after Demonstration 1)	Cronbach's alpha	0.967	0.939	0.961
After using material (after Demonstration 2)	Cronbach's alpha	0.969	0.948	0.949
After two weeks (after Demonstration 3)	Cronbach's alpha	0.984	0.974	0.965

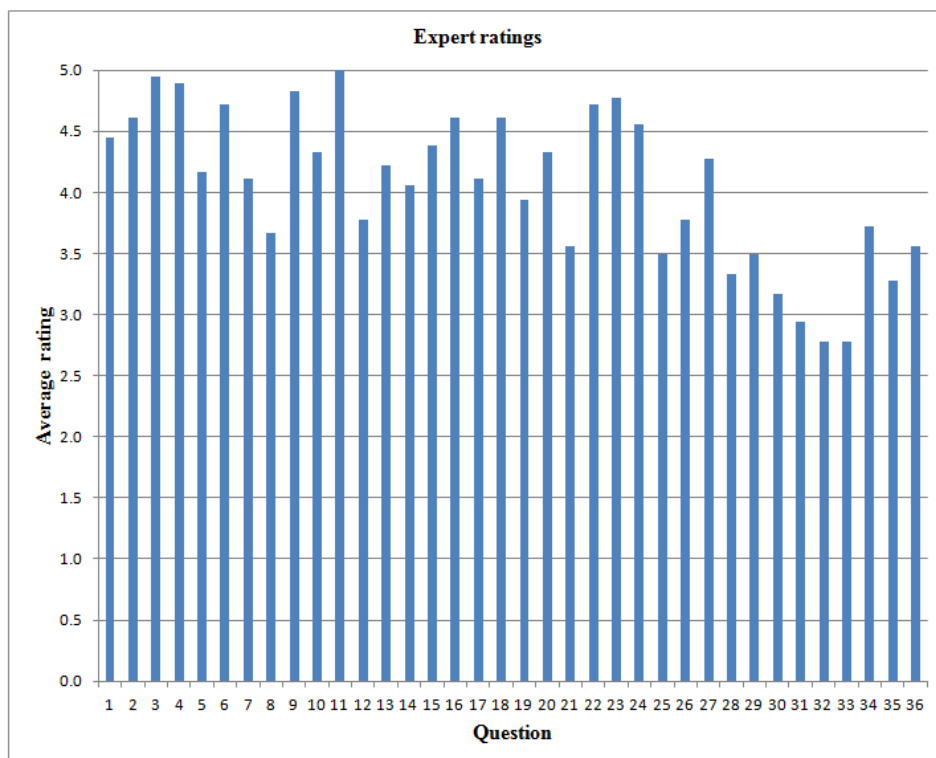
Expert Rating

The questions were reviewed and rated according to their importance (0: not important to 5: Very important) by 15 allergy nurses, 2 allergy clinicians and 1 trained carer.

Table A5.2 Experts who reviewed and rated the questions

Participants	Gender	Occupation	Years of experience with anaphylaxis management	Location
1	1	Allergy nurse	15	West Yorkshire
2	0	Allergy nurse	3	North West
3	0	Allergy nurse	10	North West
4	0	Allergy nurse	2	London
5	0	Allergy nurse	12	East Midlands
6	0	Allergy nurse	5	West Midlands
7	0	Allergy nurse	11	East of England
8	0	Allergy nurse	7	South West
9	0	Allergy nurse	14	Wales
10	0	Allergy nurse	10	East Midlands
11	0	Allergy nurse	6	not reported
12	0	Allergy nurse	11	not reported
13	0	Allergy nurse	16	not reported
14	0	Allergy nurse	20	not reported
15	0	Allergy nurse	6	not reported
16	1	Allergy clinician	20	Midlands
17	0	Allergy clinician	not reported	West midlands
18	1	Carer	10	West Midlands

Figure A5.1 Expert ratings



System Usability Scale (Brooke, 2006)

Scale: 1 – 5; 1:Strongly disagree, 5:Strongly agree

Paper group:

1. I think that I would like to use paper documents frequently.
2. I found paper documents unnecessarily complex.
3. I thought paper documents were easy to use.
4. I think that I would need the support of a person to be able to use paper documents.
5. I found the information in paper documents was well integrated.
6. I thought there was too much inconsistency in paper documents.
7. I would imagine that most people would learn to use paper documents very quickly.
8. I found paper documents very complicated to use.
9. I felt very confident using paper documents.
10. I needed to learn a lot of things before I could get going with paper documents.

AllergiSense groups:

1. I think that I would like to use AllergiSense frequently.
2. I found AllergiSense unnecessarily complex.
3. I thought AllergiSense was easy to use.
4. I think that I would need the support of a technical person to be able to use AllergiSense.
5. I found the various functions in AllergiSense were well integrated.
6. I thought there was too much inconsistency in AllergiSense
7. I would imagine that most people would learn to use AllergiSense very quickly
8. I found AllergiSense very complicated to use.
9. I felt very confident using AllergiSense.
10. I needed to learn a lot of things before I could get going with AllergiSense.

Usefulness (Davis, 1989)

Scale
 likely I _____ I _____ I _____ I _____ I _____ I _____ I _____ I unlikely
 extremely quite slightly neither slightly quite extremely

Paper group:

1. Using paper documents would enable me to know how to accomplish the injection of adrenaline more quickly
2. Using paper documents would improve my adrenaline injection performance
3. Using paper documents would increase my adrenaline injection productivity
4. Using paper documents would enhance my effectiveness on injecting adrenaline
5. Using paper documents would make it easier to inject adrenaline
6. I would find paper documents useful to inject adrenaline

AllergiSense groups:

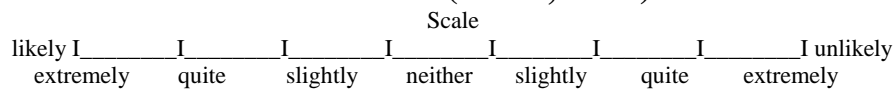
1. Using AllergiSense would enable me to know how to accomplish the injection of adrenaline more quickly.
2. Using AllergiSense would improve my adrenaline injection performance.
3. Using AllergiSense would increase my adrenaline injection productivity.
4. Using AllergiSense would enhance my effectiveness in injecting adrenaline.
5. Using AllergiSense would make it easier to inject adrenaline.
6. I would find AllergiSense useful to inject adrenaline.

Injection performance: Doing the tasks of injecting adrenaline.

Injection productivity: The capacity of producing a good injection with low effort.

Injection effectiveness: The ability to do an adrenaline injection successfully.

Ease of Use (Davis, 1989)



Paper group

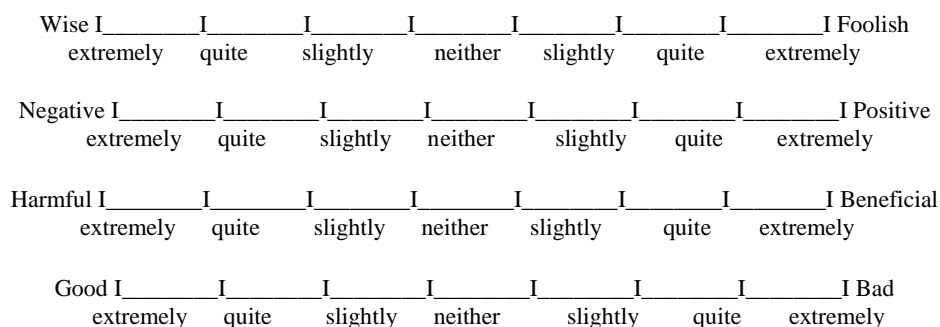
1. Learning to inject adrenaline using paper documents would be easy for me.
2. I would find it easy to get paper documents to do what I want it to do (inject adrenaline).
3. My interaction with paper documents to inject adrenaline would be clear and understandable.
4. I would find paper documents to be flexible to interact with.
5. It would be easy for me to become skilful at using paper documents to inject adrenaline.
6. I would find paper documents easy to use to inject adrenaline.

AllergiSense groups

1. Learning to inject adrenaline using AllergiSense would be easy for me.
2. I would find it easy to get AllergiSense to do what I want it to do (inject adrenaline).
3. My interaction with AllergiSense to inject adrenaline would be clear and understandable.
4. I would find AllergiSense to be flexible to interact with.
5. It would be easy for me to become skilful at using AllergiSense to inject adrenaline.
6. I would find AllergiSense easy to use to inject adrenaline.

Attitudes Towards Use (Davis, 1989)

1. Using **paper documents to know how to inject adrenaline** is



2. If **paper documents were to be available** to know how to inject adrenaline, I would use them frequently

Disagree I _____ I _____ I _____ I _____ I _____ I _____ I _____ I Agree
 strongly quite slightly neither slightly quite strongly

Whenever possible, I intend to use **paper documents** to know how to inject adrenaline

Disagree I _____ I _____ I _____ I _____ I _____ I _____ I _____ I Agree
 strongly quite slightly neither slightly quite strongly

1. Using **AllergiSense to know how to inject adrenaline** is

Wise I _____ I _____ I _____ I _____ I _____ I _____ I _____ I Foolish
 extremely quite slightly neither slightly quite extremely

Negative I _____ I _____ I _____ I _____ I _____ I _____ I _____ I Positive
 extremely quite slightly neither slightly quite extremely

Harmful I _____ I _____ I _____ I _____ I _____ I _____ I _____ I Beneficial
 extremely quite slightly neither slightly quite extremely

Good I _____ I _____ I _____ I _____ I _____ I _____ I _____ I Bad
 extremely quite slightly neither slightly quite extremely

2. If **AllergiSense were to be available** to know how to inject adrenaline, I would use it frequently

Disagree I _____ I _____ I _____ I _____ I _____ I _____ I _____ I Agree
 strongly quite slightly neither slightly quite strongly

Whenever possible, I intend to use **AllergiSense** to know how to inject adrenaline

Disagree I _____ I _____ I _____ I _____ I _____ I _____ I _____ I Agree
 strongly quite slightly neither slightly quite strongly

NASAS TLX (NASA, 2003)

We want to measure the workload you experienced in the tasks. Workload can have different factors. The factors we are measuring are:

RATING SCALE DEFINITIONS		
Factor	Endpoints	Descriptions
MENTAL DEMAND	Low/High	How much mental demand was required (e.g., thinking, deciding, looking, searching) Was the task easy or demanding, simple or complex?
PHYSICAL DEMAND	Low/High	How much physical activity was required (e.g., pushing, pulling, turning, controlling) Was the task easy or demanding, restful or laborious?
TEMPORAL DEMAND	Low/High	How much time pressure did you feel due to the rate or pace at which the tasks elements occurred? Was the pace of the task slow and leisurely or rapid and frantic?
PERFORMANCE	Perfect/ Failure	How successful do you think you were in accomplishing the goals of the task?
EFFORT	Low/High	How hard did you have to work (mentally and physically) to accomplish your level of performance?
FRUSTRATION	Low/High	How insecure, discourage, irritated, stressed and annoyed versus gratified, content and relaxed did you feel during the task?

Template suggested by the author:

Mental Demand How mentally demanding was the task?

Physical Demand How physically demanding was the task?

Temporal Demand How hurried or rushed was the pace of the task?

Performance How successful were you in accomplishing what you were asked to do?

Effort How hard did you have to work to accomplish your level of performance?

Frustration How insecure, discouraged, irritated, stressed, and annoyed were you?

The factors that affect the workload of the task may have a different weight. For example, a task might be difficult or hard because it must be completed quickly (high temporal demand) or because the intensity of mental or physical demand required was high.

From the following pairs please select the factor that represents the more important contributor to the demands of injecting adrenaline.

If you think both factors had extremely low levels, please choose the one that is slightly higher.

Effort or Performance	Temporal Demand or Frustration	Frustration or Effort	Performance or Mental Demand
Temporal Demand or Effort	Physical Demand or Frustration	Performance or Temporal Demand	Mental Demand or Effort
Performance or Frustration	Physical Demand or Temporal Demand	Mental Demand or Physical Demand	Effort or Physical Demand
Physical Demand or Performance	Temporal Demand or Mental Demand	Frustration or Mental Demand	

Semi-Structured Interview with Clinicians

1. Smartphone technology and mobile apps.

1.1 Do you use any Smartphone healthcare application?

1.2 What has it been your experience with these applications?

2. Questions about anaphylaxis challenges that need to be supported (by any means).

2.1 As a clinician, what are the main challenges you observe in the management of anaphylaxis?

2.2 What are the challenges reported by your patients and their carers?

3. Implications of Smartphone tools in anaphylaxis management.

3.1 After using AllergiSense for a few days, how do you envisage these types of tools could be used in the future?

3.2 How do you imagine this technology could be delivered in the future? (e.g., distributed by a clinic or by manufacturers)?

3.4 Who do you think could or should take the associated responsibilities?

3.5 How do you imagine this technology would be used by anaphylactic people?

3.6 Can you identify any factors that can influence the adoption of this technology?

3.7 What barriers can you see in the adoption of Smartphone applications for anaphylaxis management?

3.6 Do you imagine that data could be reported to or from AllergiSense? For example, injection scores could be sent to the allergy clinic, or the clinic could automatically send reminders about AAI expiry date? (What data would be useful?)

3.7 How do you imagine AllergiSense could be used in different settings? (e.g., in the clinic, in schools, training relatives, people of different age)

3.8 Do you think AllergiSense could improve anaphylaxis management supplementing traditional care?

4. At the beginning of the interview you mentioned challenges in anaphylaxis management. How can you see those challenges being supported by AllergiSense?

5. From the tools implemented in AllergiSense, what do you find most useful?

6. From the tools implemented in AllergiSense, what do you find less important?

7. How do you think AllergiSense could support patient self-efficacy?

8. Overall what are the advantages of AllergiSense?

9. Overall what are the disadvantages of AllergiSense?

10. Could you rate from 1-10 (1 = *not* very useful and 10 = very useful) the AllergiSense tools.

Tool	Rating									
	1: not very useful									10: Very useful
The expiry date list	1	2	3	4	5	6	7	8	9	10
The videos	1	2	3	4	5	6	7	8	9	10
The adrenaline injection training (step by step)	1	2	3	4	5	6	7	8	9	10
The adrenaline injection training (with the EpiPen trainer sensor)	1	2	3	4	5	6	7	8	9	10
Emergency what to do	1	2	3	4	5	6	7	8	9	10
Injection steps	1	2	3	4	5	6	7	8	9	10
Contact messages (sending automatic texts)	1	2	3	4	5	6	7	8	9	10
Call 999	1	2	3	4	5	6	7	8	9	10

11. Would you suggest any additions or modifications to the tools in AllergiSense?

12. Do you have any other comments or suggestions you would like to share with us?

Participant Profiles

Characteristic	Group		
	Paper	AllergiSense	AllergiSense with Feedback
N	21	21	21
Male	7 (33 %)	10 (48 %)	13 (62 %)
Female	14 (67 %)	11 (52 %)	8 (38 %)
Age range (years)			
18-20	3 (14 %)	4 (19 %)	5 (24 %)
21-30	13 (62 %)	12 (57 %)	13 (62 %)
31-40	3 (14 %)	0 (0 %)	2 (10 %)
41-50	2 (10 %)	4 (19 %)	1 (5 %)
51-60	0 (0 %)	1 (5 %)	0 (0 %)
Occupation			
Student	15 (71 %)	13 (62 %)	15 (71 %)
Staff	6 (29 %)	8 (38 %)	5 (24 %)
Other	0 (0 %)	0 (0 %)	1 (5 %)
Carry a non-smartphone	0	2 (10 %)	1 (5 %)
Carry a Smartphone	21 (100 %)	19 (90 %)	20 (95 %)
Nokia	1 (5 %)	1 (5 %)	1 (5 %)
Samsung	9 (43 %)	8 (38 %)	11 (52 %)
HTC	1 (5 %)	1 (5 %)	2 (10 %)
iPhone	7 (33 %)	6 (29 %)	4 (19 %)
Blackberry	1 (5 %)	0 (0 %)	0 (0 %)
Motorola	1 (5 %)	0 (0 %)	0 (0 %)
Other	1 (5 %)	3 (14 %)	2 (10 %)
Experience with smartphones or PDA's			
Beginner (Use mobile communication only)	0 (0 %)	1 (5 %)	2 (10 %)
Moderate (Use internet or mobile apps)	9 (43 %)	4 (19 %)	8 (38 %)
Confident (Use mobile internet, mobile apps, video games, accelerometer or other mobile sensors)	11 (52 %)	16 (76 %)	10 (48 %)
Expert programmer	1 (5 %)	0 (0 %)	1 (5 %)
Number of apps used			
0-1	0 (0 %)	2 (10 %)	1 (5 %)
2-3	2 (10 %)	2 (10 %)	3 (14 %)
>3	19 (90 %)	17 (81 %)	16 (76 %)

Inter-Coder Reliability

The independent researcher is a lecturer at the University of Birmingham.

Training with one participant, four injections.

Testing sample=10% (6 participants; 24 injections)

Participant	Demonstration 1		Demonstration 2		Demonstration 3		Demonstration 4	
	Independent researcher	Main researcher	Independent researcher	Main researcher	Independent researcher	Main researcher	Independent researcher	Main researcher
35 (Training)	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1
	1	1	1	1	0	1	1	1
	0	0	0	0	0	0	0	0
73 (Testing)	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1
	1	1	0	1	1	1	1	1
75 (Testing)	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1
	0	0	0	1	1	1	1	1
78 (Testing)	1	1	1	1	1	1	1	1
	1	1	1	1	0	0	0	0
	1	1	1	1	1	1	1	1
	0	0	1	1	0	0	1	1
15 (Testing)	0	0	1	1	1	1	1	1
	0	0	1	1	0	1	1	1
	1	1	1	1	1	1	1	1
	0	0	1	1	0	0	1	1
19 (Testing)	1	1	1	1	1	1	1	1
	1	1	1	1	0	1	1	1
	1	1	1	1	1	1	1	1
	0	0	0	0	0	0	0	0
27 (Testing)	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	0	1
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0

Cohen's kappa = 0.865

Adrenaline Injection Errors

(Number of people)

	1. Did not remove safety cap	2. Did not 'swing and jab' AAI device or press down hard enough	3. Did not hold AAI device in place for 10 seconds	4. Did not massage for 10 seconds	Total	%
Demonstration 1 (After watching clinical video)						
Paper-only	3	9	5	9	26	31.0 %
AllergiSense without feedback	3	9	4	11	27	32.1 %
AllergiSense	1	10	2	10	23	27.4 %
Demonstration 2 (After training - first time)						
Paper-only	0	3	6	15	24	28.6 %
AllergiSense without feedback	0	5	3	11	19	22.6 %
AllergiSense	0	4	2	9	15	17.9 %
Demonstration 3 (after two weeks)						
Paper-only	0	2	7	11	20	23.8 %
AllergiSense without feedback	0	5	4	12	21	25.0 %
AllergiSense	0	2	2	11	15	17.9 %
Demonstration 4 (After training - second time)						
Paper-only	0	5	5	12	22	26.2 %
AllergiSense without feedback	0	2	2	6	10	11.9 %
AllergiSense	0	0	1	2	3	3.6 %
Total	7	56	43	119	225	
Percentage	3.1 %	24.9 %	19.1 %	52.9 %	100.0 %	