Community Equipment Services
England and Wales 2009

The Need for National Minimum Standards

An Independent Review
Brian Donnelly
February 2009

Forewords by:
Sir Bert Massie CBE
Michael Mandelstam MSc
About the author

Brian Donnelly has worked within the Public Sector for 12 years. He has worked directly within and supported approximately 15 community equipment services throughout England and Wales over the past 8 years. Some of his roles have included: Project Manager; Service Manager; Consultant; Head of Service & Development, and most recently, National Development Officer for CES, within the Welsh Assembly Government.

Brian is qualified in Purchasing & Supply. He is also a registered PRINCE2™ practitioner (project management), and holds relevant post graduate qualifications in Management Studies and Health & Social Care.

Brian has brought several unique initiatives to CES over the years. For example, in 2004 he introduced a countywide multi-agency children’s equipment service in Buckinghamshire, which was the first service of this kind in the UK. He has also proposed a unique initiative in Wales to introduce a national all-sector service to deal with specialist, complex and children’s equipment, which is currently underway.

Brian has co-written national policy guidelines in relation to CES for the Welsh Assembly Government, and has produced a wealth of support material which is currently available on the Social Services Improvement Agency website (SSIA).

Brian has a genuine interest in community equipment services, understanding the huge benefits this service can bring to clients, and has therefore written this review paper in a personal and voluntary capacity. It is his sincere hope that National Minimum Standards will be introduced to community equipment services throughout England and Wales.
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Forewords

Community Equipment Services in England and Wales 2009 –
'The Need for National Minimum Standards'

Sir Bert Massie CBE writes:

As a user of National Health Service equipment for 60 years I have the strong impression that the current service, which was created following critical reviews by the Audit Commission, represents a significant improvement on anything we had before. I can well remember the disputes about whether a piece of equipment should be provided through the Social Services Departments of local authorities or through the Health Service. To add to the confusion some equipment was and is provided through the Department for Work and Pensions. Determining who was responsible was dependent on how the equipment would be used. However, as every user of equipment knows, helpful equipment is used in a variety of ways beyond the imagination of the funding authority.

The bringing together of local authorities and health services to provide a unified service surely makes sense and it is good that this has happened. Unfortunately, many people within government and elsewhere still fail to appreciate that the right equipment supplied at the right time can be hugely cost-effective. This report illustrates the financial implications of that folly. The wrong wheelchair might well save a few pounds but can cause such damage to the user that the health service and then social services incur bills of tens of thousands of pounds. The original saving was illusory. This report is a clarion call for Community Equipment Services to be adequately funded. Happily, if they were the Exchequer would make a saving.

I suspect that there will always be a tension between health and safety considerations and the need to get on with life. Life is a dangerous business and the only way to prevent accidents is to wrap people in so much cotton wool that they suffocate.
Nonetheless, this report makes a strong case that some equipment is not adequately tested and some users receive inappropriate equipment which is dangerous for them.

It is the nature of reports such as this that not everybody will agree with everything it contains. That is not as important as debating the issues openly and, if nothing else, this vital report should stimulate that debate.

Sir Bert Massie CBE

Sir Bert Massie CBE has been a disability rights campaigner for almost 40 years. He has wide experience of voluntary organisations and of working with government and governmental agencies.

He was Chairman of the Disability Rights Commission from January 2000 to 2007, now part of the recently created Equality and Human Rights Commission (EHRC). Prior to that, he was Chief Executive of the Royal Association for Disability and Rehabilitation (RADAR).

Sir Bert Massie is currently a Commissioner for the EHRC in conjunction with his new role at the Commission for the Compact. He is also a Governor of Motability, the leading car scheme for disabled people, and a Trustee of Habinteg Housing Association. In addition he is Vice President or Patron of a number of disability charities.
Forewords


Michael Mandelstam writes:
Community equipment services have long been problematic. A damning Audit Commission report in 2000 summed up only what numerous reports over some three decades had repeatedly found.

Since then, attempts have been made at improvement, most notably in an English, and subsequently a Welsh, initiative known as “integrating community equipment services” (ICES). Largely concerned with organisational issues, it has attempted to bring together local authority (social services) and NHS provision of equipment. Most recently, a further English policy called “transforming community equipment services” (TCES) is beginning to take shape. This concerns development of a “consumer retail market” model of provision. Prescriptions are issued to service users who then use the private sector to purchase equipment.

However, both these policies fall short in at least two fundamental respects. First, they are generally silent about safety and risk which, as Brian Donnelly points out, are very real issues. Second, they are equally and notably silent about people’s legal entitlement to equipment provision from local authorities and the NHS.

Is the general silence warranted? I believe not. As this document points out, serious lapses can occur in terms of safety, including appropriate provision, checking, inspection, maintenance and infection control. And, too many local authorities and NHS bodies are unclear about people’s legal entitlement to equipment; in my experience, unlawful and
restrictive policies, procedures and practices are legion. This of course is in no way to
criticise those local equipment services that do provide a high quality of service.

Thus the author points, cogently and clearly, to the human, financial and legal
implications of these matters. He calls for national standards. Of course, some may be
tempted to view such standards as bureaucratic excess. They may even see them as
inimical to the TCES initiative and to the wider policy in social and health care of
“personalisation”, “self-directed support” and “personal budgets” – involving greater
choice and flexibility for service users. I do not agree. Talk of choice, and of high quality
equipment provision, is empty if not premised on basic safety and on statutory
entitlement. Without a solid foundation, a policy of choice is specious and could lead even
to an erosion of people’s safety and welfare. Standards, as proposed by the author, could
shore up that foundation.

In sum, in my view, this document is timely and admirably to the point. It is to be
commended.

Michael Mandelstam MSc

Michael Mandelstam is a leading writer and adviser in Community Care law. Michael
has worked for the Disabled Living Foundation and the Department of Health; he has also
produced a wealth of books and support material on Community Care related legal issues.
He currently works independently, running many legal training courses for NHS Trusts,
local authorities and voluntary organisations, throughout the United Kingdom.
Executive Summary

Introduction
The purpose of this document is to highlight significant risks and concerns relating to the delivery of community equipment services (CES) and the impact this is having on clients, organisations, and the English and Welsh welfare economies as a whole. In view of these issues the document goes on to stress the need for introducing National Minimum Standards, demonstrates the benefits this would bring, and identifies what areas of service delivery these should apply to.

Background
There are approximately 150 community equipment services in England and Wales, which issue around 10 million pieces of equipment each year to 3.5 million users. CES are vitally important in supporting key policy objectives in England and Wales. The spectrum of the community equipment range is vast, and CES are used by almost every clinical professional responsible for providing care in the community.

The increased significance in recent years of the prevention, rehabilitation and independence agenda, together with the increase in the ageing population, has placed unrelenting pressure upon CES.

CES operate within a broad framework of legal and welfare related obligations. Recently enacted legislation e.g. Corporate Manslaughter Act 2007 (enacted April 2008), and the Health and Safety (Offences) Act 2008 (enacted January 2009), has resulted in greater exposure to legal action, and the potential for more serious penalties e.g. imprisonment.

In addition, CES now must ensure compliance with the obligations set out within the UN Convention on the Rights of Persons with Disabilities (signed by the UK in 2008, to be ratified in spring 2009).
Summary of Risks and Concerns within CES

This document demonstrates that despite attempts to improve the service the risks and concerns relating to CES are very extensive. The following list outlines some of the main areas of concern:

- There is a lack of understanding of the complexities in service provision, particularly at commissioning level, and of the range of legal requirements that CES operate within.
- There are regular breaches of legal and welfare related obligations which carry the risk of prosecution or even imprisonment.
- There are many community equipment related incidents and avoidable fatalities reported to Medicines and Healthcare products Regulatory Agency (MHRA) and the Health and Safety Executive (HSE) every year.
- There are serious quality of care issues in the delivery of CES which result in unnecessary hospital admissions, delayed transfers of care, acquired infections, long term developmental implications, and even unnecessary deaths.
- There is evidence that the NHS and Social Care could potentially be spending billions unnecessarily by not giving CES due care and attention, and that they are not fully realising their strategic and policy objectives by neglecting this essential service area.
- None of the regulatory bodies in England and Wales (e.g. Healthcare Commission, CSCI, and CSSIW) reviews CES - probably because they lack the appropriate knowledge and expertise. Neither are services inspected in relation to any specific standards.

Benefits of introducing National Minimum Standards to CES

This document asserts that the risks and concerns identified above could be addressed by introducing National Minimum Standards for CES. There are many benefits with this approach including:
• Better patient care
• Reduced legal exposure by ensuring CES comply with various legislation e.g. Corporate Manslaughter Act 2007
• Compliance with various Health & Safety regulations
• Enabling a common benchmark for all CES providers
• Allowing services to be regulated
• Enabling better planning & commissioning
• CES providers and clients being clearer about what is expected from them
• Support of key policy objectives e.g. NSFs
• Better governance and risk management
• Reduction in the number of fatalities and serious incidents
• Improvements on wider health & social care issues e.g. admission avoidance, delayed transfers of care, at a fraction of the current cost

Recommendations
In view of the many issues raised throughout this document the following steps are recommended.

1. Agreement is sought for introducing National Minimum Standards
2. National Minimum Standards are developed
3. A concordat arrangement is sought between the different regulatory and inspection bodies e.g. HSE, MHRA, Care Quality Commission\(^1\), CSSIW
4. Further discussion to take place to explore the need for regulating CES

\(^{1}\) The Care Quality Commission (England) was established by the Health and Social Care Act 2008 to regulate the quality of health and social care, and look after the interests of people detained under the Mental Health Act. It will bring together the work of the Commission for Social Care Inspection (CSCI), the Healthcare Commission, and the Mental Health Act Commission. The Care Quality Commission became a legal entity in October 2008 and takes up its responsibilities for the quality of health and social care in April 2009.
Conclusion
The many areas of concern identified within this document clearly demonstrate the need for urgent attention to be given to this key service area.

It is hardly believable that such a critical service has no robust measures in place for ensuring an acceptable level of performance, quality and safety is maintained, given that this is such a high risk environment. It is also demonstrated within this document that without robust measures in place for monitoring performance there is a huge financial impact on other health and social care related services.

This document concludes that by introducing National Minimum Standards to CES there would be a significant reduction in the current and future risks, allowing a safer and better quality service to be provided for users and carers. There would also be reduced legal exposure for health and social care organisations, and employees.

The serious nature of risks identified within this document suggests that CES may need to become regulated, and this is an option which needs to be explored further.

“If a medicine was discovered with a similar cost-profile, it would be hailed as the wonder drug of the age”

Source: Audit Commission Report on CES, Fully Equipped 2000
1. Introduction

There are approximately 150 community equipment services (CES) in England and Wales, which issue around 10 million pieces of equipment each year to 3.5\(^2\) million users. It is expected that demand could increase by 40% for these services by the year 2022 (PSSRU, 2005).

Community equipment services are vitally important in supporting key policy objectives in England and Wales e.g. Older People’s NSF (DH 2001, WAG 2006); NSF for Children, Young People and Maternity Services (DH 2004, WAG 2005); Our health, our care, our say White paper (DH 2006); Designed for Life (WAG 2005); Fulfilled Lives, Supportive Communities (WAG 2007); Putting people first: a shared vision and commitment to the transformation of adult social care (DH 2007).

In view of the prevention, rehabilitation and independence agenda having increased significantly over recent years, together with the increase in the ageing population, there has been unrelenting pressure placed upon CES. These services are used by almost every clinical professional responsible for providing care in the community, and they are crucial in ensuring policy objectives can be achieved.

CES have evolved from an almost unknown entity within relatively few years, and have had to make every attempt to keep pace with the huge and increasing demands placed upon it. Despite recent attempts to improve the service there is still a general lack of understanding of the complexities and difficulties in service provision, and of the range of legal requirements that CES operate within. Neither does there appear to be a full appreciation for the impact of not providing an effective service, nor the consequence this

is having upon health and social care as a whole e.g. safety, quality and client related issues.

Despite the many health and social care regulatory bodies currently in place within England and Wales, and the various standards e.g. Standards for Better Health\textsuperscript{3}, The Healthcare Standards for Wales\textsuperscript{4}, Care Standards, and National Patient Safety Standards, \textit{none of the regulatory bodies reviews CES, nor are the services inspected in relation to any specific standards}. It is believed the regulatory bodies lack the necessary expertise to inspect the service.

According to Medicines and Healthcare products Regulatory Agency (MHRA)\textsuperscript{5}, there were \textbf{30 fatalities} and \textbf{1482} reported\textsuperscript{6} incidents in England and Wales in 2008, relating specifically to the assistive technology equipment supplied by community equipment services, wheelchair services, and other equipment related services. There have also been numerous equipment related incidents and fatalities reported to the Health and Safety Executive (HSE) specifically relating to CES, some of which are currently under investigation.

There are serious quality of care issues in the delivery of CES, which are believed to be a direct result of not commissioning and providing these services properly e.g. unnecessary hospital admissions, delayed transfers of care, acquired infections, long term developmental implications, and even unnecessary death. \textit{Furthermore, there is evidence

\textsuperscript{3} This document was published formally as an integral part of National Standards, Local Action (July 2004) which set out the framework for all NHS organisations (England) and social service authorities to use in planning and commissioning etc.


\textsuperscript{5} Visit: www.mhra.gov.uk for details. The MHRA investigates adverse incidents involving medical devices and equipment; issues safety warnings; provides advice and guidance on safety and quality issues; and, acts as the UK Competent Authority, the regulator for the medical devices industry

\textsuperscript{6} According to Medicines and Healthcare products Regulatory Agency (MHRA) the ‘reported’ number only reflects the absolute minimum of incidents and fatalities, as no doubt there will be those that are not reported
to suggest that the NHS and Social Care could be unnecessarily spending billions by not giving CES due care and attention.

CES operate within a broad framework of legal and welfare related obligations – see Appendix 1 for details. Failings in the standard of service provision mean that legal requirements are being breached regularly – as becomes apparent during investigations when a serious incident occurs.

Given the statistics quoted above for reported fatalities and incidents there is good reason to suppose that some breaches could result in prosecution, and even imprisonment, under the recently enacted Corporate Manslaughter Act 2007 (enacted April 2008), and the Health and Safety (Offences) Act 2008 (enacted January 2009).

This paper therefore takes an in-depth look at the legal, governance and health & safety parameters CES operate within, whilst highlighting underlying areas of concern together with specific breaches which potentially could arise.

The paper also sets out the case for introducing National Minimum Standards and explains how this will improve the overall quality, safety and efficiency of CES.

“Across Government, the shared ambition is to put people first through a radical reform of public services, enabling people to live their own lives as they wish, confident that services are of high quality, are safe and promote their own individual needs for independence, well-being and dignity.”

2. Aims and Objectives

This paper is intended to be read as a discussion paper which aims to cover the following areas:

- An overview of general difficulties with CES provision.
- The legal and welfare context which should be considered by those commissioning and/or providing these services.
- Points to the specific legal, governance and health & safety concerns, whilst highlighting areas for potential breaches.
- Examines the severity of the risks present within CES.
- Highlights the impact poor service delivery can have upon the client, the responsible organisations, health and social care, and the overall English and Welsh welfare economies.
- Examines the relevance of existing health and social care standards, together with pertinent inspection and regulatory issues, to see how these apply to CES.
- Outlines the benefits of introducing National Minimum Standards to CES.
- Provides recommendations on areas where National Minimum Standards should be introduced to CES.

This paper does not:

- Carry out in-depth research into specific areas.
- Reflect the difficulties within every individual service.
- Intend to undermine some of the excellent services operating within England and Wales, nor the commitment of CES staff.
- Provide specific National Minimum Standards that should apply.

Please note, although this review is focussed specifically upon community equipment services, the principles within the document also apply to most other community based equipment providers throughout England and Wales e.g. wheelchair services.
3. Background

3.1 What are community equipment services, and what role do they have?

The spectrum of the community equipment range is vast and is required to meet, for example: therapeutic, mobility, communication, educational, environmental, independence and rehabilitation needs. Equipment can be provided for use in the home, school, work, or for social purposes. The service is key in prevention of hospital admissions, reducing care home admissions, reducing delayed transfers of care, and has more immediate benefits such as preventing and reducing the development of pressure ulcers, and enabling clients to recover more quickly following surgery.

The role, scope and activity of community equipment services is increasing continually, mainly due to the following factors:

- The increasing numbers of older people
- More services moving into the community setting (independence and rehabilitation)
- People generally living longer
- Uncapped expectations of what the service provides and,
- More complex cases to support

It is difficult to define exactly what services, functions and equipment types are provided by community equipment services as they differ greatly throughout the UK. Generally services and equipment types will consist of, but are by no means limited to:

1. Home nursing e.g. pressure relieving mattresses
2. Aids for daily living e.g. shower chairs, kettle tippers
3. Children’s equipment e.g. postural support chairs
4. Sensory impairment equipment e.g. flashing doorbell, listening devices
5. Minor adaptations e.g. ramps, grab rails
6. Wheelchairs (short term)
7. Communication aids
8. Telecare e.g. environmental aids

It is important to note that some organisations even provide very technical and complex equipment which can in some cases be issued to keep clients alive e.g. ventilators. This will usually be provided for continuing healthcare reasons. Because of new technologies becoming available all the time, new equipment types are acquired regularly e.g. bespoke equipment tailored to meet individual clients’ needs.

3.2 How are CES commissioned?
At present CES are generally commissioned by local partnership boards. The partnership boards are made up of members from both health and social care organisations. Community equipment services can be provided by either internal or external providers – although most are internal providers.

The partnership boards are responsible for agreeing levels of service on behalf of their respective organisations in the form of a service specification; this ideally should include activity levels and health and safety standards etc. The service specification will form part of a service level agreement or a formal contractual arrangement with the community equipment service provider.

The partners will usually be working within a Health Act 1999 s.31 (England)/2006 s.33 (Wales) flexibilities agreement. This is basically a formal legal agreement documenting how the partners aim to spend their pooled funds. This document should factor in a breakdown of the costs for the different activities of the service e.g. acquisition, maintenance and disposal.\footnote{For further information see: Vaughan, S. Donnelly, B. (2008). Guidelines for Developing and Integrating Community Equipment Services in Wales, Cardiff: Welsh Assembly Government}
It is the responsibility of the partnership board members, or individual commissioners where a partnership arrangement does not exist, to ensure that all risk, governance, and health & safety obligations and standards are specified, and that the appropriate controls are in place to monitor and evaluate the performance of the provider to ensure the agreed standards are being met.

### 3.3 What Legal and Welfare parameters do CES operate within?

The legal and welfare obligations and parameters that CES currently operate within are huge; a significant number of these could unknowingly be breached on a daily basis, as there are rarely measures in place to ensure compliance. In essence there are three types of obligation as shown by the following diagram:

![Diagram](Overarching health & safety, governance and legal obligations for CES)

#### 3.3.1 The overarching obligations

The following list outlines overarching legislation which directly applies to CES. Each of these obligations places a significant responsibility upon CES, and all have serious consequences, if breached.

- UN Convention on the Rights of Persons with Disabilities
- Corporate Manslaughter Act 2007
- The Health and Safety (Offences) Act 2008
- Disability Discrimination Act 1995 (DDA)
- Common law of Negligence
- Health and Safety at Work Act etc 1974
- Management of Health and Safety at Work Regulations 1999
The first three of the above legislative requirements are not yet widely understood, in terms of their application to CES, due to their relatively recent introduction, but they have a particular bearing upon CES so it is worth considering these more closely.

**UN Convention on the Rights of Persons with Disabilities**

The UN Convention on the Rights of Persons with Disabilities was signed by the UK in 2008, and is expected to be ratified in spring 2009; this should have a significant impact upon the decision making process in relation to CES – especially where commissioning is concerned.

The purpose of the Convention is: “To promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity”.

The Convention is intended as a human rights instrument with an explicit, social development dimension. It adopts a broad categorization of persons with disabilities and reaffirms that all persons with all types of disabilities must enjoy all human rights and fundamental freedoms. It clarifies and qualifies how all categories of rights apply to persons with disabilities and identifies areas where adaptations have to be made for persons with disabilities to effectively exercise their rights and areas where their rights have been violated, and where protection of rights must be reinforced.

Although the convention is quite broad and comprehensive, the key areas which mostly relate to partnership boards/commissioners and CES providers are to ensure their service provision reflects and includes: Participation and Inclusion of disabled people, Non-

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8 It is understood that the UN Convention has been signed by the UK in 2008, and will be ratified in Spring 2009. Lord McKenzie of Luton restated the Government’s intention to ratify the UN Convention on the Rights of Persons with Disabilities and said that it is its ambition to do so in Spring 2009 in an answer to a Parliamentary Question on 18 December 2008 – see Office for Disability Issues for details:  
discrimination, Accessibility, Personal mobility and rehabilitation. See Appendix 2 for full details, and particular relevance to CES.

**Corporate Manslaughter Act 2007**
According to the Ministry of Justice⁹ the 2007 Act puts the law on corporate manslaughter onto a new footing, setting out a new statutory offence. In summary, an organisation is guilty of the offence if the way in which its activities are managed or organised causes a death and amounts to a gross breach of a relevant duty of care to the deceased. A substantial part of the breach must have been in the way activities were managed by senior management.

The offence is particularly concerned with organisations, including partnerships. Individuals can still be prosecuted separately for health & safety negligence by, for example, the Health & Safety Executive.

The Act has overcome a key defect in the law where previously organisations could only be convicted of manslaughter if there was a “directing mind” personally liable. The new law therefore allows for collective decisions like, for example, partnership board decisions.

For the offence to apply, an organisation must have owed a “relevant duty of care” to the victim. The Act defines a duty of care as “…an obligation that an organisation has to take reasonable steps to protect a person’s safety”. This includes for example equipment used by employees, systems of work, products and services supplied to customers – or in this case, clients.

Some of the ‘duties’ outlined within section 2 of the Act are connected to: supplying goods and services; commercial activities; construction and maintenance work; using or keeping

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⁹ A Guide to the Corporate Manslaughter and Corporate Homicide Act 2007
plant, and vehicles or other things. **All of these have a direct bearing upon the day-to-day activities carried out by CES.**

**The Health and Safety (Offences) Act 2008**
The Health and Safety (Offences) Act 2008 came into effect from 16 January 2009. The Act makes substantial amendments to the whole landscape of health and safety law by increasing fines for most existing health and safety offences from £5,000 to £20,000 in the Magistrate's Court (they remain unlimited in the Crown Court).

In addition, **the Act creates the threat of imprisonment for all employees who may have contributed to a health and safety offence by their consent, connivance or neglect.** These will include, for example, cases of serious neglect; reckless disregard for health and safety requirements; repeated breaches which create significant risks; false information and serious risks which have been deliberately created to increase profit. In view of the issues to be discussed throughout this document, this poses a significant risk to all those involved in commissioning or providing CES throughout England and Wales.

Due to the Act having been introduced very recently (January 2009), there remains to be clarity given in terms of the direct application this will have upon health and social care services, and CES in particular – although compliance with existing health and safety law is a good guide to follow.

> **“Employees could find themselves at risk of imprisonment under the new law if they fail to take reasonable care of the health and safety of others or even themselves.”**

**Source:** NHS Employers commenting on the new Health and Safety (Offences) Act10 2008.

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10 Can be viewed at: [http://www.nhsemployers.org/practice/practice-4553.cfm](http://www.nhsemployers.org/practice/practice-4553.cfm)
3.3.2 Service-specific obligations and legal requirements

Some examples of the main service-specific legislation, guidance and recommendations CES are expected to comply with include the following:

- Consumer Protection Act 1987 (Part 1)
- General Product Safety Regulations 2005
- Medical Devices Regulations 2002 (Amended 2003)
- Sale and Supply of Goods Act 1994
- MHRA Managing Medical Devices DB2006 (05) November 2006
- Lifting Operations and Lifting Equipment Regulations 1999 (LOLER)
- Provision and Use of Work Equipment Regulations 1998 (PUWER)
- The Carriage of Dangerous Goods by Road Regulations 1996
- Control of Substances Hazardous to Health Regulations 2002 (COSHH)
- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)

An explanation of how this legislation applies to CES can be found in Appendix 3.

3.3.3 Welfare obligations and legal requirements

The following list shows the main statutory requirements and welfare legislation which apply to equipment provision:

- Chronically Sick and Disabled Persons Act 1970
- NHS and Community Care Act 1990
- Health and Social Care Act 2001
- Health Services and Public Health Act 1968
- National Assistance Act 1948
• Education Act 1996
• Children Act 1989
• Fair Access to Care Services
• Carers and Disabled Children Act 2000
• Carers (Recognition and Services Act) 2005, and Carers (Equal Opportunities) Act 2004

Please refer to Appendix 3 in order to gain a fuller explanation of the particular legal and welfare obligations applicable to CES, how they specifically apply to CES, and where potential breaches may occur.

3.4 The Development of CES
3.4.1 A Review of CES carried out by the Audit Commission

Until March 2000 CES were almost an unknown entity, until the Audit Commission carried out a review of these services in England and Wales\textsuperscript{11}. The main findings of their review paper stated that the organisation of these services was a recipe for confusion, inequality and inefficiency. The paper further suggested that services lacked leadership and were failing to meet the demands of clinical governance, and that, users were getting poor quality equipment together with poor quality outcomes being achieved.

The Audit Commission review, in general, touched upon some of the obvious concerns in the running of these services e.g. poor commissioning, poor information and the difficulties with having no clear eligibility criteria. It also highlighted the absence of good medical device management procedures including purchase, acceptance, decontamination, maintenance, repair, recall and training for users and staff.

In summary, this was a condemnatory review which criticised almost every aspect of the service. Urgent action was called for by the Audit Commission. The review was followed

up by an update in 2002\textsuperscript{12} highlighting that \textit{little or no action had resulted from the first report in 2000.}

The Audit Commission went on further to review services for disabled children in England and Wales (2003)\textsuperscript{13}. A report was produced entitled ‘\textit{Services for disabled children – A review of services for disabled children and their families.}’ Again findings for this service area were very unsatisfactory.

\textbf{3.4.2 Response to Audit Commission findings}

In response to the Audit Commission’s findings and recommendations initiatives were undertaken by both the Department of Health and the Welsh Assembly Government e.g. the Integration of Community Equipment Services in England (ICES, 2003/4), and Community Equipment Service Integration programme in Wales (CESI, 2006/7). Both programmes worked to specific objectives e.g. integrating health and social care services and pooling funds using Health Act flexibilities. Capital grant funding was made available to support both initiatives – approximately £200m in England (although this was not ring-fenced) and £12.5m in Wales.

As part of the change it was recommended for local areas to set up partnership advisory boards, single managers, unified stock, supported by integrated IT systems. Service performance was to be monitored by imposing relevant key performance indicators (KPIs) e.g. percentage of equipment delivered to the client within 7 days from the decision to supply date.

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Both initiatives mainly focussed on the provision of ‘routine’\textsuperscript{14} equipment, leaving the outstanding issues with children’s and complex equipment unaddressed, partly due to the difficulty and complexity in making changes to this service area.

3.4.3 Current Developments
In addition to these developments, the following changes, or proposals to change, are currently underway in England and Wales.

\textbf{England}
Although many services in England are continuing with the ICES programme, there is currently a new programme being piloted in the North West of England. This is known as ‘Transforming Community Equipment Services’ (TCES)\textsuperscript{15}, and has been instigated by the Department of Health Care Services Efficiency Delivery (CSED) team. It is believed by the DoH that TCES is an important element of health and social care policy described in ‘Putting People First’. The TCES agenda was originally intended to cover Wheelchair services, although as yet this area has not been included.

It is hoped that the TCES Model will eventually improve the way that users can obtain community equipment, and that it may also improve choice. The Model hopes to leverage the strengths of the Third and Private Sectors in an attempt to meet increases in demand. It is hoped that accredited suppliers of equipment will become approved retailers where clients will be able to redeem prescriptions for equipment.

The Model proposes that clients would be able to get basic equipment, ‘Simple Aids to Daily Living’, e.g. grab rails, from retailers. The Model also proposes having a national store to obtain large pieces of equipment, ‘Complex Aids to Daily Living’, e.g. beds and hoists. (Note: This is a misleading heading as beds and hoists etc. are not generally known

\textsuperscript{14} E.g. walking frames, hoists and commodes
\textsuperscript{15} Details can be viewed on the CSED website: \url{http://www.csed.csip.org.uk/solutions/solutions/transforming-community-equipment.html}
as ‘Complex Aids’ in the community equipment environment.) To date the TCES Model has not addressed Complex, Specialist and Children’s equipment difficulties, and it has been suggested that local services still ‘locally commission’ these.

There is ambiguity around how the proposed TCES Model would interface with the existing health and social care partnership arrangements i.e. section 31 pooled funding arrangements, if indeed partnership arrangements would still apply.

The TCES Model is not mandatory, and local areas can choose whether to follow it or not.

**Wales**

In addition to the integration of services, and pooling of funds etc., CES in Wales have been focussing on the problems inherent in the delivery of services e.g. training of staff and commissioning. Wales are currently looking to design an accredited training programme for all staff involved with CES, including commissioners.

The Welsh Assembly Government has also embarked upon a project to introduce an all-sector national store which will exclusively look after Complex, Specialist and Children’s equipment. It is hoped that the national store would support the existing regional stores who would be focussing on routine equipment.

The Welsh Assembly Government procurement arm, Value Wales, in association with Welsh Health Supplies, is currently in the process of introducing a national procurement framework for ‘routine’ equipment. It is hoped that this will improve time, cost and quality for local services.

There are also workshops taking place throughout Wales, particularly aimed at senior management, to focus on the legal and health & safety aspects of the service. These groups
are supported by: Welsh Assembly Government; Health & Safety Executive (HSE); MHRA; College of Occupational Therapists (COT), and external legal advisors.

Some local services are in the process of exploring the benefits of moving to a Social Enterprise delivery model.

4. What are the general areas of concern relating to CES?

“We still don’t know very much about how safe care in primary care is”


As previously mentioned there have been many fatalities and serious incidents with community equipment and wheelchair related services over recent years. For example, according to HSE there have been 20 fatalities specifically relating to Bedside Rails in the past 10 years\(^\text{16}\). There have also been a series of reported equipment related fatalities and incidents in care homes over recent years which has also resulted in the production of HSE support material.

Because CES is community based not all incidents are recorded, as clients may never inform anyone, perhaps because they do not know whom to inform – especially if the appropriate information and contact details are not provided by CES.

In addition to the incidents directly related to equipment, there are other less tangible aspects of service provision where, for example, failing to deliver the right equipment, delivering the equipment late or quite simply not providing equipment at all, will have

\(^{16}\) See BUPA and HSE produced CD on Bedside Rails. Available from HSE
adverse implications for clients, and could result in a breach of the organisation’s responsibilities. For example:

- A client getting the wrong equipment may need to be admitted to hospital unnecessarily.
- A client waiting for equipment for a considerable time could develop pressure sores and have to be admitted to hospital.
- A client not getting equipment in a timely manner may fall unnecessarily in the meantime.
- A client receiving equipment not properly cleaned could acquire an infection.
- A child not provided complex equipment could develop long term developmental implications, be denied access to the local school and may have to be placed out of county, or may even need to have one parent become a full-time carer.
- Carers not getting the right equipment could result in an injury e.g. bad back.

Although there are many reasons for these incidents and failings occurring, there are underlying problem areas and complexities inherent in the constitution and management of CES which impact on the quality and safety of service provision. The following pages highlight the main areas of concern from which problems may arise. These include:

- Commissioning & Governance
- Clinical Governance
- Eligibility Criteria
- Medical Device Management
- Health & Safety Management
- Training
- Provision of complex, specialist and children’s equipment
- Wider health and social care cost issues
4.1 Commissioning & Governance

Most CES providers are commissioned and governed by partnership boards (under Health Act 1999 (Wales: 2006) flexibilities pooled funding arrangements) regardless of whether they are in-house or outsourced services. There can be a considerable amount of ambiguity when specifying service requirements. For example if the actual service activities or components are not specified in terms of numbers etc. this can have a resource impact upon the providers, which can result in all sorts of failings e.g. not having sufficient funds to maintain equipment in the community.

The responsibilities of these boards, or commissioners, are very broad. For example they will have responsibility and overall accountability for ensuring the following issues are managed appropriately: Quality; Performance; Risks; Finances; Contractual arrangements, and Clinical Governance.

Part of the difficulty for the partnership boards is their lack of understanding, generally, of how these services operate. In fact when the Audit Commission reviewed services in England and Wales in 2000 and 2002 they reported that “Auditors found the standard of commissioning of equipment services to be exceptionally weak”. They further added that there was a lack of knowledge about the underlying level of demand; there was short term thinking; and inappropriate commissioning currencies i.e. funding bearing no relationship to activity or service requirements – current or future.

Although the front end of service delivery has changed over recent years, and is currently changing, this reflection by the Audit Commission of commissioning CES may still be true for a lot of services.
4.2 Clinical Governance

It is also the overall responsibility of the commissioners to ensure clinical governance arrangements are maintained, especially as a significant element of providing a community equipment service is about clinically assessing the needs of the client.

According to the NHS Clinical Governance Support Team\(^\text{17}\) clinical governance is here to ensure safe, high quality care from all involved in the patient’s journey and to ensure patients are the main focus and priority.

The support team outline several key components and themes, all of which, when effective, combine to make up good clinical governance. They are:

- Patient, Public and Carer Involvement
- Strategic Capacity and Capability
- Risk Management
- Staff Management and Performance
- Education, Training and Continuous Professional Development
- Clinical Effectiveness
- Information Management
- Communication
- Leadership
- Team Support

It is unfortunate that, in a community equipment setting, a significant part of the above list is often not covered by clinical governance arrangements set out within service specifications or contracts. Most of the clinical aspects therefore rely upon the ability and the integrity of the individual professionals.

\(^\text{17}\) Can be viewed at: [http://www.cgsupport.nhs.uk/About_CG/default.asp](http://www.cgsupport.nhs.uk/About_CG/default.asp)
Some of the specific issues which could be covered within the specification, but generally are not, would be things like: the training required to prescribe certain types of equipment; the process for reviewing/revisiting the clients’ needs, following a specified time.

It has to be acknowledged however that some of the above will be addressed by direct clinical supervision.

4.3 Eligibility Criteria
As CES are usually integrated between health and social care, with pooled funding arrangements in place, difficulty is presented in applying single eligibility criteria when issuing equipment.

There are certain demarcations between health and local authority eligibility criteria. For example, under the Fair Access to Care Services (FACS) guidance local authorities are required to specify what level of need they will meet in relation to independence i.e. critical, substantial, moderate or low; this is usually determined by the level of funds available. They are required to specify this at the beginning of the financial year.

In contrast, the NHS does not usually specify the level of need it will meet, and can, in special circumstances, refuse to provide some equipment where it can be proved financial resources were not available.

It should be noted that some authorities apply blanket policies on equipment types and minimum financial threshold restrictions, even though this is contrary to all pertinent legislation. These issues can result in clients not receiving the appropriate equipment, or even not receiving equipment at all.
4.4 Medical Device Management

Good medical device management is a fundamental part of providing a safe community equipment service. Failure to ensure medical devices are managed appropriately has resulted in many fatalities and adverse incidents.

Medical device management is a very broad topic area and covers for example:

- Policies and procedures
- Reporting incidents
- Medical device management board
- Acquisition processes
- Electrical safety testing (portable appliance testing)
- Repair and maintenance (Lifting operations and lifting equipment regulations - LOLER)
- Training for professional and end users
- Information and record management e.g. user instructions
- Decontamination & disposal processes

“If a device malfunctions after repair or maintenance and leads to the death or serious injury of a user, the responsible organisation and the repair service provider are far more likely to be held liable for the injuries caused if the device was not repaired in accordance with the manufacturer’s instructions. …they could be held responsible under health and safety law and civil liability should a user or member of staff die or sustain personal injury or damage as a result”

Source: MHRA, Managing Medical Devices DB2006 (05) November 2006
Commissioning boards responsible for CES generally do not appear to give this very important topic area the necessary care and attention required to reduce risk to an acceptable level. This view is supported by the number of ongoing reported fatalities and incidents occurring. There is also very little evidence of CES being engaged in, or discussed at, medical device management boards – where they exist.

**MHRA adverse incident reports and statistics 2007**

The importance of incident reporting should not be underestimated, and without the existence of a medical device management board it is hard to see how incidents involving medical devices in the community can be reported or managed safely.

The following statistics released by the MHRA for 2007 give some indication of the serious incidents that do occur with medical devices generally. It is important to note that the following figures only represent those incidents which have been reported.

- 8,634 Reports on Medical Devices overall of which **193 involved fatalities**
- 842 Reports on wheelchairs and seating
- 659 Reports on other assistive technology products e.g. alternating pressure mattress (assistive technology devices give rise to 17% of all incidents)
- **6 Fatalities** from wheelchairs and seating
- **15 Fatalities** on other assistive technology products

Assistive Technology received a total of 1,501 adverse incident reports during 2007 of which 383 were investigated in depth by medical device specialists due to the seriousness of the risks involved.

"We know that a significant gap exists between the number of incidents that are reported by the NHS and the number that happen in reality…"

**Source:** Anna Walker, Chief Executive of the Healthcare Commission – commenting on NPSA findings

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18 An MHRA Device Bulletin is issued to give a summary of each year’s adverse incidents DB 2008(02) covers the year 2007.
The following information breaks down some of the product specific cases to illustrate the pertinence to community equipment services.

**Beds**
In 2007 MHRA received 115 adverse incident reports concerning beds and mattresses; investigation of these led to 5 Medical Device Alerts being issued, which included: occupant entrapment risks; risks of fire and explosion due to battery charging problems; risks to users or others from cracking welds on bed frames and, contamination risks due to inadequate cleaning/decontamination procedures for mattresses.

**Wheelchairs and children's buggies**
In 2007 MHRA received an alarming 842 adverse incident reports concerning many different types of powered and non-powered wheelchairs used by children and adults. Investigations led to many changes in designs and instructions for use, and 4 Medical Device Alerts were issued, which included: unexpected failures of seating and frame structures and the possibility of burns from a charger.

**Hoists and slings**
In 2007 MHRA received 132 adverse incident reports involving hoists and slings, and investigations lead to 4 Medical Device Alerts being issued. These included: the potential for an occupant to fall due to drive motor/gearbox failure; risks from poor compatibility; poor laundering; poor maintenance practices; potential for the occupant to fall if the sling attachment device failed in use; potential for the operator to receive burns whilst using an overheating handset.

MHRA have developed very comprehensive guidance in support of the management of medical devices within health and social care organisations, most of which is pertinent to
CES\textsuperscript{19}. In addition they have specifically developed guidance on decontamination for CES\textsuperscript{20}. These are perhaps the best reference documents produced which highlight the clear responsibilities of every provider, also pointing to relevant legislation. \textit{If considered rightly against current practice within CES, these documents expose the many potentially unsafe and illegal practices.}

4.5 Health & Safety Management

Given the nature of community equipment services, and the potential for exposure to serious risk e.g. electrocution, cross contamination, health and safety management should play a significant role in the day to day running of CES.

The main aims of the Health and Safety at Work Act Etc. 1974 (HASAWA) are to impose on an employer a statutory duty of care for the health, safety and welfare of:

- its employees, and
- other people who may be affected by its activities (eg. service users, the employees of contractors or members of the public).

Failure to comply with the Act – whilst factoring in reasonable practicability - could result in prosecution. With the recent enactment of the Health and Safety (Offences) Act 2008, there is now real potential for imprisonment of employees held responsible.

There seems to be a generally unspoken view that care in the community is not subjected to the same Health and Safety at Work Act Etc. 1974 (HASAWA) requirements as those in, for example, an acute hospital. This view may be adopted because people feel that the ‘community’ is outside their work environment, and therefore Section 2 of the HASAWA ‘General duties of employers to their employees’ does not apply. This is not the case; Section 2 covers all areas where employees carry out their duties.

In relation to those using the equipment other than employees e.g. users and carers, Section 3 of the Act specifically covers these activities by outlining ‘General duties of employers and self-employed to persons other than their employees’. Basically Section 3 of the Act sets out the duty of employers to ensure that persons not in their employment are not exposed to risks (so far as is reasonably practicable) to their health and safety. This Section also states that it is the responsibility of every employer to provide appropriate information to such individuals about the way undertakings are conducted which might affect their health and safety.

In a community equipment environment the context of health and safety is very broad, but factoring in both section 2 & 3 of the HASAWA, and also the Management of Health and Safety at Work Regulations 1999, basically health and safety policy should aim to cover:

- Appropriate, reasonable and explicit contracting arrangements
- Risk Management processes – including monitoring and reviewing
- Compliance with Medical Device issues
- Compliance with Electricity at Work Act
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) processes

More specifically the Health & Safety Executive (HSE) would look for evidence of compliance with relevant legislation such as: General Product Safety Regulations 2005; Manual Handling Operations Regulations 1992; Medical Devices Regulations 2002; Lifting Operations and Lifting Equipment Regulations 1999 (LOLER); Provision and Use of Work Equipment Regulations 1998 (PUWER); The Carriage of Dangerous Goods by Road Regulations 1996; Control of Substances Hazardous to Health Regulations 2002 (COSHH)

Other aspects of the HASAWA apply in a CES setting e.g. 1. General duties of employees at work: 7 HSWA 1974. 2. Offences by bodies corporate: 37 HSWA 1974.
According to ‘careandhealthlaw’\textsuperscript{21}, a website which provides legal information relating to health and social care, the Health and Safety Executive (HSE) are increasingly considering prosecution of healthcare providers, including both the NHS and private sector, where health and safety regulations are breached.

Furthermore, the new Corporate Manslaughter Act will not affect the provisions of the Health and Safety at Work Act 1974 or its associated health and safety regulations. Prosecuting authorities will be able to consider a prosecution for both Corporate Manslaughter and breaches of existing health and safety legislation.

\textit{Generally speaking CES do not have the appropriate governance structure and arrangements in place to ensure the above issues are monitored and/or reviewed regularly. It is also rare that the health & safety specifics are detailed within service specifications.}

The diagram below illustrates HSEs recommended structured process for ensuring ‘Successful Health and Safety Management’ is achieved – (known by the acronym ‘POPMAR’).

It is important to note that should a HSE investigation take place as a result of an incident inspectors would generally look for evidence of adherence to the following process:

\textbf{Fig.1 HSE POPMAR Model}

\textsuperscript{21}\textit{Visit:} http://www.careandhealthlaw.com/Public/Index.aspx?ContentID=66&IndexType=2&TopicID=61&Category=1
To view a brief summary of the individual POPMAR processes please see Appendix 4.

Basically the POPMAR process involves:

- setting a Policy
- Organizing staff
- Planning and setting standards
- Measuring performance
- Auditing and Reviewing

In relation to CES it is very difficult to imagine how this Model can actually be applied if the governance arrangements are not robust, where the standards are not set, or where the service is not part of a medical device management group, if at all one exists.

4.6 Training
Training appears to be an area that is massively overlooked within CES. Training needs to be viewed broadly as applying to all aspects of service provision e.g. commissioning, stores management, technical staff, professional and end users.

The MHRA have emphasized the importance of appropriate training in their recent guidance ‘Managing Medical Devices’, and have detailed the considerations to be given for each role. They have stated that all aspects of training in relation to service provision should be incorporated into a policy document which should be developed by the medical devices management group – should one exist.

Professional & End Users
The MHRA document explains that the professional user needs to understand how the manufacturer intends the product to be used; and that the end user (client) needs to understand the intended use and functions of the device in order to use it safely.
Professional users e.g. therapists, are generally qualified to identify the equipment need. There is also a ‘Trusted Assessor’ course widely available for clinical staff which looks primarily at assessment, use and fitting of basic daily living equipment. However, this area of training still requires consideration due to the potential for serious error, as seen in the following example where a client was issued with the wrong equipment.

Recent Case Example:

“South Birmingham primary care trust has been fined £20,000 after a 90-year-old patient fell to her death from a battery operated hoist that was too large for her, as two auxiliary nurses lifted her from a commode to a bed…”

Source: Health Service Journal p.10 11th December 2008

Technical Staff
The MHRA document also stresses that individuals providing repair and maintenance services, in-house or otherwise, need to be adequately trained and appropriately qualified. The guidance suggests that for simple devices NVQ level 2, or equivalent may be appropriate, and for complex equipment NVQ level 3 would be required. An organisation known as SEMTA have developed occupational standards specifically for community equipment technicians, both level 2 & 3.

However, this particular course is not mandatory across the UK for CES technicians, and it is alarming to note that most technical staff are NOT trained at all. Technical staff working within CES do not have essential minimum entry qualifications, unlike for example, hospital based biomedical engineers (EBME departments) who need to have a degree, or similar level, to carry out their jobs.

22 Visit: www.dlf.org.uk/professional/training/courses/acctat.html for further details
23 ‘Semta’ is the Sector Skills Council for science, engineering and manufacturing technologies in the UK.
“Individuals providing repair and maintenance services need to be adequately trained and appropriately qualified. This applies to directly employed staff, contracted services or others”.

**Source:** MHRA Device Bulletin. Managing Medical Devices DB2006(05)

**Management of CES**

A report recently submitted to the Welsh Assembly Government\(^{24}\) highlighted the importance of training and awareness courses for all individuals involved within CES, including management and commissioners of the service. The report highlighted the absence of relevant training provision and the potential impact this was having, for example:

- Compromised quality of service to clients;
- Failed wider health and social care targets e.g. admission avoidance;
- Increased corporate risks e.g. Corporate Manslaughter (duty of care);
- De-motivated workforce – no support or opportunities;
- Difficulty attracting competent workforce;
- Service delivery more costly due to poor performance.

The report suggested possible topic areas where training could be provided, which included:

1. **Policy & Procedures** – local, corporate and national
2. **Health, Safety and Legislation**
3. **Performance and Contract Management** (including how to commission)
4. **Stores and Stock Management**
5. **Technical & Maintenance Management**
6. **CES IT Systems** – Store, Clinical & Information
7. **Financial Management** (including Health Act Section 31/33 (Wales) Pooled Funding)

\(^{24}\) Donnelly, B (2008) *Training & Development needs for Community Equipment Staff…*” please note this is not a published document, but is available upon request.
8. Supporting Corporate Strategy and Clinical Priorities

The report shows that the clear absence of any formal training for all the appropriate individuals involved in CES could be having a disastrous overall impact on the quality and safety of the services provided throughout England and Wales.

The report concluded that all of the factors outlined combined to create an urgent need for some type of formal training and development to be introduced, especially in view of the increasing importance of CES. In response to this report, the Welsh Assembly Government intends to work with its local partnerships to address these training difficulties.

4.7 Provision of complex, specialist and children’s equipment
This is a huge and very complicated area which directly impacts upon the lives and wellbeing of many vulnerable individuals throughout the UK. There is significant difficulty with providing a service to clients with specialist, complex or children’s equipment needs.

Equipment can range from complex wheelchairs and children’s postural support equipment to bariatric beds, communication aids and sensory impairment aids – basically all non-routine community equipment.

The difficulties when providing complex equipment are not directly related to infrastructure, or resources, but rather that the local service areas are too small and do not have the capacity, expertise at a local level, nor the economies of scale in order to deal with them, neither is there any joined up working throughout the different sectors on a larger scale (Audit Commission, 2002).
Some of the main issues which result from not delivering these services effectively include:

- Poor compliance with key policy objectives e.g. NSFs.
- Huge delays in equipment provision for clients – this can be up to 6 months.
- Children with complex needs requiring out of county placements – this can cost as much as £3000 - £4000 per week.
- Unnecessary hospital admissions; delayed transfers of care; long waiting lists; poor service support to rehabilitation, independence and disability initiatives.
- Poor compliance with legislation e.g. Chronically Sick and Disabled Persons Act, Disability Discrimination Act, Health & Safety Act Etc. 1974.
- Failure to meet Medical Device Regulations, and Governance arrangements.
- Duplicated services locally and nationally (inefficiencies).
- Little or in most cases no information about the services to support strategic planning/joint working – Social Care, Health, Education, Voluntary Sector, Public and Commercial/Industry Sector – together with no clear responsibilities for each sector.
- Confusion over who provides what equipment categories for the client – eligibility criteria inconsistent.
- Lack of core skills e.g. clinical, technical, product knowledge and procurement.
- Very few economies of scale, poor purchasing and huge stock holding costs – huge quantities of unused/obsolete stock held by individual services and sectors – an estimate of the value could be in the region of £60-£70 million in England and Wales\textsuperscript{25}, excluding stock holding and management costs - local services are too small to recycle specialist equipment quickly.
- Little evidence of sharing equipment throughout the regions and sectors, therefore potentially huge cost avoidance savings are missed, together with a reduction in lead times.

\textsuperscript{25} These figures are extrapolated based on findings from a project carried out in Buckinghamshire (England) for a countywide multi-agency children’s service in 2004.
As can be seen above, evidence points to massive waste of resource. More importantly, there are citizen-centred issues, such as long lead times for equipment; which could be radically improved if that resource were appropriately redeployed.

The Audit Commission shared similar views in a review they undertook in England and Wales26 (2003) of services for disabled children. Some of the key findings from their report identified that:

1. There was a lottery of provision. Services offered were based very much on where people live and how hard people push;
2. Services rarely based on priorities and need;
3. Equipment provided too little too late;
4. Lack of information passed on about services – families having to struggle through a maze of services to get any information.

Unfortunately there is little evidence of improvement in this service area since this report was produced. In order to illustrate and reinforce the point, the following pictures of a store for children’s equipment in England highlight the standard of service some areas currently provide in relation to complex equipment. Note that some areas do not provide a service at all.

The particular service above did not have any formal decontamination or maintenance processes in place – clinical staff were maintaining equipment themselves. The equipment pictured is intended for re-issue to clients. Equipment was not electronically recorded or tracked, so equipment could not be recalled if it needed to be.

It is anticipated that if a service like this was inspected by the Health & Safety Executive it would be closed immediately. For example the store above would have been potentially in breach of the following legal obligations:

- Disability Discrimination Act 1995 (DDA)
- Common law of Negligence
- Health and Safety at Work Act Etc 1974
- Management of Health and Safety at Work Regulations 1999
- The Health and Safety (Offences) Act 2008
- Corporate Manslaughter Act 2007
- Consumer Protection Act 1987 (Part 1)
- General Product Safety Regulations 2005
- Medical Devices Regulations 2002 (Amended 2003)
- Sale and Supply of Goods Act 1994
- Lifting Operations and Lifting Equipment Regulations 1999 (LOLER)
- Provision and Use of Work Equipment Regulations 1998 (PUWER)
- Control of Substances Hazardous to Health Regulations 2002 (COSHH)

Please refer to the explanatory notes in Appendix 3 for details of how the above legislative/welfare requirements could have been breached.

If a child died as a direct result of having been issued faulty or dangerous equipment from this store, or similar stores around England and Wales, a case could be brought for
Corporate Manslaughter on the grounds of gross negligence, given the inadequacy of storage and decontamination procedures for equipment. There would also be the real potential for imprisonment under the new Health and Safety (Offences) Act 2008, should the breach be considered serious enough.

“Children and young people with complex needs, including children with disabilities or those in situations that make them vulnerable, do not always get the attention and care from healthcare services that they need.”


Furthermore, it is difficult to imagine how the above service, and similar services throughout England and Wales, complies with the ambitions set out within the NSF for Children, Young People and Maternity Services 2004 (England) 2005 (Wales); for example:

From Standard 6 of the NSF (England 2004)\textsuperscript{27}

“Local Authorities and Primary Care Trusts ensure that:

- Commissioning of services for disabled children and their families includes consideration of their housing, community equipment and wheelchair needs.

- Disabled children are able to use/access the equipment and assistive technology they need in all places they typically spend time (e.g. school, home, short-term care settings)

- Parents and other carers are given training and support in the use of the equipment and assistive technology, including who to contact in an emergency and out-of-hours;

- Services are in place to meet the particular housing, equipment and wheelchair and transport needs of looked after children;

- Community Equipment Services are integrated across health, social services and education and develop multi-agency protocols that set benchmarks for the assessment and provision of children’s equipment, including wheelchairs.

- Multi-agency arrangements are in place for the provision and maintenance of equipment and supplies.”

\textsuperscript{27}http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4089112
From the NSF for Children, Young People and Maternity Services in Wales (2005)

“There are integrated community equipment services that supply equipment to disabled children and young people, managed by a designated lead agency. The lead agency monitors that the following criteria are met:

- assessment for equipment for disabled children is carried out by the most appropriate person in the multi-disciplinary team within four weeks of referral;
- equipment is supplied within 6 weeks of assessment according to jointly agreed eligibility criteria for essential equipment;
- the equipment store has dedicated resources for children which are distinct from adult resources;
- a supply of continence equipment is available to meet the assessed needs of children and young people;
- local emergency supplies are immediately available;
- There are effective mechanisms in place for the retrieval of unwanted equipment. This includes databases that record where equipment is, when it is due for servicing, cleaning or requires repair;
- The child’s equipment requirements are reviewed at least annually.”

It is important to note that the NSFs for children in England and Wales are 4-5 years old, and to date there is very little evidence of compliance with these as far as CES is concerned. There is also no way at present for monitoring how service provision aligns with the strategic objectives set out within the NSFs.

“We acknowledge that there is a gap between national policy and people’s real experiences”

4.8 Wider health and social care cost issues

It is generally accepted that costs for health and social care can escalate without timely interventions, or appropriate prevention measures e.g. providing timely equipment can prevent hospital admissions.

Unfortunately there is very little collective evidence or research available which examines the overall impact of not providing equipment to the client e.g. impact upon delayed transfer of care, number of out-of-county placements, number of unnecessary hospital admissions.

There are however good pockets of helpful and supportive information and studies available which look at the benefits and cost implications of providing good intervention and/or preventative clinical care e.g. NICE guidance. There are also useful tools available for establishing the costs for care etc. such as ‘Unit Costs of Health and Social Care’28.

More specifically to CES there has been a very useful report produced by the University of Bristol for the Office for Disability Issues, which looks at the benefits of providing equipment from a financial perspective29. The document very strongly argues the case that by providing these services right better outcomes will be achieved for lower costs.

Some examples from the report state:

- Two wheelchair users were able, after the adaptation of suitable properties, to leave residential care that had been costing the local authority a total of £72,800 per year. The report asserts that “\textit{this will achieve savings of over £30,000 per year for each of them after the first year. 1-2 similar cases per housing authority would produce savings in England of £10 million a year, growing incrementally each year.”}

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• There were also incredible savings for one 30 year old man, *where savings in residential care costs of £1.6 million* were projected over an assumed life-expectancy of 20 years, as a result of investment in home modifications.

**Other facts and figures provided in the report include:**

• People fall whilst waiting for adaptations, which are frequently delayed by lack of funding. The average cost to the State of a fractured hip is £28,665.

• Figures from 2000 suggest falls leading to hip fracture are a major problem, and cost £726 million pa – that is probably near **£1 billion** in today’s prices.

• Parent care-givers without adaptations and equipment have a 90% chance of **musculoskeletal damage**; falls leading to hospitalisation; and stress caused through inadequate space.

• Adaptations produce improved quality of life for 90% of recipients and also improve the quality of life of carers and of other family members.

“The Audit Commission and other bodies have asserted that increased investment in housing adaptations and equipment would bring significant savings to the National Health Service and to social services budgets, but funding and structures, compounded by the lack of clear evidence, have created barriers to such investment.”


To illustrate the financial impact upon health and social care of not providing CES effectively, the following calculations have been carried out. (Note that without full research into this specific area the costs are only approximates.)
The calculations are based on the fact that failure or delay in providing appropriate equipment can result in the necessity for further care, with associated costs, as shown below:

<table>
<thead>
<tr>
<th>Episodes of Care</th>
<th>Approx. Weekly Cost</th>
<th>Annual Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homecare</td>
<td>£500</td>
<td>£25000</td>
</tr>
<tr>
<td>Residential Care</td>
<td>£800</td>
<td>£40000</td>
</tr>
<tr>
<td>Hospital Stay</td>
<td>£1400</td>
<td>£70000</td>
</tr>
<tr>
<td>Treatment of Pressure Ulcer</td>
<td>£200</td>
<td>£10,500 (one-off)</td>
</tr>
<tr>
<td>Out of county placement (special schools for children)</td>
<td>£2,500</td>
<td>£156,000</td>
</tr>
<tr>
<td>Operation &amp; rehab following a fall e.g. hip replacement</td>
<td>£550</td>
<td>£28,665 (one-off)</td>
</tr>
<tr>
<td><strong>Average Cost per “failure”</strong></td>
<td><strong>£1000</strong></td>
<td><strong>£55,000</strong></td>
</tr>
</tbody>
</table>

**Table of CES related episodes of care and approximate costs**

- Cost at failure rate of 1% | £100m per week | £5.5bn per annum
- Cost at failure rate of 10% | £1bn per week  | £55bn per annum

**Sources of Costs:**
- Better outcomes lower costs. University of Bristol;
- Unit Costs for Health and Social Care. PSSRU 2007

**Supporting notes:**
- Approximately 10 million pieces of equipment are issued annually to 3.5m users in England and Wales.
- Equipment not provided, delivered late, the wrong equipment delivered, or an incomplete order, can lead to a secondary episode of care e.g. hospital admission, delayed transfer of care, falls, pressure ulcers etc.
- Some people going into care may remain in care for several years, and may never return home - particularly the elderly. Others may only be in care for weeks or months. For simplicity, the assumption has been made that each “failure” has a consequential cost of one year – although weekly costs can also be viewed.
• Clients requiring specialist, complex or children’s equipment can regularly wait for several months before receiving equipment.

• The formula calculation is very general and does not factor in Quality-adjusted life years (QALYs).

• “Failure rate” means percentage of deliveries which are late or incorrect, and results in one of the episodes of care listed above.

• Services currently provide approximately 70% of equipment within 7 days, under PAF targets – where these are measured. Note that some services report an actual rate as low as 20%. Therefore a 1% or even a 10% “failure rate” overall is a conservative estimate.

It is acknowledged that these costs need further examination, and also that any equipment costs would need to be offset against the total. However, even with these factors considered, it is believed that there are still huge unnecessary costs being incurred as a direct consequence of not providing equipment or ensuring high performance levels in the delivery of these services are being maintained.

“Equipment services could play a vital part in strategies to optimise capacity, prevent unnecessary admission to hospital and facilitate prompt discharge of patients. However, a real leap of faith is needed to spend hard cash now in anticipation of these future benefits”


5. What are the specific risks relating to CES?

Without carrying out a full risk assessment into every aspect of CES it is not possible to provide a comprehensive list of all of the specific risks. However, in order to demonstrate the seriousness of the risks present within services, some specific examples of the most obvious risks have been identified in the following table.
Each of the identified risk factors has been graded using parts of the commonly used risk matrix developed by the NHS National Patient Safety Agency (NPSA)\(^{30}\). This helps to ascertain the severity of each risk, especially when considered alongside the consequence and likelihood factors.

**The step by step process included:**

1. Some examples of the main risk factors present within CES were identified.
2. The risk factors were assessed, and accordingly scored, in relation to the potential consequences they might have.
3. The likelihood of the risk occurring was also assessed and accordingly given a score.
4. The combined scores for the consequence and likelihood factors were then multiplied using the NPSA scoring system, to establish the overall severity and grading of the risks.
5. Combined scores should then be evaluated against the risk grading table to ascertain the grade of each risk.

**NPSA Risk Grading Table**

<table>
<thead>
<tr>
<th>Score Range</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 3</td>
<td>Low risk</td>
</tr>
<tr>
<td>4 - 6</td>
<td>Moderate risk</td>
</tr>
<tr>
<td>8 - 12</td>
<td>High risk</td>
</tr>
<tr>
<td>15 - 25</td>
<td>Extreme risk</td>
</tr>
</tbody>
</table>

For further details of the process used in this method of risk grading, please see *Appendix 5*.

---

<table>
<thead>
<tr>
<th>Potential risk factors</th>
<th>Possible Consequence/Supporting notes</th>
<th>Consequence (C)</th>
<th>Likelihood (L)</th>
<th>Risk (C x L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical staff not trained</td>
<td>This is very common. Could be fatal for the client, and exposes duty of care</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>No formal management training for CES</td>
<td>This is almost universal. Could result in sub-optimal decisions</td>
<td>3</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Commissioners not fully understanding the service requirements</td>
<td>Not knowing level of current and future activities is quite common. This impacts upon service provision</td>
<td>4</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Life support and complex equipment issued to clients direct from suppliers without maintenance support</td>
<td>Some authorities e.g. PCTs, LHBs, occasionally issue complex equipment to continuing healthcare clients without technical support. Has been fatal in the past.</td>
<td>5</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Poor governance arrangements</td>
<td>There are few CES which sit on medical device groups. There are also poor arrangements for audit and review</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Poor performance e.g. KPIs</td>
<td>Impacts upon admissions and delayed transfers of care etc. Very costly</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Poor decontamination/cross Infection processes in place</td>
<td>Very common. Can have huge impact upon spread of acquired infections</td>
<td>5</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>Poor information systems</td>
<td>Quite common. Impacts upon maintenance and product recalls etc.</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Clinical staff not trained on equipment</td>
<td>Not very common. But still needs covered by policy</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Poor planned preventative maintenance schedules in place</td>
<td>Quite common. High risk area which also breaches legal requirements. Could be fatal for the client.</td>
<td>5</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Lack of understanding of Legal/welfare parameters CES operate within</td>
<td>Many services breach legal requirements regularly. Could be fatal. Legal exposure</td>
<td>5</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>Services under-funded</td>
<td>Quite common. Impacts hugely upon performance. Creates false economy</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>No medical devices management group for CES</td>
<td>Very common. Exposure to corporate manslaughter liability.</td>
<td>5</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Putting in blanket policies in relation to financial thresholds</td>
<td>Very common illegal practice. This is otherwise known as ‘fettering discretion’. Can be more expensive in the longer term.</td>
<td>3</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Unclear/inconsistent eligibility criteria</td>
<td>Very common. Impacts high risk/high cost clients. Exposure to discrimination</td>
<td>4</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>No out-of-hours arrangements</td>
<td>Quite common. Can be fatal for the client.</td>
<td>5</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Poor stock management arrangements</td>
<td>Impacts upon performance. Very costly.</td>
<td>3</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------------------------------</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>No provision for specialist, complex or children’s equipment</td>
<td>Extremely common. Exposure to every legal aspect. Can impact greatly upon the client, can be fatal</td>
<td>5</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Clinical staff transporting clean and dirty equipment in personal vehicles (could be 10 -20,000 staff)</td>
<td>Approximately 20-40% of clinical professionals do this. Staff not properly insured generally, and risk spreading infections</td>
<td>4</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Clients expected to collect, install and dispose equipment themselves</td>
<td>Becoming more of an issue in England under personalization agenda. Dangerous territory at present.</td>
<td>5</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Little information e.g. user instructions, contact details, given to clients</td>
<td>Very common. Illegal practice and dangerous for the client</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>No formal processes for reviewing and assessing risk management issues</td>
<td>Quite common. Exposure to H&amp;S prosecution &amp; corporate manslaughter. Dangerous for the client.</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Equipment issued into care homes without highlighting responsibilities</td>
<td>Very common. Should be covered in governance arrangements. Confusing responsibilities.</td>
<td>3</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>Poor formal health and safety arrangements in place</td>
<td>Quite common. Exposure to H&amp;S prosecution &amp; corporate manslaughter. Dangerous for the client</td>
<td>5</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Having large waiting lists for equipment</td>
<td>Very common. Impacts immensely upon admissions, and is largely expensive e.g. unnecessary episodes of care</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
</tbody>
</table>

As can be seen from the table above, alarmingly, when the overall scores in relation to the risk factors are examined against the risk grading table, all but one of the risk factors identified have been allocated either **High** or **Extreme** Risk grades.
6. Are CES currently subjected to any existing standards, inspections or regulations?

_A CES are not formally inspected, nor are they subject to any specific regulations_ - this may be an issue relating to the competency and expertise of inspectors to inspect CES. However, because most CES are hosted by local authorities, the _general_ performance of services should be picked up by CSCI (England) or CSSIW (Wales), when they carry out social service inspections.

General performance issues would normally be measured against Performance Assessment Framework (PAF) performance indicators. The most common indicator particular to CES is the D54 (England), which looks at the percentage of equipment delivered within 7 days. Wales currently do not have formal social services indicators which specifically assess community equipment performance – although guidance KPIs for CES have been produced, which propose 1 day, 7 day, and 28 day KPIs.

Although the D54 serves a purpose in giving an indication of overall performance, it is quite narrow in that it doesn't pick up any of the risk factors highlighted above. Nor does it measure quality of services; for example, a community equipment service which gears its service toward fulfilling 100% of urgent end-of-life requests, may as a result report a lower KPI percentage for routine requests.

Furthermore, the 7 day KPI allows for some circumstances to be mitigating e.g. bespoke equipment, and these are not shown on the D54 indicator; but such cases are where some of the major problems lie within the service. There is also a very real risk of those clients who have failed to get equipment within 7 days, falling into a black hole waiting list, because there are currently no approved measures for assessing performance for those clients.
There are also some NHS performance indicators e.g. emergency readmissions following discharge from hospital, and various other service and financial framework (SaFF) and ‘best value’ targets, influenced by equipment provision, but generally these are very difficult to capture, and not widely used in practice. There were also some Commission for Health Improvements (CHI) indicators used in the past, which have since expired.

In terms of standards, generally speaking, CES fall outside of other standards currently in place, both from a health and social care perspective. The following standards or assessment tools bear some relevance to CES, but fail to be directly applied to services.

**National Service Framework Standards – England & Wales**

These are pertinent to CES, but there is no evidence to suggest that they are taken into account when commissioning CES and services are not assessed against them. As such they remain ineffective as a means of improving service provision.

**The National Service Framework (NSF) for Older People**

This NSF was introduced in March 2001 in England, and March 2006 in Wales. The NSF for Older People set new national standards and service models of care across health and social services for all older people, whether they live at home, in residential care or are being looked after in hospital. The standards which indirectly apply to CES include:

- **Standard 2 - Person centred care**
  The aim of this standard is to ensure that older people are treated as individuals and that they receive appropriate and timely packages of care which meet their needs as individuals, regardless of health and social services boundaries
➢ **Standard 3 - Intermediate Care**
The aim of this standard is to provide integrated services to promote faster recovery from illness, prevent unnecessary acute hospital admissions, support timely discharge and maximise independent living.

➢ **Standard 6 - Falls (and Fractures)**
The aim of this standard is to reduce the number of falls which result in serious injury and ensure effective treatment and rehabilitation for those who have fallen.

**National Service Framework for Children, Young People and Maternity Services**

**September 2004 (England) 2005 (Wales)**
The National Service Framework for Children, Young People and Maternity Services establishes standards for promoting the health and well-being of children and young people and for providing high quality services that meet their needs. Some of the standards which apply to CES include:

➢ **Standard 1 - Promoting Health and Well-being, Identifying Needs and Intervening Early**
➢ **Standard 3 - Child, Young Person and Family-centered Services**
➢ **Standard 4 - Growing Up into Adulthood**
➢ **Standard 6 - Children and Young People who are ill**
➢ **Standard 8 - Disabled Children and Young People and those with Complex Health Needs**

To see how some of these standards relate to CES (children’s services) please refer to section 4.7 under the heading ‘Provision of complex, specialist and children’s equipment’.

*In practice these standards are quite remote and there are no measures in place for determining whether CES are meeting these standards.*
• **Standards for Better Health**[^31], *(National Standards, Local Action, Health and Social Care Standards and Planning Framework)*. Again, these standards are quite remote from CES. It is unfortunate that the Healthcare Commission do not inspect CES against these criteria, as the 7 domains used within the standards could apply in part to the service, namely:

1. **Safety**
2. **Clinical and Cost Effectiveness**
3. **Governance**
4. **Patient Focus**
5. **Accessible and Responsive Care**
6. **Care Environment and Amenities**
7. **Public Health**

**The Healthcare Standards for Wales**[^32] equally set out certain domains and standards for improving the quality and regulation of services, all of which would also apply, namely:

1. **The Patient Experience**;
2. **Clinical Outcomes**;
3. **Healthcare Governance**;
4. **Public Health**.

[^31]: This document sets out a standard-based planning framework for health and social care and standards for NHS health care to be used in planning, commissioning and delivering services. It covers the core and development standards covering NHS health care and the health and social care planning framework and targets for 2005–2008.

The National Patient Safety Agency (NPSA) has produced a wealth of useful guidance and tools in order to assess and potentially improve the quality and standards of services. One such tool is their Risk Matrix33, which examines certain risk factors, whilst taking into consideration additional factors including, Likelihood and Consequence. The risk assessment tool looks at ‘domains’, all of which are pertinent to CES. These include:

1. Impact on the safety of patients, staff or public (physical/psychological harm)
2. Quality/complaints/audit
3. Human resources/ organisational development/staffing/ competence
4. Statutory duty/ inspections
5. Adverse publicity/ reputation
6. Business objectives/ projects
7. Finance including claims
8. Service/business interruption/ environmental impact

Although this tool is extremely useful, it seems that it is only really applied within an Acute Hospital setting, or for clinical services within the community, but is not directly applied in relation to CES. It is almost as if the ‘patient’s journey’ does not include any equipment.

- Lastly, the existing National Minimum Standards for care services, under the Care Standards Act 2000, do not specifically relate to CES.

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33This risk management guidance has been developed for the purpose of assisting NHS risk managers in implementing an integrated system of risk assessment. This can be accessed at: http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/risk-assessment-guides/risk-matrix-for-risk-managers/
In conclusion, it can be seen that *the overall performance, quality and risk issues relating to CES are not being adequately reviewed or inspected, nor is there any direct application to CES of the existing standards in place.*

7. What are National Minimum Standards?
The National Minimum Standards constitute the minimum expectations the State sets for English and Welsh care providers in the services they deliver. The existing standards for other services have been brought in progressively since the passing of the Care Standards Act 2000, which overhauled the system of regulating and assessing the quality of social care services in the two countries.

National Minimum Standards currently in place for some care services are the product of the 1998 Modernising Social Services white paper issued by the Department of Health, which reported that there were "huge differences in standards and levels of service" across England and Wales.

Some examples of services covered by the minimum standards include: Care homes; Domiciliary care; Children’s homes; Adoption and Fostering services; Nurses agencies.

The standards are comprehensive and would appear to cover most aspects of service provision e.g. choice, health and personal care, environment, staffing, management, finance, record keeping, health & safety, administration.
8. Why should National Minimum Standards be introduced for community equipment services?

“Minimum standards are required in service provision”

Source: Improving the life chances of disabled people, Prime Minister’s Strategy Unit, 2005

The preceding sections of this document have highlighted the concerns and risks in evidence in CES, all of which clearly demonstrate the need for a baseline standard of service to be applied, to ensure risks to clients are minimised as well as to reduce exposure to legal action.

In this section, further issues are raised which support the need for introducing National Minimum Standards to CES. A summary of this section is as follows:

- **Case study scenario** – this provides an example scenario of how services currently operate, and points to legal and welfare failings.

- **Difficulty assessing existing performance and standards of service provision** – this explains why the current arrangements for CES make it virtually impossible to accurately assess quality and performance.

- **Current developments do not reduce the need for National Minimum Standards** – this section explains that the various initiatives currently underway in CES in England and Wales do not negate the need for National Minimum Standards.
National Minimum Standards can improve performance – this looks at evidence provided by CSCI that Minimum Standards result in improved performance.

Care Quality Commission’s (CQC) vision of high quality care - as set out in the recent manifesto produced by CQC, this section looks at how the introduction of National Minimum Standards to CES aligns with this vision of high quality care.

Force field analysis – this section utilises a well known analytical tool to demonstrate the overwhelming advantages of introducing National Minimum Standards.

SWOT Analysis – this section utilises a commonly used and simple analytical device used within the public sector, SWOT, in order to view side-by-side the strengths, weaknesses, opportunities and threats involved in introducing National Minimum Standards to CES.

8.1 Case Study Scenario
To illustrate what can go seriously wrong within a CES setting and to demonstrate the need for and benefits of introducing National Minimum Standards, the following case study scenario has been developed. Although the scenario is not a real life example, it is based on actual events which have occurred.

Note: This scenario is one of a series developed as part of Health & Safety, and Medical Device Management workshops, including MHRA, HSE and the College of Occupational Therapists (COT), with input from Michael Mandelstam, carried out in Wales in 2008.

34 This can be viewed at: http://www.cqc.org.uk/pdf/CQC%20manifesto%20November%202008.pdf
The following summary outlines the main points.

**Case study scenario**

A community equipment service partnership board is set up between health and social care partners. The partnership produces a general service specification and partnership agreement, but does not include any of the following details:

- Actual numbers of activities to be carried out in terms of deliveries and collections.
- Actual numbers and details of equipment subject to maintenance regulation e.g. Portable Appliance Testing (PAT), Lifting Operations and Lifting Equipment Regulations 1999 (LOLER).
- Details of governance arrangements including medical device management and decontamination processes etc.

The partnership allocates an inadequate sum of money to the CES provider, which bears no relation to the actual service requirements. As a result the provider is unable to service all equipment on loan in the community.

If an inspection took place in the event of a serious incident to a client relating to faulty equipment, the potential breaches in legislation, from both a clinical and operational perspective, arising from this scenario, may include:

**HSWA 1974.**

Failure to inspect and maintain equipment may result in a breach of s.2 (duty to employees) or s.3 (duty to non-employees) of the HSWA 1974, if the NHS body or local authority is deemed to have failed to do all that was reasonable practicable to safeguard the health and safety of patients and clients (i.e. non-employees). Reasonable practicability would be weighed up looking at the level of risk as against the resources, time and effort required to manage the risk. Significant risk would legally need dealing with, even if it carries resources implications. The HSE can bring cases under s.2 & s.3.
**LOLER and PUWER**
Regulations such as LOLER 1998 and PUWER 1998 could quite easily be breached. They do not carry the “reasonable practicability” proviso, and impose various duties that have been interpreted relatively strictly and punitively by the courts. Employees could bring cases under these regulations as well as the HSE.

**Negligence**
Alternatively, if a patient or client seeks a legal remedy for an accident involving equipment which had not been correctly maintained, they might sue for damages in the common law of negligence, arguing that the NHS body or local authority has fallen below the expected standard of care and caused harm to a service user.

**Liability**
In relation to safety failures (i.e. equipment in the community not being maintained) it would arguably be the organisation(s) responsible for the system of equipment provision (e.g. the partners).

**How would National Minimum Standards help to reduce or mitigate these potential breaches?**
A well constructed set of National Minimum Standards would aim to cover all aspects of CES, including contractual arrangements, service specification requirements, governance arrangements, and funding allocations. For example, the commissioners (partners) would have to state in the service specification that legal requirements in respect of testing equipment on loan in the community (e.g. LOLER, PAT), must be adhered to by the provider. The provider may then have had to request additional funding to meet this requirement, but this would prevent breaching relevant legislation and also reduce risks to clients and employees. Minimum Standards would also inform commissioners, providers and inspectors so that they have a better understanding of the service.
8.2 Difficulty assessing existing performance and standards of service provision

Apart from the scant measures currently available for reviewing the overall performance and standards of CES, as already discussed, another great difficulty is that it is virtually impossible to make like for like comparisons between services, as each area in England and Wales provides a unique service. For example some services will provide short term wheelchairs and telecare, while others won’t. Some services will issue continuing healthcare equipment and incontinence products, where others won’t. This in effect could mean that although one service could be showing a 85% D54 indicator KPI level, a neighbouring county could be performing better whilst only showing a 65% KPI level, as they might provide additional components e.g. short term wheelchairs, telecare, whilst the other service does not.

According to ‘Community Care’ the National Minimum Standards currently in place for other care services are basically guidelines for providers, commissioners and users to judge the quality of a service. Inspectors take them into account when judging whether providers are compliant with regulations35. Minimum Standards are also designed to make sure everyone understands what is expected from them, so services can actually be measured.

In view of the current difficulties the introduction of National Minimum Standards would serve to provide clarity for all parties, and would also allow a baseline level of service to be consistently applied to all the variations of provision. There would also be an opportunity to benchmark, to a degree, performance levels and quality standards on a like for like basis.

35 Source: http://www.communitycare.co.uk/Articles/2008/06/23/108563/national-minimum-standards.html
8.3 Current service developments for CES do not reduce the need for introducing National Minimum Standards

Although current developments in England and Wales are designed to improve quality and performance of CES, the risks inherent in CES, as shown within this document, are extensive and run very deeply throughout all aspects of service provision. It is very unlikely that changes made to the front-end of service provision will be sufficient in themselves to reduce risk to an acceptable level, although certain elements will undoubtedly be improved – e.g. introduction of training programmes in Wales should reduce the risk of a client being supplied with inappropriate equipment.

Furthermore, without National Minimum Standards in place, there is no way of assessing whether the quality and performance of a service is adequate, or of measuring the effectiveness of new initiatives introduced to improve services.

In fact, some current developments could make it more difficult to assess quality and performance in the future. For example:

- In the areas which adopt it, the TCES Model in England will replace what is currently, in effect, a one-stop-shop, with a fragmented service; for example, equipment could be delivered by retailers, collected from retailers, delivered directly from the supplier, be supplied by a local store or by a national store, depending on the type of equipment. Without having National Minimum Standards in place, reviewing quality and performance of such a service would be virtually impossible.

- It is not clear how the D54 indicator will work in areas which implement the TCES Model in England, due to the variety of sources for equipment. It is difficult to envisage how, say, three separate providers would capture three separate KPI recordings for the same client.
• As the TCES Model is not mandatory, some areas may adopt it while neighbouring areas do not. This could result in a “postcode lottery” with great variety in quality of service across the country. **Introducing National Minimum Standards would ensure that an acceptable service level is applied across the whole country, regardless of method of provision.**

This paper acknowledges that the TCES Model does intend to have some form of accredited ‘regulation’ on the retailers, to ensure certain pre-standards are met before qualifying as an approved retailer. However this only assesses the suitability of the retailer and does not assess overall performance, commissioning, assessment processes etc.

• In Wales, various initiatives such as a National Store for Complex, Specialist and Children’s Equipment, and the Social Enterprise Model, likewise would fragment provision and create local variations as in England, making services harder to assess and compare.

**Without the introduction of Minimum Standards, such fundamental changes as are underway could make it extremely difficult to assess quality and performance issues, as well as creating the possibility of great variations in the standard of provision across England and Wales.**

**8.4 National Minimum Standards can improve services**

According to CSCI in its 2008 report, *State of social care in England -2006-07*\(^{36}\), over 80% of care services had met National Minimum Standards in 2007, up from 55% (average) in 2003/4. That is approximately a 45% increase in compliance with the Standards. This is a huge increase in a relatively short period, and if National Minimum Standards were

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\(^{36}\) This can be viewed at: [http://www.csci.org.uk/about_us/publications/state_of_social_care_07.aspx](http://www.csci.org.uk/about_us/publications/state_of_social_care_07.aspx)
applied to a CES setting it is believed significant health and social care benefits could be realised.

8.5 Care Quality Commission’s vision of ‘high quality care’

The Care Quality Commission (England) was established by the Health and Social Care Act 2008 to regulate the quality of health and social care, and look after the interests of people detained under the Mental Health Act. It will bring together the work of the Commission for Social Care Inspection, the Healthcare Commission, and the Mental Health Act Commission. The Care Quality Commission became a legal entity in October 2008 and takes up its responsibilities for the quality of health and social care in April 2009. In their Manifesto which outlines their vision and values, they give a definition of high quality care, that it should:

- Be safe
- Have the right outcomes, including clinical outcomes
- Be a good experience for people that use it
- Help to prevent illness, and promote healthy, independent living
- Be available to those who need it when they need it
- Represent good use of resources

As explained thus far in this paper, there are currently concerns relating to all of the above quality of care issues within CES, namely: safety; experiences for people; prevention and independent living; availability of equipment, and inadequate use of resource.

*The introduction of National Minimum Standards would firstly allow the quality of CES to be measured, and would also enable this vision of high quality care to be realised within CES.*

---

8.6 Force Field Analysis

As a tool to view the case for introducing National Minimum Standards over against the current arrangements within CES, the following force field analysis has been developed.

Force field analysis is a powerful technique for viewing all the forces ‘for’ and ‘against’ a decision side by side. It was developed by Kurt Lewin (1951) and is widely used to inform decision-making, particularly in implementing change management programmes in organisations.

Results from the analysis below found that 42 out of a potential 45 points were granted in favour of introducing National Minimum Standards for CES, and 21 out of 45 points for why they should not be introduced.

Please note scores have been allocated based upon evidence presented within this report. Furthermore, it is believed that most, if not all, the opposing forces ‘against’ the introduction of National Minimum Standards are surmountable, and have accordingly been allocated relatively low scores.
FORCE FIELD ANALYSIS

Adapted from Lewin’s Force field Analysis

Without needing further elaboration, the scores shown above, overwhelmingly in favour of introducing National Minimum Standards, highlight the benefits and necessity for doing so.

<table>
<thead>
<tr>
<th>Forces FOR Introducing standards</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in the number of fatalities and serious incidents</td>
<td>5</td>
</tr>
<tr>
<td>Meets National Patient Standards Agency requirements</td>
<td>4</td>
</tr>
<tr>
<td>Meets CSCI, CSSIW &amp; Healthcare Standards</td>
<td>5</td>
</tr>
<tr>
<td>Improves performance e.g. admission avoidance, delayed transfer of care</td>
<td>5</td>
</tr>
<tr>
<td>Better patient care/experience</td>
<td>5</td>
</tr>
<tr>
<td>Provides common benchmark for all services in England &amp; Wales</td>
<td>5</td>
</tr>
<tr>
<td>Reduces exposure to legal liability e.g. corporate manslaughter</td>
<td>4</td>
</tr>
<tr>
<td>Better commissioning and governance arrangements, including risk management</td>
<td>4</td>
</tr>
<tr>
<td>More economic, better use of resource. Increases future capacity</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>42</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Forces AGAINST Introducing standards</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient in-depth knowledge about service area to carry out inspections</td>
<td>4</td>
</tr>
<tr>
<td>May meet with some resistance e.g. commissioners and service providers etc.</td>
<td>2</td>
</tr>
<tr>
<td>May be viewed as more bureaucratic: ‘red tape’</td>
<td>2</td>
</tr>
<tr>
<td>Inspection bodies may not have capacity to carry out inspections</td>
<td>3</td>
</tr>
<tr>
<td>Additional costs may be required to introduce minimum standards</td>
<td>3</td>
</tr>
<tr>
<td>May be considered that the effort is more than benefits</td>
<td>1</td>
</tr>
<tr>
<td>Service area not considered important enough</td>
<td>2</td>
</tr>
<tr>
<td>It might be believed that the existing arrangements are acceptable</td>
<td>2</td>
</tr>
<tr>
<td>It may be believed that current developments are sufficient and will overcome any H&amp;S and risk issues</td>
<td>2</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>21</strong></td>
</tr>
</tbody>
</table>

Scoring
Weak 1 2 3 4 5 Strong
8.7 SWOT Analysis

The strengths, weaknesses, opportunities and threats involved in introducing National Minimum Standards to CES can be viewed in the following SWOT Analysis template. The SWOT analysis is the most common and simplest analytical device used within public sector industries (Wheeler & Grice 2000 p.171). When viewed side by side the strengths and opportunities for introducing National Minimum Standards far outweigh the potential weaknesses and threats. This has proved a worthy exercise and again illustrates the clear advantage of introducing the Standards.

<table>
<thead>
<tr>
<th><strong>STRENGTHS</strong></th>
<th><strong>OPPORTUNITIES</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Better Patient care/experience</td>
<td>• Apply NMS for similar services e.g. Wheelchair services</td>
</tr>
<tr>
<td>• Supports various Acts e.g. Corporate Manslaughter 2007</td>
<td>• Save significant sums on wider health &amp; social care costs</td>
</tr>
<tr>
<td>• Aligns with UN Convention on the Rights of Persons with Disabilities</td>
<td>• Have a more competent trained workforce e.g. technicians</td>
</tr>
<tr>
<td>• Complies with various H&amp;S regulations</td>
<td>• Improvements on wider health &amp; social care e.g. admission avoidance, delayed transfers of care</td>
</tr>
<tr>
<td>• Common benchmark</td>
<td>• Reduced number of fatalities and serious incidents</td>
</tr>
<tr>
<td>• Allows services to be regulated</td>
<td>• Clearer decision making processes by having improved eligibility criteria</td>
</tr>
<tr>
<td>• Provides clearer understanding of responsibility and accountability to all parties</td>
<td>• Allow inspecting bodies e.g. Care Quality Commission, to better understand the service area</td>
</tr>
<tr>
<td>• Reduced legal exposure</td>
<td>• Allow current and future developments in CES to excel, without further fragmentation</td>
</tr>
<tr>
<td>• Enables better planning &amp; Commissioning</td>
<td></td>
</tr>
<tr>
<td>• CES providers, and clients clearer what is expected from them</td>
<td></td>
</tr>
<tr>
<td>• Supports key policy objectives e.g. NSFs</td>
<td></td>
</tr>
<tr>
<td>• Better governance, including risk management</td>
<td></td>
</tr>
<tr>
<td>• Aligns with Medical Device Management requirements</td>
<td></td>
</tr>
<tr>
<td>• Supports Care Quality Commission’s vision of high quality care</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>WEAKNESSES</strong></th>
<th><strong>THREATS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• National Minimum Standards would need to be developed</td>
<td>• May be viewed as more bureaucratic (‘red tape’)</td>
</tr>
<tr>
<td>• Requires high level engagement</td>
<td>• Commissioners may resist the introduction of NMS</td>
</tr>
<tr>
<td>• Requires concordat agreement and involvement from different regulatory bodies e.g. HSE, MHRA</td>
<td>• Relevant skills may not be available to ensure compliance with NMS</td>
</tr>
<tr>
<td></td>
<td>• Inspection bodies may not have capacity</td>
</tr>
</tbody>
</table>
9. What areas of CES should National Minimum Standards apply to?

The type of service provided by CES varies greatly across England and Wales. However, there are common areas regardless of exactly what service is provided. It is recommended that the following common areas, involved in the provision of CES, have National Minimum Standards applied to them. These are illustrated in the following diagram:

- **Commissioning & Governance**
  - Arrangements for CES
    - E.g. Service Specifications, Governance Structures, Eligibility Criteria

- **Provider of CES**
  - E.g. Health & Safety Mgmt, Training, Quality, Performance

- **Clinical Services Supported by CES**
  - E.g. Training (trusted assessor), Unified Assessment

- **Peripheral & Specialist Areas**
  - Complex, Specialist & Children’s Equipment
  - Continuing Health Care Equipment
  - Equipment in Care Homes
  - Links to Related Services e.g. Wheelchairs, Telecare, Disabled Facilities Grants (DFGs)
  - Hospital Discharge
  - Managed Contracts

**Potential areas for National Minimum Standards within CES**
10. Recommendations
In view of the many issues raised throughout this document the following steps are recommended.

1. Agreement is sought for introducing National Minimum Standards
2. National Minimum Standards are developed
3. A concordat arrangement is sought between the different regulatory and inspection bodies e.g. HSE, MHRA, Care Quality Commission, CSSIW
4. Further discussion to take place to explore the need for regulating CES

11. Conclusion
The many areas of concern identified within this document clearly demonstrate the need for urgent attention to be given to this key service area. It is hardly believable that such a critical service has no robust measures in place for ensuring an acceptable level of performance, quality and safety is maintained, given that this is such a high risk environment. The absence of such measures is unnecessarily impacting upon clients, organisations, and the welfare economy as a whole. Failings in service provision are also compromising current and future health and social care strategies and policy objectives.

CES operate within a wide framework of significant legal and welfare requirements. Yet there are very few measures in place for ensuring compliance with relevant legislation, which results in regular breaches. With the recent enactment of further, stricter, legislation (e.g. Corporate Manslaughter Act 2007, and Health and Safety (Offences) Act 2008), employers are currently exposed to the real threat of prosecution and even imprisonment.

This document concludes that by introducing National Minimum Standards to CES there would be a significant reduction in current and future risks, allowing a safer and better quality service to be provided for users and carers. There would also be reduced legal exposure for health and social care organisations, and employees.
National Minimum Standards would also provide a common benchmark for all CES service provision, regardless of the different methods of service delivery, thus allowing better planning, monitoring and control, to ensure alignment with key policy objectives, which ultimately will improve health and social care in England and Wales, at a fraction of the current cost.

The serious nature of risks involved in this area of service provision, suggests that CES may need to become regulated, and this is an option which needs to be explored further.
References


Care and Health Law Website: http://www.careandhealthlaw.com/Public/Index.aspx?ContentID=66&IndexType=2&TopId=61&Category=1 Accessed 5/12/2008


National Patient Safety Agency: 

Office for Disability Issues. Independent Living Strategy. Cited in: 


APPENDICES

Appendix 1 - Diagram of Legal and Welfare Parameters for CES 79

Appendix 2 - The UN Convention on the Rights of Persons with Disabilities in relation to CES 80-82

Appendix 3 - Legal/Welfare Parameters for CES and Potential Breaches (Explanatory Notes) 83-102

Appendix 4 - Health and Safety Executive POPMAR Model 103-104

Appendix 5 - National Patient Safety Agency Risk Management Matrix 105-107
## APPENDIX 1

### Overarching health & safety, governance and legal obligations for CES

- UN Convention on the Rights of Persons with Disabilities
- Common law of Negligence
- Management of Health and Safety at Work Regulations 1999
- Corporate Manslaughter Act 2007
- Disability Discrimination Act 1995 (DDA)
- Health and Safety at Work Act etc 1974
- The Health and Safety (Offences) Act 2008

### CES Service specific legal obligations

- Consumer Protection Act 1987 (Part 1)
- General Product Safety Regulations 2005
- Medical Devices Regulations 2002 (Amended 2003)
- Sale and Supply of Goods Act 1994
- MHRA Managing Medical Devices DB2006 (05) November 2006
- Lifting Operations and Lifting Equipment Regulations 1999 (LOLER)
- Provision and Use of Work Equipment Regulations 1998 (PUWER)
- The Carriage of Dangerous Goods by Road Regulations 1996
- Control of Substances Hazardous to Health Regulations 2002 (COSHH)
- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)

### Legal/Welfare obligations for services supported by CES

- Chronically Sick and Disabled Persons Act 1970
- NHS and Community Care Act 1990
- Health and Social Care Act 2001/2008
- Health Services and Public Health Act 1968
- National Assistance Act 1948
- Education Act 1996
- Children Act 1989
- Fair Access to Care Services
- Carers and Disabled Children Act 2000
- Carers (Recognition and Services Act) 2005, and Carers (Equal Opportunities) Act 2004
The UN Convention on the Rights of Persons with Disabilities

The following points highlight the specific parts of the Convention which pertain to Community Equipment Services:

Purpose of Convention (Article 1)
TO PROMOTE, PROTECT AND ENSURE THE FULL AND EQUAL ENJOYMENT OF ALL HUMAN RIGHTS AND FUNDAMENTAL FREEDOMS BY ALL PERSONS WITH DISABILITIES, AND TO PROMOTE RESPECT FOR THEIR INHERENT DIGNITY

The Convention is intended as a human rights instrument with an explicit, social development dimension. It adopts a broad categorization of persons with disabilities and reaffirms that all persons with all types of disabilities must enjoy all human rights and fundamental freedoms. It clarifies and qualifies how all categories of rights apply to persons with disabilities and identifies areas where adaptations have to be made for persons with disabilities to effectively exercise their rights and areas where their rights have been violated, and where protection of rights must be reinforced.

General Principles (Article 3)
- Respect for inherent dignity, individual autonomy including the freedom to make one’s own choices, and independence of persons
- Non-discrimination
- Full and effective participation and inclusion in society
- Respect for difference and acceptance of persons with disabilities as part of human diversity and humanity
- Equality of opportunity
- Accessibility
- Equality between men and women
- Respect for the evolving capacities of children with disabilities and respect for the right of children with disabilities to preserve their identities

Participation and Inclusion

- Participation is important to correctly identify specific needs, and to empower the individual
- Full and effective participation and inclusion in society is recognized in the Convention as:

38 Can be accessed at: http://www.un.org/disabilities/
A general principle (article 3)
A general obligation (article 4)
A right (articles 29 and 30)

Non-discrimination
- Fundamental principle of international human rights law
- Includes direct and indirect discrimination
- *reasonable accommodation* must be made for persons with disabilities
- *reasonable accommodation*: ‘necessary and appropriate modification and adjustments not imposing a disproportionate or undue burden, where needed in a particular case, to ensure to persons with disabilities the enjoyment or exercise on an equal basis with others of all human rights and fundamental freedoms’

Accessibility
- Important as a means to empowerment and inclusion
- Both a general principle and a stand-alone article (article 9)
- Access must be ensured to:
  - Justice (article 13)
  - Living independently and being included in the community (article 19)
  - Information and communication services (article 21)
  - Education (article 24)
  - Health (article 25)
  - Habilitation and rehabilitation (article 26)
  - Work and employment (article 27) - human resource policies and practices
  - Adequate standard of living and social protection (article 28)
  - Participation in political and social life (article 29)
  - Participation in cultural life, recreation, leisure and sport (article 30)

Why a Convention?
- A response to an overlooked development challenge: approximately 10% of the world’s population are persons with disabilities (over 650 million persons). Approximately 80% of whom live in developing countries
- A response to the fact that although pre-existing human rights conventions offer considerable potential to promote and protect the rights of persons with disabilities, this potential was not being tapped. Persons with disabilities continued being denied their human rights and were kept on the margins of society in all parts of the world. The Convention sets out the legal obligations on States to promote and protect the rights of persons with disabilities. It does not create new rights.
Article 4...
1 (g) To undertake or promote research and development of, and to promote the availability and use of new technologies, including information and communications technologies, mobility aids, devices and assistive technologies, suitable for persons with disabilities, giving priority to technologies at an affordable cost;

Article 20
Personal mobility
States Parties shall take effective measures to ensure personal mobility with the greatest possible independence for persons with disabilities, including by:
(a) Facilitating the personal mobility of persons with disabilities in the manner and at the time of their choice, and at affordable cost;
(b) Facilitating access by persons with disabilities to quality mobility aids, devices, assistive technologies and forms of live assistance and intermediaries, including by making them available at affordable cost;
(c) Providing training in mobility skills to persons with disabilities and to specialist staff working with persons with disabilities;
(d) Encouraging entities that produce mobility aids, devices and assistive technologies to take into account all aspects of mobility for persons with disabilities.

Article 26
Habilitation and rehabilitation
1. States Parties shall take effective and appropriate measures, including through peer support, to enable persons with disabilities to attain and maintain maximum independence, full physical, mental, social and vocational ability, and full inclusion and participation in all aspects of life. To that end, States Parties shall organize, strengthen and extend comprehensive habilitation and rehabilitation services and programmes, particularly in the areas of health, employment, education and social services, in such a way that these services and programmes:

(a) Begin at the earliest possible stage, and are based on the multidisciplinary assessment of individual needs and strengths;
(b) Support participation and inclusion in the community and all aspects of society, are voluntary, and are available to persons with disabilities as close as possible to their own communities, including in rural areas.
2. States Parties shall promote the development of initial and continuing training for professionals and staff working in habilitation and rehabilitation services.
3. States Parties shall promote the availability, knowledge and use of assistive devices and technologies, designed for persons with disabilities, as they relate to habilitation and rehabilitation.
Please note the following table has been compiled by Brian Donnelly, with input from Michael Mandelstam - particularly on the welfare issues. The table has been developed for the intended purpose of supporting this overall review document on National Minimum Standards, and although this may serve as a useful guide for individual community equipment services, it should not be treated as a separate document. Prior consent should be sought from the author should any secondary use of this document be required. Please contact brian.donnelly7@googlemail.com for permission, should any other use be required e.g. training material. © Brian Donnelly January 2009

### Health & Safety, Governance and Legal/Welfare obligations for Community Equipment Services

<table>
<thead>
<tr>
<th>LEGAL/WELFARE PARAMETERS</th>
<th>RELEVANCE TO COMMUNITY EQUIPMENT SERVICES</th>
<th>POSSIBLE LEGAL BREACHES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overarching health &amp; safety, governance and legal obligations</strong></td>
<td>The main purpose of the Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity.</td>
<td>Failing to provide a service to certain client groups would most certainly breach the convention rules e.g. children requiring equipment to access the education system.</td>
</tr>
<tr>
<td>UN Convention on the Rights of Persons with Disabilities *</td>
<td>It will be a requirement for Partnership boards/commissioners and CES providers to ensure their service provision reflects and indeed includes: Participation and Inclusion, Non-discrimination, Accessibility, Personal mobility and rehabilitation issues, as set out in the Convention</td>
<td>Failing to provide equipment to certain client groups whose needs have been assessed, but are not provided equipment – particularly when the need fits within the eligibility criteria, could also be in breach of the Convention.</td>
</tr>
</tbody>
</table>

*Although not yet ratified at the point of writing this document (Dec 2008) the United Kingdom have signed the convention on disability rights with the view to ratification in Spring 2009.
**Corporate Manslaughter Act 2007**

In summary, an organisation is guilty of Corporate Manslaughter if in the way in which its activities are **managed or organised** causes a death and amounts to a gross breach of a relevant duty of care to the deceased. A substantial part of the breach must have been in the way activities were managed by **senior management** – which would most likely would be partnership board members/commissioners.

The offence is particularly concerned with organisations, including partnerships. Individuals can still be prosecuted separately for health & safety negligence by, for example, by the Health & Safety Executive – and by the Crown Prosecution Service for gross negligence manslaughter in common law.

The new law therefore allows for collective decisions like, for example, partnership board decisions.

For the offence to apply, an organisation must have owed a **“relevant duty of care”** to the victim. The Act defines a duty of care as “...an obligation that an organisation has to take reasonable steps to protect a person’s safety”. This includes for example equipment used by employees, systems of work, products and services supplied to customers – or in this case, clients.

Some of the ‘duties’ outlined within section 2 of the act are connected to: supplying goods and services; commercial

The Health and Safety Executive (HSE) writes concerning the Corporate Manslaughter Act that: “Companies and organisations should keep their health and safety management systems under review, in particular, the way in which their activities are managed and organised by senior management.”

In view of this, a potential breach could be the partnership board/commissioners failing to specify or have any controls in place for managing high risk areas e.g. not getting equipment maintained to save on cost.

Obviously this is quite a broad area but the most obvious factors which could potentially lead to a breach are serious failings with: Health & Safety at Work Act etc. 1974, Management of Health and Safety at Work Regulations 1999, and the Governance arrangements in place.
activities; construction and maintenance work; using or keeping plant, and vehicles or other things. All of which have a direct relate to the day-to-day activities carried out by community equipment services.


This relates more to the decision making process with the community equipment service, from both the commissioner, prescriber and provider of the service. These must ensure that people have the right not to be subjected to ‘inhuman or degrading treatment’ – see article 3 for further details.

In addition article 8 outlines the right to respect for home, family and private life

Article 14 suggests that there should be freedom from any form of discrimination

**Discretionary decisions, including omissions to act, (ie all policy making, practices, procedures, actions, individual decisions) will become potentially challengeable for a breach of human rights**

Where the consequences of not providing a piece of equipment have been made clear, where the client would be subjected to inhuman/degrading circumstances e.g. having to urinate in the living room - assuming the client has been assessed and is eligible – and a decision is made not to supply, there could be a potential breach of the Act/Convention

**Disability Discrimination Act 1995 (DDA) Provision of goods and services**

Under the DDA 1995 providers of goods and services to the public, including NHS and local authorities, have a duty not to discriminate or provide less favourable treatment on grounds relating to a person’s disability. This therefore applies to examples of breach might be excluding certain client groups because of complicated or costly equipment needs e.g. not providing equipment to children with

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39 [http://www.careandhealthlaw.com/Public/Index.aspx?ContentID=66&IndexType=2&TopicID=69&Category=1](http://www.careandhealthlaw.com/Public/Index.aspx?ContentID=66&IndexType=2&TopicID=69&Category=1)
commissioners and clinical staff responsible for deciding what client groups and equipment types will and will not be provided.

Under s.49A of the Act, local authorities and NHS bodies must carry out what are broadly referred to as disability impact assessments in relation to their policies and their effects on disabled people.

Health and Safety at Work Act etc 1974

Health and Safety at Work Act Etc 1974, s.2. Employers have a duty to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all their employees'.

Duty of employers to non-employees: Health and Safety at Work Act 1974, s.3. Every employer has a duty to conduct its undertaking in such a way as to ensure, so far as is reasonably practicable, that people not in its employment but who may be affected by the undertaking are not thereby exposed to risk to their health and safety.

Section 2 of the HASAWA looks at the ‘General duties of employers to their employees’, and includes activities carried out in the community. Section 3 covers users and carers by outlining the ‘General duties of employers and self-employed to persons other than their employees’. Basically Section 3 states the duty of employers to ensure persons not in their employment

complex disabilities without clinical justification, or people in end of life circumstances
are not exposed to risks (so far as is reasonably practicable) to their health and safety, and also it is the responsibility of every employer to provide appropriate information to such individuals about the way undertakings are conducted which might affect their health and safety.

Particular relevance to CES under s.2 and s.3 would include such things as: Appropriate acquisition methods, inspecting, checking, recording, tracking, recall, training, maintenance, cleaning, storing, demonstrating, lifting operations, delivering, instructions, repair, replacement, and emergency call-out.

### Management of Health and Safety at Work Regulations 1999

The regulations state: ‘Every employer shall make a suitable and sufficient assessment of:

(a) the risks to the health and safety of his employees to which they are exposed whilst they are at work; and

(b) the risks to the health and safety of persons not in his employment arising out of or in connection by him of his undertaking’

The regulations also require all employers, and in this context CES partners/commissioners, to plan, organise, monitor and review work procedures. This also requires formal assessment of risks, especially where employees and any others might be affected by health & safety failures.

Failure to conduct any of the tasks listed opposite safely could potentially breach this Act. It is worth noting that there have already been some prosecutions relating to these type of issues e.g. hoists, bedrails

There would be a clear breach of these regulations if there was a serious untoward incident, and it was discovered that there were no written governance arrangements in place, including risk management processes. It is likely that poorly written contractual arrangements would also breach the regulations, in the event of an incident.
| **The Health and Safety (Offences) Act 2008**<sup>40</sup> | The Health and Safety Offences Act 2008 came into effect on 16 January 2009 and increased the number of circumstances in which employees may be imprisoned for health and safety breaches.

According to NHS Employers<sup>41</sup> the Act introduced tough new penalties to act as a deterrent to organisations that are tempted to flout the law. Certain offences are now triable in either the Magistrates’ Court or the Crown Court. Employees could find themselves at risk of imprisonment under the new law if they fail to take reasonable care of the health and safety of others or even themselves. In addition, a director and senior manager can infringe the law where the problem was caused with their consent, connivance or neglect. The highest fine that can be imposed by the lower courts has risen from £5,000 to £20,000. Higher courts can impose unlimited fines. |
| --- | --- |
| **Common law of Negligence** | The common law of negligence asserts that everyone owes a duty of care which requires one to consider the consequences of their acts and omissions and to ensure that those acts and/or omissions do not give rise to a foreseeable risk of injury to any other person.

In simple terms it requires everyone to owe a duty not to injure |

An example of this might be that a serious untoward incident occurs where a service provider failed to maintain equipment in accordance with manufacturer’s instructions. |

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<sup>40</sup> This can be viewed at: [http://www.opsi.gov.uk/acts/acts2008/plain/ukpga_20080020_en_2](http://www.opsi.gov.uk/acts/acts2008/plain/ukpga_20080020_en_2)

other people by our negligent acts and omissions and that is an individual duty which each of us owes all of the time to our 'neighbours', or those we are providing a service to.

Obviously the relevance of this to CES is quite broad, but does however fit into almost every part of service delivery and commissioning.

<table>
<thead>
<tr>
<th><strong>Legal/Welfare obligations for services supported by CES</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chronically Sick and Disabled Persons Act 1970</strong></td>
</tr>
<tr>
<td>This relates more specifically to the local social services authority in its legal obligations and provision of services in terms of assessment etc. However CES will in a majority of cases be expected to meet the assessed equipment needs of the client e.g. ramps, adaptations</td>
</tr>
<tr>
<td>The particular section within the act which is most relevant to CES is as follows:</td>
</tr>
<tr>
<td>(e) the provision of assistance for that person in <strong>arranging for the carrying out of any works of adaptation</strong> in his home or the provision of any <strong>additional facilities designed to secure his greater safety, comfort or convenience</strong>;</td>
</tr>
<tr>
<td>A failure to provide any equipment following an assessed need, which falls into the definition of the section (e) opposite, assuming the clients needs fall within the eligibility criteria applied by the local authority, is likely to be in breach of the Act.</td>
</tr>
<tr>
<td><strong>NHS Act 1977 (supplanted by the</strong></td>
</tr>
<tr>
<td><strong>A potential breach may be difficult to specify in relation to CES for this Act.</strong></td>
</tr>
<tr>
<td>Act</td>
</tr>
<tr>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>NHS Act 2006 in England, and the NHS (Wales) Act 2006 in Wales</strong></td>
</tr>
<tr>
<td><strong>NHS and Community Care Act 1990</strong></td>
</tr>
<tr>
<td><strong>Health and Social Care Act 2001/2008</strong></td>
</tr>
<tr>
<td><strong>Health Services and Public Health Act 1968</strong></td>
</tr>
</tbody>
</table>
generally. (As opposed to older, disabled people who would fall anyway under the Chronically Sick and Disabled Persons Act 1970). In particular authorities have a power, but no duty, to make arrangements to provide practical assistance in the home including assistance in the carrying out of works of adaptation or the provision of any additional facilities designed to secure greater safety, comfort or convenience.

<table>
<thead>
<tr>
<th>National Assistance Act 1948</th>
<th>Section 21 of the National Assistance Act 1948 places a duty on local authorities to make arrangements for those in need of care and accommodation who are unable to make such arrangements themselves.</th>
<th>Failure to provide equipment which supports such arrangements could quite easily be a breach of the National Assistance Act.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education Act 1996</td>
<td>Section 324 of the Act states that, within a statement of special educational needs, educational needs must be met – by the local education authority if nobody else (such as the NHS). In the case of non-educational needs, the authority has a power only. Educational needs are generally taken to apply to provision required to allow the child to follow the curriculum. This duty and this power could apply to equipment provision. There are other more general duties relating to disabled children in the Education Act 1996 that could apply to the provision of equipment but which do not have the force of the s.324 duty. The duty under the Disability Discrimination Act 1995, not to disadvantage substantially disabled pupils, does not extend</td>
<td>Under s.324, a failure by a local education authority to ensure provision (by itself or another body) of equipment - required to meet a specified educational need – could be unlawful.</td>
</tr>
</tbody>
</table>
either to altering or removing physical features, or to providing auxiliary aids or services (s.28C).

<table>
<thead>
<tr>
<th>Children Act 1989</th>
<th>A failure to provide services or equipment required by a child under s.17 of the 1989 Act is unlikely to be held unlawful by the courts. They have consistently held the s.17 duty to be barely enforceable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 17 of the Children Act 1989 places a general duty on local social services authorities to safeguard and promote the welfare of children in need within their area. This widely drawn duty can include provision of equipment. It can also include provision not just for the child, but for any member of the family.</td>
<td></td>
</tr>
<tr>
<td><strong>Section 22 contains a more specific duty to safeguard and promote the welfare of any child legally looked after by the local authority.</strong></td>
<td></td>
</tr>
<tr>
<td>Section 23 contains a duty to provide accommodation for a child in local authority’s care (including a child placed with family) and to maintain the child. If the child is disabled, there is a duty to ensure that the accommodation is not unsuitable for child’s particular needs. This could arguably include ensuring that the child has suitable equipment.</td>
<td></td>
</tr>
<tr>
<td>The Fostering Services Regulations (SI 2002/57, in Wales SI 2003/237), made under s.22 of the Children Act, place a duty on fostering service providers to ensure that a child is provided with individual support, aids and equipment which the child may need because of health needs or disability (r.15). There is also a duty on the provider to provide foster parents with training, advice, information, support (r.17).</td>
<td></td>
</tr>
<tr>
<td>However, in the case of a disabled child, the obvious enforceable duty would lie under s.2 of the Chronically Sick and Disabled Persons Act 1970, which applies to both adults and children.</td>
<td></td>
</tr>
<tr>
<td>But failure to meet the equipment needs of a disabled child under s.22 or s.23 and the Fostering Services Regulations, could result in a finding of unlawfulness, as these duties focus on individual children, rather than (as under s.17) the generality of children in need in the local area.</td>
<td></td>
</tr>
</tbody>
</table>
| **Fair Access to Care Services** | This relates particularly to eligibility criteria for adult social care, but should be considered when looking at joint eligibility criteria.

CES are bound to supply the equipment in support of the agreed eligibility criteria e.g. critical, substantial. There is a responsibility upon CES to be able to provide the agreed criteria.

There is also a responsibility for the commissioners (partnership boards) of these services to ensure the right eligibility criteria is both specified and met. |
| **Carers and Disabled Children Act 2000; Carers (Recognition** | Fair access to care guidance is regarded as “statutory” guidance. This means that although it is not law, nonetheless a failure to follow it could result in a finding of unlawfulness. For example, the English guidance states clearly that local authorities should not have blanket policies not to provide specific services (or, by implication, equipment). Many local authorities do have such blanket policies and are potentially in breach of the guidance.

In addition, such blanket approaches may also be unlawful because they “fetter the discretion” of the authority – or because the effect of such policies may in some cases mean that a person’s assessed, eligible, need is not met, contrary to the NHS and Community Care Act 1990 and the Chronically Sick and Disabled Persons Act 1970. |

| **Carers and Disabled Children Act 2000; Carers (Recognition** | The net effect of this legislation is that a local social services authority has a duty to assess the ability of informal carer to care for an adult or child who may in need of community care |
| **Carers and Disabled Children Act 2000; Carers (Recognition** | A failure to assess a carer’s needs could clearly be unlawful. |
and Services Act) 2005; and Carers (Equal Opportunities) Act 2004) services, or services under Part 3 of the Children Act respectively. The duty is triggered if the carer is providing regular and substantial care and if he or she requests an assessment. The local authority must however tell carers about this right to assessment. The local authority must also consider the carer’s involvement, or wish to be involved, in work, education, training, leisure. The local authority has a power to provide services, including equipment, for the carer. Other bodies, such as the NHS, have a duty to give due consideration to a request by the local authority in terms of assisting carers.

The needs of a carer may be related to equipment, not only equipment being used by the person being cared for, but also by the carer in his or her own right. For instance, a mobile phone, a washing machine, manual handling training, or driving lessons.

<table>
<thead>
<tr>
<th>Community Equipment Services Specific Legal Obligations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consumer Protection Act 1987 (Part 1)</strong></td>
</tr>
<tr>
<td>Part 1 of the Consumer Protection Act 1987 transposes the Product Liability Directive (85/374/EEC and 1999/34/EC) into UK law. The legislation imposes strict liability on producers for harm caused by defective products. The legislation applies to all consumer products and products used at a place of work. The direct application to CES might be where it manufactures products e.g. banisters</td>
</tr>
<tr>
<td>There would be a case for breaching the Act where a product manufactured by CES had a defect with the potential to cause harm. There may also be a case against CES if they modified equipment, which subsequently was issued with a defect in it, without first consulting the original</td>
</tr>
</tbody>
</table>
| General Product Safety Regulations 2005 | According to BERR, Department for Business Enterprise & Regulatory Reform\(^\text{42}\), in principle, the 2005 Regulations apply to all products (new and second-hand) used by consumers, whether intended for them or not.

The 2005 Regulations maintain the general duty placed on producers and distributors to place on the market (or supply) only products that are safe in normal or reasonable foreseeable use. The principal responsibility for day-to-day enforcement of the Regulations lies with local authorities.

For the first time, the Regulations recognise certain technical standards as carrying a presumption of conformity with the general safety requirement, meaning that products that comply with them are deemed to be safe. | An obvious breach would be issuing unsafe products into the community e.g. issuing equipment with exposure to electrical parts, walking frames that break easily, beds or chairs with exposure to entrapment |
| Manual Handling Operations Regulations 1992 | This applies to any aspect of the service where a manual handling risk applies.

In a CES setting this could be with a store, delivery, installation, maintenance or user or carer use of the equipment. For example a considerable amount of heavy equipment is required upstairs in peoples homes e.g. beds, hoists. | A serious breach of these regulations might be where an injury occurs to a driver, for example, who is expected to deliver a two person task single handed e.g. beds. The case would be strengthened if there was no evidence of risk assessments or governance arrangements in place for monitoring and assessing risks. |

The employer, or individual partners, will be responsible for ensuring all manual handling risks are avoided, where possible, which could otherwise result in injury. There should be appropriate risk assessments and governance arrangements in place, together with processes for monitoring and reviewing assessments on an ongoing basis.

Ideally these arrangements should be set out within the service specification.

“Where equipment is provided to reduce the risks involved in manual handling (e.g. hoists, slings, trolleys etc.), it should go without saying that adequate training, information and instructions on the use of the equipment must be provided. Merely providing such equipment (and any necessary training) will not absolve an employer from further responsibility or from liability: use of the equipment should be monitored and encouraged.”

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<tr>
<th>Medical Devices Regulations 2002 (Amended 2003)</th>
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<tr>
<td>These regulations require certain duties to be followed by manufacturers of equipment in particular e.g. performance and safety standards, CE Marking. The direct application upon CES would be the standards which they manufactured equipment to e.g. banisters, and also the difficulties arising from modifying CE</td>
</tr>
</tbody>
</table>

To avoid a breach there would need to be evidence to demonstrate:

- attempts have been made to avoid the manual handling operation, so far as is reasonably practicable;
- where manual handling cannot be avoided, a suitable and sufficient risk assessment is carried out, factoring in the task, working environment, the physical capabilities of the individuals involved, and other relevant factors.
- Appropriate steps have been taken to reduce the risk to health to the lowest level reasonably practicable

Potential breaches could be:

- Manufacturing a substandard product
- Adapting or modifying certain pieces of equipment
- Acquiring equipment inappropriately

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43 http://www.careandhealthlaw.com/Public/Index.aspx?ContentID=66&IndexType=2&TopicID=79&Category=1
| Sale and Supply of Goods Act 1994 | The Sale and Supply of Goods Act (which factors in the Sale and Supply of Goods and Services Act 1982) require a supplier of a service to carry out that service with reasonable care and skill and, unless agreed to the contrary, within a reasonable time and make no more than a reasonable charge.

The Act states that ‘Any goods supplied in the course of the service must be as described, of satisfactory quality and fit for their purpose. If they are not, the consumer is entitled to a repair, replacement or compensation.

A claim can be pursued through the courts for up to six years providing it can be shown that the problem was due to the work not being carried out properly or the goods or materials used not being of satisfactory quality.

The most direct relevance to CES would be where a product is manufactured and issued to a client from the service e.g. banister.

This might also be applicable where there are top-ups, direct payments or prescriptions issued by CES, or indeed where equipment is sold direct from a provider to the client. |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible breaches may be easier to pinpoint if for example the equipment service was outsourced, although in-house services would also be expected to comply with ‘quality’, ‘care’, and ‘skill’ elements.</td>
<td></td>
</tr>
<tr>
<td>Where services use top-ups, or prescriptions, responsibility may lie with the commissioner to ensure service standards are specified.</td>
<td></td>
</tr>
<tr>
<td>MHRA Managing Medical Devices DB2006 (05) November</td>
<td>In relation to the provision of equipment this is perhaps the most informative and comprehensive piece of guidance produced to date. It covers all aspects of managing medical devices. It also</td>
</tr>
<tr>
<td>This is a very comprehensive and explicit piece of guidance which has been made available for the specific purpose of</td>
<td></td>
</tr>
</tbody>
</table>
sets out recommended processes and directly relates to pertinent legislation, e.g. health & safety, consumer protection.

In the unfortunate event of an untoward, fatal or serious accident, relating to any aspect of a CES medical device, it is very likely service standards would be investigated in line with the principles set out in this guidance.

A serious breach of this guidance could potentially result in gross negligence or failed duty of care.

This guidance should be in the possession of every partnership board/commissioner, and all providers of community equipment services.

Managing medical devices services. The guidance covers almost all aspects of medical device management relating to community equipment services, and assistive technologies.

The guidance points to all pertinent legislation and guidance in relation to community equipment services.

It is likely that this guidance would be used as a benchmark in relation to performance if services were being inspected in the event of an untoward incident.

| Lifting Operations and Lifting Equipment Regulations 1999 (LOLER) | Lifting equipment is defined as ‘work equipment for lifting or lowering loads and includes attachments for anchoring, fixing or supporting it.’

These regulations have a huge impact upon CES as a significant number of equipment categories fall under the LOLER remit e.g. hoists, stairlifts.

In many service areas there is huge ambiguity around what should and what should not be subject to regular LOLER inspections. A clear breach of these regulations would be failing to carry out recommended LOLER inspections. It is also important to note that the regulations do not only cover the once or twice a year inspection, but also require such things as ensuring:

a. The equipment is of adequate strength and stability for the purpose it is to be used. |
examination e.g. beds, bathlifts. However according to Michael Mandelstam (Legal Advisor, Community Care), the test of whether equipment used at work is an item of lifting equipment should depend on a `primary purpose' test; for instance, hoists and lifts are clearly lifting equipment, whereas an adjustable height bed is probably, primarily a bed and only secondarily lifting equipment. Clearly there will be grey areas and, ultimately it would be for the courts to decide what is, and what is not, lifting equipment. However, all this need not cause equipment and adaptation providers undue concern, since the range of duties - including a strict duty of maintenance in the Provision and Use of Work Equipment Regulations 1998 anyway apply to all work equipment, not just lifting equipment\textsuperscript{45}.

Section 3 of the H&S at work Act covers equipment subject to LOLER regulations in the client’s homes

The Lifting Operations and Lifting Equipment Regulations 1998 impose further obligations relating to the examination and inspection, strength and stability, positioning and installation of equipment. There is also very much an overlap with PUWER regulations set out below.

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\textsuperscript{45} Mandelstam, M (2003). \textit{Using the law to develop and improve equipment and adaptation provision}. The Stationery Office Bookshop, Edinburgh
| Provision and Use of Work Equipment Regulations 1998 (PUWER) | PUWER requires all equipment used by employees - also users, carers and clinical staff etc. under S3 of health & safety at work act – to be: 1. suitable for the intended use and for conditions in which it is used; 2. safe, maintained, inspected to ensure it continues to be safe; 3. used only by the people who have received adequate information, instruction and training; and, 4. accompanied with suitable safety measures, e.g. protective devices, markings, warnings. It is most likely that the commissioners would have to request compliance with these regulations, and that the provider would be responsible for meeting these  

“The Provision and Use of Work Equipment Regulations 1998 make it the employer’s responsibility to ensure that work equipment is so constructed or adapted as to be suitable for the purpose for which it is used or provided. The regulations also impose a strict liability duty to maintain equipment in an efficient state, efficient working order and in good repair.”  

| The Carriage of Dangerous Goods by | This legislation requires strict control on many transporting arrangements. | The Provision and Use of Work Equipment Regulations 1998 make it the employer's responsibility to ensure work equipment is constructed or adapted in order to be suitable for the purpose for which it is used or provided.  

Possible breaches might be:  
- inappropriate assessments and equipment selection by clinical staff  
- equipment not maintained properly with planned preventative maintenance programmes in place  
- safety information and warnings not issued with equipment  

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46 [http://www.careandhealthlaw.com/Public/Index.aspx?ContentID=66&IndexType=2&TopicID=79&Category=1](http://www.careandhealthlaw.com/Public/Index.aspx?ContentID=66&IndexType=2&TopicID=79&Category=1)
In relation to CES consideration needs to be given to the packaging and handling of contaminated equipment, and segregation of clean and contaminated equipment. Securing of loads and safe methods of transportation would also have to be given consideration.

This may also apply to clinical staff transporting equipment in their personal vehicles unsafely, and uninsured. It may even apply to clients or members of the public, being expected to unreasonably transport, or collect, their own equipment.

- Inappropriate cleaning of vehicles
- Mixing clean and contaminated equipment
- Unsuitable packaging
- Clinical staff using personal vehicles to transport equipment unsafely, and uninsured

In addition to the usual requirements within the workplace under this regulation e.g. the management of chemicals or detergents, CES should strictly adhere to this regulation in relation to the control of biological agents such as bacteria and other dangerous micro-organisms.

This regulation especially relates to infected or contaminated equipment. There should be clear policies and procedures developed to ensure potential infectious diseases are kept under control e.g. protective clothing, decontamination/infection control guidance

A most likely breach would be the failure to comply with COSHH requirements—especially in the event of an untoward incident e.g.

- Assessing risks
- Deciding on precautions needed
- Measures to prevent and control risks
- Ensuring control measures are used and maintained
- Monitoring exposure and health surveillance
- Informing, instructing and training employees about risks and precautions
The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR), place a **legal duty** on employers and people in control of premises to:

Report work related deaths, major injuries or over three day injuries, work related diseases, and dangerous occurrences (near miss accidents).

Equipment related injuries etc. should be reported to the appropriate H&S coordinator, or medical devices board. CES partners/commissioners should ensure appropriate H&S, Risk Management and Governance arrangement are in place.

An obvious breach of these regulations would be to not have any reporting mechanisms in place for allowing injuries etc. to be reported.

There would also be serious breach of the regulations if injuries and dangerous occurrences etc. were known about and purposely not reported.

It has been argued by some lawyers that COSHH regulations could apply to MRSA and Clostridium Difficile (CDiff) issues – although this may be difficult to prove at present. However failing to control substances likely to cause infection or contamination would be treading on dangerous ground.
APPENDIX 4

Health and Safety Executive POPMAR Model

The following summary of the POPMAR Model has been adapted from HSE’s ‘Successful Health and Safety Management booklet’.

Step 1: Set a Policy

H&S policy should be developed to influence the selection of people, equipment and materials, the way work is done and how goods and services are provided. A written statement on the arrangements for implementing and monitoring policy shows that hazards have been identified and risks assessed, eliminated or controlled.

Step 2: Organise Staff

To make the H&S policy effective, staff should be involved and committed to making it work. This is often referred to as a 'positive health and safety culture', of which the following five 'C's are the essential aspects – as set out by HSE:

- **Commitment** in being clear about your intent to achieve excellence in Health and Safety.
- **Competence**: training and advice for all staff, using specialists where necessary.
- **Control**: monitor staff knowledge and awareness.
- **Co-operation**: involve staff in the reviewing of problems and procedures.
- **Communication**: regular discussion on Health and Safety and easy access to information.

Step 3: Plan and Set Standards

Planning is the key to ensuring that Health and Safety works. It is advisable to record plans in writing. Planning should provide for:

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47 *Successful Health and Safety Management; HS(G)65; 1997; HSE Books; ISBN 0 7176 1276 7*
• Identification of hazards and risk assessment.
• Compliance with the health and safety laws that apply to your business;
• Consultation with staff, managers, neighbours and subcontractors.

Standards set out how staff in your organisation deliver the policy and control risks. The standard must be 'measurable, achievable and realistic'.

**Step 4: Measure Performance**

As in other areas it is necessary to measure health and safety performance to judge success. There are two key components to effective monitoring:

- **Active monitoring** (before things go wrong): Regular inspection to ensure standards are being implemented and objectives are being met.
- **Reactive monitoring** (after things go wrong): Investigating injuries, cases of illness, property damage and near misses - identifying why performance was substandard.

Priority should be given where risks are greatest and information referred to people with authority to take remedial action, such as organisational and policy changes.

**Step 5: Audit and Review – learning from experience**

Audits, by staff or outsiders, complement monitoring activities by looking to see if H&S policy, organisation and systems are actually achieving the right results. They should be concerned with the reliability and effectiveness of H&S policy and pay particular attention to:

- The degree of compliance with H&S performance standards (including legislation);
- Areas where standards are absent or inadequate;
- Achievement of stated objectives within given time-scales;
Appendix 5
National Patient Safety Agency Risk Management Matrix

The process used for identifying the scores and grades for the specific risk factors relating to CES

The following process was used for identifying the scores and grades for the specific risk factors relating to CES. The consequence and likelihood for the risk factors occurring within CES have been analysed using some of the principles of a risk matrix developed the NHS National Patient Safety Agency (NPSA)\(^{48}\).

The first step used in this process was to establish the specific risks present within CES. These were then taken through the process of looking at the potential consequence, looking at the likelihood of the risk occurring, and then combining these factors using a scoring system, to establish the overall severity and grading of the risks.

Table 1 Consequence scores

Once the risk was identified this is then worked along the columns below to assess the severity of the risk on the scale of 1 to 5 to determine the consequence score, which is the number given at the top of the column. There is a brief definition of possible consequences, taken from the NPSA risk matrix, to assist with the process of identifying the most probable consequence.

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The next step in the process was to establish what is the likelihood of the consequence occurring.

Table 2 Likelihood score (L)

Once the consequence and likelihood of risks occurring were identified the results are given a combined total score to help establish the overall severity of the risk – as seen below. The risk score is determined by multiplying the consequence by the likelihood: C (consequence) x L (likelihood) = R (risk score)
Table 4 Grading Risk
And lastly, for grading risk, the scores obtained from the risk matrix are assigned grades as follows:

<table>
<thead>
<tr>
<th>Likelihood score</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rare</td>
<td>Unlikely</td>
<td>Possible</td>
<td>Likely</td>
<td>Almost certain</td>
</tr>
<tr>
<td>5 Catastrophic</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>4 Major</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>3 Moderate</td>
<td>3</td>
<td>6</td>
<td>9</td>
<td>12</td>
<td>15</td>
</tr>
<tr>
<td>2 Minor</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>1 Negligible</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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</tbody>
</table>