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Review Article

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Whole-Body Vibration Exposure from Incubators in the Neonatal Care Setting: A Review

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ABSTRACT

The World Health Organisation (WHO) estimates that approximately 1 in 10, or 15 million babies are born prematurely worldwide each year. Neonatal intensive care forms a vital component of the survival chances of premature babies; whether from an inter or intra-hospital setting. Incubators by their design, emit vibration that potentially can have a negative impact on the neonate. ISO 2631-1:1997 details comprehensive methodologies for the measurement of whole body vibration and outlines a Comfort Scale Rating for determining severity of exposure. Whilst legislation exists from an occupational perspective, there are currently no legal limits with regards whole body vibration exposure to the neonate. The majority of the existing studies have limitations with regards sample sizes, use of neonates versus use of mannequins and transport modes. However, the vibration emission data collected and published to date is at the upper end or exceeds the Comfort Scale Rating as per ISO 2631-1:1997. There is limited data published on whole body vibration emissions from incubators in situ in the hospital setting. Recommendations to reduce exposure thus far are focused on improved design of incubator systems with a view to dampening vibration sources to reduce emissions. A better understanding of the lifespan of incubators, the preventative maintenance requirements, and ancillary equipment specifications of mattress and incubator frames is required in response to the ever-evolving design of neonatal incubators.

What is already known about the subject?: Studies to date suggest that the whole body vibration emissions from neonatal incubators during intra and inter hospital exceed the exposure action and limit values, and present on the upper scales of the Comfort Scale Rating in the vast majority of cases.

What are the new findings?: There exists a lack of whole body vibration emission data from incubators in situ in the hospital setting.

How might this impact on policy or clinical practice in the foreseeable future?: Ancillary equipment such as mattresses and frames associated with incubators, as well as equipment lifespan and frequency of preventative maintenance are important determinants of vibration emission from incubators. A comprehensive policy on equipment lifespan and use of approved replacement ancillary equipment has the potential to reduce vibration emissions meeting and exceeding the existing legal limits.

Search strategy and selection criteria: This Review was an analysis of the literature on vibration emissions from neonatal incubators, informed by expert opinion. We reviewed English language literature for studies on vibration exposure in the neonatal care setting. Our search terms included whole body vibration, incubator, neonatal and neonate. The search returned 68 results, of which 25 were eligible for inclusion in this Review. Data were extracted regarding reported vibration emissions as measured under ISO 2631:1997, the hospital setting and neonatal transfer via air and road. Further studies related to WBV were included for contextual purposes.

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Introduction

Although neonatal intensive care and hospital transfer is a crucial part of neonatal care it is not without risk to the patient. Several studies have identified whole body vibration (WBV) emission values well in excess of the European occupational exposure action and limit values for adults exposed to WBV in the workplace setting[1-5, 6-15]. Furthermore, WBV exposure of these magnitudes is categorized at the upper end of the ISO 2631:1997 Comfort Rating Scale. Despite the growing recognition of WBV as a risk to the neonate during hospital transport, to date, little data exists around the risk of WBV in-situ in the hospital incubator setting. In this Review, previous studies which involved a live neonate and / or neonatal mannequin were included. There exists a wide variation across study design, sampling population and hypotheses among existing studies. This Review aims to summarize up-to-date information about WBV exposure in the neonatal setting from an inter-hospital, and intra-hospital perspective. A summary of the study design, sampling strategy, findings and key recommendations is included in (Table 1).

Table 1. EAV and ELV standardised to an eight-hour reference period for WBV as per SI 299/2007

WBV EAV	WBV ELV
0.5 ms^2	1.15 ms^2

Definition of a Neonate

The World Health Organisation (WHO) defines preterm birth as babies born alive before 37 weeks of pregnancy are completed [16]. WHO estimate that approximately 1 in 10, or 15 million babies are born prematurely worldwide each year [16]. There are sub-categories of preterm birth, based on gestational age: Extremely preterm (<28 weeks); Very preterm (28 to <32 weeks); Moderate to late preterm (32 to <37 weeks). A systematic review and modelling analysis of data on preterm birth in databases of national civil registration and vital statistics, supplemented with population-representative surveys and research studies on a global level was conducted on data recorded in 2014 [17]. The study reports that an estimated 10•6% of livebirths worldwide were preterm in 2014. Estimated pre-term birth rates and proportion of global pre-term births were reported for regions based on United Nation Standard Country or Area Codes for Statistical Use. These rates were reported respectively as follows: Asia (10.4%; 52.9%), Europe (8.7%; 4.7%), Latin America and the Caribbean (9.8%; 7.2%), North America (11.2%; 3.3%), North Africa (13.4%; 5.2%), Oceania (10%; 0.4%) and Sub-Sahara Africa (12%; 28.2%). The Irish Neonatal Health Alliance (INHA) states that 'globally over 15 million infants are born too early, too small and too sick each year: that's one in 10 babies. From an Irish perspective the figure stands around 4,500 and that equates to one baby born prematurely every 116 minutes' [18]. According to the Central Statistics Office (CSO), 67295 births were registered in Ireland in 2014 [19]. This equates to a preterm birth percentage in Ireland of approximately 6.7% in 2014, which is lower than the estimated preterm births for Europe as published previously [20].

Whole Body Vibration (WBV) Legislation

The European Directive 2002/44/EC on the minimum requirements regarding the exposure of workers to the risks arising from physical agents (vibration) is applicable to occupational exposures to WBV and hand-arm vibration (HAV). The Directive was transposed into Irish law by the Safety Health and Welfare at Work (General Application) Regulations 2007 (SI 299/2007) [21]. WBV is defined in the legislation as 'the mechanical vibration that, when transmitted to the whole body, entails risks to the safety and health of employees, in particular lower-back morbidity and trauma of the spine [20,22]. The Directive defines exposure action values (EAV) and exposure limit values (ELV) for WBV (Table 1), based on a standardised eight-hour reference period, simulating a typical workday.

(Table 2)

Table 2. Comfort Scale Rating as per ISO 2631-1:1997

Vibration Emission (ms^2)	Comfort Scale Rating
<0.315 ms^2	Not uncomfortable
0.315 ms^2 to 0.63 ms^2	A little uncomfortable
0.5 ms^2 to 1 ms^2	Fairly uncomfortable
0.8 ms^2 to 1.6 ms^2	Uncomfortable
1.25 ms^2 to 2.5 ms^2	Very uncomfortable
>2.5 ms^2	Extremely uncomfortable

The legislation places an obligation on the employer to risk assess, and if necessary, measure the levels of exposure to mechanical vibration. The results of the risk assessment must be recorded. The risk assessment is required to be updated at regular intervals, particularly if there have been significant changes which could deem it insufficient or inadequate. To the author's knowledge, no specific exposure action or limit values with regards WBV exposure to infants and children in a hospital setting exists.

From an occupational perspective, where the risk assessment results in WBV emission values in excess of the legal limit values, a programme of control measures to eliminate or reduce the exposure so far as is reasonably practicable is required. The National Institute for Occupational Safety and Health (NIOSH) developed the 'Hierarchy of Control' as a means of determining how to implement feasible and effective control solutions.

(Figure 1)

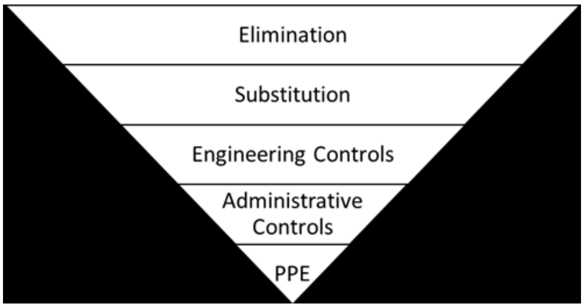

Figure 1. NIOSH Hierarchy of Control Principles

Table 3. Summary of studies on WBV exposure of neonates

Author and Year	**Study Design**	**Sample and Population**	**Hypothesis**	**Findings**	**Recommendations**
Shenai et al, 1981	Observational, measurements of rms values	141 Neonates	Measurements of Mechanical vibration Experienced by Neonates in transit	Vibration more predominant in lower frequency ranges.	Further research to determine safe levels. Further research into vibration levels in air transport
Campbell et al, 1984	Observational – Measuring vibration In horizontal and Vertical axes, in ambulance Fixed wing and rotary	1028 Neonates	Measurements of sound and vibration experienced by neonates in 1. Ambulance 2. Fixed Wing 3. Rotary Wing	RWA highest vibration emission.	Improved design of incubator with vibration dampening and sound absorption treatment.
Sherwood et al, 1994	Observational 3 phases – site of Measurement, Different mattress types, Modification to tray.	Mannequin	To study the effects of mechanical vibration on neonates during ambulance transport	Difference in vibration levels can be influenced by mattress type	Research needs to be repeated with humans to study physiological effects
Gajen-dragadkar et al, 2000	Observational	24 runs 2 routes, 3 times each=24 runs Mannequin	That a gel mattress is most effective in attenuating mechanical vibration	A gel mattress produced the least accentuation of vibration.	Further research needed for more effective devices to reduce vibration.
	Randomised block study of 4 mattress combinations				Further studies involving human neonate and the physiological effects.

Bailey van Kuren and Shukla, 2005	Feasability analysis of vibration isolation systems	Transport Incubator	To determine whether air-spring based passive and active systems reduce the vibration level	Air-spring based passive and active systems are effective vibration isolation mechanisms on a nenoatal transport system	Further research to apply magneto-rheological (MR) fluid-based dampers to reduce vibration.
Shah et al, 2008	Observational Comparisons of mattresses in x, y and z axis	Interhos-pital (20) intrahos-pital (5) Mannequin	To quantify the magnitude of the impulse experienced by neonates during intra/ inter hospital transport, determine whether specialised mattress can reduce the impulse	Use of the air foam mattress decreased impulse to the mannequins head compared to the standard mattress in all the study designs.	Further studies to determine what impulse values are acceptable, if such values are dimension specific and if transport produces a stress response
Browning et al, 2008	Observational. Measurements of vibrations in the z-axis	Transport Incubator	To classify the severity of vibrations within the incubator/assess degradation of the vibration isolation components	Development of baseline values.	The information provides greater understanding of the critical transport systems vibration isolation components
Bouchut et al, 2011	Observational Comparison	15 ground transfers, 5 helicopter transfers Neonates	To compare whole body vibrations in ground transfers and helicopter transfers.	Incubator whole-body dynamic exposure was higher but more stable in helicopter transports compared to transfer by ground ambulances.	Further studies into pathophysiological impact of transport of newborn babies to determine impact of difference between ambulance and helicopter.
Karlsson et al, 2012	Observational	16 Neonates	Measurement of effect of sound and whole body vibration on heart rate and heart rate variability during ground and air ambulance transport	Higher whole body vibration associated with lower heart rate. Higher sound level associated with higher heart rate.	

	Measurement of sound levels and whole body vibrations.				
Prehn et al, 2015	Prospective observational study measuring sound and vibrations.	Mannequin	Levels of sound and vibration during ground transport of a very low birth weight infant and compare following modifications to the transport incubator aimed at reducing levels	Vibrations were reduced using the gel mattress in combination with an air chambered mattress. Sound levels were not decreased.	Transport teams can reduce levels of vibration through modifying mattresses. Further research is needed in order to reduce vibrations for different weight infants
Blaxter et al. 2016	Quantify vibration and linear head acceleration during inter-hospital transfer.	35 Neonate (12) Mannequin	Provide a baseline assessment of exposure of neonates to head and torso vibrations, focusing on what is the contribution of the mattress type, road and vehicle speed on the WBV exposure	Vibration isolation differed substantially between sponge and air mattresses.	Further research on design of the transport trolley to reduce vibration.
Shimizu et al, 2018	Comparative study on vibration emissions during air and road transfers	1 journey combined air and road transfer Neonate	To determine if air transfer exposes the neonate to higher WBV levels	Neonatal transfer by air is more stable than road transfer, even during take-off and landing	Further evaluation of vibrational stress and means of attenuating vibration to enhance patient safety.
Bailey et al, 2018	Convenience sample and measurement of noise and vibration levels on air and road transfers	109Neonates Air (67) Road (42)	To compare sound and vibration levels during air and road transfers to current recommendations and correlate to neonatal physiological stability	Transported neonates are exposed to excessive noise, and to vibration levels that exceed the acceptable adult standards. Despite this physiological stability remained constant.	Future research on neonatal research may include investigating the impact of sound and vibration on other outcome measures such as family stress levels, developmental outcomes, and hearing acuity

Green et al, 2018	An analysis of patient vibration exposure during interhospital transports and compares the new equipment with the previous neonate transport equipment.	24 Mannequin	A comparison of the vibrations induced on a neonatal patient during inter – hospital transport using the old and new transport equipment. Three different mannequins were used to simulate patients with different masses, and four different mattress configurations within the isolette was examined.	Statistical analysis of measured accelerations indicates significantly higher vibration with the new equipment deck. Results also indicate that all examined mattress types are effective in mitigating the transmission of vibrations from equipment to patient.	Future studies will leverage the additional sensor modalities, analyze the frequency power spectrum, and examine ground and air transportation.

The Hierarchy of Control is a top-down approach to the management of risk. The application of the Hierarchy of Control requires consideration of the headings in the order shown in (Table 3), and not simply selecting the most convenient control measure to implement [23].

Neonatal incubator compliance falls under two significant pieces of European legislation when it comes to their design and specification; Machinery Directive 2006/42/EC [24] and Medical Device Regulations 2017/745 [25].

Annex I of the Machinery Directive 2006/42/EC details the Essential Health and Safety Requirements (EHSR's) relating to the design and construction of machinery, and specifically states with respect to vibration; 'Machinery must be designed and constructed in such a way that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.' Furthermore, Annex I calls for instructions to be provided relating to the installation and assembly of machinery to reduce vibration emissions. The accompanying instructions must give the following information concerning vibrations transmitted by the machinery to the whole body:

- the highest root-mean-square (rms) value of weighted acceleration to which the whole body is subjected, if it exceeds 0.5 m/s2. Where this value does not exceed 0.5 m/s2, this must be mentioned.

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced. Any uncertainty surrounding the measurements, the operating conditions or the measurement code must be described [24].

Neonatal incubator systems are generally classified as a Class II medical device. Annex 1 of the Medical Device Regulations 2017/745 outlines the general safety and performance requirements of a medical device. Manufacturers are required to establish, implement, document and maintain a risk management system. This is an iterative process which involves identifying and analyzing known and foreseeable hazards, evaluating their risk during intended use and eliminating the hazards where possible. With regards vibration, the Regulations state 'Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance' [25].

Whole Body Vibration (WBV) Exposure

It is almost impossible for any person to avoid vibration exposure in today's world. Vibration exposure can occur at work, commuting between home and work, and in leisure activities. The effects of whole-body vibration on the human body have been a subject of research since the early 20th century [26]. It is well known that any form of transportation will expose humans to some degree of mechanical vibration, or more specifically, WBV. The detrimental effects of WBV and their effect on humans has been researched and documented across the world [26]. WBV exposure can result in large variations between subjects with respect to biological effects. Most often, it is the lumbar spine and the connected nervous system that may be affected by WBV exposure [27]. Other studies have highlighted the neck-shoulder, the gastrointestinal system, the female reproductive organs, the peripheral veins, and the cochleo-vestibular system are also assumed to be affected by WBV [28-30]. The effects are complex and depend at least on the vibration amplitude, direction, frequency, duration and to which part of the body it is directed. A major part of previous studies on WBV has been about measuring and analysing the vibration exposure levels concerning health for various work environments, machinery and equipment.

Vibration has deleterious effects on pregnant women and foetuses. There are studies presenting evidence of the detrimental effects of whole-body vibration on pregnancy. One such study found "that the higher risk of premature birth and menstruation disorders can be attributed to long-term exposure to whole body vibration, and no safe exposure limits can be established to avoid the enhanced risk to the woman's health in the prenatal period" [31]. Furthermore, qualitative studies have indicated that pregnant women exposed to WBV on private (car) and public (tram) transport can result in similar complaints, such as spine aches, abdominal complaints, dizziness & headaches [28].

There is often a requirement to transport neonates across various hospital departments (i.e. birthing suite to NICU), as well as inter-hospital transportation for the purposes of specialised neonatal care. Many physical stressors exist in the neonatal care settings, both within hospital and during inter-hospital transfer. Exposure to WBV is a physical hazard of concern with potential to cause harm to the neonate. Several studies have measured, analysed, and some have attempted to predict the long-term health effects of WBV exposure on the neonate. Primary studies investigating the level of vibration that neonates were exposed to during transport between hospitals were first undertaken in the 1980's. The first published study measured the vibration produced by vertical acceleration of the infant and recorded the time spent by neonates in land-based transit [12]. A further study was similar in observational design but included transfers completed by road and air [11].

WBV Measurement Methodology

International Standards Organisation (ISO) 'ISO 2361-1:1997 Mechanical vibration and shock – Evaluation of human exposure to whole-body vibration' is the only globally recognised Standard for the assessment of WBV. The Standard states "There can be large variations between subjects with respect to biological effects. WBV may cause sensations (e.g. discomfort or annoyance), influence human performance capability or present a health and safety risk [32]. Clause 7 and Annex B concern the effects of periodic, random and transient vibration on the health of persons 'in normal health' exposed to WBV during travel, work and leisure time. WBV in respect of Clause 7 is measured as acceleration and is reported as root mean square (RMS) acceleration, with the highest level of vibration during a timed sample as the peak acceleration. Several previous studies on neonatal WBV exposure use this value to report emission values [1–5]. The vibration dose value (VDV), the fourth power vibration dose method, a more sensitive evaluation approach, may also be utilised where peaks are to be expected in the dataset. An American based study reported VDV emissions as the data obtained during an ambulance ride with occasional shocks [8]. Annex B of ISO 2631:1997 indicates 'Health Guidance Caution Zones' which takes account of the frequency-weighted vibration acceleration and the expected daily exposure, from an occupational perspective.

To the author's knowledge, no International standards exist for the measurement of infant exposure to WBV. Several previous studies have used ISO 2631:1997 guidelines for adults' exposure of WBV with respect to health as a guideline for infants and neonates in the hospital and inter-hospital transfer settings. A number of these studies [6,7] have compared WBV emission values to the 'comfort reactions to vibration environments' published in ISO 2631:1997 as presented in (Table 2).

(Table 2)

For measurements, transducers shall be located to indicate the vibration at the interface between the human body and the source of its vibrations [32]. ISO 2631:1997 sets out the basicentric axes of the adult human body in three positions – seated, standing and recumbent. The standard further details specific locations for transducers to be placed for adults in the recumbent position, as under the pelvis, the back and the head. There exists a wide variation when locating transducers in previous studies; from placement on the head and incubator frame [5], under the mattress [9,10], on the head and incubator base [4], on the incubator frame [2] , and on the incubator tray only[3].

ISO 2631:1997 requires that the duration of WBV measurements be reported. Whilst no specific guidance is provided on the length of measurements, the standard states 'the duration of measurement shall be sufficient to ensure reasonable statistical precision and to ensure that the vibration is typical of the exposures which are being assessed' [32]. Similar to the transducer location requirement, there exists large variations between measurement durations in previous studies. Examples of convenience sampling durations varied from 34 hours [1] to 10 hours [2] for road transfers but were more aligned for air transfers at 2 hours [2] , 127 minutes [6] and mean transport time of 2 hours 30 minutes across 16 air journeys [10].

Factors that Affect WBV Emissions Reported

(Table 3) summarizes previous study design and hypotheses on neonatal WBV exposure. Whilst all studies applied the ISO 2631:1997 approach to measurement, there exists a broad variation between the parameters reported in the respective methodologies.

(Table 3)

Sample sizes varied significantly across the studies included in this review; from 1 to 1028. The methodology adopted by researchers influenced the significant difference; some chose to analyze complete journeys [6], and others defined criteria for replicate samples based on comparison of ancillary equipment such as mattresses[4,5,14]. The populations varied from neonate only [2,6,9-12], mannequin only [4,5,7,14,15], or a combination of both [1]. Research time constraints and ethical approval were the cited barriers to use of neonates. The focus of some studies was on the transport system and the potential impact of design changes on vibration emissions, rather than the impact on the safety and comfort of the neonate [3,8].

Inter-hospital neonatal transport occurs when patients in neonatal units are transported to other neonatal or paediatric units for on-going care. Modes of transport include road (ambulance) and air (fixed wing or rotary wing). Neonates requiring transport of either form may already be in a compromised health condition. Comparisons of air and road travel hypothesised the misconception that air travel would emit higher levels of WBV. Air transfers have been found to emit higher levels of WBV, when compared to road travel due to the shock and dynamic events that occur during road transport. Road transfers are subject to more 'impulsive' events compared to air transfer [2]. However, WBV emission levels were also found to the contrary; road travel exposes the neonate to higher levels of WBV. Transport via air emits more stable vibration levels, even during take-off and landing compared to road transfer. This would indicate that air transfer is more comfortable than the alternative road option when compared to (Table 2) [6] Efforts to minimize vibration emissions during transport result in moderate success [7,11,33]. Road classification and vehicle speed were analysed further to determine their influence on vibration magnitude during neonatal transfers. Similar studies in the construction sector reported that terrain type is a significant predictor of vibration magnitude across a range of mobile machinery and plant [34]. Exploration of road transfer WBV emissions have shown that as speed increases a continual upward trend in vibration is noted, however, road type appears to have a weak influence on vibration [1].

Studies to reduce WBV and the effect on back pain in mobile plant and machinery have utilised suspension applications [35] and damping systems [36] as effective means of reducing the health effects of WBV. Acceptable levels of WBV have not been defined in literature or legislation for neonates. Simulated scenarios have been designed and analysed for the in-hospital setting, which focus on the influence of vibration isolation components of the neonatal incubator system, such as latching mechanisms and varying wheel types. The study involves an empty incubator being pushed over a selected route within the hospital setting, as varying speed and configurations of isolation components. Vibrations increase substantially if any part of the shock suppression system is malfunctioning and emphasises the importance of a preventative maintenance programme for neonatal incubators [3]. Comparative studies of different design of neonatal transport systems further support the need for vibration suppression systems to be in place. Bracing mechanisms on neonatal incubator frames emit significantly lower vibration than those systems not diagonally braced, particularly when traversing floor surfaces, for example, entering and exiting an elevator [5].

Investigations of the effect of different mattress types have yielded various results. The first such study took place in the early 1990's. Mattresses are typically categorised as sponge, foam, air or gel-filled; the design of which have evolved over the years, making it difficult to compare results across studies. In general findings show that gel-filled mattresses are more efficient in decreasing the vibration magnitude emitted, however limitations of these studies outline the use of mannequins only [4,15]. Interestingly the lower the weight of the mannequin reduced the efficiency of the gel-filled mattress' attenuation [4]. In-hospital transfers from delivery rooms to neonatal units demonstrated that air-foam mattress experienced less impulsive vibration compared to the standard mattress [14]. Combinations of mattress type have been analysed in observational studies, yielding improved attenuation of vibration with a gel mattress placed on top of an air mattress [7]. In contrast, results have been found to be inconsistent, therefore making it difficult to recommend a specific type of mattress over another [5].

Conclusion

Important questions remain regarding the exposure of neonates to whole body vibration, particularly in the hospital setting. The majority of the literature has limitations with regards sample sizes, use of neonates versus use of mannequins and transport modes. However, what is clear is that there exists an urgent need to determine the exposure of neonates from incubators in situ in the hospital setting. Neonates may spend a number of days/weeks in the neonatal incubator setting, therefore analysis of the WBV exposure will aid in determining the exposure in relation to legislative action and limit values, as well as the Comfort Scale Rating of ISO 2361:1997. Recommendations thus far are focused on improved design of incubator systems with a view to dampening vibration sources and subsequent risk. A better understanding of the preventative maintenance requirements and ancillary equipment specifications of mattress and incubator frames is required in response to the ever-evolving design of neonatal incubators.

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