The effect of device position and use of transparent covers on the irradiance distribution of LED phototherapy devices

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Background. Effective phototherapy reduces neonatal jaundice and its complications. Irradiance increases as the distance of the light source decreases from a single phototherapy light. There are limited studies of the effect of distance and positional changes on different light-emitting diode (LED) light designs on achieving effective phototherapy.
Objectives. To describe and compare the effect of distance, angle and plastic barriers on three different LED lights of different design.
Methods. Comparisons were made using a Servolite, a General Electric (GE) Lullaby and a Ningbo David LED phototherapy light. Measurements were done according to methods described by the International Electrotechnical Commission (IEC). The effective irradiated area was measured on a grid measuring 60 × 30 cm subdivided into 5 × 5 cm squares. Measurements were done for the following scenarios: light placed at the manufacturer's recommended distance, 20 cm closer, 20 cm further, at an angle, through clear plastic and through scuffed Perspex.
Results. When the lights were placed closer to the irradiated surface than the manufacturers' recommendations, the maximum irradiance increased, but the median irradiance and uniformity ratio decreased. When the lights were angled at 45°, the median irradiance was decreased. A decrease in the median irradiance was also seen when phototherapy lights passed through scuffed plastic and food-grade plastic.
Conclusion. Our study demonstrated that the placing of LED lights closer than the manufacturers' recommendations, the use of transparent barriers and the use of lights at an angle, compromised phototherapy irradiance and distribution. Only the GE light met IEC standards.

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Neonatal jaundice (NNJ) occurs in the majority of healthy term and late-preterm newborns within the first week of life, owing to the accumulation of bilirubin in the blood.[1] Unconjugated bilirubin at high concentrations can cross the blood-brain barrier and cause bilirubin-induced neurological dysfunction (BIND), but effective phototherapy can prevent BIND.[2]

Phototherapy using light wavelengths corresponding to the absorption spectrum of bilirubin in the blue-green spectrum peaking at 460±30 nm, reduces serum bilirubin.[3,4] Intensive phototherapy was defined by the American Academy of Pediatrics (AAP) in 2004 as irradiance in the 430 - 490 nm spectrum, of at least 30 μW/cm²/nm, 'measured at the infant's skin directly below the center of the phototherapy unit'.[5] The South African (SA) phototherapy guidelines recommend the use of intensive phototherapy when total serum bilirubin (TSB) exceeds time-dependent thresholds.[6] If bilirubin levels continue to rise despite phototherapy, the AAP guidelines suggest bringing phototherapy lights closer to the infant to increase irradiance.[7] There are limited, device-specific studies showing a decrease in irradiance when a transparent barrier is placed between the neonate and the light source,[8-10] but neither the AAP nor the SA guidelines discuss the impact of transparent barriers. Despite the recommendations in the AAP guidelines, the manufacturers of light-emitting diode (LED) phototherapy devices in use at the authors' institution do not advocate using the device at a distance closer than the recommended distance; LED devices differ from older devices using fluorescent lights by having multiple small LED lights arranged with overlapping light cones. The device brochure for the General Electric (GE) Lullaby LED phototherapy light (GE Healthcare, Laurel, USA) states that the optical design ensures a uniform light distribution.[11] The focusing of the lights and strategic overlapping suggests that placement of LED devices closer to, or further away from, the infant will have a significant and probably negative effect on irradiance – different to the beneficial effect observed with fluorescent lights.

We hypothesised that placement of LED phototherapy devices closer than recommended by manufacturers will not achieve appropriate light intensity and distribution. We therefore aimed to compare the effect of phototherapy device position, distance and the presence of transparent barriers on the irradiance distribution maps of three devices frequently used in Cape Town, SA.

Objectives

1. To describe the irradiance distribution and the mean, maximum and minimum irradiance in the 420 - 480 nm spectrum in three LED phototherapy devices in the following situations:
   - at the distance recommended by the manufacturer with the device horizontally aligned and at 20 cm higher and 20 cm lower
   - at the distance recommended by the manufacturer with a mildy scuffed incubator Perspex hood between the device and the measuring radiometer
   - at the distance recommended by the manufacturer with a single sheet of clear food-grade plastic bag between the device and the measuring radiometer
   - at the distance recommended by the manufacturer with the device and aligned at an angle corresponding to the slope of an incubator.
2. To produce irradiance distribution maps for each of the devices and settings described above.

Methods

Study design and ethics approval

This was a bench-side observational study. The irradiance distributions of three phototherapy units were measured under different circumstances. The study was approved by the Paediatric Departmental Research Committee – approval from the Human Research Ethics Committee was not required because there were no human or animal participants.

The devices (the study sample)

Three new LED phototherapy devices were supplied by the distributors for comparison:

1. a Servolite (SL) LED phototherapy light (Servocare Medical Industries, South Africa (SA)), with five focused high-power blue LED lights producing overlapping light cones
2. a General Electric (GE) Lullaby LED phototherapy light (GE Healthcare, USA) with two separate clusters of high-power blue LED lights that produce two beams which overlap in the middle of the irradiated area
3. a Ningbo David (ND) XHZ-90L LED light (Ningbo David Medical Device Company, China) with multiple blue LEDs spaced to create a broad beam of light.

These devices were chosen as they were in the most frequent use in the authors' neonatal services. They also represent different styles of LED orientation. The irradiance of the devices was measured in several different scenarios that are frequently encountered in clinical practice. The distances recommended by the manufacturers for each device listed above are: 50 cm, 35 cm and 50 cm, respectively.

Data collection (irradiance measurement)

We used the standardised method of measuring irradiance distribution described by the International Electrotechnical Commission (IEC).[12] The IEC defines the effective irradiated area (EIA) as the 'intended treatment surface which is illuminated by phototherapy'. Previously, the EIA was referred to as the effective surface area (ESA). The IEC recommends an EIA of 60 cm × 30 cm with irradiance measurements on a grid with 10 cm or less separating each measurement. The EIA is further defined by the IEC as the area whereby the ratio of minimum irradiance to maximum irradiance, the uniformity ratio (UR), is >40%. Irradiance should be measured with the phototherapy device at the height and position recommended by the manufacturer. Hence, the IEC recommends a desired value for minimum irradiance of 0.4 x maximum irradiance to ensure uniformity of irradiance.

We placed a 60 × 30 cm template, with a grid of 5 cm squares (Fig. 1) on the surface where irradiance was measured. Irradiance was measured using the Ohmeda Medical BiliBlanket Meter II (GE Healthcare, USA). This radiometer measures a spectral range of 400 - 520 nm with a centre wavelength of 450 nm and a bandwidth of 60 nm. The measuring range of its spectral irradiance is 0.1 - 2 99.9 μW/cm^2/nm. The manufacturer states that the device can be used to measure irradiance from LED, fluorescent, halogen and fibre-optic phototherapy devices. The Ohmeda radiometer was the preferred device for irradiance assessment by GE Healthcare – the manufacturers of the other two devices did not specify a preference in their brochures. Irradiance was measured by placing the radiometer in the centre of each square on the grid with the phototherapy device directed on it in different situations, as described below. The values obtained were recorded on a hard-copy grid and then entered into an Excel (Microsoft Corp., USA) spreadsheet with columns and rows labelled according to their position on the measuring grid.

Vreman *et al*.[13] recommend measuring and plotting irradiance over a rectangular grid of 50 × 30 cm. They also recommend assessing irradiance over a silhouette of a term infant placed in the centre of the bed, with approximate length of 40 cm and approximate greatest width of 20 cm, to determine the percent treatable body surface area (BSA).[14]

Irradiance was measured for each device in the following scenarios:

1. The device was positioned above the middle of the grid, in the same position that it would be if the grid was enclosed in an incubator, horizontally orientated, using a spirit level, with no obstructions. Irradiance was measured at the height recommended by the manufacturer, at 20 cm higher (far position) and 20 cm lower (close position), measured with measuring tape and a plumb line from the centre of the device to the centre of the grid.
2. The device was positioned as above at the height recommended by the manufacturer with a single layer of food-grade clear plastic covering the light meter (but not touching it).
3. The device was positioned over a mildly scuffed incubator, the grid was placed on the mattress of the incubator, the light centred over the middle of the grid, horizontally orientated, at the height recommended by the manufacturer.
4. The device was positioned centrally but slightly to one side as it would be on the side of a closed incubator, orientated at an angle of 45 degrees, with no obstructions, at the height recommended by the manufacturer. The position as it would be with a closed incubator is shown in Fig. 2.

Data analysis

Stata Version 12 (StataCorp., USA) was used for statistical analysis. The mean, median, maximum and minimum irradiances and the UR were calculated for each scenario over the 60 × 30 cm grid and also when the EIA was decreased to 50 × 30 cm and 40 × 20 cm. Irradiance was represented graphically as a map or 'footprint' for each scenario. Since several data distributions within the light footprints were not symmetrical, median irradiance was compared using the Wilcoxon signed-rank test for matched samples.

Results

Measurements over an EIA defined by a 60 × 30 cm grid (1 800 cm^2)

The irradiance measurements over the entire 60 × 30 cm grid for each device and setting are shown in Table 1 and Figs 3 - 5.

The frequent differences between mean and median irradiances demonstrate the non-normal distribution of the data. Minimum irradiance was below 2 μW/cm^2/nm for all devices when positioned at the recommended distance. The UR was substantially less than 0.4 in all cases and it decreased further as lights were brought closer. When the devices were placed 20 cm closer than manufacturers' recommended distances (close position), the maximum and mean irradiance increased, and the median irradiance decreased compared with the mean irradiance, but the minimum irradiance decreased in all cases except the ND. The maximum irradiances at the close position were very high and ranged from 60 - 249.8 μW/cm^2/nm. All devices showed a very rapid fall-off in irradiance around the edges of a small high-intensity area when placed at the close position. When the GE was placed at the close position, this resulted in two separate small high-intensity patches of irradiance separated by very low irradiance between (Fig. 4).

When the lights were angled at 45°, the maximum irradiance decreased with the SL and GE, but increased with the ND. In this

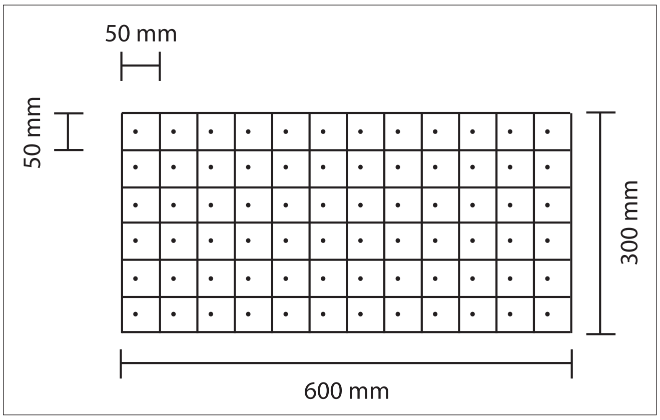

Fig. 1. The irradiance measuring grid.

Fig. 2. Angled position demonstrated with the General Electric device and a closed incubator.

position, the median irradiance decreased by 27.8%, 7.6% and 13.9% in the SL, GE and ND, respectively. There was a marginal decrease in median irradiance when phototherapy light passed through mildy scuffed incubator plastic of 3.7%, 3.1% and 0.7% in the SL, GE and ND respectively – and maximum irradiance decreased in all devices. A single layer of food-grade plastic decreased the irradiances by 10.8%, 0.4% and 27.8% in the SL, GE and ND respectively – maximum irradiance decreased with the SL and ND but was marginally increased with the GE.

Measurements over an EIA of 50 × 30 cm (1 500 cm^2)

The irradiance measurements when EIA is defined as 50 × 30 cm are shown in Table 2. The irradiance map for this area can be appreciated in Figs 3 - 5 by ignoring the first and the last rows. The maximum irradiance was the same as for the 60 × 30 cm grid, but minimum irradiance and UR only increased marginally. The only device with UR >0.4 was the GE – at the far position. The UR for both the SC and the ND were highest at the far distance – and the minimum irradiance was highest at the far distance for these devices. The median irradiance was unchanged or decreased when transparent barriers were in place; the decrease ranged from 0 - 21%.

Measurements over an EIA of 40 × 20 cm (800 cm^2)

The irradiance measurements when EIA is defined as 40 × 20 cm are shown in Table 3. The pattern of variation in irradiance for these areas can be seen in Figs 3 - 5; the 40 × 20 cm area is obtained by ignoring the first two rows, the last two rows and the first and the last columns. The maximum irradiance was the same as for the 60 × 30 cm grid. The minimum irradiance and URs increased further compared with the 50 × 30 cm grid, but the GE was still the only device with UR >0.4 – at all positions except the close position and when plastic covered the radiometer. The UR and the minimum irradiances for both the SC and the ND were again highest at the far distance. The changes in irradiance with devices angled at 45 degrees were similar to those observed over the larger grids, but larger changes in irradiance were observed with transparent barriers in place. Decrease in irradiances through incubator plastic were: 18.2%, 7.2% and 7% for the SL, GE and ND, respectively. Decreases in irradiance through food-grade plastic were: 8.3%, 2.1% and 20.2% for the SL, GE and ND, respectively.

Discussion

Three different LED phototherapy lights were chosen for the study based on their frequency of use and their design. The designs included overlapping beams from clustered LEDs, focused beams from overlapping light cones, and multiple LEDs spaced out to create a broad beam of light.

The present study demonstrates that the distribution of irradiance intensity changes substantially when placing these LED phototherapy devices 20 cm closer or further away from the target treatment surface. Placing the devices 20 cm closer than recommended by the manufacturers resulted in a large increase in maximum irradiance, but minimum irradiance was decreased to levels well below 8 - 10 µW/cm^2/nm in peripheral areas and, in the case of the GE device, also in the central area of the light footprint – these decreases resulted in a substantial reduction of the effective irradiated area. Irradiance intensity changed by over 100 µW/cm^2/nm within as little as 5 cm in several cases but there was wide variation between the devices. The placement of incubator or food-grade plastic between the device and the therapeutic target had marginal effect on maximum irradiance but decreased median irradiance in all devices over 40 × 20 cm grid by up to 20%. There were similar changes when using the device at an angle, but the maximum irradiance increased by over 80% with the ND.

The IEC do not stipulate a minimum or maximum irradiance, since the optimal irradiance of phototherapy has not yet been established.[12] An irradiance of 8 - 10 µW/cm^2/nm was defined by the AAP in 1994 as 'standard phototherapy' – this was based on the irradiance of 'conventional' or 'standard daylight units' at a

Table 1. Total irradiance for bilirubin using different phototherapy devices, distances and barriers on a 60 × 30 cm grid (1 800 cm²)

Device	Distance from surface (cm)	Barriers or angle	Max. irrad.*	Min. irrad.*	0.4 × max. irrad.*†	Min:max ratio (UR)	Mean irrad. (SD)*	Median irrad. (IQR)*	*p*-value‡
SL	70	None	56.1	2.7	22.4	0.048	25.4 (15.7)	26.0 (10.3 - 36.7)	0.535
SL	30	None	249.8	0.6	99.9	0.002	31.7 (55.4)	4.3 (1.2 - 29.8)	0.002
SL	50	None	115.8	0.8	13.8	0.007	31.1 (32.2)	19.4 (4.0 - 53.9)	§
SL	50	Angle	95.0	0.9	38.0	0.009	27.4 (28)	14.0 (3.6 - 47.7)	0.004
SL	50	Incubator	90.4	1.4	36.2	0.015	26.0 (25.8)	15.7 (1.4 - 90.4)	<0.001
SL	50	Plastic	105.3	0.9	42.1	0.009	28.2 (28.4)	17.3 (4.1 - 45.8)	0.001
GE	55	None	33.1	9.2	13.2	0.278	19.6 (6.5)	19.0 (13.9 - 24.4)	<0.001
GE	15	None	218.6	1.6	87.4	0.007	36.3 (51.4)	10.6 (5.0 - 56.5)	0.558
GE	35	None	60.0	2.5	24.0	0.042	28.6 (15.1)	27.5 (16.1 - 41.5)	§
GE	35	Angle	50.8	1.7	20.3	0.033	25.1 (13.3)	25.4 (15.4 - 36.4)	0.003
GE	35	Incubator	56.8	4.1	22.7	0.072	26.9 (13.6)	24.4 (16.6 - 38.3)	0.067
GE	35	Plastic	63.9	2.4	25.6	0.038	28.1 (15.1)	27.4 (15.4 - 41.7)	0.082
ND	70	None	34.4	1.9	13.8	0.055	15.3 (9.4)	14.7 (6.7 - 22.1)	0.011
ND	30	None	62.3	1.5	25.0	0.024	20.9 (19.9)	14.4 (3.2 - 40.4)	0.017
ND	50	None	49.5	1.3	19.8	0.026	17.6 (14)	15.1 (4.1 - 26.7)	§
ND	50	Angle	89.6	1.3	35.8	0.015	17 (14.9)	13 (4.6 - 26.4)	0.008
ND	50	Incubator	44.7	2.0	17.9	0.045	16.8 (12.6)	14.4 (5.4 - 25.5)	0.036
ND	50	Plastic	47.0	1.3	18.8	0.028	15.4 (13.5)	10.9 (4.0 - 25.1)	0.001

Irrad. = irradiance; UR = uniformity ratio; SD = standard deviation; IQR = interquartile range; SL =servolite; GE = General Electric; ND = Ningbo David.
*µW/cm²/nm.
‡*p*-value denotes comparison with standard recommended position and distance.
†0.4 × maximum irradiance is the desired value for minimum irradiance in order to comply with International Electrotechnical Commission uniformity recommendations.
§No *p*-value as this is the recommended distance.

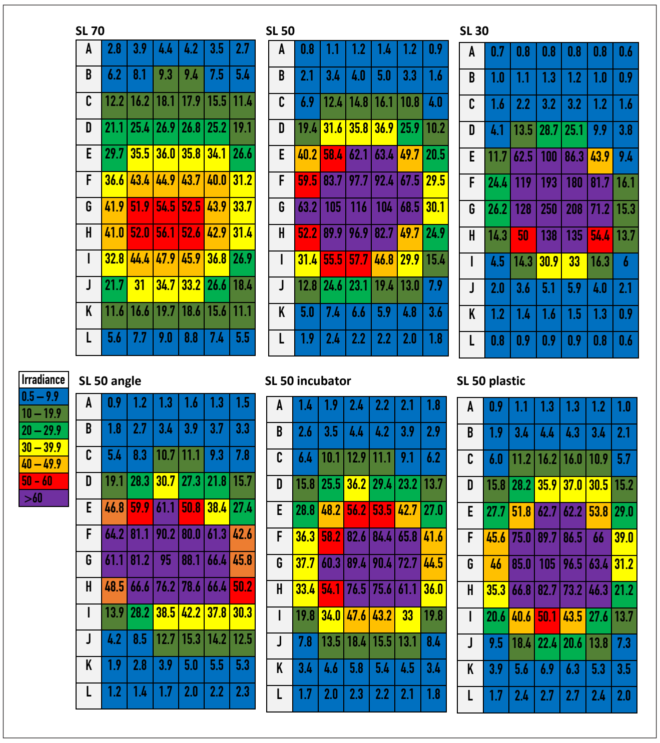

Fig. 3. The irradiance map of the Servolite phototherapy light in different settings. (SL 70 = Servolite at 70 cm; SL 50 = Servolite at 50 cm; SL 30 = Servolite at 30 cm; SL 50 angle = Servolite at 50 cm at an angle; SL 50 incubator = Servolite at 50 cm through an incubator; SL 50 plastic = Servolite at 50 cm through food-grade plastic.)

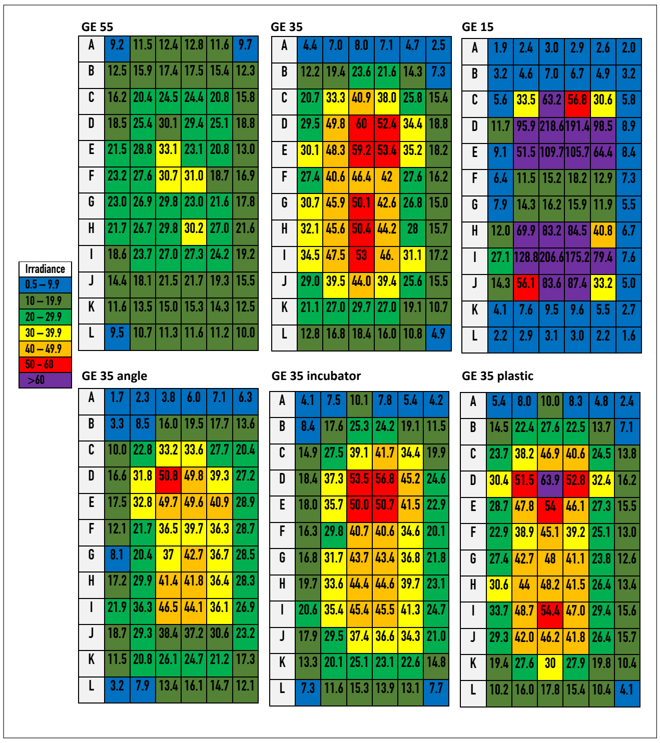

Fig. 4. The irradiance map of the General Electric phototherapy light in different settings. (GE 70 = General Electric at 70 cm; GE 50 = General Electric at 50 cm; GE 30 = General Electric at 30 cm; GE 50 angle = General Electric at 50 cm at an angle; GE 50 incubator = General Electric at 50 cm through an incubator; GE 50 plastic = General Electric at 50 cm through food-grade plastic.)

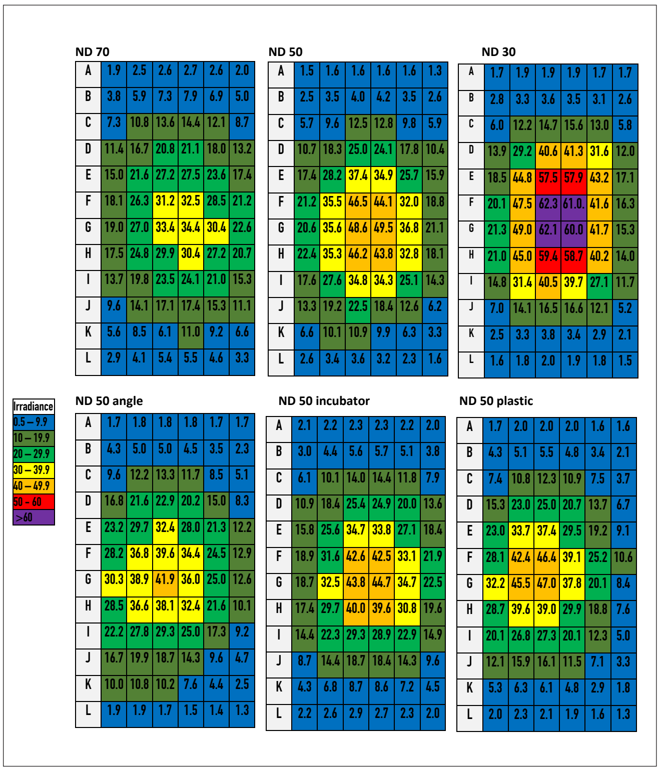

Fig. 5. The irradiance map of the Ningbo David phototherapy light in different settings. (ND 70 = Ningbo David at 70 cm; ND 50 = Ningbo David at 50 cm; ND 30 = Ningbo David at 30 cm; ND 50 angle = Ningbo David at 50 cm at an angle; ND 50 incubator = Ningbo David at 50 cm through an incubator; ND 50 plastic = Ningbo David at 50 cm through food-grade plastic.)

distance of 20 cm.[15] The AAP recommend standard phototherapy when bilirubin levels are 34 - 51 µmol/L below the threshold for intensive phototherapy.[1,15] The AAP 2004 guidelines suggest that optimal irradiance is 30 µW/cm²/nm, also referred to as 'intensive phototherapy' – based on data at the time suggesting that higher intensities would not be effective at lowering bilirubin levels.[5] However, previous and more recent studies using LED phototherapy lights have shown a linear correlation between light irradiance at 5 - 55 µW/cm²/nm and percentage change in serum bilirubin – the linear relationship suggests that saturation will not occur at higher doses.[3,4] Hence, doses of 30 - 55 µW/cm²/nm may be considered optimal, spread evenly over the surface of the neonate with UR >0.4.

The practice of bringing phototherapy lights closer was recommended at the time when special blue fluorescent bulbs were commonly in use.[5] Light intensity with these lights is inversely related to distance from the source and, when these lights are moved closer to infants, serum bilirubin falls more rapidly.[16] The National Institute for Health Care and Excellence (NICE) guidelines, developed in the United Kingdom and updated in 2016, do not refer to 'optimal' or 'intensive' phototherapy – they refer only to 'phototherapy' and 'intensified phototherapy' without defining these terms with irradiance measures.[17] They suggest 'increasing the irradiance of the original light source' or adding more lights, and they state that phototherapy devices should be used according to manufacturers' instructions.

Although a randomised trial of aggressive v. conservative phototherapy in preterm infants showed improved neurodevelopmental outcomes with aggressive phototherapy and no significant effect on death,[18] there are concerns that prolonged phototherapy may be associated with DNA damage; the occurrence

Table 2. Total irradiance for bilirubin using different phototherapy devices, distances and barriers on a 50 × 30 cm grid (1 500 cm²)

Device	Distance from surface (cm)	Barriers or angle	Max. irrad.*	Min. irrad.*	0.4 × max. irrad.*†	Min:max ratio	Mean irrad. (SD)*	Median irrad. (IQR)*	*p*-value‡
SL	70	None	56.1	5.4	22.4	0.10	29.5 (14.1)	30.4 (18 - 41.5)	0.120
SL	30	None	249.8	0.9	99.9	<0.01	37.9 (58.9)	10.8 (1.8 - 47)	0.021
SL	50	None	115.8	1.6	46.3	0.01	37 (32.2)	27.7 (9.1 - 59)	§
SL	50	Angle	95.0	1.8	38.0	0.02	32.5 (28)	27.4 (7.9 - 55.4)	0.007
SL	50	Incubator	90.4	2.6	36.2	0.03	30.8 (25.7)	25.6 (8.1 - 46.1)	<0.001
SL	50	Plastic	105.3	1.9	42.1	0.02	33.5 (28.2)	27.7 (8.4 - 51)	<0.001
GE	55	None	33.1	11.6	13.2	0.40	21.3 (5.7)	21.5 (16.6 - 26.1)	<0.001
GE	15	None	218.6	2.7	87.4	0.01	43 (53.9)	14.3 (7.2 - 67.2)	0.760
GE	35	None	60.0	7.3	24.0	0.10	32.4 (31.9)	30.4 (20.9 - 44.1)	§
GE	35	Angle	50.8	3.2	20.3	0.06	28.6 (11.7)	28.6 (20 - 36.9)	0.004
GE	35	Incubator	56.8	8.4	22.7	0.15	30.5 (11.9)	29.7 (20.1 - 40.7)	0.056
GE	35	Plastic	63.9	7.1	25.6	0.11	31.9 (13.6)	29.4 (22.5 - 43.4)	0.084
ND	70	None	34.4	3.8	13.8	0.11	17.7 (8.4)	17.4 (10.9 - 23.9)	<0.001
ND	30	None	62.3	2.1	24.9	0.03	24.8 (19.7)	16.6 (6.5 - 41.5)	0.005
ND	50	None	49.5	2.5	19.8	0.05	20.7 (13.4)	18.4 (10 - 32.4)	§
ND	50	Angle	89.6	2.3	35.8	0.03	20.1 (14.5)	18 (9.8 - 28.4)	0.013
ND	50	Incubator	44.7	3.0	17.9	0.07	19.7 (11.8)	18.4 (9.2 - 29.1)	0.009
ND	50	Plastic	47.0	1.8	18.8	0.04	18.1 (13.2)	14.5 (6.5 - 27.7)	0.002

Irrad. = irradiance; UR = uniformity ratio; SD = standard deviation; IQR = interquartile range; SL =servolite; GE = General Electric; ND = Ningbo David.
*µW/cm²/nm.
†0.4 × max irradiance is the desired value for minimum irradiance in order to comply with International Electrotechnical Commission uniformity recommendations.
‡*p*-value denotes comparison with standard recommended position and distance.
§No *p*-value as this is the recommended distance.

Table 3. Total irradiance for bilirubin using different phototherapy devices, distances and barriers on a 40 × 20 cm grid (800 cm²)

Device	Distance from surface (cm)	Barriers or angle	Max. irrad.*	Min. irrad.*	0.4 × max irrad.*†	Min:max ratio	Mean irrad. (SD)*	Median irrad. (IQR)*	*p*-value‡
SL	70	None	56.1	15.5	22.4	0.28	37.3 (11.9)	36.4 (26.9 - 45.4)	<0.001
SL	30	None	249.8	1.2	99.9	< 0.01	65.6 (69.6)	38.5 (7.9 - 110)	0.694
SL	50	None	115.8	10.8	46.3	0.10	54.4 (31.9)	52.6 (25.3 - 83.2)	-§
SL	50	Angle	95.0	8	38.0	0.08	44.2 (28.7)	38.5 (14.8 - 66.5)	<0.001
SL	50	Incubator	90.4	9.1	36.2	0.1	44.3 (26)	43.0 (20.9 - 63.5)	<0.001
SL	50	Plastic	105.3	10.9	42.1	0.1	49.7 (27.7)	48.2 (25.0 - 70)	<0.001
GE	55	None	33.1	18.1	13.2	0.55	25.4 (4.1)	25.2 (21.7 - 29.1)	<0.001
GE	15	None	218.6	11.5	87.4	0.05	73.9 (58.3)	63.8 (24.4 - 97.2)	0.003
GE	35	None	60.0	25.6	24.0	0.43	42.1 (9.5)	43.3 (34.8 - 49.1)	-§
GE	35	Angle	50.8	20.4	20.3	0.4	36.9 (7.9)	36.6 (32.2 - 41.6)	0.004
GE	35	Incubator	56.8	27.5	22.7	0.48	40.1 (6.9)	40.2 (35.0 - 44.5)	0.161
GE	35	Plastic	63.9	23.8	25.6	0.37	41.3 (10.1)	42.4 (35.3 - 47.9)	0.221
ND	70	None	34.4	10.8	13.8	0.31	23.0 (6.7)	23.6 (17.3 - 28)	<0.001
ND	30	None	62.3	12.1	24.9	0.19	38.4 (17.1)	41 (21.9 - 53.3)	<0.001
ND	50	None	49.5	9.6	19.8	0.19	29.2 (11.8)	30.1 (18.8 - 36.2)	-§
ND	50	Angle	89.6	8.5	35.8	0.09	25.1 (9.7)	24.8 (18.0 - 33.4)	<0.001
ND	50	Incubator	44.7	10.1	17.9	0.23	27.3 (10.1)	28 (18.6 - 34.2)	0.001
ND	50	Plastic	47.0	7.1	18.8	0.15	25.4 (12.3)	24 (14.8 - 37.6)	0.002

Irrad. = irradiance; UR = uniformity ratio; SD = standard deviation; IQR = interquartile range; SL =servolite; GE = General Electric; ND = Ningbo David.
*µW/cm²/nm.
†0.4 × max. irrad. is the desired value for minimum irradiance in order to comply with International Electrotechnical Commission uniformity recommendations.
‡*p*-value denotes comparison with standard recommended position and distance.
§No *p*-value as this is the recommended distance.

of very high irradiances focused on small areas when placing the devices close may not be safe.[19] A preferable approach may be to select a higher-intensity setting (if the device offers it). Alternatively, additional lights could be added so that the lights remain focused in the optimal position, increased surface area of skin is exposed, and there is a more uniform increase in irradiance. This is a topic for further study.

The large variation in irradiance intensities when phototherapy devices are moved very close to the therapeutic target is further demonstrated by very low UR. The UR >0.4 required by the IEC precludes the use of any devices we studied in the close position.[12] When used at recommended distances, only the GE device achieved this ratio in our study, and only over an EIA of 40 × 20 cm.

UR decreases with decreasing size of the EIA. Treatment of babies smaller than this size is expected to be associated with improved UR and higher minimum irradiance. The ND and SL (at 50 and 70 cm, respectively) may provide irradiance at levels in line with IEC recommendations when applied to the smaller area of a preterm baby – this concept should be explored in further research.

Several methods of assessing irradiance, other than those of the IEC and Vreman, have been recommended.[20-22] Dicken *et al.*[20] measured irradiance levels over a rectangular area, based on the assumption that one-third of skin surface area is available for treatment – irradiance was measured over 20 cm × 35 cm for term neonates. Subramanian *et al.*[21] recommended measuring irradiance at 5 cm intervals over a rectangular grid of 60 cm × 30 cm and then tracing onto the grid an outline of a term baby with a two-dimensional surface area of 780 cm² to determine the BSA. Irradiance was measured at the centre and at four peripheral points and maximum, minimum and mean irradiance were measured within the outline of the neonate. Reda *et al.*[22] recommended measuring and plotting irradiance at 7.5 cm intervals over a rectangular grid of 60 cm × 30 cm. We did not use an infant silhouette and we did not calculate treatable BSA, because the measurement of treatable BSA assumes that the infant lies still throughout treatment and that light approaches in a single plane, which is not the case. This method is also complex and the actual size of the silhouette and minimum irradiance to define 'treatment' have not been clearly defined, making it a difficult method to reproduce. Instead, we measured irradiance parameters over a 40 × 20 cm area, which is similar to the rectangular space occupied by a baby, is the area that lights are focused around in practice, and is also similar to the area described by Dicken *et al.*[20]

In addition to irradiance variation with height, the presence of physical barriers to light around neonates can also have an effect. Phototherapy irradiance provided with fluorescent bulbs decreases with the use of plastic blankets and heat shields.[8,9] A decrease in irradiance has also been described when phototherapy is applied through a scratched incubator surface.[10] Our data with LED lights are similar.

The present study has several limitations. Each irradiance measurement was only taken once. However, 72 measurements were taken on each grid and the consistency of measurement can be appreciated from the irradiance maps (Figs 3 - 5). The operation and maintenance manual states that the Ohmeda Medical BiliBlanket Meter II measures irradiance continually with an accuracy of ~3%. We performed a *post hoc* evaluation of accuracy by taking 72 measurements (the number of measurements in each grid) in the same position. The mean (standard deviation) of 72 measurements taken at 35 cm below the centre of the Lullaby device was 39.6 (0.1) µW/cm²/nm. Further limitations are: only one device of each type was evaluated; and the distance between the plastic cover and the light source may have had a more profound effect than we observed without the cover. The positions used were based on what is done in clinical practice.

Conclusion

We have demonstrated that the most appropriate distance to place LED phototherapy lights depends on the design of the lights. Placing lights closer than recommended significantly compromises the light distribution and irradiance. The use of transparent barriers decreases irradiance further. All three lights had maximum irradiance of at least 30 uW/cm²/nm (sufficient for intensive phototherapy) at all the distances, but minimum irradiance was only ≥8 uW/cm²/nm (sufficient for standard phototherapy) for most devices over the small grid of 40 × 20 cm. The UR only met IEC-recommended standards with the GE light. The SL device had improved uniformity with acceptable irradiance when used at 70 cm rather than the recommended 50 cm.

Although the GE device is the only device that meets both IEC and AAP recommendations for standard and intensive phototherapy, it only does so over a 40 × 20 cm grid. There is no evidence to show that the use of device with uniformity ratios <0.4, very high maximum irradiance and low minimum irradiances below 8 uW/cm²/nm is associated with unacceptable performance.

Clinicians should be aware of the recommended distance and the shortcomings of phototherapy devices. Further research is needed to (*i*) evaluate consistency of performance between devices from the same manufacturer; (*ii*) determine the effect that distance and angle have on irradiance when barriers are used; (*iii*) determine the effect on irradiance of using more than one light; and (*iv*) determine simple rapid bedside irradiance assessment methods. The terms ‘intensive’ and ‘standard’ are misleading and poorly defined – there is a need to establish more appropriate terms that adequately describe the dose of phototherapy being given.

Declaration. This manuscript is the work of both authors without input from any other parties. It has not been published anywhere else in any other format, but it will form part of a Master of Medicine (Paed) degree.

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