

Emirates Osteopathic Conference

NEONATOLOGY AND OSTEOPATHY PROJECT

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NEONATOLOGY AND OSTEOPATHY PROJECT

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Outline

- Discuss the history of osteopathy in neonatology at the light of EBM
- Present the state of the art of the ne-o project
- Introduce the recent evolution of the ne-o project: The RAISE
- Propone a multidisciplinary platform for the study of osteopathy in the context of neonatology/pediatrics



RESEARCH

Open Access

Effect of osteopathic manipulative treatment on gastrointestinal function and length of stay of preterm infants: an exploratory study

Gianfranco Pizzolorusso^{1*}, Patrizia Turì¹, Gina Barlafante², Francesco Cerritelli¹, Cinzia Renzetti², Vincenzo Cozzolino², Marianna D'Onofrio², Paola Fusilli², Fabrizio Carroli¹ and Carmine D'Incecco³

Cerritelli et al. *BMC Pediatrics* 2013, **13**:65
<http://www.biomedcentral.com/1471-2431/13/65>



Do placebo effects associated with sham osteopathic procedure occur in newborns? Results of a randomized controlled trial



Marta Martelli^{4,5}, Lucia Cardinali⁴, Gina Barlafante^{4,5}, Gianfranco Pizzolorusso^{4,5}, Cinzia Renzetti^{4,5}, Francesco Cerritelli^{4,5,6}



RESEARCH ARTICLE

Open Access

Effect of osteopathic manipulative treatment on length of stay in a population of preterm infants: a randomized controlled trial

Francesco Cerritelli^{1,2*}, Gianfranco Pizzolorusso^{1,2}, Francesco Ciardelli², Emiliano La Mola², Vincenzo Cozzolino², Cinzia Renzetti², Carmine D'Incecco³, Paola Fusilli³, Giuseppe Sabatino⁴ and Gina Barlafante^{1,2}



METHODOLOGY

Open Access

Introducing an osteopathic approach into neonatology ward: the NE-O model

Francesco Cerritelli^{1,2*}, Marta Martelli^{1,2}, Cinzia Renzetti^{1,2}, Gianfranco Pizzolorusso^{1,2}, Vincenzo Cozzolino^{1,2} and Gina Barlafante^{1,2}

Research Article

The Effect of Optimally Timed Osteopathic Manipulative Treatment on Length of Hospital Stay in Moderate and Late Preterm Infants: Results from a RCT

Gianfranco Pizzolorusso^{1,2}, Francesco Cerritelli^{1,2}, Alessandro Accorsi^{1,2}, Chiara Lucchi^{1,2}, Lucia Tubaldi², Jenny Lancellotti², Gina Barlafante^{1,2}, Cinzia Renzetti^{1,2}, Carmine D'Incecco⁴ and Francesco Paolo Perri¹

days of hospitalisation

	LOS (days)		Univariate O.R.		Adjusted O.R.	
	< 28	≥ 28	O.R. (95%CI)	p > χ^2	O.R. (95%CI)	p > χ^2
N	267 (76.3)	83 (23.7)				
Gender						
Females [R.C]	128 (75.3)	42 (24.7)	1	-	1	-
Males	139 (77.2)	41 (22.8)	0.90 (0.55-1.47)	0.765	<u>1.40 (0.63-3.10)</u>	<u>0.412</u>
Gestational Age						
≤ 32	21 (25.6)	61 (74.4)	38.10 (16.40-88.20)	< 0.001	10.90 (3.53-33.72)	< 0.001
> 32, ≤ 35	128 (90.8)	13 (9.2)	1.33 (0.55-3.22)	0.680	0.76 (0.27-2.15)	0.609
> 35 [R.C]	118 (92.9)	9 (7.1)	1	-		
Birth Weight (grams)						
≤ 1700	9 (15.5)	49 (84.5)	120.60 (42.70-340.60)	< 0.001	43.23 (11.63-160.66)	< 0.001
> 1700, ≤ 2200	103 (79.2)	27 (20.8)	5.80 (2.40-13.80)	< 0.001	3.01 (1.05-8.68)	0.041
> 2200 [R.C]	155 (95.7)	7 (4.3)	1	-	<u>1</u>	<u>-</u>
Oral feeding at admission						
No	186 (72.1)	72 (27.9)	2.85 (1.44-5.66)	0.003	3.11 (1.05-9.25)	0.041
Yes [R.C]	81 (88.0)	11 (12.0)	1	-	1	-
OMT						
No [R.C]	133 (70.7)	55 (29.3)	1	-	1	-
Yes	134 (82.7)	28 (17.3)	0.51 (0.30-0.85)	0.012	<u>0.22 (0.09-0.51)</u>	<u>< 0.001</u>

gastro-intestinal effects

	Average Daily Gut Symptoms*		Univariate O.R.		Adjusted O.R	
	≤ 0.44	> 0.44	O.R. (95%CI)	p > χ ²	O.R. (95%CI)	p > χ ²
N	262 (74.9)	88 (25.1)				
Gender						
Females [R.C]	129 (75.9)	41 (24.1)	1	-	1	-
Males	133 (73.9)	47 (26.1)	1.11 (0.68-1.80)	0.759	1.08 (0.65-1.79)	0.777
Gestational Age						
≤ 32	57 (69.5)	25 (30.5)	1.20 (0.65-2.21)	0.670	1.02 (0.43-2.40)	0.965
> 32, ≤ 35	112 (79.4)	29 (20.6)	0.71 (0.40-1.25)	0.293	0.72 (0.39-1.32)	0.292
> 35 [R.C]	93 (73.2)	34 (26.8)	1	-	1	-
Birth Weight (grams)						
≤ 1700	39 (67.2)	19 (32.8)	1.54 (0.80-2.96)	0.265	1.39 (0.55-3.46)	0.481
> 1700, ≤ 2200	100 (76.9)	30 (23.1)	0.95 (0.55-1.63)	0.952	1.03 (0.55-1.93)	0.927
> 2200 [R.C]	123 (75.9)	39 (24.1)	1	-	1	-
Oral feeding at admission						
No	192 (74.4)	66 (25.6)	1.09 (0.63-1.90)	0.860	1.18 (0.67-2.13)	0.583
Yes [R.C]	70 (76.1)	22 (23.9)	1	-	1	-
OMT						
No [R.C]	128 (68.1)	60 (31.9)	1	-	1	-
Yes	134 (82.7)	28 (17.3)	0.45 (0.27-0.74)	0.002	0.45 (0.26-0.74)	0.002

Pizzolorusso G, Turi P, Barlafante G, Cerritelli F, Renzetti C, Cozzolino V, D'Orazio M, Fusilli P, Carinci F, D'Incecco C. Effect of osteopathic manipulative treatment on gastrointestinal function and length of stay of preterm infants: an exploratory study. *Chiropr Man Therap.* 2011 Jun 28;19(1):15.

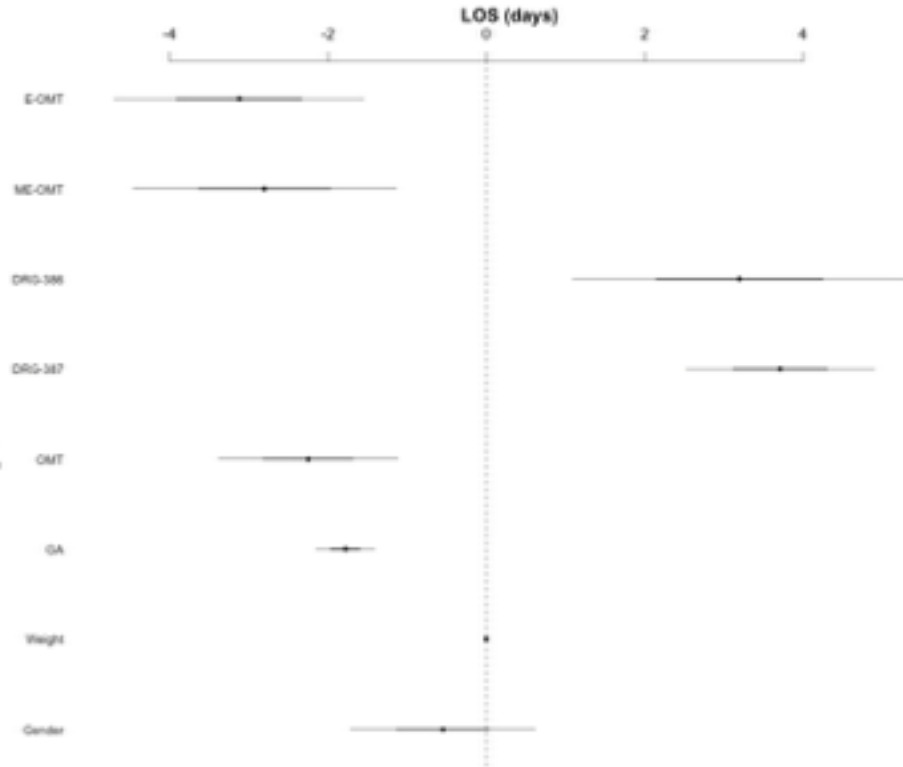
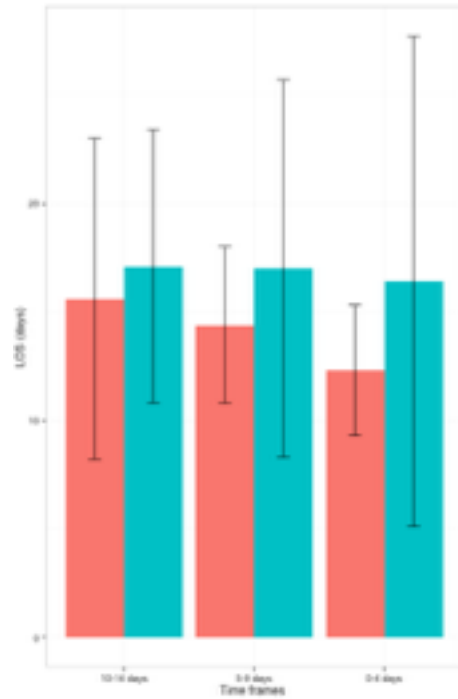
Clinical effectiveness

β	95%c.i.		$p > \chi^2$
-5,906	-7,944	-3,869	<0,001
-3,373	-3,916	-2,830	<u>0,001</u>
0,002	-0,004	0,009	<u>0,44</u>
-0,014	-0,016	-0,009	<u>0,001</u>
-1,899	-3,930	0,127	<u>0,07</u>

Reduction of costs

	Costs (2012€)		
	Estimate	95% C.I.	p>χ ²
Male	576.14	-173.65 , 1325.93	0.13
Gestational Age	-120.76	-371.79 , 130.27	0.34
Birth Weight (gr)	0.49	-0.43 , 1.43	0.28
LOS	78.96	38.17 , 119.75	<0.001
OMT	-2,724.91	-3,491.73 , -1,958.09	<0.001

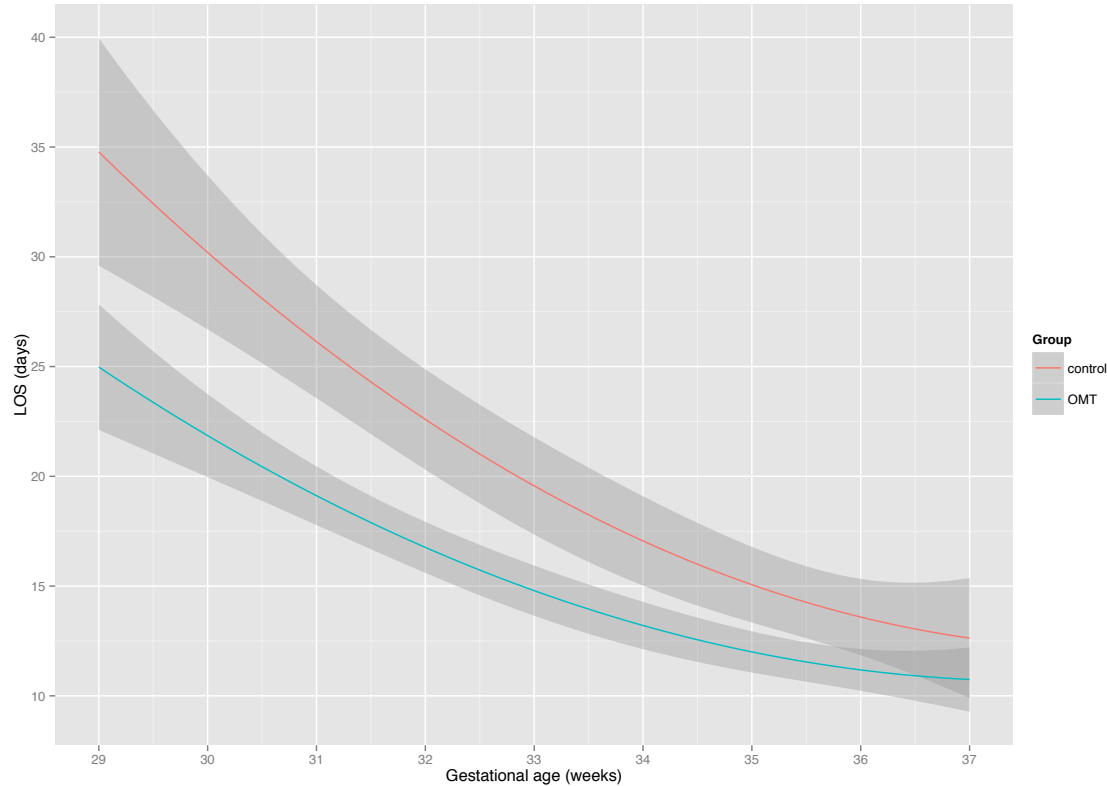
LOS



Costs

	Costs (2012€)		
	Estimate	95%C.I.	p> χ^2
Gender	375.67	-208.89 960.24	0.21
Gestational age	159.93	-46.45 366.31	0.12
Birth weight (gr)	-0.62	-1.36 0.12	0.10
LOS	62.66	10.68 114.64	0.02
OMT time frame	102.09	14.30 189.87	0.02
OMT	-739.94	-1319.54 -171.33	0.01
DRG-388 (R.C.)	1	1	1
DRG-387	1883.12	1275.93 2490.31	<0.001
DRG-386	5190.54	4099.19 6281.89	<0.001

Subgroup analysis - GA



OLS-Costs

Table 3. Results of ordinary least square regression for cost estimates.

	Costs (2013€)		
	Estimate	95%C.I.	p> t
Gender	-12.87	-447.25; 421.51	0.95
Gestational age	-187.93	-329.39; -46.47	<0.01
Birth weight (gr)	-0.41	-0.84; 0.02	0.06
LOS	113.99	93.69; 134.30	<0.001
OMT	-1250.65	-1690.72; -810.59	<0.001

LOS = length of stay; OMT = osteopathic manipulative treatment.

doi:10.1371/journal.pone.0127370.t003

Total savings for NICUs: ~€500,000.00

OLS-Costs

Table 3. Results of ordinary least squares regression

	p> t
Gender	0.95
Gestational age	<0.01
Birth weight (gr)	0.06
LOS	<0.001
OMT	<0.001

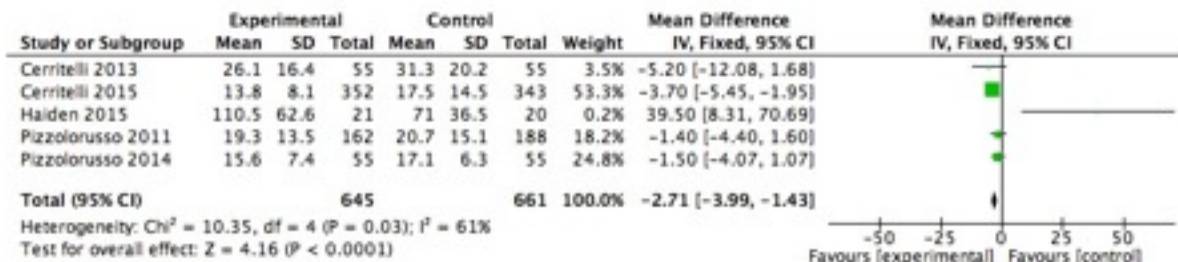
1. Cost-benefit effect of OMT
2. The earlier the OMT intervention the more clinical effective

LOS = length of stay; OMT = osteopathic manipulative treatment.

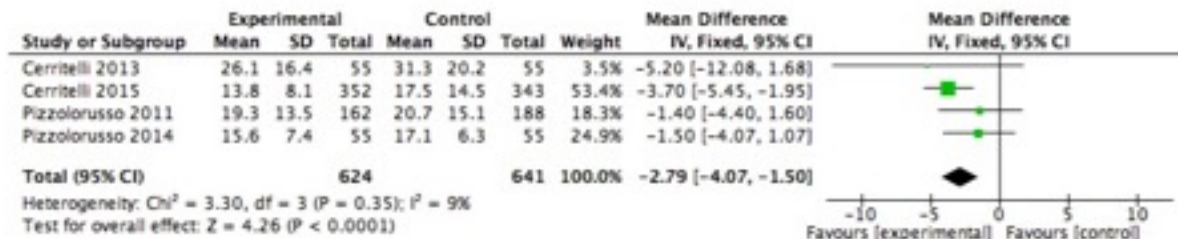
doi:10.1371/journal.pone.0127370.t003

Total savings for NICUs: ~€500,000.00

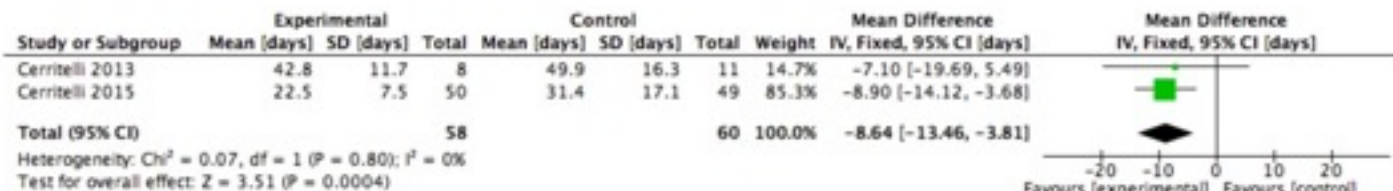
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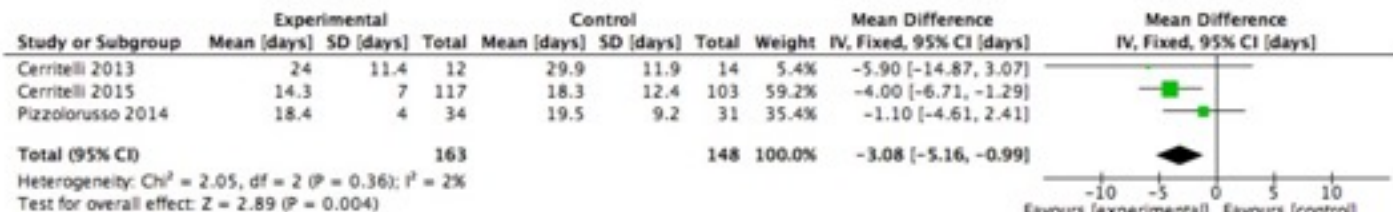
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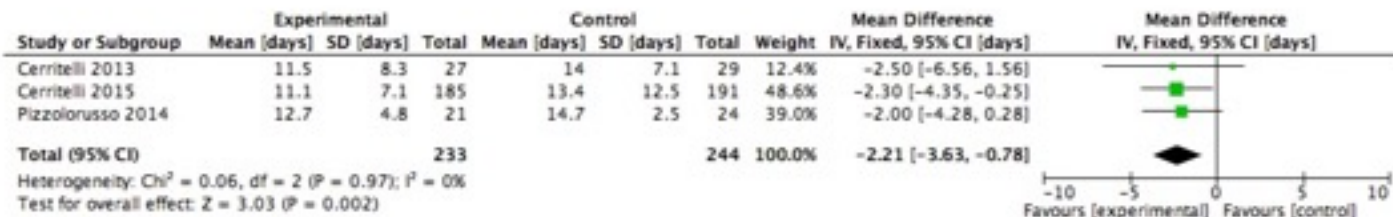
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B



C





Cerritelli et al. Introducing an osteopathic approach into neonatology ward: the NE-O model. *Chiropr Man Therap.* 2014 May 9;22



<http://www.comecollaboration.org/it/ne-o/>

Vision



Osteopathy as part of the neonatal IPC

Mission



Produce compelling evidence of osteopathy effects in preterm infants

Working streams

1. health information
2. health-related research
3. biological research
4. neurological research
5. public health research

Health information

development of a data collection platforms

- minimum perinatal dataset with standard metrics
- maternal outcomes
- key programme coverage data
- osteopathic data

Health-related research

role of osteopathy on improving health outcomes

- Efficacious field research
- Preventive field research
- Social research

Biological research

understanding of the biological effects of osteopathy

- stress-related outcomes
- inflammatory outcomes

Neurological research

exploring the sequelae of OMT in regards to central and peripheral nervous system functions

- clinically based:
i.e. neurocognitive developmental outcomes
- neuroscience based:
 - central: brain imaging, ANS
 - peripheral

Public health research

impact of OMT and its use on health care system

- health improvements [DALY, HALE]
- health economics
- health service
- health policy

Population target

- 10000 premature infants in several international hospitals in 3 years
 - without complications
 - with complications

Outcomes

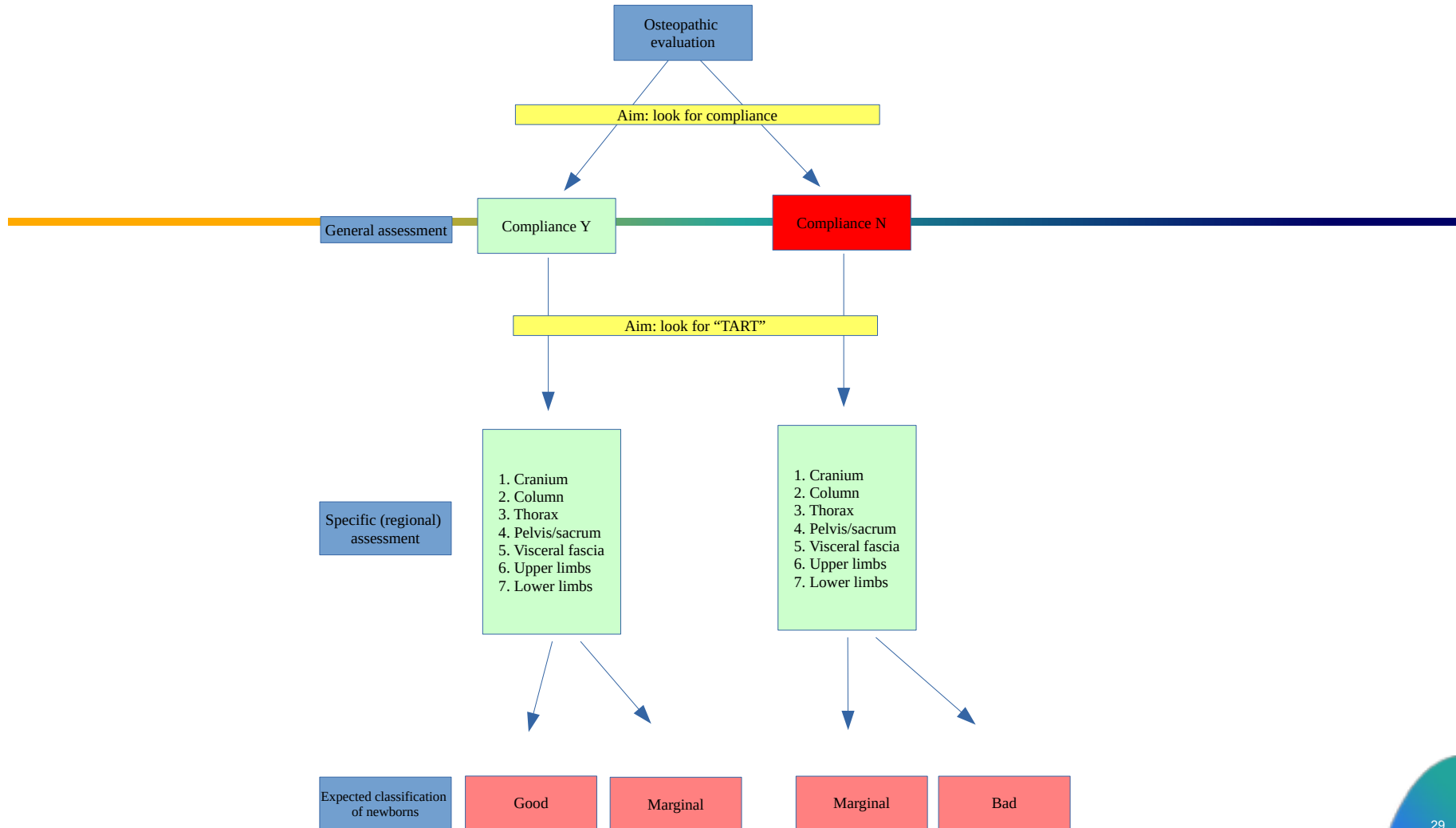
Specific AIM 1: NAME index validation

Specific AIM 2: Correlate the NAME index to clinical parameters.

Specific AIM 3 (clinical outcomes)

Specific Aim 1

The Neonatal health Assessment Manual score (NAME) index is a battery of tests that can be used to evaluate the general condition of the newborns from a manual-based complementary perspective. The ultimate goal is to have different categories of newborns (bad, marginal and good), which can be used as additional diagnosis to classify newborns' health.



Compliance

- Compliance (flexibility)= “the property of a material of undergoing elastic deformation or (of a gas) change in volume when subjected to an applied force. It is equal to the reciprocal of stiffness” (oxford dictionary).
- Medicine “the ability of an organ to distend in response to applied pressure” (oxford dictionary).
- manual procedures == applying pressure/forces == producing reactions/responses, we can hypothesise that each manual test is eventually assessing the compliance. This can be both at specific (i.e. joint, tissue) and general level, which can be referred as ***bodily compliance***.

Resilience

- “person’s reaction to a situation that in ordinary circumstances leads to maladaptive outcomes” (Taylor and Thomas 2001, 9).
- A recent quantitative systematic review analysed self-reported measurements used to quantify resilience. Authors concluded that among the 15 questionnaires, only few of them have been considered of moderate quality (Windle, 2011)

www.theraise.org



RAISE

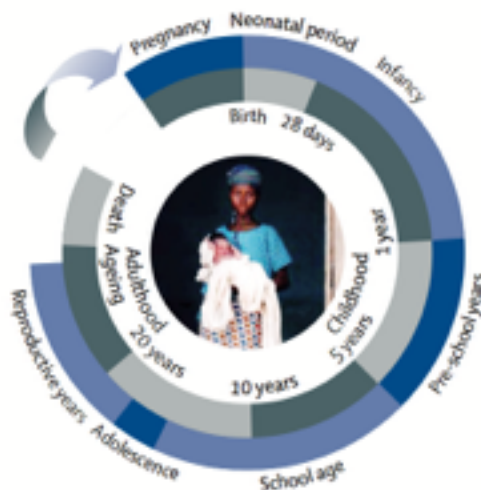
Research and
Assistance for
Infants to
Support
Experience

Impact

Lifecourse centred on birth outcomes

Human capital loss related to birth outcomes

Societal effects



Deaths (annual for 2012)

Maternal
0-29 million

Stillbirths
2-6 million

Neonatal
2-9 million

Deaths 1-59 months from later complications of neonatal conditions*
0-5 million

Adult deaths with non-communicable diseases (NCDs) subsequent to SGA/preterm

Disability and lost development potential (annual for 2012)

Preterm births
15-1 million

Term SGA*
10-4 million LBW
19-6 million not LBW

Stunted children subsequent to SGA/preterm
3-7 million

Women with fistula/long-term complications

Preterm related NDI and retinopathy of prematurity
0-9 million

Infections NDI (only meningitis/tetanus)
23 000

Intrapartum related NDI
0-4 million

jaundice related NDI
62 000

Neurocognitive loss for children who are stunted

Adults with NCDs related to SGA and preterm birth

Socio-economic development:

- Human capital
- Educational attainment
- Employment and economic productivity

Enhanced social capital:

- Burden of long-term care to health system and families
- Family grief and loss, stigma especially for women

Environmental gains:

- More rapid fertility transition in view of increased newborn survival/healthy children

Consequences of inaction to improve birth outcomes by 2035

116 million deaths

99 million with lost development potential (including 31 million disabled), plus a time bomb of millions of adults with NCDs

multi-disciplinary collaboration



World Health
Organization



NICU



Brown et al, Pediatrics 2003

Thank you for your attention

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