IT'S HARD TO DO GOOD

'ThermoSpot' and the struggle to reduce infant mortality

ABSTRACT: *In 1996, instrument-maker John Zeal responded to a request that he invent a give-away device to monitor the core body temperature of newborns, four million of whom die each year in the developing world because illiterate mothers and carers have no way of detecting hypothermia. Zeal responded by creating ThermoSpot®. The pediatrician who asked for this device, Dr. David Morley, had spent much of his career in developing countries. (Morley was the first recipient of the King Faisal Award for International Health.) Statistics continue to show an urgent need for this indestructible, give-away tool but, despite a decade of tests showing the device to be successful, Zeal and Morley are disappointed that ThermoSpot is not more widely used.*

Each year, four million babies in the third world die in their first month of life. Combinations of malnutrition and disease kill infants by inducing abnormally low temperatures in the body core, a condition known as hypothermia. It is hypothermia, its effects often masked by malnutrition or disease, that kills infants in a wide swath across tropical Africa and Asia.

Many might be saved if illiterate mothers could take their baby's temperature with a free, simple tool that revealed hypothermia. If mothers could detect this invisible killer they could press their infants skin to skin between their breasts as a first resort, before seeking help at the nearest village clinic. What the third world needs is a virtually no-cost, re-useable, indestructible indicator that would reveal an infant's condition without ambiguity. Instrument-maker John Zeal created such a device, ThermoSpot®, in the mid-1990s, only to learn how difficult it is to win the world's acceptance of a new life-saving tool.

Zeal's grandfather founded GHZeal Ltd. in 1888 to make glass and mercury thermometers for Victorian London. In 1955, Zeal, then 20, followed his grandfather and father into the family firm, starting at the workbench to learn the skills of company artisans: glass blowing, calibration, graduation and testing.

A series of severe British winters in the early 1950s revealed a condition hitherto unreported in medical literature: hypothermia in adults. (Hypothermia

in infants was already well known.) Depressed core body temperatures contributed at the time to a spike in mortality among Britain's elderly and poor. Since hypothermia in adults was new to science, conventional thermometers, including GHZeal's, were not calibrated to detect it. Zeal's father immediately put his son in charge of designing a new product line of thermometers calibrated to reveal abnormally low body temperatures, defined as a "low body core temperature dropping to 35 degrees Celsius (95 degrees Fahrenheit) or below". Zeal became an authority on measuring hypothermia.

In 1990 the company's financial fortunes forced Zeal to sell the firm his grandfather had founded. Zeal and his wife Kathy, a pharmacist, set up a consultancy, which they still run. Zeal transformed himself from a manufacturer to a sales and marketing executive, distributing a modern, American-made clinical thermometer so reliable that NASA sent it aloft with space shuttle crews. Business grew. Zeal made many contacts at Britain's private and National Health hospitals.

Then came the March day in 1996 when David Morley telephoned. John Zeal was 63 when he took the call that would alter his mission in life.

Professor David Morley, CBE, MD, FRCP, now 85, is among the world's leading pediatricians—still working, twenty years after taking mandatory retirement at 65 from his post as the first Professor and Head of the Tropical Child Health Unit at London University's Institute of Child Health. The first recipient of the King Faisal Award for International Health, and once nominated for the Nobel Peace Prize, Morley had worked with the World Health Organization and UNICEF on child health programs, spending much of his career in third world conditions. "You might be able to help with an urgent problem I found in my work overseas," Morley told Zeal in that first conversation. "We need urgently, in fact we need it *now*, a low range thermometer to identify hypothermia among newborns in the third world." Would Zeal be prepared to find a solution?

Morley then set out the parameters: "There are really only two points you should bear in mind," he told Zeal. "First, the device is for the third world, so it has to cost nothing—and I mean *nothing*; secondly, it must be capable of

being understood and used by illiterate mothers. This," he added, handing Zeal a Herculean task, "is all you need consider."

John Zeal was in no shape to consider anything: months after that first conversation with Morley he had surgery for a brain tumor. The ensuing seven months of recuperation gave him time to think. To solve the "almost impossible requirement that the device had to cost 'nothing' it had to be reusable," he says, "and because it would be used to a large extent by illiterates, it had to be an 'indicator' rather than a 'thermometer'.

"For a low cost temperature indicator I chose liquid crystal technology. That was an easy decision. I didn't know much about the organic chemistry involved other than that British mothers were using a liquid crystal device as a 'forehead thermometer.'"

For his part, as a young doctor studying pediatrics in Newcastle upon Tyne, Dr. Morley had taken a job "as a pediatrician in West Africa in a church-related hospital, with a West African Council grant to make a study of children." In Newcastle he had observed a longitudinal study of children growing up. Working from the Wesley Guild Hospital in Ilesha, western Nigeria, he studied "about four hundred children in a local hill village, Imesi." That meant, as he puts it, "I watched. All the children admitted to hospital in the wet season had hypothermia and showed degrees of malnutrition." This became the first significant study of hypothermia among children in the tropics, but Morley is eager to share the credit. "I had a wonderful local assistant and translator," he stresses.

In the children's ward at the Wesley Guild Hospital, he noticed that "children's temperatures dropped right down below 93 Fahrenheit" (33.8 degree C). "Hypothermia in the tropics! People just don't think about that."

"In a way, Western medicine did this," Morley adds, "because in a traditional African society no child would sleep alone. They would sleep with their mother or cuddle with their siblings to keep each other warm. But we like to keep children and babies in beds and cots by themselves, where there is real danger of infants getting cold. Quite a lot of mortality in the tropics was

happening in small hospitals, particularly among babies—and those who were cold were largely malnourished."

By 1997, John Zeal had recovered from surgery and, on September 2nd that year—he remembers the date as if it were his birthday—he met an expert on liquid crystal technology in Poole, Dorset, just ten miles from his home. Mike Parsley, Ph.D., is an entrepreneur, one of whose companies, Hallcrest Inc., manufactures "colour change thermometers" and other monitoring instrumentation. Parsley agreed to help Zeal by producing and testing samples until they could satisfy the Morley criteria. The resulting ThermoSpot temperature indicator was born: cheap, reusable, indestructible, its message to illiterate mothers is unambiguous. A ThermoSpot indicator is a small circle of tough, flexible plastic the size of a small coin. Its back is self-adhesive and its front—before use—resembles a simple black circle 12 millimeters across. In fact the black surface is suffused with a sophisticated temperature-sensitive liquid crystal compound. [***ILLUSTRATION ON FINAL PAGES***]

"We can stick it on over a child's jugular vein at the base of the neck where the great vessels are," says Morley. "It works well there. And it projects above bedding or clothes, where you can see it." When a child's temperature is in the normal range, from 36.5 to 37.5 degrees Celsius, the black dot turns into a green happy face.

On the other hand, mothers equipped with a ThermoSpot indicator are taught, "If the dot stays black, immediately put your child skin to skin against you," Morley explains. "The Kangaroo Mother Care Method of raising small babies is being adopted to some extent in Britain, and widely overseas, where babies are nursed between a mother's breasts, against her body. That's one way of keeping a baby's temperature at the right level, and it does not cost anything either!"

In 1997, as a first practical test, Zeal asked consultant pediatrician Dr. Ivan Blumenthal to give sample ThermoSpots to nurses in the special care baby unit at the Royal Oldham Hospital in Lancashire (which delivered the world's first test-tube baby). Each time a baby was born a nurse applied a ThermoSpot over its liver. "The liver is a good location," says Dr. Blumenthal. "It's disproportionately large in newborns." Results were favorable. "I could see

the value of ThermoSpots straight away," he adds. "We're a modern hospital with a warm neonatal ward, but just occasionally we'd be working with a bassinette door open and the ThermoSpot's green face would disappear. They're also practical. We found that they stayed on for a week to two weeks."

Other trials reported positive results, including a significant field trial in Malawi. ThermoSpot seemed ready for launch. But more than a decade later it still hasn't happened. Blumenthal comments, "It still surprises me that ThermoSpots have not taken off in a big way."

In 2003, Zeal managed to interest researchers in including a ThermoSpot component in a public health project in the state of Uttar Pradesh, where one quarter of India's one million neonatal deaths occur each year. Researchers from Johns Hopkins Bloomberg School of Public Health, in Baltimore, and Chhatrapati Shahuji Maharaj Medical University, Lucknow, combined to write a protocol for a study called "Newborn Thermal Care Practices in Rural India: A Community-based Program to Prevent and Improve Recognition and Management of Hypothermia." The Bill and Melinda Gates Foundation supplied $300,000, and Save the Children/US another $100,000 to fund the study (sometimes abbreviated the JHSPH/Saksham Collaboration). Co-investigator Vishwajeet Kumar, a public health specialist, stayed at John Zeal's home in Wimborne, Dorset for a week to learn from ThermoSpot's creator.

The protocol for JHSPH/Saksham, dated March 2003, lists eight points. The first three are, to "Determine [home] care knowledge, attitudes and practices regarding newborn thermal control," to "Develop behavior change communications to promote prevention, early recognition and effective management of newborn hypothermia," and to "Evaluate impact of education/behavior change communications delivered by [Traditional Birth Attendants] and Change Agents, as a preventive measure, on prevalence of hypothermia."

Zeal and Morley helped to develop the protocol. This "Comment" by Morley in the formative stage gives an idea of what might complicate the researchers' clinical approach. "Because of the high mortality there are many beliefs

around birth. For example the fear of the evil eye is common if a baby is 'praised.'"

Five years have passed since the JHSPH/Saksham study began. There have been delays and personnel changes, but also progress. The Johns Hopkins Bloomberg School of Public Health website cites success stories, among them "ThermoSpot Helped Baby to Live," from the village of Narayanpur.

Briefly, the story goes: "Within 24 hours of delivery, Meera's baby was weak, low in birth weight, and cold to the touch… The [JHSPH/Saksham] team tested the baby with a thermospot [sic], the results of which were black, indicating that the baby was hypothermic." Along with other assistance it gave, the team "asked the mother to give skin to skin care to the baby," warming it between her breasts. The story continues, "After one hour of skin to skin care the temperature of the baby increased to 33 degrees Celsius (91.4 degrees Fahrenheit). The mother and the sister-in-law were asked to take special care to ensure that the baby should under no circumstance be exposed."

The JHSPH/Saksham team used ThermoSpot to monitor the infant for four days, by which time family members understood the importance of keeping the baby warm. By the fourth day the infant's temperature had risen to a safe 36.7 degrees Celsius (98 degrees Fahrenheit).

Johns Hopkins' account concludes: "Meera [the infant's mother] feels that in villages, where awareness level is so low, the practice of skin to skin care and the use of thermospot [sic] will prove beneficial to the community. The thermospot [sic] will also help mothers monitor the temperature of the baby even if they are unable to read a thermometer. And today, Meera, as an Anganwadi worker and a JHSPH/Saksham volunteer, spreads awareness on essential newborn care in her community."

By 2008, Vishwajeet Kumar had become the principal author—the first among sixteen names—of the JHSPH/Saksham study when its findings were reported in the more formal pages of the British medical journal, *The Lancet* (2008; 372:1151-1162), where ThermoSpot receives positive mention. This paper does not deal with the fact that ThermoSpot "was thought to result in a

20% improvement in identification of hypothermia by care providers." Those results are "to be reported separately." But the paper's Discussion does conclude:

> "The intervention that included the use of the ThermoSpot did not seem to have an advantage over the package of essential newborn care [provided as hands-on health care, training and education by local health workers and volunteers]. However, in other settings, and for a lower intensity intervention with fewer visits by trained community workers, the ThermoSpot might still offer an advantage for timely recognition, prevention, and management of hypothermia."

The first part of that assessment seems trite. With knowledgeable, well-equipped health care workers present, ThermoSpot might well be redundant. It works most effectively in the conditions for which it was designed: where women care for newborns assisted by little or nothing in the way of healthcare support.

Kumar, who had stayed with Zeal in his Dorset home for a week in 2003, acknowledges Zeal's support in *The Lancet* article: "for instruction in temperature measurement using thermometers and the ThermoSpot device." ThermoSpot has received positive reviews from many professionals: as a consequence of its field trials in Malawi; and it has reaped positive comment in *The Lancet*, *Tropical Doctor*, *The Indian Journal of Pediatrics*, and *Archives of Disease in Childhood – Fetal and Neonatal Edition 2006*. The device satisfies Dr. Morley's two requirements: it is virtually cost-free to end-users (and cheaper than any other option to agencies distributing it); and the accurate statement it makes about an infant's core temperature can be "read" by the most illiterate of carers.

And yet news headlines and web pages repeat the statistic, that "four million newborns die every year." Meanwhile, John Zeal writes,

> "The United Nation's Millennium Development Goals (MDG 4 and 5) are receiving enormous attention to reduce by some 40% the current horrendous statistic of 9.8 million deaths annually of children under the age of 5 years. The biggest single category for reduction in this area are

the 4 million newborns who die throughout the disadvantaged world within their first 28 days of life."

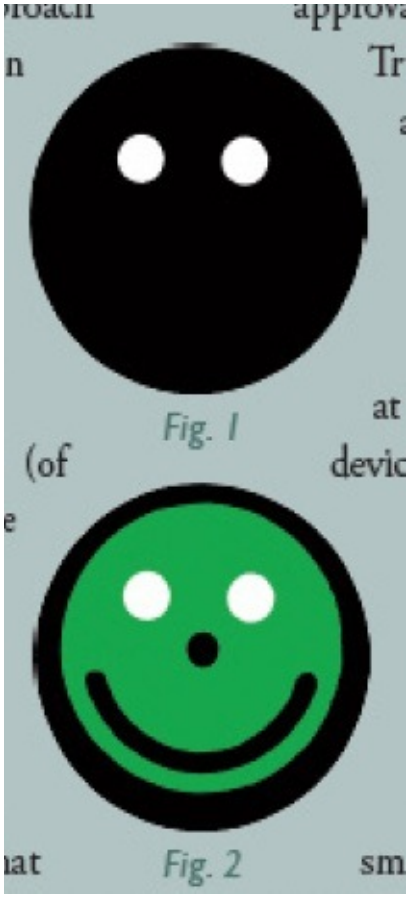
"So why has ThermoSpot not been picked up?" he asks. That's a good question. ThermoSpot has been available for over a decade, during which agencies, NGOs, charities and foundations have spent fortunes working among the very populations which Zeal created ThermoSpot to serve. (Look at the figures above and surmise how many lives might have been saved had ThermoSpot been in general use for the past ten years.)

So, "Why this apparent delay in using elsewhere?" Zeal wrote in the margin of a Johns Hopkins report he mailed to me. My intuitive response: It may be too cheap to attract the attention of major aid agencies.

At 75, Zeal feels a profound urgency to place his product where it can do good. He is not hoping to get rich by spending the balance of his life promoting a product he designed to be given away! Indeed, his wife Kathy works as a pharmacist's locum near their home in Wimborne to finance her husband's work on ThermoSpot. This seemingly simplest of life-saving devices may some day cross a tipping point, win acceptance, and save lives. But that day is not yet.

A ThermoSpot®

Important note: A new (black) ThermoSpot will not react in any way when stuck on an adult's body. Adults just don't emit enough heat unless they are running a fever. To demonstrate function, an adult can stick a disk in the centre of the palm of one hand and rub it vigorously with a finger of the other hand. Then, the ThermoSpot will change colour. The same disk will repeat this time and time again, showing how tough and reusable the product is.



A ThermoSpot is a tough, flexible plastic disk 12 mm across.

Fig. 1 shows a new unit, or one that remains black, indicating hypothermia. Fig. 2 shows that a baby's core temperature is in the safe zone, between 36.5°C to 37.5°C.

Written instructions to literate users, such as healthcare workers, state: "In the first 10-20 minutes of life, the temperature of a *newborn* may drop by as much as 2-4°C with even greater falls subsequently if proper care is not provided…"