

MediTimes from the desk of Medical Services brings the latest trending healthcare news.

The **In focus** highlights on the Hemophilia in the backdrop of World Haemophilia Day.

*Need to Know* section features on Hepatitis.

*The trending news comprises articles on foot blisters, biomarker for New TB vaccine and many more...*

*Hope this April issue of Meditimes would be an informative reading*

*Happy Reading!!!*

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## New research discovers gene that causes common deafness



New research funded by the charity Action on Hearing Loss has taken scientists a step closer to finding a treatment for one of the most common causes of hearing loss among young adults following the discovery of a new gene which causes otosclerosis.

Otosclerosis, a hereditary condition which affects 1 in 200 people resulting in conductive hearing loss, is associated with abnormal bone growth in the middle ear, which over time grows onto the stapes and stops it moving when sound waves enter the ear - meaning sound waves can no longer be efficiently transmitted into the inner ear.

The breakthrough comes as scientists from the Ear Institute at University College London showed that

faults in the SERPINF1 gene can cause otosclerosis by investigating the genome of four families with inherited otosclerosis and a further group of 84 unrelated individuals with a family history of otosclerosis. The researchers identified a



range of changes in SERPINF1 that can cause the condition. The gene encodes a protein known to be important in bone formation and repair, and has been shown to be active in the stapes - the middle ear bone affected by otosclerosis.

Dr Sally Dawson, lead researcher at University College London said: 'We have known for some time

that otosclerosis can be inherited, but until now the actual identity of the genes involved have eluded us. Our discovery of the first otosclerosis causing gene is very significant as it tells us about the biological processes involved in the development of the condition and with support from Action on Hearing Loss we are continuing to search for more genes that cause this common form of deafness.'

Dr Ralph Holme, Action on Hearing Loss Head of Biomedical Research said: 'We urgently need better treatments for otosclerosis and that's why this latest discovery is so important to the thousands of people affected by this condition across the UK, giving them hope that drug treatments to prevent abnormal growth of bone on the stapes can be developed.'



## Stanford trial shows paper tape can help prevent foot blisters

Ten years ago, Grant Lipman, MD, an emergency medicine physician, was working as a doctor for endurance athletes who were running 25 to 50 miles a day in various parts of the world, from China to Antarctica to Chile.

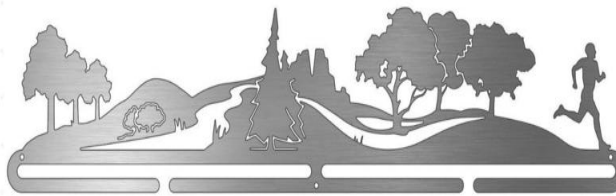
Despite the harsh conditions and extreme exercise, the most common complaint that Lipman heard from the athletes was about the pain and debilitation caused by foot blisters, the same kind that plagues lots of people, from hikers to women in heels.

"What I kept hearing was, 'Doctor, I'd be doing so well, if only for my feet,'" said Lipman, clinical associate professor of emergency medicine. "Their feet were getting decimated."

Multiple methods of blister prevention have been tried, Lipman said, including powders, antiperspirants, lubricants, tapes and adhesive pads. But despite the numerous scientific studies on blister prevention over the years, there is little evidence to show that any of

these methods work well, he said, until now.

In a new study, Lipman and colleagues report that inexpensive paper tape, the kind available at most drugstores, when applied to blister-prone areas prior to exercise, successfully prevented both the incidence and frequency of foot blisters. The



tape, commonly referred to as surgical tape, is used for wound treatment. It is only mildly adhesive -- an advantage because it doesn't tear the blisters if they do occur.

### 155-mile experiment

Lipman and his colleagues recruited 128 runners participating in the 155-mile, six-stage RacingThePlanet ultramarathon event that crosses deserts around the globe, including the Gobi Desert and deserts in Jordan and Madagascar.

Paper tape was applied to just one of each of the runners' feet. The untaped areas of the same foot served as a control. (Which foot got the tape and which didn't was chosen at random). The tape was applied by trained medical assistants to either the participants' blister-prone areas or, if they had no blister history, to randomly selected locations on the foot.

The paper tape was applied in a smooth, single layer before the race and at subsequent stages of the race, Lipman said.

The medical assistants followed the runners for 155 miles over seven days.

For 98 of the 128 runners, no blisters formed where the tape had been applied, whereas 81 of the 128 got blisters in untaped areas.

"It's cheap, easy method of blister prevention," Lipman said. He added, "The best way to make it to the finish line is by taking care of your feet."



## Biomarker discovery offers hope for new TB vaccine

A team of scientists led by Oxford University have made a discovery that could improve our chances of developing an effective vaccine against Tuberculosis.

The researchers have identified new biomarkers for Tuberculosis (TB) which have shown for the first time why immunity from the widely used Bacillus Calmette-Guérin (BCG) vaccine is so

variable. The biomarkers will also provide valuable clues to assess whether potential new vaccines could be effective.

With a pressing need for a TB vaccine that is more effective than BCG, a research team drawn from a number of groups at Oxford University, working with colleagues from the South African Tuberculosis Vaccine Initiative at the University of Cape Town and the London School of Hygiene & Tropical Medicine, set out to identify immune correlates that could facilitate TB vaccine development. The team,

funded by the Wellcome Trust and Aeras, and led by Professor Helen McShane and Dr Helen Fletcher, studied immune responses in infants in South Africa who were taking part in a TB vaccine trial.



The team carried out tests for twenty-two possible factors. One - levels of activated HLA-DR+CD4+ T-cells - was linked to higher TB disease risk. Meanwhile, BCG-specific Interferon-gamma secreting T-cells indicated lower TB risk, with higher levels of these cells directly linked to greater reduction of the risk of TB.

Antibodies to a TB protein, Ag85A, were also identified as a possible correlate. Higher levels of Ag85A antibody were associated with lower TB risk. However, the team cautions that other environmental and disease factors could also

cause Ag85A antibody levels to rise and so there may not be a direct link between the antibody and TB risk.

Professor McShane said: 'These are useful results which ideally would now be confirmed in further trials. They show that antigen-specific T cells are important in protection against TB, but that activated T cells increase the risk'.

Dr Helen Fletcher from the London School of Hygiene & Tropical Medicine, said: 'For the first time we have some evidence of how BCG might work, and also what could block it from working. Although there is still much work to do, these findings may bring us a step closer to developing a more effective vaccine for TB.'

Dr Tom Scriba said: 'TB is still a major international killer. These findings provide important clues about the type of immunity TB vaccines should elicit, and bring us closer to our vision, a world without TB.'





## Electronic skin that tracks health status steps closer

Researchers in Japan have developed an ultra-thin material that attaches to skin and contains electronics that monitor blood oxygen levels.

The e-skin has a protective film comprising five alternating layers of an inorganic material called silicon oxynitride and an organic material called parylene. This protects the onboard electronics from water vapor and air, extending device lifetimes from the few hours achieved in previous designs to days.

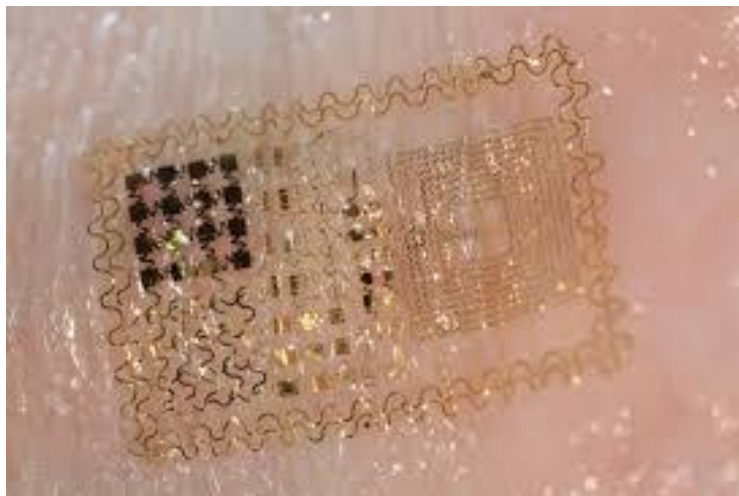
In their paper, the researchers describe incorporating transparent electrodes into the film without damaging it. Once this was achieved, they then created polymer light-emitting diodes (PLEDs) and organic photodetectors using the material.

Next, they devised a blood oxygen level monitor that is worn on the finger. Red and green PLEDs shine light into the finger, and the reflected light from inside the finger is caught by a photodetector, providing a measure of blood oxygen and pulse rate, which

problems of previous designs. It enables the creation of ultra-thin and ultra-flexible electronic devices that remain stable in air for several days.

The PLEDs that the team created were only 3 micrometers thick and their efficiency was six times greater than that of previously reported ultra-thin PLEDs. This means they require far less power and produce a lot less heat - making them particularly suitable for attaching directly onto the body.

The researchers hope their e-skin will lead to the creation of devices that measure and display not only blood oxygen and pulse rate but other vital functions. They also suggest that: "Ultimately, flexible organic optical sensors may be directly laminated on organs to monitor the blood oxygen level during and after surgery."



can be displayed as a reading on a PLED display.

### **Material enables 'e-skins with multiple electronic functionalities'**

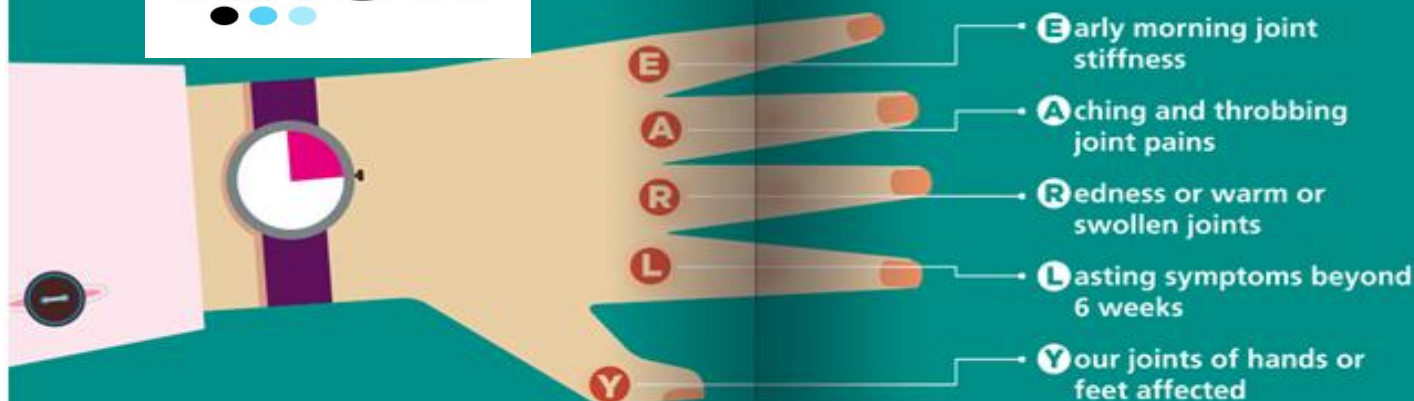
The e-skin that senior author Takao Someya, a professor at Tokyo's Graduate School of Engineering, and colleagues have developed appears to overcome many of the



## Rheumatoid Arthritis

need to  
**know**

If you spot the symptoms below, speak to your Doctor, as **EARLY** possible.

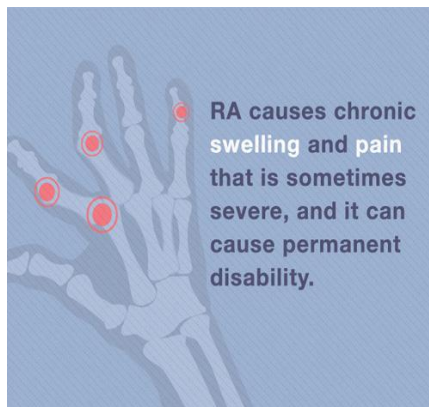


### RHEUMATOID ARTHRITIS (RA)

is an autoimmune disease that attacks tissues near joints and other body parts.



RA causes chronic swelling and pain that is sometimes severe, and it can cause permanent disability.



A number of factors may contribute to

**RA:**



Heredity



Environment



Lifestyle

3%  
RISK

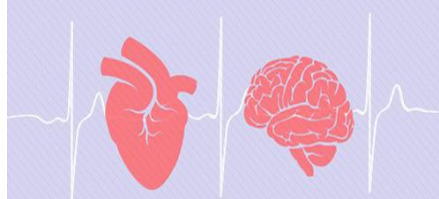
4%  
RISK

RA generally starts in women between the ages of

10 20 30 40 50 60 70 80 90

(slightly later for men)

RA increases the risk of heart attack and stroke.



Risk of a heart attack increases 60% one year after diagnosis.



Infections may be responsible for 25% of deaths in people with RA.

People with RA are 2x as likely to suffer from depression.



### How is RA diagnosed?

You should see your Doctor as you spot the symptoms of RA. Doctor will ask you about your symptoms and look at your joints. They may offer you blood tests and x-rays to help make the diagnosis. If they think you have RA, you should be offered a referral to a specialist in rheumatology.

### What treatment is there?

There are a number of effective treatments available that will help to control RA and reduce the symptoms. Therapies are also important for treating RA. Physiotherapy, occupational therapy and podiatry can help to ease the symptoms. Occasionally, surgery is needed.

### How can I manage RA?

As well as taking your medication and having regular check-ups, you can help to manage your RA. By striking a balance between rest and exercise, eating healthily, avoiding unnecessary strain and getting a good night's sleep, you can live as normal a life as possible.





## Hemophilia



Hemophilia is a group of inherited blood disorders in which the blood does not clot properly. Bleeding disorders are due to

Queen Victoria was a carrier and passed the mutation to her son Leopold, and through several of her daughters to members of the royal families of Spain, Russia, and Germany.



defects in the blood vessels, the coagulation mechanism, or the blood platelets. An affected individual may bleed spontaneously or for longer than a healthy person after injury or surgery.

The blood coagulation mechanism is a process which transforms the blood from a liquid into a solid, and involves several different clotting factors. The mechanism generates proteins when it is activated, which together with the platelets, stops the bleeding.

When coagulation factors are missing or deficient the blood does not clot properly and bleeding continues. Patients with Hemophilia A or B have a genetic defect which results in a deficiency in one of the blood clotting factors.



"Many members of royalty in Europe inherited their hemophilia from Queen Victoria".



## Haemophilia A:

Haemophilia A is a bleeding disorder where a protein made by the body to help make blood clot is either partly or completely missing. This protein is called a clotting factor: with haemophilia A there is a deficiency of clotting factor VIII.

Haemophilia A mainly affects boys and men. Women can be 'carriers' of the affected gene and may experience symptoms. Although it is the most common type of haemophilia it is a rare condition.

The reported number of patients with haemophilia A in India is 11,586 while the estimated prevalence could be around 50,000 patients.

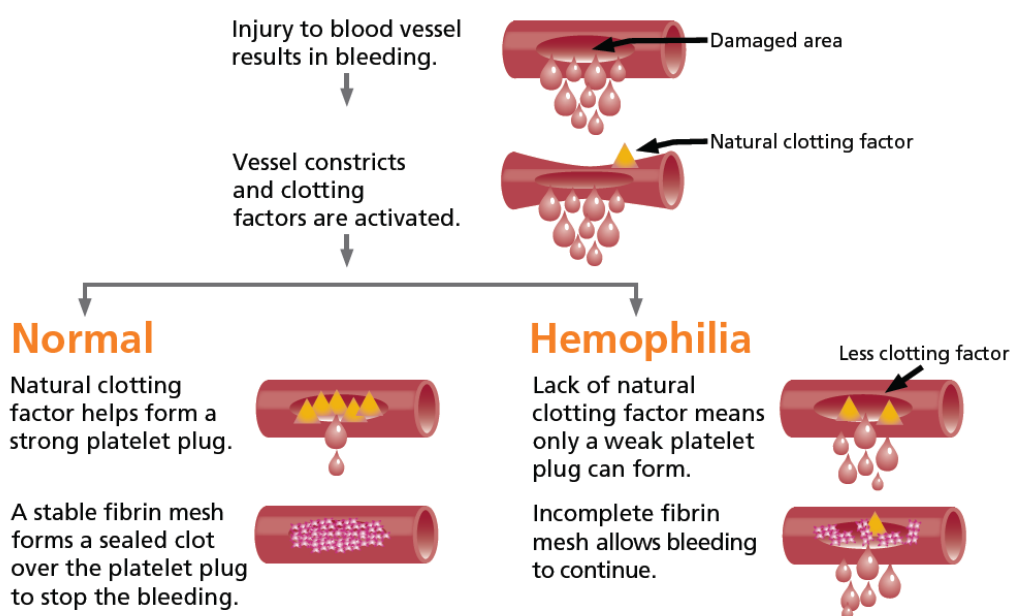
## Haemophilia B

Haemophilia B is a bleeding disorder where a protein made by the body to help make blood clot is either partly or completely missing. This protein is called a clotting factor: with haemophilia B there is a deficiency of clotting factor IX (nine).

Only about 20% of people with haemophilia have haemophilia B, so it is a rare condition, affecting about one in every 50,000 males.



## Injury Occurs



Adapted from: Human Disease: Blood Clot Disease (Hemophilia). Jan 26, 2015. Accessed at: <http://humansanatomy.org/2015/01/26/blood-clot-disease-hemophilia/> on 02.26.2015.





**The main symptoms are:**

- A tendency to bruise easily especially in early childhood
- Excessive bleeding from cuts that takes a long time to stop
- A tendency to bleed into joints and muscles causing pain, swelling and limitation of movement

**Treatment :**

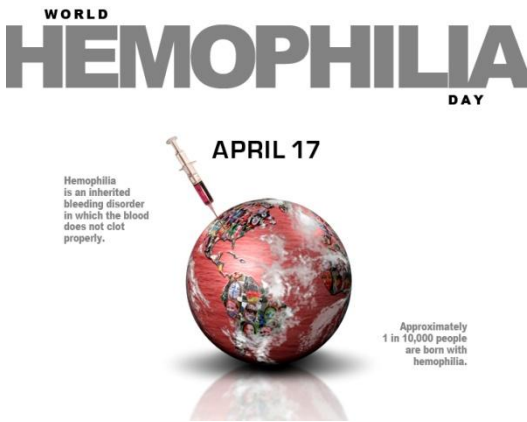
Most people with haemophilia A&B are treated with clotting factor concentrate .

Bleeding episodes must be treated promptly to avoid lasting effects. Once the bleeding stops, pain rapidly diminishes and, in the case of limbs, full use returns.

With the right treatment and care, people with haemophilia patients can lead fulfilled and healthy lives into old age.

**Haemophilia A is treated by replacing the missing clotting factor VIII in the blood through an intravenous infusion of clotting factor concentrate.**

**Haemophilia B is treated by replacing the missing clotting factor IX in the blood through an intravenous infusion of clotting factor concentrate.**



Date	Observed as
7	World Health Day
17	World Haemophilia Day
19	World Liver Day
22	Earth Day
25	World Malaria Day



# Water Melon

Wonderfully are the great source of much-needed water and electrolytes to tame tropical summer temperatures.

Watermelon originated from southern African countries and from where it spread to rest of the tropical and subtropical regions.

Varieties of watermelon-fruits are cultivated world over, featuring variation in their size, shape, and color of the flesh (red, orange, and yellow).



## *Health benefits of watermelon:*

Rich in electrolytes and water content, melons are nature's gift to beat tropical summer thirst.

Watermelons are very low in calories (just 30 calories per 100 g) and carry minimal fats. Nonetheless, they plentiful in numerous health promoting phyto-nutrients and anti-oxidants essential for optimum health.

Watermelon is an excellent source of Vitamin-A, which is a powerful natural anti-oxidant. 100 g fresh fruit provides 569 mg or 19% of daily-required levels of this



vitamin. It is one of essential vitamin for vision and immunity. Vitamin-A is also required for maintaining healthy mucosa and skin. Consumption of natural fruits rich

in vitamin-A is known to protect from lung and oral cavity cancers.

It is also rich in anti-oxidant flavonoids like lycopene, beta-carotene, lutein, zeaxanthin and cryptoxanthin.

These antioxidants have been found to offer protection against colon, prostate, breast, endometrial, lung, and pancreatic cancers. Phyto-chemicals present in watermelon like lycopene and carotenoids have the ability to help protect cells and other structures in the body from oxygen-free radicals. Watermelon is an excellent source of carotenoid pigment, lycopene and indeed, superior to raw red tomato. 100 g of fresh melon provides 4532 µg lycopene, whereas this value only 2573 µg for tomatoes. Studies suggest that lycopene offer certain protection to skin against harmful UV rays.



Watermelon fruit is a good source of potassium; Potassium is an important component of cell and body fluids that helps controlling heart rate and blood pressure. It, thus, offers protection against stroke and coronary heart diseases.

Furthermore, it contains a good amount of vitamin-B6 (pyridoxine), thiamin (vitamin B-1), vitamin-C, and manganese. Consumption of foods rich in vitamin-C helps the body develop resistance against infectious agents and scavenge harmful oxygen-free radicals. Manganese is used by the body as a cofactor for the antioxidant enzyme, superoxide dismutase.

Principle	Nutrient Value	Percentage of RDA
Energy	30 Kcal	1.5%
Carbohydrates	7.6 g	6%
Protein	0.6 g	1%
Total Fat	0.15 g	0.5%
Cholesterol	0 mg	0%
Dietary Fiber	0.4 g	1%
<b>Vitamins</b>		
Folates	3 µg	1%
Niacin	0.178 mg	1%
Pantothenic acid	0.221 mg	4.5%
Pyridoxine	0.045 mg	3.5%
Thiamin	0.033 mg	3%
Vitamin A	569 IU	19%
Vitamin C	8.1 mg	13.5%
Vitamin E	0.05 mg	0.5%
<b>Electrolytes</b>		
Potassium	112 mg	2.5%
<b>Minerals</b>		
Calcium	7 mg	0.7%
Copper	42 µg	4.5%
Iron	0.24 mg	3%
Magnesium	10 mg	2.5%
Manganese	0.038 mg	1.5%
Zinc	0.10 mg	1%
<b>Phyto-nutrients</b>		
Carotene-alpha	303 µg	--
Crypto-xanthin-beta	78 µg	--
Lutein-zeaxanthin	8 µg	--
Lycopene	4532 µg	--





# Active Pharmaceutical Ingredients (API) Approval Process in India

Active pharmaceutical ingredients (API) are those components present in drugs due to which medications work. Though it is far from being such a simple thing and process as it sounds. There are a series of regulations and laws that surround everything regarding API and license laws are just the beginning

APIs have been called bulk actives, bulk pharmaceutical chemicals, and even bulk chemicals. No matter what they are called, these materials are critical to the drug approval process in all regions of the world. Since APIs are the compounds that actually provide the activity and effectiveness of all drugs, they are subject to a significant amount of review during the filing and approval processes. In order to obtain a marketing authorization for a drug product the applicant has to show evidence of efficacy, safety and quality of the drug product

## Approval process:

The main national pharmaceutical oversight agency is the Central Drugs Standard Control Organization (CDSCO). The CDSCO is commonly referred to by the title of its head official, the Drugs Controller General India (DCGI).

The following major documents are required to be submitted in the following manner and order for the Import & Registration of the bulk drug(s) and finished product(s) in India: -

- Covering Letter
- An Authorization letter
- A duly filled Form 40
- TR 6 Challan
- Power of Attorney

**The Following major documents is required for permission to manufacture/import of Bulk Drug already approved in the country**

- Application in Form-44 duly filled and signed by the competent authority
- Treasury Challan of Rs. 50,000/- upto 1 year from initial approval and Rs. 15,000/- for other drugs up to 4 years
- For manufacturing:-  
Copy of manufacturing license in Form-25/ Form-26 for any bulk drug to manufacturer and Form-29
- For import:-  
Copy of drug sale license in Form 20B and 21B
- Pharmaceutical & Chemical Information
- Manufacturing Process including in process control
- Specifications and methods of analysis
- Structural elucidation data
- Sub-acute toxicity data generated with the applicant 's bulk drug in two species
- Stability data of three different lots as per Schedule -Y of Drugs and Cosmetics Rules
- CDTL Test report



## Fun Corner



## DIMAG KI BATTI JALAO



1. New research discovers gene that causes common deafness. What is the name of this gene?

2. Which clotting factor is deficient in patients with haemophilia A?

3. If there are 100 mangoes and you take away 74, how many do you have?



Please send your quiz answers to [medicals@microlabs.in](mailto:medicals@microlabs.in) and winner will get a surprise gift