Child India

June 2023

Monthly e-Newsletter of Indian Academy of Pediatrics

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Editor's Note

Dear friends,

Greetings from the June issue of Child India!

The days celebrated in June include: World Milk Day (Theme "Showcasing how dairy is reducing its environmental footprint, while also providing nutritious foods and livelihoods"; International Day of Innocent Children Victims of Aggression - 4th June; World Environment Day - 5th June (Theme - "Beat Plastic Pollution"); World Blood Donor Day - 14th June (Theme - "Give blood, give plasma, share life, share often."); World Sickle Cell Day - 19th June ('Building and strengthening global sickle cell communities, formalizing newborn screening and knowing your sickle cell disease status'.; and International Day against Drug Abuse and Illicit Trafficking - 26th June ("People first: stop stigma and discrimination, strengthen prevention").

Kudos to IAP President Dr Upendra Kinjawadekar, HSG Dr Vineet Saxena, IAP OB and EB 2023 for initiation the process for IAP Constitutional Reforms. The NC ECD workshops are nearing the finishing line and evaluation of the program will soon be under way. The 10 very useful IAP Action Plan workshops are being enthusiastically conducted and 2 are to be released soon. Please submit reports with photographs of these events as and when they happen.

This issue of Child India focuses on Vaccinology and we thank all the experts for their contributions. A special thanks to Dr Srinivas Kasi for coordinating the submissions.

Wishing you all a great month ahead.

Jai IAP!

Dr Jeeson C Unni

Editor-in-Chief

President's Address

My fellow IAPans,

Greetings from CIAP!

On 14th May 1796, when Edward Jenner inoculated eight-year-old James Phipps with pus from cowpox blisters on the hands of a milkmaid, the world (and perhaps Jenner himself) was unaware of the tremendous breakthrough that man was making over dreadful naturally occurring diseases. A new chapter in the history of medicine began when this simple experiment led to the production of an effective vaccine which contributed to the complete eradication of smallpox nearly two centuries later. From the latter half of the twentieth century, rapid developments have taken place in vaccine production and coverage. Closer to home, the Mission Indra Dhanush program implemented by GoI has been a great contributor to increase the immunization coverage in our country at the community level. The success of India's COVID vaccination program too was noted by the entire world. Gaining confidence from these experiences, as well as our successful wild polio elimination, India is now on mission mode to prevent measles and rubella by 31st December 2023. I appeal to each and every IAPan working in private or public health to ensure that no child under your care misses two doses of MR containing vaccine before their second birthday.

More recently, the rapidly changing population dynamics, advances in immunology and temporal trends in the epidemiology of communicable diseases have led to the need for the development of newer vaccines. Hence the busy practitioner requires a parallel update on developments in vaccination practices. This issue of Child India precisely focuses on that.

Topics like the vaccination of children receiving immunosuppressive medicines, vaccine safety and the development of new vaccines, general principles of vaccination, vaccine storage etc., are written by reputed experts in the field. I'm sure we will not only stay updated with these articles but have sound basic knowledge on vaccination.

Happy reading!

Dr Upendra Kinjawadekar
National President 2023
Indian Academy of Pediatrics

Secretary's Message

Dear Colleagues,

Greetings,

"Coming together is a beginning. Keeping together is progress. Working together is success."

I am pleased to share with you some of the remarkable achievements we have accomplished in the month of June, as we continue to work hard to improve the lives of children and families across the country. We have organized various workshops, campaigns, and events in this month. We have also strengthened our partnerships with other organizations and stakeholders who share our mission and vision.

One of the highlights of this month was the conduct of two major administrative meetings: IAP Executive Board Meeting on 3rd June 2023 at Ooty Tamil Nadu. Various matters related to our organization, such as budget, policies, programs, activities, challenges, opportunities, and future plans has been discussed in this meeting. Also, we have successfully conducted Special General Body Meeting on 3rd June at Ooty, Tamil Nadu. This meeting was held to discuss and adopt the amendments to the Constitution of the IAP. I would like to thank all Office bearers, Executive Board members, for their active involvement and contribution in making these meetings productive and successful.

Another highlight of this month was the celebration of Complementary Feeding Day across the country on 6th June 2023. This day was observed to raise awareness about the importance of timely introduction of appropriate complementary foods for infants and young children, along with continued breastfeeding. Various activities were organized by our branches, such as seminars, webinars, workshops, rallies, camps, competitions, etc., to educate and sensitize parents, caregivers, health workers, and community members about the benefits of complementary feeding for child growth and development. I would like to appreciate and commend all Office bearers, Executive Board members, and Office bearers of branches for their enthusiastic participation and support in making this day a grand success.

On the programmatic front, we have conducted workshops under the Presidential Action Plan 2023 on the following modules: 2 of "Risk Stratification Assessment Clinical Monitoring Early Stimulation in high-risk neonate"(RACE); 4 of Infectious Case Conundrum (ICC); 2 of Understanding Lab Test Rationale (ID ULTRA); 2 of Comprehensive nutrition Module (CNM); 2 of Hematology - from care to cure. Regarding the ECD, we have completed a total of 169 workshops of ECD so far and 2 workshops of ECD in June 2023.

These workshops are aimed at improving the quality of care and outcomes for children in India. They are also a platform for sharing best practices, experiences and challenges among pediatricians. I hopes that these workshops will contribute to IAP's vision of a healthy future for every child in India.

On behalf of IAP, I urge you to organize various activities in the best interest of the health and welfare of the country's children.

Long Live IAP, Jai IAP

Yours sincerely,

Dr Vineet Saxena
Hon. Secretary General 2022 & 23

President's Engagements

Friends,

Govt of India is determined to have Measles elimination by 2023! Attended and represented IAP in the IEAG meeting for the same on 13-14/6/23 at New Delhi. Shri Rajesh Bhushan principal secretary of health, Shri Ashok Babu Jt Sec, Dr Veena Dhavan addl commissioner immunisation MOHFW, Dr T. Jacob John, Dr Naveen Thacker,WHO, UNICEF officials and representatives of state government as well as partners attended and actively participated in the meeting. Mission Indradhanush will be implemented in intensified way over the next six months. Let's ensure that every child gets two doses of MR containing vaccine before the second birthday. Let's actively co-operate and collaborate with Government agencies in this mission in whatever capacity. Finally while addressing misinformation/ rumours about vaccination, we must ensure that we report every case of fever with rash to local authorities. Elimination of Measles and Rubella by December 2023! Yes it's possible.

President's Engagements

Since last 15 years IAPans all over the country are very well aware of the fact that that if it is June it is the month for the national CME of IJPP and 2023 was no exception!

Today we had the 15th National CME of IJPP held in Chennai. Dr Ratna Kumari EIC of IJPP, organising secretary Dr Lakshmi vel Murugan, Treasurer Dr Durai Arasan President TNSC Dr Suresh Balan, IPCC president Dr Shyamala and past editors Dr GowriShankar, Dr Nedunchelian, Dr Ramachandran, Dr Thangavelu sir were the guiding force behind the successful execution of the event.

The best part of this IJPP CME is all 371 registered delegates were in their seats sharp at 8:30 a.m. and left only at 5:00 p.m. after completion of the entire scientific program which was extremely meticulously planned by the scientific team.

Past and present EB members Dr Janani Shankar, Dr MS Vishwanathan and Dr Somasundaram were actively involved in the proceedings.

Happy that I could also visit the IJPP office in Chennai today. CIAP is extremely proud of all the wonderful endeavours undertaken by IJPP over the last many years.

President's Engagements

IAP Rajasthan State and IAP Jaipur organised its 1st SSS module in NIMS International School Today on 26th June separately in two class rooms . for the Junior and Senior Section. Dr Upendra sir Dr Shalini mam gave the lectures on various topics. It was a great success and there was lot of enthusiasm from both sides.... We have many more sessions planned in the coming weeks...

President's Engagements

President's Engagements

Executive Board meeting at Ooty on 3-6-23

President's Engagements

Sankalp Sampoorna Swasthya program launched in Chennai, Tamilnadu on 19th June.

Dr M S Viswanathan, Dr Janani Shankar, Dr Chenthil, Dr Vinod Kumar and

State President Dr Suresh Balan with the team are committed to take it across the state

Nashicon held on 10-11/6/23 at Nashik was a memorable event. Dr Anirudh Bhandarkar,Dr Sachin Patil, Dr Milind Bharadia, Dr Nitin Surana and team put up a fantastic scientific event.

President's Engagements

10th Bangalore Pedicon and National ID summer CME was an excellent academic event organised by BPS. Dr SM Prasad, Dr Chidananda, Dr Harilal Naik and team showed excellent team work in conducting the program

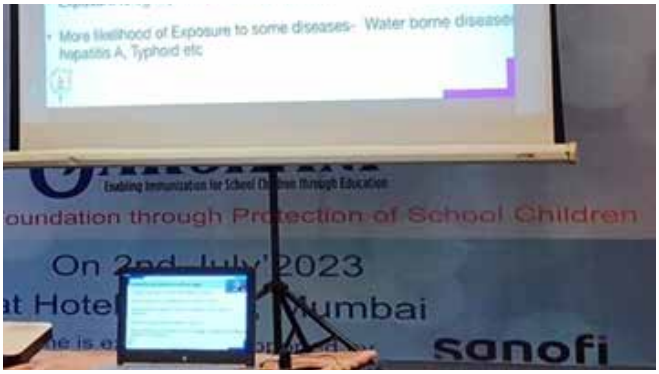
President's Engagements

On Tuesday 27th June it was the turn of Rungta public school at Bhillai Chhattisgarh to host SSS program. Dr Omesh Khurana, Dr Vinay singh, Dr Naresh Motwani and team IAP Durg Bhillai took extraordinary efforts for the successful implementation of the program.

Most respected Dr Pukhraj Bafna,Dr LP Dulhani, Dr Amarsingh Thakur, Dr Arvind Sawant attended and gave their valuable suggestions.

Our EB member Dr Ashwani Agrawal along with some senior pediatricians will try to collaborate with Govt of Chhattisgarh for SSS implementation.

President's Engagements



IAP action plan 23 - *Saksham*- Enabling immunisation in school children through education was launched in Mumbai on 2-7-23. Through Mission indradhanush as well as by active and intensified vaccination drive by IAPans the infants and toddlers are better protected from VPDs than before. However the school age children From Jr Kg to standard 10 aren't getting adequate protection from many infectious diseases though there is availability of vaccines for the same. On top of that the waning immunity from earlier vaccination also needs to be boosted.

Through Saksham IAP will address these issues first by sensitising IAPans and then society at large through schools. Heartfelt gratitude to Dr Nitin Shah, Dr Vijay Yewale,Dr Surendranath ,Dr Sunil Agrawala,Dr N P Singh,Dr Chetan Trivedi and Dr Sumitha Nayak for actively contributing to prepare the module. Dr GV Basavaraja, Dr Yogesh Parikh,Dr Rohit Agrawal, Dr Bakul Parekh, Dr S Sanjay,Dr Shivananda, many EB 23 colleagues have also given valuable inputs for the same

 # *Every child deserves complete protection from VPDs#*

General Practices of Immunization

DR SUMITHA NAYAK

MD(PED), DNB, FIAP, INT CERTIFICATE IN VACCINOLOGY (IVI, S. KOREA), PGDMLS, PGDGC

Consultant Pediatrician, Bangalore

Introduction

The practice of immunization begins when the practitioner enquires about the vaccination status of the child. This process further includes several steps, which then concludes with the administration of the vaccine to the child.

The aim of this activity is to enable the safest and the best possible immunological response in the recipient, to the administered vaccine.

Counselling of patients

This is the first step that in the vaccination process. It involves providing information about the disease and the vaccine to prevent that disease.

The important points to be discussed with the parents include the following:

1. The risk of developing the disease-the literature data can be quoted to suggest the disease risk in the Indian community. Risk of complications is higher in younger and undernourished children.
2. Vaccine efficacy: while it is a fact that no vaccine can provide 100% protection, most vaccines do offer a high degree of protection, including prevention of disease, long term protection, prevent infection and partially prevent complications.
3. Vaccine safety: newer technologies and methods of vaccine production and testing ensure that most of the current vaccines have a high safety margin. Serious adverse effects are very rare and the benefits of vaccination outweigh the risk of side effects.
4. Cost of vaccines: the decision regarding the affordability of the vaccines is best left to the parents.It is important to emphasise that all vaccines are equally effective and have been tested and proven before being marketed.
5. The final comment should emphasize that the discussion and recommendations are based on the current understanding of disease and vaccine requirements. However, the recommendations for individual vaccines could change based on evolving data.

Consent for vaccination:

Consent for vaccination is implied when the parents voluntarily bring their child for vaccination. It also implies that adequate information is provided to the parents regarding the benefit, risk and cost of the vaccine.

Injection Procedure

Hand hygiene:

If the hands are visibly dirty, the hands must be washed with soap and water for at least 2 minutes, using the WHO's 6 -step technique. In between patients, alcohol based antiseptic rub can be used. There is no need to wear gloves, unless the vaccinator has open skin lesions the

hands or is likely to come in contact with infected body fluids or secretions.

Needles must be sterile and disposable. Using disposable syringes especially auto disable ones (AD) which have a self-locking mechanism, will ensure sterility. Use a separate needle and syringe for each vaccine.

Do not externally mix different vaccines, unless it is recommended by the manufacturer and licensed for such usage.

If multidose vials are used, ensure that the septum is swabbed with alcohol prior to every withdrawal. Do not leave the needle behind after every withdrawal.

Changing needles between drawing from the vial and administration to the recipient is not required.

Avoid pre-filling the syringes because of the potential errors of administration, as most vaccines have similar appearance.

Administer vaccines immediately upon reconstitution or withdrawal from the vial / ampoule.

Discard the used syringes and needles immediately after use, to prevent needle stick injury as well as reuse. Disposal must happen in a tamper proof sharps container.

Do not recap needles before disposal.

Alleviating pain and discomfort associated with vaccination

Several methods are used to decrease the pain during the procedure of immunization. Measures to comfort include playing music, pretending to blow away the pain and other distraction measures may be useful. Administering sweet liquids (2ml of 24% dextrose), a few minutes before the vaccination can help in calming some infants.

Vapocoolant sprays can help in short term reduction of the pain. Pre-treatment given at least 30 minutes earlier of 5%topical lidocaine and prilocaine emulsion causes a superficial anesthesia and decreases the pain of vaccination.

Pre-treatment with anti-pyretics is not recommended.

INJECTION SITE, ROUTE, METHOD AND NEEDLE LENGTH

The route of administration varies between vaccines and is specified by each manufacturer. This is dependent on eliciting the best immunological response by a particular route for a particular vaccine preparation. Any deviation from this could result in suboptimal vaccine efficacy or a higher likelihood of adverse effects.

Generally, all live vaccines are recommended to be administered by the subcutaneous (SC) route.

All inactivated vaccines are recommended to be administered by the intramuscular (IM) route

Route of administration is crucial for inactivated vaccines: HBV, HPV, Rabies. The dose should be repeated if administered SC.

Route of administration is not crucial for live, attenuated: MMR, Varicella, other live attenuated parenteral vaccines, HAV, IPV, PPSV23. The dose need not be repeated if administered SC.

Aspiration before injection of vaccines or toxoids is not recommended because no large blood vessels are present at the recommended injection sites, and a process that includes aspiration might be more painful for infants.

However, if you do aspirate and get a flash of blood, then the procedure is to withdraw the needle and start over. The syringe, needle, and contaminated dose of vaccine should be discarded in a sharps container, and a new syringe and needle should be used to draw up and administer another dose of vaccine. This is a waste of expensive vaccine that could be avoided by simply not aspirating.

The site of injection must be selected in such a way as to minimize the possibility of neural, vascular, local or tissue injury.

Adjuvant containing vaccines must be administered into the muscle mass. if these are administered subcutaneously or intra -dermally there could be skin discoloration, irritation, induration, inflammation or granuloma formation.

Multiple Vaccinations

Any number of antigens can be administered on the same day. PCV13 and Menactra (in children with functional or anatomic asplenia) should not be administered at the same visit; separate these vaccines by at least 4 weeks and administer PCV first.

PCV13 & PPSV23 should not be administered together, PCV13 to be given first followed at least 8 weeks later by PPSV23.

The interval between two doses of an inactivated vaccine is 28 days. Vaccine doses administered up to 4 days before the minimum interval or age can be counted as valid (Grace period), (Day 1 is the day before the day that marks the minimum age or minimum interval for a vaccine.)

If the vaccine is administered > 5 days before minimum period, that early dose is invalid. It should be repeated. This holds true for live parenteral vaccines.

Spacing of live and inactivated vaccines	
Type of Antigen	Minimum interval between 2 doses
2 or more inactivated	Simultaneously or at any interval
Inactivated and live	Simultaneously or at any interval
2 or more live parenteral	Simultaneously OR at 4 weeks interval

Simultaneous administration implies administering different vaccines on the same clinic day (conventionally a clinic day consists of 6 hours).

Using combination vaccines containing certain antigens not indicated at the time of administration to a patient might be justified when

1. the extra antigen is not contraindicated and is known to be safe,
2. products that contain only the needed antigens are not readily available,
3. potential benefits to the patient outweigh the potential risk for adverse events associated with the extra antigens.

An extra dose of many live-virus vaccines and Hib or hepatitis B vaccine has not been found to be harmful. Additional doses of Tetanus toxoid & PPSV23 may increase local adverse reactions.

If a vaccine is to be given together with an immunoglobulin preparation, they must be administered at different anatomical sites. If the same limb is to be used for two vaccines, the anterolateral thigh is the preferred site and the vaccines should be given at least 1 inch apart. The site of the vaccine must be documented in the record.

Spacing between Vaccines and Ab containing products:

If vaccine is administered first, antibody may be administered at least 2 weeks later.

If antibody is administered first, wait for at least 3 months or longer before administering a live vaccine. This rule does not apply for monoclonal antibodies.

Exceptions include Rabies, Tetanus and Hepatitis B, wherein vaccine and antibody are administered together.

Protection by any vaccine dose begins not earlier than 2 weeks after administering the vaccine.

A minimal interval of 4 months between priming and boosting allows optimal affinity maturation of memory B cells and thus more robust secondary responses.

Interchangeability of brands: As far as possible brands should not be interchanged. If previous brand is unknown or unavailable, any available brand may be administered. Vaccination should not be postponed.

Lapsed schedule: An interruption in the vaccination schedule does not require restarting the entire series of a vaccine or toxoid or addition of extra doses.

Only written and dated records as evidence of vaccination.

Documenting Vaccinations: The following should be documented:

Brand name

Lot number

Date of Expiry

Site of administration: Right Deltoid (RD), Left Deltoid (LD), Right Upper Thigh (RUT), Right Lower Thigh (RLT), Left Upper Thigh (LUT), Left Lower Thigh (LLT).

Preventing Adverse Reactions

Vaccine adverse events are also called as Vaccine side effects

They are classified as: local, systemic or allergic reactions

- Local reactions- commonest side effect. Is the least severe. Includes local pain, redness, swelling etc.

- Systemic side effects- these occur less frequently than local reactions. Fever, myalgia and malaise are some systemic reactions

- Allergic- these are the most severe adverse effects. They are rare.

- Syncopal attacks common in adolescents and may cause injuries.

- After immunization, it is recommended to observe the patient for at least 15 minutes and for 30 mins where there is a higher risk for allergic reactions.

Managing Acute vaccine reactions

Early recognition and management of anaphylactic attacks is the key to best outcomes. Rapid imitation of therapy will prevent the occurrence of cardiac collapse.

Symptoms include flushing of the face, edema, itching, swelling of the mouth and throat, wheezing and difficulty in breathing . The patient must be placed supine with elevation of the foot end.

Administer epinephrine (1:1000) and it can be repeated in 10-15 minutes. Airway maintenance and oxygen administration is essential. Arrange for immediate transport to a facility for further observation and management.

Contraindications to Vaccinations;

A contraindication increases the chances of developing a serious adverse event.

In case there are contraindications to a particular vaccine, it should not be administered to the patient. Most contraindications are temporary and hence the vaccine can be administered at a later date.

Two types of contraindications exist:

a. Absolute contraindications

b. Relative contraindications

Absolute/ Permanent contraindications

Under these situations the concerned vaccine should never be administered to the patient

i. Anaphylaxis to a previous dose of the vaccine-

ii. Encephalopathy occurring within 7 days of a pertussis containing vaccine with no other attributable cause

iii. Severe combined immunodeficiency- rotavirus vaccine is not to be given

iv. History of intussusception- no rotavirus vaccine to be given.

Relative/ Temporary Contraindications

Vaccines can be administered later, once the condition leading to the contraindication does not exist

I. Immunosuppression

II. Pregnancy

Precautions

A precaution is a condition in a recipient that may increase the risk for a severe adverse reaction, may cause diagnostic confusion or may compromise the ability of the vaccine to produce immunity. It may result in injury but to a lesser extent than with an existent contraindication.

Some precautions include:

1. Presence of a moderate- severe acute illness, with or without fever
2. Personal or family history of seizures is a precaution for MMRV vaccine
3. Receiving antibody containing preparations
4. GBS <6 weeks after receiving a tetanus containing vaccine
5. Use of aspirin containing products is a precaution for varicella vaccine
6. History of Arthus type hypersensitivity reactions after a previous diphtheria toxoid/ tetanus toxoid containing vaccine. Defer vaccine for at least 10 years after the last tetanus toxoid containing vaccine
7. Progressive or unstable neurological disorder/ uncontrolled seizures/ progressive encephalopathy under the condition has stabilised and treatment is begun.
8. History of thrombocytopenia or thrombocytopenia purport is a precaution for MMR vaccine

Further Reading:

1. Centers for disease control and prevention. Vaccine recommendations and guidelines of the ACIP. Available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/intro.html. Accessed on 8 May 2023
2. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5102a1.htm
3. Advisory committee on Vaccines and Immunization Practices. IAP Guidebook on Immunization 2018-2019. Jaypee 2020. New Delhi;39-49.
4. Centers for disease control and prevention. Contraindications and precautions. Available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html. Accessed on 21 My 2023.

Vaccine Storage in Office Practice

DR S G KASI
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Advisor ACVIP 2022-23

Introduction:

Vaccines, being biological products, are sensitive to physical factors: heat, cold and sunlight. Potency of the vaccine can be maintained, throughout its shelf life, only if the vaccines are stored in the recommended manner. Improperly stored vaccines may lose potency and result in vaccine failures. Loss of potency is an irreversible process. Hence the importance of maintaining the cold chain in an efficient manner, in office practice.

Different surveys, studies and site visits have found that about 17–37% of healthcare providers expose vaccines to improper storage temperatures. Refrigerator temperatures are more commonly kept too cold rather than adequately cool.

Vaccines damaged by Freezing:

DTP & DTP containing combination vaccines (aP & wP)

Hepatitis A-Inactivated

Hepatitis B

HPV

All conjugate vaccines-PCV, Meningo-coccal conjugate, Typhoid conjugate

Vaccines not damaged by Freezing:

BCG-freeze dried

JE vaccines-live

MMR

Varicella

OPV

Most heat sensitive vaccines:

BCG-reconstituted

OPV

Rotavirus

Varicella

BCG, MMR, Varicella DTaP containing vaccines, HPV vaccines and Rotavirus vaccines are sensitive to strong light, sunlight, ultraviolet, fluorescents (neon), and exposure of these vaccines to light should be avoided.

Equipment for vaccine storage in office practice:

Three electrical equipment are available for storage of vaccines in office practice

1. Domestic refrigerator
2. Ice lined refrigerator (ILR)
3. Purpose built refrigerator

Domestic refrigerator:

The domestic refrigerator, which is used by a sizeable numbers of paediatricians in office practice, is not designed for the special storage temperature needs of vaccines. The drawbacks include:

1. Temperature varies significantly every time the door is opened.
2. Excursions beyond the safe range of $+2^0$C to $+8^0$C is not uncommon
3. Temperature rises during defrosting in cycle in cyclic defrost and frost-free refrigerator.
4. Cabinet temperature is easily affected by ambient temperature.
5. Temperature setting using dial is crude and inaccurate.

The WHO does not recommend domestic refrigerators for vaccine storage. However, since it is the most commonly used cold chain equipment in office practice, it is essential to be knowledgeable about the optimum methods of using it.

Requirements of a domestic refrigerator:

1. The freezer and storage compartment should have separate doors. Single door and bar-type refrigerators should not be used.
2. Automatic defrost should be preferred over the manual defrost types. Direct-cool refrigerators should not be used.
3. The vaccine fridge should be dedicated for vaccine storage ONLY.
4. The door seals should be in good condition and sealed tightly. Insert a sheet of paper and close the door. If the sheet can be pulled out without much effort, the seal is inefficient and needs to be replaced.
5. The door closes properly automatically on leaving it free. The front of the fridge should be a few millimetres higher than the back of the fridge. This can be achieved by adjusting the screws at the bottom of the fridge.
6. The refrigerator should be free from any coolant or water leak.

Placement of refrigerator:

1. Should be placed away from direct sunlight and away from doors and windows.
2. A distance of 10 cms should be maintained all around to permit air circulation.
3. Should be placed on a stand at least 5 cms in height.
4. The electric socket should be switchless or the switch should be taped to avoid accidental switching off.

Stabilizing the refrigerator before storing vaccines:

The new fridge should be turned on and the thermostat should be set at ~ $+5^0$C for the main compartment and ~ -20^0C for the freezer compartment. The temperatures should be recorded atleast twice daily. Once two consecutive days of temperatures recording are within the recommended range, the unit is stable and ready for use. This may take 2-7 days.

Placement of vaccines in fridge:

1. Contents of the fridge should no block the vents inside the refrigerator
2. Vaccines should be stored in transparent labelled containers, to identify needed vaccines a soon as possible.
3. Within a container and between containers, space should be maintained to permit air circulation.
4. In the freezer compartment, ice-packs are to be stored upright to maintain a cold mass
5. Vial of OPV can be stored in the freezer compartment

6. Vaccines should not be stored in the chiller tray
7. The top shelf should contain the most heat-sensitive vaccines: OPV, freeze-dried BCG, Rotavirus, Varicella, MR/MMR, Yellow fever vaccine.
8. The middle shelf should contain vaccines which are not very heat sensitive: DPT containing combination vaccines, PCV, IPV, TCV, Inactivated Influenza, HPV, Rabies, Hep A, Hep B, JE.
9. The lower shelf should store diluents and Hep B, Rabies, HPV (short term storage).
10. Vaccines should not be stored in the vegetable tray or doors.
11. The vegetable compartment and door should have water bottles, for increasing the cold mass.
12. Vaccines with a shorter expiry should be placed in front.

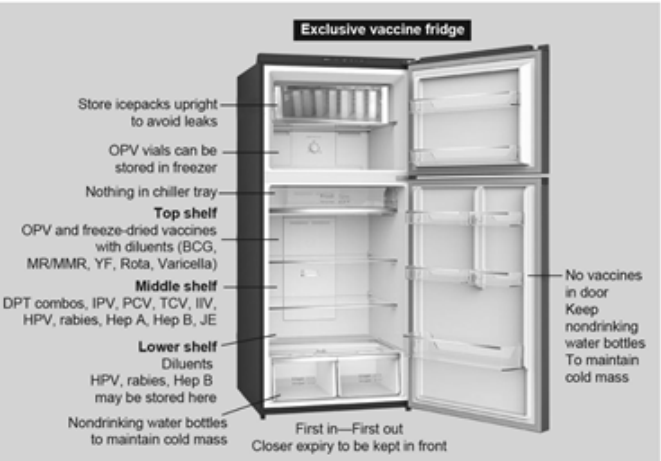


Fig. 8: Storage protocol in domestic fridge. (BCG: bacillus Calmette–Guérin; DPT: diphtheria, pertussis, and tetanus; HPV: human papillomavirus vaccine; Hep: hepatitis; JE: Japanese encephalitis; MMR: measles, mumps, and rubella; OPV: oral poliomyelitis vaccine; YF: yellow fever; IIV: inactivated influenza vaccine; IPV: inactivated polio vaccine; PCV: pneumococcal conjugate vaccine; TCV: typhoid conjugate vaccine)

From Purple book. 2022. Indian Academy of Pediatrics

Care of the refrigerator and vaccines:

1. Clean the fridge, exterior and interior, with a clean damp cloth, periodically
2. The rubber beading of the doors should be periodically cleaned with warm water.

3. The condenser coils should be cleaned by the fridge maintenance staff.

The cold chain equipment should be operated by authorized personnel only.

Ice lined refrigerators:

One of the most important link in the cold chain is the Ice Lined Refrigerator(ILR), which is also the preferred vaccine storage device by the WHO, at the peripheral level.

The ice-lined refrigerator (ILR) consists of a cabinet, with a lining of water containers (ice packs or tubes) fitted all around the walls and held in place by frame. While the refrigerator is operating, the water in the containers freezes and if the electricity supply fails, the ice lining keeps the temperature inside the refrigerator at a safe level for vaccines. It can keep vaccine safe with as little as 8-hour continuous electricity supply in a 24-hour period. ILRs have the longest "holdover time" among all cold chain equipment. With as little of 8 hours of power supply, the ILR can maintain temperature at $+2^0$C to $+8^0$C, for as long as 72 hours. Thus in situations wherein power

outages are frequent, the ILR is the preferred cold chain equipment.

Generally, ILRs have a top-opening lid which prevents loss of cold air during door opening. It has inbuilt thermometers and alarm for temperature excursions beyond the safe range.

In an ILR, vaccines should be stored in baskets to avoid direct contact with the sides and the bottom, which may result in freezing of vaccines.

Generally, the coldest part of the ILR is at the bottom. Hence, vaccines are stored in a manner reverse to that stored in a domestic fridge; most heat-sensitive vaccines in the bottom compartment and the less heat-sensitive vaccines in the middle and upper compartment.

Bottom: Measles, MR, MMR, BCG, OPV, YF, live-JE, Varicella, Rotavirus, Live attenuated Hepatitis A vaccine.

Middle and Upper: All the pertussis containing combination vaccines, inactivated hepatitis A vaccines, TVC, PCV, MCV, Inactivated Influenza vaccine, HPV, rabies, Inactivated JE vaccines.

The later versions have a uniform temperature range throughout the ILR.

The ILR should be "stabilized" before use, as discussed for the domestic refrigerator above.

Purpose-built refrigerators:

This is the ideal vaccine storage equipment when a constant, assured source of power supply exists.

The advantages of a purpose-built refrigerator include

1. The temperature regulating mechanism has a very quick response time to excursions outside the recommended range.
2. A small heating element around the cooling coils prevents any frost formation constantly. This prevents temperature excursions often seen with regular defrosting.
3. The temperature in the entire storage area is uniform.
4. Internal temperature is not affected by ambient temperatures.
5. The unit is equipped with inbuilt digital temperature monitoring (inbuilt data logger) and/or digital temperature indicators (minimum and maximum temperature displays)
6. Good temperature recovery—when the fridge is open to access the vaccines.
7. Entire space is available for vaccine storage
8. Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor)

9. Fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature.

10. The glass doors permit easy identification of stored vaccines.

Cold box:

A cold box is an insulated container that can be lined with ice-packs to keep vaccines and diluents cold during transportation and/or short period storage (from two to seven days). The cold box should be packed with the recommended number of conditioned icepacks. A cold box should be kept in every clinic to enable storage of vaccines during power outages of longer duration.

Storage of diluents:

Diluents should be stored between +2^{0}C and +8^{0}C. If limitations of storage space exist, the diluents may be stored at room temperature but transferred to the refrigerator/ILR atleast 24 hours before usage. Using a diluent stored at room temperature may cause a "thermal shock" and inactivation of the vaccine.

Ice packs:

Ice packs are key component of the cold chain. Ice packs are plastic containers filled with water.

They are used for

1. Increasing the cold mass within the fridge
2. Maintaining the required temperature range in vaccine carriers and cold boxes.

The ice packs should be filled with tap water till the mark and kept in the freezer compartment for up to 24 hours, till the water in them is frozen. The frozen ice packs can be stored in the freezer compartment to increase the cold mass.

Before using the frozen ice packs (which are at a temperature of -15^0 C to -25^0 C), the ice packs should undergo "conditioning or sweating", by keeping them at room temperature till beads of water appear on the surface. The temperature on the "sweated" ice packs is between +2^{0}C to +8^{0}C.

Vaccine carriers generally need 4 icepacks, while the cold boxes, depending on capacity, may need 20-40 ice packs.

Temperature monitoring devices (TMD):

Temperature of ILRs/Freezers used for storage of vaccines must be recorded twice daily, at 10 am and 4 pm. This should be recorded in a log book.

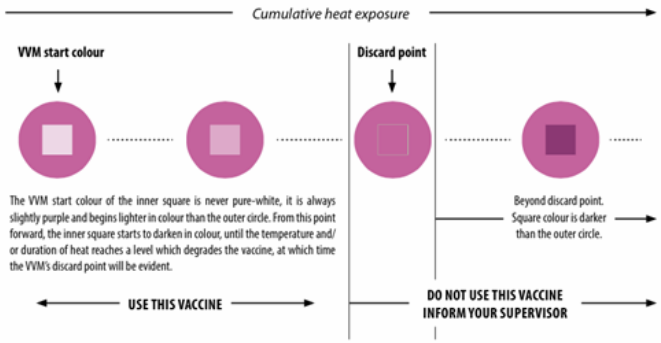
All cold chain temperature monitoring devices should be calibrated once in 6 months or earlier , if necessary.

1. Vaccine vial monitors (VVM):

The VVM records the cumulative heat exposure through a gradual change in color. If the color of the inner square is the same color or darker than the outer circle, the vaccine has been exposed to too much heat and should be discarded. VVMs are designed to meet the vaccine's heat stability curve, allowing a margin of safety. Good correlation has been observed between the vaccine vial monitor and vaccine potency of OPV. The VVM type depends on the vaccine, as shown in table:

VVM Type	No. days to end point at +37°C	No. days to end point at +25°C	Time to end point at +5°C	Vaccines
VVM 30	30	193	>4 years	BCG, HPV, HBV Rabies, PCV
VVM 14	14	90	>3 years	DPT/DT/TT, YF, MV/MR/ MMR LPV, IPV
VVM 7	7	45	>2 years	
VVM 2	2	NA	225 days	OPV

Figure 2.10 VVM showing colour change sequence and interpretation



2. Digital Data Loggers (DDL):

A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). A DDL can record temperatures over a long period of time, at preset intervals as well as can provide visual and audio alarms. The unit is to placed in the central part of the ILR/fridge.

Temperature data from a DDL can either be downloaded to a computer using an app or retrieved from a website.

MAINTENANCE OF Data loggers:

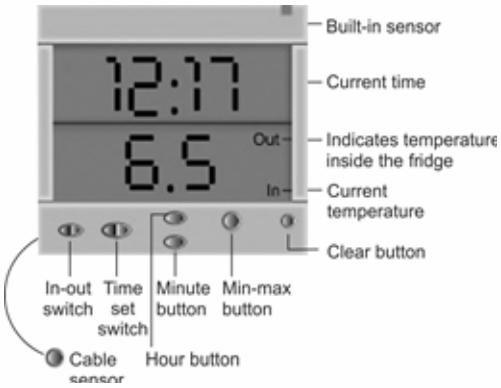
- Recalibrate the data logger annually.
- Change the data logger battery at least every 12 months or as indicated by the manufacturer.
- Check the accuracy of the thermometer at least annually

3. Electronic thermometers:

These provide temperature reading at a point of time. There is no provision for recording of minimum and maximum temperatures, nor do they store the recorded temperatures. They need to be calibrated periodically.

4. Maximum and minimum thermometers

This device monitors the temperature and display 3 values: current temperature, maximum temperature recorded since last reset and minimum temperature recorded since last reset. However, storage and retrieval of data is not possible.



Maintenance of thermometers:

Thermometers require annual checks to ensure accurate measurement. This can be done in a simple way.

Take a plastic cup, fill 2/3rd with water and keep in freezer till a thin layer of ice is formed. This may take about 2-2.5 hours.

Place the thermometer probe in the cup such that it should not be touching the side or bottom of the cup. After 2 mins record the temperature. It should read between + 1^0C and – 1^0C. If the recording is outside this range, change the batteries and repeat the process. If the recording is still beyond this range, change the thermometer.

Electronic freeze indicators & Freeze tags:

These are not used in office practice.

What is to be done in the event of a power failure?

- If the vaccines are stored in an ILR: Appropriate temperature can be maintained for 24-72 hours.
- Domestic fridge: with adequate "cool mass" and doors unopened, appropriate temperature can be maintained for upto 4 hours.
- If power outage > 4 hours and no backup power supply: shift vaccines to a large ready Cold Box. Unopened cold box (20L) can maintain appropriate temperature for up to 6 days.
- If none available; shift vaccine to a distributor

Maintenance Staff:

- All relevant staff should be trained in vaccine-related practices and be familiar with storage and handling of vaccines
- Written instructions should be provided on vaccine receiving from dealers, accounting, storing and vaccine nexpenditure.
- Receptionist/clinic manager should be in charge of maintaining stocks, monitoring Cold Chain, giving appointments.
- Vaccine fridge to be opened only by authorized personnel.
- Contact numbers of maintenance personnel for Fridge/ILR and other equipment should be pasted in a prominent place.

Suggested reading:

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3. World Health Organization. Immunization in Practice (WHO/EPI/ PHW/84.01 to 84.07). 2015 Geneva: WHO; https://apps.who.int/iris/ handle/10665/193412.
4. Purple book 2022. Indian Academy of Pediatrics.

Vaccination of children receiving immunosuppressive medications

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Advisor ACVIP 2022-23

Children receiving immunosuppressant medications are at increased risk of severe infectious disease, hence, the need to prevent infectious disease in them is more than in healthy individuals. However, the failure to appreciate the need of prevention of infectious diseases in these children, the sub-optimal response to inactivated vaccines, the fear of severe adverse effects of live attenuated vaccines and the supposed risk of potential interferences of vaccination on the underlying disease, results in many of these children remaining unvaccinated or incompletely vaccinated.

Immunosuppressive medications can influence the innate humoral and cellular immune responses and can influence the effectiveness of immunization. In fact, each of the steps of the immune response can be the target of an immunosuppressive drug.

Immunosuppressive medications block the clonal expansion of specific T and B cells. The primary immune response to a new antigen is more severely affected than a secondary immune response. The secondary immune response is also significantly affected as the clonal expansion of the memory cells will be reduced, the antibodies produced are qualitatively and quantitively inferior, thus resulting in a shorter duration of protection.

Primary vaccination with a new inactivated antigen may result in a sub-optimal immune response. Hence the need to document antibody titers post-vaccination, to decide the need for additional doses. The same applies to booster doses as well.

Following administration of a live vaccine, inhibition of the clonal expansion of T and B cells may lead to the inability to clear the replicating attenuated vaccine-strain virus, leading to the possibility of severe vaccine-associated disease. Hence, live vaccines are usually contraindicated during immunosuppressive treatment.

Glucocorticoids(GCs):

GCs are among the most potent anti-inflammatory drugs and inhibit the immune response at various levels. They inhibit chemokines and cytokines, limit the trafficking of leucocytes to the inflammation sites, suppress pro-inflammatory signals, inhibit the activation of various transcription factors in T cells. Thus, GCs affect the adaptive and innate immune responses.

Low dose of GCs is defined as prednisolone <20mg/day in those >10 kg body weight or <2mg/kg/day in those weighing <10 kgs, or equivalent doses. These doses are not immunosuppressive and all vaccines, live and inactivated, can be safely administered.

If the dose is >20mg/day in those >10 kg body weight or >2mg/kg/day in those weighing <10 kgs and the duration of therapy is <2 weeks, the child is immunosuppressed during therapy and should not receive live vaccines while on therapy. It is generally agreed that the child can receive live vaccines immediately after stopping

therapy. If the disease for which steroids are being given is inherently immunosuppressive, it would be prudent to wait for a longer period(~4 weeks) before administering live vaccines.

If the dose is >20mg/day in those >10 kg body weight or >2mg/kg/day in those weighing <10 kgs and the duration of therapy is >2 weeks, the child is has prolonged immunosuppression and live vaccines should be offered not earlier than 4 weeks after stopping the GC therapy.

Inhaled, topical and alternate day (1.5mg/kg/day) therapy are not immunosuppressive.

Methotrexate (MTX):

This drug acts by inhibiting cell division by inhibition of DNA synthesis by inhibiting the uptake of Pyrimidine. It is widely used in rheumatic conditions as a disease modifying agent.

A dose of ≤0.4 mg/kg/week (≤15 mg/m2/week) is not immunosuppressive and all live vaccines can be administered while on therapy. At higher doses, live vaccines can be administered after an interval of 1-3 months, depending on the dose and duration of therapy.

Azathioprine (AZT) and 6-Mercaptopurine (6-MP):

Both act by inhibiting purine synthesis. AZT is converted within tissues to 6-MP.

Doses ≤3 mg/kg/day for AZT or ≤1.5 mg/kg/day 6-MP are not considered immunosuppressive and all live vaccines can be administered while on therapy. With higher doses, an interval of 3 months after stopping therapy, is recommended, before administration of live vaccines.

Mycophenolate (MMF):

It inhibits the synthesis of guanine nucleotides. B and T cell proliferation and the production of immunoglobulins by B cells is mainly inhibited. The innate immune response is also affected by diminished recruitment of lymphocytes into inflammatory sites and the activation of T cells by DCs. Both, primary and secondary immune response following vaccination is severely affected by MMF.

High-dose immunosuppression is defined as dosages >1200 mg/m2 and is a contraindication for live vaccines. MMF regimen are more immunosuppressive than that caused by tacrolimus (Tac) or cyclosporine A (CsA).

Live vaccines may be considered 1-3 months after cessation of high dose therapy. However, even after low dose therapy, caution should be exercised while administering live vaccines.

Cyclophosphamide:

It act on all phases of the cell cycle, irrespective of whether or not the cells are replicating. Dosage of 0.5–2 mg/kg/day is considered as high dose and contraindicates live vaccines for 1-3 months after stopping therapy.

Cyclosporine:

A dosage ≤2.5 mg/kg/day is considered as not immunosuppressive. For tacrolimus, a blood level of <8 ng/mL is considered as not immunosuppressive. Live vaccines may be offered in these situations. For higher doses, an interval of 1-3 months should be maintained before administration of live vaccines.

Sirolimus and Everolimus:

No live vaccines to be administered during therapy. Live vaccines may be offered 3 months after completion of therapy.

Sulfasalazine, Colchicine, HCQ, Thalidomide:

These drugs do not cause significant immunosuppression and live vaccines may be administered during therapy.

Anti-TNFα (Adalimumab, Golimumab, Certolizumab, Infliximab, Etanercept):

Live vaccines should be administered at least 4 weeks before initiation of therapy or 3 months after cessation of therapy. For etanercept , live vaccines may be administered 1-2 months after cessation of therapy.

Anti-IL-1 (Anakinra):

Live vaccines are contraindicated during therapy. Live vaccines should be administered at least 4 weeks before initiation of therapy or 1–3 months after cessation of therapy.

Anti-IL6 (Tocilizumab):

Live vaccines are contraindicated during therapy. They may be administered at least 3 months after cessation of therapy.

Rituximab:

Therapy with Rituximab severely impacts the antibody response to vaccines. Any vaccine history prior to rituximab therapy should be disregarded and complete re-immunization should be done. Once B-cell and Ig levels have recovered, immunization should be recommenced, which is generally 6 months for inactivated vaccines and 12 months for live vaccines, after cessation of rituximab therapy.

Janus Kinase (JAK) Inhibitors:

Live vaccines should be administered at least 4 weeks before initiation of therapy or 1–2 months after cessation of therapy.

In utero exposure to BRMs:

Infants born to women who received BRM during pregnancy avoid live viral vaccines during the first year of life. BCG, OPV, and MMR/MR, should be avoided in the first year of life. The safety of rotavirus vaccines in such infants is debatable and hence may be avoided.

Suggested reading:

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2. American Academy of Pediatrics. [Chapter title.] In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. Red Book: 2021 Report of the Committee on Infectious Diseases. Itasca, IL: American Academy of Pediatrics: 2021. Pg 72.
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4. Zerbo O, Modaressi S, Goddard K, et al. Safety of Live-Attenuated Vaccines in Children Exposed to Biologic Response Modifiers in Utero. Pediatrics. 2022;150(1):e2021056021

Vaccine Safety

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Vaccines are among the most successful and cost-effective public health tools for preventing deaths and diseases. Vaccines save 2 to 3 million lives annually. However, like all medical interventions, vaccines are not completely without risk of side effects or other adverse outcomes. Since, immunizations are typically administered to healthy people and are often recommended to provide individual or societal protection, a very high level of safety is expected of vaccines. As with all medicines, every vaccine needs to go through extensive and rigorous testing before it can enter clinical usage. Once they are in use, they must be continuously monitored to make sure they are safe for the people who receive them. An optimal immunization safety system requires rigorous attention to safety during prelicensure research and development; active monitoring for potential safety problems after licensure; and clinical research and risk-management activities, including risk communication, focused on minimizing potential vaccine adverse reactions. Prelicensure activities form the foundation of vaccine safety. Rapid advances in biotechnology are leading to the development of new vaccines and novel delivery technologies, such as DNA vaccines and new adjuvants and they pose new challenges.

Historical events:

In 1942, the military injected hundreds of thousands of American servicemen with a yellow fever vaccine, stabilized with human serum contaminated with hepatitis B virus. As a consequence, 330,000 soldiers were infected with hepatitis B, severe disease developed in 50,000, and 62 died.

In 1955, inadequate inactivation of the wild polio virus used in the IPV manufactured by Cutter's laboratories, 40,000 developed mild polio, 200 being permanently paralyzed, and 10 died. It was one of the worst biological disasters in American history.

Acute encephalopathy, Guillain-Barré syndrome (GBS) ,paralytic polio following live attenuated oral polio vaccine, anaphylaxis following several different vaccines, severe or fatal viscerotropic disease following yellow fever vaccine, and intussusception following rotavirus vaccine, are few examples of problems associated with the use of vaccines, though causality is not proven in many such AEFIs.

As vaccine use increases and the incidence of vaccine-preventable diseases decreases, vaccine- related adverse events become more prominent. Thus, vaccine safety is a major concern and needs to be studied and monitored vigorously.

New vaccine development:

Vaccine development involves the process of identifying a new antigen or immunogen and developing this substance into a final vaccine. It involves phases of pre-clinical development and clinical development studies to determine the safety and efficacy of the resultant vaccine. During this process, the product's components,

in-process materials, final product specifications, and manufacturing process are defined.

Vaccine development is difficult, complex and a highly risky task. The risk is high because most vaccine candidates fail in preclinical or early clinical development and less than 1 in 15 vaccine candidates entering Phase II achieves licensure.

Clinical development involves studies of the effects of vaccines on patients for dosing, safety, immunogenicity, and efficacy through a staged process:

Exploratory and Preclinical stage – done in Animals.

Identifying natural or synthetic antigens and testing in animals for immunogenicity and safety. This is also called proof-of-concept testing. Subsequently, a submission is prepared for application as an investigational new drug (IND).

Clinical phases of vaccine development:

Phase 1 Vaccine Trials

This phase is done in small group of adults (20-80 subjects). Vaccines targeting children will first be tested in adults and then gradually step down the age of the test subjects until they reach their target age. Phase I trials may be non-blinded. The goals of The aims of Phase 1 testing are to assess the safety and immune responses of the candidate vaccine. Challenge studies may be performed I this phase. A promising Phase 1 trial will progress to the next stage.

Phase 2 Vaccine Trials:

This phase is done a larger group of several hundred individuals. Some individuals may belong to groups at higher risk of acquiring the disease. These trials are randomized and well controlled, and include a placebo group. The goals of Phase II testing are to study the candidate vaccine's safety, immunogenicity, proposed doses, schedule of immunizations, and method of delivery.

Phase 3 Vaccine Trials:

This phase involves thousands to tens of thousands of people. The Phase III trials are randomized, double blind, and placebo controlled, or with another indicated vaccine as a control group.

The goals of Phase 3 trials include assessment of vaccine safety in a large group of people and to detect adverse effects which were not detected in the smaller phase 1 and 2 trials. Vaccine efficacy is also assessed against prevention of disease, prevention of infection. Both humoral and cell mediated immune responses are assessed.

Technological advances in the evaluation of safety, before vaccines are licensed should lead to the development of safer vaccines.

Phase 4 Vaccine trials:

Post licensure studies of safety and efficacy of vaccines are essential and represent a large additional cost. Reactions that are rare, delayed, or which occur in only certain subpopulations or new onset medical conditions, may not be detected before vaccines are licensed, post licensure evaluation of vaccine safety is critical. During public health emergencies such as Covid-19, when no licensed vaccine or treatment exists, vaccine candidates may be licensed for emergency use, if they have made it to the end or nearly the end of phase 3 trials and the evidence suggests they are safe and effective. Even if the vaccine has received emergency use authorization and rolled out into the general public, it is monitored very closely for a number of years to keep a close eye on side effects.

Vaccination in pregnancy is unique in that it can affect the pregnant woman, the developing fetus, and the newborn infant. Pregnant women, however, are usually excluded from prelicensure clinical trials, making postlicensure

monitoring key for evaluating safety of maternal immunizations.

Vaccine adverse events (AEFI) reporting systems:

Passive reporting systems, including vaccine adverse event reporting system-Informal or formal passive surveillance or spontaneous reporting systems (SRSs) have been the cornerstone of most post licensure safety monitoring systems because of their relative low cost of operations. However, pre-established large, linked databases (vaccine safety assessments by linking data across national registries) have enhanced the capabilities to study rare adverse events after specific immunizations. Such systems may detect variation in rates of adverse events by manufacturer or specific lot. The national reporting of adverse events (AEFIs) following immunizations can be done through the same reporting channels, on same lines as is done for VPD surveillance system in India or through the IdSurv option in the IAP website. Following the receipt of an AEFI occurrence, a series of procedural steps are initiated leading to causality assessment of the AEFI. Internationally accepted and validated protocols are implemented by the Govt. of India for causality assessment. Emerging patterns of possible safety problems should be explored thoroughly, with the results of these analysis promptly communicated to the public. This will help in maintaining the overall confidence in vaccination programs. The efficacy of these reporting systems is exemplified by the reports of an increase in GBS was after the introduction of a new meningococcal conjugate vaccine (MCV4, TTP after the Astra-Zeneca Covid-19 vaccine and myopericarditis after the mRNA Covid-19 vaccines .

Good manufacturing practices:

The vast majority of the more than 1 billion doses of vaccines manufactured worldwide each year are given to perfectly healthy people. Hence, Good Manufacturing Practices guidelines have been made mandatory for all pharmaceutical product including vaccines.

Good manufacturing practices (GMP) is mandatory for ensuring high-quality production processes, obtaining a safe product for human use, with a positive impact on public health.

The GMP protocol consists of 3 parts: (1) the principles for the manufacture of medicinal products, (2) the basic requirements for active substances used as starting materials, (3) clarifies all the documentation for regulatory certification.

Regulatory authorities:

In India DCGI and Food and Drug administration department is responsible for all licensure procedures and monitoring .

In the United States, the U.S. Food and Drug Administration's (FDA) and the Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines..

In the European Union, animal and human vaccines are regulated by the European Medicines Agency (EMA).

Harmonization/standardization of licensing and regulating procedures for vaccines worldwide, is a necessity and has obvious benefits in rapidly delivering safe and effective vaccines to the market.

Vaccine injury compensation programme and liability of manufacturer, licensing authority, administrator and claims arising out of it is a complex matter and is still in evolving phase.

Risk benefit concept:

When treating a disease, risks are largely confined to two broad categories: the risks associated with a particular intervention and the risks of doing nothing. Risk is bound to change in different geographical settings, low and middle income countries Vs developed countries, based on endemicity, outbreaks and interplay of host

and genetic factors. Globally, the risk of diseases is subject to wide geographical, national, and occupational variability. Still in all cases, high rates of vaccination among communities are widely credited with preserving the low incidence of many vaccine-preventable diseases.

Every vaccine is bound to have some minor or major side effect which can be a common occurrence or rare one . But the decision to offer vaccine to a person is dependent on risk benefit ratio and is invariably complicated by the uncertainty associated with any assessment of risks and benefits.

No vaccine is actually 100% safe or effective for everyone because each person's body reacts to vaccines differently

Safety of mass immunization campaigns:

In mass-immunization campaigns during which many people are vaccinated in a short time, it is critical to have a vaccine safety monitoring system in place that can detect potential safety problems early so that corrective actions can be taken as soon as possible. Mass-immunization campaigns are often conducted in developing countries, which poses a particular challenge of ensuring injection safety.

In any setting in which large numbers of immunizations are being administered, more adverse events will coincidentally occur following immunization. Thus, it is important to have background rates available of expected adverse events to allow rapid evaluation of whether reported adverse events are occurring at a rate following immunization that is higher than would be expected by chance alone.

Rare side effects and delayed reactions might not be evident until the vaccine is administered to millions of people. Some adverse events in which evidence favours causality are febrile seizures followed by MMR vaccine, encephalopathy/ transient arthralgia & thrombocytopenia after MMR vaccine, deltoid bursitis following administration etc.

Some examples of particularly controversial issues where the evidence does not favour a causal association are pertussis vaccines and SIDS, vaccines and autism, hepatitis B vaccine and multiple sclerosis, and vaccines and type 1 diabetes etc.

Vaccine safety controversies and misconception:

Some of these include:

1. Whole cell pertussis and permanent brain damage
2. Deaths following vaccination
3. SIDS and vaccination
4. Vaccination and cancer
5. Thiomersal and Autism and neurodevelopmental delay
6. Vaccines overload the immune sysyem
7. Vaccines weaken host immunity
8. Vaccines causes autoimmunity,
9. Vaccines causes allergy and asthma

All the above issues have been extensively investigated and no causal relationship has been proven between the above mentioned conditions and administration of vaccines.

The Global advisory committee for vaccine safety (GACVS) an independent advisory board of WHO, has reviewed several such key topics and from evidence analysed from multiple sources the committee found a lack of association between vaccination and such events.

Safety to vaccinator and safety of vaccinee are of prime importance. The WHO has promoted the use of safer autodisposable syringes and disposal boxes and prefilled syringes. Right patient, right vaccine, right manner, right route, right age, right documentation are all pillars of vaccine safety initiatives. Proper biomedical waste disposal system should be in place to

ensure safety of community and society as a whole.

Vaccine risk communication & vaccine hesitancy:

As immunization programs successfully reduced the incidence of vaccine- preventable diseases, vaccine safety and adverse events become more prominent in decision making because vaccine-preventable diseases often are not perceived as a real threat by parents . Parents searching for information about vaccines on the Internet are likely to encounter sites that encourage vaccine refusal. These factors may affect parental beliefs about immunizations. Although the majority of parents support immunizations, surveys have found that many parents have concerns or misconception that could erode their confidence in vaccines. Within this context, the art of addressing vaccine safety concerns through effective risk communication has emerged as an increasingly important skill for healthcare providers who administer vaccines.

Providing knowledge about approved vaccine information websites, use of social media, websites, information booklets to parents, educational talks or lectures , use of vaccination mobile apps, all should be used to dissipate information about vaccine safety. Health literacy and overall literacy in a population is of utmost importance when risk benefit ratios are communicated.

Sustaining the gains in global vaccination programmes requires maintain public trust in both vaccine efficacy and vaccine safety. It is critically important that public health agencies, medical organizations, associations like IAP and other influential authorities continue to focus on the safety of vaccines and assure public confidence by providing clear, consistent messages on vaccine safety concerns. Ultimately, however, the success of vaccination depends on maintaining widespread public trust, and unwavering awareness for vaccine safety issues without which vaccination programs cannot succeed.

References:

1. 1) WHO guidelines and recommendations on vaccine safety.
2. 2) Plotkins textbook of Vaccinology.
3. 3) CDC guidelines and recommendations on vaccine safety issues.
4. 4) IAP guide book on immunization.

PEDICON 2024 – ANNOUNCEMENT

RATES PEDICON 2024 KOCHI

Category	Early Bird upto 31Mar 23	Up to 30 Jun 23	Upto 30 Sep 23	upto 31 Dec 23	From 01 Jan 24
IAP member	11000	18700	27500	37400	45000
Accompanying	11000	18700	27500	37400	45000
Non IAP	16000	37400	44000	55000	66000
Accompanying	16000	37400	44000	55000	66000
PG student	6000	9000	10000	12000	16000
Accompanying	11000	18700	27500	37400	45000
SR citizen	-			11000	11000
Accompanying	11000	18700	27500	37400	45100
SAARC	$250	$250	$300	$550	$750
Non SAARC	$450	$450	$550	$750	$950
Corporates	25000	38500	44000	49000	60000
Accompanying	25000	38500	44000	49000	60000

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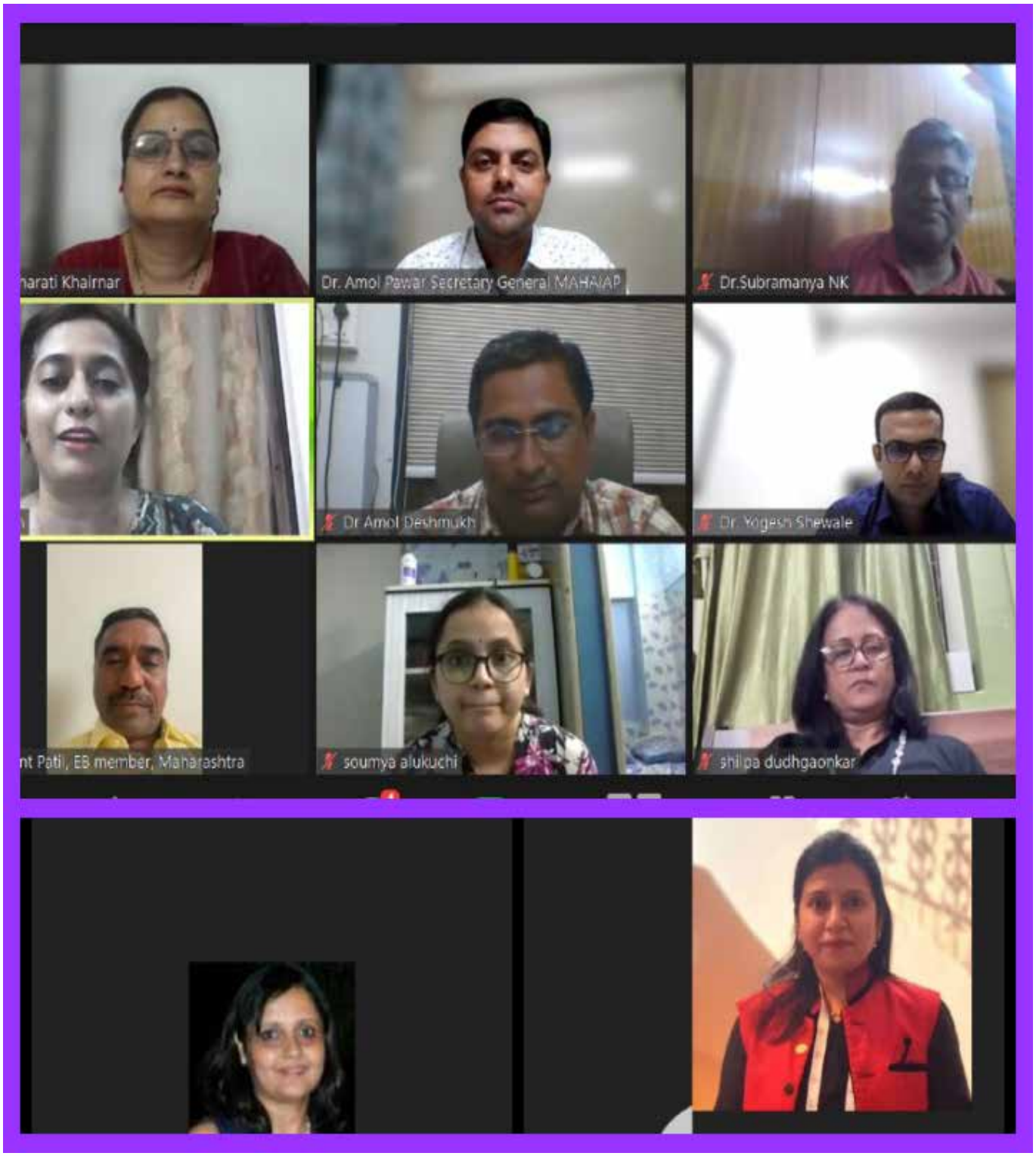
DR S. SACHIDANANDA KAMATH
Organising Chairman

DR M. NARAYANAN
Organising Secretary

DR M. I. JUNAID RAHMAN
Organising Treasurer

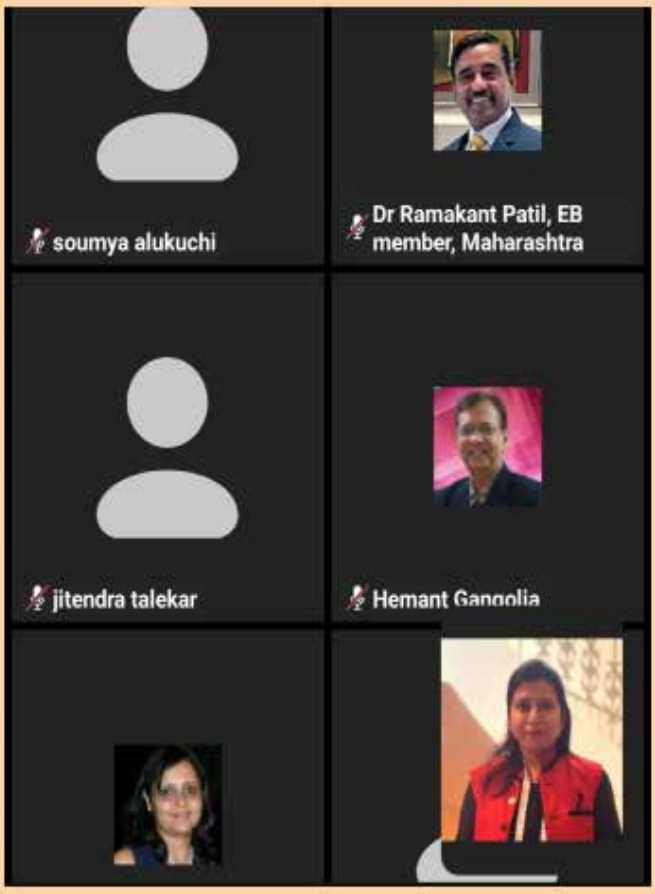
FOR ASSISTANCE
Contact Conference Secretariat @ 7012025938

Activities of Women's Committee MahaIAP



World No tobacco day by Resp Dr Khadse Mam, WC Patron

Activities of Women's Committee MahaIAP



Tuesday Takes Session of 20th June by Expert Resp Dr NK Subramanyam

Activities of Women's Committee MahaIAP

12st June 23. दैनिक हिंदुस्थान. अमरावती

भारतीय सौर २ आषाढ १९४५ ५

आंतरराष्ट्रीय योग दिवसानिमित्त...

सध्याच्या तांत्रिक युगात आपली सर्वांची रोजच धावपळ सुरू असते. या धकाधकीच्या जीवनामुळे स्ट्रेस म्हणजे तणाव सर्वत्र दिसून येतो. या तणावातून शांतता मिळण्यासाठी योग पद्धती सर्वोत्तम उपाय, हे सर्वांना माहित आहे. रोजच मोठ्या संख्येने आपण महिला - पुरुष आणि वृद्धांना सुद्धा योगासने करताना बघतो. सध्या मोठ्यामध्ये योगासने, प्राणायाम, इत्यादीचा प्रकार प्रचलित झालेला आहे. योगासने व त्याचे शारीरिक आणि मानसिक आरोग्य प्राप्तिकर फायदे सर्वांना माहित आहेत. म्हणूनच योगासनं करण्याच्या पद्धतीत वाढ दिसून येत आहे.

२१ जून हा आंतरराष्ट्रीय योग दिवस आपल्या प्रिय पंतप्रधान नरेंद्र मोदी यांनी सुरू केला. विविध योग संघटना बऱ्याच ठिकाणी योगासने व योग साधना करून हा दिवस साजरा करतात. ह्या दिवसाच्या उद्देशाने, आपल्या देशाच्या प्राचीन संस्कृतीची जपवणूक होते.

* पण आपल्याला माहित आहे का योगासने ही लहान मुलांसाठी पण तितकीच महत्वाची असतात. जसे शिक्षण लहानग्यांसाठी महत्वाचा आहे तसंच योग प्रशिक्षण सुद्धा त्यांच्यासाठी अतिशय महत्त्वाचा ठप्पा आहे. योगसाधनेचे भरपूर फायदे लहान मुलांमध्ये आहेत. तसेच किशोरवयीनांमध्ये सुद्धा योग आणि प्राणायाम यांचे खूप महत्त्व आहे.

* लहान मुलं तसेच किशोर वर्गांमध्ये अभ्यासामुळे,पालकांच्या वाढत्या अपेक्षेमुळे किंवा

परिस्थितीत प्राणायाम, ध्यान आणि योगासने फायदेशीर ठरतात.

* किशोरवयीन आणि लहान मुलांमधे चिंताची एकाग्रता, मन:शांती, निर्णयक्षमता आणि विवेकबुद्धीचा वापर योगासनाने वाढतो. स्मरणशक्ती वाढण्यास मदत होते.

* मासपेशींची योग्य वाढ आणि चळवळकटपणा योगद्वारे येतो. शारीरिक वा मानसिक विकास होते. मुलांचे मन आनंदी राहते.

* कोणते कोणते आसने, प्राणायाम आणि ध्यान कसे करायला हवेत हे सर्व योग्य प्रशिक्षकाकडून शिकून घेणे महत्त्वाचे आहेत. त्यानंतर त्यांच्या किंवा पालकांच्या निगराणी मध्ये योगासने आणि प्राणायाम करता येईल.

* किशोरांमधील व्यसनाधीनता मग ती मोबाईल, टीव्ही, गेम्स चि असो किंवा एखाद्या विशिष्ट वस्तुची. ह्या सर्व गोष्टींचं व्यसन, योग साधनेने, काही प्रमाणात कमी होऊ शकते. कारण योग मानसिक आरोग्य वाढवते.

* हल्ली डायटिंगचे चलन किशोरींमध्ये आढळून येते. योगा आणि पौष्टिक आहार, लठ्ठपणा नियंत्रित करतो.

* प्राणायाममुळे मुलांची रोग प्रतिकारशक्ति वाढते. वातावार होणार्या साथ रोग सर्दी खोकला पासून त्यांना काही प्रमाणात दिलासा मिळतो. निरोगी राहण्यासाठी मुलांमधे योग महत्त्वाचे आहे. थोडक्यात सांगायचे झाले तर योगासने करणाऱ्या मुलांचा सर्वांगीण विकास होतो.

● डॉ. सोनाली शिरभाते

NewsPaper cutting on WC

Activities of Women's Committee MahaIAP

IAP Amravati Hematology Module

Activities of Women's Committee MahaIAP

IAP Amravati Hematology Module on 28th May 23. The Experts were Dr Dipti Jain, Dr Pankaj Dwiwedi, Dr Atish Bakane, Dr Anju Mehrotra. President Dr Kausthubh Deshmukh & Secretary Dr Nitin Raut.

IAP Navi Mumbai

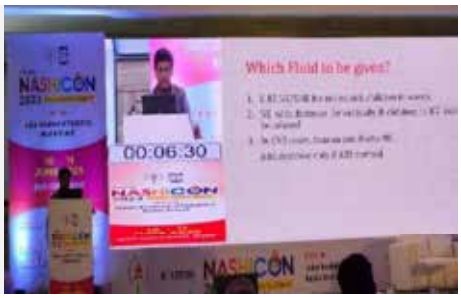
. 30th June 2023 - **Diamond Jubilee Academic Series: PgReach of CIAP**

Supported by Apollo Institute of Child Health

Expert - **Prof Dr S Balasubramanian & Prof Dr Srinivasan**

https://us02web.zoom.us/j/86387491649?pwd=REF2L0FhNWhaYVJ6dlFOOWRucFFFQT09

https://diapindia.org/event-details.php?event=2182&title=IAP-PG-Teaching-Sessions---Supported-by-Apollo-Institute-of-Child-Health#_bottom



IAP Navi Mumbai

IAP Navi Mumbai

NMAP TIP No.21. Authors: Dr.Vijay Yewale ,Dr.Jeetendra Gavhane .

Dengue is endemic with seasonal increase. Now is the Dengue season

Circulated in social media groups of Pediatrician across NaviMumbai & Maharashtra.

IAP Pune

World Thalassemia Day was celebrated on 8th May by IAP Pune in association with Dept of Pediatrics, Smt Kashibai Navale Medical College.

Several patients with Thalassemia and their parents attended the program. Information about Govt facilities and schemes for thalassemics was given to the parents as well as their doubts about treatment and BM transplantation were discussed. The children had a colouring activity followed by snacks, as well as song recital by one of our patients.

World Thalassemia Day - 8th May 2023

IAP Nagpur

5th JUNE- World Environment Day

- Unique CME and workshop-

  Pediatric Pulmonology with active participation from NEERI(National environmental engineering Research institute)

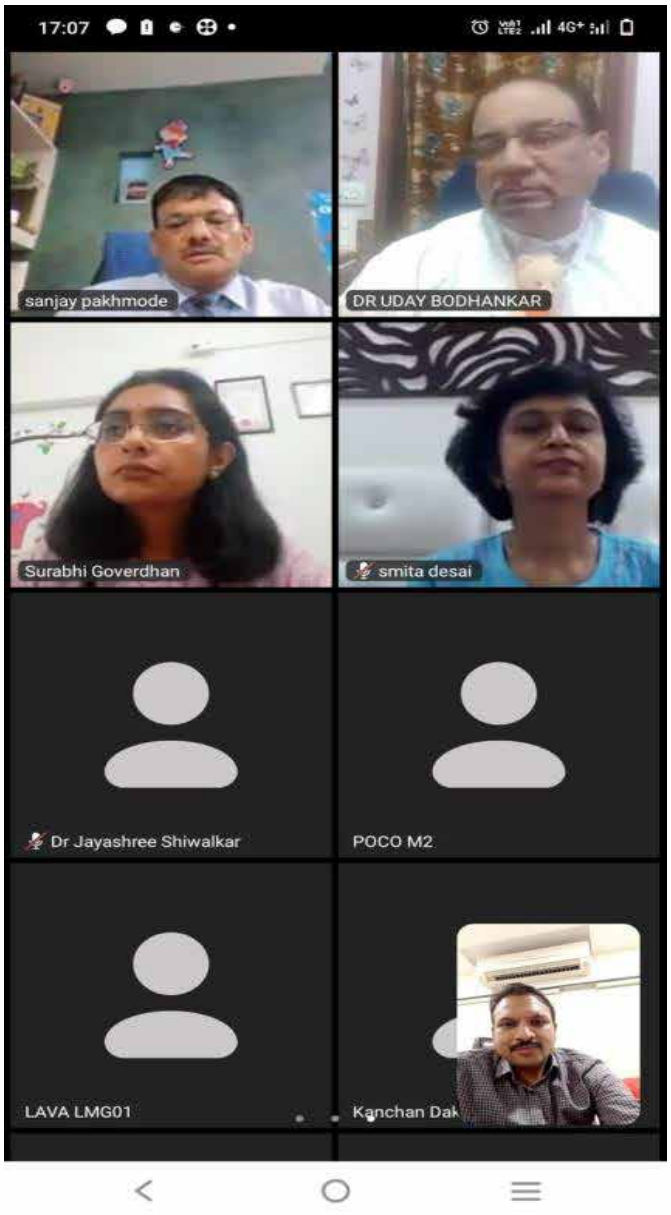
- Lecture by Dr Atul vaidya(Director NEERI)-Environment necessary Evil
- Lecture by Dr Vijayasekaran (Senior consultant- Pediatric Pulmonology- Kanchi kama koti)- Asthama- Recent concepts
- Lecture by Dr Vivek charde(Pediatric pulmonolgist - Nelson hospital)- what is Asthama what is not
- Lecture by Deopujari(Senior Pediatrician and academician Nelson Hospital) - smart phone app for management of acute asthama-
- Workshop and hands of training on spirometry

IAP Nagpur

5th JUNE- Complementary Feeding Day

Short lecture series for parents and doctors

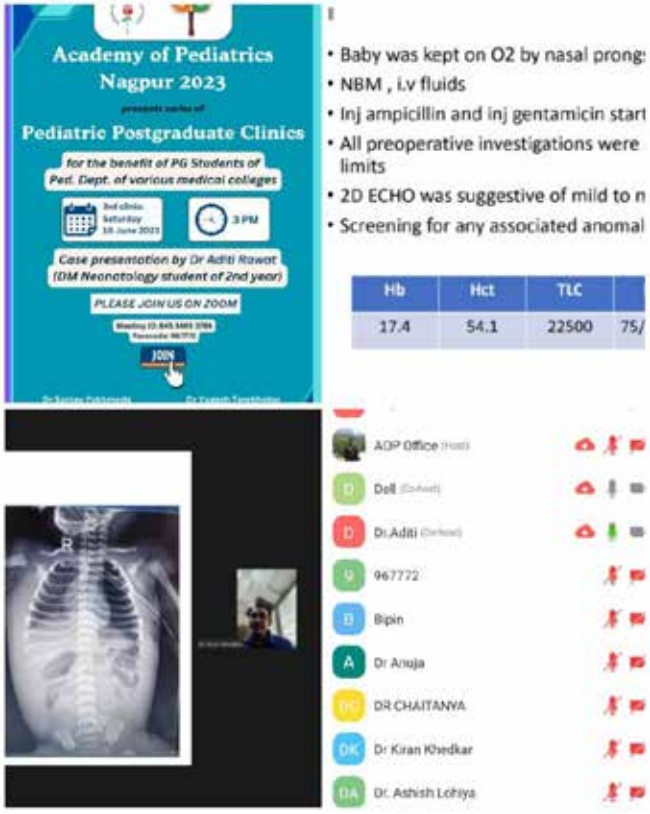
- How Critical & Crucial to Stat Complementary Feeding at Ri ght time - Sanjay Pakhmode
- Factors Responsible for Indequate Complementary Feeding.- Dr Smita desai
- Complementary Feeding & Anaemia Other Nicronutrient Deficiencies- Dr Jayashree Shiwalkar
- Homemade Recipes / Fortified Infant Cereals.- Dr surabhi
- Complementary Feeding How To Improve Communication with Parents- Dr Uday Bodhankar sir



IAP Nagpur

10th JUNE- Pediatric Postgrduate Clinic

- Pediatric post graduate clinic
- Interesting case discussion with guidance by the masters .
- This was 3rd in series .
- Co ordinator Dr Bhawana Lakhtar Dr Ashish Lothe Team AOP Nagpur



10th JUNE- School Health Check UP

- AOP in association with school of scholars conducted health check up camp and Healthy Baby contest.
- Winners were given attractive prizes .
- Co ordinator Dr Smita Desai(EB member team AOP)Dr Rishikesh Gadekar Team AOPNagpur

IAP Nagpur

18TH June- Financial Education for Doctors

- Planning is Bringing the Future into present
- CME on Financial Education by the doctors for the doctors
- Team AOP Nagpur in association with New Healthcity hospital
- Topics discussed were How to invest in share Market,How to invest in Mutual Funds, Insurance, Loans,How to be smart investor in life(Gold, Property..etc).
- Attended by more than 50 participants

IAP Nagpur

19th June World sickle cell day

- Sickle cell association of Nagpur in association with AOP, IMA,AMS
- Free hydroxyurea camp for sickle cell patients at India Gandhi Medical College.Similar camp was conducted at Gadhachiroli on 12 th June .
- Dr Sanjay Pakhmode (Senior Pediatrician and President AOP Nagpur)Dr Atish Bakane(Pediatric Hematologist and EB member team AOP nagpur) actively participated in the camp

IAP Jalandhar

1. **IAP UG Quiz:** College round of IAP Undergraduate quiz was conducted at PIMS Jalandhar. Anurag Goyal and Komal Aggarwal from MBBS Final year part II were winners. Team of Sahiba Bedi and Aman Jindal was first runner up. Winning teams were rewarded by were rewarded by Dr Kanwaljit Singh , CEO PIMS, HOD Paediatrics Dr HS Bains and Secretary JAP Dr Anuradha Bansal

IAP Jalandhar

2. Basic NRP workshop was organised at PIMS Jalandhar on June 3, 2023. Dr HS Bains, Dr Jatinder Singh and Dr Gurdeep Singh trained the nursing staff in skills of basic NRP

IAP Jalandhar

3. **(A) Complementary feeding day June 6, 2023:**
Dr Rohit Chopra, President JAP organised an activity for nursing staff and parents of infants, educating them about about timely, appropriate and safe introduction of complementary feeding

(B) Dr Anuradha Bansal , Secretary JAP , published a blog as well as a youtube video emphasising the importance of complementary feeding

IAP Kerala

PAEDIATRIC SNIPPETS

STATE LEVEL INAUGURATION

IAP Kerala

MBFHI accreditation Govt Medical College, Thrissur

IAP Kerala Family meet

IAP Kerala

BLS programme IAP Trivandrum

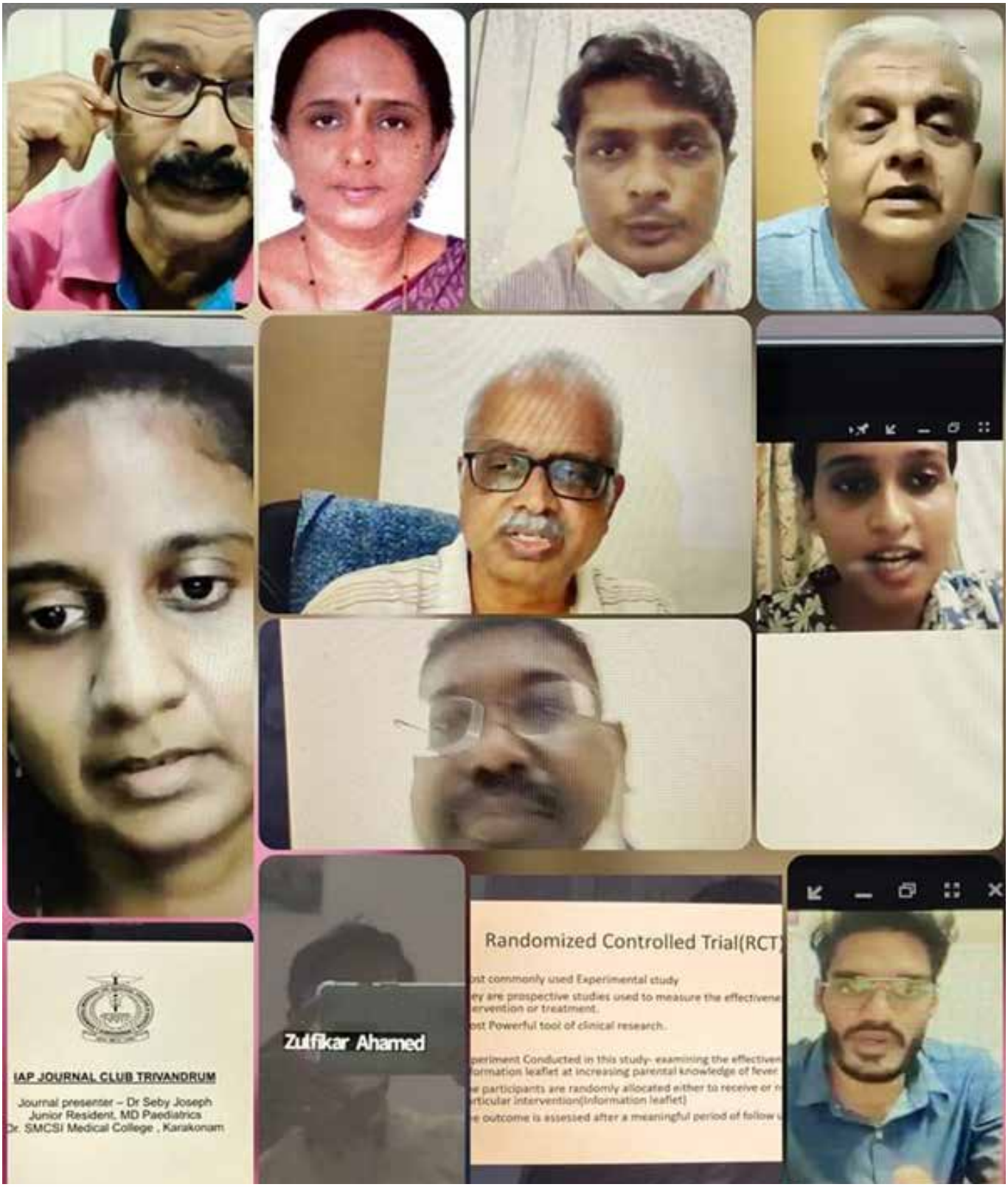
IAP Kerala

BLS programme IAP Trivandrum

IAP Kerala

Family meet IAP Wayanad

IAP Kerala



Journal Club IAP Trivandrum

IAP Kerala

Monthly CME IAP Pariyaram