EFI Bulletin

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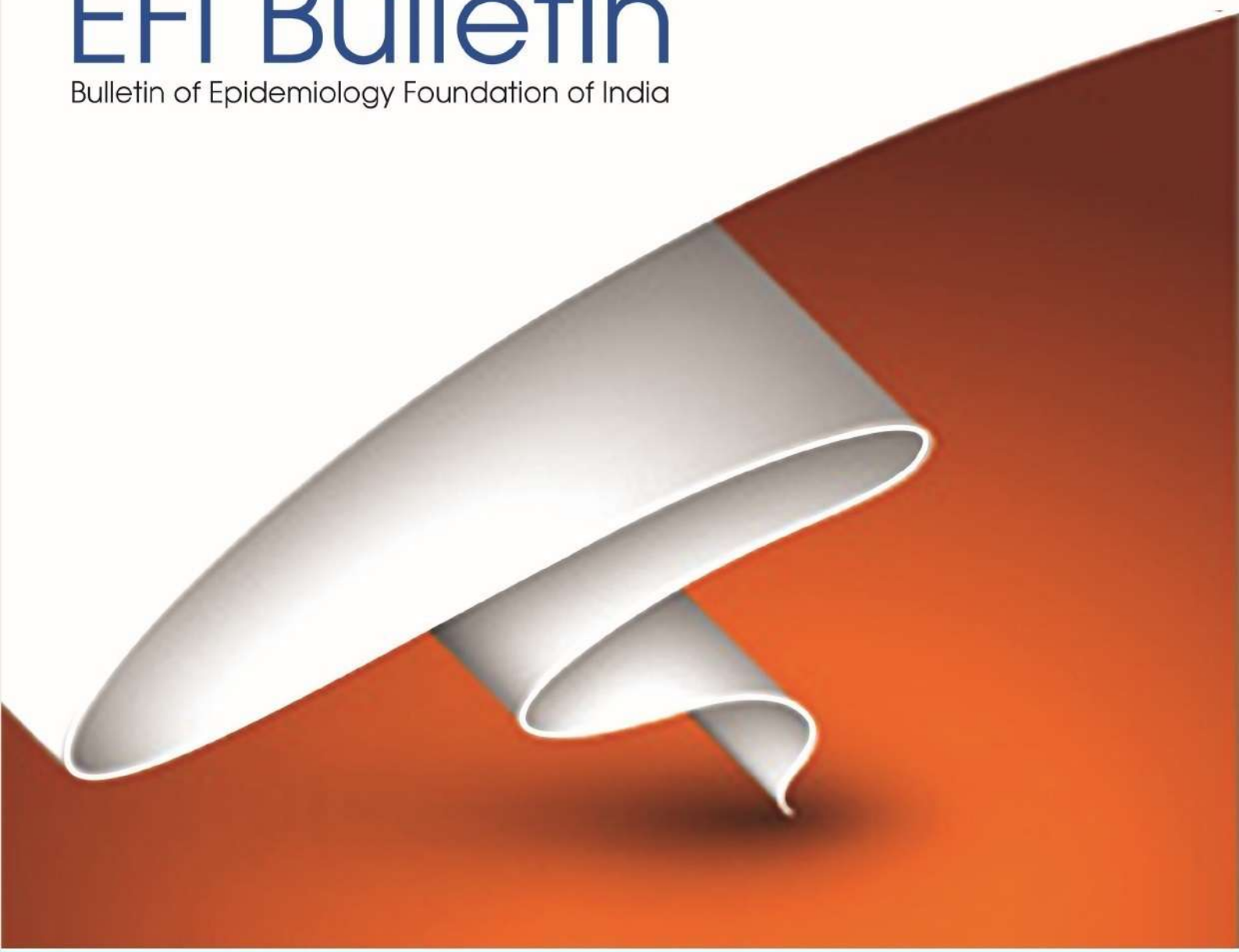
EFI Bulletin

Bulletin of Epidemiology Foundation of India



Epidemiology Foundation of India

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In this issue

Featured Articles

EFI Governing Body

Aims of EFI

To identify and promote areas of cooperation and understanding among researchers and like-minded organizations, individuals, scientific networks and other Governmental and Non-Governmental, National & International agencies which are contributing towards realizing the objectives of the Foundation.

Benefit of becoming a member of EFI

- Networking with renowned Epidemiology experts worldwide and partnership with Professional organizations in field of Epidemiology.
- Receiving announcements of EFI activities.
- Eligibility to receive travel scholarship / support for attending EFI sponsored courses / meeting.
- Reduced registration fees for attending EFI Training Courses, CME, Regional meeting and Annual Conference.
- Joint membership of International Epidemiological Association (IEA)

Types of members

- Life Memberships
- Annual Memberships
- Early Career Researcher: Epidemiologist / Scientist.

IEA joint memberships with EFI

Special rates for joint membership for regular member is 25 USD and for ECE is 10 USD do visit http://www.ieaweb.org/ for more details.

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Editorial Board

From the Editor

Hopefully, by now most of the members of EFI should already have registered with the countdown of days for the upcoming EFICON-22 at AIIMS Patna, during the first week of November. Ahead of that long-awaited opportunity for academic and personal interactions, we invite prospective presenters of oral as well poster papers to consider their full write-ups making worthy to be published in subsequent issues of EFI- Bulletin.

We feel happy that the regional event reporting has just began with PSGIMSR, Coimbatore's brief overview of an advance workshop on 'clinical epidemiology and biostatistics' held during August 1-12th, 2022. But would like to remind once again that several of our esteemed members are regularly being invited to various official and other prestigious academic forums including reputed TV channels for professional 'health-talks' and important deliberations on active topics including pandemic and endemics. Unfortunately, we miss such reporting due to lack of communication in sharing of such valuable information. It is an earnest appeal to please help us manage and properly organize the **'member news'** column with their professional achievements as well sharing the national & international news and events.

The Editorial by Dr R K Srivastava, former DGHS, MOHFW, and also being the Chair of MCI board of Governors, New Delhi, on **"Digital Health and Medical Statistics - A Transformational Challenge"** is of great interest. It opens-up an opportunity for the young-energetic fellows of EFI to be the leading partners in this sophisticated innovative endeavor.

This time in absence of any submissions for the CME column, I have to repeat continuing with some basic thoughts in research. Even though the President's corner write-up on certain recommendations on screening is an effort towards continuing education, we would love to have a few more articles on evaluation of diagnostic-screening tests. Such write-ups on screening with appropriate examples would be very helpful even at the cost of repetition. Simple but narrative discussions on Odds Ratio vs Relative Risk as well deliberations on other risks, ratios and proportions shall be continued. The confusion still prevails in understanding well the difference between efficiency, efficacy and effectiveness measures of the various health programmes. Specific contributions are invited for the future CME columns of the Bulletin.

Invariably there seem to be a lack of articles on non-communicable diseases as well on health and nutrition aspects. However, we have in this issue three important articles focused on 'Hepatitis-C'. Also, a study on Malaria in the UT of Puducherry and a cross-sectional study on investigating potential outbreaks during the large social and religious gatherings add value to this Bulletin. We are personally grateful to all the contributors for their voluntary efforts towards the timely submissions.

Members are encouraged to participate by recommending and sharing to the initiative of a dedicated column on 'Selected Abstracts in Evidenced based Epidemiology'. Even though, its first appearance in last issue was based on the selected communications of interest periodically sent out to the members by the President-EFI. Looking forward to continue our fruitful discussions during EFICON2022.

Ajit Sahai

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President's Corner

Screening recommendations require adequate consideration of its harms

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Screening for diseases seems like an intuitively obvious thing to do. Detecting a disease early on in its course and starting treatment would allow the disease to be contained before it becomes a problem. However, as it turns out, things are not so simple. As more nuances about the harms and benefits of screening come to light, many recommendations about disease screening are being reversed. It is clear that the downsides of screening are much less obvious than the upsides, and the benefits of disease screening can be affected by a number of factors. Included amongst these are the harms of screening, overdiagnosis, lead time bias and length time bias, all of which present major lacunae in screening literature and limit the benefits of screening. Unfortunately, these have not been widely acknowledged. In emphasizing only the benefits of screening and placing little emphasis on its harms, we may be doing a disservice to the population.

Overdiagnosis

To illustrate the problem of overdiagnosis, let us take into account the example of screening mammography. Many patients diagnosed with breast cancer on mammography are convinced that their lives were saved due to the cancer being detected earlier. This belief is corroborated by a lot of experts who have made strong statements about the benefits of aggressive mammography. While it may be true that lives are saved through screening mammography, a closer look at the data reveals where the controversy lies. Based on the meta-analysis by Nelson et al, in order to prevent one breast cancer death, about 1904 women aged 39 to 49, and 377 women aged 60 to 69, would need to be invited for screening.(1) Each woman's life is of incalculable value, and this would be acceptable if there were no harms associated with screening. But as it turns out, there are harms. One of the most important limitations of cancer screening is a phenomenon known as overdiagnosis. This happens when a screening test shows a lesion that in itself was never destined to cause a patient's death. For some cancers such as breast and prostate cancer, this is surprisingly common. According to a systematic assessment of breast cancer screening, for a 40- or 50-year-old woman undergoing 10 years of annual mammograms, about 19% of the cancers diagnosed would not have become clinically apparent without screening (overdiagnosis).(2) This means that for three women that clearly benefit as a result of screening, 104 will be over-diagnosed with breast cancer and will undergo treatments such as surgery, chemotherapy and radiotherapy for a disease that was never destined to cause harm. These are not benign treatments, and this is a very significant problem.(3) Treatment of an over diagnosed cancer subjects a patient to the harms of treatment without benefits, since the tumor would not have caused problems if undetected. Overdiagnosis is the Achilles heel of cancer screening. It is large problem for breast cancer, and an even larger problem for prostate cancer.(4)

False positives

Evidence suggests that among 10 000 women aged 50 years undergoing annual mammography for 10 years, approximately 6130 (95% CI, 5800-6470) will have at least one false-positive result.(5) According to the Breast Cancer Surveillance Consortium, the 10-year cumulative risk of at least one false-positive result is 61.3% for women starting screening at ages 40 or 50 years and 49.7% for women aged 66 to 74 years undergoing annual screening.(6)

False-positive results raise suspicion for breast cancer and instigate a cascade of further investigations, such as additional imaging or invasive biopsy, but do not result in a cancer diagnosis. It is important to acknowledge the psychosocial consequences of false positives (eg, anxiety, negative effect on sleep and behavior) in the period after their abnormal screening result until they were declared free of cancer suspicion. In a quantitative longitudinal study, 1, 6, 18, and 36 months after their screening, women who had false-positive screening results had significantly higher (worse) mean scores than women who had not screened positive on a validated questionnaire

specific to psychological consequences of breast cancer screening.(7)

Lead time bias and length time bias

There are several issues that make screening look better than it actually is. Survival, as measured from the time of diagnosis, may be increased not because patients live longer but because screening lengthens the time that the disease becomes known to the patient (lead-time bias). Furthermore, people whose disease is discovered by screening may appear to do better or live longer than patients whose disease presents clinically with symptoms because diseases that are destined to progress slowly, and have a better prognosis, are more amenable to being detected by screening (length-time bias).(8)

These are important reasons why observational studies on screening may be misleading. Conducting a randomized controlled trial to evaluate the benefits of a screening intervention presents a valuable solution to these problems. Randomisation can ensure balance between screened and unscreened populations, through equal distribution of the heterogeneity of cancers. Due to the problem of lead time bias described above, reporting of results in terms of survival time is misleading. An RCT can eliminate lead time bias by conducting analysis by intention to screen, and by measuring the outcome as overall mortality rather than as survival time.(9) However, If screening and interventions in the real world are not of the same quality as those in the trials, the benefits will be smaller and the harms will be greater than the ones calculated from trial data.

There are several other considerations as regards the issue of disease screening, such as healthy volunteer bias. From the societal perspective, there are opportunity costs and considerations of cost-effectiveness. At the end of the day, we have a responsibility to carefully consider all the ways screening can be beneficial or fail.

Counselling, a patient about screening presents an opportunity for shared decision making, where they must be made aware about the both the benefits and pitfalls of screening. Making recommendations about screening, whether for cancer, diabetes, hypertension, or any other disease, is a situation where the patient has not come with a problem, but we are informing them that they may be at risk and may need treatment. So the responsibility of being sure that we are doing people some good is way greater in the screening situation than in the diagnosis situation. Where the benefits and limitations present a close call, such as in the case of breast and prostate cancer, it may be circumspect to view screening as a personal choice, giving due credence to values and preferences of patients.

References

1. Nelson HD, Tyne K, Naik A, Bougatsos C, Chan BK, Humphrey L; U.S. Preventive Services Task Force. Screening for breast cancer: an update for the U.S. Preventive Services Task Force. Ann Intern Med. 2009;151(10):727-737.
2. Pace LE, Keating NL. A Systematic Assessment of Benefits and Risks to Guide Breast Cancer Screening Decisions. JAMA. 2014;311(13):1327–1335.
3. Independent UK Panel on Breast Cancer Screening. The benefits and harms of breast cancer screening: an independent review. Lancet. 2012;380(9855):1778-1786.
4. Etzioni R, Gulati R, Mallinger L, Mandelblatt J. Influence of study features and methods on overdiagnosis estimates in breast and prostate cancer screening. Ann Intern Med. 2013;158(11):831-838.
5. Hubbard RA, Kerlikowske K, Flowers CI, Yankaskas BC, Zhu W, Miglioretti DL. Cumulative probability of false-positive recall or biopsy recommendation after 10 years of screening mammography: a cohort study. Ann Intern Med. 2011;155(8):481-492.
6. Braithwaite D, Zhu W, Hubbard RA, et al; Breast Cancer Surveillance Consortium. Screening outcomes in older US women undergoing multiple mammograms in community practice: does interval, age, or comorbidity score affect tumor characteristics or false positive rates? J Natl Cancer Inst. 2013;105(5):334-341.
7. Brodersen J, Siersma VD. Long-term psychosocial consequences of falsepositive screening mammography. Ann Fam Med. 2013;11(2):106-115.
8. Guyatt, Gordon; Rennie, Drummond; Meade, Maureen O.; and Cook, Deborah J. Users Guides to the Medical Literature: Essentials of Evidence-Based Clinical Practice, Third Edition. New York: McGraw-Hill Education, 2014.
9. Bell KJ, Bossuyt P, Glasziou P, Irwig L. Assessment of changes to screening programmes: why randomisation is important. BMJ. 2015;350:h1566.

EDITORIAL

Digital Health and Medical Statistics- A Transformational Challenge

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A fast pace digital transformation is happening in the health sector of India after National Health Policy (2017). It is impacting medical care, health system, pharma research, medical devices, supply chain management and R&D with an unprecedented speed by the creation/application of big data, which helped digitally advanced countries in development of solutions for health problems, faced by system world over. With digital transformation of Indian health sector, India is being seen as potential market for sale of their wearables, platforms, dashboards, EHR platform, Tele-medicine system, SCM system, Hospital Management System and Health insurance system. However, GoI through its NDHM (2019) and AB:DM (2020) is parallelly developing its system to offshoot this challenge.

In old parlance of medical science, medical statistics as a subject was taught to doctors during their training and qualified teachers were appointed in Medical School for this purpose. Medical Statistics is conventionally defined as" science and art of dealing with numbers, used for collection, summarization, presentation, and analysis of data to get information on objective basis". So Medical statistics is also dealing with data, as digital health is using, and both consider it as information; the only difference is that in former, it is captured manually, hence slow, while in later, it is through computer, hence it is fast and since computation speed is doubling every 2 years (Moore's law); the storage, analysis, projection, prediction and analytic application is fast-tracking the development of digital solutions for health system.

In past, medical statistics had been used for medical R&D, population based studied, priority-setting exercise, validation of association amongst variables, risk assessment for diseases/disorders at individual and population level, comparative inter-state analysis of health indicators, monitoring and evaluation of health intervention/program at individual and population level, drug/vaccine development data analysis, Health Technology Assessment(HTA), Hospital Information & Management system, Inventory Control and Management System, Supply Chain Management System, Bill payment system, Insurance system etc. So, there were methods, professional and systems for it.

Now Digital Health System, build on the principle of Enterprise Architecture with goal of creation of district-level electronic data base, establishment of registries for diseases of public health importance and finally creating a Federated National Health Information Architecture (FNHIA) will be able to do it faster, safer, cheaper and easier in future. There are/ will be more App, Platform, Dashboard analytic software, which are/will be user-friendly, accurate, fast and safe. Its short time, in big country like India, it will be resulting in a Big Data Creation in health sector, which will be consistent with Metadata and Data Standards (MDDS) in health sector as a whole and in all its sub-segments. In simple words, all relevant STAKEHOLDERS like pharma, medical college/teachers, research and development, hospitals and labs system, health care services(population/individual care) , all SYSTEMs like Allopathy, AYUSH, 3-tier public health system etc., all Health Human Resource(HHR) like service providers/researcher/allied health professional and all Clinical Establishments like clinic, polyclinic, hospital(private/public), labs/imaging center etc. ; will be connected through a digital network to generate this Big Data, which will be utilized for development and application of various digital solution within health care system of India. It is called Digital Transformation.

Like medical statistical system, digital system also derives all its relevant information(data) from individuals/population/facility as primary data and subject them to analysis by using different tools (statistical or digital), so as to create evidences to be used in health care /research.

Like statistical system, in digital system also, data are collected from multiple sources and presented in different forms(tables/graphs), which are used to generate useful information after analysis and interpretation- the only difference is that in traditional statistics, it is done by medical statistician/biostatistical expert, while in later, mostly by computer/digital health expert. However digital system uses different terminologies like data, datasets, data mining, data integration, data analytics, platform, dashboard, the world of data

(WOD), world of evidences (WOE) etc., which are also used in our old statistics by different names.

In both the system, the data can be quantitative (numbers) or qualitative (names/orders). Quantitative data can be discrete (number of patients/beds) od continuous (Hb recording in pregnant ladies at each ANC), while qualitative data can be Y/N, Black/White, M/F or ordinal (Grade of Tumor). Data summarization convert them into percentile, quartile, measures of central tendencies (mean, median & mode), measures of dispersion (range, variance, SD, SE, co-officiant of variation)

So, the operational value of digital and medical statistics will remain more or less same in health sector, but speed, accuracy and spectrum/scope will give digital data system a superior edge.

Till now, these data were being used for service delivery, medical education, research and development. Ministry of health has got a statistical division, headed by a SAG/HAG level chief statistician, who operate through 5-6 statistical assistants. Similarly, ICMR has a National Institute of Medical Statistics (NIMS), headed by a Statistician, who used to provide expertise in data analysis science for all R & D activities of ICMR.

Digital system came in after the release of National Health Policy (2016), when MOHFW created National Digital Health Mission (NDHM) in 2019 under National Health Authority, on the basis of expert's report known as National Digital Health Blueprint (NDHB) of 2018.Finally, AB: DM is created under NDHM with a separate Mission Director of Additional Secretary rank and a dedicated team of staff and consultants.

With above development, 2 verticals were created under MOHFW- one under NHM which was generating, compiling, analyzing data through its statistical division and other was under NHA, which are doing same by digital means under AB:DM, which is gradually building its own state system vertically and harmonizing with available program like IDSP horizontally. The weight is shifted towards digital system, because NHP laid significant emphasis on leveraging digital technologies for enhancing the efficiencies of delivery of healthcare services. Existing system of deploying technologies was fragmented, hence NHP set specific goal for developing digital health on principle of Enterprise Architecture-which simply means as to whatever system (hybrid cloud, private cloud or public cloud), it is going to use in its blueprint of organization of a national IT system, so as to do 4 main jobs of 1. Analysis 2. Design 3, Planning and 4. Implementation of all information derived from big health data for betterment of health system. in real-time and seamlessly Its goals included creation of district level electronic data bases, creation of registries for all diseases of public health importance and establishing "Federated National Health Information Architecture" (FNHIA). The purpose was to roll out and link systems across public and private providers at state/central level, consistent with Meta data and Data Standards (MDDS). After doing a pilot in 6 UTs, NHA created UID/ABHA, TM guidelines, PHR/EHR, e-pharmacy and a Unified Health Interphase (UHI) as connector of all data base.

With this fast-track development, it is evident that the future is tilting towards digital data system. It can be stand alone or hybrid, where digital and manual data base system identify their independent roles/operation and a digital platform integrate them to create big data base, which can go into chosen cloud system for analysis, design, planning and implementation integrating digital solution for betterment of health care delivery and research. It is time for Indian Statisticians and statistics institutes to understand, learn, use digital system with in their own statistical system.

Two major barriers are visible in India. First, most of statistical organization do not want to learn and change. Second is present digital system is still operating in silos.

No readymade solution is available today, but it is expected that this digital transformation will soon enter into maturation stage, when the old statistical model will start realizing usefulness of digital solution.

Organization like Epidemiology Foundation of India can play an import role in maturation of this process.

Following role are suggested:

1. Engaging with NHA and AB:DM as professional body in digital transformation
2. Assessing the strategy/action plan under AB: DM and sharing professionally vetted White Papers on related issues
3. Assisting the POA of center/state government under AB:DM through partnership/or as technical support agency

4. Strengthening Government action by voluntary responsibility sharing on issues like Electronic Health Record, Clinical Digital Support System, Digital Health Information and Management System.
5. Pro-bono M&E of POA of NHA for digital transformation /outcome and impact assessment

In order to worthiness of EFI, certain challenges need to be clearly understood by us, so that it can prepare to face these challenges fast and full.

First challenge is that EFI need to realize that India is number 2 contributor to big data globally-cutting across all the sectors and not limiting to health data. In 2018, the big data generated globally was 2.5 quintillion /day, which was projected to be 463 exabytes by 2025.India share more than 1/7 of world population, so its contribution can be estimated proportionately. Health big data is just 1/10th of total big data of India. The challenge is to realize that India is generating huge big data in health everyday and most of it is wasted. Mind you, big data only means unmanageable data, which can be structured, unstructured and semi-structured. Health care system generate it day in and day out from machine, human resource, OPD/IPD/Diagnostic services, hospitals, medical colleges medical records, pharmacy, business transaction, files, publications, registries etc. Volume/velocity and variety are three pillars, which operate from 4 variables-volatility/vulnerability/value and validity. Medical statistics had been operating on the same pillars and variables.

Second challenge is Knowledge Creation for Big data and its epidemiological value. EPI can create a Strategic Planning Group (SPG) to create white paper, POA for EPI for next 3 years for Training/Capacity Building and operative model creation for PSM department in Medical/colleges and lastly signing MoU with major players like IIIT, IIHMR, IIT, BITS Pilani and AI based industry organization to apply for project/pilot which are increasingly floated online by WHO/Microsoft/BMJF/JHI, etc.

Third challenge is to create a partnership with the State/Center so that EPI value and contribution for ABDM is established. It needs entry as a professional body in the National Academy of Medical Sciences, National board of Examination, and National Medical Commission.

Fourth challenge is to create online e-training program, which is modular in nature and credit based for faculty development in medical colleges and public health training institution.

Fifth and last challenge is that EFI need to fan out to states with state chapter/regional chapter.

Easier would be to fan out as regional chapter through AIIMS like institution, which will act as extended arm of EPI for first 3 years and thereafter as independent state chapter, if it can enroll prescribed membership strength. It is necessary, because 1-4 challenges can only be met if EFI has a national network

Finally, EFI can play catalytic role in digital transformation in health sector if we plan in advance and act fast. It is also possible that EFI is recognized as national partner by AD:DM, NMC, NBE and digital Health Industry, if we together can showcase our worth seamlessly for coming 3 years

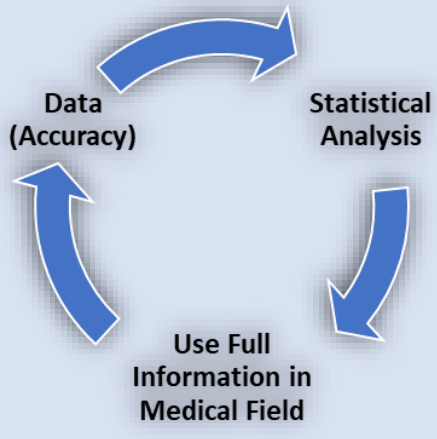

Figure 1

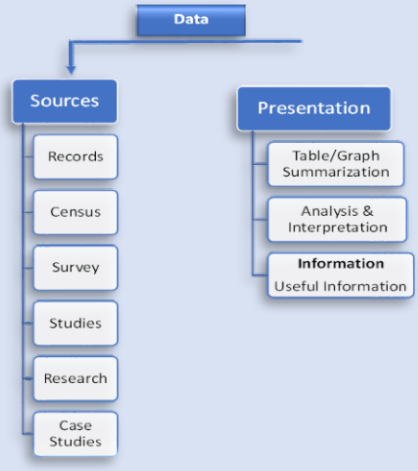

Figure 2

CME

The Foundations in Research - II – Some Basic Thoughts

(Continued from EFI Bulletin Vol 2 (4))

Dr Ajit Sahai

Validity (Statistical): One of the foremost concepts invariably used in scientific endeavours is the validity of the measurement instruments or scales, questionnaires or interview schedules etc.; that are frequently deployed for evaluation studies or to examine the applicability of tests especially in the fields of psychology, sociology and education. Similarly, the requirements in practicing research-methodology are the concepts of validity of tools, techniques, methods (including design and sampling procedures) and even to say the skills to be used to achieve the specific objectives of that focused research.

The simple meaning of the word valid derived from the Latin term 'validus' is 'strong' or 'worthy'. But various disciplines in science have attempted to decode it further in their own ways or to define the term 'strong' or 'valid' by deriving a wide-spectrum concepts such as; Internal & external validity; face & predictive validity; criterion & content validity; construct & concurrent validity; ecological & population validity; and so on so forth.

However, our initial focus should rather be limited to understanding the fundamental concepts of validity involved in biometrics that frequently deploy a variety of tools and techniques of measurements in experimentations for scientific observations or for validating and evaluating the effect of interventions and actions. Once these concepts are properly understood should easily be applied to a variety of situations encountered in the science of research. We shall agree to the fact that with an objective to measure the weight of an individual subject or object the use of a BP instrument is not at all valid instead the use of a weighing machine would certainly be valid. But we may require simultaneously weighing machines of varied precision to weigh an elephant or an adult human being or to monitor the growth of human foetus or a neonate and similarly still higher precision may be needed for weighing jewels of silver or gold or diamond or platinum and still highly sophisticated and precise equipment is a must to know the weight of an atom or electron of an element and so on.

Therefore, it is quite clear that a weighing machine with a fixed calibration or limited sensitivty and precision can never be universal or so versatile to serve a variety of weighing objectives. The above situations do make it clear that even for measuring weight there cannot be something like an absolute rather relative validity concept must be appreciated.

Even-though the concept of 'objective' validity should be agreed upon, its applications in performing on a variety of specific tasks would certainly invite 'subjectivity' under compulsions of varied understanding. This is bound to happen, as the generous definition of the validity suggests that any specific performance (of a tool or definition) to be valid should ensure to achieve what it was **intended or purported to achieve**. But finally this crucial decision on its choice of recruitment for a specific task and implied verification of the end result or achievement has to be left to the subjectivity of the discrete wisdom of the investigator.

An old but well circulated and popular example used in explaining the concept of validity is creating a variety of scenarios (**Figure-1**) based on (usually 5 to 10) **15 rounds** of shooting exercise of a targeted "**bull's eye**". That also is used in deriving the understanding of certain other important quality qualifying terms of interest like; Error & Bias, Consistency, Reliability, Accuracy, Precision and Sensitivity etc. that are strongly associated with the concept of Validity.

Is there anything wrong if we claim that in all the four Quadrants (Q) - A, B, C & D of Figure -1, each set of fifteen shots conform to the norms of **validity**? Of course, that is depending on the separate criteria defined for each quadrant each time i.e. either innermost (red) for - Q-B; middle (yellow) for - Q-D or the outer circles (yellow & green) for - Qs-A & C (the face validity). So taking a cue from the above example of using weighing machines of different calibrations the concept of validity has been more focused or narrowed down in Q-B, whereas, less in Q-D, and still left lose for Qs-A & C matching well with objectives.

While we should agree that not even a single quality qualifying terms were compromised or sacrificed in Q-B; Why objectionable become the use of terms like errorless, unbiased and consistent & reliable; or even accurate & precise, if these qualities are performing well in their respective zones predefined, as depicted in Q-A, C and D? In fact here

should begin the debate on the extent of objectivity and subjectivity involved in decision-making with reference to the prefixed criteria.

In contrast, however, in **Figure –2** in all the four Quadrants, A, B, C, & D, the concept of validity is not at all visible but systematic **errors** & **bias** are prevailing throughout even for a lose criteria of allowing shooting at least within the outermost green circle, as in each Quadrant all the fifteen shots consistently go beyond the prescribed boundary. Presuming that the recruitments of the shooter as well the shooting equipment were ensured to be valid before the performance, is it not a fit case of **validity** being compromised for the sake of a **strong bias**? Is it not happening with ongoing advanced research? Mostly, designing of strict research protocols are ensured in the beginning but frequently get loose or diluted during their implementation part to lead a risk for false interpretations of results and sometimes even to wrong conclusions?

While **Figure-2** demonstrates an extreme example of violation of validity for the purpose of easy explanations and understanding, but we may notice that quite frequently the researchers choose to construct the mixed-models with borderline situations to plead their own bias either by mistake or sometimes other way round.

Errors and Bias: Is it a true statement that no experimentation or observation or measurement can either ever be totally free from errors or can always escape from being called biased? Yes, it may probably prove to be true and realized, if and only if, the proper scrutiny to discover that error or bias is subjected to a high order sensitivity. In other words, the undetected errors, if any in question, would certainly be identified depending upon the sensitivity and precision of the scrutiny tool.

Therefore, it is warranted that the suitability of choosing a microscopic or a Nano-metric or a Pico-metric sensitive scale should be predetermined before its deployment for a critical scrutiny. However, to define it still more clearly, we must understand that even if the observations or measurements are valid, but they do show any lack in desired precision and accuracy, irrespective of the magnitude or quantity or the direction of deviation from the intended measurement should be called errors. Furthermore, one sided repeated **errors** or systematic errors are called **bias**.

In accordance with the above definitions, we conclude that bias is taking place for sure in Quadrants C & D of Figure-2, along with the quality qualifying parameters of consistency and reliability. But we also observe that shooting is once again biased in Quadrants A & B, as all the shots go systematically beyond the outermost green circle; not even a single shot is within red, yellow or green zones. While in later cases the consistency and reliability is lost as the shots are scattered, why not accept the fact that an overall strong bias is in favour of shooting beyond the outermost green circle prevailing in all the four Quadrants, even at the cost of compromising validity? If this overall peculiar shooting is just to be attributed to the error term and not as strongly biased, at least a few shots should have hit somewhere else touching the inner areas of the three circles demanding varied precision and accuracy. This happening repeatedly and deliberately not hitting the targets is a more serious bias than what we have been looking for. It is certainly not the case of hitting a target by a gold-smith versus iron-smith's hammer or crude versus refined actions. Also, it is not the gap between communication and understanding. Rather sometimes it may be deliberate and purposeful for claiming the same is being delivered but with entirely a different or biased objective.

Capturing these motivated errors and biases or better to call them '**noise'**, performed intelligently beyond the set objectives is also equally important considering their consistent prevalence within a large but specific domain; whether virtual or real. Do we notice it happening with everyday science around us? Is it an intelligent intellectual mistake or brainwash? Although many of us do claim to be pure scientists respecting ethical research, after all we are human beings living with our own inherent biases that are 'but natural' and bound to be reflected in our research outputs as well.

Now let us come out of the "bull's eye" scenarios created by us and try to examine an overall bias sometimes sitting in our subconscious mind that cannot be helped out. We understand well that the science of religion and faith is not always to match with principles of modern science, mainly because the two are independently logical and valid but biased to their own domains of philosophical or scientific reasoning. In such a case both bring undesired 'noise' in the functioning of each other. Similarly, the pharmaceuticals and drugs practiced in Allopathic medical sciences in contrast to the treating preparations prescribed with their own

spiritual and psychological touch in other systems of medicines like AYUSH (Ayurveda, Yoga, Unani, Siddha and Homeopathy), and Naturopathy including several other indigenous systems of healing with faith may once again be scientific, logically valid, but biased to their own independent domains of wisdom. None of these systems may be error free or perfect but the comparisons of the bias of any two systems may neither be valid nor feasible at all. Usually the basic philosophy of one system is not understood by the other and therefore, working with divergent distancing is preferred considering that they cannot be complementary to each other. Only a few systems respect each other having something in common and prefer to work together in convergence.

The above discussions are summarized to caution that each research process or scientific thinking has the right to claim its own validity and to have its own bias. These overall generalized biases and the question of their validity prevailing around us should be differentiated from the bias and the validity of the tools used in biometrics to deal with specific scenarios satisfying well our logic and reasoning compartments. Realizing that even-though there exists a very thin difference between these scientific streams of thinking, in practice extra care is needed into identifying and differentiating their simultaneous but silent happening that is quite likely to go unnoticed frequently.

We experience these generalized as well specific errors and biases while preparing and implementing research protocols, collecting data, analysing and transforming data into meaningful results, and also at the stage of struggling with inferential statistics to derive reliable conclusions, or claiming good estimators in statistics, and so on. There exist **hundreds of errors and biases** specific to statistics in research, design & sampling, interpretation & decision-making, not only limited to 'epidemiology', 'medicine & health', rather more frequently used in 'Agriculture & Forestry', 'Ecology & Environment' and 'Biology & Genetics', as well for a variety of applied research and for many more other scientific activities. However, our objective here is not to enlist a series of errors and biases frequently encountered by the science of biometrics. But we must identify and recognize them for their elimination as far as possible or to control and minimize their effects. For example, selection or allocation biases, measurement biases, instrumental errors & biases, inter & intra investigator or observer's biases, misclassification biases and so on so forth, are some of the frequently encountered biases. We know well that the standardization of techniques and procedures, blinding, randomization, replication, selection of appropriate controls and to a great extent the experimental study designs do help us to overcome some of them.

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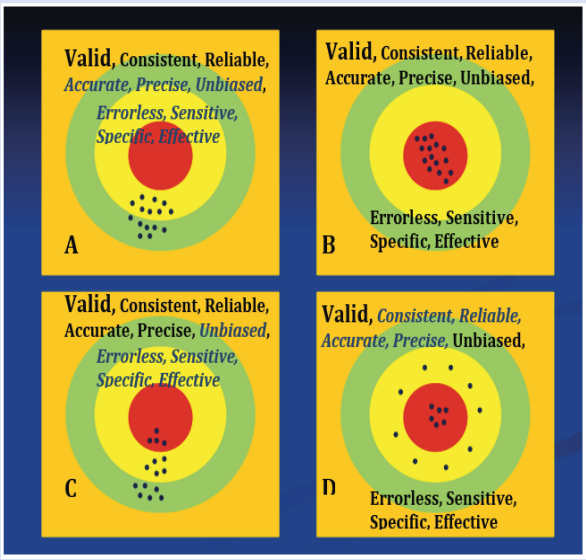

Figure 1

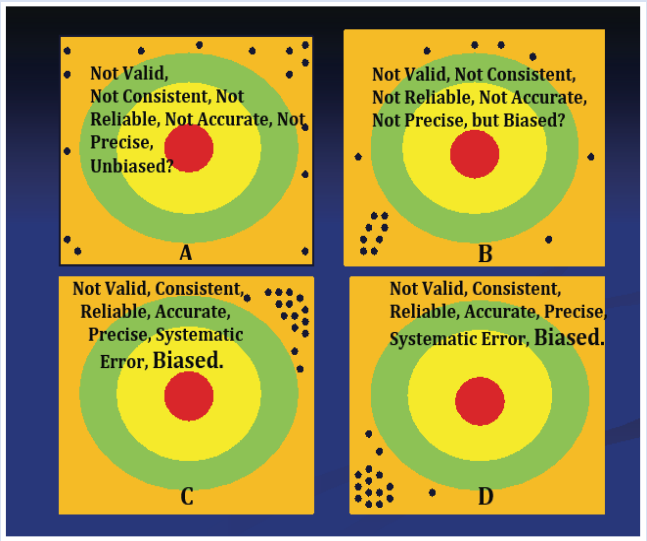

Figure 2

Communicable Diseases

A Study of Malaria in the Union Territory (U.T.) of Puducherry

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Abstract
Background: To the best knowledge of the author, there is no available literature on the status of Malaria in the U.T. of Puducherry. Hence the preparation of this document. **Objectives**: To find out the parameters of Malaria in the U.T. of Puducherry till as recently as possible. **Methods**: By studying the documents prepared by the National Vector Borne Disease Control Programme (NVBDCP), the website of the National Health Mission (NHM), Puducherry under which the State NVBDCP functions and an internet search. **Results**: It is seen that the Annual Parasite Incidence (API) of Malaria in the U.T. of Puducherry had come down to the very low level of 0.04 in 2018 and that there was only 1 imported case of Malaria during 2021 (up to 29th April). **Conclusions**: The U.T. of Puducherry is very close to achieving Malaria-elimination goals.

Keywords: Malaria, Puducherry, API, NVBDCP, WHO

Introduction
The U.T. of Puducherry lies in the southern part of India. It consists of four geographically unconnected districts. Puducherry district and Karaikal district are bounded by Tamil Nadu. Yanam district is enclosed by Andhra Pradesh while Mahe district is enclosed by Kerala. (**Figure 1**)

Material & Methods
The study design included analysis of the annual reports of the Malaria Division of the National Vector Borne Disease Control Programme (NVBDCP), a study of the website of the National Health Mission (NHM), Puducherry under which the State NVBDCP functions and an internet search.

Results
According to the most recent data available on the NVBDCP website (data for 2018), the API for the U.T. of Puducherry was 0.04[2]. It's comparison with the API from 2017 can be seen from the following (**Table 1)**

Thus, it is seen that the API in 2018 was the same as that seen in 2017.

In 2018, the API was not uniform throughout the U.T. but varied between the districts. This can be seen from the following (**Table 2)**

A study of the NHM Puducherry website was not useful because the data on Malaria there pertained to the years 2010 till 2015 and hence was not referred to.4

An internet search revealed the following information on Malaria cases in the U.T. of Puducherry during 2020 and 2021 and is shown in the following (**Table 3)**

Discussion
Beginning in 2018, there has been a decline in the incidence of Malaria in the U.T. of Puducherry.
In 2016, the Government of India adopted a framework for Malaria Elimination in India covering the period 2016 – 2030.[6] This was based on WHO's Global Technical Strategy for Malaria covering the period 2016 – 2030 which was adopted in 2015 and updated in 2021.[7]
The aim is to reach zero Malaria cases by 2027 and then wait for three years before WHO can grant Malaria-free status certification. It is already nearly the middle of 2022 and India is about to reach the halfway mark of the period from 2016 to 2027.

Conclusion
Although the U.T. of Puducherry did not reach zero Malaria cases in 2021, it did reach a figure of 1 case during that year. Therefore, it is a good candidate for being the first administrative jurisdiction in the country close to being able to achieve Malaria elimination goals.

References
1. Map of U.T. of Puducherry. Available from https://censusindia.gov.in/nada/index.php/catalog/43 Accessed on 25 September 2022.
2. Government of India. Annual Report of National Vector-Borne Disease Control Programme 2018. Available from: https://nvbdcp.gov.in/Doc/Annual-Report-2018.pdf Accessed on 25 September 2022.
3. Government of India. Annual Report of National Vector-Borne Disease Control Programme 2017. Available at

https://nvbdcp.gov.in/Doc/Annual-Report-2017.pdf Accessed on 25 September 2022.
4. Government of Puducherry. National Health Mission. Available at https://nhmpuducherry.org.in/WebResources/html_pdf/subpages/22.pdf Accessed on 25 September 2022.
5. Government of India. National Framework for Malaria Elimination in India 2016 – 2030. Available at https://nvbdcp.gov.in/WriteReadData/l892s/National-framework-for-malaria-elimination-in-India-2016%E2%80%932030.pdf Accessed on 25 September 2022.
6. World Health Organization. Global Technical Strategy for Malaria 2016 – 2030. Available at https://www.who.int/publications/i/item/9789240031357 Accessed on 25 September 2022.
7. https://www.thehindu.com/news/cities/puducherry/health-dept-renews-mission-to-achieve-zero-malaria-amid-a-decline-in-cases/article34434731.ece Accessed on 25 September 2022.

Table 1. API of the U.T. of Puducherry, 2017 and 2018

U.T.	Year	
	2017	2018
Puducherry	0.04	0.04

[Sources:(2) and (3)]

Table 2. API of the Districts of the U.T. of Puducherry, 2018

S. No.	District	API
1	Puducherry	0.04
2	Karaikal	0.01
3	Mahe	0.02
4	Yanam	0.01
U.T.	PUDUCHERRY	0.04

[Source:(2)]

Table 3. Data on Malaria Cases in the U.T. of Puducherry, 2020 and 2021

Reference Period	Number of Malaria Cases	
	Indigenous	Imported
2020	7	8
2021 (till 29th April)	0	1

[Sources: (5)]

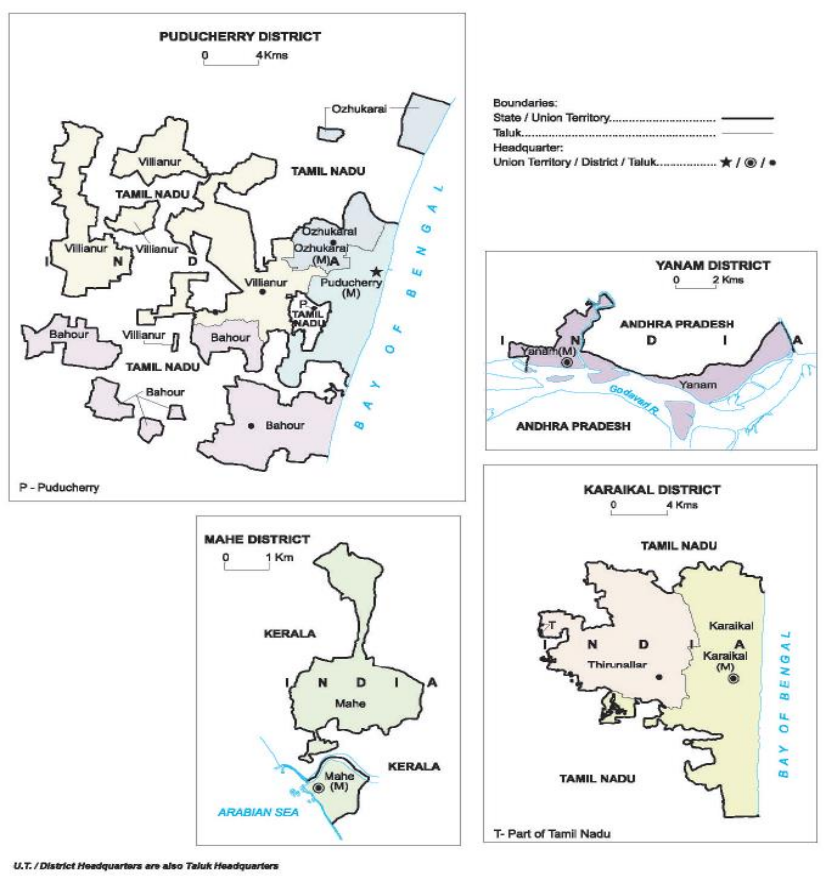

Figure 1 Map of U.T. of Puducherry [Source: (1)]

Recent Advances in Prevention of Hepatitis C

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Viral hepatitis is an entrenched threat to individual and community health in many parts of the world. Five hepatotropic viruses namely hepatitis A to E, are responsible for majority of hepatitis cases. Hepatitis A, B and E infection results in acute hepatitis whereas HBV and HCV culminate in chronic hepatitis.

In 2015, viral hepatitis led to 1.34 million deaths, a number commensurate to tuberculosis and HIV related mortality. Out of total viral hepatitis related mortality 96 % was due to chronic HBV and HCV infection whereas HAV and HEV infections accounted for 0.8% and 3.3% deaths, respectively. (1) WHO estimates that in 2015, 3.5% of the world population, were living with chronic HBV infection whereas 1% with HCV infection, out of this 1.75 million new HCV cases were reported in 2015 alone.(1)

Mortality from viral hepatitis has increased by 22% since 2000 to 2015. To halt this rising trend and eliminate viral hepatitis as a public health threat, in 2016, the World Health Assembly (WHA) approved a global strategy which targeted reduction of incidence of viral hepatitis by 90% and reduction of mortality by 65% by 2030.(1)

To combat hepatitis C as a public health threat, several evidence-based strategies has been developed in recent times, targeting to boost the cofactors that cease the transmission; promotes treatment uptake and compliance and halts the progression of HCV infection to end stage liver disease especially in populations at risk.

Availability of card based rapid diagnostic HCV antibody test and confirmatory viral load test along with introduction of curative, short-course direct-acting antiviral (DAA) therapy in 2014 has made early diagnosis and cure attainable. Introduction of evidence-based WHO guidelines for straightforward public health approach for HCV testing and treatment along with recommendations for a treat-all approach regardless of disease stage utilizing a few pan-genotypic DAA regime has scaled-up of testing, treatment and cure. (2,3,4,5)
Safe injection practices in health-care settings with increasing use of auto-disabled syringes and harm reduction for People Who Inject Drug (PWID) is vital in halting HCV transmission. Based on a modelled estimate, in 63% of the countries worldwide new HCV infections are occurring mainly through unsafe health-care procedures and injection drug abuse; 31% of countries have more than 90% of their new infections among PWIDand 6% of countries were estimated to have more than 90% of new infections arising in health-care settings (6)

An Egyptian study has demonstrated cost-effectiveness of introducing the safety-engineered syringe (SES) to reduce hepatitis C burden as a result of unsafe injection practices in healthcare facilities. SES introduction as a preventive strategy has resulted in improved quality-adjusted life-years and reduced costs. (7)

Syringe Service Programs (SSP), Medications for Opioid Use Disorder (MOUD), and the SSP in combination with MOUD are evidence based cost-effective as well as cost-saving harm-reduction strategies in PWID-HCV subgroup. (8)

Integration of HCV testing and DAA treatment services with treatment sites providing harm reduction services, prison and community clinics along with task shifting from specialist to trained primary care physicians has shown to increase linkage to care, treatment and cure rate. (9)

In July 2021, WHO released HCV Self Testing (HSVST) guidelines which recommends HCVST as an additional approach to HCV testing services. Various studies across the world have shown that people are willing and able to perform HCVST with minimal support, this approach is acceptable and feasible in a range of populations and settings, it has the potential to increase equity by reaching those who may not otherwise test, HCVST may cost more per diagnosis as compared to facility-based testing, nonetheless more cases would be diagnosed. (10)

Overall, to achieve hepatitis elimination targets by 2030, additional resources are needed to make these innovations widely available. Region-specific strategies should be cure based on regional epidemiology and supported by sufficient resources for implementation.

References

1. World Health Organization. WHO Global Hepatitis Report. 2017.
2. WHO. Global report on access to hepatitis C treatment: focus on overcoming barriers. October, 2016. https://apps.who.int/iris/ handle/10665/ 250625 (accessed 25 September 2022).
3. Easterbrook PJ, WHO Guidelines Development Group. Who to test and how to test for chronic hepatitis C infection—2016 WHO testing guidance for low- and middle-income countries. J Hepatol 2016; 65 (suppl): S46–66.
4. WHO. Guidelines on hepatitis B and C testing. February, 2017. https://www.who.int/hepatitis/ publications/guidelines-hepatitis-cb-testing/en (accessed on 25 September 2022).
5. WHO. Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection. July, 2018. https://www. who.int/hepatitis/publications/hepatitis-c-guidelines-2018/en (accessed on 25 September 2022).
6. Trickey A, Fraser H, Lim AG, Peacock A, Colledge S, Walker JG et al. The contribution of injection drug use to hepatitis C virus transmission globally, regionally, and at country level: a modelling study. Lancet Gastroenterol Hepatol. 2019;4(6):435–44.
7. Mostafa A., El-Sayed M. H., El Kassas, M. Elhamamsy, M. &Elsisi, G. H. Safety-Engineered Syringes: An Intervention to Decrease Hepatitis C Burden in Developing Countries-A Cost-Effectiveness Analysis From Egypt. Value in health regional issues. 2019;19:51–58. https://doi.org/10.1016/j.vhri.2018.11.009
8. Ijioma, S. C., Pontinha, V. M., Holdford, D. A., & Carroll, N. V. Cost-effectiveness of syringe service programs, medications for opioid use disorder, and combination programs in hepatitis C harm reduction among opioid injection drug users: a public payer perspective using a decision tree. Journal of managed care & specialty pharmacy. 2021;27(2), 137–146. https://doi.org/10.18553/jmcp.2021.27.2.137
9. Oru E., Trickey A., Shirali R., Kanters S., Easterbrook P. Decentralisation, integration, and task-shifting in hepatitis C virus infection testing and treatment: a global systematic review and meta-analysis. Lancet Glob Health 2021;9(4):e431–45
10. WHO. Recommendations and guidance on Hepatitis C virus self-testing. July, 2021. https://www.who.int/publications/i/item/9789240 031128.

Moving towards the elimination of HCV from India: challenges and way forward

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Viral hepatitis is one of the most devastating diseases in this world, accounting for more than 350 million population infected and approximately 1.1 million deaths globally (as per 2019 WHO data). Following its discovery as Non-A /Non-B hepatitis in 1975, the virus was identified as hepatitis C virus (HCV) in 1989. In 2020, Drs. Harvey J. Alter, Michael Houghton and Charles M. Rice were rewarded with the Nobel Prize for "the discovery of HCV"1. During the past 50 years, remarkable achievements have been made in treating HCV infection: it has changed from being a life-threatening chronic disease to being curable.(1) Globally, we are looking for the elimination of HCV by 2030. Hepatitis C is known to be one of the fastest viral diseases to be identified and cured and, to date, remains the only chronic viral illness that can be completely cured.(2) The discovery of direct-acting antivirals (DAA) for the treatment of HCV has been a game changer with a success rate of > 95%.(3) In 2016, WHO proposed an initial roadmap to eliminate Viral Hepatitis as a public health threat. In 2018, on the occasion of World Hepatitis Day, National Viral Hepatitis Control Program (NVHCP) was launched by the Government of India with salient goals to overall achieve a reduction in new cases by 90% and mortality by 65% by 2030.(4)

Is the elimination of HCV achievable by 2030? What is the status in India and its challenges?

NVHCP has been one of the most critical successes in initiating action toward eliminating HCV from India. NVHCP will be implemented in each state through the State Health Mission program. Complete diagnostics (serological and molecular testing) for both HCV and HBV will be provided free of cost to the patients. Despite this, hesitancy to enrol in the program is due to lack of awareness, limited centres and delayed implementation in many states due to the ongoing COVID-19 pandemic. Supportive and pre-treatment investigations are not accessible in the program, and management costs for complicated cases are not included. Viral load is accessible only at the State Laboratories; hence time to get the viral load results for the initiation of treatment is slightly prolonged. This causes the loss of patients from the cascade of care. Therefore, to successfully eliminate HCV, we really must focus on decentralized testing approaches, so that patient retention in the cascade of care till the cure is maintained. In Delhi, a pilot study was done to compare three decentralized approaches to testing and treating HCV patients through district hospitals, polyclinics and organizing camps. It was found that the most cost-effective strategy is the ONE STOP SHOP i.e. service care model where all the facilities are provided simultaneously to the patient with a faster report turnaround time for HCV RNA within 24 hours.(5) Decentralized HCV testing and diagnosis in Delhi resulted in significantly higher seropositivity and retention compared to other places where patients were referred for viral load testing, underlining the importance of decentralized HCV testing in low-resource settings.

The availability of generic DAA drugs in our country has substantially reduced the overall cost of treatment for HCV. Still, there are other costs the patient has to bear i.e., pre-treatment investigations and management costs for the complications. All this should also be provided free to the patient to eliminate HCV successfully.

Geographical mapping of the disease has been done in India, but ambiguity still exists regarding the epidemiology and prevalence in less than 15 years and more than 60 years.(6) People older than 60 should be a top priority in screening for HCV. Accessibility to all geographical areas is one of the bottlenecks, especially potential HCV "hotspots", geographic HCV clusters. Escalating the efforts to identify such hotspots is an effective way to reduce overall HCV transmission.

Another essential point in HCV management is monitoring adherence to DAA therapy. Most treatment failure, i.e., non-attainment of sustained virological response (SVR), is due to giving gaps in the medicines. Improper intake of antivirals will also lead to the development of drug-resistant mutants as HCV is an RNA virus prone to error-prone replication and mutations. The studies have shown that the frequency of occurrence of resistance-associated substitutions (RAS) has increased from its natural prevalence.(7) At present due to less use of DAA, the problem of resistance is not seen in our country. Still, continuous surveillance for drug

resistance in circulating genotypes should be done once there is rampant use of DAA. Treatment options should change accordingly if we have to eliminate the infection.(8,9)

Both reinfection (infection with a different viral strain after SVR) and relapse (occurrence of infection with a similar strain before attaining SVR) are reported in HCV infection. Therefore, follow-up of patients after attaining SVR and counselling related to lifestyle modifications and behavioural changes is essential, especially in Persons Who Inject Drugs (PWIDs). Follow-up visits during and after post-anti-HCV treatment should be made to assess the efficiency of treatment outcomes and late HCV relapse, if any. A significant concern is the occurrence of Hepatocellular carcinoma (HCC) even after total viral clearance. This is usually in older patients and patients with cirrhosis. Thus, screening for infection in asymptomatic and early treatment initiation will help preserve healthy condition of the liver and prevent HCC occurrence.

Last but not the least, all viral infections tend to come back if there is no host immunity. The most significant unmet medical need in HCV is a prophylactic vaccine. In developed countries, most new HCV infections occur in PWIDs, and even a partially effective vaccine would substantially lower the overall incidence of infection. Emerging data indicate that individuals cured with DAAs remain susceptible to reinfection and viral persistence. The recent surge in zoonotic monkeypox virus among humans has made scientists think that even after eradicating a virus, another similar animal virus can cause human infections. Apart from HCV, in the genus hepacivirus, many more zoonotic hepaciviruses are present; this underscores the importance of a prophylactic vaccine against HCV, which might offer protection in case, any cross-species transmission of hepaciviruses occurs.

HCV elimination in India by 2030 is difficult but possible. Mass awareness in public regarding preventive and treatment options for HCV is needed. Utilize decentralized testing and treatment model for retaining patients in the cascade of care, and extensive research toward HCV vaccine development is imperative.

References

1. Ghany MG, Lok ASF, Dienstag JL, Feinstone SM, Hoofnagle JH, Jake Liang T, Seeff LB, Cohen DE, Bezerra JA, Chung RT. The 2020 Nobel Prize for Medicine or Physiology for the Discovery of Hepatitis C Virus: A Triumph of Curiosity and Persistence. Hepatology. 2021; 74(5):2813-2823.
2. Hu W, Zhang C, Shi JJ, Zhang JY, Wang FS. Hepatitis C: milestones from discovery to clinical cure. Mil Med Res. 2020;7(1):59.
3. Cox AL, El-Sayed MH, Kao JH, Lazarus JV, Lemoine M, Lok AS, Zoulim F. Progress towards elimination goals for viral hepatitis. Nat Rev Gastroenterol Hepatol. 2020;17(9):533-542.
4. National Viral Hepatitis Control Program (https://wbhealth.gov.in/NVHCP/)
5. Markby J, Gupta E, Soni D, Sarin S, Murya M, Katapur P, Tewatia N, Ramachandran BE, Ruiz RJ 3rd, Gaeddert M, Tyshkovskiy A, Adee M, Chhatwal J, Miglani S, Easterbrook P, Sarin SK, Shilton S. Feasibility, effectiveness and cost of a decentralized HCV care model among the general population in Delhi, India. Liver Int. 2022;42(3):532-540. Epub 2021 Nov 29.
6. Fact sheet, Govt. Of India (https://ncdc.gov.in/linkimages/guideline_hep20158117187417.pdf)
7. Howe AYM, Rodrigo C, Cunningham EB, Douglas MW, Dietz J, Grebely J, Popping S, Sfalcin JA, Parczewski M, Sarrazin C, de Salazar A, Fuentes A, Sayan M, Quer J, Kjellin M, Kileng H, Mor O, Lennerstrand J, Fourati S, Di Maio VC, Chulanov V, Pawlotsky JM, Harrigan PR, Ceccherini-Silberstein F, Garcia F; SHARED Collaborators. Characteristics of hepatitis C virus resistance in an international cohort after a decade of direct-acting antivirals. JHEP Rep. 2022;4(5):100462.
8. Gupta E, Choudhary MC, Upadhyay N, Singh G, Nayak SL, Kumar M, Sarin SK. Lower Rates Of Naturally Occurring Resistance-Associated Substitutions (RASs) In Hepatitis C Virus (HCV)-Infected Chronic Kidney Disease (CKD) Patients Than In HCV-Infected Patients With Only Liver Disease. Infect Drug Resist. 2019;12:3635-3640.
9. Gupta E, Samal J, Pandey A, Singh G, Gupta HAS, Agarwal R, Sharma MK. Treatment Response and Drug Resistance Profiling of Genotype 6 of Hepatitis C Virus in HCV/HIV Co-Infected Patients: A Pilot Study from INDIA. Viruses. 2022;14(5):944.

Role of academic institutions in mass awareness generation under National Viral Hepatitis Control Programme

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Introduction

National Viral Hepatitis Control Programme (NVHCP), India, was launched on World Hepatitis Day on July 28, 2018 with an aim to attenuate the perpetually rising burden of viral hepatitis. Viral hepatitis, especially B and C, is among the leading causes of liver cancer, cirrhosis of liver and acute liver failure. World Health Organisation, through its Sustainable Development Goals, aims to reduce, by 2030, the incidence of chronic hepatitis infections by 90% and mortality by 65% as compared to baseline data of 2015.(1)

NVHCP, which is under the purview of National Health Mission, has upgraded facilities for diagnosis and treatment, primarily of hepatitis B and C, in different health institutions of the country. The cornerstone component of NVHCP, however, is prevention of viral hepatitis wherein the focus is on:- i) awareness generation and behaviour change communication; ii) increased immunization of hepatitis B (birth dose, high risk groups, health care workers); iii) increased safety of blood and blood products; iv) improved injection safety; v) promotion of safe socio-cultural practices; vi) advocating consumption of safe drinking water; and vii) promoting availability of hygienic and sanitary toilets.(2)

Rationale

Even though NVHCP has been very well received with respect to its objectives and components to achieve the target of national elimination of hepatitis by 2030, the community outreach has been limited thus far.

Academic institutions like medical colleges are an important cog in the wheel of awareness generation by engaging with community at a grassroot level.(3) Awareness generation workshops and webinars can bring about a positive change in the level of understanding about health issues and the significance of risk reduction measures.(4) Recent studies have shown poor awareness and gaps in the knowledge regarding prevention and control of hepatitis in staff of healthcare institutions in India.(5,6)
Institute of Liver and Biliary Sciences (ILBS), New Delhi, has taken an initiative to engage academic institutions as an added service to the NVHCP.

Objectives

The present exercise was conducted to raise awareness regarding viral hepatitis among the students, faculty members and staff in the academic institutions and to promote them to disseminate knowledge on prevention and control of viral hepatitis among their peers and community members.

Methodology

Fourteen webinars were planned and executed in liaison with principals/deans of various academic institutions and ILBS between January and March, 2022 (**Table 1**). Scientific agenda for the sessions was developed in consultation with faculty and staff of departments of epidemiology, virology and hepatology of ILBS and faculty members from partnering academic institutions.

The webinars were held via online mode, where in participants attended the sessions either individually or as a group from their respective institutional lecture halls/classrooms. The broad topics included burden of hepatitis B and C in India, transmission and prevention of hepatitis B and C at community level, screening, vaccination strategy and health education for hepatitis B and C at community level. At the end of each webinar, a question-and-answer session was conducted. I Pledge oath was administered wherein the participants were asked to promise to:- i) Try to keep the liver healthy; ii) Get themselves & their family tested and vaccinated; iii) Generate dialogue with colleagues on Hepatitis; iv) Teach ten people about Hepatitis; v) Not discriminate against people living with Hepatitis; and vi) Contribute in empowering people against Hepatitis. Finally, background material and other scientific documents were shared with the participants at the end of each webinar. Baseline and post webinar qualitative assessment was done in real time before and after the webinar, respectively, with the help of online Google Forms. The thematic areas were regarding knowledge of participants with respect to epidemiology of hepatitis B and C, its prevention and control measures and general preventive practices to be followed at home and in the community.

Results

These webinars raised awareness amongst the participants regarding the cause and mode of transmission of hepatitis, signs and symptoms, associated complications and status of availability of treatment against hepatitis and various steps to prevent spread of hepatitis B and C. It helped in mass awareness generation regarding the importance of hepatitis B birth dose and its relation to reduced incidence of chronic Hepatitis B. It also helped address one of the most important aspects related to Hepatitis i.e. raising voice against the social discrimination of Hepatitis patients. The participants took an I pledge to create a snowball effect in raising awareness about this disease by teaching ten more people about it and not discriminate people living with Hepatitis.

Conclusion

Online medium of imparting Information, Education and Communication (IEC) is a low cost and fitting way to engage with the institutes spanning across the country especially when the COVID-19 pandemic is yet to subside in totality. It is recommended that healthcare institutions like medical, nursing and other colleges of allied sciences may utilize this adept approach to further the cause of country wide elimination of viral hepatitis by 2030. Further, such strategies involving academic institutions can be put to use for awareness generation regarding other diseases of public health importance as well.

References

1. Global health sector strategy on viral hepatitis, 2016-2021. World Health Organization. Available from: http://apps.who.int/iris/bitstream/10665/246177/1/WHO-HIV-2016.06-eng.pdf?ua=1 website. [Last accessed on 2022 September 25]
2. National Viral Hepatitis Control Program (NVHCP). New Delhi. available from https://www.nhp.gov.in/national-viral-hepatitis-control-program-(nvhcp)_pg. [last accessed on 2022 September 25]
3. Pati S, Sinha R, Mahapatra P. Non-communicable Disease Risk Reduction Teaching in India: A Curricular Landscape. Front Public Health. 2019;7:133. doi:10.3389/fpubh.2019.00133
4. Asharose, Saizen I, Sasi P. Awareness Workshop as an Effective Tool and Approach for Education in Disaster Risk Reduction: A Case Study from Tamil Nadu, India. Sustainability [Internet]. 2015;7(7):8965–84. Available from: http://dx.doi.org/10.3390/su7078965
5. Kumar M, Ahmad S, Devi RS, Shah K, Aruna CN, Jha RK, Jyoti D. Awareness Regarding Hepatitis C among Dental Students in Bangalore, India: A Cross-Sectional Survey. Saudi J Med. 2021;6(12): 414-8.
6. Ajaz K, Dar AH, Ashraf A. Awareness about hepatitis-B, among the nurses of Shri Maharaja Hari Singh Hospital (SMHS), Srinagar –a tertiary care hospital: a cross sectional study. Int J Community Med Public Health 2021;8:1930-4.

Table 1: List of national webinars conducted by ILBS, Delhi on creating awareness on viral hepatitis B & C

SN	Date	Name of Organization	Total Participants
1.	02/02/2022	Engender Health, New Delhi	147
2.	03/02/2022	Dr B R Sur Homoeopathic Medical College, Hospital & Research Centre	443
3.	04/02/2022	Indian Medical Association (IMA), Nagpur	353
4.	08/02/2022	Department of Physiotherapy Faculty of Allied Health Sciences Manav Rachna International Institute of Research and Studies	266
5.	09/02/2022	ILBS College of Nursing, New Delhi	39
6.	11/02/2022	Department of Nutrition & Dietetics, Faculty of Allied Health Sciences Manav Rachna International Institute of Research & Studies	143
7.	14/02/2022	National Academy of Medical Science	500
8.	23/02/2021	Department of Periodontology, Manav Rachna Dental College, FDS, MRIIRS	282
9.	25/02/2022	All India Institute of Medical Sciences, Deoghar	282
10.	28/2/2022	Department of Periodontology Manav Rachna Dental College, FADS, MRIIRS	161
11.	02/03/2022	A & U Tibbia College & Hospital in collaboration with Dr B R Sur Homeopathic Medical College & Hospital	286
12.	09/03/2022	AIIMS, Manglagiri	250
13.	10/03/2022	United Way Mumbai	723
14.	12/03/2022	Lady Irwin College, New Delhi	596
	Total		**4472**

Table 2: Sample scientific programme schedule of national webinar on creating awareness on viral hepatitis B & C

SN	Time	Session Topic
1.	10.30 am	Registration of the Participants
2.	11.00 am	Welcome and Objectives of the Webinar
3.	11.20 am	Keynote address
4.	11:40 am	Burden of HBV and HCV in India
5.	12.00 pm	Transmission and prevention of HBV and HCV at Community level
6.	12:15 pm	Screening, Vaccination strategy and Health Education for HBV & HCV at Community Level
7.	12:20 pm	Administration of I Pledge, Display of I Pledge Video, I Pledge (Oath Ceremony)
8.	12:35 pm	Open House Discussion, Questions and Answers Session
9.	12:45 pm	Concluding remarks/vote of thanks
10.	1:00 pm	Distribution of E certificates and study material

Investigating a potential outbreak during a social and religious gathering in India: A cross sectional study

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INTRODUCTION

COVID-19, an infectious respiratory illness caused by the severe acute respiratory syndrome–corona virus 2 (SARS-CoV2), has now spread to multiple countries including India. reference The stride at which the disease has spread in the last one year, since it was first recognized from China, is unprecedented. This article summarizes the burden of infection, transmission dynamics, and other related epidemiological features regarding on the social and religious matters. The disease is progressively spreading in India as well, threatening the health and economy of the country. Broadcasting the asymptomatic cases, early symptomatic phase, as well as limited access to testing in different settings are factors that have led to the rapid spread of this infection. The meticulous mode of transmission of this virus is unknown. At this present-day situation, there is no evidence for airborne transmission of the virus. The present-day global propagation of COVID-19 is heterogeneous, with slow transmission ongoing in many countries and exponential propagation in others, where the time that it took for the explosive spread to begin to diversify greatly. reference It is projected that this could be explained by cascading superspreading events, in which new infections caused by a super spreader are more likely to be highly infectious. The mechanism proposed for this is related to viral loads. Introduction to high viral loads may result in high-intensity infection, which exposes new cases to high viral loads reference. This concept is supported by secondary research groomed on superspreading events in religious and social events such as Shahi snans at Kumbh mela and the Markaz event in 2020.

Kumbh Mela is a gigantic congregation of Hindu devotees and sages at the banks of rivers on certain auspicious days in the Hindu calendar. The Maha kumbh is held every 12 years between January and April. It was for the 1st time in the history of the grand religious congregation held on the banks of the Ganga in Haridwar This year 2021, Government restricted the event to one month in understanding the COVID -19 pandemic.

There had been a total of 9 Ganga Snan this year in Kumbh 2021:

1. January 14, 2021- Makar Sankranti Snan
2. February 11, 2021- Mauni Amavasya Snan
3. February 16, 2021- Basant Panchami Snan
4. February 27, 2021- Magahi Poornima Snan
5. March 11, 2021- Maha Shivratri Snan
6. April 12, 2021- Somavati Amavasya Snan
7. April 14, 2021- Baisakhi Snan
8. April 21, 2021- Ram Navami Snan
9. April 27, 2021- Chaitra Purnima Snan

Aim and Objective

- To investigate an outbreak due to large religious gathering.
- Gather insights to develop a policy brief for management of outbreaks during large gatherings.
- The proliferation of SARS-CoV-2 has shown it to be heterogeneous at a global scale, but the potential COVID spread in India by virtue of religious and social gatherings is documented in this paper.
- An exponential growth in the number of cases, despite many of them taking drastic measures to control the pandemic, yet still need to gather information regarding the eruptive potential of the hotspot due to large social gatherings.

Methodology

It appears that Second wave of Covid-19 was spreading gradually within a region unless a chain reaction of transmission is triggered. Independent superspreading events due to individual variation cannot explain this significant heterogeneous pattern of transmission. Therefore, to anticipate that infections caused by contact with super spreaders are more likely to spread in new super spreaders we have collected some interviews regarding few Kumbh attendees focusing mainly on the remarks made by the subjects related to prevailing categories of factors influencing the exponential growth of covid-19 cases from several reviewed literatures reference. The inferential approach of analysing qualitative data was adopted from the

Transcriptions that were made in vernacular language were later translated into English. reference.

Evidential information was collected from March 2021 through various newspapers both in vernacular language and in English, Government websites, twitter, other websites Based on the preserved grey literature and documented data, subsequently table and graph was plotted to enunciate the spread of COVID-19 in different geographiocal areas of Uttrakhand by travelling of pilgrims and devotees who visited Kumbh Mela

A Hindu Priest of 80 years old Kumbh returnee arrived to Haridwar on 15th March to participate in the festival. On 4th April, just four days after the festival officially began, he was tested positive for Covid-19 and was advised to quarantine in tent in Haridwar but instead of isolating he travelled 1,000km (621 miles) to the city of Varanasi. From there he shared a taxi with his son to their village 20km (12 miles) away in the adjoining district of Mirzapur. After returning to his village, he stayed at home and quarantined himself. However, his return has prorogued Covid symptoms in his son and some of the villagers. According to a Villager, who made a full recovery, said that their village has witnessed "13 deaths in the past fortnight from fever and cough".

The infections to the villagers might have a direct connection with the Hindu priest who returned from the Kumbh mela.. Acording to an interview of BBC, Haridwar's chief medical officer, told that crowd management became "very difficult" because people didn't come with negative reports and that they "couldn't turn back the devout who had come all the way driven by faith. With crowds of that size, SOPs became almost impossible to follow. They look very good on paper, but it's impossible to implement them." Another Kumbh Attendee expected stringent Covid security no checks at the airport or in Haridwar. The officials were found to be unable to impose the standard operating procedures (SOPs) also on the seers of Akharas and the ash-smeared ascetics thronging Har Ki Pauri ghat of Haridwar on the two Shahi Snans because of time constraints. Thirteen Akharas had to take holy dip at before sunset.

All the qualitative findings were discussed with selected participants of the study to establish member check and in order to find relevance with their expressions. The study was scrutinized concerning consolidated criteria for reporting qualitative studies and initiated compliant with the guidelines except for disclosure of partaking subject's identity. (**Figure 1**)

as devotees and pilgrims coming from different parts and many moved back to their home or stayed in kumbh and those who went back after kumbh can become spreader of the virus and cause outbreak to the areas they are going and by this way outbreak can be transmitted from inside to outside and outside to inside. This all event can happen between starting of kumbh to end of kumbh. (**Figure 2**)

Data extracted from world o meter and Uttarakhand COVID 19 Health Bulletin report shows active cases which gradually increased during the kumbh in Haridwar and India including two major bathing dates in the 12th and 14th of April. Along with disease spread model, Increasing COVID 19 case positivity rate before the onset of kumbh and during the kumbh signifies the high level of transmission rate of the virus in the community. Case positivity rate was taken from 4 th March to 28th April. And calculated by taking the daily positive cases divided by sample tested ,7day average value is taken further with the increasing case positivity rate in Haridwar, Uttarakhand and India. Further 14days follow up was taken in order to find potential hotspots in Uttarakhand.

With 14% case positivity rate of Uttarakhand in 29th april further stretch the study to find out district wise case positivity rate from 29th april to 12th may. Key findings came out for Nainital with highest case positivity rate during this two weeks follow up. Sudden spike of cases was seen in the districts Almora and Uttarkashi.

RESULTS

The findings of this secondary research based on quantitative and qualitative evidence led to understand the direct relation of upsurge of Covid-19 cases in thirteen districts of Uttarakhand with mass gathering in the Kumbh Mela 2021. Moreover, not following the Kumbh Mela standard operating procedures by devotees and Government official's itself rapid the process of transmission which shows the spread of infection through the quadrants in Figure.

Limitations

This study limits to the data about exact number of visitors from particular states and there travel history. There is no information about daily test

conducted and number of positive cases during the Kumbh. In addition, in social gatherings like kumbh mela it is hard to find any index case.

Conclusion

2021 is a very fascinating and enchanting year, because this year the Ganges had roared up to purify the sins of the devotees after 12 years. When millions of devout Hindus gathered in the month of April in the Himalayan town of Haridwar to participate in the Kumbh Mela festival even as India battled a distressing second wave of coronavirus, many feared that it would turn out to be a "super-spreader event." And now we think the fears had come true, as many Kumbh returnees were tested positive, are the possible spreaders of this infection throughout various parts of the country. In the prevailing situation of an economic, social and health care crisis due to covid-19 pandemic it is essential to have a realization of public health implications. This study would be useful for the preparation and will give overview of how the disease transmission would take place for the upcoming 3rd wave. It gives a clear view that how data plays a crucial role in understanding the spectrum of transmission.

Analysis

To speculate the eruptive potential of the hotspot due to large social and religious gatherings had planned and prosecuted our ideas and hypothesis by dividing the map of Haridwar and corresponding surrounding states into four equal quadrants to record the mobility of the pilgrims from and within the states to the center position the Haridwar. Reference.

Amongst these dates April 21st and April 27th was cancelled due to huge upsurge of covid-19 cases. Therefore, we focused on two main dates 12th of April and 14th of April. Tests were conducted between 10th to 14th April were 2,36,751. Total population of pilgrims who attended two major Shahi Snan were 48.51LAKH (on 12th and 14th of April). Out of total 5909 active cases from Kumbh there are only 1662 cases from Haridwar. We can presume that there were approximately 4247 cases from outside Haridwar which constitute of 71.88%.

It appears that Second wave of Covid-19 was spreading gradually within a region unless a chain reaction of transmission is triggered. Independent superspreading events due to individual variation cannot explain this significant heterogeneous pattern of transmission. Therefore, to anticipate that infections caused by contact with super spreaders are more likely to spread in new super spreaders we have collected some interviews regarding few Kumbh attendees focusing mainly on the remarks made by the subjects related to prevailing categories of factors influencing the exponential growth of covid-19 cases from several reviewed literatures reference. The inferential approach of analysing qualitative data was adopted from the Transcriptions that were made in vernacular language were later translated into English.

A Hindu Priest of 80 years old Kumbh returnee, arrived to Haridwar on 15 March to participate in the festival, during this time the cases of Covid-19 were already rising in many parts of India. On 4 April, just four days after the festival officially began, the 80-year-old Hindu priest tested positive for Covid-19 and was advised to quarantine in a tent in Haridwar but instead of isolating, he packed his bags, boarded a train and travelled 1,000km (621 miles) to the city of Varanasi. From there he shared a taxi with his son to their village 20km (12 miles) away in the adjoining district of Mirzapur. After returning to his village he stayed at home and quarantined himself. But his return has prorogued Covid symptoms in his son and some of the villagers. A Villager, who made a full recovery, says their village has seen "13 deaths in the past fortnight from fever and cough".

The infections to the villagers might have a direct connection with the Hindu priest who returned from the Kumbh mela. Haridwar's chief medical officer, told that crowd management became "very difficult" because people didn't come with negative reports and that they "couldn't turn back the devout who had come all the way driven by faith. With crowds of that size, SOPs became almost impossible to follow. They look very good on paper, but it's impossible to implement them."

As most of the evidence we collected speaks of Huge groups of mask-less pilgrims sitting on the river banks of Ganges. Another Kumbh Attendee expected stringent Covid security checks. But he faced no checks at the airport or in Haridwar. He says that the festival shows crowds at the banks, waiting to take a dip on one of the nights. Many people can be seen not wearing a mask or pulling it down to their chin.

Despite the best efforts brought by the police could not impose the standard operating procedures (SOPs) on the seers of akharas and the ash-smeared

ascetics thronging the various Ghats on the two major bathing days due to severe time constraints.

Findings were discussed with selected participants of the study to establish member check and found relevant with their expressions. The study was scrutinized concerning consolidated criteria for reporting qualitative studies and initiated compliant with the guidelines except for disclosure of partaking subject's identity.

Figure 1 Disease spread model I and outside kumbh with movement of travellers

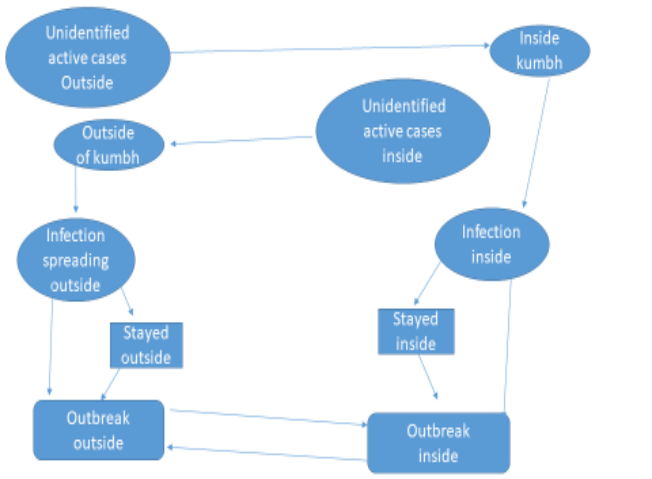
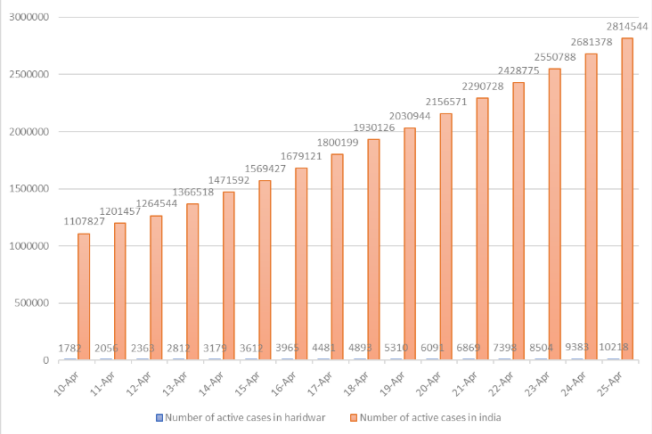


Figure 2 Number of COVID-19 active cases: Haridwar with respect to India during Kumbh Mela 2021



A significant behavior that impacts SARS-CoV-2 transmission is travel to and social contact in different settings. According to our observation the pilgrims who visited the Kumbh mela during the dates 10th of April to 14th of April showed a gradual high peak in the cases in Haridwar but same aspect to be taken into consideration we observed that there was a gradual decrease in cases in India at that point of time.

Figure 3 COVID-19 Case Positivity Rate in India, Haridwar, Uttarakhand from 04th March to 28th April

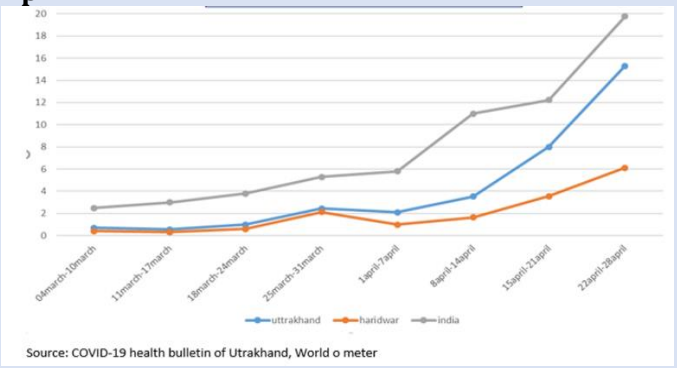


Table 1 District (Uttarakhand wise population

Districts	29th april-5th may	6th-12th may
Almora	18.47	40.65
Bageshwar	14.89	14.38
Chamoli	24.02	24.87
Champawat	16.21	19.15
Dehradun	23.48	32.50
Haridwar	6.8	15.21
Nainital	34.37	42.49
Pauri Garhwal	20.43	24.07
Pithoragarh	13.72	20.27
Rudraprayag	22.92	21.12
Tehri Garhwal	30.08	24.05
US Nagar	21.40	37.39
Uttarkashi	13.76	40.47

Selected Abstracts in Evidenced based Epidemiology

Sneak-peek into iron deficiency anemia in India: The need for food-based interventions and enhancing iron bioavailability

***Citation**: Khare A, Samudre S, Arora A. Sneak-peek into iron deficiency anemia in India: The need for food-based interventions and enhancing iron bioavailability. Food Research International. 2022;162(Part A):111927. https://doi.org/10.1016/j.foodres.2022.111927*

Malnutrition is among the top 6 risk factors for death in India, and iron deficiency anemia (IDA) is regarded as one of the major contributors, with nationwide prevalence > 60 % among women. Nutritional anemia accounts for ~70 % anemia prevalence among Indian children and adolescents, specifically in females. Evidence suggests that current supplementation and fortification practices alone may make little difference in reducing the risk of IDA. Sustainable food-based strategies need to be determined. This review provides an overview of IDA in India and elaborates the food-based solutions. Factors that affect iron bioavailability have been discussed while exploring different plant-based food synergies to improve iron absorption. Nutritional and non-nutritional challenges have been highlighted. A case study has been incorporated that analyses Health Management Information System data for certain pregnancy outcomes among severely anemic pregnant women. It highlights the need for implementing alternative food-based strategies apart from the government programs. Iron-rich plant sources, with appropriate ratios of bioavailability enhancers and inhibitors can be utilized to develop effective products. However, this cannot be easily achieved. Obtaining higher concentrations of iron from food sources alone is challenging. Processing techniques may lower antinutrient content but risk mineral loss and vitamin degradation from the food matrix. Most studies focus on increasing iron content via fortification rather than enhancing its bioavailability. Safety, accessibility, and affordability issues of previous approaches need to be addressed. It is essential to understand the chemistry behind iron bio-accessibility and absorption to develop ready-to-eat plant-based food formulations, with highly bioavailable iron, which could be a plausible solution.

The feudal structure of global health and its implications for decolonisation

***Citation:** Keshri VR, Bhaumik S. The feudal structure of global health and its implications for decolonisation. BMJ Glob Health. 2022;7(9):e010603. doi: 10.1136/bmjgh-2022-010603. PMID: 36167407; PMCID: PMC9516156.*

Global health as a field has its epistemological roots in related fields of tropical medicine and international health.1 2 These fields are not only products of colonialism, they also enabled imperialism through the destruction of traditional knowledge and consequent capture of the knowledge ecosystem.2–4 Efforts
to decolonise global health are therefore much needed. Calls to reform global health institutions, global health education, agenda setting, resource allocation, the problem in 'gaze' and equitable institutional partnerships have been made.1 5–7 Unfortunately, diversity, equity and inclusion (DEI) remains a dominant framing of ongoing discussions on decolonising global health.5
Efforts around DEI are indeed necessary—as a part of anti-racism and other social movements promoting inclusiveness of all forms of minorities in decision-making8 9; but they do not effectively address the structural imbalance of power between high-income countries (HICs) and low/middle-income countries (LMICs). To undo the persistence of colonialism in global health, it is necessary to understand how feudal structures helped imperial forces to sustain political colonisation. In this editorial, we highlight the similarities of those feudal structures to the current global health ecosystem, and why DEI efforts alone may only strengthen this feudal structure. Moving forward, dismantling the feudal structure of global health should be a target for efforts to decolonise global health.

Fortification of salt with iron and iodine versus fortification of salt with iodine alone for improving iron and iodine status

***Citation**: Baxter JB, Carducci B, Kamali M, Zlotkin SH, Bhutta ZA. Fortification of salt with iron and iodine versus fortification of salt with iodine alone for improving iron and iodine status. Cochrane Database Syst Rev. 2022 Apr 21;4(4):CD013463. doi: 10.1002/14651858.CD013463.pub2. PMID: 35446435; PMCID: PMC9022669.*

Background: Iron deficiency is an important micronutrient deficiency contributing to the global burden of disease, and particularly affects children, premenopausal women, and people in low-resource settings. Anaemia is a possible consequence of iron deficiency, although clinical and functional

manifestations of anemia can occur without iron deficiency (e.g. from other nutritional deficiencies, inflammation, and parasitic infections). Direct nutritional interventions, such as large-scale food fortification, can improve micronutrient status, especially in vulnerable populations. Given the highly successful delivery of iodine through salt iodisation, fortifying salt with iodine and iron has been proposed as a method for preventing iron deficiency anaemia. Further investigation of the effect of double-fortified salt (i.e. with iron and iodine) on iron deficiency and related outcomes is warranted.

Objectives: To assess the effect of double-fortified salt (DFS) compared to iodised salt (IS) on measures of iron and iodine status in all age groups.

Search methods: We searched CENTRAL, MEDLINE, Embase, five other databases, and two trial registries up to April 2021. We also searched relevant websites, reference lists, and contacted the authors of included studies.

Selection criteria: All prospective randomised controlled trials (RCTs), including cluster-randomised controlled trials (cRCTs), and controlled before-after (CBA) studies, comparing DFS with IS on measures of iron and iodine status were eligible, irrespective of language or publication status. Study reports published as abstracts were also eligible.

Data collection and analysis: Three review authors applied the study selection criteria, extracted data, and assessed risk of bias. Two review authors rated the certainty of the evidence using GRADE. When necessary, we contacted study authors for additional information. We assessed RCTs, cRCTs and CBA studies using the Cochrane RoB 1 tool and Cochrane Effective Practice and Organisation of Care (EPOC) tool across the following domains: random sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; selective reporting; and other potential sources of bias due to similar baseline characteristics, similar baseline outcome assessments, and declarations of conflicts of interest and funding sources. We also assessed cRCTs for recruitment bias, baseline imbalance, loss of clusters, incorrect analysis, and comparability with individually randomised studies. We assigned studies an overall risk of bias judgement (low risk, high risk, or unclear).

Main results: We included 18 studies (7 RCTs, 7 cRCTs, 4 CBA studies), involving over 8800 individuals from five countries. One study did not contribute to analyses. All studies used IS as the comparator and measured and reported outcomes at study endpoint.

With regards to risk of bias, five RCTs had unclear risk of bias, with some concerns in random sequence generation and allocation concealment, while we assessed two RCTs to have a high risk of bias overall, whereby high risk was noted in at least one or more domain(s). Of the seven cRCTs, we assessed six at high risk of bias overall, with one or more domain(s) judged as high risk and one cRCT had an unclear risk of bias with concerns around allocation and blinding. The four CBA studies had high or unclear risk of bias for most domains.

The RCT evidence suggested that, compared to IS, DFS may slightly improve haemoglobin concentration (mean difference (MD) 0.43 g/dL, 95% confidence interval (CI) 0.23 to 0.63; 13 studies, 4564 participants; low-certainty evidence), but DFS may reduce urinary iodine concentration compared to IS (MD −96.86 µg/L, 95% CI −164.99 to −28.73; 7 studies, 1594 participants; low-certainty evidence), although both salts increased mean urinary iodine concentration above the cut-off deficiency. For CBA studies, we found DFS made no difference in haemoglobin concentration (MD 0.26 g/dL, 95% CI −0.10 to 0.63; 4 studies, 1397 participants) or urinary iodine concentration (MD −17.27 µg/L, 95% CI −49.27 to 14.73; 3 studies, 1127 participants). No studies measured blood pressure.

For secondary outcomes reported in RCTs, DFS may result in little to no difference in ferritin concentration (MD −3.94 µg/L, 95% CI −20.65 to 12.77; 5 studies, 1419 participants; low-certainty evidence) or transferrin receptor concentration (MD −4.68 mg/L, 95% CI −11.67 to 2.31; 5 studies, 1256 participants; low-certainty evidence) compared to IS. However, DFS may reduce zinc protoporphyrin concentration (MD −27.26 µmol/mol, 95% CI −47.49 to −7.03; 3 studies, 921 participants; low-certainty evidence) and result in a slight increase in body iron stores (MD 1.77 mg/kg, 95% CI 0.79 to 2.74; 4 studies, 847 participants; low-certainty evidence). In terms of prevalence of anaemia, DFS may reduce the risk of anaemia by 21% (risk ratio (RR) 0.79, 95% CI 0.66 to 0.94; P = 0.007; 8 studies, 2593 participants; moderate-certainty evidence). Likewise, DFS may reduce the risk of iron deficiency anaemia by 65% (RR 0.35, 95% CI 0.24 to 0.52; 5 studies, 1209 participants; low-certainty evidence).

Four studies measured salt intake at endline, although only one study reported this for both groups. Two studies reported prevalence of goitre, while one CBA study measured and reported serum iron concentration. One study reported adverse

effects. No studies measured hepcidin concentration.

Authors' conclusions: Our findings suggest DFS may have a small positive impact on haemoglobin concentration and the prevalence of anaemia compared to IS, particularly when considering efficacy studies. Future research should prioritise studies that incorporate robust study designs and outcome measures (e.g. anaemia, iron status measures) to better understand the effect of DFS provision to a free-living population (non-research population), where there could be an added cost to purchase double-fortified salt. Adequately measuring salt intake, both at baseline and endline, and adjusting for inflammation will be important to understanding the true effect on measures of iron status.

Adding rapid diagnostic tests to community-based programmes for treating malaria

***Citation**: Allen EN, Wiyeh AB, McCaul M. Adding rapid diagnostic tests to community-based programmes for treating malaria. Cochrane Database Syst Rev. 2022 Sep 8;9(9):CD009527. doi: 10.1002/14651858.CD009527.pub3. PMID: 36073718; PMCID: PMC9453882.*

Background: The World Health Organization (WHO) recommends parasitological testing of all suspected malaria cases using malaria rapid diagnostic tests (mRDTs) or microscopy prior to treatment. Some governments have extended this responsibility to community health workers (CHWs) to reduce malaria morbidity and mortality through prompt and appropriate treatment. This is an update of a Cochrane Review first published in 2013.

Objectives: To evaluate community-based management strategies for treating malaria or fever that incorporate both a definitive diagnosis with an mRDT and appropriate antimalarial treatment.

Search methods: We searched CENTRAL, MEDLINE, Embase, five other databases, and three trials registers up to 14 September 2021.

Selection criteria: We included individually randomized trials and cluster-randomized controlled trials (cRCTs), controlled before-after studies, and controlled interrupted time series studies in people living in malaria-endemic areas, comparing programmes that train CHWs and drug shop vendors to perform mRDTs and provide appropriate treatment versus similar programmes that do not use mRDTs, and versus routine health facility care.

Data collection and analysis: We used standard Cochrane methods. For each dichotomous outcome, we extracted the number of participants with the event and the total number of participants in each group, unless studies presented results at a population level only. Primary outcomes were all-cause mortality, hospitalizations, and number of people receiving an antimalarial within 24 hours. Secondary outcomes were malaria-specific mortality, severe malaria, outcomes related to antimalarial treatments, antibiotic prescribing to people with a negative microscopy or polymerase chain reaction (PCR) result, parasitaemia, anaemia, and all adverse events.

Main results: We included eight studies from several African countries, Afghanistan, and Myanmar. Staff included CHWs and drug shop vendors.

Community use of malaria rapid diagnostic tests compared to clinical diagnosis

Compared to clinical diagnosis, mRDT diagnosis results in reduced prescribing of antimalarials to people who are found to be malaria parasite-negative by microscopy or PCR testing (71 fewer per 100 people, 95% confidence interval (CI) 79 to 51 fewer; risk ratio (RR) 0.17, 95% CI 0.07 to 0.40; 3 cRCTs, 7877 participants; moderate-certainty evidence). This reduction may be greater among CHWs compared to drug shop vendors. People diagnosed by mRDT are more likely to receive appropriate treatment; that is, an antimalarial if they are microscopy- or PCR-positive and no antimalarial if they are microscopy- or PCR-negative (RR 3.04, 95% CI 2.46 to 3.74, 3 cRCTs, 9332 participants; high-certainty evidence). Three studies found that a small percentage of people with a negative mRDT result (as read by the CHW or drug shop vendors at the time of treatment) were nevertheless given an antimalarial: 38/1368 (2.8%), 44/724 (6.1%) and 124/950 (13.1%). Conversely, in two studies, a few mRDT-positive people did not receive an antimalarial (0.5% and 0.3%), and one small cross-over study found that 6/57 (10.5%) people classified as non-malaria in the clinical diagnosis arm received an antimalarial. Use of mRDTs probably increases antibiotic use compared to clinical diagnosis (13 more per 100 people, 95% CI 3 to 29 more; RR 2.02, 95% CI 1.21 to 3.37; 2 cRCTs, 5179 participants; moderate-certainty evidence). We were unable to demonstrate any effect on mortality.

Community use of malaria rapid diagnostic tests compared to health facility care

Results were insufficient to reach any conclusion.

Authors' conclusions: Use of mRDTs by CHWs and drug shop vendors compared to clinical diagnosis reduces prescribing of antimalarials to people without malaria.

Deaths were uncommon in both groups.

Antibiotic prescribing was higher in those with a negative mRDT than in those with a negative clinical diagnosis.

Nutritional supplements for people being treated for active tuberculosis

***Citation**: Grobler L, Nagpal S, Sudarsanam T, Sinclair D. Nutritional supplements for people being treated for active tuberculosis. Cochrane Database of Systematic Reviews. 2016(6). doi: 10.1002/14651858.cd006086.pub4*

Background: Tuberculosis and malnutrition are linked in a complex relationship. Tuberculosis may cause undernutrition through increased metabolic demands and decreased intake, and nutritional deficiencies may worsen the disease, or delay recovery by depressing important immune functions. At present, there is no evidence-based nutritional guidance for adults and children being treated for tuberculosis.

Objectives: To assess the effects of oral nutritional supplements in people being treated with antituberculous drug therapy for active tuberculosis.

Search methods: We searched the Cochrane Infectious Disease Group Specialized Register, Cochrane Central Register of Controlled Trials (CENTRAL; Issue 1, 2016), MEDLINE (from 1946 to 4 February 2016), EMBASE (from 1980 to 4 February 2016), LILACS (from 1982 to 4 February 2016), the metaRegister of Controlled Trials (mRCT), the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP), and the Indian Journal of Tuberculosis up to 4 February 2016, and checked the reference lists of all included studies.

Selection criteria: Randomized controlled trials that compared any oral nutritional supplement given for at least four weeks with no nutritional intervention, placebo, or dietary advice only for people being treated for active tuberculosis. The primary outcomes of interest were all-cause death, and cure at six and 12 months.

Data collection and analysis: Two review authors independently selected trials for inclusion, and extracted data and assessed the risk of bias in the included trials. We presented the results as risk ratios (RR) for dichotomous variables, and mean differences (MD) for continuous variables, with 95% confidence intervals (CIs). Where appropriate, we pooled data from trials with similar interventions and outcomes. We assessed the quality of the evidence using the Grading of Recommendation Assessment, Development and Evaluation (GRADE) approach.

Main results: Thirty-five trials, including 8283 participants, met the inclusion criteria of this review.

Macronutrient supplementation

Six trials assessed the provision of free food, or high-energy supplements. Only two trials measured total dietary intake, and in both trials the intervention increased calorie consumption compared to controls.

The available trials were too small to reliably prove or exclude clinically important benefits on mortality (RR 0.34, 95% CI 0.10 to 1.20; four trials, 567 participants, very low quality evidence), cure (RR 0.91, 95% CI 0.59 to 1.41; one trial, 102 participants, very low quality evidence), or treatment completion (data not pooled; two trials, 365 participants, very low quality evidence).

Supplementation probably produces a modest increase in weight gain during treatment for active tuberculosis, although this was not seen consistently across all trials (data not pooled; five trials, 883 participants, moderate quality evidence). Two small studies provide some evidence that quality of life may also be improved but the trials were too small to have much confidence in the result (data not pooled; two trials, 134 participants, low quality evidence).

Micronutrient supplementation

Six trials assessed multi-micronutrient supplementation in doses up to 10 times the dietary reference intake, and 18 trials assessed single or dual micronutrient supplementation.

Routine multi-micronutrient supplementation may have little or no effect on mortality in HIV-negative people with tuberculosis (RR 0.86, 95% CI 0.46 to 1.6; four trials, 1219 participants, low quality evidence), or HIV-positive people who are not taking antiretroviral therapy (RR 0.92, 95% CI 0.69 to 1.23; three trials, 1429 participants, moderate quality evidence). There is insufficient evidence to know if supplementation improves cure (no trials), treatment completion (RR 0.99, 95% CI 0.95 to 1.04; one trial, 302 participants, very low quality evidence), or the proportion of people who remain sputum positive during the first eight weeks (RR 0.92, 95% CI 0.63 to 1.35; two trials, 1020 participants, very low quality evidence). However, supplementation may have little or no effect on weight gain during treatment (data not pooled; five trials, 2940 participants, low quality evidence), and no studies have assessed the effect on quality of life.

Plasma levels of vitamin A appear to increase following initiation of tuberculosis treatment regardless of supplementation. In contrast, supplementation probably does improve plasma

levels of zinc, vitamin D, vitamin E, and selenium, but this has not been shown to have clinically important benefits. Of note, despite multiple studies of vitamin D supplementation in different doses, statistically significant benefits on sputum conversion have not been demonstrated.

Authors' conclusions: There is currently insufficient research to know whether routinely providing free food, or energy supplements improves tuberculosis treatment outcomes, but it probably improves weight gain in some settings.

Although blood levels of some vitamins may be low in people starting treatment for active tuberculosis, there is currently no reliable evidence that routinely supplementing above recommended daily amounts has clinical benefits.

Wheat flour fortification with iron and other micronutrients for reducing anaemia and improving iron status in populations

***Citation**: Field MS, Mithra P, Peña-Rosas JP. Wheat flour fortification with iron and other micronutrients for reducing anaemia and improving iron status in populations. Cochrane Database Syst Rev. 2021;1(1):CD011302. doi: 10.1002/14651858.CD011302.pub3. PMID: 33461239; PMCID: PMC8407500.*

Background: Anaemia is a condition where the number of red blood cells (and consequently their oxygen-carrying capacity) is insufficient to meet the body's physiological needs. Fortification of wheat flour is deemed a useful strategy to reduce anaemia in populations.

Objectives: To determine the benefits and harms of wheat flour fortification with iron alone or with other vitamins and minerals on anaemia, iron status and health-related outcomes in populations over two years of age.

Search methods: We searched CENTRAL, MEDLINE, Embase, CINAHL, 21 other databases and two trials registers up to 21 July 2020, together with contacting key organisations to identify additional studies.

Selection criteria: We included cluster- or individually-randomised controlled trials (RCTs) carried out among the general population from any country, aged two years and above. The interventions were fortification of wheat flour with iron alone or in combination with other micronutrients. We included trials comparing any type of food item prepared from flour fortified with iron of any variety of wheat

Data collection and analysis: Two review authors independently screened the search results and assessed the eligibility of studies for inclusion, extracted data from included studies and assessed risks of bias. We followed Cochrane methods in this review.

Main results: Our search identified 3538 records, after removing duplicates. We included 10 trials, involving 3319 participants, carried out in Bangladesh, Brazil, India, Kuwait, Philippines, South Africa and Sri Lanka. We identified two ongoing studies and one study is awaiting classification. The duration of interventions varied from 3 to 24 months. One study was carried out among adult women and one trial among both children and nonpregnant women. Most of the included trials were assessed as low or unclear risk of bias for key elements of selection, performance or reporting bias.

Three trials used 41 mg to 60 mg iron/kg flour, three trials used less than 40 mg iron/kg and three trials used more than 60 mg iron/kg flour. One trial used various iron levels based on type of iron used: 80 mg/kg for electrolytic and reduced iron and 40 mg/kg for ferrous fumarate.

All included studies contributed data for the meta-analyses.

Iron-fortified wheat flour with or without other micronutrients added versus wheat flour (no added iron) with the same other micronutrients added

Iron-fortified wheat flour with or without other micronutrients added versus wheat flour (no added iron) with the same other micronutrients added may reduce by 27% the risk of anaemia in populations (risk ratio (RR) 0.73, 95% confidence interval (CI) 0.55 to 0.97; 5 studies, 2315 participants; low-certainty evidence).

It is uncertain whether iron-fortified wheat flour with or without other micronutrients reduces iron deficiency (RR 0.46, 95% CI 0.20 to 1.04; 3 studies, 748 participants; very low-certainty evidence) or increases haemoglobin concentrations (in g/L) (mean difference MD 2.75, 95% CI 0.71 to 4.80; 8 studies, 2831 participants; very low-certainty evidence).

No trials reported data on adverse effects in children (including constipation, nausea, vomiting, heartburn or diarrhoea), except for risk of infection or inflammation at the individual level. The intervention probably makes little or no difference to the risk of Infection or inflammation at individual level as measured by C-reactive protein (CRP) (mean difference (MD) 0.04, 95% CI −0.02 to 0.11; 2 studies, 558 participants; moderate-certainty evidence).

Iron-fortified wheat flour with other micronutrients added versus unfortified wheat flour (nil micronutrients added)

It is unclear whether wheat flour fortified with iron, in combination with other micronutrients decreases anaemia (RR 0.77, 95% CI 0.41 to 1.46; 2 studies, 317 participants; very low-certainty evidence). The intervention probably reduces the risk of iron deficiency (RR 0.73, 95% CI 0.54 to 0.99; 3 studies, 382 participants; moderate-certainty evidence) and it is unclear whether it increases average haemoglobin concentrations (MD 2.53, 95% CI −0.39 to 5.45; 4 studies, 532 participants; very low-certainty evidence).

No trials reported data on adverse effects in children.

Nine out of 10 trials reported sources of funding, with most having multiple sources. Funding source does not appear to have distorted the results in any of the assessed trials.

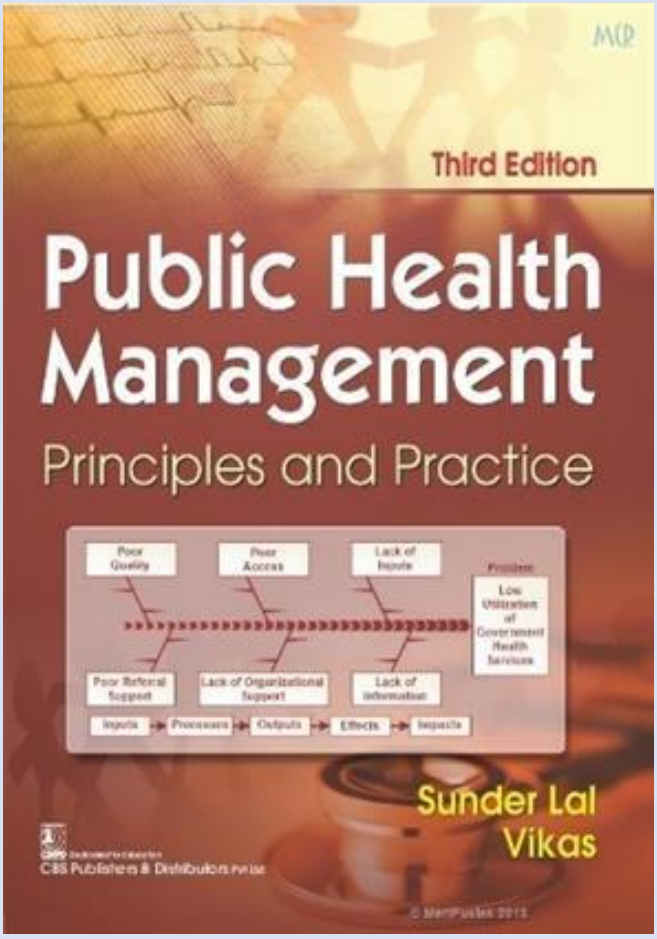
Authors' conclusions: Fortification of wheat flour with iron (in comparison to unfortified flour, or where both groups received the same other micronutrients) may reduce anaemia in the general population above two years of age, but its effects on other outcomes are uncertain.

Iron-fortified wheat flour in combination with other micronutrients, in comparison with unfortified flour, probably reduces iron deficiency, but its effects on other outcomes are uncertain.

None of the included trials reported data on adverse side effects except for risk of infection or inflammation at the individual level. The effects of this intervention on other health outcomes are unclear. Future studies at low risk of bias should aim to measure all important outcomes, and to further investigate which variants of fortification, including the role of other micronutrients as well as types of iron fortification, are more effective, and for whom.

BOOK REVIEW

Public Health Management Principles and Practice, 3rd edition



The book provides a most holistic coverage of the various facets of Public Health Management. Crisp, concise concepts; lucid, coherent presentation of facts and abundant, relevant information on the subject, all add up together to constitute the most suitable recipe for the enlightenment of its readers, including various categories of students viz; undergraduate, post-graduate students, students of Community Medicine in other settings, MPH, MHA as well as their faculty.

One of the best features of this book is the due weightage given to the presentation of the current developments and recent advances made in the field of Public Health in our country. From the evolution of health reforms to the development of various health programs and policies in India and the salient features of health management functions and best practice, the book leaves no aspect of PHM untouched.

The use of various tools and techniques such as elaborate case studies and innovative diagrammatic representations of the text to elucidate the numerous important concepts give this book an edge over the others.

A hint of personal touch to the text here and there and appropriate treatment of sensitive issues and topics such as ICTC for HIV and the ethical and moral implications of Community Health Service make this book a powerful tool for training as well as sensitisation of Public Health Workers, providing them with cutting edge knowledge and information regarding the subject.

All in all, this book carries enormous potential to detangle the intricacies of Public Health Management including those of relatively challenging topics like Health Finance & Budgeting and shows great promise in its field of discussion.

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EFI News & Upcoming Events

Clinical Epidemiology and Biostatistics Workshop
August 1-12th, 2022

Dr. Anil C Mathew
Division of Biostatistics
Department of Community Medicine
PSG Institute of Medical Sciences and Research,
Coimbatore, India

This workshop was conducted from August 1-12th, 2022 at PSG Institute of Medical Sciences and Research. This workshop was mainly targeted to medical postgraduates to provide them with the knowledge to evaluate and judge applied clinical research and data analysis and give a sufficient scientific and methodological background to actively participate in clinical studies. The main objective of the workshop was to make the postgraduates to understand and be familiar with bio-statistical principles in clinical diagnosis and management and to understand the reports of the medical research done by others. The topics covered include: formulate a concise clinical research question; find and appraise the level of evidence and apply the information to patient care (evidence based medicine); different study designs in clinical epidemiology and identify the best type of study to answer clinical research questions; locate and critically appraise original research articles from journals; identify major sources of bias and their likely influence on results and implications in clinical practice; understand and interpret 95% confidence intervals and p values; understand, calculate and interpret prevalence, incidence, relative risk and odds ratio; calculate and interpret sensitivity, specificity; pre- and post-test probability of disease. In addition, a hands on training on EXCEL, SPSS and EPIINFO was conducted on the last day.

A total of 22 internal and 13 external medical postgraduates attended and got benefitted from this program.
The session feedbacks were: it was a good experience, very well conducted, very useful sessions, lot of new information, able to clarify all doubts in a friendly manner and in general more than 95 % reported in each session that it was excellent/good.

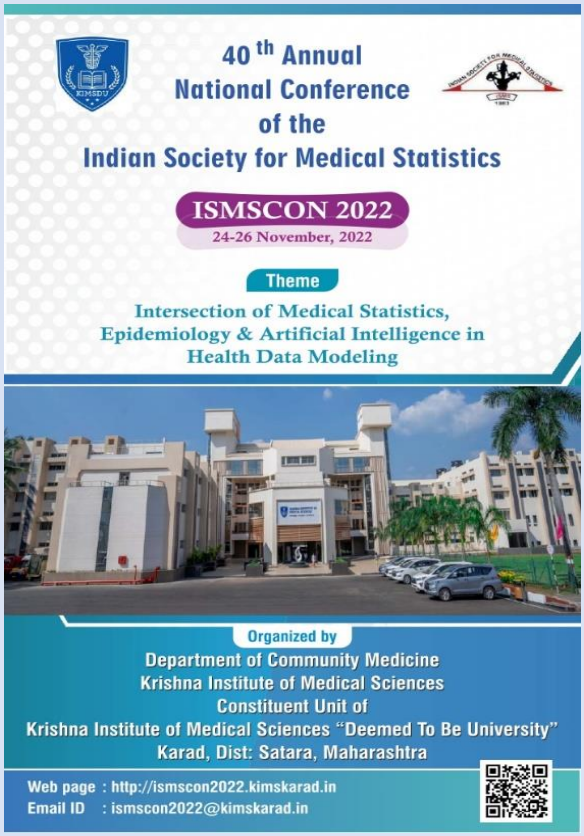
The workshop was organized by Dr. Anil C Mathew, Professor of Biostatistics and Dr. V Sandhiya, Senior Resident, Department of Community Medicine led by Dr. Sudha Ramalingam, Professor and HOD of Community Medicine. All faculty in the Department of Community Medicine were the resource persons .In addition there was cultural events by the participants.

Upcoming Events

EFICON 2022

NAMS-EFI Symposium

ISMS 2022



IAPSMCON 2023