Using environmental monitoring data from apex predators for chemicals management: towards better use of monitoring data from apex predators in support of prioritisation and risk assessment of chemicals in Europe

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POLICY BRIEF **Open Access**

Using environmental monitoring data from apex predators for chemicals management: towards better use of monitoring data from apex predators in support of prioritisation and risk assessment of chemicals in Europe

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Abstract

A large number of apex predator samples are available in European research collections, environmental specimen banks and natural history museums that could be used in chemical monitoring and regulation. Apex predators bioaccumulate pollutants and integrate contaminant exposure over large spatial and temporal scales, thus providing key information for risk assessments. Still, present assessment practices under the different European chemical legislations hardly use existing chemical monitoring data from top predators. Reasons include the lack of user-specific guidance and the fragmentation of data across time and space. The European LIFE APEX project used existing sample collections and applied state-of-the-art target and non-target screening methods, resulting in the detection of > 4,560 pollutants including legacy compounds. We recommend establishing infrastructures that include apex predators as an early warning system in Europe. Chemical data of apex species from freshwater, marine and terrestrial compartments should become an essential component in future chemical assessment and management across regulations, with the purpose to (1) validate registration data with 'real world' measurements and evaluate the predictability of current models; (2) identify and prioritise hazardous chemicals for further assessment; (3) use data on food web magnification as one line of evidence to assess biomagnification; (4) determine the presence of (bio)transformations products and typical chemical mixtures, and (5) evaluate the effectiveness of risk management measures by trend analysis. We highlight the achievements of LIFE APEX with regard to novel trend and mixture analysis tools and prioritisation schemes. The proposed advancements complement current premarketing regulatory assessments and will allow the detection

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of contaminants of emerging concern at an early stage, trigger risk management measures and evaluations of their effects with the ultimate goal to protect humans and the environment. This is the second policy brief of the LIFE APEX project.

Keywords: Bioaccumulation, Chemical regulation, Early warning system, Wide scope target and non-target screening, Wildlife

Status quo in the use of apex predators in chemicals management

Pollution is one of the greatest Anthropocene challenges

The intention of global and European chemical regulations such as the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [1] is to protect the environment and humans from hazardous substances. Despite these efforts, chemical pollution has become one of the Anthropocene's greatest environmental challenges. Humanity has likely exceeded safe thresholds of planetary boundaries for chemical pollution [2] with humans and wildlife in Europe are being exposed to a wide range of types of chemical pollution including plant protection products, biocides, pharmaceuticals, industrial chemicals and personal care products together with numerous transformation products, which pose substantial threat to biodiversity [3]. Concerns exist for apex predators in particular as they are exposed to high concentrations of biomagnifying substances [4, 5]. Recognising these challenges, the European Commission (EC) has developed strategies, enacted legally binding regulations and joined multilateral agreements. The European Green Deal [6] sets a 'zero pollution ambition' and measures to achieve this are set out in the EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' [7] and the European Chemicals Strategy for Sustainability Towards a Toxic-Free Environment [8]. The key challenge is to streamline the prioritisation, assessment and, where necessary, the restriction of the many thousands of chemicals marketed under various regulations such that chemical pollution is prevented more effectively in the future.

Apex predators are underused sentinels for pollutant exposure

Top predators such as raptors and marine mammals play a key role in contaminant monitoring and wildlife toxicology as they integrate contaminant exposure over a long lifetime and, in some cases, large foraging areas. Certain chemicals bioaccumulate in their tissues and, with high energy turnover from lower trophic levels, biomagnify to high concentrations through the food chain. Population declines of top predators have been among the most alarming impacts of chemical pollution and have driven public pressure to enact treaties aimed at reducing such pollution [9, 10]. Persistence and bioaccumulation of chemicals are of particular concern to regulators since they can lead to chronic exposure to high and unpredictable levels [11]. Accordingly, a number of regulatory frameworks specifically address the bioaccumulation in top predators, such as the Stockholm Convention [12] or assessing persistent (P), bioaccumulative (B) and toxic (T) or very persistent (vP) and very bioaccumulative (vB) property assessments under REACH, the EU Water Framework Directive (WFD, [13], and the EU Marine Strategy Framework Directive (MSFD) [14].

The European Chemicals Strategy calls for a more efficient use of contaminant monitoring data from humans and ecosystems as key to improve risk assessment and the understanding of pollution impacts [8]. Furthermore, there is a need for an effective early warning system based on monitoring data and other indicators. Pioneering work with raptors under the European Raptor Biomonitoring Facility (ERBFacility, www. erbfacility.eu) has provided guidance on species and matrix selection for pan-European contaminant monitoring [15, 16] including a review of archive capacities [17, 18]. However, a European research infrastructure designed to support contaminant screening using top predators from different environmental compartments as bioindicators and as sentinels for early warning is still lacking. At present, many contaminant monitoring data in top predators are fragmented over time, are regionally dispersed, and often motivated by project-based initiatives rather than meeting the long-term needs of a comprehensive exposure assessment in the context of chemical risk and hazard assessment and the needs for effectiveness evaluations. To date, few monitoring activities (e.g. under the MSFD or Regional Sea Conventions) are organised in a consistent way over time that allows for temporal trend analysis. Furthermore, these monitoring data are not stored in a centralised database yet. This is a major drawback in sustainable chemicals management, including the safe placing on the market, and post-market surveillance, of substances and products, and for assessing the effectiveness of regulatory measures, especially considering the evolving patterns of chemical substitution and diversification.

With recent advances in analytical chemistry, the scientific and technical means are now available to generate unparalleled amounts of data for chemical and (eco) toxicological fingerprinting and the biological and ecological functions of ecosystems [19]. For instance, rapidly advancing non-target and suspect screening techniques based on high-resolution mass spectrometric data now allow the screening of thousands of contaminants, which can substantially support the identification and risk assessment of contaminants of emerging concern [20–22]. Applied to a large number of yet underused biota and apex predator specimens available in research collections, natural history museums and environmental specimen banks [18, 23–25] these techniques offer new possibilities to characterise biomagnifying contaminants of emerging concern, and to use top predators both as an early warning system and for long-term monitoring.

EU prioritisation and risk assessment practices are often limited and lack a field context

The EC aims at high-quality risk assessment outputs to avoid costly impacts on human and environmental health and ineffective risk management measures**.** Current screening, prioritisation and assessment methods as applied under the different European chemical and environmental regulations are usually based on in silico approaches, in vitro data and/or in vivo testing using algae, aquatic invertebrates, and fish to estimate chemical effects on a population or ecosystem. Higher tier tests like mesocosm studies or field studies are in general not required as part of the authorisation process of chemicals with the exception of plant protection products. Thus, present hazard and risk assessments to demonstrate the safe use of substances are mainly based on data generated under laboratory conditions and exposure modelling and do not reflect an empirical ecological context [26]. For REACH chemicals a major challenge remains since only a small fraction of the marketed chemicals has been sufficiently evaluated regarding their (eco)toxicological properties and exposure, while limited data are available for the majority of substances [27]. Many of the > 22,000 compounds registered under REACH either lack data due to poor quality of registration dossiers or data are not sufficient for a comprehensive assessment, e.g. of PBT properties [28]. One reason is that chemical legislation requires only lower tier hazard testing for REACH chemicals with a production volume < 10 tonnes per year. Moreover, terrestrial ecosystems are as yet hardly considered in environmental risk assessment. For instance, existing assessment strategies and test guidelines to assess bioaccumulation are restricted to aquatic organisms and do not consider the accumulation of substances in air-breathing organisms and biomagnification in terrestrial food webs ([29]. In general, risk assessment guidelines are based on conservative approaches, but risk is assessed for each intended use and scenario which does not cover the aggregated exposure at landscape level from different current and historical uses, including hotspots and biomagnification processes relevant for apex predators. In addition, current approaches neglect the fact that humans and ecosystems are exposed to chemical mixtures leading to potential cumulative effects even if the concentrations of individual substances remain below their respective effect thresholds [30–32]. Moreover, risk assessment and regulatory action is still assessed substance by substance and lags behind the rapid increase in the volume and diversity of chemicals [33, 34]. Given the increasing number of substances on the market [33] it becomes unlikely that these compounds can all be screened and assessed for hazards and risks individually without enormous efforts. Regulatory risk assessments focus on premarket authorisations, and should be complemented with post-market environmental vigilance. Landscape aggregated exposure models have been conceptualised [35, 36], but are still under early development, particularly in connection with population dynamics [37]. In this context, monitoring data using apex predators can be used to improve the current risk assessment methods as well as for realistic retrospective assessments. This calls for automated, cost efficient and effective tools for prioritisation of pollutants and use of *all* available resources, including the systematic use of environmental and human biomonitoring data. Current monitoring programmes under the WFD or MSFD are insufficient in this respect as they focus on few selected compounds and are mostly based on simplistic prioritisation approaches.

Lack of guidance on the generation and use of chemical monitoring data

A particular challenge and a reason for the limited use of biota field data is the lack of guidance on harmonised sampling, processing, archiving, and shipping of wildlife samples, which is an important prerequisite to generate high quality and comparable data. The comparison of premarket estimations with monitoring data is essential for assessing real exposure and effect levels, as well as for updating risk assessment methods. Additionally, practical advice for industry and regulators on the use of biota field data under the different European chemical regulations are lacking such as the Guidance on PBT assessment developed by the European Chemicals Agency [38, 39]. Limited access to data from research programmes is a general challenge. Consensus upon consistent guidance and assessment approaches using biota field data is currently hampered by the fact that registration and risk assessment of chemicals on the EU market is fragmented across different legal frameworks [40]. This is now addressed by the EU Chemicals Strategy for Sustainability, which fosters coherent policies and action by all relevant international organisations.

Achievements

Lessons learned from the LIFE APEX project

Aims and scope of the LIFE APEX project are explained in detail in the first policy brief [41]. In total, about 200 pooled top predator and prey samples were screened for organic pollutants by wide-scope target and suspect screening, for presence of more than 65,000 chemicals. Overall, about 4,500 chemicals were detected of the assessed biota samples, i.e. freshwater fish, and marine mammals, raptors and fish. Those compounds included man-made pollutants and some naturally occurring compounds. These results reflect that apex species were exposed to thousands of pollutants, making up chemical cocktails that are covered by different regulations. Chemical mixtures included compounds known or expected to bioaccumulate in top predators but also a wide range of substances that had not been detected before, including plant protection products, biocides, human pharmaceuticals and industrial chemicals. While the LIFE APEX project demonstrated that contamination in European apex predators was widespread, the effects at the population level remain largely unknown. LIFE APEX also demonstrated that existing sample collections could be combined with state-of-the-art target, suspect and non-target screening methods to provide a more comprehensive picture of chemical exposure in samples of top predators and prey. We further provided these data to regulators for respective risk assessment. All LIFE APEX chemical data are publicly available through NORMAN and LIFE APEX database systems (https://www.norman-network.com/apex/). Specific LIFE APEX actions and case studies included:

Robust prioritisation and screening scheme using chemical data from apex species

All substances detected in top predators within LIFE APEX have been screened with the open access JANUS software (www.vegahub.eu/portfolio-item/janus/), which allows the identification of hazardous chemical properties based on laboratory data and in silico estimates for PBT, endocrine disruption and cancerogenic, mutagenic and reprotoxic (CMR) properties. JANUS is based on a battery of quantitative structure–activity relationship (QSAR) models in specific workflows for each endpoint [42, 43]. A list of top-ranked pollutants (ranked by hazard scores, regulatory status and frequency of appearance) was provided to ECHA and national regulatory agencies to aid further assessment.

In addition to hazard prioritisation, LIFE APEX data also allow the identification and exploration of inconsistencies between exposure estimates and registration status, e.g. if substances pre-registered under REACH are frequently found in apex predators, even if they should not be on the market or produced in Europe. Overall, we demonstrated that LIFE APEX approaches, including the prioritisation methods, were suitable to identify previously unknown and potentially problematic substances from a large set of chemicals detected in top predators and to make this information available to regulators.

Use of LIFE APEX chemical data in support of prioritisation, substance evaluation and restriction under REACH

The list of top-ranked chemicals, as described above, was subject to further in-depth assessment by the German Environment Agency with regard to PBT properties. REACH explicitly requires that all available information in registration dossiers and the open literature, including monitoring data, be considered in a weight of evidence approach to draw a conclusion on hazard endpoints. Thus, this in-depth assessment followed procedures for substance evaluation as laid out in REACH (Annex XIII; [38, 39]) considering physico-chemical, in vitro, in silico and in vivo data (if available) from the REACH dossiers as well as data derived from LIFE APEX.

The results from the LIFE APEX project were used to support regulatory substance evaluations under REACH. As an example, the occurrence and concentrations of the fragrance Galaxolide (CAS: 1222-05-5) measured in LIFE APEX were used as additional evidence to evaluate the bioaccumulation behaviour. Galaxolide has been initially found not to meet PBT properties [44] before REACH. New data on intrinsic properties for a re-assessment of the PBT status of Galaxolide, especially for persistence and bioaccumulation, are now available. Thus, France has initiated a re-evaluation of Galaxolide by the inclusion of the substance on the community rolling action plan in 2022 in order to clarify concerns related to its suspected PBT/vPvB properties, potential endocrine disruptor, consumer use and exposure of environment. According to a preliminary bioaccumulation assessment, standard laboratory data reported bioconcentration factors (BCF) for fish between 600 and 1,600 L/kg, which were below the B-criterion (BCF = 2000 L/kg) and the vB criterion (BCF = 5000 L/kg) according to REACH Annex XIII. In contrast, a field study reporting a bioaccumulation factor (BAF) far above 5000 L/kg indicates that Galaxolide might be even very bioaccumulative [45]. This finding is in line with the LIFE APEX data provided to the French chemical authority, where Galaxolide was detected in

58% of all pooled samples ($n = 67$) of four species (otter, seals, buzzards and fish) from Sweden, Germany, Netherlands and UK. High concentrations were detected in livers of buzzard (342 µg/kg), fish otters (3361 µg/kg) and harbour porpoises (3790 µg/kg), which highlights the ubiquitous distribution of the substance in the environment and may indicate an increased potential for biomagnification. Furthermore, LIFE APEX data were used in the restriction processes of per- and polyfluoroalkyl substances, to confirm environmental distribution behaviour and hazards, in particular PBT properties.

Tool to determine typical chemical mixtures in top predators

The combined chemical risk arising from exposure to chemical mixtures and transformation products is as yet hardly considered in European chemical risk assessment although new approaches are being developed [30–32]. LIFE APEX developed a mixture assessment tool (www.norman-data.eu/apex) for occurrence data to visualise the co-exposure to various chemicals and to determine typical mixtures in apex predators. Moreover, the tool allows filtering of the chemicals by their frequency of appearance, species and matrix. The results are presented in an interactive and downloadable graph map.

Statistical considerations regarding effectiveness evaluation

The work in LIFE APEX with regard to effectiveness evaluations showed the extent to which raptor samples could be pooled while still allowing the detection of significant trends over time in contaminant concentrations following the introduction of risk management measures. This knowledge facilitates more cost-effective monitoring of the effectiveness of mitigation measures at the European scale.

Development of guidance for use of chemical apex data in PBT screening and bioaccumulation assessments

- Practical guidance documents and protocols were elaborated within LIFE APEX on the interpretation of field data from apex species, addressing uncertainties in PBT screening and bioaccumulation assessments. These guidance documents are provided online (www.lifeapex.eu).
- Currently, results of LIFE APEX are being used in the revision process of the ECHA *Guidance on information requirements and chemical safety assessment. Chapter R.11: PBT assessment* [38] and *R.7c: Endpoint specific guidance* [39]. These ECHA guidelines have to be followed in registrations under REACH and aim to aid industry to conduct and improve risk and hazard assessment as part of the registration process.

Recommendations

We propose a number of actions and advancements to allow detection and prioritisation of contaminants of emerging concern at an early stage, with the goal of timely risk management measures to protect humans and the environment from exposure to hazardous chemicals. We here focus on the 'early warning system' function, notwithstanding the importance of long-term monitoring efforts.

Establish a European research infrastructure for the use of top predators as sentinels in early warning systems and in risk and hazard assessment

Monitoring data are required for evidence-based approaches in support of EU Chemical Strategies for Sustainability Towards a Toxic-Free Environment. Over recent decades, experience has been mainly gained by the regulatory and scientific community with contaminant monitoring of water, sediment and soil, and mainly lower trophic marine biota. Today, raptors, terrestrial and marine mammals at the top of the food chain are available in research collections, natural history museums and some environmental specimen banks, to allow for pan-European contaminant monitoring in a complementary way [18, 23–25]. To this end, including top predator samples to monitor and screen for contaminants in freshwater, marine and in particular terrestrial ecosystems would be a cost- and resource-efficient solution to track levels of contaminants, to screen for contaminants of emerging concerns, chemical mixtures and transformation products, as well as to check the effectiveness of chemical regulations [5, 15]. This approach could support all chemical regulations, including those for industrial chemicals, plant protection products, biocides, and pharmaceuticals as well as WFD and MSFD.

Specifically, we recommend the following actions:

- Establish a pan-European research and monitoring infrastructure in support of chemical risk assessment that responds to regulatory needs for the systematic use of apex predator and other wildlife samples in chemical monitoring and early warning systems. A first step could be to incorporate top predators into the sampling regime of WFD and MFSD. As the detection of chemicals in apex predators reflects food web bioaccumulation and biomagnification, the chemical exposure at the top of the food chain is also linked to human exposure potential. Experience exists with links to human exposure from Arctic monitoring of top predators and Inuit populations with a traditional subsistence lifestyle [46, 47]. This relates the call of the EC Chemicals Strategy for Sustainability Towards a Toxic-Free Environment for the development of an EU early warning tool to ensure that EU policies address emerging chemical risks as soon as identified by monitoring. By combining EU legal instruments for reducing contaminant releases to the environment and resulting exposures with the application of chemical monitoring in wildlife, a scientifically sound and more comprehensive basis for action can be developed.

- Making better use of targeted, suspect and non-target screening approaches using appropriate samples from top predator collections to respond to the needs of specific EU regulatory processes, for example:

a. To unravel inconsistencies in registration and approval data by matching exposure estimates with 'real world' levels in top predators.
b. To screen chemicals detected in apex species for classification as PBT compounds, endocrine disruptors and chemicals hazardous for human health (e.g., CMR), using in silico hazard screening tools such as JANUS (https://www.vegahub.eu) or the OECD toolbox (https://qsartoolbox.org/). This screening could support prioritisation [48] and decision-making processes for follow-up regulatory action for emerging compounds and chemical groups.
c. To provide evidence to better understand and assess biomagnification processes of chemicals, for example using samples from selected food webs [49] and/or matched samples of predator and prey.
d. To provide evidence on the occurrence of (bio)transformation products and typical chemical mixtures in top predators of different food webs, which can support advancements in risk modelling and assessment methods that are currently being developed with the ultimate goal to identify and manage hazardous chemicals more efficiently.
e. To establish retrospective time trends. Archived samples of apex species allow for retrospective analysis of contaminants of emerging concern as e.g. shown for Arctic top predators [50] and Scandinavian otters [51]. Retrospective time trends support the prioritisation of contaminants of emerging concern [48, 52]) and the effectiveness evaluation of management options for regulated compounds. Temporal data can also be used to forecast future trends in relation to linear, cumulative and systemic approaches [27].
f. To evaluate the predictability of current risk assessment schemes, and the effectiveness of chemical risk mitigation measures in particular by time trends analysis as e.g. shown for the Arctic [50, 53, 54].

- The proposed actions should build upon the considerable experiences and knowledge gained from the monitoring, modelling and assessment of chemical status by, e.g. dedicated efforts of ECHA, the European Food Safety Authority (EFSA) and EU Member States and international efforts in relation to the Stockholm Convention. To this end, the engagement of all relevant stakeholders including industry, the scientific community, sample providers, regulators and public representatives should be encouraged, to support these approaches and amendments and to enable their successful implementation. This can be achieved, for example, within the recently launched EU Partnership for the Assessment of Risks from Chemicals (PARC) [55], which will foster the collaboration of established working groups across the different chemical regulations.

Develop specific guidance to support regulatory consideration of chemical data from apex predators

- Current challenges, needs and perspectives from industry and regulators across regulations need to be systematically evaluated to identify where the use of biota/apex predator data can provide an added value (screening, prioritisation, assessment and management), which further approaches need to be developed, and how to incorporate them into current regulatory practices and assessment schemes. For instance, field bioaccumulation data are an ultimate example of real bioaccumulation potential and the impact of multiple releases from multiple sources.
- Recognising that field bioaccumulation data make an important contribution to the weight of evidence approach within assessments, in particular under REACH, plant protection products and biocides, we recommend further developing the section on the use of field data in the ECHA guidance [38, 39] and of the EFSA guidance on birds and mammals pesticides risk assessments [56], currently under update, to facilitate practical applications of chemical monitoring data from apex species for screening, assessment and management across EU-chemical

regulations. This could for instance be the work for a dedicated expert group in collaboration with PARC and the NORMAN network (www.norman-network.com, [55].

- Screening, prioritisation and assessment of chemicals by means of advanced monitoring or modelling approaches require both expert knowledge and resources. Since not all chemical authorities and countries currently have these capacities, an increased cooperation and knowledge sharing on methods and procedures is advisable. With regard to REACH, this could be addressed within the regulatory exchange platforms of ECHA's expert groups and with industry, e.g. by promoting the use of monitoring databases before and after registration of a chemical. PARC could also provide a forum for capacity building, in close collaborations between research institutions and environmental authorities. In the area of plant protection products, this should lead to landscape exposure assessments, aggregating the exposure from different uses and developing the basis for combined exposure assessments. A clear opportunity is the extrapolation of the cumulative assessment groups, developed by EFSA for human health, to cover also apex predators.

Conclusions and outlook

In summary, the following next steps are required for the integration of apex predators in surveillance, operational and investigative monitoring of legacy and emerging contaminants in support of EU risk and hazard assessments:

- Recognition that current concerns of exposures of humans and wildlife to legacy chemicals and contaminants of emerging concern, mixtures and (bio) transformation products require a more efficient use of existing resources, i.e. chemical monitoring data from apex and other wildlife species, which reflect 'real world' data.
- A centralised European data infrastructure is required which allows compilation, open-access and exchange of chemical monitoring data on wildlife as well as related regulatory information such as regulatory status, tonnages produced/marketed and uses [57]. Such a data platform will foster collaborative efforts in data and knowledge sharing across different stakeholder groups. Storing raw target and non-target screening data converted into a common (open) format further allows for 'on demand' access to retrospective data analysis. The NORMAN platform could be used as central data platform and knowledge hub, hosting chemical monitoring data for prioritisation and risk assessment, as well as method information and guidance to ensure high quality and comparability of chemical monitoring data. Interoperability with the EU Information Platform for Chemical Monitoring (IPCHEM) and the European Marine Observation and Data Network (EMODnet) should be considered.
- The acknowledgment by regulators of the value of top predators as key sentinels for early warning as well as to monitor ecosystems and improve risk assessment and understanding of their impacts. Monitoring data are particularly valuable for developing landscape aggregated exposure models, complementing premarket assessments.
- The development of baselines and comparable trend analysis based on spatial and temporal consistency of approaches, also supported by large-scale collaborative surveys.
- The development of coherent guidance documents should be initiated in collaborative approaches across European chemical regulations. These should address the practical application of chemical monitoring data from apex species in the screening, assessment and management of contaminants.

Abbreviations

BCF: Bioconcentration factor; CMR: Cancerogenic, mutagenic and reprotoxic; EC: European Commission; ECHA: European Chemicals Agency; EFSA: European Food Safety Authority; EMODnet: European Marine Observation and Data Network; ESBs: Environmental specimen banks; EU: European Union; IPCheM: Information Platform for Chemical Monitoring; MSFD: Marine Strategy Framework Directive; NHMs: Natural history museums; NORMAN: Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances; OECD: Organisation for Economic Co-operation and Development; PARC: Partnership for the Assessment of Risks from Chemicals; PBT/vPvB: Persistent, Bioaccumulative and Toxic/very Persistent and very Bioaccumulative; POPs: Persistent organic pollutants; QSAR: Quantitative structure–activity relationship; REACH: Regulation on the Registration, Evaluation and Authorisation of CHemicals; UNEP: United Nations Environment Programme; WFD: Water Framework Directive.

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Author contributions

GT has been responsible for the concept of the manuscript and drafted the manuscript. JK and KV helped to further elaborate the manuscript and contributed specific aspects. All authors read and approved the final manuscript.

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