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# A Framework for Linking Population Model Development with Ecological Risk Assessment Objectives†

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Key Points

- We present a framework for the development of population models for Ecological Risk Assessment (ERAs).
- We identify factors that currently prevent the use of population models in ERAs in regulatory decision making and develop a framework that addresses these inhibitory factors.
- The framework presents an approach that will guide the development of population models of varying levels of complexity based on the objective of the ERA.
- A series of case studies demonstrate the application of the framework under various regulatory statutes.

Abstract

The value of models that link organism-level impacts to the responses of a population in ecological risk assessments (ERA) has been demonstrated extensively over the past few decades. There is little debate about the utility of these models to translate multiple organism-level endpoints into a holistic interpretation of effect to the population; however, there continues to be a struggle for actual application of these models as a common practice in ERA. While general frameworks for developing models for ERA have been proposed, there is limited guidance on when models should be used, in what form, and how to interpret model output to inform the risk manager's decision. We propose a framework for developing and applying population models in regulatory decision making that focuses on tradeoffs of generality, realism, and precision for both ERAs and models. We approach the framework development from the perspective of regulators aimed at defining the needs of specific models commensurate with the assessment objective. We explore why models are not widely used by comparing their requirements and limitations with the needs of regulators. Using a series of case studies under specific regulatory frameworks, we classify ERA objectives by tradeoffs of generality, realism, and precision and demonstrate how the output of population models developed with these same tradeoffs informs the ERA objective. We examine attributes for both assessments and models that aid in the discussion of these trade-offs. The proposed framework will assist risk assessors and managers to identify models of appropriate complexity and to understand the utility and limitations of a model's output and associated uncertainty in the context of their assessment goals. 

Keywords: Population modeling, Ecological Risk Assessment, Framework, Uncertainty, Model complexity

Introduction

The value of models that link organism-level impacts of chemicals to the responses of a population in ecological risk assessments (ERA) has been described extensively over the past few decades (Pastorok et al. 2002; Munns et al. 2008; Forbes et al. 2009, 2015; Schmolke et al. 2010a, b; Grimm and Thorbek 2014; Galic and Forbes 2014; Forbes et al. 2016). There is little debate about the utility of these models in providing ecological relevance. The ability to translate multiple organism-level endpoints into a unified measure of effect to the population and the potential to incorporate multiple stressors and landscape attributes are key points in favor of utilizing population models for ERA. The scientific momentum behind population modeling for ERA has grown stronger with the widespread acceptance of the Adverse Outcome Pathway (AOP) paradigm, in which the translation from molecular initiating event through individuals to populations and communities completes the pathway (Ankley et al. 2010; Kramer et al. 2011; Conolly et al. 2017). Despite the successful implementation of population models by conservation biologists and wildlife managers to assess management options and create recovery plans for federally threatened and endangered (listed) species (McGowan and Ryan 2010; Hanson and Stark 2012), there continues to be a struggle for actual application of these models as a common practice in ERA. The basis of this is not due to scientific limitations, as there are extensive methodologies on model development. Rather, their adoption is constrained in part by a lack of guidance on when models should be used, in what form, and interpretation of model output to inform the risk manager's decision.

The goal of an ERA is to identify and describe ecological risks. The assessment goals are driven by the statute and regulations under which the ERA is being applied. While the scale of ERAs (e.g., community, ecosystem, national) vary by protection goal, they traditionally use endpoints based on individual responses. These endpoints (e.g., survival, growth and reproduction) are usually qualitatively linked to impacts at the population level. For example, a median lethal concentration (LC50) is typically available and relevant to understanding changes in survivorship of individuals of an aquatic species that might result from chemical exposure. Deterministic risk assessments are often used, in which conservative estimates of exposure are divided by an LC50 or other measure of effect in order to derive a risk quotient (RQ). RQs are compared to pre-determined levels of concern in order to determine whether or not there is potential for effects. Additional refinements of exposure or effects may be made if potential risk is identified by the RQ. This individual-level analysis is used as a surrogate for population-level impacts. The National Research Council (NRC 2013) urged for the inclusion of population models in ERA of risks to listed species from pesticides. This recommendation is complicated by the need to protect over a thousand species across the U.S. and its territories, that differ in life history, geographic range, and amount of information known about the species and chemicals. There is no single approach that can be applied for all species and all chemicals (or chemical mixtures), which have different effects. Most reviews agree that development of a population model for ERA should be based on the objectives of the assessment and should optimize model complexity, flexibility and practicality (e.g., Pastorok et al. 2002). However, clarification on how to incorporate available information into a robust model that can support regulatory decision making is lacking.

General frameworks for using population models in ERAs have been proposed that guide risk assessors to 1) identify if a population model is warranted, 2) determine if it will add value, 3) select models based on ecosystem, chemicals, and endpoints of interest to the assessment objectives, and 4) develop a conceptual model containing complexity that is based on level of realism and precision desired and is commensurate with the quality and quantity of data available or to be derived (Pastorok et al. 2002; Wentsel et al. 2008). Here, we propose a framework that will expand on previous work and contribute to guidance for developing and applying population models in regulatory decision making. We propose a framework that is centered on the tradeoffs of generality, realism, precision, and complexity for both ERAs and models with consideration of resource investment (i.e. time). To develop this framework, we consider what risk assessors and managers need out of a population model and then discuss why models are not being used in ERA. We propose a framework that addresses these roadblocks by linking ERA objectives with population model output with discussion of resource investment and demonstrate the application of the framework through a series of case studies. The framework aids in model development and use by describing a system by which ERAs can be categorized, after which model development is identified relative to the ERA category and information and resource availability. Since the work combines terminology from both risk assessment and modeling disciplines, a glossary of terms is provided in Table 1 to ensure readers from both backgrounds share a common understanding of terms used herein. The first mention of words defined in Table 1 are in ***bold italics*** in the order they appear in the text.

What do risk assessors and managers need out of a population model?

While ERAs follow a standard paradigm (USEPA 1998), they are customized for the regulatory statute, specific scenario, and data availability. Regulatory statutes for the United States, Canada, and the European Union under which ERAs are conducted have been described elsewhere (Biddinger et al. 2008; Hommen et al. 2010) and the detailed process of conducting an ERA will not be discussed here. For all assessments, protection goals are defined during the problem formulation phase and are an agreement between the ***risk assessor*** and ***risk manager*** to ensure the risk manager has enough information to make an informed decision relevant to the protection goals. Also in problem formulation, ***measurement endpoints*** are identified. Measurement endpoints are explicitly identified using available models and toxicity data and are generally at the individual level; however, protection goals may be at the population, community, or ecosystem level. Traditionally, individual-level measurement endpoints are used as surrogates for the population-level protection goals which comes with assumptions and uncertainties. However, at this stage a risk assessor could identify if a population model may be useful to translate the individual-level measurement endpoints to the level of biological organization of the protection goal (e.g., population). In doing so, assumptions may be reduced and uncertainties could be quantified.

***Tiered ERAs*** may be performed under many statutes. In this process, a Tier 1, or screening assessment, is qualitative and intended to identify cases where it can be confidently concluded that risk is low, typically with a “yes” or “no” outcome. For example, if exposure of a taxon to a given chemical is well below effect levels, that scenario can be eliminated from further consideration. Tier I assessments are typically conservative in nature (e.g., relying on 90$^{th}$ percentile estimates of exposure), simple, and efficient to execute. They are intended to screen out low risk scenarios, allowing risk assessors to focus time and effort on refining input assumptions where additional information is needed (i.e., refined risk assessments). The progression from Tier 1 to higher tiers involves an increase in information (e.g., on species, habitat, and chemical) and effort on the part of the risk assessor. Higher tiers may quantify risk (e.g., the most likely magnitude of mortality to exposed birds) and associated certainty/uncertainty.

As an ERA moves from screening to higher tiered assessments the risk analysis requires more data and information to better define the system. Here, risk assessors need to ensure an ERA is scientifically defensible while acquiring data and generating model output in a timely manner. As such, some desirable qualities of models are flexibility related to data requirements, input parameters, time, space, physical and biological scale, and applicability. This information is important in understanding how different population models may be incorporated into a tiered risk assessment framework. Models should contain clear requirements for needed inputs, be able to work with available data, and have clearly defined utility of the range of its outputs (e.g., *What do the results mean and how easy are they to understand?).* Risk assessors need to be able to understand and explain the statistical error inherent in the model output, which could be in the form of a ***sensitivity analysis***, ***validation***, ***verification***, or

***confirmation***. Model error may also include understanding how modeled ***mechanisms*** contribute to model outputs or where uncertainty in inputs lead to more or less certainty in the outputs. Models that yield probabilistic outcomes can represent error in parameter estimation and provide a risk assessor with confidence bounds around model output. Even when an appropriate model exists, practical and technical considerations for risk assessors are the amount of time and resources needed to run the model, portability, transparency, public availability, status of peer review, external validation, and whether the model is technically supported to ensure it represents the best available science.

Risk managers are charged with interpretation of ERA outputs to make sound management decisions. In this role, they also require a clear understanding of the range of model outputs and their utility. They need to ensure their decisions reflect the strong scientific basis of the models used and understand the ramifications of both ***qualitative*** and ***quantitative uncertainties*** in the models. Under some statutes, risk managers may be required to provide mitigation plans. Thus they also need to understand the ability and limitations of a model to characterize mitigation under alternative scenarios. For a model to be applied in decision context it needs to be made available to the public with complete documentation to allow transparency for review by stakeholders.

## Why aren't population models being used in ERA?

In a recent review of models used in ERAs for listed species, Forbes et al. (2016) noted that out of approximately 400 studies containing scientifically defensible population models, only 2 were actually used to assess the risk of pesticides to species listed under the endangered species act (ESA). Additional reviews have repeatedly concluded that the scientific basis for population modeling in ERA is defensible (e.g., Pastorok et al. 2002; Barnthouse et al. 2008; Galic et al. 2010; Forbes et al. 2015), yet these models are not commonly incorporated into the ERA process. In this section we explore the reasons population models are not being used and identify several factors that prevent them from being widely used by risk assessors: complexity, uncertainty, translation of model output into an endpoint that is useable by the risk assessor for their objective, added investment, availability, and general acceptance of the model itself.

Choice of ***model complexity*** is a critical element of good modeling practice (Schmolke et al. 2010a); however, there is little guidance on selecting the level of model complexity appropriate for specific ERA objectives. Defining model complexity is challenging in itself; indeed, a general definition for the term is unlikely to be widely agreed upon by the modeling community (Brooks and Tobias 1996). Considering its importance in the development and acceptance of models for ERA, we provide a broad definition for this context. We refer to complexity in terms of the mathematical formulae, the mechanisms that represent the system being modeled (e.g., migration, density dependence, seasonally-varying demographic rates, heterogeneous landscape features, and other interactions with the environment and its stressors), and the connectedness of how elements are linked (Brooks and Tobias 1996). By definition, all models are a simplification of reality; however, the degree of simplification varies. The simplest population models, such as the logistic model, are limited in the number of mechanisms they include and make more broad-based assumptions about a system (e.g. spatial homogeneity, identical behavior among members of the population, etc). As such, these models have fewer input requirements and may be quickly developed to provide a generalized phenomenological perspective for screening or lower tiered assessments. Conversely, highly complex models, such as Individual Based Models (IBMs), which include a number of mechanisms described by empirical relationships, can be linked across landscapes for a more descriptive view of a system and can have expensive information requirements. Regardless of model formulism, selecting the appropriate level of model complexity is a critical element on any assessment (Barnthouse et al. 2008).

Model uncertainty is directly related to data reliability and availability, which can be confounding issues in developing population models for ERAs. Uncertainty is quantitative when it describes imprecision of parameters estimated from data, such as variability associated with empirical estimates for fecundity. Qualitative, or knowledge-based, uncertainties are those associated with limited data or limited knowledge about the animal/plant subject or ecosystem. An example of a qualitative uncertainty would be excluding density dependence, but including a discussion of how the mechanism could influence the model outcome and the utility of the model outcome in its absence. If there are ecological factors that are expected to influence risk (e.g., habitat constraints), using models that either ignore them (qualitative uncertainty) or misrepresent them using inaccurate functions (quantitative uncertainty) can result in dramatically inaccurate conclusions for the ERA (Forbes and Calow 2013). Increased data availability allows for a shift from qualitative to quantitative uncertainty as more mathematical relationships could be incorporated into the model. However, it is important to note that more data do not necessarily result in reduced uncertainty if data quality is low or not adequate to develop validated mathematical functions. A risk assessor must make defensible decisions on when to either use data that might result in large quantitative uncertainties or exclude a mechanism that results in unquantifiable, knowledge-based uncertainties. These uncertainties, and the decisions that led to their incorporation, must be described and transparent both to the risk manager and to stakeholders.

Translating model output into a form useful for the ERA objective requires that the model endpoints be relevant to the ERA and that the model system is consistent with the concern of the ERA. This can be challenging when the scale of the model (e.g., population) is not commensurate with the scale of the protection goals (e.g., communities). For example, a risk manager may not see the relevance of models that predict relative changes in ***population growth rate*** (***PGR***) in a surrogate species for national level assessment. To facilitate this, the model scope must be appropriately defined. For example, a risk assessment that determines impacts on broad taxonomic groups (e.g., birds) can apply a model developed for a given species, provided the extent to which that model may represent other species within the taxon is understood. Alternatively, species-specific models may be more appropriate for ESA consultations than a model developed for a surrogate, but taxonomically related species. In addition to model scope, model endpoints (e.g., population abundance, age structure, extinction risk, etc.) should be a metric that is translatable to the ERA objective.

A significant influence on the decision to include a model in an ERA is the added time and financial investment involved in developing a model relative to the value it adds to the conclusions of the assessment. Most published models are not presented in a manner that allows for ease of use or transfer across species or ecosystems. While a risk assessor may see demonstrated potential of a model from a published paper, extracting the pieces in a functional format so that it may be used with the data for the specific assessment and programming the model to obtain output may involve an unrealistic time investment. There are a number of modeling platforms that provide a friendly user-interface for practical application (e.g., Spencer and Ferson 1997; Schumaker 2010). While these applications still require some baseline knowledge of population ecology and may present some limitations associated with cost and flexibility, they are available for reproducible model development and analyses. In addition to the time investment of running a model, the expense of acquiring model input data can also be a limiting factor. In many cases, desired input data may either not exist or exist in the literature in a format that requires manipulation or translation prior to use in models.

Availability and general acceptance of the model itself is a critical element for risk assessors, in part because it implies (correctly or not) a greater degree of peer-review. Peer review enhances the credibility of any model used in a contested assessment. Additionally, model code must be available for any model that will be used in regulatory decision making. In addition to the reasons already discussed, models must be transparent so that stakeholders can understand the origin and validity of the information that informs the model, as well as the mathematical formulation of the model. For this reason, some risk assessor may prefer simple models, which are more easily interpreted and accepted by a wide range of stakeholders. However, simple models have limitations in capturing ecosystem specific features, so assessors may prefer more complex models that captures process of interest to the assessment. To gain general acceptance of a model, a risk assessor must be able to use it to adequately address the "*So what?*" question.

## Framework Development

It is impossible to simultaneously optimize all desirable properties of ecological models, and tradeoffs between model qualities are further enhanced by resource constraints. Inherent in the challenge of selecting a model is determining the appropriate balance of model ***realism***, ***generality***, and ***precision*** necessitated by the application. Levins (1966) first introduced the concept that model building is bound by tradeoffs in these three model attributes that cannot be simultaneously optimized. For example, a model developer may increase realism and precision, but at the cost of generality. Balancing the tradeoffs of this trilemma has been referenced previously in guidance for developing models for ERAs (Munns and Mitro 2006; Forbes et al. 2016); however, central to our framework is the concept that it is also useful to consider ERAs in the context of these tradeoffs, which can be used to guide the selection and development of a model that best suits the assessment's objectives. For example, in a refined superfund assessment (USEPA 1997) realism and precision may be preferred by the ERA objective, in which case a model may be developed that sacrifices generality. The concepts of realism, generality, and precision are intuitive and provide a common language for discussing model attributes and trade-offs; however, we acknowledge that challenges emerge when concepts such as these are strictly applied and tightly defined (Levins 1993). Furthermore, we recognize that Levins' scheme was originally proposed for model building and the tradeoffs proposed in the original context may require a shift in thinking to apply them to ERAs.

Also central to our framework is the concept that complexity is not independent of these tradeoffs, increasing as models move both from general to realistic and from lower to higher precision. Complexity can increase such that knowledge-based, or qualitative, uncertainties are reduced by adding mechanisms or more complex model functions that represent real-world scenarios. We refer to this as ***qualitative complexity***. Complexity may also increase such that the level of precision, or confidence in model output, is increased through the addition or improvement of mathematical functions that reduce quantitative uncertainty, which we refer to as ***quantitative complexity***. While all functions could be initially viewed as "quantitative" in nature, they do not all improve prediction robustness so are distinguished here to demonstrate that model complexity takes on different meanings depending on the type of model formalism and the mechanisms included. For example, species migration may be added to a model for a system where it is known to be important. In some cases, migration may be an arbitrary function based on professional judgement that lacks validation or precision accuracy (e.g., Awkerman et al. 2016, discussed below in Case Study 3). Here, qualitative complexity is added that increases realism but does not increase precision. Alternatively, a migration function may be added that is based on long-term mark-recapture estimates that improves both realism and precision (e.g., USFWS 2011, discussed below in Case Study 5). Therefore, qualitative complexity represents the functions associated with increase realism while quantitative complexity is associated with precision. These tradeoffs can be independent, as demonstrated by the framework and described in the case studies presented below. It is important to note that with respect to quantitative complexity, simply increasing the number of mathematical functions does not reduce quantitative uncertainty if those functions are not based on sound data.

The conceptual framework which describes ERAs and population models by their level of generality, realism, precision, and complexity is depicted in Figure 1. In this presentation, generality and realism are represented as a continuous gradient along which precision may be targeted or sacrificed.

Since generality and realism occur across a continuous spectrum, ERAs or models can lie in between depending on the mechanisms they include. For both ERAs and models, realism increases with species specificity, clear spatial definition, temporal resolution, and inclusion of real world complexity, whereas generality is often based on surrogate species, contains less defined spatial and temporal scales, and had broad applicability across locations. As an ERA or model seeks to increase realism, its qualitative complexity increases; as an ERA or model seeks to increase output confidence (i.e., precision) as represented by quantitative confidence bounds, its quantitative complexity increases.

To demonstrate these trade-offs, we identify five points representing various locations within the framework: General, General-Precise, General-Realistic, Realistic, and Realistic-Precise (Figure 1). Since the framework axes are continuums, it should be noted that these categories are general reference points and some ERAs may lie in between the locations identified in Figure 1. We do not define just "Precise" as a unique category of its own, as it is assumed that an assessment that targets precision will either do so under general scenarios (General-Precise), realistic scenarios (Realistic-Precise), or some point in between (General-Realistic). The General-Realistic category is situated in the center of the framework in Figure 1 to demonstrate that an ERA or model may contain increased precision depending on the qualitative complexity included. In the context of this framework, attributes of ERAs and models associated with each of these points are described in Tables 2 and are also demonstrated through the case studies described below.  It is important to note that these descriptions are used for categorization of models within an ecological risk assessment context specifically and do not necessarily apply in other applications.

The framework contains three model investment levels that vary in the amount of time and resources required to develop the model. The first investment level includes general and simple models that can be developed with limited available information and yield low precision. The second level requires additional information and time to either increase the level of precision or realism. The third level contains the highest investment of time, data collection, expertise, and potential stakeholder agreement to develop for policy decisions. As a conceptual framework, these levels are intended to be relative and do not denote a quantitative value of resources.

Applying the Framework: Demonstrations with Case Studies

Applying the framework is a two-step process that first identifies the level of complexity for the assessment and then identifies modeling needs to fulfill the assessment objective. This first step requires a risk assessor to identify where their ERA is located in the framework based on the attributes in Table 2 (taxonomic specificity, spatial context, temporal considerations, minimal exposure information available) and the objective of the ERA. Inherent overlaps in categories will exist along the complexity gradients (Figure 1). For example, attributes that make an ERA General (e.g., no site specificity) will contribute the element of generality to the General-Precise and General-Realistic. Where two categories could be considered based on the attributes in Table 2, the objective of the ERA or available data used to determine the final category.

Once a risk assessor identifies the position of their ERA within the framework, they then identify the relevant model complexity associated with that position for the second step. To do this, the model first needs to match the taxonomic specificity, spatial context, and temporal considerations identified for the ERA to contain the same endpoints and resolution and equivalent trade-offs of generality, realism, and precision. Recommendations for additional model attributes associated with each position in the framework are listed in Table 2. We focus here on model data, attributes, and functions that address the needs of an ERA in the respective category, but do not prescribe model formalisms or approaches to parameterization, which has been covered extensively elsewhere (e.g., Barnthouse et al. 2008). To demonstrate this step using the case studies, we describe how the models are consistent with the framework category of the ERA but do not walk through a decision process of model development (e.g., Schmolke et al. 2017).

For population-level risk assessments where the population model will be strongly weighed in the risk management decision, the ERA and model should occur in the same category in the framework. If the investment of developing the model for an assessment in a given category is too high, a model from a lower investment level can still be used as part of the weight of evidence provided the qualitative and quantitative uncertainties are properly weighed. We demonstrate the application of this framework by presenting assessments performed under various statutes, identifying their location within the framework, and then describing models that have or could have been used to support the objectives of the assessment. Further details on both the assessments and models presented in the case studies are provided in the Supplemental Information.

Case Study 1: This case study describes the development of Ambient Water Quality Criteria (AWQC) for diazinon performed under the Clean Water Act (CWA; USEPA 2005). AWQC are guidelines that reflect the latest scientific knowledge of the extent to which pollutants affect aquatic life and may be adopted by states or tribes as enforceable water quality standards of the pollutant in the water. Although states and tribes may modify their water quality criteria to reflect local conditions and exposure patterns, the objective of the AWQC is to establish Criteria Maximum Concentrations (CMC, acute criterion) and Criteria Continuous Concentration (CCC; chronic criterion) that preserve the integrity of water (including groundwater) nationwide. AWQC have no taxonomic or spatial specificity. Temporally, AWQC only consider if exposure is acute or chronic. Based on these attributes, AWQC are General (Table 2).

A simple life table model was developed for *Daphnia pulex* from daily survival and reproduction measured on organisms exposed to 11 diazinon concentrations through 65 days in the laboratory (Stark and Vargas 2003). Data were used to determined PGR and stable age distribution of *D. pulex* populations at each concentration and determine the concentrations above which populations would decline or go extinct. Although the model was developed for *D. pulex*, it represents the most sensitive group of organisms (crustaceans) reported in the literature that were used to derive the AWQC, which assumes the most sensitive species will be protective of other species. Consistent with the lack of spatial context or temporal dynamics of the criteria and the use of a surrogate species to protect a wide range of taxa, the model is categorized as General. The model demonstrated that population level effects, determined as PGR significantly lower than control, occurred at concentrations > 2 μg diazinon/L. These results could add to the weight of evidence that the Final Chronic Value (0.17 ug diazinon/L; USEPA 2005) derived for freshwater from minimal test data and acute-to-chronic ratios is protective of populations of sensitive taxa.

Case Study 2: This case study describes a refined ERA performed under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) to evaluate the risk to birds from exposure to malathion applied on corn (Etterson et al. 2017). The objective of the national level assessment was to determine whether malathion application poses unacceptable risks to birds using agricultural fields and nearby habitats. Using the attributes in Table 2, the taxonomic specificity is birds (ie., taxa); the spatial context is corn fields (ie. habitat) in the upper Midwest, USA (ie., general location); temporal considerations include timing of application relative to bird nesting, and exposure information available for the assessment includes pesticide body load modeled over an hourly time step (Etterson et al 2017). Based on these attributes the ERA could be considered General-Precise or General-Realistic (Table 2). To select between these two categories, we refer to the objective of the assessment which is focused on malathion impacts from the realistic label use across a generalized geographic area. Given the environmental heterogeneity that occurs through the large spatial scale of the assessment, precision is sacrificed and we categorized it as General-Realistic.

The model demonstrated for this case study addresses the needs of the ERA by combining the Terrestrial Investigation Model (TIM), the Markov Chain Nest Productivity model (MCnest; Bennett & Etterson 2007; Etterson and Bennett 2013), and a 2-stage (juvenile, adult) matrix population model (unpublished data). Survival and reproductive endpoints measured in the northern bobwhite quail (*Colinus viriginianus*) and mallard (*Anas platyrhynchos*) were translated into estimates of breeding season productivity and survival for 31 bird species (Etterson et al. 2017). These productivity and survival estimates could then be used as input into the matrix population model for a representative species with a weekly time step to predict changes in PGR and bird abundance throughout the year. The model is consistent with the ERA's taxonomic specificity and spatial considerations by focusing on bird species that are representative of corn fields and associated habitats. It is consistent with temporal considerations and available exposure scenarios of the ERA by modeling breeding cycles and multiple breeding attempts with respect to pesticide application windows. It does not contain an explicit spatial context or predict bird abundance for any specific area with high precision. As such, it is also considered General-Realistic. A risk assessor can use this model output to describe the magnitude of risk and the probability of unreasonable, adverse effects to passerine bird populations in and near corn fields.

Case Study 3: This case study describes an assessment of the impacts of the Deepwater Horizon oil spill on small estuarine fish (Awkerman et al. 2016) as an example of a model that could be applied to a preliminary Natural Resource Damage Assessment (NRDA) conducted under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). In April 2010, the Deepwater Horizon oil spill became the largest accidental marine oil spill in the history of the petroleum industry with an estimated 5 million barrels of South Louisiana crude oil discharged into the Gulf of Mexico over the course of 5 months (Cornwall 2015). Weathered oil washed on the shores of Louisiana, Mississippi, Alabama, and Florida, with the heaviest hit area in Barataria Bay, LA. Trustees under NRDA performed damage assessments with the objective of determining if injuries occurred to natural resources as a result of the oil spill. The appropriate taxonomic specificity is species native to northern Gulf of Mexico estuaries; the relevant spatial considerations are the specific locations in the northern Gulf of Mexico impacted by the oil spill; the necessary temporal scale requires future protections to aid in mitigation scenarios; and existing exposure resulted in trackable observations of spatial, qualitative contaminant patterns in the environment. Based on these attributes, the assessment could be classified as Realistic or Realistic-Precise (Table 2). Since there were no existing baseline population estimates for native populations to compare to post-spill conditions and the majority of exposure data were qualitative, precision of the damage assessment will be low, so this assessment is categorized as Realistic.

The model developed was a three stage (embryo/larva, juvenile, adult) matrix model developed for the sheepshead minnow (*Cyprinodon variegatus*), a native resident of Gulf of Mexico estuaries (Awkerman et al. 2016). The model was developed specifically for Barataria Bay, LA, and accounted for habitat suitability, migration, temporally varying demographic rates of the fish, qualitative temporal changes in oil, spatial heterogeneity of oil distribution, potential fish oil avoidance behavior, and toxicity impacts of oil as measured in laboratory exposure studies (Awkerman et al. 2016). The model matches the taxonomic specificity and spatial considerations of the assessment needs by focusing on a species that is widespread throughout the region and the location of the greatest impact. By using a spatially explicit scenario, the model meets the temporal needs of the assessment to be able to demonstrate the long-term effects of changing oil distribution and severity as well as the influence of various mitigation scenarios on fish abundance. Because the model included a number of mechanisms that reflected fish population dynamics in the natural habitat but lacked precision in many of the model functions (e.g., oil distribution, avoidance behavior, migration), it is categorized as Realistic. The model is not considered realistic-precise because it contains several functions (e.g., fish movement, oil concentration) that are not based on empirical data. The model predicted a decline in the population within the study area and demonstrated that injury is likely to occur to estuarine resources as a result of the oil spill. This model is better suited to meet the objectives of the assessment than laboratory toxicity effects data and the limited available measured oil concentrations by providing a time frame in which populations are expected to be impacted and the relative magnitude of that impact. The model also has the potential to assess mitigation options.

Case Study 4: This case study describes NOAA's National Marine Fisheries Service's (NMFS; NMFS 2012) Biological Opinion (BO) of potential impacts to salmon under Oregon's freshwater acute cadmium criterion as part of a Section 7 consultation under the ESA and Clean Water Act. Section 7 consultations are performed to ensure the actions of federal or state agencies do not jeopardize the continued existence of a listed species or adversely modify its critical habitat. A biological evaluation (BE) was conducted by the US Environmental Protection Agency (USEPA) to determine if the maximum cadmium concentration allowable under Oregon's revised criteria is likely to adversely affect salmon or its critical habitat. The National Marine Fisheries Service responded with a BO that described its level of concurrence with the BE. The BO is taxa-specific (e.g., salmonid), addresses future cadmium exposure to salmonids across the entire state from any possible source, and does not include temporal variability in estimated exposure concentrations (EEC). Based on these attributes, it could be considered General or General-Precise (Table 2). Since the objective of the BO under the ESA requires it to have a high level of confidence for the protection of listed species, it is placed in the category of General-Precise (Table 2).

Life history models were developed for three species of salmon (*Oncorhynchus kisutch*; *O. nerka*; *O. tshawytscha*) using matrix models that varied across species by female lifespan, time to reproductive maturity, and the relative contribution of the reproductive ages classes (Spromberg and Meador 2006). The models incorporated the impacts of direct mortality and reduced growth rate to predict changes in population growth rate for salmon following both acute and chronic cadmium exposure. The models are general because they did not depict specific populations due to the difficulty in acquiring run-specific data and are consistent with the state-wide spatial context of the BO; however, demographic model parameters and toxicity effects were drawn from distributions of measured data and the model developers optimized confidence in model output. As such, the model is categorized as General-Precise. The model outputs consisted of changes in population growth rate of salmon populations exposed to both acute and chronic cadmium criteria, which concluded that the proposed acute criteria would reduce endangered salmon populations. This model output was a contributing factor to the conclusion that the proposed acute criteria would potentially jeopardize endangered salmon. As a result of this ***jeopardy*** finding, the USEPA formally approved the Oregon freshwater chronic criteria and disapproved the acute criteria for cadmium (USEPA 2013).

Case Study 5: This case study describes the recovery plan for the Northern spotted owl developed by the USFWS under the ESA. The objective of the plan is to develop site-specific management actions to achieve the recovery and delisting of the spotted owl using objective and measurable criteria and provide estimates of the time and costs of achieving recovery. The stressor in this example is non-chemical habitat alteration, the taxonomic specificity is the listed species, the spatial considerations is the specific critical habitat of the spotted owl throughout its range, habitat alteration is temporally and spatially explicit, and the objective of the recovery plan require it to have a high level of precision. It is therefore categorized as Realistic-Precise within the framework (Table 2).

A spatially-explicit, female-only, individual-based model (IBM) was developed to describe the dynamics of the population throughout its range (USFWS 2011). The model was developed from detailed data on spotted owl distribution, home ranges, and demographic rates available from various publicly available sources. The model provided simulations for spotted owl populations in physiographic provinces that were based on forest types and state boundaries. Habitat model cross-validation showed high confidence and robustness of the habitat suitability model and the model's performance was evaluated by comparing simulated population size to field data. Because of the specificity of the model and the high confidence in its output, it is consistent with the attributes of the recovery plan and is also categorized as Realistic-Precise. The model output provided the USFWS with the habitat conservation network that will continue to support the recovery of the spotted owl in accordance with the recovery goals.

## Discussion

Numerous reviews of population models in ERA have highlighted the technical basis, added value, and best practices in developing models and all agree on the need for more comprehensive guidance to assist risk assessors in developing models for ERAs (Pastorok et al. 2002; Forbes et al. 2009; Schmolke et al. 2010a; Forbes et al. 2016). We develop a framework that will help risk assessors identify appropriate population model complexity for an ERA objective as it pertains to the trade-offs among generality, realism, and precision of both the assessment and the model. While previous studies have discussed both model complexity and the trade-offs of the Levins (1966) trilemma as important factors in selecting models for ERA (Munns et al. 2008), our framework advances these recommendations by: 1) establishing that ERAs are bound by the same trade-offs and varying levels of complexity, 2) identifying the relative position of the ERA in the framework as the driver for model trade-offs and complexity, 3) identifying model attributes and complexity that correspond to ERA objectives and scale, and 4) demonstrating the framework with case studies specific to various regulations and taxa. This framework could be used in conjunction with previous guidance on population-level risk assessments (e.g., Barnthouse et al. 2008).

Our evaluation of why population models are not widely used in ERA identified lack of guidance on model complexity, understanding model uncertainty, translation of model output into an ERA endpoint, added investment, limited resources, model availability and general acceptance as major roadblocks in their application. The framework addresses these restrictions by providing guidance on model complexity for different ERA applications by asserting that the trade-offs in generality, realism, and precision of the model should be guided by those same trade-offs made within the ERA. In doing so, this allows the risk assessor to focus on the appropriate discussion of model uncertainty. For example, a general ERA need not require discussion of quantitative uncertainty of survival estimates used in a general model of a surrogate species, as it is beyond the scope of both the model and the assessment. Model outputs can range from relative changes in PGR in laboratory-exposed groups of individuals (e.g., Stark and Vargas 2003) to probability of extinction depending on the model formulation and complexity (e.g., USFWS 2011). Translating ecological outcomes produced by population models into risk assessment endpoints will vary based on the ERA, but the case studies presented here demonstrated this process for each of the five categories within the framework. Our framework depicts the relative costs of developing models of varying levels of complexity, but also demonstrates that models that require less investment cost still add value in assessments. It is difficult to quantify added investment of model development; however, models that have been used in policy decisions represent a significant research effort to develop widely available models that will have general acceptance through peer review (Spromberg and Meador 2006, Etterson & Bennett 2013). Models already developed specifically for ERA could be applied in other ERAs with very similar objectives. Accordingly, if the number of models developed for ERAs increases, future applications might become less resource intensive.

Model attributes identified as desirable for risk assessors included a strong scientific basis, flexibility, and a clear understanding of required input, utility of output, uncertainty, and limitations. A strong scientific basis has been extensively demonstrated for the use of population models in ERA (Pastorok et al. 2002; Barnthouse et al. 2008), but what has been lacking is the basis for applying models of varying complexity in the context of different ERAs. The framework presented here provides that basis, as well as examples on the type of models, that will serve as minimum information required for population models to produce an output that is useful for an individual ERA. Our guidance identifies taxonomic specificity, spatial context, and temporal considerations as the most important model attributes to match to an ERA as the first step in model development. Beyond that, a number of functions are recommended that could be included in model development for each category (Table 2); however, we purposefully do not expand on prescribing specific model formulism or functions for each category as these are dependent on data availability. Additional guidance on model development for each category could include a decision tool that would guide a risk assessor through questions related to the framework categories and data availability (e.g., Schmolke et a. 2017).

Using models for any purpose requires confirmation that the output is consistent with what is known about the focal species (Oreskes et al. 1994). For all models, validation and verification are important to demonstrate for ERAs in any framework category, the effort of which should be consistent with the investment level of the respective category. For example, it may only be possible to validate a general model against laboratory data but not possible to confirm that the model or data are in agreement with a species in a natural system. However, as demonstrated by Case Study 1, where the general model is used as weight of evidence in a general assessment, that level of confirmation is adequate for the model to provide value where data are limited. Conversely, models that are developed for assessments that require a higher level of precision (e.g., Case Studies 4 and 5) will require confirmation that the model is in agreement with natural systems. As model complexity increases and verification and confirmation of the model with the natural system become more difficult, sensitivity analysis becomes more important in explaining a model's inherent uncertainties and the relative importance of functions to model output.

Conceptually, the framework is a continuum of trade-offs discretized to five categories of general, general-precise, general-realistic, realistic, and realistic-precise with definitions, including attributes of ERA and models, associated with each category. Previously proposed frameworks of model selection for ERAs have focused largely on model formalisms (Pastorok et al. 2002; Munns et al. 2008).

We purposefully avoid discussion of specific model formalisms with respect to each of the categories, but do not disagree that some formalisms are more likely to be associated with some categories than others (Munns et al. 2008). Our categorization scheme targets matching the level of model complexity to that of the ERA objective to assist the risk assessor in understanding the data requirements and output potential for model application. Within this scheme, users may define a subcategory that mirrors their specific assessment more closely than those described here; however, the basis of matching the model complexity with that of the assessment within the framework would still apply. Even when considering this simplified classification, formalizing the concepts of generality, realism, and precision into definitions is a challenge and it is important to note that the categorization of models described here is within the context of ERAs and similar assessments and may not necessarily apply to other applications. Regardless of these challenges, we feel that the benefits of describing model development in terms of these intuitive concepts outweigh the shortcomings that may arise when heuristics such as these become applied too strictly (Levins 1993).

In model building, parsimony is always strived for such that a model should never be more complex than what is necessary for its purpose, but should be sensitive enough to demonstrate an adverse effect that may be observed in the environment. For risk assessors to use population models in ERAs, it must be clear how the models add value to the assessment (Wentsel et al. 2008). Our framework improves upon guidance previously provided (e.g., Pastorok et al. 2002; Barnthouse et al. 2008) by 1) initiating the process from the desk of a risk assessor, 2) providing definitions and examples of the trade-offs of generality, realism, and precision specific to ERAs, 3) using trade-offs determined for ERAs to directly guide the trade-offs for model building, and 4) demonstrating the application of model output to meet the objectives of ERAs in different trade-off categories. While we believe our framework presents significant improvements to aid a risk assessor in walking through the process of identifying what a model needs to contain to add value to an ERA, we also recognize that additional guidance on model building that specifically addresses data availability and quality would complement this framework (Schmolke et al. 2017). As we highlight here, the endpoint of the model and the objective of the ERA should be considered in conjunction with the appropriate level of model complexity and data available. Despite the attraction of models that are highly specific to a species or an area, we demonstrate that models that sacrifice these aspects of realism still have great utility in ERA.

Supplemental Information - The supplemental information describes case studies that demonstrate the actual or potential application of population models of varying levels of complexity and accuracy to meet objectives of policy decisions. The models highlighted in the five case studies represent five types of models from various positions within the framework: General, General-Precise, General-Realistic, Realistic, Realistic-Precise.

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**DATA ACCESSIBILITY**

No original data are associated with this manuscript.

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Figure Legend

Figure 1. Conceptual framework for population model selection for ERA identifying five categories that represent trade-offs among generality, realism, and precision. The categories lie in one of three investment levels (IL) which describe the relative level of resource investment (e.g., time, cost) associated with each position in the framework. IL 1 is the lowest investment amount and IL 3 is the highest.

Table 1. Glossary of terms commonly used on risk assessment and ecological modeling disciplines.

| Term (in order of appearance) | Context | Definition |
|---|---|---|
| Risk assessor | ERA | Investigates the existence, nature, and severity of environmental hazards; ensures the ERA addresses all important ecological concerns |
| Risk manager | ERA | Charged with protecting societal values; ensures that the ERA will provide relevant information to make decisions |
| Measurement endpoint | ERA | An expression of an observed or measured response to a hazard. A measurable response variable |
| Tiered ERA | ERA | A systematic approach, in which details progressively increase, to determine the level of investigation appropriate for an ERA |
| Sensitivity analysis | Modeling | Quantification of variability in the output of a model attributed to the variability of its inputs |
| Validation | Modeling | Reproducibility of a model within the context it is applied |
| Verification | Modeling | A demonstration that the model formula is correct |
| Confirmaion | Modeling | A demonstration that there is agreement between model predictions and natural observations |
| Mechanism | Modeling | A causal process that uses estimated parameters to describe physical or biological relationships |
| Qualitative uncertainty | ERA & Modeling | Identification of unknown or undetermined relevant information, relationships, or parameters |
| Quantitative uncertainty | ERA & Modeling | Measurement of error surrounding parameter estimation or empirical relationships |
| Model complexity | Modeling | Processes described by the model that includes the mechanisms represented, connectedness of parameters, and mathematical formula |
| Population growth rate (PGR) | Modeling | The rate at which population abundance increases over a given time period |
| Realism | ERA & Modeling | Contains independent variables known to have an important effect on the natural system |
| Generality | ERA & Modeling | Applies to more than one system |
| Precision | ERA & Modeling | Predictions or conclusions that are bound by narrow confidence limits |
| Quantitative complexity | ERA & Modeling | Mathematical complexities that increase outcome confidence |
| Qualitative complexity | ERA & Modeling | Knowledge-based complexities that represent real-world scenarios |
| Receptors | ERA | Any living organism, habitat, or natural resource that could be adversely affected by environmental contamination |
| Jeopardy | ERA | In the context of the Endangered Species Act, when an action is expected to diminish, directly or indirectly, a species' numbers, reproduction, or distribution |

Table 2. Ecological Risk Assessment attributes associated with each framework category.

| Framework Category | Taxonomic Specificity | Spatial Considerations | Temporal Considerations | Minimum Exposure Information | Life History Data | Example ERAs | Additional Potential Model Attributes | Potential Model Output |
|---|---|---|---|---|---|---|---|---|
| General | None | None | None; duration of exposure[1] | Modeled Expected Environmental Concentrations (EECs) | Laboratory estimates for surrogate species | Screening (all statutes) | None; age structure | Relative changes in PGR or age/stage distribution at EEC |
| General-Precise | Species or taxa | None, habitat, general location | None; Timing of exposure; | EEC or modeled temporal patterns of exposure | Field measurements for native species | ESA[2] step 3 | Age Structure; density dependence; spatial habitat structure | Expected changes in PGR at EEC; quantitative changes to relative population size |
| General-Realistic | Native or surrogate species; higher taxonomic level | Habitat or general location | Timing of exposure | Measured or modeled realistic patterns of exposure | Laboratory data for surrogate species or field measurements for native species | FIFRA[3] Refined (Tier 2) | Demographic variation; spatial habitat structure; genetic variation; toxicokinetics/toxicodynamics | Relative changes in PGR, age/stage structure, and population size |
| Realistic | Native species or taxa | Specific location | Time varying exposure | Measured or modeled realistic patterns of exposure | Laboratory data for focal taxa or field measurements for native species | CERCLA[4] Refined (Tier 3+) | Density dependence; spatial habitat structure; indirect effects; genetic variation; toxicokinetics/toxicodynamics | Relative magnitude of impact on population density, population viability/time to extinction, mitigation potential |
| Realistic-Precise | Native species | Specific location | Time varying exposure | Temporal and spatially explicit patterns of exposure; environmental concentrations measured in the environment | Field measurements for native species | ESA step 3, CERCLA refined (Tier 3+) | Density dependence; spatial habitat structure; indirect effects; genetic variation; toxicokinetics/toxicodynamics | Expected magnitude of impact on population density, population viability/time to extinction, mitigation potential |

[1] Acute or chronic

[2] Assessments performed under various statutes as part of Section 7 Endangered Species Consultation

[3] Federal, Insecticide, Fungicide, Rodenticide Act (1947)

[4] Comprehensive Environmental Response, Compensation, and Liability Act (1980)

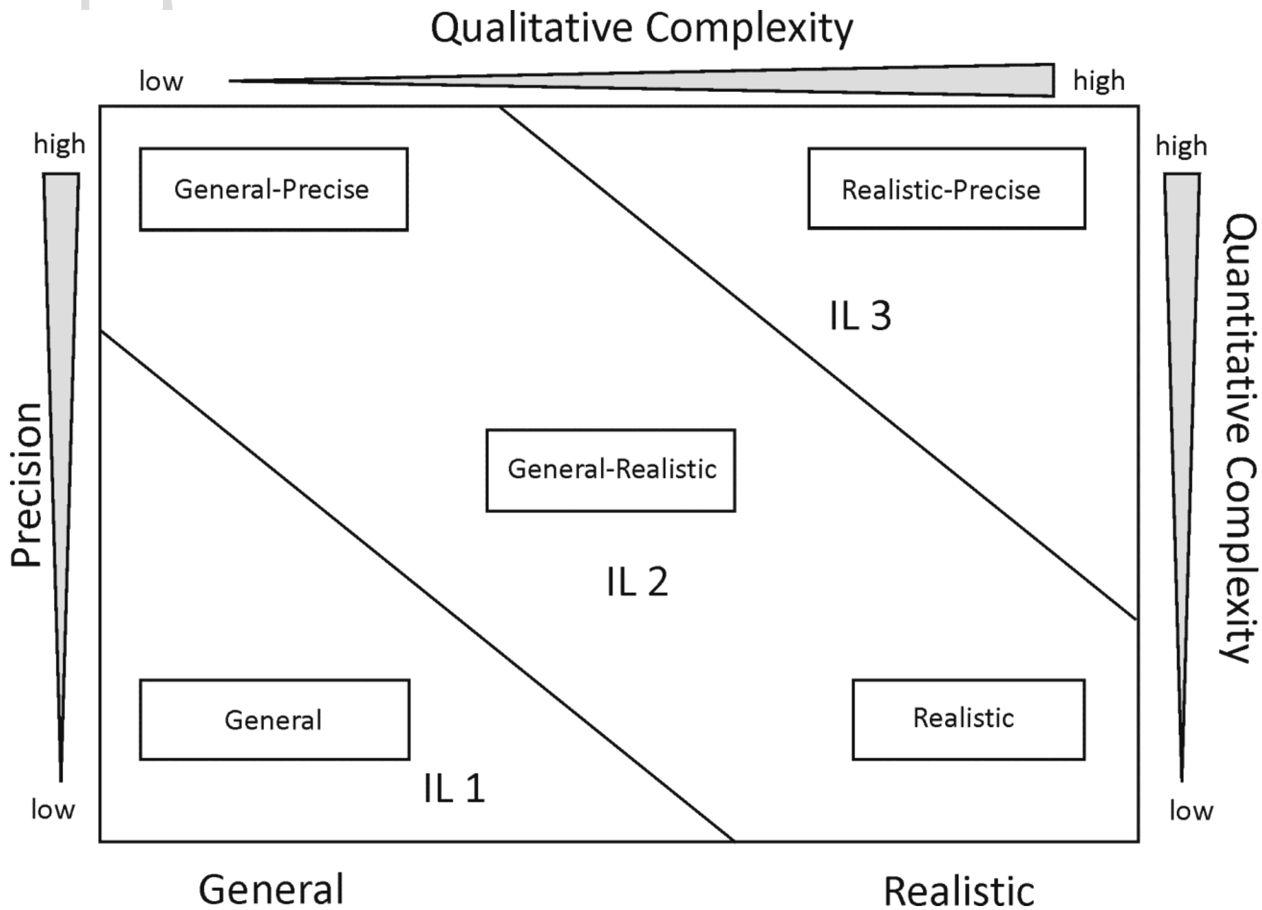
Qualitative Complexity
low
high
high
General-Precise
Realistic-Precise
high
Quantitative Complexity
IL 3
Precision
General-Realistic
IL 2
General
Realistic
IL 1
low
low
General
Realistic

*Figure 1*