PRA: A Global Perspective, Present and Future

R. Griffin
Coordinator, IPPC Secretariat
FAO, Rome

Introduction:

Pest Risk Analysis (PRA) is a term invented by the phytosanitary community approximately ten years ago to distinguish the type of risk analysis done to support official decision making for the application of phytosanitary measures. This paper is to give an overview of PRA in the context of its evolution with the International Plant Protection Convention (IPPC), in particular as regards the accomplishments and challenges of global harmonization.

Background:

The fundamentals of risk analysis are well-known and have a long history of practice in other disciplines. However, the systematic application of risk analysis methodologies for phytosanitary decision making is a relatively new area. This form of risk analysis emerged rapidly in the late 1980's, mainly as a result of negotiations in the GATT on what would later become the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

As the SPS became reality, governments suddenly became keenly aware of the need for PRA capacity to justify their phytosanitary measures and also to evaluate the measures of their trading partners. This increased awareness was manifested in several ways, including:

- structural changes at national level to make provision for PRA;
- accelerated national and international dialogue on concepts and procedures;
- calls for technical assistance; and
- pressure for global harmonization.

Because of its new relationship with the SPS and its history as a global focal point for plant quarantine, the IPPC became the natural place to join international initiatives. The newly formed Secretariat and the infant work programme for standard setting offered mechanisms for beginning to address the international aspects, in particular as regards harmonization. As a result, PRA was one of the first (and arguably most important) standard setting initiatives of the IPPC.

Ten years later, the IPPC has seen extensive effort and resources invested in the development of harmonized guidelines for PRA. These efforts continue as a high priority is given to adding breadth and depth to standards on PRA. Likewise, the

emergence of new issues and increasing expertise among national plant protection organizations (NPPOs) has served to further amplify the scope and underline the need for greater clarity and detail in future work on PRA standards.

The basis for PRA in the SPS Agreement and the IPPC:

A fundamental tenet of the SPS Agreement is that measures for the protection of plant, animal, or human health or life are based on international standards or an assessment of risk taking into account scientific principles and evidence. This is found in Article 2 (Basic Rights and Obligations) and is the subject of Article 5 (Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection). The concept also has close linkages to other principles and terms in the SPS Agreement as well as in the IPPC and associated standards.

Both the SPS Agreement and the IPPC emphasize a systematic process for gathering, evaluating, and documenting scientific and other information as the basis for SPS measures affecting trade. In the SPS, this involves consideration of economic as well as biological aspects of pest risk for animal and plant health. However, it should be noted that the SPS does not indicate that economic factors are to be considered directly in risk assessments for human health. This represents a major distinction in the SPS between the type of risk analysis done for human health versus those done for plant or animal health.

Another distinction worth noting is that the IPPC is very specific about the proportionality of measures, referring to PRA as the means for determining “the strength of measures”. This relationship is not as clear in the SPS Agreement. Likewise, the IPPC refers exclusively to “potential economic importance” (cf. definition of a quarantine pest) where the SPS refers to “biological and economic consequences”. Discussions within the IPPC on this point have reinforced the position that all consequences may be considered in economic terms whether or not having direct market values. The point returns again in discussions on the application of the IPPC’s PRA procedures to the evaluation of environmental pest hazards.

SPS-IPPC Relationships in Risk Analysis:

The SPS Agreement states that a risk assessment is not required where measures are based on international standards. This is because the risk basis for the standard is already internationally agreed. However, deviations from standards must be justified by a risk assessment (Article 3). Provisional measures may be put in place without the benefit of a standard or a complete risk assessment and such measures may deviate from standards but they must have a reasonable scientific basis and must be reviewed using risk assessment when more complete information is available (Article 5.7). Further, jurisprudence on SPS disputes indicates that governments have an obligation to actively pursue the information needed to complete a risk assessment for provisional measures.

The requirements of the SPS Agreement create a direct relationship between risk assessment and international standards that are established by the relevant

international organizations. Part of this relationship involves the presence or absence of standards. Where standards do not exist or are deemed inappropriate, risk assessment is needed to provide the justification for measures. Another part of the relationship involves the standards developed for performing risk assessment. In both cases, the standard setting organizations play a significant role in providing governments with the means to justify and challenge their SPS measures.

The IPPC is identified in the SPS Agreement as the reference point for phytosanitary standards. Although pursuing an ambitions program of standard setting to meet the expectations of the SPS, standard setting in the IPPC is only in its early stages. To date, most of the effort devoted to IPPC standards has been directed toward establishing a foundation of concept standards from which more specific standards may be developed later. However, at this early stage in phytosanitary standard setting, there are not yet specific standards that can form the basis for measures in lieu of risk assessment. Therefore, where phytosanitary measures are concerned, WTO Member governments must base their phytosanitary measures on risk assessments. This means that the process used for phytosanitary risk assessment becomes extremely important to all countries.

At some point in the future, one could imagine that PRA would become less important for determining measures as more measures are agreed in international standards. When this becomes the case, the primary use of PRA will be to justify deviations from standards or to evaluate the measures of others that deviate from standards. However, given the present rate of standard setting in the IPPC and the enormous range of measures to be covered, it is unlikely that such a situation will exist in the near-term. Thus it may be assumed that PRA will continue to be the primary means for establishing phytosanitary measures and that countries will therefore continue to place a high priority on the elaboration and harmonization of PRA procedures.

Risk Assessment – Risk Analysis – PRA:

The SPS Agreement does not refer to PRA or to risk analysis, but uses the term “risk assessment”. The IPPC and the other standard setting organizations identified in the SPS Agreement (OIE and Codex) use the term “risk assessment” to describe a fundamental component of risk analysis. This is the characterization of risk based on an evaluation of the evidence to estimate the likelihood and consequences of an adverse event, and the associated uncertainty. In the case of plant protection, the “adverse event” is normally the introduction (entry and establishment) or spread of a pest.

The other key element common to risk analysis for all three SPS disciplines is “risk management”. In this context, risk management refers to the analytical process used to identify risk mitigation options and evaluate these for efficacy, feasibility and impacts in order to decide or recommend the most appropriate means to mitigate risks that are found to be unacceptable as a result of risk assessment. The SPS Agreement does not refer to risk management per se,

although the concept is implicit in that the theme of the Agreement is “measures” which should result from risk-based decisions.

Other elements commonly identified in risk analysis processes may vary. For instance, “risk communication” is sometimes distinguished as a separate element or other times may be addressed less directly as a factor to be emphasized throughout the process. To date, the IPPC has devoted little attention to risk communication per se.

Elements of transparency, such as documentation and uncertainty are also sometimes given the status of distinct elements in risk analysis processes. The label and level of recognition given to these points in any particular process may change for various reasons. The primary reason for differences between each of the disciplines covered by the SPS Agreement (plant, animal, and human health) is that each community has unique characteristics, history, and usage of terms.

Although the mix of terms and emphasis may seem to complicate the meaning and role of risk analysis in the SPS Agreement, there exists in practice very strong consistency in the understanding and use of the concepts. To this end, the IPPC strives to encourage consistency across disciplines and promote harmonization in the interpretation and application of risk analysis concepts both within the phytosanitary community and across other related areas. This includes the “sister” standard setting organizations under the SPS Agreement and increasingly involves areas of overlap with the environmental community.

ISPMs:

ISPM No. 2 (*Guidelines for Pest Risk Analysis*) was adopted by the IPPC in 1995 after three years of development. This standard was designed to provide basic background regarding the concept of risk analysis and its application in practice for phytosanitary purposes. It has enjoyed wide recognition and use by national plant protection organizations throughout the world as a reference outline for phytosanitary risk analysis.

Even before the establishment of ISPM No. 2, the IPPC began the development of detailed standards directed specifically to key aspects of the PRA processes outlined in ISPM No. 2. The original idea was to formulate “supplemental standards” that supported ISPM No. 2 by providing greater detail.

Topics for which supplemental standards were drafted include:

- Pest categorization (September 1994);
- Economic impact assessment (November 1994);
- Probability of introduction (January 1995); and
- Pest risk management (March 1995).

The draft supplemental standards were combined into a single document based on the recommendations of the Committee of Experts on Phytosanitary Measures (CEPM) 1996. However, further work was delayed pending the

adoption of the revisions to the IPPC in 1997. Afterward, the Secretariat and experts undertook to combine the documents into a single supplemental standard including the concept of regulated non-quarantine pests which had emerged from the revision of the Convention.

Efforts by the Secretariat and PRA experts to extend the scope of the draft supplemental standard to cover PRA for both quarantine and regulated-non quarantine pests in a single document proved both complex and awkward. Instead, the Secretariat undertook to complete a draft dealing only with quarantine pests and developed preliminary suggestions for revisions to ISPM No.2. The decision was taken by the CEPM to defer revisions to ISPM No. 2 until the new standard was completed. The CEPM also recommended that the new standard be designed as a stand-alone document on *Pest risk analysis for quarantine pests* rather than a supplement to ISPM No. 2.

Subsequent development of the draft standard was guided by agreement on the concept of three related but independent standards for PRA: ISPM No. 2, *Guidelines for pest risk analysis*; PRA for quarantine pests; and PRA for regulated non-quarantine pests (see Figure 1). Following this agreement, the new draft document evolved through several more iterations before it was finally approved for distribution to governments in 1999. In this case, the consultation period was extended beyond the normal four months due to numerous requests from governments for additional review time. In November 2000, the Interim Standards Committee was able to reconcile the comments from governments and approved the draft that was then adopted by the Interim Commission on Phytosanitary Measures as ISPM No. 11 in April 2001 - a full seven years after beginning the process.

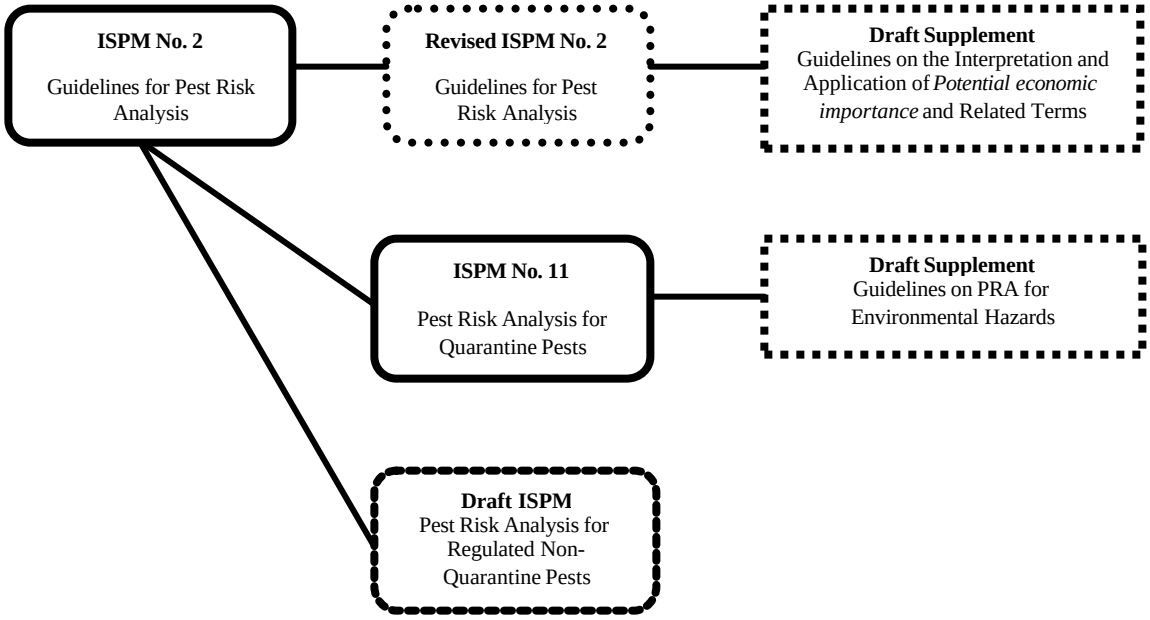
ISPM 11 now stands as the centerpiece for PRA in the IPPC. It updates, corrects, and clarifies ISPM No. 2 and adds significant detail to many aspects of the PRA process. Although ISPM No. 2 has not been formally withdrawn, it is recognized that revision is necessary to adjust the standard to be compatible with the revised Convention and ISPM No. 11. At the same time, it is recognized that a complementary stand-alone standard on PRA for regulated non-quarantine pests is required to complete the core “family” of PRA standards for the IPPC. It is anticipated that work on this standard will follow adoption of the concept standard on regulated non-quarantine pests (expected in 2002).

The idea of supplemental standards was not abandoned when it was decided to merge early supplements into ISPM No. 11. Indeed, the appeal of shorter, more focussed supplements has increased after the prolonged effort required for ISPM No. 11. One such initiative currently underway involves a supplement to ISPM No. 11 specifically addressing pests as environmental hazards. Another is a possible supplement to ISPM No. 2 (or alternatively the Glossary of Phytosanitary Terms) regarding the interpretation of “potential economic importance and related terms”.

Examples of other supplements that have been suggested include:

- The interpretation and application of the concept of "appropriate level of protection";
- Risk communication;
- Methodologies for economic analyses;
- Quantitative methods;
- Estimating establishment thresholds;
- The assessment of specific risk mitigation conditions (e.g., low-mobility pests);
- Criteria for the interpretation of "not widely distributed";
- Methodologies for comparing, ranking and prioritizing risks;
- Feedback mechanisms for improving the accuracy of PRA.

Figure 1: The Current Status and Relationship of PRA Standards



Issues and challenges:

Ten years of development, discussion, and implementation by the phytosanitary community has resulted in a substantial degree of PRA harmonization. It has also served to highlight key issues and raise new ones. Following is a summary of some current issues and challenges for the harmonization of PRA in both a conceptual and operational context.

Initiation and pest categorization

At the time ISPM No. 2 was developed, few national plant protection organizations had first-hand experience with the systematic application of risk analysis. Much of the discussion and input leading to the standard was based on relatively limited experience and exposure to risk analysis in other disciplines combined with a degree of speculation on how such concepts and procedures would be operationally applied in a phytosanitary context.

A key aspect of this stage in the evolution of ISPM No. 2 was the focus on the definition of a quarantine pest. The definition was considered to provide the primary criteria for identifying the hazard. This represents a critical point because it became a fundamental element of the "initiation stage" in ISPM No. 2 and later the "pest categorization stage" in ISPM No. 11, both which are roughly analogous to "hazard identification" in conventional risk analysis.

This is sometimes considered awkward because the relevant definitions require a sort of mini-assessment in order to understand whether a pest meets the defining criteria and therefore can be considered a hazard that merits assessment. The approach of many plant quarantine organizations has been to consider that measures are justified for any pest that meets the defining criteria (i.e., all quarantine pests require maximum measures). As a result, there is often reluctance to proceed with further assessment to confirm the status of the pest, determine the magnitude of the potential hazard, the strength of measures, and the comparative risk/strength of measures compared to other risks and measures.

Despite considerable attention being given to achieving a common understanding of this aspect of the PRA process, it continues to cause problems for many countries at an operational level. The issue is further complicated by concerns for invasive alien species where these may be considered pests affecting the environment. This is because alien invasive species do not have the same relationship with definitions[1].

Uncertainty and precaution

A key issue under international scrutiny and debate is the role and use of precaution in the regulation of hazards to plant, animal, and human health and the environment. A concept known as the precautionary approach (and also as the "precautionary principle") has emerged from the international framework for environmental protection to become a contentious issue in other fora where the concept is not understood or not expressed in the same terms.

The lack of clarity in this regard is often mistaken for the lack of precaution or the lack of concern for the importance of precaution. It has even been characterized by some as a "missing principle" in the SPS Agreement, while others argue that all SPS measures are inherently precautionary to a greater or lesser degree depending on the evidence. The point is further complicated by interpretations of "provisional measures" (Article 5.7 of the SPS Agreement) as the SPS equivalent of precautionary measures. Another common misunderstanding comes from the assumption that the SPS Agreement requires scientific certainty (it does not).

Within the IPPC framework and indeed within the conventional wisdom associated with risk analysis in general, precaution is an element of decision-making related to the level of uncertainty associated with risk analysis. However,

[1] Definitions currently used by the CBD require that an organism be established outside its normal range before it can be classified as an alien species, whereas a quarantine pest is labelled as such based on its potential threat to an endangered area.

due to the emphasis placed on scientific evidence and principles, the importance of uncertainty in risk analysis and the criteria for governments to use for disciplining their judgements on uncertainty is not well understood or internationally harmonized. Significant opportunity exists to articulate the role and importance of uncertainty in risk analysis as the basis for phytosanitary measures and thereby clarify the application of the precautionary approach within the framework of PRA.

Risk management and the efficacy of measures

The entire area of risk management has received little attention in PRA standards until recently. The experience gained from drafting standards on systems approaches and wood packaging has highlighted the need for harmonized criteria and procedures to assess the efficacy and equivalence of measures. Efforts are underway to begin this process in 2002 but the needs are diverse and deal with a level of complexity that rivals even the efforts to date on PRA. In particular, there is the need to raise the general level of awareness and competency in quantitative methods. Fundamental concepts that have already surfaced such as tolerance, prevalence, and the relationship of pest mortality to risk, have proven difficult due to the lack of exposure and understanding. Development in this area will require parallel technical assistance to promote developing country support and avoid creating a wider divergence between developed and developing country implementation.

Quantitative and qualitative methods

ISPM Nos. 2 and 11 provide the framework for PRA but do not describe specific methodologies or make clear the advantages and disadvantages of using different methodologies under different circumstances. One area of considerable misunderstanding is the meaning and use of qualitative and quantitative methods. In particular, there is considerable interest in understanding the technical specifications of each and their appropriate applications. This follows closely the development of guidance on the efficacy of measures as described above, but it is not limited to risk management. Indeed, the focus of most interest has been on risk assessment methods. The primary difficulty has been the emphasis to date on the most sophisticated applications with little or no effort to also establish and promote less complex but more generally practical methods. Possibilities exist for a number of very useful supplemental standards for this purpose.

Invasive alien species, GMOs, and Biosafety

Interest has grown rapidly for understanding the relationship of PRA to concepts emerging from the Convention on Biological Diversity (CBD). The ICPM has recently clarified the role of the IPPC with respect to invasive alien species, genetically modified organisms (changed to living modified organisms), and biosafety. The establishment of a standard on PRA for living modified organisms was identified as a priority and specifications for this purpose have been drafted. In addition, the ICPM requested the elaboration of relevant elements of PRA as they apply to the assessment of plant pests as environmental hazards. This has resulted in the development of a draft supplement to ISPM No. 11 that is currently under review.

It is expected that these and further developments in this regard will involve collaboration with the CBD Secretariat and relevant experts. This is particularly important as issues arise from conceptual differences and terminology. Although the IPPC is relatively advanced in elaborating harmonized guidelines for PRA compared to the environmental community, there are significant differences in approach and detail which are not likely to be easily resolved. Nonetheless, it is extremely useful for the IPPC to strive for maximum harmonization in order to facilitate understanding and implementation at the operational level and for the CBD to benefit from the phytosanitary community's experience and expertise in this area.

Abbreviated procedures

ISPM No. 11 is perceived by some countries to create detailed and complex PRA procedures. This is compounded by training and other initiatives where the most sophisticated and detailed analyses are presented as examples. In fact, the minimum requirements for PRA (as regards international obligations) are relatively simple and logical. A conscious effort was made to indicate in ISPM No. 11 that much of the information in the standard is designed to provide additional detail in areas where greater guidance is needed, but that most PRA should be simple and routine. The key point that is often lost is the need to have sufficient depth of understanding to know what methodology and what level of detail is most appropriate.

Outlines, checklists and other abbreviated approaches to PRA are appealing because they simplify the process and may give the impression of covering all essential elements without the need for a deeper understanding and critical thinking. In some cases, these approaches have reduced the process to a "fill-in-the-blank" format that lends itself to completion by personnel with minimal technical qualifications. The difficulty with this is that it can destroy much of the analytical aspect of PRA and reduce it to an administrative exercise that may be claimed to be consistent with international standards. The primary dangers are that risk analysts will not develop or improve their understanding of PRA and that policy makers will be disadvantaged by the lack of analytical depth.

Resources and Cooperation

The level of resources devoted to PRA depends on many diverse factors and is not limited to resources provided by the national plant protection organization. The government assumes the responsibility for any decisions based on PRA. However, in principle, anyone including private interests and trading partners may perform the PRA.

The most important resources needed for PRA are information, methods, and experience. In the vast majority of cases, PRA is a relatively simple and straightforward process that follows a systematic approach to decisionmaking including basic documentation regarding the process and information. Methods and experience are gained with time and through ongoing efforts to improve PRA. However, the gathering of relevant information normally requires more time and effort than any other aspect of PRA.

One source of information for PRA is the scientific literature. The Internet has proven to be a significant aid to all countries trying to obtain information for PRA from experts and literature. Other sources are scientific journals and publications to the extent that these may be available. Scientific inputs may also be provided through direct communication with researchers and credible sources having firsthand experience or observations.

An extremely important source of information for PRA is official lists, reports and responses from the national plant protection organization in the country of origin. The exchange of information through official IPPC contact points is particularly useful for the verification of pest status and indications of the risk management measures that may be used or available. In instances where such information is requested for PRA, it is essential that officials receiving the request make a reasonable effort to obtain the needed information and respond in a timely manner. Where it is not possible to provide the requested information, the government should be open to provision for such information collection as may be provided through other means.

Many governments are experiencing severe difficulties in both obtaining and providing such information. This results in frustrating delays in PRA and often translates into uncertainty that causes the estimation of risk to be more conservative and measures to be stronger than may be necessary.

Linkages

Risk analysis is central to the linkage of key players involved in, or impacted by, the establishment of phytosanitary measures. The national plant protection organization uses PRA to establish the technical basis for regulations but is highly dependent on scientific inputs from the research community as well as official information from trading partners. Likewise, the private sector (industry, trade, etc.) may be important in providing information, proposing risk management options, and judging the feasibility of options suggested for implementation. It must also be noted that policy makers are bound by the obligations of their country to ensure that their decisions are in conformity with the provisions of the SPS Agreement and the IPPC, i.e., based on an evaluation of the risks using scientific principles and evidence. Finally, it is essential that policy makers in one area (e.g. agriculture) are aware of, and involved with, relevant policy making in other areas (e.g., environment, trade, foreign policy, etc.) for national consistency. In many cases the linkages between these groups are weak or non-existent resulting in diminished value and benefit from PRA.

The future:

There is no question that the global harmonization of PRA has made significant progress under the IPPC, but not without considerable effort. As the understanding of fundamental concepts increases and the practice of PRA becomes more prevalent, the demand for more guidance and additional detail becomes greater. A number of foundation stones still need to be laid, especially as regards risk management and the efficacy of measures. A the same time, growing complexity and sophistication in this and other areas of PRA needs to be

carefully managed to ensure that the chasm between believers and non-believers does not widen. Finally, there are questions of commitment and resources - that is, the commitment of national plant protection organizations to cooperate in moving forward and then devoting resources to do so. In the final analysis, this will determine how fast and how far the IPPC will move with the global harmonization of PRA.

PRA
A Global Perspective
Present and Future

R. Griffin
Coordinator

Secretariat of the
International Plant Protection Convention

Global Perspectives?

- Global ‘pieces’
  - The good, bad, and the ugly
- Global commonalities - harmonization
  - What is harmonized
  - What may be harmonized
  - What should be harmonized
  - What is hopeless

Harmonization

- Technically sound
  - Scientific disagreement
  - Natural variability
- What can be agreed
- Experience
- Willingness and resources

Global Frameworks

- The SPS Agreement
- The IPPC-SPS relationship
- Harmonization = standard setting
- The “phytosanitary” approach to risk analysis

Ten Years of Harmonization

- NAPPO Int'l Workshop (Oct 1991)
- SPS Agreement (1995)
- ISPM No. 2 (1995)
- Supplemental standards (1994-96)
- PRA for Quarantine pests (2001)

The IPPC PRA Family

- ISPM 2
  - Potential economic importance
  - Other supplements
- ISPM (X) PRA for RNQP
  - Supplements?
- ISPM 11 PRA for Q-pests
  - Supplement on environmental hazards
  - Supplement on LMOs
  - Others?

In the Pipeline

- PRA for regulated non-quarantine pests (2002-?)
- Explanation of potential economic impacts (2002-?)
- Supplement to ISPM 11 for environmental pest hazards (2002)
- Supplement (?) on LMOs (2002)

Possibilities for the Future

- Quantitative method(s)
- Methods for assessing economic impacts
- Comparative risks & risk ranking
- Risk communication
- Uncertainty

Challenges

- Pest categorization
- Uncertainty and precaution
- Efficacy of measures
- Quantitative vs Qualitative methods
- CBD & environmental approaches
- Abbreviated procedures
- Linkages

Advice?

- Practice
- Share
- Look around
- Evolve

Don’t allow the horizon to become the edge of the rut!