MILLIMAN WHITE PAPER

Use of real-world healthcare data to widen the evidence base

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NICE's[1] consultation paper[2] on the use of data and analytics is open for comment until 13 September 2019. In this paper, we outline some of the key considerations associated with using real-world data (RWD) to widen the evidence base used in economic evaluations. These considerations are discussed with a focus on the English NHS but apply more generally to any healthcare system considering the use of RWD.

Consultation paper outline

The consultation paper sets out how NICE intends to use broader sources of data and analytic methods to enhance its existing methods and processes. The consultation paper considers the type of evidence NICE currently uses (e.g. clinical, social care and public health guidelines and published evidence), other types of data that are available (e.g. observational research datasets, primary and secondary care database and data collected through digital health technologies) when and why these should be considered and the practical considerations associated with data analytics.

The availability of real-world data and the recognition of its value are on the rise, both in the UK and overseas. It is encouraging to see that this is being considered as a potential complement to existing guidance and published literature used to inform economic evaluations/cost-effectiveness studies and policy decisions.

What is real-world data?

In a previous Milliman publication, 'Breaking through the hype of real-world evidence'[3], real-world data (RWD) is described as data relating to patient health status or the delivery of healthcare collected during the course of clinical care and captured in a variety of data sources, such as administrative claims, electronic health records (EHRs) and product and disease registries[4]. Real-word evidence (RWE) is generated through the analysis and/or synthesis of RWD and can identify the effects of healthcare interventions, such as benefits, risks or resource use that are not routinely collected during randomised control trials (RCTs). It can also supplement findings about endpoints observed in RCTs by providing information from longer periods of observation or for broader patient populations than those enrolled in the RCT. Further, RWD may enable research that is not possible to model using RCTs (e.g. due to ethical considerations, limited durations or limited sample sizes) but that may be possible through real-world evidence and pragmatic trials[5].

Using real-world data

When considering the use of RWD, we think the following questions should be kept in mind from the outset and initial decision-making phase on whether or not to use RWD right through to the analysis and producing results. This will ensure that the sources of data, how they are used and the ultimate methodology that is followed can lead to making recommendations and policy decisions with confidence.

1. What is the primary research question and what is the study methodology?

Having a clear definition of the study purpose can help inform what type and granularity of data are required by helping the researcher to address initial high-level considerations. For example, geography and healthcare system, healthcare services and setting (e.g. inpatient, outpatient or community).

1 NICE (The National Institute for Health and Care Excellence) provides national guidance and advice to improve health and social care

2 https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/how-we-develop-nice-guidelines/consultation-data-and-analytics-statement-of-intent

3 http://us.milliman.com/uploadedFiles/insight/2019/breaking-through-hype-real-world-evidence.pdf

4 http://us.milliman.com/uploadedFiles/insight/2019/breaking-through-hype-real-world-evidence.pdf

5 https://www.rand.org/content/dam/rand/pubs/research_reports/RR1900/RR1972/RAND_RR1972.pdf

2. What is being measured?

Typically, we would want to use healthcare data to measure cost, utilisation and/or outcomes.

It is important to determine whether the cost included in the data represents the actual cost of the service or a reference cost, as reference costs may misrepresent the true costs. This is particularly relevant when considering the use of SUS[6] and SLAM[7] data in the NHS. Further, it is important to consider from whose perspective the cost is being reported. For example, the funder (e.g. Clinical Commissioning Group (CCG) or NHS), the provider (e.g. hospital) and/or any out-of-pocket payments made by the patient (this is less relevant for most services in an NHS context where there are few out-of-pocket payments).

Utilisation may be captured with varying degrees of detail, as this will usually be captured according to how it is reimbursed. Understanding the financial incentives that drive the structure and quality of data is important. For example, data relating to hospital admissions paid for on a packaged basis using case rates (e.g. healthcare resource groups (HRGs) or diagnostic related groupers (DRGs)) may lack detail regarding the exact services provided. Further, depending on how consultant physicians are reimbursed, we may or may not expect to see detail around provider costs. For example, when consultant doctors are paid a salary by the hospital, we may not see explicit cost and utilisation for consultants in the data, but in countries where doctors are paid fee-for-service, the real world data can contain extremely rich information about the services that each doctor provided.

Real-world outcomes data is unlikely to include measures such as QALYs, symptoms and side effects but may include other outcome measures of interest such as physical status outcomes (e.g. walkers, wheelchairs or nursing homes), co-morbidities, re-admission rates, mortality, condition incidence and prevalence and condition severity.

3. Does the data reconcile?

Real-world data should reconcile to other relevant data sources and/or relevant financial statements. For example, when using SUS activity data, it would be important to reconcile this to the corresponding SLAM data and understand the reasons for differences in cost and activity within each dataset. Further, it would be important to reconcile to clinical commissioning group (CCG) financial statements to ensure that the data included in the study represents the actual cost borne by the system. This can be a long and arduous process since the data required to produce this reconciliation is often held by multiple organisations (e.g. CCGs, community providers, GP surgeries and hospitals), has inconsistent structures and is reported from multiple perspectives e.g. a community provider on a block contract may not have accurate activity counts and may report cost from their perspective rather than the CCG's. Further, RWD can be compared to incidence or prevalence rates reported in literature to identify and investigate any discrepancies.

4. How coherent is the data?

Linked datasets allow us to obtain a more comprehensive view of a patient's journey through the healthcare (and perhaps social care) system. The benefits of using linked datasets include: identify additional patterns, associations and causations; increased sample size; better prediction of risk factors for disease; increased volume and speed of research; more complete safety profiles and more realistic assessments of possible adverse events; and more comprehensive identification of environmental, genetic and socio-economic risk factors;[8]. In certain contexts, linked data may not be required and non-linked data may be perfectly adequate for the study purposes[9]. It is therefore important to consider if the benefits of linked data are relevant for the particular study or if it is possible to proceed without it, particularly if it is difficult or costly to obtain.

When assessing the coherency of data from multiple different sources, it is important to consider if the data relates to the same healthcare system, set of patients and time periods or if any adjustments need to be made when linking the data. Further, any data protection or anonymisation requirements will need to be adhered to. For example, the General Data Protection Regulation (GDPR)[10] aims to protect all EU citizens from privacy and data breaches in today's data-driven world[11] and any economic evaluation using personal data for EU citizens will need to comply with this regulation.

5. Does the data have internal and external validity?

We can think of the validity of a study in two ways[12]:

- **Internal validity** – the extent to which the observed results represent the truth in the population we are studying and, thus, are not due to methodological errors.
- **External validity** – refers to the extent to which the results of a study are generalisable to patients in daily practice, especially for the population the sample is thought to represent.

External validity should be assessed by considering generalisability and/or transferability. The ability to generalise and/or transfer RWD may be greater than for RCTs, while RCTs may have greater internal validity. Data is generalisable if it can be applied in an alternative setting without any adjustment while it is

6 Secondary Uses Service (SUS) data is a single, comprehensive repository for healthcare data in England. It includes patient-level information in line with national standards and activity costed with national Payment by Results (PbR) tariff.

7 In the NHS, Service Level Agreement Manager (SLAM) datasets enable the interchange, in a uniform and consistent format, of monthly contract monitoring between purchasers and providers of healthcare and reflect local costings.

8 https://www.rand.org/content/dam/rand/pubs/research_reports/RR1900/RR1972/RAND_RR1972.pdf

9 For example, the discovery of how to use non-linked data was critical to the development of mortality tables.

10 https://gdpr-info.eu/

11 https://eugdpr.org/the-regulation/

12 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6188693/

transferable if it can be adapted to apply in other settings[13]. For transferable data, appropriate adjustments and assumptions need to be made to ensure that the data is relevant for the setting. For example, it may be appropriate to use utilisation rates from the RWD with adjustments to the unit costs to reflect service costs in the setting of interest. Alternatively, it may be necessary to make adjustments to utilisation rates to reflect differences in disease burden or clinical practice.

6. Is there sufficient data?

Having a sufficient volume of data is crucial to arriving at robust conclusions and RWD can be used to achieve this. Insufficient volumes of data can result in spurious results and data from a single RCT may not be relevant to additional patient populations.

In certain cases, data from non-UK sources could be considered where there is insufficient data from UK sources. RWD can prove to be especially useful in the case of rare conditions and highly specialised technologies where data from a single regional or even national database may not be large enough to provide statistical credibility and more powerful insights may be generated by using a combination of datasets from multiple sources.

7. Is the data of high enough quality?

Despite the sheer volume of healthcare data that is sometimes available and the enormous amount of detail it contains, data quality issues can cause major problems with analysis, create biases and impair decision making. Input errors and incomplete records in healthcare data can lead to errors in interpretation by data users. The importance of data quality warrants investment in data assessment tools to assure data confidence, given the importance of the resulting decisions.

If data is coherent, relevant, of sufficient volume and over an appropriate time period but is of poor quality, its value will be limited.

In a previous Milliman publication, 'Role of data in transforming UK private medical insurance analytics'[14], we demonstrate how our data quality tool has helped us assess the quality of data in the UK private medical insurance (PMI) market. The principles used to develop this tool apply for any RWD healthcare data. The data quality tool is centred on four main principles:

- Data validation: Review key data fields, the values within them and specifying requirements and thresholds for acceptability.
- Data audit: Assess the credibility of data within each field, distributions of cost, activity and outcome fields and erroneous entries within the data e.g. negative ages.
- Combinational integrity: Coherency across datasets to allow for linking of datasets without statistically significant loss of data.
- Reconciliation: Ease with which data can be reconciled with financial information, control totals and other relevant datasets.

As the types and volumes of RWD data continue to expand, increased care and attention will need to be given to data quality. For example, administrative medical insurance claims data is fairly mature in many developed markets around the world while data from recent technologies, e.g. wearable devices, is newer and less well-structured and understood, as well as not being as straightforward to collect as administrative claims data.

8. What time period is being covered?

Using RWD enables the collection of cost, utilisation and outcomes data over a longer time period than traditional RCT methods.

When considering the observation period for the analysis, it is important to balance having a long enough time period to conduct a robust trend or longitudinal study against using older data that may no longer be relevant. Historical data may also need to be adjusted to reflect changes that have occurred between prior time periods and the current system state. For example, trend adjustments for cost and utilisation are common adjustments that are made to reflect changes in the cost of services and utilisation patterns over time. However, we may also need to consider other (less straightforward) adjustments such as changes in the overall healthcare system, how therapeutic changes have affected how patients are treated, the way data is captured, the services covered, medical advances and disease burden.

9. Has the potential for bias been identified?

When conducting an economic evaluation, we need to be confident that conclusions made about a particular intervention are due to the actual intervention rather than other phenomena and sources of bias. Figure 1 sets out a few examples of the types of bias to look out for[15] and if these types of bias could be present in RWD data, traditional data types (RCTs and literature) or both:

FIGURE 1: TYPES OF BIAS

BIAS TYPE	DESCRIPTION	TYPE OF DATA AT RISK OF BIAS
Admission rate bias	Variables under study affected by selection of hospitalized subjects leading to bias between exposure and disease under study.	Both
Allocation bias	Systematic difference in how participants are assigned to comparison groups in a clinical trial.	Traditional
Attrition bias	Unequal loss of participants from study groups in trial.	Both
Chronological bias	Study participants allocated earlier to an intervention or group are subject to different	RWD

13 https://www.valueinhealthjournal.com/article/S1098-3015(11)71836-8/pdf?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301511718368%3Fshowall%3Dtrue

14 http://assets.milliman.com/ektron/data-transforming-UK-health-insurance.pdf

15 https://catalogofbias.org/biases/

BIAS TYPE	DESCRIPTION	TYPE OF DATA AT RISK OF BIAS
	exposures or are at different risk to participants who were recruited later.	
Compliance bias	Compliant and non-compliant participants differ in some way from those who are not compliant, which can systematically affect outcome of interest.	RWD
Confirmation bias	Search of and use of information to support an individual's ideas, beliefs or hypotheses.	Both
Confounding	Distortion that modifies an association between an exposure and an outcome because a factor is independently associated with the exposure and the outcome.	Both
Hawthorne effect	When individuals modify an aspect of their behavior in response to their awareness of being observed.	Traditional
Industry sponsorship bias	A tendency for the methods and results of a study to support the interests of the funding organisation.	Both
Informed presence bias	The presence of a person's information in an electronic health record is affected by the person's health status.	RWD
Outcome reporting bias	Selective reporting of pre-specified outcomes in published clinical trials.	Traditional
Performance bias	Systematic differences in the care provided to members of different study groups other than the intervention under investigation.	Traditional
Positive results bias	The tendency to submit, accept and publish positive results rather than non-significant negative results.	Traditional
Selection bias	Occurs when individuals or groups in a study differ systematically from the population of interest, leading to a systematic error in an association or outcome.	Both
Starting time bias	Arises when there is a failure to identify a common starting time for an exposure or a disease.	Both
Substitution game bias	Substitution of the clinically important endpoint, or an exposure, with a surrogate marker for the disease.	Both

Further, it is important to be confident that the results are not due to chance, random variation or regression to the mean. Regression to the mean is a statistical phenomenon that can make natural variation in repeated data look like a real change. It happens when unusually large or small observations tend to be followed by observations that are closer to the mean[16].

Add these to your toolbox

Beyond the considerations set out in the questions above, the data type and quality will also be important factors in steering the study methodology and interpretation of results. Robust methodologies should consider the following:

Population stratification and risk adjustment

Population stratification and risk adjustment using RWD may help address the 'efficacy effectiveness gap' mentioned in the Consultation Paper. The efficacy effectiveness gap relates to the observed discrepancy between the effects of a health intervention in routine clinical practice (effectiveness) and the effects demonstrated in RCTs (efficacy). Differences in patients and diseases are a potential driver of this gap.

Population stratification is the process that allows us to stratify a population by predefined characteristics (e.g. age/sex/clinical condition), where patients within a particular population stratification group are considered to have similar risk profiles. For example, in the context of healthcare, we may expect patients within the same group to have similar levels of healthcare resource utilisation. Risk adjustment is the process that allows us to analyse the healthcare resource utilisation of these groups by taking their specific risk profile characteristics into account.

Before embarking on any population stratification process, we ask ourselves the following four key questions, defined by Lisa Iezzoni in 'Risk Adjustment for Measuring Healthcare Outcomes'[17], to determine the most appropriate stratification methodology.

NO.	QUESTION	EXAMPLE ANSWERS
1.	Risk of what outcome?	High cost, mortality, hospital admission or readmission.
2.	Over what timeframe?	During one year, hospital admission or clinical episode.
3.	For what population?	Entire population, clinical definition, regional stratification or member characteristic such as age group.
4.	For what purpose?	Population health management, cost-effectiveness study, disease management programme, risk-based contracting

The data required for population stratification will vary depending on the exact nature of the exercise but may take into account a combination of demographic (e.g. age, sex, geography) and clinical (healthcare resource use, diagnoses, treatments, co-morbidities) factors.

Sensitivity analysis

Sensitivity analysis involves identifying key assumptions and parameters and testing for the impact of changes in these assumptions and parameters on the study results. If the results are particularly sensitive to particular assumptions or groups of assumptions, this may warrant further investigation to determine the likelihood of these more extreme values being observed in real-world scenarios. The sensitivity analysis will also help with considering the repeatability of the study and identify future scenarios that may result in different conclusions and decisions.

16 https://academic.oup.com/ije/article/34/1/215/638499

17 Iezzoni, L. (2012). *Risk Adjustment for Measuring Healthcare Outcomes*, Fourth Edition

Professional standards

Given the importance of the decisions that are made as a result of economic evaluations, it is important that they are produced with a high level of quality with appropriate levels of technical and contextual review. Professional frameworks and robust peer review processes can help ensure that users of work are able to place a high degree of reliance and trust on the information's relevance.

In the UK, actuaries are members of a professional body (the Institute and Faculty of Actuaries (IFOA)). The IFOA's Actuaries' Code[18] is centred on principles of integrity, competence and care, impartiality, compliance, speaking up and communication.

The actuarial profession also has a framework, 'Technical Actuarial Standards 100 (TAS 100)'[19] that is applied to all work undertaken by members of the profession. The framework has been developed to support an overall 'reliability objective' that reads as follows:

> "Users for whom actuarial information is crated should be able to place a high degree of reliance on that information's relevance, transparency of assumptions, completeness and comprehensibility, including the communication of any uncertainty inherent in the information."

The TAS 100 requirements cover six categories to address the full spectrum of actuarial work products: judgement, data, assumptions, models, communications and documentation. See Appendix A for the full list of requirements.

The Consultation Paper mentions that 'sharing of the code used to identify study populations and carry out analysis would be considered best practice for transparency and reproducibility.' We note that this level of transparency may not always be possible as certain algorithms used by organisations to produce their tools, products and analyses may form part of its protected intellectual property. However, for the purposes of transparency and reproducibility, it would be reasonable to expect a detailed methodology statement (e.g. as required by TAS 100) that sets out the logic and approach followed for the analysis.

Consultation paper questions

NICE is seeking feedback on the following particular questions. For questions one to five, respondents have the option to indicate how strongly they agree with the statement on a scale of one to five: 1) Strongly disagree 2) Disagree 3) Neither agree nor disagree 4) Agree 5) Strongly agree.

QUESTION 1

Is the overall approach set out in the statement of intent clear and understandable?

Our response:

5) Strongly agree – the statement of intent is clear and understandable

The consultation paper clearly sets out NICE's reasons and objectives for exploring alternative sources of data.

QUESTION 2

Does the statement of intent appropriately take account of current and future trends?

Our response:

4) Agree – the statement takes account of current and future trends.

While the statement considers current and future trends, it is important to note that any framework or guidance will need to recognise that trends will evolve. For example, the use of data from wearables and other new technologies is still immature and there is limited evidence on the effectiveness of wearables on improving health and the power of wearables data. Frameworks will need to be flexible enough to adapt as the evidence and data in this space mature.

To monitor future trends, it is also worthwhile to consider how other healthcare systems are developing in this space. For example, the FDA in the US has published guidance and frameworks for the use of real-world data and evidence in healthcare decisions.

QUESTION 3

Are there any obvious gaps or omissions in the scope of ambition in the statement of intent?

Our response:

1) Strongly disagree – the scope of admission has no obvious gaps

We have not identified any obvious gaps in the scope of ambition in the statement of intent. We note that considering the source of real-world data and processes and methodologies followed to extract it, assess its quality and analyse it will be crucial. Using inappropriate data or poor quality data may lead researchers to question the validity of RWD in general when the use of RWD itself is not problematic but rather the fact that appropriate methods have not been applied for its use.

18 https://www.actuaries.org.uk/system/files/field/document/Revised%20Actuaries%27%20Code%20FINAL.pdf

19 https://www.frc.org.uk/getattachment/b8d05ac7-2953-4248-90ae-685f9bcd95bd/TAS-100-Principles-for-Technical-Actuarial-Work-Dec-2016.pdf

QUESTION 4

Does NICE's ambition appropriately align with relevant external initiatives?

Our response:

4) Agree – NICE's ambition aligns with relevant external initiatives.

NICE's stated ambition and the use of RWD data are consistent with the overall NHS ambitions to provide higher quality care and make the best use of the allocated budget. For example, in the context of developing population health management initiatives and primary care networks, RWD has an equally important role to play and the frameworks and guidelines developed for economic evaluations will have a natural place in these environments too.

QUESTION 5

Does the statement appropriately set out the scope of the data NICE should be considering?

Our response:

4) Agree – the statement appropriately sets out the scope of the data NICE should be considering.

Being able to perform a robust reconciliation and sensitivity analysis should also be key considerations.

Real-world data should reconcile to other relevant data sources and/or relevant financial statements to ensure that the data included in the study represents the actual activity and cost borne by the system. For example, when using SUS activity data, it would be important to reconcile this to the corresponding SLAM data and understand the reasons for differences in cost and activity within each dataset. Further, it would be valuable to reconcile to clinical commissioning group (CCG) financial statements to ensure that the reported costs are familiar to relevant stakeholders.

Sensitivity analysis involves identifying key assumptions and parameters and testing for the impact of changes in these assumptions and parameters on the study results. If the results are particularly sensitive to particular assumptions or groups of assumptions, this may warrant further investigation to determine the likelihood of these more extreme values being observed in real-world scenarios. The sensitivity analysis will also help with considering the repeatability of the study and identify future scenarios that may result in different conclusions and decisions.

QUESTION 6

Are there any additional sources of data that should be captured for consideration which are not included in the categories listed in the statement of intent?

Our response:

In certain cases, data from non-UK sources could be considered where there is insufficient data from UK sources. This can prove to be especially useful in the case of rare conditions and highly specialised technologies where data from a single regional or national database may not be large enough and more powerful insights may be generated by using a combination of datasets from multiple sources.

Further, administrative medical encounter or "claims" data from UK and non-UK health insurance systems could prove valuable since this would include cost, utilisation and some outcome measures for large patient populations with associated demographic and clinical information.

QUESTION 7

What steps should NICE take to maintain transparency and support validation and reproducibility in the use of applied analytics?

Our response:

Steps taken should include having ethical, analytical and data quality frameworks in place to ensure that users of the data and resulting work are able to place a high degree of reliance and trust on the information's relevance. Using the framework developed by the actuarial profession as an example, the Institute and Faculty of Actuaries (IFoA) has an Actuaries' Code centred on principles of integrity, competence and care, impartiality, compliance, speaking up and communication. The actuarial profession also has a framework, 'Technical Actuarial Standards 100 (TAS 100)' that is applied to all work undertaken by members of the profession. The TAS 100 requirements cover six categories to address the full spectrum of actuarial work products: judgement, data, assumptions, models, communications and documentation.

Conclusion

The use of RWD to generate RWE has the potential to enhance economic evaluations by expanding the breadth of information available to researchers as they work to inform important policy decisions. RWD can supplement many of the shortcomings of traditional data sources but its use should be coupled with appropriate considerations regarding the study context, reconciliation to key financials, coherency of the data, relevance of its contents, sufficiency of data volumes, data quality and bias. Beyond the data, researchers should also consider how the available RWD may shape the methodology followed and specifically consider the requirement for and ability to perform population stratification and/or risk adjustment as well as recognise the importance of sensitivity analysis and identifying key areas of uncertainty. Having robust ethical, professional and analytical frameworks in place will help tie all of these important considerations together.

Appendix A: TAS 100 requirements

TAS-100 SECTION	REQUIREMENT NO.	REQUIREMENT
Judgement	***1.***	***Judgement shall be exercised in a reasoned and justifiable manner; material judgements shall be communicated to users so that they are able to make informed decisions understanding the matters relevant to the actuarial information.***
Data	***2.***	***Data used in technical actuarial work shall be appropriate for the purpose of that work so that users can rely on the resulting actuarial information.***
	2.1	Data shall be relevant for the purpose of the technical actuarial work.
	2.2	If data is insufficient or unreliable it shall be improved by adjusting or supplementing it to the extent that is proportionate.
	2.3	Data used in technical actuarial work, the checks and controls that have been applied to that data and any actions taken to improve insufficient or unreliable data shall be documented.
	2.4	Communications shall describe the data used in the technical actuarial work, the source of the data, the rationale for the selection of the data, whether checks and controls have been applied, any material uncertainty in the data, and the approach taken to deal with that uncertainty.
	2.5	Communications shall state any limitations in the actuarial information resulting from the use of insufficient or unreliable data and provide an indication of their impact on the actuarial information.
Assumptions	***3.***	***Assumptions used, or proposed for use, in technical actuarial work shall be appropriate for the purpose of that work so that users can rely on the resulting actuarial information.***
	3.1	Unless set by the user, a third party or by regulation, assumptions used in technical actuarial work, shall be consistent with each other and shall be derived from as much relevant information as is sufficient or, if there is insufficient relevant information, as is available.
	3.2	Assumptions used in technical actuarial work shall be documented.
	3.3	Communications shall state the material assumptions and describe their rationale.
	3.4	Communications shall include a comparison of the assumptions with those used in the previous exercise carried out for the same purpose (if one exists) with an explanation of any differences, and description of any change in the rationale underlying the assumptions used.
	3.5	Communications shall state when assumptions are set by a user, a third party or by regulation. Communications shall state whether any assumptions set by a user or a third party are not reasonable for the purpose of the technical actuarial work and provide an indication of their impact on the actuarial information.
Models	***4.***	***Models used in technical actuarial work shall be fit for the purpose for which they are used and be subject to sufficient controls and testing so that users can rely on the resulting actuarial information.***
	4.1	An explanation of how a model is fit for the purpose for which it is used and what it does shall be documented.
	4.2	Controls and tests that have been applied to a model shall be documented.
	4.3	Communications shall explain the methods and measures used in the technical actuarial work and describe their rationale.
	4.4	Communications shall include an explanation of any changes to the methods and measures used from the previous exercise carried out for the same purpose (if one exists).
	4.5	Communications shall include explanations of any significant limitations of the models used and the implications of those limitations.
Communications	***5.***	***Communications shall be clear, comprehensive and comprehensible so that users are able to make informed decisions understanding the matters relevant to the actuarial information.***
	5.1	Communications shall state its users, the scope and purpose of the technical actuarial work and who commissioned the work. Each component communication shall state its purpose and to whom it is addressed.
	5.2	The style, structure and content of communications shall be suited to the skills, understanding and levels of relevant technical knowledge of their users.
	5.3	Material information provided orally shall be confirmed in permanent form.
	5.4	Communications shall include a comparison of results of calculations with the previous exercise carried out for the same purpose with an explanation of any differences (if one exists).
	5.5	Communications shall: a) indicate the nature and extent of any material uncertainty in the actuarial information they contain. b) state the nature and significance of each material risk or uncertainty faced by the entity in relation to the technical actuarial work and explain the approach taken to the risk.
	5.6	Communications shall indicate any material changes or events that are known by a person responsible for the communication to have occurred since the effective date of the data and other information on which the technical actuarial work is based.
	5.7	If a person responsible for a component communication becomes aware of any evidence of that communication not being understood by any user, that person shall provide clarification or information to correct the misunderstanding.
	5.8	Communications shall not include information that is not material if it obscures material actuarial information.
Documentation	***6.***	***Documentation shall contain enough detail for a technically competent person with no previous knowledge of the technical actuarial work to understand the matters involved and assess the judgements made.***

How Milliman can help

Milliman consultants have considerable experience in working with real-world data to produce meaningful insights and help clients achieve decision confidence. Our approaches are rooted in applying sound actuarial principles and control cycles with diverse, multi-disciplinary teams including actuaries, health economists, clinicians, analytics and product technology specialists.

In the US and globally, we hold multiple sources of high quality healthcare data and have vast experience in using RWD in economic evaluations.

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If you have any comments or questions on this paper or on the subject of real-world data, please contact any of the consultants below or your usual Milliman consultant.

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