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RECOMMENDATIONS

Recommendations for the diagnosis of respiratory syncytial virus (RSV) infection in children. The Polish Society of Paediatrics and the National Paediatric Consultant's recommendations

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ABSTRACT

Respiratory syncytial virus (RSV) is one of the most important aetiological factors in acute respiratory tract infections, and the availability of diagnostic methods, including rapid antigen tests (RADTs) and molecular-based assays, is increasing in Poland. The Polish Society of Paediatrics presents these recommendations in order to unify the clinical approach to RSV testing and clarify confusion related to testing. We hereby provide a comprehensive overview of general characteristics of the test methods, recommendations for interpretation of test results and practical implications of the results. We also indicate the goals of RSV testing and recommendations for selected clinical diagnoses. The aim of the guidelines is to maximise the use of available tests in both inpatient and outpatient settings and to assist paediatricians in making clinical decisions.

KEY WORDS:

respiratory syncytial virus, RSV, rapid antigen tests (RADTs), molecular-based assays.

INTRODUCTION

Respiratory syncytial virus (RSV) is one of the most important aetiological factors in acute respiratory tract infections, with an estimated 33 million cases worldwide each year [1]. The highest incidence of symptomatic RSV infection is observed in children under 2 years of age, with a rapid decline after 2 years of age and a progressively lower incidence of RSV in subsequent age groups [2]. The vast majority of children are infected at least once

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by the age of 3 years (anti-RSV seroprevalence > 90%) and a clinical presentation can vary from mild upper respiratory tract infection to severe lower respiratory tract infection (LRTI) such as bronchitis, bronchiolitis, or pneumonia [1, 3, 4]. Approximately 3.6 million episodes of RSV-associated hospitalization occur annually in children under 5 years of age, with the highest hospitalization rates reported in the first 12 months of life [1, 5]. RSV incidence estimates are mostly based on hospital admission data, which are prone to the risk of underestimation, and the true burden of outpatient RSV remains unknown; in Poland, the rate of hospitalization in children under 12 months of age reached 11.3/1000, while in Spain it was 55.5/1000 and for the European Union 74.9/1000 [4–7]. The problem of under-recognition of RSV disease is also present in older children and adults, especially the elderly, and there is a strong need for well-designed epidemiological studies; although awareness of the disease is increasing, the limited availability of testing methods is the main reason for inappropriate incidence assessment [8, 9].

Two of the most commonly used RSV testing methods are antigen testing and molecular-based techniques; however, viral culture and serological testing are only occasionally used in clinical practice because of the long turnaround time for results (in the case of viral culture) or delayed serological host response, and are used for epidemiological studies or theoretical research and should not be recommended for routine patient testing [10]. Antigen tests and some molecular-based techniques are able to provide results in a short time (with only slight differences between manufacturers, ranging from 10 to 15 minutes for rapid antigen diagnostic tests, rapid antigen tests (RADTs), and from 20 to 120 minutes for rapid real-time reverse transcription-polymerase chain reaction (rRT-PCR) [11].

Both RADTs and molecular assays are available as singleplex RSV tests and as multiplex tests that also look for other common aetiological agents of respiratory tract infections; some tests are also able to indicate RSV subtype (A versus B), although the practical implications of this latter distinction are not clear and it is not widelyrequested to distinguish RSV A from RSV B infection [10]. A comparison of singleplex versus multiplex RT-PCR showed a pooled sensitivity of 96%, although slightly lower sensitivity was seen in some molecular multi-pathogen studies, leading to the conclusion that the choice between single and multiplex molecular assays is not critical in the context of RSV testing, especially as the latter look for other aetiological factors [12]. A general advantage of molecular testing is higher sensitivity (and slightly higher specificity) at the expense of higher test costs; however, the most important issue from a clinical perspective is the relatively long turnaround time for results, which is not a problem with the availability of rapid molecular tests. The shortest possible time to diagnosis is essential in the hospital setting, where delayed diagnosis has been shown to be associated with longer hospital stay and/or more frequent use of antibiotics [13, 14].

The aim of the recommendations is to present the position of the Polish Society of Paediatrics and national consultant in paediatrics on RSV testing in order to unify the clinical approach among paediatricians in Poland. We present general characteristics of the tests, including safety, efficacy, and timing of test performance, advice on interpretation of test results, practical implications and goals of RSV testing, and recommendations for selected clinical diagnoses.

GENERAL CHARACTERISTICS

SAFETY FEATURES

A sample from a patient can be obtained from a nasopharyngeal swab (used in 48.9% of studies according to a recent literature review), but also from a nasopharyngeal wash, nasopharyngeal aspirate or nasal swab, aspirate or wash [11]. In general, nasopharyngeal swabs are considered to be safe, with only minor adverse effects such as local irritation, epistaxis or broken swabs, and the benefits of testing outweigh the risks [15, 16]. However, it is important to note that most specimens are taken from the upper respiratory tract when the site of infection is in the lower respiratory tract (LRT), e.g. pneumonia or bronchiolitis. Of course, it is also possible to perform a test on a sample from the LRT, but it is not a regular practice due to very narrow indications to perform such a study, problems with cooperation with the patient and/or an unfavourable balance of risks and benefits [12]. This raises the question of how test results from the upper respiratory tract relate to the aetiology of LRTI, and this will largely determine the practical implications of RSV testing. It is worth noting, however, that meta-analyses have not shown an increase in test sensitivity after the addition of a sample from LRT in children, as opposed to diagnostics in adults. We postulate that upper respiratory tract sampling should be treated as a substitute for LRT testing because of its low invasiveness and practicality, bearing in mind that confirmed presence of RSV in the upper respiratory tract does not exclude co-infection but should prompt RSV infection control measures, and that a negative RSV test does not exclude it as an aetiological factor in the infection, nor does it guarantee the absence of RSV spread from the patient, although the risks are reduced.

RECOMMENDATION 1

We recommend using upper respiratory tract sampling as a substitute for lower respiratory tract testing.
We recommend the use of nasopharyngeal swabs as the preferred sampling method.

EFFICACY

The sensitivity of RADTs ranges from 25.7% to 100% and is generally lower than that of molecular-based techniques (66.7% to 100%), although some extremely low sensitivities have been reported in certain patient groups (8% in one study in infants), values are mostly in the 60–70% range and results above 90% sensitivity are often reported [17–20].

On the other hand, the specificity of both RADTs and molecular-based rapid RSV tests is high, reaching 80.3–100% and 94.3–100%, respectively, with the vast majority of studies showing over 90% specificity [11].

In line with the high specificity and lower sensitivity of RADTs, high positive predictive values (PPV) and moderate negative predictive values (NPV) have been reported: PPV is often close to or reaches 100%, but NPV is reported in the literature to be around 70–94% [17, 21–24].

It is important to emphasize that there may be some significant differences and that, from a methodological point of view, there is still an important gap in our knowledge and the results are difficult to generalize, since the majority of studies assessing test performance were conducted in hospital settings, not in outpatient or household settings, and the results apply mostly to the paediatric population, not to adults [11]. While results may vary depending on test manufacturer, host and virus characteristics, there are a limited number of studies that provide important clues for optimal test performance, including, but not limited to, shorter duration of symptoms – sensitivity decreases with time since illness onset, especially after day 5 [25, 26]. The studies also mention age as an important factor, with better test performance observed in younger patients when comparing children to adults and in the case of RSV A (versus RSV B) subtype infection, but from a practical point of view this does not change test interpretation, although it may influence the choice of test method [25, 26].

TIMING OF THE TEST

RSV testing can be performed at any stage of illness, regardless of the duration of symptoms, as longer duration of illness does not exclude a positive test result. In addition, a patient with prolonged symptoms may be RSV positive because of, for example, a healthcare-associated infection – the increased number of outpatient/emergency department visits or prolonged hospital stay may increase the risk of acquiring RSV infection. In patients with prolonged symptoms, tests with higher sensitivity, i.e. molecular-based tests, should be considered as the test of choice.

RECOMMENDATION 2

RSV testing can be performed at any stage of the disease. Consider a molecular-based test in those who present with prolonged symptoms, especially those lasting more than 5 days.

INTERPRETATION OF TEST RESULTS

A positive test result (either RADT or molecular based) can be interpreted as confirmation of aetiology, or more precisely, as RSV positive, with all the implications of a positive result. There is a theoretical risk of a false-positive result, but in practice the more important question is not about the false-positive result itself (the risk is very low), but about a relationship with disease, especially if a patient has a positive result without signs/symptoms of disease. Nevertheless, the literature indicates that RSV (especially RSV B) is one of the viruses with the lowest likelihood of asymptomatic tested patients; for example, a study by Teoh showed that the odds ratio of a detected viral infection being symptomatic was 8.9 and 5 for RSV B and A, respectively, and the frequency of asymptomatic patients among those who are RSV positive may be as low as 3% [27]. A higher risk of detecting RSV in asymptomatic patients is expected with the use of molecular-based tests, as they are characterized by higher sensitivity even at lower viral loads [4, 27, 28].

A negative test result, especially a negative RADT, cannot exclude RSV infection. The rationale for such a conservative approach is based on the possibility of a false negative test result, but also on the possibility that a true negative test result may be obtained in an upper respiratory tract specimen, but the virus may be confined to the lower respiratory tract or may be present in sites other than those swabbed.

The interpretation of test results should not depend on virus circulation or the actual epidemiological situation, and the test should be performed when a patient presents with symptoms that prompt a physician to perform an RSV test. RSV seasonality used to be fairly stable and repeatable in the northern hemisphere, depending on latitude, and the peak season in Poland was observed between January and March [4, 5, 29]. However, an early "off-season" start of the RSV epidemic season in 2021 – probably related to a specific epidemiological situation and previous non-pharmaceutical counter-pandemic interventions, which were able to stop the spread of many viruses, including RSV (for a period of time), but created a kind of "immunity debt" and consequently increased the population's susceptibility to infections – raised awareness of the need for close epidemiological surveillance and preparedness for RSV [30, 31]. Thus, while a positive result is more likely to be obtained during the high RSV season, RSV cannot be forgotten and neglected out of season, and the time of year should not influence test interpretation.

RECOMMENDATION 3

Test results should be interpreted in the same way regardless of the epidemiological season.
A positive test result can be treated as confirmation of RSV.
A negative test result, especially a negative RADT, does not exclude RSV infection.

REPEATED/COMBINED RSV TESTING

There is no need to repeat RSV testing in an RSV-positive patient, either to exclude infection or to determine the end of disease or infectiousness. Due to the high specificity and lower sensitivity, a single positive RSV test result should be treated as RSV confirmation and cannot be invalidated by one (or more) negative results. It should be emphasized that while a negative result is invalidated by a positive test in the same patient (e.g. when RT-PCR is performed after a negative RADT), even a molecularly negative test result cannot invalidate a positive RADT, although it is not uncommon practice to "verify" RADT results; the only exception may be when both RADT and RT-PCR are performed on the same specimen. A negative RSV result in a patient previously diagnosed with RSV does not necessarily translate into any kind of clinical improvement, nor does it guarantee that such a patient is not infectious. In addition, it may be difficult to test for RSV in a patient who has recently been diagnosed with RSV, has improved, and within a short time presents with signs/symptoms of new RSV disease. Viral RNA can persist for a prolonged period, especially in immunocompromised patients, so in such cases repeated RSV testing may be false positive due to the previous RSV disease, but if it can potentially change clinical management, the test can be repeated [32–34].

In the case of a negative test result, from a statistical point of view, adding another test with the same or better characteristics would increase the number of RSV cases detected. However, a recent meta-analysis of 157 studies showed only small improvements in the RSV detection rate with additional testing, and multiple testing of respiratory specimens (by any method) resulted in a statistically nonsignificant increase in RSV detection [12]. However, the differences may play an important role in clinical management, but the decision to perform another RSV test should be considered individually for each patient, taking into account both the benefits of the study and the risks associated with the test, especially the traumatization of the patient by another swab.

Interpretation of ambulatory/self-performed test results

There is no need to repeat the RSV test in hospital if a positive result was obtained in an outpatient/household setting. Repeating the test exposes the patient to an unnecessary procedure and traumatization. It should not influence the reimbursement policy by *Narodowy Fundusz Zdrowia* (NFZ, the Polish National Health Fund) – the reimbursement policy is based on the final diagnosis, and there may be differences between established and unknown aetiology of LRTI (currently there are significant differences). Nevertheless, it is not necessary to perform the test in the hospital. Similar to anamnesis, medical history (including history of cough, runny nose, or outpatient test results) is based on mutual trust, and no evidence is required to diagnose, for example, bronchiolitis caused by RSV (if a parent/caregiver reports a positive RSV test performed during the same illness). We advise ambulatory care physicians to inform the parents/caregivers of the patient about the positive/negative RSV test result, especially if the patient is referred to the hospital – in such a case, the information should be included in the referral letter.

If the RSV test performed in the outpatient/household setting is negative, this is also important information, although it does not rule out RSV infection, and the further course of action should be similar to that for a negative test obtained in the hospital setting, with special attention paid to parent/caregiver performance of the test with detailed questions about it.

RECOMMENDATION 4

The decision to repeat the RSV test should always be made on an individual basis.
There is no need to repeat RSV testing in RSV-positive patients. Patients who have already been diagnosed with RSV should not be retested.
In the case of newly developed symptoms, if new RSV infection is likely, testing may be performed within a short interval of a positive RSV test, but special attention should be paid to possible supra-infections.
In selected cases, confirmation of a negative RSV test result by performing another test may be warranted. A molecular-based test (if available) should be performed to verify a negative RADT. In most cases, there is no need to confirm a negative molecular study.
Do not repeat the RSV test in hospital if a positive result was obtained in an outpatient/household setting.

PRACTICAL IMPLICATIONS OF THE RSV TEST RESULTS

Both positive and negative test results will require some further action.

Patient benefits are detailed below. Regarding infection control measures, parents/caregivers of RSV-positive patients should be advised as follows [35]:
- avoid contact with other people in general,
- avoid close contact with others, such as shaking hands or kissing, in particular,
- avoid exposing others to virus droplets from coughing or sneezing (by covering coughs or sneezes with a tissue or sleeve),
- wash your hands before touching surfaces, especially commonly used surfaces such as doorknobs and taps,
- do not share eating utensils, glasses, cups, etc. with others.

RECOMMENDATION 5

The need for immediate implementation of infection control measures is obvious as soon as a positive RSV test is obtained.

GOALS OF RSV TESTING

Any medical intervention should be undertaken for a reason, and only a justified decision to test should lead to testing. With regard to RSV infection, 3 major groups of objectives can be identified: 1) patient benefit, 2) societal benefit, 3) epidemiological surveillance.

PATIENT BENEFITS

The most important question before RSV testing should be: will my patient benefit from the RSV test result? As there is currently no targeted anti-RSV or RSV-specific treatment, it could be argued that RSV testing is unnecessary; this was one of the reasons for not recommending RSV testing in bronchiolitis guidelines [36]. However, in addition to targeted treatment, there are other patient benefits that may be important in deciding whether to test.

Avoid unnecessary procedures/therapies (including antibiotics)

A number of studies have shown that a positive RSV test is associated with a reduced risk of antibiotic therapy and, in some settings, with a shorter duration of antibiotic treatment, while some other studies did not find an effect on antibiotics, but RSV positivity was associated with a reduced number of unnecessary investigations, such as chest radiographs or blood cultures [14, 37–39]. In the vast majority of RSV infections, antibiotic treatment is irrelevant and should not be given, and statistically, a positive RSV test would reduce the risk of unnecessary antibacterial treatment. Nevertheless, it is important to remember that RSV infection does not rule out bacterial co-infection, it only reduces the risk; given that RSV can facilitate bacterial supra-infection by disrupting epithelial barrier integrity or upregulating the expression of adhesion molecules on the cell membrane, RSV-positive patients are at risk of bacterial infection, particularly caused by *Streptococcus pneumoniae* or non-typeable *Haemophilus influenzae*, which can lead to serious infections, including sepsis, and antibacterial treatment can be life-saving [40]. In addition to viral testing, other solutions to differentiate between pure viral infection and bacterial superinfection are being tested, focusing on the use of proinflammatory markers such as procalcitonin or interleukin-6 [41, 42].

Minor bacterial supra-infections are seen more frequently, and can lead to bacterial pneumonia, but the most frequent RSV complication is acute otitis media (AOM), which occurs in 47–77% of cases [28, 43–45]. AOM is associated with an increased risk of antibiotic therapy, and the majority (66–71%) of younger patients (i.e. infants and children under 3 years of age) require antibacterial treatment for AOM [44, 45]. The interplay between the airway microbiota and RSV is complex; RSV can lead to viral AOM without further bacterial co-infection, but the increased risk of bacterial co-infection in younger children is reflected in the Polish recommendations for the management of respiratory tract infections, which advise immediate antibacterial treatment in the case of AOM in children under 6 months of age or bilateral AOM in children under 2 years of age [46].

More predictable disease course, detailed information for parents/caregivers

Diagnosis of the aetiological factor may also have other benefits based on knowledge of specific pathogens, such as RSV. RSV has been associated with a more severe course of lower respiratory tract infections, such as more frequent need for oxygen therapy or respiratory support, or transfer to an intensive care unit; most studies have compared the course of RSV versus non-RSV bronchiolitis, but also in community-acquired pneumonia, the detection of RSV has been associated with a more severe course of disease [47–51]. Nonetheless, there are no data to suggest that, apart from risk groups and clinical presentation, a patient with RSV bronchiolitis requires hospitalization or any particular type of treatment (e.g. oxygen therapy), or that non-RSV patients are not at risk of a severe course of disease that would result in the need for hospitalization at the time of a positive test. **We therefore recommend that the decision to admit, treat or discharge a patient should always be based on an individual risk assessment and the patient's actual clinical presentation, not on a test result.** A real added value of the established aetiological factor is the possibility to predict the course of the disease and the time frame of deterioration – symptoms in RSV patients, especially those with bronchiolitis, tend to peak between 3 and 5 days after the onset of the disease, with a mean time from onset to admission of 5.2 days for RSV A and 3.8 days for RSV B, and such a message should be communicated to parents/caregivers [52, 53]. RSV testing may therefore add predictive value in terms of clinical course and time of clinical deterioration and assist in risk stratification [47].

In short, in the context of patient benefit, our advice is to answer the question: will a positive RSV test change my management of the patient? If the answer is positive, then you should seek a positive RSV result. Otherwise, a negative RSV test may also lead to a significant change in patient management, such as looking for aetiological factors other than RSV (e.g. *Bordetella pertussis*, which is also an aetiological agent of pneumonia or bronchiolitis)

and targeting treatment, so lack of RSV confirmation may also be a valuable piece of information [54].

Reduced risk of nosocomial infection

Another group of patient benefits is related to the reduced risk of nosocomial infections and a general understanding of the benefits of improved public health data, mainly epidemiological surveillance, which will be discussed below.

RECOMMENDATION 6

A positive RSV test reduces the risk of antibiotic therapy.
RSV infection does not unequivocally exclude concomitant infections, including bacterial infections and the need for antibiotic therapy.
Always look for RSV-specific sequelae that may alter clinical management, especially acute otitis media.
Inform parents/caregivers of what to expect regarding the illness and when to expect clinical deterioration. This is particularly important in the outpatient setting, since during the RSV infection, the child's condition can deteriorate within 3–5 days.
A child with RSV infection, especially an infant, requires constant monitoring of the general status.

SOCIETAL BENEFITS

Patient isolation or cohorting should be guided by confirmation of the aetiological factor, although a characteristic clinical picture may also influence the decision. Patient isolation is the preferred method of preventing the nosocomial spread of infection, but it is often not possible during the peak RSV season, especially in the northern hemisphere where the peak infection seasons for RSV, influenza and other infections, including SARS-CoV-2, overlap, making isolation difficult in the vast majority of paediatric wards. When patient isolation is not possible, cohorting of patients is the most widely used and accepted preventive method, with mutual benefits for both RSV-positive and -negative patients, reducing the risk of cross-infection. Both subtype (A versus B) and genetic differences between specific strains need to be recognized, but as long as it is not possible to isolate all patients with highly infectious disease, cohorting may be the best option.

We recommend 3 main rules for isolation/cohorting in each of the 3 different settings (inpatient, outpatient and household): 1) protect the most vulnerable, 2) protect the most affected, 3). stop the spread.

1. Inpatient setting

RSV testing in hospital settings is essential and prevents the spread of RSV.

a. We recommend isolation from RSV of all groups at risk of severe RSV disease course, especially premature babies, neonates and young infants (under 3 months), immunocompromised patients (irrespective of its cause), and those with chronic lung disease (including but not limited to bronchopulmonary dysplasia), neuromuscular disorders, or haemodynamically significant congenital heart disease [52].
b. Patients from RSV risk groups should be preferred for isolation from other RSV cases as long as patient traffic allows it, since supra-infection with another RSV subtype or genetically different virus is possible and increases the risks,
c. We recommend isolating RSV-positive patients with the most severe disease for the same reasons as specified above.
d. We recommend cohorting RSV-positive patients who are not in at-risk groups and do not have severe disease, unless there are free hospital rooms that would remain unused. If tests used in the facility differentiate between RSV subtypes A and B, preference should be given to cohorting infections caused by the same subtypes.
e. In the event of low RSV community activity (especially at the beginning and at the end of the RSV season), we recommend isolating all newly hospitalized RSV patients for as long as possible – this may delay/reduce the peak RSV season as well as advancing its end.
f. If there is a need to cohort RSV-positive patients, the time of symptom onset should be taken into account, i.e. preference should be given to cohorting patients whose RSV disease is of similar duration. The stage of their disease, including viral load and viral shedding, should also be similar, and this may reduce the risk of nosocomial transmission.

2. Outpatient setting

In contrast to the inpatient setting, RSV testing does not appear to add much to measures to control the spread of the disease.

a. As a general rule, as long as the local appointment system is still operational, it should be used to the maximum to reduce the risk of exposure to infectious diseases; this applies not only to known RSV-positive cases, but to all patients presenting with symptoms of infection. Priority should be given to neonates, small infants, premature babies or immunocompromised patients, who should be seen before other patients or in a special area for healthy children; if not possible, make an appointment at the end of the outpatient clinic's working hours, preferably after infection control measures have been applied.
b. Try to avoid contacting RSV-positive patients with other infections, especially influenza or SARS-CoV-2.
c. If a patient with a more severe course of RSV can be managed in the outpatient setting, every effort

should be made to avoid exposure to other infectious agents.

d. The diagnosis should be accompanied by brief information on the infectivity of RSV and methods of reducing it, including information on contacts in the household and in day-care centres/schools.

3. Household setting

In a household setting, RSV testing does not appear to add significant value, although it provides an opportunity for patient education.

a. RSV testing should not be considered the most important factor in protecting the most vulnerable or severely ill patients in the household; we recommend using common sense instead. Parents/caregivers should be informed that if there is someone in the household who is at risk of severe illness (not just RSV – many risk groups overlap, e.g. influenza or SARS-CoV-2), such a patient should be isolated from all household members who present with symptoms of infection from the onset of illness, not just from RSV-positive patients. This recommendation does not apply to breastfeeding mothers and does not change the general or specific rules in such cases. With regard to RSV testing, a negative result should not reduce protective measures, as it does not exclude RSV infection, while a positive result may only increase the need to isolate high-risk household members.

b. There are no data on the use of additional anti-infective measures in a household following a positive RSV result, and again common sense should be used, emphasizing the need to reduce exposure to infection (see the practical implications section above).

c. Nevertheless, the most important step in limiting the spread of RSV is to inform patients, parents and caregivers about RSV infectivity in general and the current epidemiological situation in particular. A physician should keep abreast of the situation and follow current epidemiological trends in order to inform parents/caregivers of increased RSV activity in the population. In particular, if there is a patient or household member who is expected to have a more severe course of disease, parents/caregivers should be advised to limit social activities and exposure due to the increased number of RSV cases. We recommend a cocooning strategy for all newborns/infants up to (at least) 12 weeks of age – since a significant number of RSV cases are transmitted to the youngest infants by older siblings, temporary withdrawal from day-care and other peer contact, if possible, can significantly reduce the risk of RSV infection during the most vulnerable period.

EPIDEMIOLOGICAL SURVEILLANCE

The incidence of RSV is underestimated, and any effort to improve knowledge of the true epidemiological situation is necessary, although testing patients "just to check" for RSV infection should not be recommended except in epidemiological surveillance networks where strict, repeatable procedures and indications for testing are followed. It is important to remember that from 24 February 2023, any RSV infection confirmed by either RADT or molecular testing must be reported to the relevant epidemiological authorities [55].

Length of isolation/cohorting

Data on RSV shedding are scarce, but the published literature suggests that over 90% of patients shed RSV on day 7 after symptom onset and about half of patients on day 14, with a longer shedding period for RSV A than for RSV B (mean 9.7 days versus 6.5 days) [53]. On the other hand, the mere presence of RSV in tested samples does not equate to infectiousness; in particular, prolonged detection of RSV does not correlate strictly with the presence of RSV in the air around RSV patients [56].

Thus, we recommend isolating or cohorting RSV patients for the entire period of hospitalization. No data can be presented for the outpatient settings, as contact with healthcare and other patients is much less frequent than in the inpatient setting, in contrast to the household settings, where exposure is often unavoidable. **For both settings (outpatient and household), we recommend continuing preventive measures at least for the duration of signs/symptoms.**

The use of molecular-based tests can reduce the time to patient isolation in the event of a false-negative RADT result, resulting in a reduction in the number of nosocomial infections, length of stay and costs – see the section below on the choice of RADT vs. molecular testing [14, 57, 58].

On the other hand, studies show that RT-PCR can limit the isolation of negative patients, freeing up already limited hospital resources, especially isolation rooms [14, 57]. However, we recommend that this approach should only be used in the first instance in non-risk patient groups and those without severe disease, as even a true negative result does not exclude RSV disease, but only reduces the likelihood.

RECOMMENDATION 7

Patients with a negative RSV molecular test can be released from further isolation, but contact with patients from risk groups or severe RSV cases should be avoided.
Negative RADT does not exclude RSV disease.
If release from isolation is required and this results in contact with risk groups or a severe case of RSV, RT-PCR should be considered in such a patient. If RT-PCR is not available, a second negative RADT reduces the risk of the patient being RSV positive.

SELECTED CLINICAL DIAGNOSES

The topic of specific clinical case definitions is beyond the scope of these recommendations, but a brief comment on RSV case definitions must be made. Clinical studies evaluating the frequency of signs/symptoms and the accuracy of different definitions of RSV lower respiratory tract infection (RSV-LRTI) report that 4 symptoms occur in at least about 80% of patients with laboratory-confirmed RSV infection, including (in descending order of frequency) cough, runny nose, nasal congestion, and wheezing [59]. Based on frequency, RSV-LRTI (for the purpose of vaccine trials) was defined by the World Health Organization in 2015 as a history of cough or dyspnoea accompanied by a decrease in SpO_2 < 95% and/or an increased respiratory rate in a patient with PCR-confirmed RSV infection, while a protocol definition in the study by Englund and colleagues extended the clinical picture to include a history of runny and/or blocked nose [59, 60]. Practical evaluation of the definitions showed high concordance and, interestingly, that while tachypnoea is present in the majority of RSV LRTI cases (almost 90%), decreased oxygen saturation is not a very common finding [59]. An inverse question is when to suspect RSV infection, and we recommend using the clinical definitions proposed by Hryniewicz *et al*. [61] in their recommendations for the management of respiratory tract infections.

UPPER RESPIRATORY TRACT INFECTION

We emphasize that in the majority of cases of upper respiratory tract infection, there is no need to test for RSV unless it helps to make a decision to withhold unnecessary medical procedures or antibiotic therapy, or to enforce the implementation of infection control measures. For example, a young infant admitted to hospital with a fever and diagnosed with RSV may not need to undergo a septic evaluation, including a lumbar puncture, especially if inflammatory markers are low and there are no other red flags. On the other hand, while in the hospital setting any patient diagnosed with RSV is a potential source of nosocomial infection and should be isolated/cohorted, in other settings (outpatient, household) any symptomatic patient should be treated as a source of infection to vulnerable individuals, and indeed other aetiological agents than RSV can also be potentially harmful. Given that the vast majority of RSV cases do not require hospitalization (in fact, cohort studies assessing the frequency of hospitalization report percentages as low as 2.4–6.7% and up to 15% when emergency department visits were included) and that there is no evidence that a patient infected with RSV will require hospitalization in the future, we recommend NOT testing for RSV upper respiratory tract infections unless there is one of the above reasons [3, 27, 44]. An exception may be made in the hospital setting, where all patients with respiratory tract infections should be tested for RSV during the RSV peak season.

RECOMMENDATION 8

Inpatient setting: During the RSV peak season, test all patients with respiratory symptoms if possible because of the potential infection control benefits. Testing outside the RSV season may also be considered.

Outpatient setting: DO NOT test patients with upper respiratory tract infection for RSV unless it helps to avoid unnecessary medical procedures/antibiotic therapy or to enforce the implementation of infection control measures.

LOWER RESPIRATORY TRACT INFECTION

Bronchiolitis

Inpatient setting: Test all hospitalized cases of bronchiolitis – the test result adds information on the expected course of the disease, helps to isolate/cohort patients, may initiate the search for aetiological agents other than RSV, provides epidemiological warnings (usually the beginning of the RSV season is noticed due to cases of bronchiolitis, which is a typical clinical presentation of RSV infection) and has been shown to reduce the frequency of antibiotic therapy.

Outpatient setting: There is no need to test outpatient bronchiolitis cases, although a general benefit must be considered – in the case of lower respiratory tract infection, RSV testing could significantly reduce the use of antibiotics.

Bronchitis

Inpatient setting: In contrast to bronchiolitis, the literature does not correlate the identification of the aetiology of bronchiolitis with a significantly different or more severe course of the disease, nor does it influence clinical management. The only benefit may be in the area of patient isolation/cohorting.

Outpatient setting: Although there is even less benefit from RSV testing of outpatient bronchitis cases, the main benefit needs to be repeated here – reduction in antibiotic use.

Pneumonia

Inpatient setting: RSV testing, in addition to improved patient flow management, can reduce antibiotic use, especially when complemented by a broader patient assessment that includes low inflammatory markers (e.g. procalcitonin). However, there is a significant knowledge gap regarding children aged 0–3 months – the Polish recommendations advise antibiotic therapy without focusing on the aetiological factor, which is in line with the other most

TABLE 1. Summary of indications for RSV testing in inpatient and outpatient settings depending on clinical diagnosis

	Inpatient	Outpatient
Upper respiratory tract	Recommended during high RSV season, potentially beneficial outside the season	Not recommended
Bronchiolitis	Always test	Always test
Bronchitis	Test during high RSV season, consider outside of season	Always test
Pneumonia	Test during high RSV season, consider for viral-like pneumonia outside of season	Always test

prominent pneumonia recommendations that do not advise withholding antibiotic therapy in this particular age group due to lack of source data [46]. However, recent developments in the diagnosis of viral infections have been substantial, and future studies are assured. As with bronchiolitis, RSV is a major contributor to the number of paediatric pneumonia cases, and a thorough search for RSV in community-acquired pneumonia may also be an indicator of increasing RSV activity. Testing in viral-like pneumonia, i.e. in cases without high fever and with low serum inflammatory markers (C-reactive protein, procalcitonin), may support the decision not to use antibiotic therapy and may also help to detect RSV activity.

Outpatient setting: In the outpatient setting, the benefits of RSV testing may be even more pronounced, as lack of or difficulty in obtaining additional testing may lead to more frequent overuse of antibacterials in the outpatient setting. The time-series association between positive viral tests and antibiotic use estimated that approximately 14% of antibiotics prescribed to children were due to viral infections, with RSV consistently associated with the highest proportion of antibiotics, especially amoxicillin and macrolides [62]. In these recommendations, we highlight the potential future role of viral testing in limiting antibiotic overuse for viral infections and the fact that most of the impact may depend on outpatient care, where the majority of patients are seen.

RECOMMENDATION 9

Inpatient setting: During the RSV high season, test all patients with lower respiratory tract infections for patient management and infection control; outside the RSV high season, test all cases of bronchiolitis, while testing for pneumonia and bronchitis should depend on test availability and patient/parent willingness to test, as well as hospital economic assessment.
Outpatient setting: Test all patients with lower respiratory tract infections, especially during the RSV peak season, as this can significantly reduce antibiotic overuse.

SELECTING A TEST METHOD

A fundamental difference between RADTs and molecular-based tests is that the latter are more sensitive but also more expensive. While the issue of false-negative results may be less of a concern in the outpatient setting, a more reliable test method may be needed for inpatient infection control or patient management. However, we emphasize that the choice of test is a clinician's decision.

In order to get the most out of the test methods available, there are a few guidelines to follow:

1. Outpatient setting: **RADT** should be considered as **a first-line** diagnostic approach in the outpatient setting. The benefits of a more sensitive method (RT-PCR) do not outweigh the costs associated with molecular testing, nor is it readily available in the outpatient setting. If parents/caregivers prefer to pay for molecular testing, this can be done instead of RADT.

2. Inpatient setting: We leave the **choice** of diagnostic methods to **hospital management**. On the other hand, due to financial differences in hospital reimbursement policies, bed occupancy, and length of hospital stay, a lower unit cost does not always translate into a cheaper price – it depends on the hospital management calculations. In view of the medical benefits, we recommend that hospital managers consider a preference for molecular testing. We propose that physicians in hospitals should be informed (in a structured way, e.g. through internal hospital communication systems, e-mail messages or short training sessions) about the diagnostic options available and preferred in the hospital. Even if a hospital decides to use RADTs, we strongly recommend that the option of molecular testing be kept open and that information on detailed procedures (e.g. when and where to send a sample, how to store the sample before analysis) and indications for molecular testing be disseminated among hospital staff.

One of the options presented by Borszewska-Kornacka *et al.* [4] recommends performing **RADT in the emergency department** and, in case of a **negative result, verifying it by RT-PCR**. This approach seems justified; positive RADTs have all the advantages of a positive RSV result, in particular a shorter time to isolation, but are more affordable.

3. Self-testing: Although self-testing in paediatrics is more of a test by proxy and may raise some concerns about the safety and quality of the test, the SARS-CoV-2 pandemic has shown that general acceptance is quite high and no significant problems with "self-testing" have been reported. It increases public awareness of RSV, reduces unnecessary procedures and antibiotic treatment, and we recommend that self-testing be one of the **accepted** diagnostic methods if caregivers are willing to perform

the test. It is important to remember that self-testing is not a substitute for seeking medical advice.

4. All settings: Choice of simplex versus multiplex testing – there are some conflicting data on the sensitivity of multiplex testing and the number of tested pathogens, but we recommend that **multiplex** tests be **preferred** because the clinical features of different viral diseases may overlap and the expected benefits of identifying an aetiological factor (other than RSV) may outweigh the costs (often not significantly different from single tests).

IMPACT OF THE RECOMMENDATIONS

We hope that these recommendations will help to reduce the spread of RSV in the hospital setting and will help to improve management, in particular to reduce unnecessary antibiotics. We recognize the costs associated with widespread implementation of testing, although testing for RSV is reimbursed in the outpatient setting, whereas in the inpatient setting, a diagnosis with an established aetiological factor may change the reimbursement for the hospitalization. We believe that widespread testing will increase awareness of RSV among both physicians and patients. We also aimed to reduce the unnecessary use of RSV testing, which exposes patients to unnecessary procedures and generates costs. Finally, we emphasize that these are only suggestions for clinical practice and cannot be treated as applicable law regarding physician liability.

SUMMARY OF RECOMMENDATIONS

GENERAL

1. **Use upper respiratory tract sampling as a substitute for lower respiratory tract testing.**
2. **Use nasopharyngeal swabs as the preferred specimen collecting method.**
3. **RSV testing can be performed at any stage of disease.**
4. **Consider molecular-based testing in those with prolonged symptoms, especially those lasting more than 5 days.**

TEST INTERPRETATION AND PRACTICAL IMPLICATIONS

1. **Interpret results in the same way regardless of the epidemiological season.**
2. **Positive test result = RSV confirmation.**
3. **No need to repeat RSV testing in RSV-positive patients. In the case of new onset of symptoms, an RSV test may be performed within a short interval of a previous positive RSV test, but special attention should be paid to possible supra-infections.**
4. **Do not repeat the RSV test in hospital if a positive result was obtained in an outpatient/household setting.**
5. **Implement infection control measures as soon as a positive RSV test is obtained.**
6. **A positive RSV test reduces the risk of antibiotic therapy, but does not rule out concomitant infections.**
7. **Always be aware of RSV-specific sequelae that may alter clinical management, especially acute otitis media.**
8. **Inform parents/caregivers of what to expect regarding the illness and when to expect clinical deterioration.**
9. **A negative test result, especially a negative RADT, does not exclude RSV infection.**
10. **To verify a negative RADT, perform a molecular-based study (if available). In most cases, it is not necessary to verify a negative molecular study.**
11. **Negative RADT does not exclude RSV disease; if release from isolation is required and results in contact with risk groups or severe RSV case, consider performing RT-PCR in such a patient. If RT-PCR is not available, a second negative RADT reduces the risk that the patient is RSV positive.**
12. **Patients with a negative RSV molecular test can be released from further isolation, but avoid contact with patients from risk groups or severe RSV cases.**

WHEN TO TEST

UPPER RESPIRATORY TRACT INFECTION

1. **Inpatient: Test (if possible) all the patients with respiratory symptoms during the RSV high season test; consider testing outside of RSV season.**
2. **Outpatient: DO NOT test unless there is a change in management.**

LOWER RESPIRATORY TRACT INFECTION

1. **Inpatient setting:**
   a) **during RSV peak season – all patients;**
   b) **outside RSV peak season – all cases of bronchiolitis, while testing for pneumonia and bronchitis should depend on test availability and patient/parent willingness to test, as well as hospital economic assessment.**
2. **Outpatient setting: all patients with lower respiratory tract infections, especially during peak RSV season, as this can significantly reduce antibiotic overuse.**

TEST CHOICE

1. **Outpatient: RADT as a first line diagnostic.**
2. **Emergency department: RADT as a first line test, if negative – verify it with RT-PCR.**
3. **Inpatient: preference for RT-PCR, subject to hospital management decision.**
4. **Self-testing (with RADT): accepted.**
5. **Multiplex tests should be preferred.**

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